PAEDIATRIC HIV AND TB LEADERSHIP DIALOGUE VATICAN CITY STATE 3 – FEBRUARY 2025

COMPRHENSIVE REPORT

OVERVIEW

This report summarizes key takeaways, recommendations, and next steps discussed at the *Leadership Dialogue on Paediatric HIV and TB* convened by the Vatican Academy for Life and the Dicastery for Promoting Integral Human Development in February 2025.

The annex section includes:

- The Rome Paediatric HIV and TB Action Plan 2025, outlining stakeholder commitments and asks to accelerate research and development (R&D), introduction, rollout, and access to optimal HIV and TB diagnostics, treatment products, and strategies.
- Minutes of the two-day Leadership Dialogue, detailing key challenges, solutions, opportunities, and recommendations discussed.
- A list of participants involved in the Dialogue.
- A link to the presentations delivered during the meeting.

Steering Group of the Leadership Dialogue

Paediatric HIV and TB Leadership Dialogue
Casina Pio IV, Vatican City State
3 – 4 February 2025

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1. Executive Summary

On 3-4 February 2025, the Vatican Pontifical Academy for Life and the Dicastery for Promoting Integral Human Development convened the *Leadership Dialogue on Paediatric HIV and TB* to advance solutions for improving health outcomes among children and their mothers through stronger leadership and greater collaboration across key stakeholders. Amidst the current global health and development crisis, the dialogue, which brought together over 70 leaders from various sectors, served as a strategic space to realign priorities, foster collaboration, and drive concrete solutions in paediatric HIV and TB, maternal treatment, and child health.

The discussions emphasized:

- The need for stronger leadership from high-burden countries, ensuring country-led strategies, community-driven solutions, and cross-sector collaboration.
- The importance of rethinking partnerships, consolidating resources, and eliminating inefficiencies to accelerate access to diagnostics and treatment.
- The shift from siloed health interventions to integrated, patient-centered models, addressing maternal, child, and adult healthcare together.
- The critical role of artificial intelligence, digital platforms, and real-time data tracking in strengthening health systems, supply chain, and regulatory frameworks.
- The necessity of public-private partnerships, engaging new actors beyond traditional donors to secure sustainable financing.
- The call for harmonized regulatory frameworks to fast-track access to paediatric and maternal HIV and TB innovations.
- The need to redefine global health leadership, creating an inclusive multi-stakeholder platform uniting governments, the private sector, faith-based networks, civil society, and community organizations.

A radical shift was called for in how success is measured: instead of focusing on institutional sustainability, outcomes should be based on the number of children whose lives are saved.

As way forward, the Steering Group of the Leadership Dialogue[1] will oversee the implementation of the *Rome Action Plan 2025* (Annex 1), ensuring progress toward commitments. In addition, it is proposed to advance this work through two interconnected discussions:

[1] The Steering Group of the Leadership Dialogue is composed by: Monsignor Robert J Vitillo, Dr Meg Doherty, Prof. Sandy Thurman, Mr. Chip Lyons, Ms. Catherine Connor, Mr. David Ruiz Villafranca, Mrs. Francesca Merico

- Technical Group: Focused discussions to advance solutions and commitments identified during the Leadership Dialogue and contained in the Rome Action Plan 2025.
- Champions/Thinkers Group: A dedicated forum for prioritizing children's health, implementing Leadership Dialogue recommendations, and contributing to discussions on shaping a new global health leadership model.

2. Introduction

On 3 and 4 February 2025, the Pontifical Academy for Life and the Dicastery for Promoting Integral Human Development, hosted the *Paediatric HIV and TB Leadership Dialogue* at Casina Pio IV (Pontifical Academy of Sciences) in Vatican City. The event was co-organized by the President's Emergency Plan for AIDS Relief (PEPFAR), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO), and the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), in partnership with Faith-Based Organizations (FBOs).

The Dialogue brought together 70 key leaders from diagnostic and pharmaceutical companies, multilateral organizations, governments, regulatory agencies, faith-based organizations, civil society, and community organizations, all directly engaged in paediatric HIV and TB services and broader child health initiatives. Participants engaged in a comprehensive, solutions-oriented discussion on the challenges and opportunities in paediatric HIV, TB, and broader child health. This Dialogue built on previous high-level gatherings held at the Vatican, all aimed at identifying solutions and fostering collaborations to accelerate the research, development, introduction, rollout out of and access to optimal HIV and TB diagnostics and treatment tools and strategies for children and their mothers.

During a period of profound instability in global health and development, marked by disruptions to programs and established frameworks, the meeting provided an opportunity for strategic reflection on priority actions to tackle HIV and TB in children. Given the current instability in global health governance, this gathering was more crucial than ever, providing a platform to realign priorities, foster collaborations and commit to concrete solutions in a rapidly shifting landscape.

The need to reprioritize health and development on the global agenda was a central theme. All participants recognized that every paediatric HIV or TB infection represents a failure that must be confronted with collective responsibility, urgency, and accountability.

The discussions reinforced that this moment demands urgent and transformative change and it called for a new approach to global health leadership. Stakeholders must be willing to embrace radical reform, challenge current systems, and prioritize the needs of children in this new context. The dialogue emphasized the urgency of a new, technology-driven, people centered, and collaborative approach to global health

leadership. Efforts should go beyond traditional models to create a multi-stakeholder platform that unites heads of state, industry leaders, religious organizations, community and civil society groups. Leadership must foster cross-sectoral collaboration to effectively address the health challenges faced by children, marginalized populations, and communities most impacted by health crises.

A radical shift was called for moving away from fragmented, siloed efforts toward an inclusive, country-led approach that integrates maternal and child health, adult healthcare, and broader systems-based solutions. To achieve this, artificial intelligence, digital platforms, and real-time data tracking should be leveraged to centralize health data, improve coordination, and drive evidence-based decision-making. Additionally, public-private partnerships must be reimagined, also by engaging new actors, to overcome inefficiencies in supply chain, demand forecasting, regulatory processes and program implementation.

The discussions culminated in the *Rome Paediatric HIV and TB Action Plan 2025*, outlining stakeholder commitments and asks.

This report summarizes key takeaways, recommendations, and next steps to advance children's health, starting from paediatric HIV and TB. The annex section includes:

- The Rome Paediatric HIV and TB Action Plan 2025, outlining stakeholder commitments and requests to accelerate research and development (R&D), introduction, rollout, and access to optimal HIV and TB diagnostics, treatment products, and strategies.
- Minutes of the two-day meeting, detailing key challenges, solutions, opportunities, and recommendations discussed.
- A list of participants involved in the discussions.
- A link to the presentations delivered during the meeting.

3. Takeaways

The discussions emphasized the necessity of engaging new actors and rethinking traditional funding models to counteract financial instability and ensure continued progress in research, development, and access to optimal interventions for children. The moral responsibility to address widespread suffering, division, and systemic failures was highlighted, with a clear call for collective action to ensure that children's health remains a global priority.

Scientific advancements have significantly improved paediatric HIV and TB care, yet many children still lack access to early diagnosis and optimal treatment. Persistent resource shortages, personnel gaps, and supply chain inefficiencies continue to limit progress, exacerbating inequities in access to care. The discussions emphasized the critical need for sustained leadership, innovative financing, and community-driven solutions to

overcome barriers in prevention, diagnosis, and treatment for children affected by HIV and TB. These efforts are integral to fostering multi-sectoral collaboration and reinforce collective commitment to reducing child morbidity and mortality and ensuring equitable access to life-saving interventions.

A fundamental shift is needed in how success is measured. The focus must move away from institutional sustainability toward a child-centered approach where outcomes are defined by the number of children whose lives are saved, rather than the continued existence of organizations. The global response must be guided by bold and clear targets that move beyond technical frameworks toward zero new infections, zero deaths, and zero stigma.

To address fragmentation, duplications and inefficiencies of current global health structures, we must rethink partnerships, consolidate resources, and eliminate redundancies. It was recognized that leadership must emerge from high-burden countries, alongside innovative financing, community-driven solutions, and diverse stakeholder engagement. In some cases, structural reforms, including mergers and redefined roles, may be necessary to eliminate inefficiencies and align efforts more effectively.

Integrated child health approaches and models of care were identified as critical for success, emphasizing the need to move away from siloed approaches. Holistic service delivery must be prioritized by merging vertical programs for HIV, TB, malaria, and pneumonia into comprehensive, patient-centered health systems. Key priorities include:

- Consolidating fragmented supply chain to guarantee uninterrupted access to medications.
- Developing unified treatment guidelines for multiple diseases to ensure consistency in care, particularly for children and pregnant mothers.
- Adopting sustainable service delivery models that emphasize long-term impact and country ownership.
- Harmonizing regulatory frameworks emerged as a critical issue: we must create greater harmonization of regulatory processes across health sectors to accelerate access to new technologies and treatments.
- Focusing R&D on the child: paediatric research and development must no longer be an afterthought, but rather a central focus and the starting point in global health strategies and interventions.

Innovation remains a key driver of progress, particularly in an era of diminishing resources. Research and development efforts must be targeted, strategic, and streamlined to ensure that new diagnostics, treatments, and service delivery models remain high-quality, efficient, and accessible. It was also recognized that R&D is only effective if coupled with robust access plans and sustained industry commitment.

Digital technologies and real-time data analysis were highlighted as powerful tools to:

- Centralize data collection and track progress more effectively.
- Enhance coordination of interventions in high-burden areas.
- Improve efficiency in supply chain and service delivery systems.

Significant concerns were raised regarding shifting global health priorities and declining funding commitments. The need to redefine financing models was emphasized, particularly by engaging the private sector beyond traditional pharmaceutical investments. There was a strong call for:

- Protecting paediatric drug and diagnostic markets by creating sustainable incentives for suppliers and manufacturers.
- Prioritizing direct country investment to transition health programs toward national self-sufficiency.
- Rebalancing global leadership by ensuring that decision-making processes are centered in high-burden countries with active participation from heads of state, religious leaders, and civil society.

Advocacy was recognized as a critical mechanism for sustaining momentum and holding governments accountable for their commitments. Key recommendations included:

- Using data-driven advocacy to push for increased national health financing.
- Engaging more intentionally with faith and community leaders and networks to mobilize public awareness and ensuring financial commitments to children's health.
- Engaging youth and digital activists to amplify awareness and policy action.
- Aligning global health strategies with political cycles to ensure sustained investment and accountability.
- Developing a bold and compelling narrative about child's health, TB and HIV to raise awareness and support.

The dialogue also confronted broader challenges in global development and health systems, including uncertainty in major donor priorities and a need to rethink longstanding institutional structures. Ongoing reorganization efforts in global health and development sectors must be seen as an opportunity to maximize efficiencies, consolidate resources, and building more responsive models. It was emphasized that past debates around reforming global health institutions must now translate into concrete, forward-thinking action.

The Rome platform was noted as a relevant space for collaborative decision-making, fostering a renewed sense of commitment to bold, creative solutions. There was a collective call for sustained pressure on decision-makers, embracing innovation while ensuring that children's health remains a core priority in global policy discussions. The need to challenge the status quo, question outdated structures, and embrace radical change was emphasized as a necessary step toward building a more effective, accountable, and child-focused global health response.

Throughout the discussions, the words of Pope Francis served as a moral compass, reinforcing the responsibility to protect the most vulnerable. His message on January 9, 2025, emphasized: "*Too often, the voices of the most fragile are ignored, the cries of children suffering from war, violence, hunger, and disease are left unheard. We must act with hope, compassion, and determination to bring them justice and dignity.*" Similarly, his address on World Children's Day 2024 was a call to action: "*Every child is a precious gift, entrusted to us by God. It is our duty to ensure that they receive the care and protection they deserve.*" These reminders underscore the fact that addressing paediatric HIV and TB, and promoting the right of each child is not just a medical obligation but a moral one.

The discussions reinforced that this moment demands urgent and transformative change and it called for a new approach to global health leadership.

4. Recommendations

The Leadership Dialogue reinforced that every new paediatric infection is a failure that we must confront collaboratively. All participants reaffirmed their commitment to driving progress and championing the cause for children's health as a shared responsibility. This Leadership Dialogue called on all stakeholders to embrace integration, innovation, and accountability as we work together to build a new future for global health, one that places children and communities at the heart of every decision. Based on the discussions, the following recommendations have emerged. The Steering Group of the platform will lead follow-up conversations to determine priority recommendations and identify actions to support their implementation:

1. **Adopt a Bold New Narrative for paediatric health, including HIV and TB**
    - **Reframe the Message and Develop Differentiated Messaging:**
        - Recognize that HIV is no longer an emergency but a long-term pandemic. Some participants suggested that we must shift from technical targets (such as the 95-95-95 framework) to more straightforward, inspiring objectives like "0 deaths, 0 infections, 0 cases of stigma."
        - Reposition and think differently about how we communicate: raise the profile and visibility of child and maternal health priorities, especially in addressing paediatric HIV and TB, requires us to be even more relentless in engaging and informing legislators, donors, and other key decision-makers.

- **Highlight Scientific Progress:** Emphasize breakthroughs like "undetectable equals untransmittable" and the life-saving impact of treatment options, including PrEP and long acting prevention and treatment. These successes as well as a a bold new narrative on paediatric HIV and TB must be communicated in a way that builds political and public solidarity.
- **Mobilize support from diverse audiences**: reaching beyond the traditional global health and infectious disease communities. We must bring more people into this conversation.

2. **Forge New, Inclusive Partnerships and Reform Structures**
    - **Break Down Silos:** Challenge existing partnership structures by fostering inclusive, digital, and multi-sectoral collaborations. Traditional models must give way to approaches that center on country-level ownership and community-driven leadership.
    - **Embrace Change:** We need to consolidate resources and, if necessary, reframe outdated institutional structures to rebuild systems that truly serve vulnerable populations. Leadership should come from high-burden countries, integrating voices from the global South, religious leaders, civil society, and policy makers. In some instances, it might be necessary to increase efficiency through mergers and consolidations. This will eliminate redundancies and foster a more cohesive, collaborative framework. A comprehensive assessment of each organization's roles and responsibilities is essential to determine how every stakeholder can best contribute to advancing children's health. The need for change does not justify and it does not equal to the abrupt interruption of services or programs.

3. **Integrate Models and Approaches**
    - **Holistic Care Delivery:** Develop integrated treatment approaches that merge vertical programs, such as those for HIV, TB, malaria, and pneumonia, into comprehensive, patient-centered care. This includes:
        - Consolidating fragmented supply chains to guarantee uninterrupted access to medications.
        - Creating unified treatment guidelines that ensure consistent, high-quality care, particularly for children and pregnant mothers. By developing and enforcing integrated guidelines, we can ensure quality and accelerate the rapid access to innovations while preventing fragmented, inconsistent care.
    - **Support Sustainable Service Delivery Models:** Effective models sustainable over the long term must be supported. These models should be based on country-led approaches that empower local communities to drive their own health agendas.
    - **Transition from Outdated Silos to Inclusive, Integrated Models:** We need to reform outdated structures and adopt inclusive, community-driven models that prioritize integrated care over fragmented, project-based approaches.

4. **Harmonize Regulatory Frameworks**

- **A regulatory reform is necessary.** Advocate for the harmonization of regulatory processes by:
  - Establishing and supporting integrated regulatory bodies committed to coherence across health sectors. Unified regulatory frameworks must be embraced to promote swift and safe access to new technologies and treatments.
  - Prioritizing paediatric research and development rather than treating it as an afterthought.

5. **Continue investing in Innovation**
   - Innovation is key to ensure the health and wellbeing of children, even more so in times of limited resources.
     - Ensure that innovation efforts in paediatric HIV and TB are guided by clear and targeted objectives. This applies to everything from diagnostics and medicines to regulatory coordination, ensuring that quality and safety are not compromised while enabling rapid delivery of new solutions.
     - Long-acting HIV prevention tools must be prioritized to end paediatric HIV transmission.
     - Long-acting paediatric HIV prevention and treatment must be prioritized.

6. **Leverage Digital Tools and Artificial Intelligence**
   - Utilize digital platforms, artificial intelligence, and data analytics to create integrated systems at the national level. Such systems would:
     - Centralize data collection and track progress in real time.
     - Facilitate the coordination of interventions in high-burden zones.
     - Leveraging digital platforms will aAllow for a centralized, technology-driven approach that ensures efficient coordination, data sharing, and real-time targeting of interventions in high-burden areas.

7. **Reprioritize Financing and Strengthen National Ownership**
   - **Innovative Funding Models:**
     - Recognize that traditional donor funding is diminishing. We must develop new financing mechanisms, particularly by engaging the full spectrum of the private sector beyond pharmaceuticals. This includes:
       - Protecting paediatric drug and diagnostic markets by creating sustainable incentives for suppliers and manufacturers.
       - Focusing on direct country support that empowers governments to transition to self-sustaining health programs.
   - **Encourage National Leadership in High-Burden Countries:**

        - National governments must be empowered to lead their HIV and TB responses, fostering self-sustaining health systems that are tailored to local contexts.
    - **Revamp Global Leadership with Local Engagement:**
        - Decision-making should be centered in high-burden countries by incorporating voices from the global South: heads of state, religious leaders, and civil society must be at the forefront to ensure that local needs drive global strategies.

8. **Strengthen Advocacy, Harnessing the Influence of Faith and Community Leaders and Networks:**
    - Faith and community leaders and networks play an important role in holding governments accountable for their health investments. Their influence should be leveraged to mobilize public support and ensure that commitments, such as those outlined in the Abuja Declaration, are met.
    - Use robust data to hold governments accountable for their health investments, particularly for the most vulnerable.
    - Engage young people and other tech-savvy stakeholders in holding governments accountable.

9. **Redefine Global Health Leadership**
    - **Support and Engage in Multi-stakeholders Platforms (such as a Global Leaders Network):** Develop a new, cohesive model of global health leadership that includes:
        - Heads of state and government from the Global South.
        - Leaders from diverse sectors, including industry, religious organizations, and civil society.
        - A multi-stakeholder platform that fosters collaboration, utilizes digital technology, and redefines our collective response to global health challenges.
    - **Extend Collaboration Beyond the Dialogue:**
        - Ensure that our partnerships and efforts extend well beyond this meeting to avoid echo chambers, driving sustained action and impact on the ground. Our collaborative efforts must not be confined to this meeting. We must build networks that extend to all stakeholders, including governments, civil society, the private sector, and faith-based organizations, among others, to ensure lasting impact.
    - **Shift Towards Broader Private Sector Partnerships:**
        - Beyond pharmaceuticals, partnerships should harness the full spectrum of private sector expertise, including digital technology and artificial intelligence, to drive innovation and improve efficiency.
    - **Enhance Political Engagement Using a clear framework to mobilize political support:**

- **A** for **Awareness**: Policymakers need to be informed about paediatric HIV and TB, if they aren't aware, change is impossible.
- **B** for **Budgets**: Securing funding through innovative financial models is crucial, as is helping governments identify and reallocate existing resources.
- **C** for **Cost**: We must articulate the cost, both in economic terms and in human suffering, of inaction.
- **D** for **Data**: Concrete data is needed to show where we are today and to model future scenarios for better policy decisions.
- **E** for (**Equity)/Elections**: Strategies must be aligned with political cycles to ensure sustainable support and accountability, especially since politicians are driven by the need to get reelected.

5. Proposed Way Forward

This meeting marks not an endpoint but the beginning of a process that will require ongoing engagement, decisive action, and continuous collaboration. We must shift our focus from merely defining WHAT needs to be done to developing effective strategies for achieving our goals (the HOW).

The Steering Group of the Leadership Dialogue proposes moving forward with two interconnected discussions:

1. **Technical Conversation:**
   Focused discussions to advance the key solutions and commitments identified during the Leadership Dialogue and contained in the Rome Action Plan 2025.
2. **Champions Group:**
   A dedicated forum of champions for children's health with three core objectives:
   - **Championing Children's Health:**
     - Explore and propose strategies to ensure that children's health, starting with paediatric HIV and TB, is prioritized within the broader global health discussions.
     - Develop a strong, unified narrative that builds solidarity and clearly communicates the urgency and importance of investing in children's health.
   - **Implementing Recommendations from the Leadership Dialogue held at the Vatican:**
     - Work to ensure that critical recommendations from the Rome Platform are not only implemented but also fully integrated into wider global health discussions and policy frameworks.

- **Further Reflecting on a New Global Health Leadership, which prioritize Children:**
  - Examine and further frame "a new approach to global health leadership", as initially discussed at the Leadership Dialogue in the Vatican, including by exploring concepts/opportunities such as a multi-stakeholder platform or Global Leaders Network that can redefine how we lead and coordinate responses to global health challenges.

Accountability remains central to the Rome Platform, with the Steering Group responsible for monitoring and evaluating progress toward the **2025 Action Plan commitments**.

ANNEX 1 – DRAFT ROME PAEDIATRIC HIV AND TB ACTION PLAN 2025

LIST OF COMMITMENTS AND ASKS

Solutions and actions related to RESEARCH & DEVELOPMENT OF DIAGNOSTICS FOR CHILDREN (HIV and TB)

Cepheid

1. Cepheid will continue to offer Xpert MTB Ultra at cost to high burden countries & commission a third-party validation of the cost annually to ensure zero profit is made from Xpert TB Ultra.

2. After delivering on our commitment to achieve Xpert MTB Ultra pre-qualification by 2024, we will invest & prioritize WHO PQ for MTB XDR in 2025

3. With 22K GeneXpert systems across High Burden Countries (HBCs) we will continue to advocate for & promote programmatic integration with a focus on HIV EID & TB.

4. Continue to supply QC verification kits with every new GeneXpert installation.

5. Continue to implement a standardized template for service level agreements that clearly spell out key performance indicators, including a call every month in 2025 with global donors, implementing partners on KPI reporting across the GeneXpert global network.

6. Drive our superuser programme across HBCs to create a superuser network with MoH to ensure fleet health.

7. Maintain our weekly call with procurers to monitor stock levels and consumption rates to improve forecasting aimed at minimising the likelihood of stockouts, maintain sufficient regional buffer stock levels and have mitigation plans in place to ensure programme continuity.

MOLBIO

8. Molbio will engage with stakeholders to initiate studies on tongue swabs and stool samples in paediatric settings.

9. The company continues to develop newer and more affordable Near and Point of Care multiplexed PCR platforms and tests.

10. Molbio currently provides service level agreements for all locations where Truenat platforms are installed.

11. Additionally, Molbio is dedicated to maximizing the effectiveness of Point of Care Diagnostics and will engage with stakeholders to identify and resolve bottlenecks for improving POC efficiencies.

NIH/NIAID

12. Continue to support research efforts for molecular based diagnostic tools for HIV self-testing for all populations, including pregnant women and children.

13. Support grants funded to explore TB biomarkers in children to eventually better diagnose children and to better understand those who will progress to active TB disease.

14. Continue to fund FIND and others' efforts to evaluate performance of current TB-CAD software, including for paediatric population. The funded work also includes assistance with setting up qualification process for this type of CAD software.

Stellenbosch

15. Co-lead work to evaluate and optimize evaluation and validation of CAD for TB detection in young children.

UNITE

16. UNITE will advocate through its parliamentarian network for increased investments in research and development for new diagnostic tools.

WHO GTB

17. With appropriate evidence, prioritize the review of additional urine-based lateral flow assays, molecular technologies (point-of-care and laboratory-based), alternative (non-sputum based) specimen types, and novel testing approaches to provide better tools for paediatric TB detection and encourage and introduce market competition.

Solutions and actions related to RESEARCH & DEVELOPMENT OF MEDICINES FOR CHILDREN (HIV and TB)

Access To Medicines Foundation

18. Completing a review of how paediatric populations are represented in the 2025 Access to Medicine Index Methodology and to building consensus to make subsequent changes to the methodology, as required to continue to reflect their unique needs by Q4 2025 (publication 2026 Index Methodology).

19. Highlighting key opportunities for the pharmaceutical companies within the scope of our research pertaining to paediatric populations as an inclusion in our collaborative engagement work aimed at moving the pharmaceutical industry further and faster on key topics by Q4 2026.

20. Exploring the unique needs of paediatric populations in the consultation process and the subsequent development of new frameworks for evaluation, as part of its 5-year Strategic Direction (2027-2031).

CHEETA

21. To identify and bring together 8-10 clinical trial sites to implement paediatric trials of new TB drugs in high-burden countries by the end of 2026.

22. Provide technical advice on child-friendly formulation characteristics and paediatric investigational plans for new TB drugs to developers including Otsuka (quabodepistat), GSK (ganfeberole) by the end of 2025.
23. To collaborate with WHO and its GAP-f partners to convene TB drug developers, funders, regulators and other stakeholders to discuss optimal design and implementation of efficient paediatric trials of new TB drugs, including through innovative approaches like a platform trial.

CIPLA

24. Commits to continue engaging in adaptive R&D to develop products that address paediatric R&D priority gaps.

25. Commits to assisting exploration of LAI for the paediatric population and ensure proper coverage of treatment for this age group. CIPLA is one of the three companies to have an agreement with ViiV and MPP to develop and deliver to LMICs as a PrEP molecule. In the meantime, we are closely monitoring the activities taken up by WHO and different procurement agencies, who are working towards addressing outstanding safety issues, implementation challenges, and understanding people's preferences for CAB-LA among other HIV prevention choices.

26. CIPLA has now completed the synthesis and development of Abacavir Lamivudine Dolutegravir 60/30/5 mg (ALD Paediatric formulation). CIPLA will continue to supply this medicine across the African subcontinent and closely monitoring the sharp transition from Abacavir Lamivudine 120/60mg.

DNDi

27. DNDi will continue to contribute to development of medicines in children by being represented in the GAP-f Strategic Group, co-leading the Product Development and Regulatory Affairs Working Group and support the development of the Paediatric Technology Hub.

EDCTP3

28. Research on paediatric HIV and TB remains a high priority for Global Health EDCTP3 and addressing major unmet needs of underserved groups, such as pregnant women and children, is and will continue to be at the core of the work we fund. Since 2022, Global Health EDCTP3 has already invested EUR 9.7 million in paediatric TB diagnosis and treatment grants and EUR 17.4 million in paediatric HIV diagnosis and treatment grants.

29. Global Health EDCTP3 is committing an additional EUR 23.4 million towards four HIV projects that are currently under grant preparation and will commence activities in 2025. These four new projects are capitalising on the most advanced treatment technologies to deliver better and safer treatment, with two projects planning to study Lenacapavir in combination with other treatment strategies across different subregions of sub-Saharan Africa.

30. Additionally, Global Health EDCTP3 has launched on 30 January 2025 amongst others the following three new calls for proposals that could support innovative research and capacity development addressing paediatric HIV and TB, with a commitment of:

    - EUR 14 million on transformative Innovations in global health
    - EUR 40 million on Global collaborative action for strengthening the Regional Networks of Excellence and Epidemic Preparedness Consortia
    - EUR 6.7 million on Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling

31. Global Health EDCTP3 has commenced discussions and preparations for potential call topics to be addressed in its work programmes for 2026-2027 and invites strategic partners to engage in discussions on the possibilities for collaboration as contributing partners for

joint calls and activities. Michael will elaborate on potential topics of relevance that are under consideration when he makes his intervention.

Ecumenical Pharmaceutical Network (EPN)

32. EPN commits to work with religious networks and other Civil Society organizations in promoting ongoing R&D efforts to build evidence-based trust before the product is prequalified for market authorization. This can start with HIV-TB new medicines and diagnostics products at late-stage R&D. FBOs can be instrumental in building trust in newly developed innovative products to accelerate their uptake and scalability.

GAP-f Network

33. GAP-f commits to work alongside regulators and Industry to convene by the end of the year targeted technical conversations to optimize clinical trial design and explore regulatory efficiencies for novel medicines: more specifically on the use of HIV medicines for postnatal prophylaxis as well as on the investigation of novel TB medicines.

34. GAP-f commits, by end 2025, to develop a collaboration framework with Industry to enhance the paediatric medicines ecosystem through public and private collaboration across therapeutic areas. This will include key milestones and best practices for collaboration and acceleration.

GILEAD

35. Providing Antiretrovirals for Trials: Supplying antiretrovirals, including novel long-acting formulations and monoclonal antibodies, for collaborative trial.

36. Collaborating with Research Networks: Working with research networks to ensure timely assessment of novel therapies in children and generating high-quality evidence to inform guidelines and policies, ensuring children and adolescents have the same treatment options as adults.

GSK

37. At GSK we are committed to develop paediatric formulations of our global health medicines in accordance with TB priorities and based on the profile of medicines we have in development.

38. We will accelerate the development of innovative TB treatments and consider the development of paediatric formulations in parallel to adult indications rather than sequentially, subject to partnerships needed to develop future regimens.

39. To develop paediatric formulations, we will engage early across our TB R&D pipeline and hold regular consultations with expert TB groups on paediatric investigation plans and paediatric study plans incl. research networks such as CHEETA, IMPAACT and PENTA.

IMPAACT

40. Phase I/II study of the pharmacokinetics and safety of Long-Acting Injectable Cabotegravir and rilpivirine in Pregnant and Postpartum Adults with HIV (CREATE). Opening to accrual April 2025.

41. Continue to implement CRAYON (LA CAB/RIL) for younger children. Phase I/II study of safety, tolerability, acceptability and PK or oral and long-acting injectable cabotegravir and rilpivirine in virologically suppressed children living with HIV two to less than 12 years of age. IMPACT 2036. [Status: Actively accruing, follow-up on going.]

NIH/NIAID

42. Continue to support IMPAACT to determine dosing and safety of DTG dispersible tablets in newborns by end of 1st quarter 2025.

43. Continue to support IMPAACT to determine safety, dosing, and acceptability of long acting injectable ART with cabotegravir and rilpivirine in children over age 2 years by Q4 quarter of 2025.

44. Continue to support the PAVE Martin Delaney Collaboratory to completion in Q2 2026. The major research goals of the grant includes defining the establishment and evolution of the HIV latent reservoir in perinatal infection and enhancing bNab delivery to achieve post treatment control of HIV-1 off of ART.

45. NIAID will co-chair the Paediatric Technology Hub (PTH) in collaboration with domestic and international partners. The PTH will serve as a major catalyst to 1) identify suitable technologies to address the needs of children globally, and 2) foster cross-sector collaboration to appropriately match these technologies with priority medicines, with the goal of launching the PTH by Q4 quarter of 2025.

46. NIAID established and will continue to support a partnership with domestic and international collaborators to test the feasibility of utilizing advanced data science technologies to modernize the STEP database by increasing available excipient data to better inform paediatric formulation development. A proof-of-concept study was initiated in 1st quarter of 2025.

47. Contribute to support paediatric formulation optimization by funding a project to test 15 priority ARVs, and TB medications to confirm activation of known bitter receptors and screen chemical libraries to identify potential bitter blockers. This initial phase of work is anticipated to be completed by Q4 of 2025.

48. When other appropriate and unmet needs exist, leverage NIAID resources to support development and evaluation of optimized paediatric formulations for priority ARVs and TB prevention and treatment medications.
49. Continue to support IMPAACT to complete IMPAACT 2037, which is assessing safety and PK of bNabs in infants exposed to HIV.

50. Continue to engage with IAVI, pharmaceutical partners, and other stakeholders for advancement of bNAbs for postnatal prophylaxis.

51. Support increasing the understanding of concurrent dosing of ARVs and TB medications.

52. Support investigation into long-acting antiretrovirals for postnatal prophylaxis.

53. Collaborate with IMPAACT, and other domestic and international partners to advance alternative statistical methodologies and trial designs, including consideration of use of platform trials, fusion designs and others to improve postnatal prophylaxis.

54. Support implementation research to improve early infant diagnosis and case finding for infants and children at higher risk of HIV infection from birth through breastfeeding.

OTSUKA

55. Facilitate access to its child-friendly delamanid formulations in collaboration with the Stop TB Partnership's Global Drug Facility (GDF) Paediatric Drug-Resistant Tuberculosis (DR-TB) Initiative, national TB programmes, and other stakeholders.

56. Finalise technology transfer and continue knowledge sharing that can expedite child-friendly delamanid formulations used to treat DR-TB.

57. Initiate and/or support stakeholders to apply to national drug regulatory authorities for approval of paediatric formulation of delamanid.

58. Expedite and/or expand development and regulatory submission of paediatric versions of new TB compounds already in the Otsuka Research and Development (R&D) pipeline, with an aim to have paediatric formulations available shortly after regulatory approval of the adult formulation.

59. Prioritize the development, registration, and commercialization of TB products in research and development plans.

60. Make paediatric formulations and data available to research networks and WHO where possible to advance paediatric PK and safety studies.

61. Timely submit data to regulatory authorities and WHO to facilitate updating of labelling and recommendations.

62. Use the following best practices, interact with key stakeholders for the design and implementation of research studies:
63. Initiate preparation for paediatric studies as soon as a given drug shows promising efficacy and safety in Phase IIb/c adult studies.

64. Assess acceptability and palatability of formulations, including for use in low-resource settings, at early stages of the formulation's development.

65. Develop and/or support development of drug susceptibility testing (DST) and methods in parallel to clinical development of new investigational compound and make pure drug substance available for DST at the time of launch of the new medicine/s.

66. Explore regulatory options to allow access to TB paediatric formulations in countries and/or regions currently without regulatory approvals.

67. Ensure all drug registration dossiers meet requirements at the time of filing and that responses to specific queries are complete and provided in a timely manner.

68. Provide multilingual Patient Information Leaflets or Instructions for Use to facilitate appropriate use by caregivers and healthcare workers.

69. Register new TB paediatric products timely in countries where registration is required and import waivers cannot be granted for procurement (regardless of source of funding).

70. Disseminate in a timely manner scientific data from studies via publication and presentations at scientific forums with a broad audience of stakeholders.

PENTA

71. Penta, building on 30 years of experience in global clinical trials in paediatric HIV and the recent success of the ODYSSEY trial in supporting the worldwide roll-out of paediatric dolutegravir formulations worldwide, is committed to:
    - establishing a sustainable clinical trial platform in sub-Saharan Africa designed for timely evaluation of the best treatments for children and adolescents with HIV (including those with advance HIV disease), synchronously as they become available for adults (e.g. Chapas 5);
    - collaborate with industries, other networks (IMPAACT)and organizations (IAVI, UNITAID etc) to develop a program for paediatric HIV cure.
    - promoting the use of real-world data in combination with clinical trial data for regulatory purposes.

STELLENBOSCH

72. Conducting implementation science research to translate findings of the recently completed MDR TB and DS TPT trials, Styudy 35 (3HP) and TB-CHAMP and WHO Sept 2024 recommendations, into practice.

73. Conduct and implement the 4 month HPMZ PK and safety trial in children (Radiant Kids).

74. Support CHEETAH and other initiatives to accelerate evaluation of novel therapeutics in children.

75. Undertake meta-analyses of available 2nd line TB drugs in children including clofazimine, moxifloxacin, levofloxacin, bedaquiline, delamanid, to inform optimal dosing recommendations.

76. Support optimization of key second line formulations including moxilofxacin, through the UNITAID-funded BENEFIT Kids project.

77. Support a neonatal PK platform studies through the UNITAID -funded PETITE and other initiatives

Unitaid

78. Unitaid will continue to collaborate with partners, including many at this meeting, to support research & development of paediatric formulations of novel ARVs for the treatment and prevention of HIV, including during the post-natal and breastfeeding periods.

Specifically, Unitaid will continue to develop novel formulations such as in the PETITE DTG study, which is now testing innovative, easy-to-administer formulations like dissolvable films, making treatment more accessible for newborns. (1-2 years).

79. Unitaid will support critical initiatives such as the Global Accelerator for Paediatric Formulations Network (GAP-f) (hosted within the WHO Science Division) and the Centre of Excellence for Long-acting Technologies (CELT) (hosted by the University of Liverpool), which promote innovation and facilitate exchange to advance new and better medicines and formulations that are inclusive of children and pregnant/lactating women.

UNITE

80. UNITE will call on its members to increase financial support for research and development of new medicines for children, pregnant and lactating women.

VIIV Healthcare

81. We are committed to improve the availability of innovative treatment options for paediatric populations. To do this, ViiV Healthcare will collaborate to facilitate clinical data sharing to support the availability of innovative treatment options including neonatal medicines (dolutegravir), oral two drug regimens (dolutegravir and lamivudine) and long-acting injectable regimens (cabotegravir and rilpivirine) for children, and adolescents. We will also consider all potential partnerships, to assess novel therapies in children which generate high-quality and timely evidence which informs guidelines and policies, so children and adolescents have the same treatment choices as adults

82. ViiV is committed to improve HIV prevention options for paediatric populations. As such we will undertake to support a PK and safety dose-finding study for neonates to start in 2026, using cabotegravir long acting injectable in the postnatal setting.

83. We recognize that addressing drug resistance in paediatric populations is a neglected priority. Therefore, ViiV Healthcare commits to support, facilitate and to generate epidemiological data on emerging resistance in paediatric populations, to proactively support optimising treatment for children. Over the next 2-3 years we intend to expand real world evidence generated on resistance, building on existing published data.

84. ViiV commits to enroll adolescents (from the age of 12) alongside adults in Phase 3 trials for new antiretroviral drugs, unless there is a scientific and/or regulatory rationale which precludes enrolment.

WHO GTB

85. Promote research to address current evidence gaps and consider emerging evidence for possible updating of the WHO guidelines and operational handbook on the management of TB in children and adolescents.

86. Review the latest pharmacokinetic data and promote pharmacometrics modelling to inform potential updates to the WHO dosing of TB medicines for children, through the work of the WHO Technical Advisory Group (TAG) on dosing and, if needed, convene meetings on Paediatric Drug Optimization (PADO) for TB to ensure that child-friendly formulations are prioritized for development.

Solutions and actions related to RESEARCH & DEVELOPMENT OF MEDICINES FOR PREGNANT AND LACTATING WOMEN (HIV and TB)

Access to Medicines Foundation

87. We commit to continuing to drive much-needed change across healthcare companies by identifying key opportunities to improve HIV product access.

88. Complete a review of how pregnant and lactating people are represented in the 2025 Access to Medicine Index Methodology, explore their unique needs in the consultation process and build consensus to make subsequent changes to the methodology, as required to continue to reflect their unique needs by Q4 2025 (publication 2026 Index Methodology).

89. Explain during the 2025 L&E sessions the importance of including pregnant and lactating people in clinical research to companies in scope with relevant products in their portfolios and pipelines (ex: HIV) and consider removing the systematic exclusion of these

groups. Highlight key opportunities for the pharmaceutical companies within the scope of its research pertaining to pregnant and lactating people as an inclusion in its collaborative engagement work aimed at moving the pharmaceutical industry further and faster on key topics by Q4 2026.

90. Highlight the unique needs of pregnant and lactating people in a short thematic publication or chapter by Q4 2026.

91. Complete a review of how paediatric populations and pregnant and lactating women are represented in the 2025 Access to Medicine Index Methodology and to building consensus to make subsequent changes to the methodology, as required to continue to reflect their unique needs by Q4 2025.

92. Highlight key opportunities for the pharmaceutical companies within the scope of our research pertaining to paediatric populations and pregnant and lactating women as an inclusion in our collaborative engagement work aimed at moving the pharmaceutical industry further and faster on key topics by Q4 2026.

93. Explore the unique needs of paediatric populations as well as pregnant and lactating women in the consultation process and the subsequent development of new frameworks for evaluation, as part of its 5-year Strategic Direction (2027-2031).

GILEAD

94. Supporting Post-PURPOSE 1 Studies: Supporting the conduct of high-quality observational and post-marketing studies to expand evidence on lenacapavir (LEN) use during pregnancy and breastfeeding.

95. Conducting Breastfeeding Studies: Undertaking pharmacokinetic (PK) studies to understand LEN's impact during breastfeeding, considering infant metabolism.

96. Facilitating Rapid Registration: Assisting national regulatory authorities in swiftly approving LEN for use during pregnancy and breastfeeding, enabling implementation studies and scale-up for HIV prevention in mothers and their offspring.

97. Providing LEN for Research: Making LEN available to countries and research networks to facilitate clinical and implementation research for treatment, with consideration for use in combination with CAB LA and in pregnancy, breastfeeding, and postpartum periods.

98. Supporting Continuation During Pregnancy: Allowing women who become pregnant to remain in studies with new informed consent, collecting data on PK and outcomes for LEN in combination with other agents where nonclinical and clinical data are supportive for use in pregnancy.

NIH/NIAID

99. Continue to support completion of HPTN 084 pregnancy sub-study (CAB-LA for prevention) (expected by end of 2026).

100. Continue to support completion of enrolment and timely dissemination of results from IMPAACT 2026 for new ARVs for use in pregnancy and postpartum.

101. Support NIAID funded clinical trial research networks to continue to report incident pregnancies occurring during the conduct of studies and collect outcomes of pregnancies as well as pregnancy and breastfeeding PK data in women who become pregnant on study.

102. Support NIAID clinical research networks to continue to ensure appropriate consultation and engagement of community members and community-based organizations through the research cycle for new therapeutics.

103. Encourage grantees to contribute documents to and share protocols with the WHO Antiretrovirals in pregnancy research toolkit to improve the standardization and optimization of the resources in the toolkit.

104. Support long-acting treatment studies in pregnancy and during breastfeeding, including the combination of Lenacapravir and Cabotegravir LA. Also continue to specifically support IMPAACT 2040 evaluating safety and PK of CAB LA and RPV LA in pregnant and postpartum women with an estimated completion date of Q4 2028.

105. Support implementation science to improve the health of pregnant and breastfeeding women by supporting studies that are of highest priority with implementers to improve the HIV prevention and treatment cascade and access to optimal regimens in these populations.

106. Continue to support a surveillance program for adverse pregnancy and birth outcomes from ART exposure within the NIH epidemiological network.

107. As appropriate, facilitate completion of embryo-fetal development (FEED/EFD) studies as needed for priority ARVs for use in pregnant and lactating women with established pharma partnerships by end of Phase 2 by applying available contract resources.

108. As appropriate, facilitate completion of pre- and post-natal development studies (PPND) as needed for priority ARVs with established pharma partnerships by the time of early Phase 3 clinical trial enrolment by applying available contract resources.

PENTA

109. Penta in collaboartion with IMPAACT is setting up a platform to test innovative strategies fro ending postnatal HIV transmission Penta is committed to: through partnerships across the global South and North to evaluate novel interventions for women with HIV and their infants, especially for rural settings where women with HIV suffer poor treatment outcomes and an unacceptable level of HIV transmission persists (RISE UP project).

Stellenbosch

110. Complete the first global IPD and meta-analysis on DS and DR-TB treatment in pregnancy to asses maternal TB and infant outcomes

Unitaid

111. Unitaid will support implementation science with innovative LA PrEP to ensure it can benefit pregnant and breastfeeding women and their babies with current grants being expanded in South Africa and Brazil. (1-2 years).

112. Unitaid will ensuring evidence generated by Unitaid-funded clinical studies to support normative work is inclusive of pregnant and breastfeeding women to ensure that mothers and their offspring benefit from the most optimized diagnostics and treatments.

UNITE

113. UNITE commits to leverage its parliamentarian network to call for more flexible frameworks that enhance and facilitate research and development of medicines and diagnostic tools for children, pregnant and lactating women.

114. UNITE will promote the engagement of its members with civil society, technical experts and private sector to enhance their understanding of the regulatory challenges for diagnostics and medicines for children and for pregnant and breastfeeding women.

ViiV

115. We are collaborating to improve health outcomes for pregnant women living with HIV through advancing the development of long-acting two-drug regimens. Subject to policy changes by key donors, this will be delivered through the IMPAACT 2040 (CREATE) study for long-acting cabotegravir and rilpivirine (CAB/RPV LA) focused on treatment in pregnancy which is anticipated to begin in 2025.

116. We commit to improve HIV prevention health outcomes for pregnant and lactating women through generating data on the use of cabotegravir long-acting injectable PrEP in this population. To this end:

- ViiV continues to collect maternal and fetal outcome data in HIV Prevention Trial Network study 084 (HTPN 084). This includes data from women who have enrolled in the ViiV sponsored study (PALISADE) which delivers ongoing drug access for study trial participants.
- We presented pregnancy data and additional outcome data at AIDS 2024 in Munich and ongoing data presentations are expected in 2025.

117. We will collaborate to improve data generation for the use of long-acting treatment and prevention before, during and after pregnancy. To deliver this ViiV Healthcare commits to support relevant studies investigating the use of long-acting treatment and prevention in pregnant and lactating women. Our accelerated data generation plan will enable those who are pregnant to choose to continue, on drug in clinical studies, should there be a favourable risk-benefit profile for the mother, fetus, and newborn.

WHO (HIV)

118. Continue to convene the HIV, Hepatitis and STIs Pregnancy and Breastfeeding Therapeutics Working Group (HHS PTWG) to develop and update appropriate standards, tools, and policies to support research, surveillance, and innovations for new HIV agents in pregnancy and breastfeeding.

119. To update WHO guidelines on the use of new long acting ARVs to prevent or treat HIV in pregnant, breastfeeding, or postpartum women by reviewing and assisting in the interpretation of new evidence, notably in:

- Formulating new recommendations related to injectable lenacapavir (LEN) for HIV prevention,
- Updating evidence in the guidelines on injectable long-acting cabotegravir (CAB LA) for HIV prevention,
- Updating evidence on the use of injectable dual long-acting therapy cabotegravir + rilpivirine (CAB /RPV) for HIV treatment

120. To examine existing data regarding once daily darunavir/ritonavir for HIV treatment during pregnancy and viral response for treatment harmonization across populations in WHO guidelines in 2025

121. To prioritize and advocate for conduct of clinical trials of new HIV agents (e.g., CAB+LEN, bNAbs) to include pregnant and breastfeeding women as well as trials comparing pregnancy and birth outcomes across new ARV drugs.

122. To contribute to the definition of a better clinical and programmatic profile (target product and target access profiles) of HIV long-acting agents inclusive of pregnant and lactating women by end of 2025

123. To continue to convene and implement a collaborative framework for the surveillance of CAB LA and extend its scope to LEN during pregnancy (including regular reporting to the WHO Advisory Safety Committee of Medical Products) by assisting implementers

with development of protocols inclusive of pregnant and breastfeeding women, regulatory considerations, and safety data interpretation.

124. To collect, review and add new materials to WHO ARV in Pregnancy Research toolkit to enable and accelerate timely inclusion and collection of data on pregnant and breastfeeding women within clinical studies and other research settings.

125. To strongly advocate for appropriate consultation and engagement of community members and community-based organizations through the research cycle for new therapeutics during pregnancy and breastfeeding and ensuring community representation on WHO guidelines revisions and CADO process.

WHO GTB

126. Promote earlier and optimal inclusion of pregnant and postpartum women in TB drug and vaccine research in line with the outcomes of a consensus meeting convened by WHO and partners in February 2025.

Solutions and actions on global, regional, and national REGULATORY PROCESSES FOR DIAGNOSTICS AND MEDICINES FOR PREGNANT AND BREASTFEEDING WOMEN (HIV and TB).

EDCTP

127. To date, the EDCTP programmes have collectively funded 128 grants to enhance ethics and regulatory capacity in sub-Saharan Africa (75 EDCTP1; 46 EDCTP2; 7 Global Health EDCTP3) and this remains a high priority area for future commitments.

128. Global Health EDCTP3 remains committed to developing clinical research capacity, ethics review, and regulatory and legal capacities in sub-Saharan African countries, and to enhancing the ability of such countries to design, conduct, and analyse the results from clinical research studies, including multi-site and multi-country studies.

129. In the Global Health EDCTP3 WP 2025 EUR 40 million has been committed to a call on global collaborative action for strengthening the Regional Networks of Excellence and Epidemic Preparedness Consortia, and a further EUR 6.7 million has been

committed to a call on Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling, in partnership with CEPI and other contributing partners. These calls are expected to play an important role in strengthening the broader health research ecosystem in Africa, regardless of the target disease.

130. In the Global Health EDCTP3 WPs 2026-2027, we intend to continue our support for the strengthening of training networks for sustained capacity building, in addition to ethics, regulatory and pharmacovigilance capacities in SSA. This could potentially include collaboration with AVAREF, AMRHI, AMA, CEPI, Gates Foundation, PEPFAR, Africa CDC and others.

Ecumenical Pharmaceutical Network (EPN)

131. EPN commits to continue collaborating with its members Christian Health Associations (CHA) and Church Drug Supply Organizations (DSO) to advocate and engage policymakers and regulatory authorities to create supportive policies and enabling environments that prioritize paediatric HIV and TB care and products. The advocacy efforts will be geared towards:

- Addressing policy and legal barriers,
- Market authorization across regional blocs and countries,
- Quality of products (including post-marketing surveillance) and
- Supply chain bottlenecks,
- Funding allocation, and
- Policy frameworks.

132. Convene church leaders and health experts from the FBO sector in "FAITH AND SCIENCE IN CONVERSATION" initiatives to:

- Understand countries' commitments on health financing "the Abuja Declaration" for advocacy and accountability.
- Understand the needs of people living with HIV and their care needs
- Commit on using resources available like the HIV Treatment Literacy for Religious Leaders.
- Translate the research progress in simple messages that can be spread by faith leaders.
- Raise a joint voice as FBO for government accountability to their commitment.

KNCV

133. Collaborate and coordinate with in-country professional and regulatory bodies to ensure countries are prepared for early uptake of new innovations/diagnostics/medicines and develop a plan for scale up.

Unitaid

134. Unitaid will collaborate with WHO through its enabler grants and other partners on the development of target product profiles, target regimen profiles and target access profiles to ensure the consideration of the needs of children and pregnant women.

135. Unitaid will support the WHO through its Enabler grant, including the on-going work of the Pregnancy and Breastfeeding Therapeutics Working Group. Also, Unitaid will support work on the development of the R&D framework for prevention, diagnosis, and treatment.

136. Unitaid will support quality assurance and regulatory mechanisms such as the WHO prequalification programme, the Expert Review Panel facilitated by Global Fund, WHO, and Unitaid, he Collaborative Review Procedure, and regional joint review and harmonization initiatives to ensure a timely and clear pathway to make available critical formulations adapted to the needs of children and pregnant/breastfeeding women. (ongoing)

137. Unitaid will support the WHO through its Enabler grant so timely guidelines and support is available for countries to adopt innovative products, as well as the WHO Prequalification team to ensure new affordable formulations can be quickly reviewed and enter the market in coordination with regional and national authorities. Unitaid will continue to support the MPP and other IP grants with civil society that can ensure a pathway for access also beyond sub-Saharan Africa.

WHO PQ

138. WHO commits to continue to support in-country registration of specific products under its Collaborative Registration Procedures.

139. WHO commits to continue collaboration on CRP-Lite.

140. WHO commits to continue supporting regulatory systems strengthening at national and regional level, promoting "smart regulation" through regulatory co-operation, harmonization, convergence, work-sharing and reliance.

Solutions and actions on IDENTIFYING AND DIAGNOSING CHILDREN (HIV and TB)

EGPAF

141. EGPAF is committed to conducting an assessment of gaps in the utilization of point-of-care (POC) technologies, despite their promising results in expediting turnaround times (TAT) for initiating treatment in children diagnosed with HIV and delivering test results. This assessment will be carried out in EGPAF-supported countries to identify critical gaps and opportunities for optimizing the use of POC technologies. The evaluation will focus on TAT performance, logistical challenges, equipment availability, and human resource capacity.

142. EGPAF is committed to supporting optimization of testing algorithms to ensure timely testing, diagnosis and treatment of children infected with HIV.

143. EGPAF commits to leverage the PMTCT service delivery platforms that the organization has established over decades of work, to integrate TB care for pregnant women and newborns provided availability of funding to support this work.

GNP+

144. The Global Network of People Living with HIV (GNP+) is committed to mobilizing PLHIV, communities and Civil society to address inequalities and structural barriers to case finding, diagnosis and treatment of children living with HIV. Including Stigma, discrimination, criminalization, and violence.

145. GNP+ commits to strengthen people living with HIV, Communities and Civil Society led advocacy to Raising awareness in global fora about the unmet case finding, diagnostic and treatment needs of children living with HIV including access to Early Infant Diagnostics (EID), Post Exposure Prophylaxis during breastfeeding, and access to treatment, management of AHD to end AIDS deaths in children.

KNCV

146. Support countries in scaling up the stool test with GeneXpert for TB diagnosis in children including development of generic SOP's, training materials and capacity building.

MSF

147. We commit to continue engaging in paediatric HIV and TB care wherever possible, to support sites where new tools and models can be piloted, to learn and disseminate and share experiences and lessons learned.

148. We commit to support the implementation of WHO guidelines wherever possible and to conduct operational research on paediatric TB care and contribute to the knowledge base for future guidelines through the TACTiC project (Test Avoid Cure TB in Children).

The Global Fund

149. The Global Fund commits to support the procurement of commodities and operational costs to maintain and further scale-up POC infant diagnosis, as well as viral load testing for infants, children, and pregnant and breastfeeding women and advanced HIV disease diagnostics, through cross-cutting diagnostic and health systems strengthening interventions as an integral part of optimized and integrated national diagnostic networks and in accordance with national plans and targets.

150. The Global Fund commits to encourage and support countries to adopt innovative contracting mechanisms designed to improve maintenance and servicing of laboratory devices (including those used for paediatric HIV and TB diagnosis and management); a shift towards all-inclusive pricing and reagent rental programs should be explored whenever possible.

151. The Global fund commits to support improved global and national coordination across donors to reduce disease funding silos for pediatric HIV and TB diagnostics, and where possible, pooling procurement volumes in negotiations with diagnostic manufacturers, and other activities.

152. The Global fund commits to support national, multi-disease diagnostic network optimization mapping exercises to maximise efficiency and increase access to paediatric HIV and TB diagnostic services. and support the introduction of multiplexing technologies for TB, HIV and other diseases affecting children.

153. Prioritize funding investments aimed at improving case detection by increasing access (new procurement and improved networks) to existing molecular WHO-recommended diagnostics (including the use of non-sputum testing, devices and consumables for non-sputum sample types), LF-LAM assays, and digital x-ray and AI technologies for screening for adults and children.

154. The Global Fund commits to encourage countries to plan for the introduction of new diagnostic tools for TB, such as near point of care tests, alternative sampling techniques and CAD for CXR technologies suitable for use in children.

155. The Global Fund commits to encourage and support countries to adopt innovative contracting mechanisms designed to improve maintenance and servicing of laboratory devices (including those used for paediatric HIV and TB diagnosis and management); a shift towards all-inclusive pricing and reagent rental programs should be explored whenever possible.

Commented [GB1]: Can maybe add wording in on computer aided Dx into this/AI

THE UNION

156. Support countries and stakeholders to prioritize the identification, diagnosis, and scale-up of TB activities that focus on active case finding and preventive treatment in children, including children living with HIV, via the Union Sub Saharan Africa Centre of Excellence for Child and Adolescent TB as well as in countries where we are working with National TB programmes.

157. Support the scale-up of access to priority formulations and diagnostics and to take steps to facilitate their wider roll-out by performing operational research when needed and ensuring The Union's existing paediatric publications and training tools are up to date and disseminated widely in a number of languages to promote the highest standard of care for all children with or at risk of TB.

Unitaid

158. Unitaid will continue to support, with WHO and partners, the roll out of a paediatric Advanced HIV Disease (AHD) package of care – including associated diagnostics and treatments, literacy and training, and enhanced monitoring & safety data platform for new and existing paediatric ARV drugs in project-countries and at global level. (1-2 years).

159. Unitaid will monitor the pipeline of new and existing diagnostic tools to support the EMTCT of HIV (as part of a program looking at the Elimination of Vertical Transmission for HIV as well as syphilis, HBV and Chagas). Further landscaping on new tools is planned for 2025. (1-3 years).

160. Unitaid will continue to advance EMTCT of HIV through forthcoming awards in 2025, in particular looking at pipeline of new and existing Dx tools and generating evidence on delivery approaches to identify and diagnose pregnant women, their partners and newborns (work including syphilis, HBV and Chagas in endemic areas).

161. Unitaid will support HIV diagnostics in the context of AHD and Stop AIDS package, in particular supporting the supply security of CD4 testing. (1-2 years).

162. Unitaid will continue to catalyse the evaluation and uptake of new tools and approaches to reduce the case detection gap through market acceleration, accuracy trials, operational research, and optimised implementation algorithms. (1-3 years).

163. Unitaid will support operational and implementation research to increase case-finding through new tools, testing procedures and algorithms, and the scale-up of product procurement in high TB burden countries. This includes the continue support of interventions on computer aided detection for TB screening for young children that also addresses affordability and other access barriers. (1-2 years).

164. Unitaid will follow-up on the outcomes from its workshop "Securing Access in TB through end-to-end Design" with key stakeholders to further ensure alignment and collaboration on access objectives and commitments to ensure access is considered as early as possible for emerging life-saving products for TB. (1-2 years).

165. Unitaid will monitor the pipeline of new diagnostic tools that support integration and can be leveraged across the diagnostic agenda for TB and HIV (1-5 years).

166. In addition to integrated screening approaches actioned through work on Triple Elimination, Unitaid will launch additional funding in 2025 for integration of diagnostics tools that will have benefits for pregnant women and children. This will enable Unitaid to continue work on accelerating the availability and affordability of innovative diagnostic tools, including those that benefit children

living with HIV, TB and other co-infections – either through funding late-stage development or product adaptations (including sample approaches) that will adapt to the settings these tools are needed, or through introduction and delivery.

167. Unitaid will support current efforts to transition from outright instrument procurement to all-inclusive bundles, or other novel pricing models to ensure in-country harmonization of commodity procurement.

UNITE

161. UNITE will advocate for improved data gathering systems so that policy decisions are based in complete, high quality, and relevant evidence.

162. UNITE will promote political support to community-led monitoring as a relevant source of information to address local challenges in access to services.

163. UNITE will advocate for parliamentarians to oversee the implementation of international commitments on health, including for HIV & AIDS, TB, universal health care, access to medicines, and maternal, newborn, and child health, among others.

164. UNITE will collaborate with donors like Unitaid and The Global Fund to support capacity building and strengthen parliamentary advocacy.

WHO GTB

165. Update WHO policy guidance to reflect the latest advances in TB screening and testing in children and adolescents, including use of new sample types, testing technologies, and testing strategies, to support informed planning and rapid uptake of new WHO policy recommendations.

166. Support countries to adopt advances in WHO guidance on TB diagnostic testing and approaches into national policies and strategic plans to ensure achievement of End TB Strategy universal access to diagnostic and drug susceptibility testing services.

WHO HIV

167. Convene a regular technical working group of child health and diagnostic experts to focus on technical and programmatic challenges at regional and country levels to strengthen diagnostic networks for children at risk of HIV or TB in order to ensure appropriate and accurate testing platforms and quality services continue to be available to all infants and children

- In collaboration with UNAIDS and UNICEF regional and country colleagues, review current challenges related to infant diagnosis in WCA and provide remote targeted TA through WHO regional MCATS to strengthen national laboratory systems to provide, process, and report accurate and timely results to inform treatment and long-term care.
- Complete a systematic scooping review on strategies for paediatric case finding to inform further systematic reviews for evidence to further guide normative policy on paediatric case finding.
- Continue to advocate for diagnostic integration to ensure health systems are able to maintain functional diagnostic equipment, efficient and reliable sample transport, standardized reporting of results, and quality assurance processes to ensure accuracy of results.
- Provide remote TA to country programs to develop a surveillance for pre-treatment drug resistance in all infants diagnosed with HIV infection using WHO-developed reporting protocols.
- Continue to work with clinical partners to monitor the emergence of drug resistance in infants, children, adolescents, and young adults with treatment failure on dolutegravir-containing regimens.

WORLD COUCIL OF CHURCHES

168. The World Council of Churches commits to educate and mobilize religious leaders and faith communities, including using the media, in six African countries, to challenge HIV stigma and discrimination as a barrier for early testing and treatment of children exposed or living with HIV.

169. The World Council of Churches commits to disseminate the *Analysis Impact of HIV stigma in the uptake of services among women, adolescents and children living with HIV*, highlighting how HIV stigma is blocking and limiting access but also proposing solutions from the community level.

World Vision

170. Expand access to stool-based and molecular diagnostics to improve early, non-invasive and accurate detection of TB in children.

171. Improve contact tracing and household screening, linking eligible children to TB Preventive Therapy (TPT).

172. Enhance Early Infant Diagnosis (EID) services to facilitate timely ART initiation for HIV-exposed infants.

173. Support growth monitoring and promotion services, including caregiver counselling, to ensure early detection of child undernutrition that may co-exist with HIV and TB.

Solutions and actions on INTRODUCTION AND SCALE-UP OF MEDICINES FOR CHILDREN AND THEIR MOTHERS (HIV and TB)

EGPAF

170. EGPAF will provide technical assistance to support and enhance collaboration among key stakeholders, ensuring rapid access to the most optimal paediatric ARV formulations (pALD, pDTG). This effort will be carried out in close consultation with civil society, communities, and people living with HIV.

171. EGPAF commits to collaborating with global partners to ensure quick access to the most optimal paediatric ARV formulations, including pDTG and pALD, as co-chair of the GAP-f pDTG Task Team (within the Product Access and Treatment Delivery working group).

172. EGPAF commits to continuing working with the GAP-f civil society and community engagement group to mobilize and align advocacy work to accelerate the introduction of optimal treatment for children.

173. Building on a decade of experience leading the access to darunavir through the New Horizons Advancing Paediatric HIV Care Collaborative (NHC), EGPAF commits to supporting the scale up to generic darunavir/ritonavir among adolescents and adults.

Additionally, EGPAF will facilitate the introduction of paediatric generic darunavir/ritonavir formulation for children with treatment failure on DTG based ART.

174. EGPAF commits to ensure equitable access to long-acting prevention and treatment of HIV in low- and middle-income countries (LMICs).

175. EGPAF commits to work with the stakeholders to assure access to the long-acting cabotegravir and cabotegravir/rilpivirine in LMICs by reaching out to at risk key populations for the prevention and transitioning eligible patients on oral ART to long-acting treatment.

176. Long-acting injectable lenacapavir is approved for HIV treatment and has demonstrated promising results in clinical trials for HIV prevention, currently pending FDA review and approval. EGPAG commits to ensure fast and equitable access to generic lenacapavir (alongside the generic sublicensees) for the prevention of HIV and treatment of multi-drug-resistant HIV.

Ecumenical Pharmaceutical Network (EPN)

177. **Product introduction in Sub-Saharan Africa.** EPN and members will support the collaborative efforts of partners and governments to adopt new and affordable innovative HIV-TB diagnostics and medicines by:

- Promoting their market introduction/authorization in conjunction with other stakeholders
- Disseminating Essential Medicine Lists (EML) for Paediatric HIV-TB, Standards Treatment Guidelines (STGs) adopted/updated for HIV and TB management in health facilities at country levels.
- Continuing training of HCWs to comply with updated treatment guidelines for HIV-TB and adoption of innovative products.
- Championing the product introduction at country level and in FBO health systems, leveraging on EPN ongoing experience in supporting the introduction of innovative MNCH products for PPH management.

178. **Building trust in innovative HIV-TB medicines.** EPN and members commit to play a central role in building trust in newly developed innovative products to accelerate their uptake and scalability.

- EPN will engage champions and faith leaders within her membership to access the evidences associated with innovative paediatric HIV-TB diagnostics and medicines
- Utilization of EPN's Treatment Literacy Guide for faith leaders to build the capacity of faith leaders on barriers affecting children's access to care, adherence to treatment, sharing updated information on nationally adopted HIV-TB treatment regimens and overall well-being.

179. **Monitoring and reporting on the quality of HIV-TB medicines and diagnostics.** EPN commit to work with its Minilab network in Sub-Saharan Africa, to continue monitoring the quality of medicines entering the church health systems and educating health care workers involved in procurement, distribution and dispensing of medicines by:

- Advocating for the adoption of rapid, cost-effective and field-adapted quality control tools to monitor the quality of HIV-TB products in the supply chain
- Training healthcare workers involved in reception of health products on visual inspection and wide use of checklists to ensure quality products are received in health facilities and dispensed to patients.
- Enhancing collaboration with National Regulatory Authorities in raising awareness on the risk of SF medicines and active participation in pharmacovigilance efforts at country and regional levels.
- Leveraging on the EPN Minilab Network in Africa to collaborate with Africa Medicine Agency and country NRAs to share information on any reported quality issues related to HIV-TB medicines across the Minilab Network.
- Continuing the reporting efforts on SF medicines through the WHO alert system.

GAP-F

180. GAP-f commits to leveraging the Task Teams established under the Product Access and Treatment Delivery (PATD) Working Group, including those focused on paediatric dolutegravir (pDTG/pALD) to strengthen collaboration, coordination, and information sharing among stakeholders to facilitate expanded roll out of pALD and introduce novel DRVr fixed dose combinations.

GNP+

181. GNP+ commits to strengthen people living with HIV, and communities led advocacy for children's health through sustaining treatment literacy, promoting benefits of HIV science though the U=U Campaign, demand creation, prioritize case finding of children

impacted by HIV and timely diagnosis and access to high-quality healthcare services for children living with HIV. Our priority will be to influence policy changes that prioritise reaching all children living with HIV, ensuring Viral suppression for children living with HIV, intention care for Advanced HIV Disease (AHD) in children living with HIV to reduce the number of deaths among children living with HIV.

182. GNP+ will continue to strengthen people living with HIV representation and participation in global level advocacy particularly mobilizing parent, caregivers and champions for children's advocacy for children's access to HIV treatment and prevention services.

IMPAACT4TB

183. (Ongoing from 2022) Generate further evidence to support adoption of short rifapentine based TB preventive treatment regimens in overlooked populations including paediatrics and pregnant women by adopting a family-centred approach to TPT. With most institutional review board and WHO ethics review board approvals in place, to the studies will start 2023.

- *Dolphin Kids*: evaluating safety, tolerability, and drug-drug Interactions of 3HP and DTG-based antiretroviral treatment in infants, children and adolescents living with HIV.
- *Dolphin Moms*: investigating the safety, tolerability, and pharmacokinetics, and potential interactions between DTG and rifapentine during pregnancy in people with HIV when RPT is given with isoniazid (1HP or 3HP) as preventive treatment.
- One to Three Trial: comparing treatment completion of 1HP to 3HP among PLHIV and household contacts in adolescents and adults.

184. (Ongoing from 2022) Accelerate access to paediatric formulation of rifapentine – Generic manufacturer filed and product expected end February 2024. *Expression of interest for early access to paediatric formulation launched in December 2023, closed end of October 2024. 13 countries have procured so far across various funding sources.* IMPAACT4TB commit to continue to implement d*emonstration study in HIV negative children. Evidence for HIV positive children on DTG-based ART will be available by Q2, 2025.*

KNCV

185. Work with National TB Programme (NTP) and country stakeholders to develop a platform and mechanism to ensure all commitments turn into action.

186. Support countries to develop national strategic plans and Global Fund concept notes that are data driven and addressing the needs of children and adolescents in the entire patient pathway.

187. Produce high quality documentation of our best practices and evidence to share at global platforms to guide global policies and guidelines. Sharing experience on the implementation of WHO guidelines on TB in children and adolescents.

188. Engage with civil society and community representatives to create sense of urgency at country level to ensure all children and adolescents needs related to TB/HIV are implemented.

189. Support countries to self-assess and quantify the programmatic implementation of WHO recommendations on the management of TB in children and adolescents and strengthened stakeholder collaboration towards ending TB in children and adolescents.

MPP

190. MPP is committed to fulfilling its 2017 and 2018 commitments to the Rome Action Plan, respectively to: facilitate access to paediatric medicines prioritized by WHO and PADO, and to inform countries about opportunities to access affordable, quality-assured WHO-recommended paediatric medicines in adapted formulations through MPP licensees. These efforts will continue to include direct licence management support to generic manufacturers.

191. Active MPP engagement in the Global Accelerator for Paediatric Formulations (GAP-f), as both a founding member and the Vice Chair of its Strategy and Coordination Committee, will also continue to be a central part of MPP's contribution to paediatric drug optimization. In particular, MPP commits to continue having a central leadership role in GAP-f as Vice Chair of GAP-f's Strategy Group at least until the end of 2025, with consideration for extension up to 2028 would MPP's funding outlook allow this possibility.

192. MPP will also aim to continue strengthening its alignment with PADO processes, especially when these overlap with MPP in-licensing prioritization efforts, for both existing and pipeline products, in HIV, TB, and other infectious and non-communicable diseases.

The Global Fund

193. The Global Fund commits to support and accelerate the introduction of innovative HIV prevention options, including lenacapavir (LEN).

194. The Global Fund, building on longstanding investments in drug optimization, commits to accelerating the rollout of pALD and pDRVr, and support the rollout other novel optimal formulations for pediatric HIV prevention and treatment, working with partners including the GAP-f pDTG task team.

195. The Global Fund commits to streamline and shorten critical quality assurance processes (such as sample testing) to accelerate the GF's ability to place a first order via the Pooled Procurement Mechanism for a new paediatric product.

196. Support the procurement of child-friendly formulations for all TB treatments (DSTB, DRTB and TPT) in line with the Program Essentials promoting short, all oral regimens.

THE UNION

197. Advocate for the rights of all children, including those living with HIV, to receive TB care and treatment and promote a human-rights based approach to TB; including ensuring that paediatric TB is highlighted in our annual World Conference on Lung Health.

198. Collaborate with countries and stakeholders who are working on the development, and monitoring, of country level roadmaps which aim to highlight critical gaps in implementation of the end-to-end TB care cascade, including policy gaps.

Unitaid

199. Unitaid will support implementation science with innovative LA PrEP to ensure it can benefit pregnant and breastfeeding women and their babies with current grants being expanded in South Africa and Brazil. (1-2 years).

200. For lenacapavir, and other LA PrEP products, Unitaid remains committed to supporting access and product intro with new grants in collaboration with partners to address the market and adoption in the fastest way possible and in as many countries as possible to ensure nobody is left behind, with a focus on young women and girls. (1-3 years).

201. Unitaid will expand its support for the adoption and implementation of better optimized DR-TB regimens in the context of comprehensive care package which is driven by communities and civil society and which considers interventions to ensure the

inclusion of children and pregnant/lactating women. This also includes the scaling up of levofloxacin for preventative therapy for children at risk for DR-TB.

202. Unitaid will continue to advance as merited a long-acting ripentine/isoniazid preventive therapy including exploring child-friendly administration methods such as microarray patches (3-5 years).

203. Unitaid will explore opportunities to support further work to improve access to innovation and quality care for children and pregnant/lactating women in TB through expert and partner consultation to build on impact from work through the BENEFIT Kids project including support for the CHEETA platform. (1-2).

UNITE

200. UNITE will advocate through its network for increased investments in health systems to increase access to essential medicines and healthcare technologies.

201. UNITE will promote regional manufacturing of health technologies.

202. UNITE will promote support for and engagement with donor organisations, such as The Global Fund and Unitaid, including by supporting their replenishment processes.

203. UNITE will leverage its informal working group on HIV/AIDS in the European Parliament to reach a resolution calling on the European Commission to develop a European Action Plan on HIV/AIDS, which includes specifically paediatric HIV and the EU's global role in tackling this problem.

WHO GTB

204. Continue to support countries to collect, and report and use data on TB in children and young adolescents. This includes data on uptake of shorter regimens, children and young adolescents tested for HIV, proportion of people with TB who are HIV-infected and access to ART, in collaboration with UNAIDS and other partners, and to publish data in the WHO Global TB Report.

205. Continue to convene the Paediatric Antiviral Working Group (PAWG) to review available evidence to inform recommendations on dosing and use of HIV agents in infants and children and though that apply and continue to promote use of harmonized paediatric weight bands across all disease areas.

- In collaboration with developers and paediatric clinical research networks, monitor the pipeline of agents that hold potential for treatment or prevention of HIV in use in infants and children (including LAI ARVs and bNAbs).
- Undertake a new PADO exercise by the end of 2025 to update priority HIV medicines and formulations for research and development.
- Convene the revision of the ARV optimal formulary and its rapid translation through the upcoming revision of WHO EMLc revision by April 2025.
- Support reporting platforms to monitor safety and effectiveness of new therapeutic agents in neonates, infants, and young children, particularly in LMIC.
- Collaborate with WHO GTB colleagues to review evidence and develop guidance on use of short course TPT regimens in infants and children with and without HIV.

WORLD COUNCIL OF CHURCHES

206. The World Council of Churches commits to mobilize religious leaders and faith communities in six African countries, particularly the women's and youth fellowships; for the preparedness and education of new HIV medications and/or new formulations for children living with HIV.

207. The World Council of Churches commits to educate, mobilize and create demand among religious leaders and faith communities in six African countries, to advocate for universal access to preventive measures for pregnant women living with HIV and exposed children. To advocate for prevention of vertical transmission of HIV in the context reproductive health.

208. In the context of drastic reduction of international aid, the World Council of Churches commits to advocate for the continuation of services to prevent vertical transmission of HIV and to ensure universal access to paediatric HIV treatment.

World Vision

209. Support the introduction and scale-up of child-friendly TB and HIV formulations, including shorter treatment regimens for DS-TB in children.

210. Increase paediatric ART coverage by 20–48% by 2026 using WHO-recommended regimens.

211. Implement and expand TPT among eligible children, especially under-fives.

212. Strengthen supply chain systems to ensure the timely and consistent availability of paediatric TB and HIV medicines.

213. Integrate supplementary feeding and Community-Based Management of Acute Malnutrition (CMAM) into paediatric TB and HIV programming for malnourished children and pregnant/breastfeeding women undergoing treatment.

ADVOCACY BROADER CHILD HEALTH COMMITMENTS

Caritas

214. Advocate for the engagement of religious leaders and the involvement of faith communities, through awareness and mobilization, to increase demand and access to paediatric HIV and TB services, while combating HIV and TB stigma and discrimination.

215. Advocate on unmet diagnostic, treatment, prevention, and retention in care needs for children with or at risk of HIV and TB, also strengthening community and places of worship activities related to PMTCT.

216. Advocate for expanding access to diagnosis and treatment for children in conflict, crises (including climate crises), and children on the move.

217. Advocate to highlight the importance of spiritual health and care and psychosocial support in children and families at risk or with HIV and TB.

218. Advocate for debt relief to address the unjust financial burdens that force governments to divert resources from essential services like healthcare, weakening systems, deepening inequalities, and leaving the most vulnerable without access to vital care, especially in the current international context, marked by the reduction on foreign aid.

EDCTP

219. Global Health EDCTP3 is also aiming to support overarching health challenges and cross-cutting societal and technological challenges. It is in this context that the use of artificial intelligence with a backbone of growing digital technology has the potential to significantly advance the field of detection and identification of infectious diseases. This could be an area that could be explored with other funders in preparation of Global Health EDCTP3 WPs 2026-2027.

EGPAF

210. Collect, analyze, and disseminate paediatric data annually to generate evidence and address disparities between children and adults in accessing HIV testing, treatment, and viral load suppression across EGPAF programs.

211. EGPAF commits to developing and supporting a comprehensive child health strategy that prioritizes HIV free survival, early childhood development and vaccination alongside HIV screening, treatment and support.

MSF

212. We commit to advocate for access to existing tools and for research and development of new tools to improve the care of children affected by HIV and TB, including tools for the diagnosis, treatment and prevention.

213. We commit to work in close collaboration with other stakeholders to address the needs of children affected by HIV and TB wherever possible.

214. We commit our utmost efforts to support national programs and local health care workers to gain competence and confidence in managing Paediatric HIV and TB patients and to Ministries of Health to scale-up HIV and TB programs.

215. We commit to the presence of MSF in stakeholders' platforms (national and international) wherever possible to share our experiences and operational lessons learned.

PMNCH Network

216. Advocating to ensure that children's health is addressed in effective policies, financing and services.

217. Leveraging the highest-level political leadership to drive transformative change, including through the Global Leaders Network for Women's, Children's, and Adolescents' Health (GLN), the first and only Southern-led global health diplomacy initiative chaired by H.E. President Ramaphosa to advance the 2030 SDGs related to women, children, and adolescents.

218. Driving accountability through multi-stakeholder platforms at national and sub-national levels, by convening actors to ensure countries and partners deliver on their existing national commitments on women's, children's and adolescent's health.

219. Catalysing public-private-philanthropic partner (PPPP) models to advance maternal, newborn, child and adolescent health and implementing new and different models of delivery of financing and care.

UNAIDS

220. UNAIDS has led the process to set new targets for 2030 for the Global AIDS response which includes specific attention to coverage of services for HIV exposed and HIV infected infants, children, and their mothers. UNAIDS commits to ensuring 2030 targets are emphasized in the new 2026-2031 Global AIDS Strategy and to support countries to adopt them in the high-level meeting of all UN member states in 2026 and to operationalize them in national strategies. UNAIDS further commits to maintaining accountability of countries for progress through collection and dissemination of regular updates on country progress against targets.

221. UNAIDS commits to promoting mother and child health service integration as an essential element of country specific HIV response sustainability roadmaps and plans.

222. UNAIDS will continue to advocate for rapid and equitable access to scientific innovations in testing, treatment and prevention for mothers and children, work with partners to promote crucial research and development agendas, and support the translation of research evidence into policy and programs

223. UNAIDS, through the Global Alliance partnership, will maintain Paediatric HIV and TB high on global and local political agendas, and champion eliminating inequities that hamper effective HIV services among mothers and children to promote country implementation at scale.

Unitaid

224. Unitaid has included women's and children's health as a key objective of its Strategy through 2027 (link) with additional dedicated efforts spanning **post-partum hemorrhage, pre-eclampsia, maternal anemia, eliminating vertical transmission of syphilis, hepatitis B, and Chagas (together with HIV) :** new grants to support systems that increase the availability to and optimal utilization of critical maternal and newborn health products, especially focused on the major causes of maternal and newborn mortality and prevention of stillbirth.

225. Unitaid will pursue opportunities to strengthen regional manufacturing of diagnostics and therapeutics, through two new grants that will be awarded in 2025.

WHO

226. Strengthen support to sustain the work of the World Health Organization in an evolving global health landscape, as the leading agency on providing strategic direction towards ending TB and HIV in children.

227. Widely disseminate, in collaboration with the WHO Civil Society Task Force on TB and technical partners, WHO policy guidance on the prevention and management of TB in children and adolescents as well as the key actions of the 2023 Roadmap towards ending TB in children and adolescents to accelerate their uptake and implementation at all levels of care. This includes, among others, support to national TB and child health programmes to adopt and implement all relevant WHO policy recommendations and ensuring that the needs of children and adolescents with TB or at risk of TB are included in national strategic plans and related funding applications.

228. Building on the Political Declaration of the 2023 UN High-level meeting on the Fight Against Tuberculosis, widely disseminate and provide country support for implementation of the 2024 WHO/ILO Guidance on social protection for people affected by TB, in collaboration with the WHO Civil Society Task Force on TB, relevant United Nations agencies and technical partners.

WHO HIV

229. Co-chair the Pillar 1 Working Group of the Global Alliance to End HIV in Children to review country programme data, disseminate global policies and resources, and provide a platform for shared learning and accountability across all partners working with infants, children, or adolescents living with or affected by HIV or TB.

- In collaboration with Global Alliance partners, support targeted ECHO sessions for regional and country colleagues on paediatric HIV, TB, or Hepatitis topics of interest including dissemination of current or new WHO HIV, TB, Hepatitis, and STI guidelines.
- Develop a feedback loop in collaboration with PATA and other child health-related professional networks to support global health leaders and decision makers to use direct evidence to inform normative health policy.
- Convene a technical working group of regional and country program managers and government representatives to identify country-specific challenges and coordinate country level assistance through a network of implementing partners.
- Commit to provide remote and routine review of Global Alliance country action plans and data on Global Alliance Pillar 1 indicators and providing coordinated feedback to program managers in *near* real time (monthly calls with schedule of data to review).

World Vision

230. Provide nutritional support, including CMAM and supplementary feeding, to children and caregivers affected by TB and HIV.

231. Promote Positive Deviance/Hearth (PD/Hearth) approaches that teach caregivers to use locally available foods to address undernutrition.

232. Engage faith-based and community structures to increase awareness, reduce stigma, and promote uptake of TB/HIV and nutrition services.

233. Establish child-friendly spaces at healthcare facilities and integrate early childhood development (ECD) into child health programming.

234. Leverage over 135,000 community health workers (CHWs) to deliver integrated TB, HIV, and nutrition services, including counselling and monitoring.

Solutions and actions related to RESEARCH & DEVELOPMENT OF DIAGNOSTICS FOR CHILDREN (HIV and TB)

To Funders:

- Commit investments on research infrastructure (such as increased number and capacity of paediatric research sites for diagnostics & treatment) necessary to accelerate paediatric investigations of new diagnostics
- Commit Investments in fundamental, clinical and implementation research
- Investment in development and evaluation of non-sputum based, point of care tests (novel biomarkers and molecular tests) to include diagnosis in children with consideration of difference between childhood TB vs adult TB

The Union, FIND, researchers and WHO:

- Include children as a focus in the annual Union update on new diagnostics (children were excluded from the FIND 2024 Union diagnostic symposium)
- Analyze and showcase the reality of the diagnostic pipeline specific to diagnostic considerations in children

To NIH, CAPTURE, FIND, UNITAID and Stop TB:

- Evaluate and Validate CAD tools for young children and ensure that they are available at reasonable and negotiated prices

To Industry, manufactures:

- Include children early in R&D for development of tools such as AI for CXR diagnosis, tongue swabs and other novel diagnostic modalities.
- Consider multiplexing for diagnostic approaches including TB for manufacturers and R&D (Cepheid, FIND, Beckton-Dickinson, Bio-Merieux, Qiagen and others)

The Union:

- Include a specific focus on children in an upcoming Union conference

WHO and Unitaid:

- Circulate specific research gaps, share TPPs, share lessons learnt from collaborative research approaches on treatment decision algorithms
- Encourage competition for existing near-POC tests, local production etc. to lower the prices of currently available tests.
- Bring to market new diagnostics in the pipeline that would address specific needs in children and ensuring affordable pricing
- Ensuring and advocating for ongoing quality assurance process for diagnostics.

Solutions and actions related to RESEARCH & DEVELOPMENT OF MEDICINES FOR CHILDREN (HIV and TB)

Ask to all stakeholders - TB remains under-prioritized and under-resourced compared to other infectious diseases. There needs to be more sustained investment in universal health services for TB paediatric R&D for TB medicines and vaccines, particularly late stage R&D.

EDCTP3's Asks

- Encourage researchers to submit applications to the WP 2025 call on transformative Innovations in global health
- Invite strategic partners to engage in discussions with Global Health EDCTP3 as potential contributing partners for a joint call (e.g. on treatment, or perhaps on co-infections and co-morbidities) to be developed in the context of the WPs 2026-2027.
    - *Highlight the EDCTP financing model and how it mobilises resources from multiple sources, combining funding from Participating States, the EU, as well as public and private partners.*
    - *Highlight the strategic funding approach we use in collaboration with other partners, such as portfolio funding, which is an approach that provides the opportunity for more coordination across phases of research and accommodates the flexibility needed for adaptive trial designs in late-stage clinical research.*

EPN's Asks

WHO, UNITAID and other partners in conjunction with R&D Pharmaceutical companies to work with CSOs platforms to promote ongoing R&D efforts in healthcare professional bodies. Learning from Covid-19, it is crucial to not wait for a life-saving product to be ready for market authorization to promote among HCWs the efforts which led to its development.

PENTA's Asks

Penta requests: Pharmaceutical companies (ViiV Health care and Gilead) commit to providing antiretrovirals (including novel long acting formulations and monoclonals for the trial More broadly we ask pharmaceutical companies commit to working with us to ensure novel therapies can be assessed in a timely way in children and a high-quality evidence is generated to inform guidelines and policies, so children and adolescents have the same treatment choices as their adult counterparts.

ViiV Healthcare's Asks

Ask to research networks - To improve availability of innovative treatment options for paediatric populations, we require research networks to revise processes to accelerate data generation. This will help avert delays in study timelines and data generation which impacts access to and availability of paediatric formulations.

Ask to Diagnostics sector – To achieve this, we request that the diagnostics sector supports expanding access to innovative and easy to administer point of care testing/early infant diagnosis and resistance testing. We recognise this is critical to speed up diagnosis and treatment initiation for children and reduce the gap between adult and paediatric treatment and outcomes.

Asks to Industry and donors

UNICEF calls on pharmaceutical companies, diagnostics manufacturers, and funders to:

- Sustain investment in paediatric HIV and TB treatments, ensuring that innovations in adult care are not delayed for children.
- Expand research efforts to include pregnant women and children, ensuring that new medicines and diagnostics are optimized for these populations from the outset.

To Otsuka (quabodepistat), GSK (ganfeberole), and TB Alliance (TBAJ-876 and others), as well as other sponsors of new TB drugs

- Commit to developing child-friendly scored dispersible tablets and working with CHEETA and other partners to initiate pediatric investigations within 1 year of opening their phase III trial to accrual.

To Global Health Partners: Strengthening Collaborative Efforts

- Appeal to **research networks and funding agencies to support paediatric research efforts** and ensure that **clinical trials are adequately resourced.**
- **Urging funders and global health partners to actively contribute to research platforms dedicated to paediatric TB.**
- **Strengthening investment in collaborative research platforms like Cheetah to drive clinical trials and innovative treatment strategies.**
- Greater **engagement from policymakers and multilateral organizations to streamline the introduction of new therapies into national HIV programs.**

To Pharmaceutical and Industry Partners: Sustaining R&D Commitments

- Urging **industry stakeholders to maintain a strong focus on HIV R&D** and **prevent deprioritization of paediatric and maternal treatment options**.
- **Encouraging continued investments** in paediatric formulations and ensuring that **new treatments are developed with equitable access in mind**.

To Donors:

- Catalytic pool funding to support pediatric investigation on better drug formulations
- Commit to increasing investments in pediatric TB R&D:
- Support development of additional research infrastructure (such as increased number and capacity of pediatric trial sites) necessary to accelerate pediatric investigations of new TB drugs, including through a platform trial or other innovative approaches

To WHO

- In collaboration with CHEETA and partners: commits to convening key stakeholders including researchers, global regulators and industry, to explore regulatory efficiencies and innovative study designs, such as a platform trial, to accelerate generation of evidence for approval and use of novel TB medicines in children.

- Encourage the link between use of TDAs and access to short term treatment (4month vs 6-month).

To Vaccine developer:

- Inclusions of children in R and D.

Solutions and actions related to RESEARCH & DEVELOPMENT OF MEDICINES FOR PREGNANT AND LACTATING WOMEN (HIV and TB)

ViiV Healthcares's Asks

- ViiV continues to collect maternal and fetal outcome data in HIV Prevention Trial Network study 084 (HTPN 084). This includes data from women who have enrolled in the ViiV sponsored study (PALISADE) which delivers ongoing drug access for study trial participants. *Asks of research networks – We invite IMPAACT to create a protocol for studying drugs in pregnancy, which can be deployed as new drugs become available – to accelerate data generation in both pregnancy and breastfeeding.*
- *ViiV requests that paediatric clinical trial networks collaborate with adult clinical trial networks to support enrolment of adolescents in Phase 3 trials.*

Solutions and actions on global, regional, and national REGULATORY PROCESSES FOR DIAGNOSTICS AND MEDICINES FOR PREGNANT AND BREASTFEEDING WOMEN (HIV and TB).

African Union Asks

- Support advocacy to ensure all African Union members ratify AMA.
- Secure funding to sustain AMA's operations.

EDCTP's Asks

- Encourage regional bodies such as AVAREF, AMRHI and AMA to make continued efforts to coordinate regulatory efforts to streamline approval processes.

- Invite strategic partners to engage in discussions with Global Health EDCTP3 as potential contributing partners in the WP 2025 calls on Regional Networks of Excellence and Epidemic Preparedness Consortia and the Strategic Training Hubs
- Invite strategic partners to engage in discussions with Global Health EDCTP3 as potential contributing partners for a joint call on ethics, regulatory and pharmacovigilance capacities in SSA to be developed in the context of the WPs 2026-2027.

EPN asks

- Investment in last-mile drug quality control.
- Ensure faith-based networks are systematically included in regulatory and supply chain planning.

Asks to regulators:

- **Fast-Tracking Approvals and Harmonizing Processes**
  - **Regulatory delays remain a major bottleneck** in ensuring that children and adults receive **timely access to new HIV treatments**.
  - Calls for **accelerated regulatory reviews and harmonized approval processes** to prevent **unnecessary delays in rolling out new treatments**.
  - Encouragement for **parallel regulatory submissions** across agencies to **improve efficiency and reduce approval timelines**.
- Standardized Regulatory Guidelines for HIV Medicines in Pregnancy & Breastfeeding: Regulators must adopt consistent global standards for paediatric HIV and pregnancy studies.
- Leveraging global research networks to facilitate data sharing, optimize study designs, and accelerate access to new TB treatments.
- Reforming Paediatric TB Drug Approvals. Move away from inefficient efficacy trials and instead rely on pharmacokinetics & safety data.
  - 1/ In recent years, regulatory authorities have requested efficacy studies in children rather than pharmacokinetics studies. We find this challenging because TB efficacy trials in children are difficult to conduct because the diagnostic and treatment infrastructure for children is not well-developed therefore TB and drug resistance are not well diagnosed in children. Subsequently, efficacy studies are lengthy, operationally complex and expensive. 2/Regulatory requirements for new TB regimens need to be clarified to help developers avoid potential delays in generating data for both adult and paediatric formulations. We propose assessing paediatric populations in pharmacokinetic, safety and tolerability studies, where appropriate to ensure timely access to novel products and regimens.

- Global Regulatory Alignment. WHO, national regulators, and pharmaceutical companies must harmonize approval processes.
- Avoid Additional Regulatory Burdens. Ensure new drug approval requirements do not introduce unnecessary delays for paediatric formulations.
- Improve Coordination Between Regulatory Authorities
    - Differences between WHO guidance and national agency requirements create inefficiencies in drug approvals.
    - Regulatory reliance must be scaled up for more predictable and synchronized processes.

- WHO ASK for TB - Regulatory requirements for stringent regulatory authority approvals and WHO treatment guidelines are not always aligned and can be contradictory. This can result in a 2-step regulatory process which is less efficient. We appreciated that last year the WHO provided guidance on evidence generation related to new regimens for tuberculosis treatment committed to provide more clarity. However, we would ask WHO to be more explicit about data requirements as well as the policy and regulatory pathway to market for new TB drugs. This reduces risks and uncertainties for developers and supports timely access to innovative products.

ViiV's Asks
- To standardize guidance for all companies undertaking registrational studies, in which pregnant and lactating women participate, regulators are invited to provide guidance which can be adopted by all companies to avert disparities in practice and underpin equity with respected to data generation and results interpretation for these cohorts.
- Regulators must adopt consistent global standards for paediatric HIV and pregnancy studies.

GSK's Asks:
- Reforming Paediatric TB Drug Approvals Regulatory requirements for new TB regimens need to be clarified to help avoid potential delays in generating data for both adult and paediatric formulations. We propose assessing paediatric populations in pharmacokinetic, safety and tolerability studies and where appropriate ensure timely access to novel products and regimens.

To Industry and donors
- Strengthen partnerships with procurement and regulatory bodies to facilitate faster approvals and distribution of essential paediatric treatments.

To all stakeholders

- Advocating for **stronger partnerships between researchers, industry, and regulatory bodies to design and implement paediatric TB trials more effectively.**
- Gilead calls on research networks, regulators, and global health partners to work together in expediting paediatric and maternal clinical trials.
- Greater focus is needed on implementation science research to ensure new therapies reach the most affected communities.

ASKs on solutions and actions on IDENTIFYING AND DIAGNOSING CHILDREN (HIV and TB)

To the Global Fund

- Advocate to improve case finding for HIV and TB in children through specific guidance notes, sensitization and political awareness raising.
- Support implementation of Global Fund Program Essentials and operational and implementation research aimed at increasing case-finding through new tools, testing procedures and algorithms, and the scale-up of WHO recommended guidelines and product procurement in high TB burden countries.

The Union's Ask:

- The Union ASKs all partners, donors and countries to prioritize activities and funding streams that will increase pediatric case detection by focusing on active case finding activities to ensure that we are achieving the targeted reduction in TB incidence rates, in children and their families, as set forth by the WHO.

GNP+'s Asks

- The Global Network of People Living with HIV (GNP+) is committed to mobilizing PLHIV, communities and Civil society to address inequalities and structural barriers to case finding, diagnosis and treatment of children living with HIV. Including Stigma, discrimination, criminalization, and violence.

- Mobilizing peer-to-peer support structures that strengthen case finding to reach all children affected by HIV towards timely diagnosis and initiation to treatment including effective management of children with AHD.

Asks to donors and funders

- Commit to work together towards reducing disease funding silos for diagnostics in order to encourage and support more comprehensive diagnostic strategies, including person-and family-centred care, diagnostic integration and network efficiencies with an emphasis on paediatric specific testing needs, which continuously lag behind adult testing coverage.
- For Funders: Ensure that upstream and downstream donors of diagnostic technologies are aligning regularly on access terms to manufacturers across the value chain – from early product development, trials, introduction and finally to scale

Countries and implementing partners.

- MSF, EGPAF, CDC/Centres of excellence, WHO together with countries should collaborae to ensure addressing policy gaps and monitoring implementation using previous policy landscape analysis.
- Advocate to develop roadmaps, include budget in national and donor budgets with a specific focus on diagnostics for children affected by TB.

Asks to WHO

- Monitoring of implementation of diagnostic guidelines and policies globally and continued reporting on case finding indicators
- Include paediatric TB as a specific focus of a WHO 2025 Global TB Report

Asks to the Global Fund:

- Grant Cycle 8 to invest in scale up of near-POC and low-complexity diagnostics.
- Commit to rapidly implementing new diagnostic tools once available, in children (AI CXR, swabs, saliva and other diagnostic tools for TB diagnosis.
- Advocate for improved case detection through sensitization efforts, political awareness raising and guidance (across HIV and TB).
- Support the implementation of Global Fund Program Essentials, as well as operational and implementation research to strengthen case finding using new tools, testing procedures, algorithms, and the scale-up of WHO-recommended guidelines and product procurement in high TB burden countries.

- Commit to working together towards reducing disease funding silos for diagnostics in order to encourage and support more comprehensive diagnostic strategies, including person-centred care, diagnostic integration and network – optimization – with an emphasis on pediatric specific testing needs, which continuously lag behind adult testing coverage.

- Ensure that upstream and downstream donors of diagnostic technologies are aligning regularly on access terms to manufacturers across the value chain – from early product development, trials, introduction and finally to scale

- Encourage and support countries to adopt innovative contracting mechanisms designed to improve maintenance and servicing of laboratory devices (including those used for paediatric HIV AND TB diagnosis and management); a shift towards all-inclusive pricing and reagent rental programs should be explored whenever possible.

Solutions and actions on INTRODUCTION AND SCALE-UP OF MEDICINES FOR CHILDREN AND THEIR MOTHERS (HIV and TB)

Asks to the Global Fund:

- Building on its longstanding investment on drug optimization for treatment and prevention of HIV, commits to play a catalytic role in the introduction of novel optimal formulations for the prevention and treatment of HIV in children. In this context they are mobilizing resources for technical support and market shaping interventions and call for the collaboration of other funders to boost urgent action and address the needs of countries in accelerating the introduction and roll out of pALD and pDRVr by the end of 2026.

Caritas' Asks:

- Increase rollout, scaling up, and accessibility of treatment and support programs for children with HIV and TB.

EPN's Asks

- Consider leveraging on the FBOs networks like EPN as strategic partner to support innovative product introduction efforts and scale up to increase access in Sub-Saharan Africa.

- Stakeholders – to partner with EPN to generate evidence from the last mile where EPN operates on the priorities related to critical formulations and needs of children, pregnant and breastfeeding women, but also on the outcome of newly introduced formulations.
- Support the EPN Minilab network in Sub-Saharan Africa, to expand the testing scope of the GPHF Minilab to TB-HIV medicines or/and providing other cost-effective rapid testing tools for HIV-TB to be adopted in the Network to increase our sampling and testing at the last mile level to save lives. Ensuring that HIV-TB products maintain their quality along the SC to the last mile (point of care) is very important.
- Partners to support EPN develop/update existing TB-HIV training with new regimens/treatment guidelines to be accessible to healthcare workers in the FBOs health systems through the EPN online training platform.

IMPAACT4TB's Ask

- Global demand generation is needed for 1HP and 3HP generally and for the paediatric formulation of rifapentine. This will likely further reduce the costs of rifapentine.

MPP's Ask

- ASKs: For MPP to be most effective in its contribution to the paediatric medicine optimization agenda, we invite innovators of priority paediatric medicines (such as those identified by PADO processes) to approach us to explore voluntary licensing opportunities early in their product development timelines, thereby ensuring their swift access for paediatric populations in LMICs. We also invite funders to explore innovative ways to continue supporting projects aimed at improving the life of children, in particular funding for cross-cutting systemic work addressing persistent issues that can only be solved through collaborative alignment and coordination.

Asks to countries and partners including GF and others

- Update any policy gaps and operational guidance in adoption and implementation of WHO recommendations including prevention of drug susceptible and resistant TB, including 3 HP and levofloxacin for TPT.
- Prepare the ground for implementation with affected communities.
- Develop roadmaps, include budget in national and donor budgets.
- Governments, funding agencies, and partners should prioritize the introduction of innovative treatment options within national HIV programs.

- Expand investment in equitable access programs.

Asks to donors

- Funding appropriate to address challenges including contact management and preventive treatment (community-based actions needed).
- Grant Cycle 8 to include child-friendly formulations but also other resources including practical toolkits
- Provide targeted funding for policy update and implementation including pilot and feasibility work outside of usual cycle.
- Prioritize paediatric needs, encourage inclusion of needs in requests and reporting.

Asks to WHO

- Monitoring of implementation of new and existing TB treatment and prevention policies.
- Including paediatric, adolescent and maternal TB as a focus of a WHO Global TB Report.

ADVOCACY BROADER CHILD HEALTH COMMITMENTS

Asks the Global Fund

- Commit to implement 2-3 surveys to refine numbers of children living with HIV in a few test countries (Ex type PHIA project). This could adequately inform investments and programming.
- Take practical steps to ensure increased attention to child health within CCMs, for example through the analysis to understand child health representation in CCMs and to the provision of concrete recommendations to CCM on child health.
- Contribute to understanding and tackling inequities in child health through the gathering, analysis and publication of data from Global Fund countries in collaboration with countries and other technical agencies (as the WHO-Global Fund Status of Inequalities Report in 2021).

Caritas' Asks:

- Support funding of nutrition-specific components and appropriate psychosocial support in HIV/TB pediatric and youth programs.
- Collaborate towards eliminating all health determinants that negatively affect health, including poverty.
- Continue to Invest in the Capacity of Faith-Based Networks and Leaders.
- Support Caritas's Jubilee campaign, Turn Debt into Hope, and the advocacy for debt relief.

GNP+'s Ask

- Convening globally, PLHIV, communities and Civil Society concerned about children's health for collaboration and advocacy work.
- Continue and strengthen collaborations with Global and national health actors to advocate for children's health. Including UN agencies, researchers, funders, and program implementers to inform policy, resource, and program planning, implementation and monitoring that impact access to HIV case finding, diagnostics and treatment among children. GNP+ is a member of the Global Alliance to end AIDS in children by 2030 and The Coalition of Children affected by AIDS (CCABA).

WHO GTB's Asks

- Building on the Political Declaration of the 2023 UN High-level meeting on the Fight Against Tuberculosis, to ensure that children and adolescents with TB or at risk of TB are being found, that they are being found early, and that they have access to appropriate, quality-assured and affordable TB diagnostics and child-friendly formulations of TB preventive treatment, treatment for drug-susceptible or drug-resistant TB.

UNITE's Asks:

- In an increasingly challenging funding environment, UNITE calls on other organizations to consider providing core financial support for its work.
- UNITE invites organizations to partner by funding Policy Desks in the areas of 'Pediatric HIV and TB,' 'Access to Pediatric Medicines,' 'Research and Development of Innovative Pediatric Medicines,' or other relevant topics within this conversation.
- UNITE calls on other organisations to support the development of activities with parliamentarians, namely thematic networks, events, or field trips to exchange views with parliamentarians and stakeholders from other countries, as well as to better comprehend different realities and the impact of multilateral cooperation and support.

- UNITE calls on all organisations to connect and collaborate for any potential events and activities that can involve parliamentarians and help promote their engagement with paediatric HIV and TB.

World Vision's Asks:

- Governments and donors prioritize child-friendly TB and HIV medicines, diagnostic (non-invasive) and nutrition commodities in national procurement and financing plans.
- Ministries of Health integrate nutrition assessment, counselling, and support (NACS) into routine HIV and TB services for children.
- Stakeholders invest in CHW systems, supporting their training, incentives, and supervision to deliver integrated services for TB, HIV, and nutrition.
- Global donors fund community-led nutrition and health monitoring platforms that improve service quality and accountability.

Asks for Industry engagement across the drug life cycle

- We recognize the commitments made by industry partners and encourage continued prioritization of paediatric and maternal health investments.
- There is a clear need for industry stakeholders to engage more proactively in addressing the unique challenges of pricing, access, and resource mobilization for child-friendly formulations.
- Additionally, early-stage engagement with regulatory bodies and governments will be essential to ensuring that new treatments reach children and mothers as quickly as possible.
- Maintain and expand investment in infectious disease R&D, ensuring that HIV and TB remain high-priority areas for research, innovation, and funding.
- Engage in multi-stakeholder partnerships to ensure that research efforts translate into accessible and affordable treatment options for children and pregnant women.

- Accelerate paediatric trials and regulatory approvals, ensuring that new medicines reach children without the traditional delays seen in previous drug development cycles.
- Support global health financing mechanisms to protect drug and vaccine markets for paediatric and maternal health needs.
- Commit to transparent and sustained engagement with research networks, regulatory agencies, and civil society organizations to align on long-term strategies for drug access and affordability.

ANNEX 2 – STRATEGIC CONVERSATION

Detailed Minutes Strategic Conversations

Participants expressed concern over the sudden change in priorities of recent weeks, which have placed immense pressure on health and development service delivery models, severely impacting the procurement of drugs and commodities, destabilizing essential supply chains, and disrupting life-saving services. The result is a global health and service delivery system in a state of crisis, where fragmentation and unpredictability threaten progress in tackling HIV, TB, and other critical health challenges. In this context, participants commited to concrete solutions to advance child's health and discussed possible ways forward.

All participants recommitted to ensure that children living with or affected by HIV and TB remain healthy and alive despite the many challenges we face today.

- Every new paediatric HIV or TB infection is a failure, and we must address that directly.
- Driving progress and championing the cause for children is our collective responsibility.

HIV is no longer an emergency: we are in the midst of a long-term pandemic. We need a bold narrative change for HIV and we must build solidarity around it:

- There's a prevalent sentiment in the political realm that HIV is already "solved."
- The ambition for epidemic control still isn't embraced broadly enough.
- HIV being a long-term pandemic.

- We need a bold narrative change for HIV, one that reflects the progress in science and the remarkable tools we now possess. For instance, the fact that "undetectable equals untransmittable" is a major win. Treatment options, including PreP, are saving lives and preventing new infections, particularly among young people and those at high risk. These messages must be reframed.
- In this context, moving from the technical 95-95-95 targets to a more straightforward goal of "0 deaths, 0 infections, 0 cases of stigma" could serve as a powerful, clear policy objective.

It was recognized that we are at a pivotal moment of change, which calls for new partnerships and a rethinking of our current approaches:

- This is a moment that some of us anticipated, while others are still in denial.
- Change is never easy and it will demand a great deal from us. Some participants called to break down existing structures, including giving up power and our traditional positions to rebuild something new.
- We must be willing to challenge existing partnership structures to adopt new ways of working.
- With new technologies at our disposal, we have an opportunity to create a new model for the 21st century rather than simply retrofitting 20th-century solutions.
- Change calls for new partnerships and a rethinking of our current approaches. What we have been doing is no longer enough. It was suggested to shift partnerships toward a more inclusive digital and multi-sectoral model.
- Change must occur at the country level, driven by governmeents and communities' ownership and leadership.
- A fundamental takeaway was the need for pragmatic thinking. Given the reality of our current world, we must be honest about the resources available and rebuild our response accordingly.

Creativity – was the leit-motif of the discussions: there is a pressing need for creativity and adaptability to navigate this new landscape effectively.

Our starting point must be the child and each family in every village. From there, we build processes and systems that achieve meaningful, measurable impact.

To create greater efficency, we must address fragmentation and rethink how we work together, on the ground in countries, and at global level:

- The discussions underscored the importance of an integrated approach: we must break down silos. There are too many lost opportunities in our current fragmented health systems. We must create synergies, act more efficiently, and ensure that our interventions genuinely impact the lives of children.

- We heard critical messages regarding regulatory fragmentation and the need to create harmonization among regulatory processes/entities: there is a need for regulatory maturity to accelerate access to medicines and technology. Participants recognized the need to reform regulatory frameworks:
- Advocating for integrated regulatory bodies that all partners commit to working with, including:
    - Engage regulatory agencies to fast-track approvals; Synchronize regulatory submissions globally rather via country-by-country approvals; Regulatory inefficiencies must be addressed systematically, not case-by-case.
    - Ensure paediatric drugs are included in global approval pathways.
    - Commit to AMA's full operationalization and support regulatory harmonization.
    - Eliminate the current choice that allows fragmented regulatory approaches to persist.
- It was strongly expressed that we must stop treating paediatric research and development (R&D) and regulation as an afterthought. The global health landscape has long been built around adult care; it's time to reverse that trend.
- We need to redesign how we operate on the ground. Change is required not only in R&D and regulatory affairs but also in our in-country work.
- It was recognized the value of implementing integrated treatment approaches that link vertical programs to more comprehensive, holistic care focused on treating the whole patient (e.g., combining HIV, TB, malaria treatment systems). This would require sstrengthening collaboration with both private and public sector partners, using their resources and influence to build more effective systems that serve vulnerable populations.
- It was recommended to integrate supply chains and service guidelines to enhance efficiency and ensure a seamless supply of medications. This can be achieved by:
    - Consolidating fragmented supply chains to reduce inefficiencies and guarantee uninterrupted access to essential medications.
    - Developing integrated treatment guidelines that address multiple diseases, such as HIV, TB, malaria, and pneumonia, within a unified framework. This approach would ensure consistent and comprehensive care, particularly for vulnerable populations, including children and pregnant mothers.
    - Stakeholders involved in the Rome Platform should advocate for harmonized regulations across health sectors, aligning treatment guidelines for HIV, TB, malaria, and pneumonia to prevent fragmented care. Additionally, integrating primary healthcare guidelines across institutions would optimize resources, enhance coordination, and reduce inefficiencies in service delivery.
- It was asked why do we permit the continued existence of multiple guidelines from different bodies. It was reccomended to advocate for a more integrated approach, where we only collaborate with authoritative regulatory bodies that demonstrate coherence across all health sectors. In some cases, we are allowing inefficiency to persist because the right things are not prioritized. And that's where we have been failing: by focusing on the wrong things at the wrong time. However, we also have the power to change this story.

- Participants were encouraged to create a completely different system, consolidating, eliminating outdated institutional structures, and working across political boundaries.
- Success must be measurable.

Innovation remains crucial in paediatric HIV and TB as well as keeping the paediatric HIV market we have created:

- At the Dialogue the private sector's commitment to innovation was strong, and it was recognizedmust that it must be focused on achieving tangible impact. We need to set clear, targeted objectives early on, because broad targets can hinder efficiency and delivery. This focus applies to everything: diagnostics, medicines, and even regulatory coordination. We must work with regulators to ensure that we do not compromise on quality or safety, yet enable rapid delivery of innovations to the children who need them.
- It is also important to recognize that innovation isn't just about developing new products; it's equally about effective delivery.
- We heard valuable insights regarding fractured supply chains and the need for improved efficiency in various therapy areas.
- We must find ways to streamline delivery on the ground.

Harness technology for greater efficiency:

- It was suggested to leverage digital platforms, artificial intelligence, and data analytics to create systems where every sector registers their commitment to global/paediatric health on a national level, ensuring that data flows freely between organizations while targeting interventions in real-time to high-burden zones.
- We should further and consistently engage with young people already using digital tools to hold governments accountable and to achieve lasting impact.
- Participants recommended to leverage digital platforms, AI, and data analytics to coordinate responses on a national level, target interventions in high-burden areas, and streamline supply chains.

Reprioritize financing and engage new donors, including from the private sector. The following points were identified:

- We must recognize the new reality: donors are withdrawing. Some stakeholders are anticipating funding reductions, we might need to plan for a future with 25-50% fewer resources.
- This is requiring a fundamental shift. We need to stop relying on old funding models. It is importamnt to innovate with private sector financing.
- We need to focus on direct country support, prioritizing on-the-ground impact over global health bureaucracy, as well as investing in country-led approaches, which have the potential to ensure sustainability beyond donor support.
- We must protect the paediatric drug and diagnostic markets, including by ensuring sustainable incentives for manufacturers.

- We need to reduce inefficiencies in the global health architecture.

Intensify Advocacy and Address the Communications Gap:

- The disparity between paediatric mortality and domestic healthcare investments is alarming and require stronger advocacy.
- We must use data to advocate for governments to take greater responsibility for their HIV and TB responses, while the private sector supports these efforts.
- Advocacy by communities and the faith sector must intensify to fulfill the Abuja Declaration and global health commitments. Years after these pledges were made, no African government has fully met its promises, and that must change. It was recognized that we need to use the influence of faith and community leaders to hold governments accountable to their commitments to health investments, especially those that directly benefit children and the most vulnerable populations. This group should further mobilize faith-based networks to amplify advocacy efforts.
- The need for stronger public awareness campaigns to sustain political and financial support was emphazized, as well as the need for a unified global narrative on paediatric HIV and TB progress.
- As governments take on more responsibility for their HIV programs, we need to empower communities, moving beyond simple task sharing or task shifting, to leverage the lessons, tools, and skills we have built over the years and hold our governments accountable through their health budgets.

Who does need to be at the table?

- It's essential to determine who truly needs to be at the table to drive meaningful change rather than simply those who wish to participate.
- We need to adopt a business mindset that ensures every player contributes effectively to moving us forward.
- We must extend our collaboration beyond the Dialogue's walls to avoid an echo chamber.
- In this context, the following actors was identified as key:

Countries' leadership and ownership	The private sector	Parlamentarians and policy/decision makers
Looking to the future, key opportunities lie within countries themselves: Leadership and decision-making processes should be centered in high-burden countries.	It was emphazised that the 'private sector' is not just the 'industry'. It's critical that we look beyond the pharmaceutical segment, which was most prominently represented at the Dialogue, and tap into the full range of	Other important actors to engage with are parlamentarians and policy/decision makers. From a policy perspective, Unite's experience with 116 countries offers a simple yet powerful **framework for calling attention**

Leadership should not be limited to political and medical leaders in wealthy countries but must include **leaders from the global South, heads of states, religious leaders, and civil society.** It was recognized that political, economic, and social leaders must work together to develop sustainable service delivery models. At the same time, we must actively engage new partners and explore innovative approaches, such as incorporating civic education into health programs and integrating HIV services into primary healthcare, particularly in communities where basic civic education is lacking. We need to ensure country ownership , by supporting governments to transition to self-sustaining health programs. It was suggested to establish a digital, B2B platform where all relevant stakeholders (governments, civil society, private organizations, religious bodies) register and actively participate. These platforms should give equal access to all sectors for come-up with shared solutions.	private sector expertise, including digital technology and artificial intelligence (AI). These skills are essential for driving efficiency and progress.	**on paediatric HIV and TB/global health, mobilize action/change and resources** using the acronym ABCDE: **A** for **Awareness**: Policymakers need to be informed about paediatric HIV and TB, if they aren't aware, change is impossible. **B** for **Budgets**: Securing funding through innovative financial models is crucial, as is helping governments identify and reallocate existing resources. **C** for **Cost**: We must articulate the cost, both in economic terms and in human suffering, of inaction. **D** for **Data**: Concrete data is needed to show where we are today and to model future scenarios for better policy decisions. **E** for (**Equity)/Elections**: Strategies must be aligned with political cycles to ensure sustainable support and accountability, especially since politicians are driven by the need to get reelected. **Strategic engagement with policymakers** is key: It was suggested to engage bipartisan stakeholders to protect international HIV & TB funding; and reform how progress is communicated, ensuring transparency and impact measurement.

A new approach to global health leadership:

- It was suggested to consider a new approach to global health leadership, building from the Global Leaders Network, a multi-stakeholder platform, which the PMNCH is already pioneering at both national and international levels, currently being implemented in ten countries with support from its members. However, it was said, we must go further. It was recognized that this is the time to move beyond traditional models and create a cohesive, technology-driven, and collaborative response to global health challenges. The Global Leaders Network is a coalition of heads of state and government, primarily from the Global South, currently in formation. However, if we aim to work differently, leadership cannot operate in isolation. Instead, heads of state must collaborate with key players from diverse sectors, including: 1. Industry leaders: executives from the world's most influential sectors; 2. Religious leaders, such as those from the Catholic Church, who hold significant global influence; and 3. Civil society organizations and grassroots groups, which play a crucial role in addressing the needs of vulnerable populations. This collective effort is essential to overhauling the global response to health challenges faced by children, marginalized groups, and impoverished communities who bear the brunt of multiple health crises.
- A Call for Radical Change: rather than fragmented efforts, we need a comprehensive, inclusive approach that brings together all stakeholders within each country, whether they focus on maternal and child health, adult health, or broader healthcare systems. Health is a shared concern; it should not be addressed in silos. To achieve this, we must leverage cutting-edge tools like artificial intelligence and digital platforms to create a national digital health platform. Such a system would:
    - Centralize data collection
    - Track progress in real-time
    - Ensure coordination among all partners
- Additionally, we need to rethink our approach to public–private partnerships. Health systems are often plagued by inefficiencies, whether through poor demand forecasting or fragmented supply chains. Disease-specific interventions, such as those focused solely on HIV and AIDS, are important but often operate in isolation. By integrating efforts and harnessing technology, we can streamline healthcare systems, reduce waste, and maximize impact across all sectors.

ANNEX 3 – OPENING SESSION

Detailed Minutes Opening Session

DAY 1 – 3 February 2025

Moderator: Monsignor Robert J. Vitillo, Advisor, Dicastery for Promoting Integral Human Development

Welcome remarks

- Rev. Mons. Anthony O. Ekpo, Undersecretary of the Dicastery for Promoting Integral Human Development
- Prof. Laura Palazzani, member of the Governing Council of the Pontifical Academy for Life and Professor of Philosophy of Law at LUMSA
- Mr. Sean Callahan, CEO, Catholic Relief Services

Why is prioritizing children's health both a moral duty and a strategic imperative at this critical moment?

- Dr. Joy Phumaphi, Board Member, Partnership for Maternal, Newborn and Child Health (PMNCH); Executive Secretary, ALMA

An activist's perspective and expectations

- Mrs. Florence Riako Anam, Co-Executive Director, The Global Network of People Living with HIV (GNP+)

Poem for Children

- Ms Abdullahi Hafsat, Winner #YouthActOnEdu @worldbank, Member @recordingacademy#GRAMMY Award winning performance-poet Global citizen Fashionista Actor writerAnti-SGBV, Nigeria

Strategizing for the Future

- Prof. Sandra Thurman, Professor, *Rollins School of Public Health at Emory University*
- Dr. Meg Doherty, Director Global HIV, Hepatitis and STI Programmes, World Health Organization
- Mr. Chip Lyons, President and CEO, EGPAF

Welcome remarks and introduction by Monsignor Robert J. Vitillo, Advisor, Dicastery for Promoting Integral Human Development (Moderator)

Monsignor Robert J Vitillo welcomed participants to the paediatric HIV and TB Leadership, Technical, and Policy Dialogue, expressing that it is a special privilege to be together in person. He introduced himself by recounting his varied experiences in service to the Church, his past roles with the Holy See in health, and his current work promoting integral human development. He noted that while many have joined these dialogues via remote conference calls, it is invaluable to meet face-to-face, reinforcing the accountability and collective action embodied in this venue.

Monsignor Vitillo framed the dialogue as an opportunity for strategic planning, reflection, and proposals for future actions to respond to the dual pandemics of HIV and TB, particularly their devastating impact on children. The meeting is intended to help reprioritize health and development on the global agenda, a mission that is especially vital during a Jubilee Year of hope at the Vatican.

He emphasized that the global health landscape is at a crossroads. Recent uncertainties and decisions have challenged traditional health service delivery models, especially those led by faith-based and non-governmental organizations that have long been the backbone of lifesaving interventions. The "Rom Action Plan" and platform (a multi-stakeholder space for urgent reflection on global health priorities and financing) is presented as a timely catalyst to shape forward-thinking leadership and narrative, using paediatric HIV and TB as a basis for broader discussion.

Monsignor Vitillo stressed the need to engage new actors beyond traditional donors to counter funding cuts and advance progress in HIV and TB research, development, and access to optimal interventions for children. He spoke passionately about the moral imperative to address the suffering and disruption affecting millions, noting that the current state of the world is marred by pain, hatred, division, and ecological disruption.

He then turned to the inspirational voice of Pope Francis, recalling his message on January 9, 2025, which expressed deep concern for those affected by conflicts, terrorism, insecurity, forced separations, and various forms of modern slavery. Monsignor Vitillo noted that while many community voices are often absent, Pope Francis remains a steadfast advocate for the marginalized. His recent messages, highlighted on World Children's Day on November 20, 2024, remind us not to forget the children enduring war, violence, hunger, and exploitation, and call on adults to act with hope, compassion, and determination.

Monsignor Vitillo concluded by urging the participants to proceed with hope and to find innovative, creative solutions that build on the progress made since the Rome Action Plan was first designed in 2016.
He thanked the audience and set the stage for the dialogue, emphasizing that this meeting marks a new beginning in our journey together.

Welcome Remarks by Rev. Mons. Anthony O. Ekpo, Undersecretary of the Dicastery for Promoting Integral Human Development

It is an honor to open this session among such a diverse group of experts and institutions, all united in our commitment to ensuring that every child affected by HIV and TB receives timely diagnosis and treatment, so they can fully develop and contribute to a more just, peaceful, and harmonious world.

Today, we are here not only to address immediate health outcomes but also to advance integral development. Our mission supports local Catholic Church initiatives that combat marginalization and address critical shortages in staff, hospital equipment, and essential medicines in low-income countries, while advocating for increased research to fight these diseases. Reflecting on our journey since our first meeting in April 2016, it is clear that scientific advances have greatly expanded our capabilities for prevention and care. Yet, despite these achievements, too many children remain without adequate care, education, or the opportunity to flourish.

I call upon you to continue building on our past successes. We must harness our collective will, technical expertise, resources, and innovative methods to ensure every child has access to early diagnosis and effective treatment. Let us remember that no human life is more sacred than another. As Pope Francis stated in 2016, "Every child is a precious gift, entrusted to us by God, and it is our duty to ensure that they receive the care and protection they deserve."

While we have made progress in reducing maternal and child mortality, recent years have seen a worrying stagnation, driven by persistent inequalities in access to care, rising costs, and limited resources amid shifting geopolitical landscapes. For instance, an estimated 120,000 new HIV infections still occur among newborns and infants each year. This is unacceptable when we have the knowledge and tools to prevent such tragedies.

This dialogue is our platform for renewed high-level discussion and strategic engagement, enabling us to develop more effective approaches for safeguarding children's health. I extend the spiritual support and prayers of my country to each of you, and I urge you to approach today's session with hope and determination.

May God, who sent His only Son to bring us hope and reconciliation, guide our planning and actions in the coming days as we strive to build a future where every child is valued and cared for.

Welcome Remarks by Prof. Laura Palazzani, member of the Governing Council of the Pontifical Academy for Life and Professor of Philosophy of Law at LUMSA

Professor Laura Palazzani, a member of the Governing Council of the Academy for Life and a professor of philosophy of law at Limsa Local Roman University, delivered the welcome remarks on behalf of His Excellency, President of the Pontifical Academy of Life. She emphasized the need for serious reflection and strategic planning to achieve greater progress in ending the fully preventable and treatable pandemics of HIV and TB, with a particular focus on the grave impact these diseases have on children.

Key points of her remarks included:

- **Prioritizing Children's Health:**
  She highlighted the importance of reprioritizing children's health, an area often mentioned under the slogan "leaving no one behind," yet not sufficiently implemented. Too frequently, the voices and needs of children go unheard in a society where economic and political interests dominate.
- **Foundational Mission of the Academy:**
  Recalling the founding of the Pontifical Academy for Life in 1919 by Pope St. John, Professor Pallazzani noted that the Academy was charged with studying and providing training on the principal issues in law and biomedicine related to the promotion and protection of life, in close alignment with Christian morality and the Church's directives.
- **Progress Since 2016:**
  The Academy acknowledges the significant progress achieved since the inaugural meeting in Vatican City in 2016. Through the collaborative efforts of Catholic and other faith-inspired NGOs, multilateral agencies, governments, private sector businesses, and regulatory bodies, substantial advances have been made in research, development, and the accessibility of diagnostic tools and medicines that have saved the lives and futures of many children living with HIV.
- **Need for Further Action:**
  Despite these successes, Professor Pallazzani stressed that much more progress is needed to prevent further infections, reduce morbidity and mortality among children, and address their broader health needs. The Academy of Life regards the work presented as a model for addressing a wider range of global health challenges, rooted in the founding values of respect for and promotion of human life from conception.
- **A Call to Collaborative Action:**
  She noted a timely convergence of efforts: while this dialogue is underway, Pope Francis is convening a meeting on children's rights, also in the Vatican, with a focus on protecting those most vulnerable. This dual focus underscores the urgent need to implement innovative strategies to help millions of children living in precarious conditions, exploited, abused, and deprived of basic rights.

Remarks by Mr. Sean Callahan, CEO, Catholic Relief Services

Mr. Callahan expressed regret for not being able to attend in person due to pressing commitments in the United States and cancellations of his planned visits to Rome and the Middle East. He emphasized that his absence does not reflect a lack of commitment to the leadership on paediatric HIV and TB; on the contrary, he underscored its critical importance.

- **Guardians of Truth:**
  He stressed the need for all participants to act as guardians of truth and custodians of fact, particularly at a time when there is an ongoing assault on the truth and the vulnerable populations they serve. He called for collective strategy and unity to ensure that the successes of past efforts and the value of their work are recognized both nationally and internationally.
- **Commitment to the Gospel in Action:**
  Sean reminded everyone of the organization's 80-year legacy of putting the Gospel into action, focusing on life, hope, human dignity, and access for the poor and marginalized. He highlighted the organization's longstanding commitment to delivering life-saving programs for HIV, AIDS, and TB treatment, as well as emergency food aid, particularly for children.
- **Current Challenges:**
  He warned that the foundations of their support are being shaken by program pauses, downsizing, and eliminations amid instability. Mr. Callahan urged that they must not be intimidated or complacent but instead speak out, ensuring that the intrinsic value of these programs is recognized.
- **Inspiration from Martin Luther King Jr.:**
  Quoting Martin Luther King Jr., he noted that true character is measured not in moments of comfort but in times of challenge and controversy. He emphasized that the current period of challenge requires bold action and unwavering commitment.
- **Reflection and Call to Action:**
  Sean concluded by posing two reflective questions:
  - How can they adapt to the new environment?
  - How can they transform these crises into opportunities for greater unity, innovation, and impact?
  - He expressed hope that the dialogue would serve as an opportunity to forge a united way forward.

Why is prioritizing children's health both a moral duty and a strategic imperative at this critical moment?

Dr. Joy Phumaphi, Board Member, Partnership for Maternal, Newborn and Child Health (PMNCH); Executive Secretary, ALMA

I appreciate the opportunity to share insights on why prioritizing children's health is not only a moral duty but also a strategic imperative.

My name is Joy Phumaphi and I serve as a board member of the Partnership for Maternal, Newborn and Child Health (PMNCH) and as Executive Secretary of Alma. I recognize the many sacrifices made to be with us today despite other pressing commitments, and I extend my sincere gratitude for your extra efforts.

As a board member of the largest alliance advocating for women, children, and adolescent health, I believe this multi-stakeholder space provides a unique opportunity to come together as a community and accelerate action in these challenging times. Today, we are here to renew our commitment to protecting children from the devastating impacts of paediatric HIV, AIDS, and TB. Our work is driven by the belief that a healthy child is the foundation for a just, peaceful, and harmonious society. In our current global context, marked by funding cuts, instability, conflict, and the effects of climate change, we face sobering challenges. With just five years remaining to meet the Sustainable Development Goals, the urgency to reduce child mortality has never been greater. In many Southern African countries, the stakes are especially high, with projections that over 100 pregnant women and newborns could lose their lives if we do not accelerate progress.

We stand at a critical moment in our journey. The work we do to protect children from paediatric HIV, AIDS, and TB is not only a moral duty but also a catalyst for transformative change within the health sector. Our efforts, rooted in the commitment to "leave no one behind", must be elevated beyond mere rhetoric. Despite previous progress, we still face daunting challenges in the final five years of the Sustainable Development Goals timeline. This meeting serves as a catalyst to reflect, recommit, and prioritize children's health so that they may fully develop into effective human capital.

The right to health for every child is enshrined in Article 24 of the Convention on the Rights of the Child, guaranteeing access to the highest attainable standard of health and essential services. We must create environments that not only keep children healthy and safe but also empower them to realize their full potential. In our global village, where our lives are interconnected, as the COVID-19 pandemic starkly reminded us, nations and societies can only progress if we nurture our most vulnerable, especially our children.

The stakes are incredibly high. We have witnessed severe challenges: women, newborns, children, and adolescents are under assault from multiple fronts. Reduced development aid, funding cuts, rising instability, conflicts, and the escalating effects of climate change are disrupting

and, in some cases, halting essential services. Alarmingly, the latest estimates indicate that 120,000 new HIV infections occur among newborns and infants every year, an outcome that is utterly unacceptable when we have the means to diagnose and treat these conditions.

We must demand a future with zero new infections for our babies and children. The current 95-95-95 targets are insufficient if our most vulnerable continue to be repeatedly exposed. It is imperative that we reassess our priorities, mobilize new partners, and develop innovative financing mechanisms. We are currently facing an annual funding gap of $33.3 billion for reproductive, maternal, and child health services, a situation worsened by the loss of human resources in developing countries since COVID.

Our focus must shift from celebrating the success of individual organizations to measuring success by the collective impact on saving children's lives and building healthier communities. When we unite our efforts, as we did 20 years ago during the height of the HIV/AIDS crisis, we can achieve remarkable progress.

I challenge all of us, including the private sector, to bring new resources to bridge these financing gaps. With 1.4 million children living with HIV at the end of 2023 and 140,000 new infections occurring every day, our current efforts are far from enough. We must set a target of zero new infections and work relentlessly to achieve it.

I call on all partners, especially those from the private sector, to address the funding gap by mobilizing innovative financing solutions. In our 74 high-burden countries, every dollar invested in maternal, newborn, and child health yields significant economic and social returns, while inaction could cost our economies an estimated $110 trillion annually.

This is a critical moment for global health. Let us come together, innovate, and forge new partnerships to deliver transformative results. I thank you all for your passion, sacrifice, and unwavering commitment.

In closing, I urge you to join me in this vital struggle for the health and future of our children. Let our collective achievements be measured not by individual accolades, but by the number of lives saved and the quality of health we build for our communities. Together, let us continue to innovate, collaborate, and hold ourselves accountable to the promise that every child deserves a healthy and hopeful future.

An activist's perspective and expectations
Mrs. Florence Riako Anam, Co-Executive Director, The Global Network of People Living with HIV (GNP+)

Mrs. Florence Riako Anam begans by recalling a powerful moment from 25 years ago: a young boy born with HIV who, standing on the stage at the IAS Conference in Durban, pleaded with world leaders to do right by children. He was heartbroken by the pain, stigma, and discrimination he and his peers suffered, and he implored leaders to ensure that mothers had access to HIV treatment and prevention to stop vertical transmission. His heartfelt plea, to be free from stigma, to attend school, and to play like any other child, continues to inspire us today.

Mrs. Florence Riako Anam reflectsed on the progress achieved over the years: many children have been freed from HIV, and adolescents continue to benefit from prevention interventions. Yet, she reminded participants that our work is far from complete. All of us in this room are champions for children living with or affected by HIV, and we remain steadfast in our vision of an HIV-free generation. However, significant challenges persist. Despite improvements in treatment regimens that are easier to use and more effective, many children still slip through the cracks. Coverage remains insufficient, and societal stigma, compounded by gender inequalities, prevents mothers from seeking the care they need and bringing their children for testing.

Mrs. Florence Riako Anam then called attention to the diagnostic challenges, particularly the long turnaround times for test results, which create immense anxiety for young mothers. Many women do not return to health facilities because of the stigma and discrimination they encounter there. She urged all participants to use this evidence to educate healthcare facilities and work closely with communities to dismantle these barriers.

Looking forward, Mrs. Florence Riako Anam called for a renewed focus on influencing policies that prioritize children's health. She stresses that while treatment is essential, it must be accompanied by comprehensive community interventions, such as case finding, adherence support, and continuous diagnostic follow-up, that have been disrupted by funding cuts and resource shortages.

Ms Abdullahi Hafsat, Winner #YouthActOnEdu @worldbank, Member @recordingacademy#GRAMMY Award winning performance-poet Global citizen Fashionista Actor writerAnti-SGBV, Nigeria

Poem: 'Pocket Sized Activism.'
How do you measure pay?
How do you rationalize suffering?
How do you determine the worth of a life?

Is it by age, race, size, or nationality?
If not, then why do you have this pocket sized activism?
Why do I get the crumbs of this healthy optimism?
Why does it seem like my life lacks the same priority?
Why does my welfare lack the same urgency?
Why do I get the remnants of the facilities that are designed for my safety?
Like stigmatization has some age regulation,
Like ignorance comes with some age appropriation.
Like viruses, content sizes, and when they need their eyes, their devices,
That minimizes the heart to soothe my weaker bones,
Why am I?
Just on this Race for Life,
The weight of HIV does not get lighter for the younger,
The agony of TB does not get smaller for the weaker.
They don't come in mean sizes for minors.
It's the same horse.
These inherited pains hurt the same as those of an adult.
So why am I overlooked as if it's my fault?
I am 6% of the population, yet a 14% death rate to date—
I'm still subject to this unfortunate statistic.
Some quarters somehow do not get as much.
So today, I beg your attention.
I beg that we do not allow ourselves to get carried away and leave anyone behind.
I beg that we radically prioritize children equally,
Living with HIV and TB in our represented community.
I beg that we save humanity through the very last one,
Because stigmatization does not come with age,
Regulation doesn't come with age application,
And HIV and TB do not have various sizes.
When the meter rises, there are no devices that minimize the heart

To soothe a child's weaker bones.
No child should be a forgotten cornerstone in this Race for Life.

Strategizing for the Future: Prof. Sandra Thurman, Professor, *Rollins School of Public Health at Emory University*

Sandy Thurman, Professor at the Rollins School of Public Health at Emory University and a long-time defender of children's health, was invited to share her insights on future strategies. Her remarks were characterized by a call for honest reflection on the current challenges and opportunities facing development and health services in the United States.

She began by expressing gratitude for being given the opportunity to participate despite other commitments, humorously noting that her age should remind everyone of the long journey she has undertaken in championing children's causes. Mrs. Thurman extended special thanks to the host for promoting Integral Human Development and to the Academy for Life, as well as to her longtime leader, "Monsignor Bob," for his steadfast guidance.

Prof. Thurman addressed the "elephant in the room" regarding the United States' current challenges in development and health, a situation that has perplexed many for over 20 years. She acknowledged that, in these rapidly changing times, there are more questions than answers, particularly concerning the nation's development portfolio. While recent decisions have allowed for a partial return to providing essential HIV treatment and prevention of mother-to-child transmission services, many uncertainties remain. She emphasized that these reorganization efforts are just beginning and that we must work together to rebuild and rethink our approaches.

She urged the group to seize this crisis as an opportunity to radically reimagine how development is conducted, to identify inefficiencies, and to foster greater collaboration among all stakeholders. Mrs Thurman noted that conversations about reforming institutions like the U.S. Department of International Development are not new—citing historical debates led by figures such as Jesse Helms, who was known for his strong focus on USAID and the use of charities as a cornerstone of development efforts.

Mrs Thurman celebrated the fact that the group was gathering once again in the sacred meeting space at the Vatican, a venue that has long been instrumental in facilitating serious, collaborative decision-making. She highlighted that this setting provides a unique opportunity to explore innovative and creative ways forward.

Concluding her remarks, Prof. Thurman invoked the powerful protest song "We Shall Not Be Moved" from the civil rights movement, using it as a metaphor for their collective determination. She called on all participants to "make good trouble" and to continue challenging the status quo to ensure that the health and development needs of children are met.

Prof. Thurman closed by thanking everyone for their contributions, expressing confidence that their collaborative efforts will guide them to a better future, and inviting the group to consider these challenges as a stepping stone toward transformative change.

Strategizing for the Future: Dr. Meg Doherty, Director Global HIV, Hepatitis and STI Programmes, World Health Organization

Reflecting on the discussions in this room, I recognize the pressing questions that we will be deliberating in the coming days and at the World Assembly. These include sustaining our life-saving interventions worldwide, responding to emergencies and outbreaks, and maintaining essential prevention of mother-to-child transmission programs, a commitment strongly reiterated by Dr. Joy.

Since our first gathering in 2016, WHO has been a steadfast partner, dedicated to the needs of children, mothers, and communities. Our collective efforts have a significant potential impact, especially in low-income countries where testing, prevention, and treatment programs for paediatric HIV must continue uninterrupted. I have personally spoken with government officials who express the need to step up their leadership. Likewise, faith leaders remain resolute in delivering innovative solutions for paediatric HIV, and we must ensure that we do not lose ground during times of conflict or policy shifts.

There are several innovations on the horizon. For example, we have been hearing about a promising new prevention tool, Lenacapavir, which, if implemented during pregnancy, could be a game changer in stopping new infections in children. It is crucial that we leverage such innovations, especially given that an HIV vaccine is unlikely to be available in the coming years, to change the trajectory of HIV for the next 20 to 30 years. Similarly, our Action Plan has galvanized efforts to strengthen prevention and treatment for TB, and we must ensure these programs are sustained and effectively rolled out.

The theme for World Health Day 2025, 'Protecting the Health of Others and Children Globally,' reminds us that we cannot afford to let progress in maternal, newborn, and child health slip. Our work requires robust partnerships, including with faith-based and private sector organizations. Many of the world's wealthiest individuals have the resources we need to reinforce our commitment to supporting ministries of health and ensuring program sustainability, especially as we integrate services into primary care under the Universal Health Coverage (UHC) umbrella.

Over the next two days, I hope we will develop new, innovative, and stronger partnerships, supported by both the private sector and local communities, to support solutions at the community and ministry levels. We will continue to deliver on our science-based guidelines, support ethical research, and ensure that ministries of health maintain durable health systems and lead the charge in our collective efforts.

We have a chance to reset our paediatric HIV response, and I am confident that, with local solutions and strong leadership, we will find the answers we need and do our part.

Strategizing for the Future: Mr. Chip Lyons, President and CEO, EGPAF

Mr. Lyons began noted his deep appreciation for the insightful comments made earlier, especially by Joy—who elevated the conversation and helped set a new level of thinking for the way forward. Mr. Lyons praised his colleagues, Monsignor Bob, Sandy, Meg, and Florence, emphasizing their reality-based approach, which he finds refreshingly grounded compared to more abstract discussions. He expressed admiration for all who have contributed to the dialogue so far.

Mr. Lyons then recalled that just a week ago, there was intense debate about whether to meet, with many urging cancellation amid disruption, confusion, and fear. Despite these challenges, the group decided to convene. He remarked: "You showed up despite all the pressures and that speaks volumes about your dedication."

Highlighting the urgent challenges in paediatric HIV and TB, Mr. Lyons stressed the critical mission of reaching zero new infections among children. He called on the group to work relentlessly toward this goal and to improve communication with partners and political leaders so that children, youth, and their families remain at the forefront of the global health agenda.

In closing, Mr. Lyons thanked everyone for their leadership and inspiration, expressing confidence that the discussions over the next two days will yield new strategies to overcome these obstacles.

ANNEX 4 – SOLUTIONS AND ACTIONS RELATED TO R&D OF HIV AND TB MEDICINES FOR CHILDREN, PREGNANT AND LACTATING WOMEN

Challenges; Opportunities, Solutions; and Recommendations

Objective: The session on solutions and actions related to research and development (R&D) of medicines for children, pregnant, and breastfeeding women focused on identifying key priorities, challenges, and pathways to accelerate progress.

Challenges

- While significant strides have been made, access to paediatric HIV and TB medicines remains inconsistent across regions.
- Innovations such as long-acting formulations and child-friendly regimens face delays in regulatory approvals and implementation.
- High-burden countries continue to struggle with procurement and sustained access to life-saving treatments.
- The need for continued R&D must be balanced with ensuring existing, proven treatments remain accessible in high-burden countries.
- Paediatric formulations often lag behind adult treatments due to sequential drug development approaches.
- Regulatory bottlenecks delay the rollout of new medicines, especially for vulnerable populations like pregnant women and infants.
- Exclusion of pregnant and breastfeeding women from early clinical trials delays the introduction of optimized treatments.
- Current research often shifts risks to real-world settings due to insufficient clinical data on safety and efficacy.
- Funding constraints and limited prioritization hinder early inclusion in studies.
- Fragmented regulatory frameworks create delays in medicine approvals, especially across low- and middle-income countries (LMICs).
- Lack of harmonization between regulatory agencies results in redundant and prolonged approval processes.
- There is an urgent need to align global regulatory strategies to accelerate access. Declining Industry Commitment to Infectious Diseases
- Recent trends indicate pharmaceutical companies deprioritizing HIV and TB R&D.
- Shrinking commercial incentives have led to the closure of key infectious disease programs.
- Market-driven solutions are needed to sustain long-term investments in paediatric and maternal medicine development.
- Inconsistent Funding and Market Sustainability
- Reduced donor funding and shifting global health priorities pose a threat to paediatric HIV and TB R&D.
- The shrinking paediatric HIV market raises concerns about future medicine availability.
- Limited financial incentives discourage pharmaceutical companies from prioritizing paediatric formulations.

Opportunities and Solutions

1. Strengthening Research and Development Strategies
    - Focus on two or three high-impact priority products to streamline development efforts.
    - Implement adaptive clinical trial designs to accelerate approvals.
    - Leverage pharmacokinetics and safety trials to optimize treatment regimens.
2. Enhancing Regulatory Coordination and Efficiency
    - Develop harmonized regulatory pathways to expedite paediatric medicine approvals.
    - Strengthen collaboration between global regulators, including the FDA, EMA, and national regulatory bodies.
    - Expand reliance pathways to facilitate faster medicine registrations in LMICs.
3. Leveraging Public-Private Partnerships for Sustainable Innovation
    - Encourage industry, donors, and research institutions to co-invest in paediatric medicine development.
    - Expand licensing agreements to improve generic manufacturing and ensure broader access.
    - Strengthen engagement with investors to promote ethical and sustainable R&D funding.
4. Prioritizing Early and Inclusive Research for Pregnant Women
    - Advocate for the inclusion of pregnant women in Phase II and III clinical trials.
    - Support implementation research to generate real-world safety and efficacy data.
    - Establish collaborative networks to ensure streamlined research efforts and evidence translation.
5. Sustaining Industry Commitment to Paediatric and Maternal Health
    - Encourage pharmaceutical companies to integrate paediatric and maternal R&D within their core business models.
    - Implement policy incentives to retain industry interest in paediatric HIV and TB medicine development.
    - Ensure parallel paediatric and adult formulation development to prevent delays.
6. Strengthening Market Viability and Supply Chain Stability
    - Foster innovative financing models to sustain procurement and distribution.
    - Develop strategic partnerships to secure long-term funding for paediatric ARVs and TB treatments.
    - Improve forecasting mechanisms to prevent supply shortages and ensure consistent medicine availability.

Recommendations

1. Commitments for Research and Development Acceleration
    - Prioritize investment in paediatric and maternal HIV and TB treatments to address research gaps.
    - Encourage early inclusion of pregnant and breastfeeding women in clinical trials.

- Establish global funding mechanisms to sustain paediatric HIV and TB research.
- Promote industry incentives to develop long-acting, heat-stable, and child-friendly formulations.

2. Regulatory and Policy Reforms
   - Strengthen global regulatory collaboration to harmonize approval processes.
   - Encourage national regulatory bodies to fast-track approvals for paediatric and maternal medicines.
   - Advocate for policy reforms that support early and optimized research inclusion.
   - Implement reliance mechanisms to expedite access to new treatments in LMICs

Detailed Minutes of the R&D Medicines Session

3 February 2025, 11:00 – 12:15 CET: Solutions and actions related to research and development of medicines for children, pregnant and lactating women (HIV and TB)

Panel, Facilitator: *Monsignor Robert J. Vitillo,* Advisor, Dicastery for Promoting Integral Human Development

- **Setting the Scene** on research and development of HIV and TB medicines
  - Dr. Martina Penazzato, Lead, Global accelerator for Paediatric Formulations (Gap-f), World Health Organization
  - Dr. Françoise Renaud, Lead, Maternal Treatment HIV, Hepatitis and STIs, World Health Organization
- **Vision Forward**: *How do strike the right balance between prioritization of interventions in a landscape of reduced resources and promoting innovations to ensure progress in tools and strategies for the wellbeing of children and their mothers? What are the opportunities to accelerate the R&D for children and their mothers in today's global health landscape?*
  - Dr. Jayasree K. Iyer, CEO, Access to Medicines Foundation
  - Ms. Audrey Abernathy, Vice President and Head of Communications and Government Affairs, ViiV Healthcare and GSK Global Health
  - Dr. Philippe Duneton, Executive Director, UNITAID
  - Dr. Carlo Giaquinto, President, PENTA Foundation and University of Padova

Setting the Scene Paediatric HIV and TB Medicines: Dr. Martina Penazzato, Lead, Global accelerator for Paediatric Formulations (Gap-f), World Health Organization

The setting the scene underscored the need for a dual approach: safeguarding access to existing medicines while simultaneously advancing research to develop new, improved formulations. Given the current global landscape, stakeholders must commit to stronger collaboration,

resource optimization, and regulatory efficiency. The work done to date has demonstrated the feasibility of achieving rapid progress, and now, more than ever, these efforts must be intensified to ensure that no child is left behind in the fight against HIV and TB.

Scientific Progress and the Importance of Innovation

- The global scientific community has made significant strides in recent years, leading to the development of transformative treatment and prevention solutions for HIV and TB.
- New long-acting products are now available or under investigation, offering the potential to improve adherence and treatment effectiveness.
- The TB pipeline is stronger than ever, providing opportunities to develop shorter, more effective, and safer regimens.
- However, there is concern that current progress may not be sustained due to shifting priorities and funding constraints.

Balancing Innovation with Immediate Access

- While investment in new tools remains critical, the focus must also be on ensuring that existing, proven treatments remain accessible to patients in need.
- There is an urgent need to maintain and scale up currently available treatments in high-burden countries.
- The question remains whether the sector can afford to pause innovation in the face of ongoing public health threats.
- If no action is taken, children will continue to face delays in accessing life-saving medicines, as historically seen when paediatric formulations followed adult treatments.

Optimizing Research and Development Strategies

- The past few years have demonstrated that stronger collaboration and coordination lead to more efficient research outcomes.
- Innovations in study design, including better regulatory strategies, streamlined trials, and improved translation of evidence into policies, have yielded tangible results.
- There is a need to focus on two or three priority products that have the highest potential to make a significant impact.
- Research methodologies should be refined to ensure efficiency, including shared controls, adaptive study designs, and greater use of pharmacokinetics and safety trials.

Enhancing Regulatory Alignment and Global Coordination

- Stronger alignment is needed across different regulatory agencies to accelerate the approval process for paediatric HIV and TB medicines.
- The regulatory landscape is evolving rapidly, requiring proactive engagement to harmonize approval mechanisms across various regions.
- There is also a need to foster deeper partnerships between innovators and generic manufacturers to ensure affordable and scalable access to new medicines.

Maximizing Resource Utilization

- Despite existing financial constraints, it is crucial to optimize and combine available resources strategically.
- Transparent and coordinated efforts are necessary to identify gaps and maximize the impact of existing investments.
- Research networks play a key role in ensuring high-quality, efficient, and rapid studies.
- There is a need for policy makers to integrate research findings into practice as swiftly as possible, facilitating a faster transition from research to implementation.

Strengthening Collaboration Between Stakeholders

- Industry, regulatory bodies, policymakers, and research institutions must work together more efficiently to ensure global access to life-saving medicines.
- Existing operational platforms provide valuable opportunities for coordination and knowledge sharing.
- Beyond technical collaboration, the sector must elevate R&D discussions to the political level, ensuring sustained commitment and policy alignment.

Setting the Scene – Maternal Treatment: Dr. Françoise Renaud, Lead, Maternal Treatment HIV, Hepatitis and STIs, World Health Organization

The setting the scene focused on the critical need to protect the health of pregnant and breastfeeding women and their infants by ensuring timely access to safe, effective medicines for HIV prevention, treatment, and TB care. The discussion underscored the importance of early and inclusive research, efficient regulatory pathways, and sustained investments in R&D. The Vatican High-Level Dialogue has played a pivotal role in galvanizing commitments and promoting accountability for maternal HIV and TB medicines, reinforcing the urgency of accelerating progress in this area.

The Need for Early and Inclusive Research in Pregnancy

- Pregnant and breastfeeding women must be included early in clinical trials, as excluding them delays the availability of safer, optimized treatments for both mothers and infants.
- The lack of pre- and post-registration studies in pregnancy shifts risks to real-world settings without sufficient clinical guidance.
- While new medicines for HIV prevention and maternal treatment have been introduced, delays in implementation studies and inadequate funding for pregnancy-related research continue to hinder progress.
- Consensus-building initiatives for maternal medicines research, including those focused on diabetes, maternal vaccines, and preclinical research standards, must be accelerated to enhance inclusion and improve outcomes.

Progress Since 2022

- A major milestone has been achieved in scientific research and regulatory enablers, including:
    - New clinical trial data on pregnancy for long-acting injectable cabotegravir.
    - Implementation studies integrating pregnant women across multiple countries.
    - Research networks adopting a more inclusive approach in maternal clinical studies.
    - Regulatory agencies, including the FDA, EMA, and global health regulators, are working collaboratively to expedite approvals and streamline access to new maternal and paediatric medicines.
- These advances are being supported through the Action Plan for the People and the Access to Medicine Foundation, with a growing emphasis on early and optimized research funding and regulatory coordination.

Challenges and Barriers to Progress

Despite these advances, several barriers persist:

- Delayed inclusion of pregnant women in research protocols due to slow regulatory processes and limited funding.
- Withdrawal of research studies on pregnancy-related medicines due to lack of drug supply.
- Industry de-prioritization of maternal and paediatric HIV and TB research, creating disparities in equitable access between high-income and low-income countries.
- Fragmentation in global research efforts, leading to inconsistent approaches and missed opportunities for coordination.

Key Priority Actions

To sustain and build upon the progress made, immediate actions must be taken:

- Expand clinical trials for pregnant women to better assess rare adverse events and long-term safety.
- Support implementation studies that are inclusive of pregnant women.
- Leverage regulatory reliance pathways for accelerated approvals and national registrations.
- Ensure the continuous supply of drugs for clinical trials and implementation studies, including cabotegravir and other HIV and TB treatments.
- Advance research on TB medicines in pregnancy, particularly in preventive and therapeutic regimens.
- Strengthen monitoring of infant exposure to medications used during pregnancy and breastfeeding.

Strengthening Policy, Regulation, and Multi-Sector Collaboration

Policymakers and regulators must take urgent steps to ensure:

- Faster integration of new maternal and paediatric medicines into national health guidelines.

- Global alignment on regulatory frameworks, minimizing delays in research approvals and market introduction.
- Expanded engagement with civil society, faith-based organizations, and community stakeholdersto promote awareness and improve research participation.
- A consensus process is underway to formalize earlier and optimal inclusion of pregnant women in clinical research, with recommendations set to be published in 2025.
- The inclusion of pregnant women must extend beyond HIV and TB, ensuring participation in key therapeutic trials, including those for TB vaccines.

Opportunities for Acceleration

- The Leadership Dialogue on HIV and TB presents a critical opportunity to advance R&D efforts that directly impact maternal and child health.
- Moving forward, stakeholders must:
    - Prioritize investment in research and development for maternal and paediatric HIV and TB treatments.
    - Encourage sponsors and researchers to integrate pregnant women into Phase II and III clinical trials.
    - Strengthen data collection on safety and efficacy in pregnancy and breastfeeding.
    - Develop frameworks for accelerating access, ensuring that medicines reach those who need them most without unnecessary delays.
    - A bold, coordinated, and well-funded response is needed to reduce maternal transmission of HIV and TB and protect the health of both mothers and infants.

Vision Forward: *How do strike the right balance between prioritization of interventions in a landscape of reduced resources and promoting innovations to ensure progress in tools and strategies for the wellbeing of children and their mothers? What are the opportunities to accelerate the R&D for children and their mothers in today's global health landscape?*

Dr. Jayasree K. Iyer, CEO, Access to Medicines Foundation

The CEO of the Access to Medicine Foundation highlighted the importance of sustaining research and development efforts for paediatric HIV and TB medicines. The discussion emphasized the critical role of access planning, industry engagement, and sustained investment in ensuring that innovations reach the children and communities that need them most. The presentation concluded with a strong call for action,

urging governments, industry leaders, research institutions, and civil society to work together to guarantee that children affected by HIV and TB receive the life-saving treatments they need without unnecessary delays.

The presentation reinforced that R&D is only effective if coupled with robust access plans and sustained industry commitment. Moving forward, stakeholders must:

- Strengthen country-level access planning to expand medicine availability beyond a limited set of countries.
- Encourage sustained industry engagement in infectious disease research, preventing further reductions in the paediatric HIV and TB pipeline.
- Prioritize long-acting and heat-stable formulations that address real-world challenges in resource-limited settings.
- Ensure that investment and financial strategies align with sustainable and ethical access models.

Current State of the R&D Pipeline

- There is a rich and promising pipeline for paediatric HIV and TB medicines, with significant efforts being made to develop new formulations.
- The latest report from the Access to Medicine Foundation found that 17% of all HIV and TB projects target children, many focusing on child-friendly formulations and long-acting injectable solutions.
- The inclusion of pregnant and breastfeeding women in late-stage studies is a positive development that must be sustained and expanded.
- Recent collaborations among industry, regulatory agencies, and research institutions have accelerated the development and availability of new medicines.

Challenges in Access and Implementation

- Persistent Gaps in Access Planning: Despite advancements in research, 40% of late-stage projects lack robust access plans.
- Limited Country Coverage: On average, access plans cover only five countries, with outliers such as HIV programs covering over 100 countries.
- Lack of Market Incentives: Many CEOs express concerns about who will purchase newly developed treatments, leading to hesitation in advancing R&D efforts.
- Declining Industry Engagement in Infectious Disease Research: The number of large pharmaceutical companies actively working in HIV and TB research is shrinking, increasing the risk of pipeline reductions and delays in bringing new medicines to market.
- Need for Long-Acting Formulations and Heat-Stable Medicines: These innovations are crucial for ensuring treatment adherence and expanding access in resource-limited settings.

Sustaining Industry Commitment and Investment

- The Access to Medicine Foundation works with 147 investors to advocate for sustainable and responsible investments in R&D.
- Industry leaders are increasingly being held accountable for ensuring broader access to their innovations, with investors raising key questions about how companies plan to expand coverage and affordability.
- Despite challenges, sustainable and ethical investing remains a driving force in ensuring the continued prioritization of paediatric HIV and TB research.

Urgency for Action and Next Steps

- There is no time to wait: paediatric formulations must be prioritized now, rather than waiting another 10-15 years for the next treatment to become available.
- Commitments made in this room matter: previous efforts have driven significant actions and industry engagement.
- The session urged all stakeholders to actively engage in ensuring that access to medicines remains a top priority in global health policy and investment discussions.

Ms. Audrey Abernathy, Vice President and Head of Communications and Government Affairs, ViiV Healthcare and GSK Global Health

We are meeting at a time of unprecedented uncertainty and insecurity in global health, particularly in the HIV and TB response. Now more than ever, driving the end of these infectious diseases in children is critical for both the scientific and broader global health communities.

GSK commitment: end TB by 2035 and remain commited to HIV despite the global context

- At GSK, we are proud to be pioneers in HIV and TB research. We have developed innovative HIV prevention and treatment options, as well as advancements in TB medicines and research. Together, we have a strong purpose: to unite our science, technology, and talent to get ahead of these diseases.
- Our ambition at GSK is to contribute to ending the TB epidemic by 2035, transforming how TB is prevented and treated.
- In healthcare, we are committed to ensuring that no person living with HIV is left behind, especially children, adolescents, and young adults. Working with global partners, including many of you in this room, we developed the first child-friendly, dispersible HIV treatment, which is now available in over 95 countries.
- However, we recognize that the world is far from where it needs to be in improving child and maternal health outcomes for those living with and affected by HIV and TB. We also acknowledge that the current political and funding landscape is more challenging than ever.

Given the evolving and uncertain environment, it is too early to determine the full implications of these significant shifts in public policy and funding.
- At GSK and ViiV Healthcare, we remain steadfast in our vision to end these epidemics. We will not pull back. We will not stop. We remain committed to advancing progress for paediatric populations and their mothers.

The power of partnerships
- The power of partnership is central to everything we do, and to everything we must do collectively in this room. It will be critical in navigating the challenges ahead and driving health impact.

Forging together a way forward
- Now is not the time to be silent. Raising the profile and visibility of child and maternal health priorities, especially in addressing paediatric HIV and TB, requires us to be even more relentless in engaging and informing legislators, donors, and other key decision-makers.
- We must develop differentiated messaging: repositioning and thinking differently about how we communicate.
- We must mobilize support from diverse audiences, reaching beyond the traditional global health and infectious disease communities. Let's bring more people into this conversation.

Harness digital AI to improve health outcomes
- Practically, there is an opportunity to harness digital and AI tools to better target interventions and improve child and maternal health outcomes. These technologies can help us strengthen access to child-friendly diagnostics and medicines, ensuring they are valued and used more widely.

Dr. Philippe Duneton, Executive Director, UNITAID

The discussion began with an honest acknowledgment of the current difficulties in global health. The speaker likened the situation to a plane losing an engine, an analogy emphasizing that while setbacks have occurred, there remains a functioning system that must be maintained.

Key reflections included:
- Many healthcare workers and patients in high-burden countries have lost jobs, resources, and hope.
- The instability of funding and policy decisions has created significant barriers to access to essential medicines.

- There is a need to openly acknowledge the challenges while simultaneously developing solutions that allow for continuity in care and innovation.

Sustaining Innovation Amid Crisis: Despite the challenges, the speaker emphasized that innovation must not be sacrificed. Lessons learned from past investments in paediatric formulations must be leveraged to continue developing optimal treatment options for children. Key points included:

- Investments in paediatric drug formulations have yielded significant progress, including child-friendly single-pill formulations.
- Efforts to improve paediatric medicine access have involved collaboration with key stakeholders, including the Global Fund, regulatory agencies, donors, and the private sector.
- While funding constraints are a reality, they should not lead to a cessation of research, development, and progress in paediatric HIV and TB medicines.
- The potential for curative treatments exists within the next 3-5 years, and all stakeholders must work together to accelerate access to these breakthroughs.

Adapting to a Changing Global Health Landscape: The speaker highlighted that global health is undergoing fundamental changes, requiring adaptation in strategy and execution:

- Traditional funding models are evolving, necessitating creative approaches to sustaining essential services.
- The way global health actors operate within countries must be redesigned to fit new realities and emerging constraints.
- Regulatory pathways, procurement systems, and implementation strategies must be reevaluated to ensure efficiency and long-term sustainability.

The speaker emphasized that while challenges persist, they should not deter stakeholders from pursuing bold solutions. Key takeaways included:

- The global community knows what works and has a strong foundation of best practices.
- There is a pressing need for creativity and adaptability to navigate this new landscape effectively.
- Stakeholders must remain focused on delivering for children, ensuring that the existing momentum is not lost due to policy shifts or funding cuts.
- The ultimate goal is to 'land the plane properly', safeguarding progress while implementing innovative solutions to secure a better future for paediatric HIV and TB care.

Dr. Carlo Giaquinto, President, PENTA Foundation and University of Padova

The intervention emphasized the critical need for prioritization and innovation in addressing paediatric HIV and TB. These two elements are deeply interconnected: **effective delivery of essential treatments requires innovative approaches**, **not only in methodology but also in rethinking relationships and collaboration among stakeholders.**

A key example of successful innovation shared was the rapid mobilization of funding and partnerships for the Multibox trial in children: In April 2024, the European Commission's EDP launched an emergency call for research funding, awarding grants within just three weeks. This swift response facilitated a trial in pregnant women through a partnership with the University of Antwerp's Institute of Tropical Medicine. Additionally, industry partners provided vaccines and supplemental funding, demonstrating a highly effective model of collaboration.

The discussion also highlighted ongoing engagement in research for paediatric HIV and TB treatments, including clinical trials supported by industry and public funding. **Existing platform infrastructures can serve as key mechanisms for leveraging public funds**, engaging regulatory authorities in licensing efforts, and collaborating with industry to test and compare new treatment strategies. Furthermore, these networks provide an opportunity to mobilize community involvement and additional funding sources.

Fostering strategic partnerships among networks, funders, industry, and communities: by embracing innovative models of collaboration, stakeholders can accelerate access to life-saving medicines and ensure that paediatric HIV and TB treatments remain a priority despite shifting global health landscapes.

- Discussion
  - Moderator: Dr. Luis Pizarro, Executive Director, *Drugs for Neglected Diseases initiative*, DNDi
  - Questions for participants:
- **Priority actions, commitments and opportunities:**
  As you share your organization's commitments, please also reflect on and share your thoughts on how we can effectively balance the prioritization of interventions in a landscape of reduced resources, with the need to maintain innovations that ensure progress in tools and strategies? What opportunities exist/or should we create to accelerate progress and avoid stagnation?
- **Asks to Other Stakeholders:**
  What are your asks to other stakeholders? What specific support would you like to request from other stakeholders that could facilitate and accelerate the actions your organization is prioritizing? The "asks/requests" are an opportunity to clarify and address some of the most pressing bottlenecks in the paediatric HIV and TB response while fostering opportunities for collaboration.

Moderator: Dr. Luis Pizarro, Executive Director, *Drugs for Neglected Diseases initiative*, DNDi

The moderator opened the discussion by highlighting that we are witnessing one of the greatest transformations in global health since World War II. The entire multilateral system is evolving, and while we are seeing a rise in regional and national approaches, we must ensure that these do not come at the expense of international solidarity. Our collective efforts in this room will be critical in shaping the path forward.

Bridging the Gaps in Paediatric Research

One of the most pressing issues we must address is the lack of inclusion of children and pregnant women in clinical research, particularly in therapeutics. These populations continue to be sidelined, delaying access to essential medicines and life-saving treatments. A concerted effort is needed to bring them into the forefront of research to ensure that new drugs reach them faster. This will be a priority discussion throughout the next two days.

Breaking Disease Silos and Advancing Integrated Care

The need to break silos has been a recurring theme, and this applies across diseases. At DNDi, we have actively pushed for more integrated approaches, such as ensuring that people living with HIV who are affected by conditions like cryptococcal meningitis receive holistic care rather than fragmented services. Similarly, the introduction of paediatric formulations for TB treatment is long overdue, given that we have made advances for adults but left children behind. This issue extends beyond TB and HIV, many diseases have suffered from this neglect, and now is the time to rethink our approaches.

Ensuring Political Commitment and Avoiding Fragmentation

- Sustained political commitment is crucial to maintaining momentum in paediatric research and access. The international community must not dilute its efforts. Coordination between stakeholders, governments, researchers, regulatory bodies, and industry, must be strengthened to avoid redundancy and maximize impact.
- An important initiative to highlight is the Paediatric Technology Hub**,** supported by the NIH, which will play a key role in accelerating paediatric drug development in the coming years. This represents the type of global collaboration that is essential to drive innovation and ensure medicines for children and pregnant women remain a top priority.

Balancing Efficiency and Scientific Ambition

Given the current financial constraints, there is an urgent need to balance efficiency with scientific ambition. The challenge ahead is ensuring that budget limitations do not slow down progress. We must continue pushing the boundaries of innovation while maintaining the momentum needed to develop and deliver new solutions for children and their mothers.

Stakeholders were then invited to share their perspectives on how we can strike this balance, ensuring efficiency without compromising the ambition necessary to keep advancing paediatric research and care.

Dr. M. Makanga, Director of the European & Developing Countries Clinical Trials Partnership (EDCTP)

Despite the uncertainties in global health, EDCTP remains committed to driving innovation, strengthening partnerships, and securing long-term investments to improve the health of children and pregnant women. We look forward to continued collaboration and the mobilization of new research efforts to ensure that no child or mother is left behind.

Breaking Silos and Strengthening Research Integration, including in National Health Systems

- Over the years, EDCTP has prioritized clinical development and product-focused implementation research, ensuring that findings are effectively translated into policy and practice. A key lesson from COVID-19 has been the growing role of adaptive clinical trial designs and flexible research platforms, which have the potential to enhance the efficiency of paediatric and maternal health research. These approaches should be further leveraged to strengthen response capacity while ensuring that critical investments in existing diseases, such as HIV and TB, remain a priority.
- The focus on outbreak preparedness and emerging health threats must not come at the expense of ongoing health crises, particularly for diseases that continue to disproportionately impact children and pregnant women. Sustainable research investments must be deeply embedded within national health systems and developed in close collaboration with governments to drive long-term impact.

Innovative Approaches to Research Investments

- EDCTP remains committed to supporting R&D and has recently launched global collaborative calls to expand investment partnerships and encourage multi-sectoral engagement. These efforts align research priorities with national strategies, ensuring that evidence generation and product development are directly responsive to country needs. More importantly, this approach allows for co-investment by governments, fostering stronger national ownership and sustainability.

Regulatory Alignment and Accelerated Access

- Regulatory alignment remains a key priority in ensuring that advances in paediatric and maternal medicines translate into faster access. We have seen considerable progress in embedding research within regulatory frameworks, but there is still work to be done in ensuring that outdated medicines are phased out and replaced with optimal, life-saving treatments.
- EDCTP is committed to accelerating the availability of new prevention and treatment tools, including those aimed at eliminating vertical transmission of HIV and TB. Despite the challenges in the global health landscape, we will continue investing in innovative solutions and scaling up promising interventions, including those already underway in South Africa and other high-burden regions.

Expanding Access and Strengthening Market Readiness

- Looking forward, EDCTP will sustain its investment in developing and advancing new tools, including long-acting therapies and macrophage-based administration approaches, which have the potential to simplify treatment regimens for children and mothers. Access planning must be embedded early in the product development process, ensuring that emerging life-saving therapies are rapidly made available to those who need them most.
- Additionally, we will continue collaborating with regulatory agencies, funders, and industry partners to ensure that children and women remain central to R&D efforts. This includes work through collaborative research networks and initiatives like the Benefit Kids project, which is advancing child-friendly formulations and improving supply chain security for paediatric medicines.

Asks - Industry Engagement

- We recognize the commitments made by industry partners and encourage continued prioritization of paediatric and maternal health investments.
- There is a clear need for industry stakeholders to engage more proactively in addressing the unique challenges of pricing, access, and resource mobilization for child-friendly formulations.
- Additionally, early-stage engagement with regulatory bodies and governments will be essential to ensuring that new treatments reach children and mothers as quickly as possible.

GSK – ViiV Healthcare

During this session, the discussion focused on sustaining and expanding pharmaceutical industry commitments to HIV and TB R&D, with a particular emphasis on paediatric formulations and maternal health interventions. The conversation reaffirmed the industry's dedication to developing innovative treatment solutions, despite concerns over recent trends indicating the closure of infectious disease programs within some pharmaceutical companies. The session emphasized the need for sustained collaboration between industry, donors, research networks, and policy-makers to ensure the uninterrupted development of life-saving treatments for vulnerable populations.

Building on previous commitments in HIV and TB, ViiV Healthcare - GSK reaffirmed their ongoing investment in global health, particularly through collaborations, research, and public-private partnerships. A major highlight was a $1 billion investment over the next decade to advance research and treatment access, including efforts specifically targeting HIV prevention, maternal health, and paediatric medicine development.

Long-Acting HIV Treatments for Pregnant and Breastfeeding Women

- Industry partners reiterated their commitment to improving treatment options for pregnant women living with HIV.

- The CREATE study (expected to launch in 2024) will evaluate long-acting HIV treatments in pregnancy, advancing safer and more effective regimens for this population.
- A key ask was directed at research networks, particularly the IMPACT network, to support accelerated data generation for the CREATE study.

Advancing Paediatric HIV Prevention and Treatment

- Industry partners are committed to expanding HIV prevention options for children, ensuring that long-acting treatment regimens are safely and effectively adapted for paediatric use.
- A new pharmacokinetics (PK) and safety dose-finding study will be undertaken for long-acting injectable formulations for paediatric populations, with a timeline set for 2026.
- This work aims to accelerate access to innovative HIV prevention and treatment options specifically designed for children, addressing historical delays in paediatric drug development.

Development of a New TB Vaccine

- A phase 3 clinical trial for a new TB vaccine, developed in partnership with the Gates Medical Research Institute, is currently underway.
- This vaccine has the potential to significantly reduce the burden of TB, particularly in high-prevalence settings.

Shorter, Safer, and More Effective TB Treatments

- Recognizing that new TB treatments require combination drug regimens, industry research efforts are focused on developing innovative therapeutic combinations that offer shorter and more tolerable treatment options.
- Public-private collaborations remain central to advancing breakthrough therapies, leveraging expertise and resources to accelerate drug development and regulatory approvals.

Accelerated Paediatric Formulation Development

- A key strategic shift is the parallel development of paediatric formulations alongside adult drug formulations, rather than the historical sequential approach that has delayed child-friendly treatments.
- This commitment underscores early-stage engagement with regulatory bodies, research institutions, and communities to ensure that paediatric HIV and TB therapies are fast-tracked for development and approval.

Reccomendations and Asks

- Maintain and expand investment in infectious disease R&D, ensuring that HIV and TB remain high-priority areas for research, innovation, and funding.

- Engage in multi-stakeholder partnerships to ensure that research efforts translate into accessible and affordable treatment options for children and pregnant women.
- Accelerate paediatric trials and regulatory approvals, ensuring that new medicines reach children without the traditional delays seen in previous drug development cycles.
- Support global health financing mechanisms to protect drug and vaccine markets for paediatric and maternal health needs.
- Commit to transparent and sustained engagement with research networks, regulatory agencies, and civil society organizations to align on long-term strategies for drug access and affordability.

Innovation must not stop, and industry leaders must remain actively engaged in paediatric HIV and TB, ensuring that the most vulnerable populations, children and pregnant women, are not left behind.

Mr. Ricardo Baptista Leite, President, Unite

The intervention emphasized the critical role of governance, policy transformation, and investment in research and development (R&D) to accelerate progress in HIV, TB, and broader health system transformation. Recognizing the interconnectedness of health governance, political mobilization, and technological innovation, the intervention called for greater engagement of parliamentarians, policymakers, and regulatory bodies in shaping sustainable, equitable health solutions.

The intervention reaffirmed a commitment to working across political, research, and regulatory spheres to accelerate health system transformation. It called for ambitious, measurable targets, such as zero new infections, and the adoption of technology-driven, market-supported strategies to deliver sustainable health outcomes.

All stakeholders were invited to move beyond traditional political advocacy and into strategic partnerships that integrate innovation, governance, and financial sustainability to ensure long-term impact for children and vulnerable populations affected by HIV and TB.

The Role of Political Leadership in Health Transformation

The importance of engaging parliamentarians and policymakers in global health governance was highlighted, as these individuals are responsible for:

- Approving national budgets for health interventions.
- Mobilizing political action for regulatory and policy reform.
- Holding governments accountable to their commitments.

- Ensuring sustainability of investments in HIV, TB, and other public health challenges.

It was noted that health system reform is not just about responding to diseases but about transitioning to proactive, health-centered governance structures. Paediatric HIV and TB were identified as pivotal entry points for transforming health systems from reactive models into preventative, well-being-focused approaches.

Commitment to Increased Investment in R&D for Diagnostics and Treatment

A renewed commitment was made to advocate for greater investment in research and development for HIV and TB diagnostics and treatment, recognizing that scientific progress must be accompanied by systemic reforms to enable widespread adoption and implementation of innovations.

Priorities for R&D investment included:

- Accelerating the development of new diagnostic tools for HIV and TB to improve early detection, especially in children.
- Strengthening market-driven solutions to ensure that new technologies are not only developed but also accessible and affordable.
- Supporting regulatory governance models that streamline approvals and accelerate access to life-saving interventions.

- Addressing Systemic Barriers to Innovation and Access

  The discussion also underscored the need for stronger governance models to overcome barriers in R&D adoption, particularly in low- and middle-income countries. It was noted that many innovative health technologies fail to reach patients due to fragmented regulatory processes and inefficient market systems.

To address these challenges, the following actions were proposed:

- Governments must proactively create the regulatory and financial ecosystems that enable new technologies to thrive.
- Stronger collaboration is needed between policymakers, private sector actors, academia, and civil society to drive sustainable health solutions.
- Investment in implementation science is essential to translate research into real-world applications that benefit patients in diverse settings.

- **Multi-Sectoral Partnerships as a Driver of Change**
  Recognizing that no single actor can drive transformation alone, the importance of building coalitions between governments, academia, industry, NGOs, and civil society movements was emphasized. Multilateral collaboration must be prioritized to ensure that:
- Regulatory frameworks align globally to avoid delays in approvals and market entry.
- Governments adopt policies that incentivize research investment and health innovation.
- Patient-driven organizations and civil society movements remain central to decision-making.

Dr. Shaffiq Essajee, Senior Advisor in HIV, UNICEF

UNICEF remains steadfast in its commitment to accelerating the development, introduction, and access to optimal paediatric HIV and TB treatments. Recognizing the critical need to bridge the gap between research and real-world implementation, UNICEF is dedicated to translating scientific evidence into policy and practice more efficiently. The focus remains on ensuring that new products reach the children who need them as quickly as possible, leveraging partnerships to prioritize and streamline the delivery of life-saving interventions.

Key Priorities and Commitments

- **Enhancing Testing and Prevention in Maternal and Child Health Programs**
  - The integration of comprehensive antenatal testing services is crucial. This includes HIV, syphilis, and hepatitis B screening to ensure that mothers and their children receive timely and appropriate care.
  - Strengthening prevention of mother-to-child transmission (PMTCT) strategies to address the 120,000 new paediatric HIV infections annually, many of which result from incident infections during pregnancy.
  - Promoting the use of antiretroviral (ARV) therapy for pregnant women at risk of HIV acquisition, ensuring they receive prevention interventions alongside treatment to reduce new infections in children.
- **Sustaining and Strengthening the Paediatric HIV and TB Market**
  - UNICEF is committed to working with partners to convene key stakeholders, including industry leaders, regulatory agencies, and procurement bodies, to develop strategies for sustaining access to high-quality paediatric antiretrovirals (ARVs) and TB medicines.
  - Given the shrinking paediatric HIV market, it is essential to explore new models for market sustainability, ensuring continued availability of child-friendly formulations despite reduced commercial incentives.
- **Accelerating the Translation of Research into Policy and Practice**

- Bridging the gap between scientific advancements and real-world impact remains a top priority.
- UNICEF is mobilizing efforts to ensure that research and development (R&D) findings are rapidly incorporated into treatment guidelines and programmatic implementation.
- Enhancing coordination between policy-makers, researchers, and implementers will shorten the timeline between drug development, approval, and widespread accessibility.

Asks to Industry and donors

Industry engagement is critical in addressing these challenges. UNICEF calls on pharmaceutical companies, diagnostics manufacturers, and funders to:

- Sustain investment in paediatric HIV and TB treatments, ensuring that innovations in adult care are not delayed for children.
- Develop and implement strategies for market viability, particularly for paediatric ARVs, to prevent disruptions in supply.
- Expand research efforts to include pregnant women and children, ensuring that new medicines and diagnostics are optimized for these populations from the outset.
- Strengthen partnerships with procurement and regulatory bodies to facilitate faster approvals and distribution of essential paediatric treatments.

Gilead

Gilead remains steadfast in its commitment to expanding access to life-saving HIV prevention and treatment options for pregnant and breastfeeding women, as well as for children. Recognizing the critical gaps in R&D for these vulnerable populations, the company is dedicated to accelerating clinical trials, regulatory approvals, and global implementation efforts.

As Gilead moves forward, it is ensuring that the commitments set in 2022 have either been achieved or remain on track, and is redoubling efforts to advance paediatric and maternal HIV drug development.

Commitments

- Expanding Research and Clinical Trials for Pregnant and Breastfeeding Women
  - Inclusion of pregnant and postpartum women in pivotal trials

    - Gilead has adopted an inclusive research approach, ensuring that pregnant and breastfeeding women are part of pivotal adult trials rather than being studied only in later phases.
    - This includes ongoing phase one studies for new long-acting HIV prevention agents, integrating pregnant and breastfeeding women into safety and efficacy evaluations.
- Post-approval observational and post-marketing studies
    - Commitment to supporting real-world evidence collection on safety and effectiveness of HIV prevention treatments in pregnancy, breastfeeding, and postpartum periods.
    - Conducting breastfeeding-specific pharmacokinetic (PK) studies to better understand drug exposure through breast milk and its effects on infants.

Accelerating Regulatory Approvals and Access to Treatment

- Global regulatory filings and approvals
    - Gilead has submitted regulatory filings with the U.S. FDA (2023) and is now actively engaging with global regulatory agencies to expand access in high-burden settings.
    - Leveraging the EU-Medicines for All (EU Met for All) mechanism to streamline the approval process across multiple countries.
- Supporting clinical evidence for use in pregnancy and breastfeeding
    - Filing data packages specifically focused on HIV prevention in pregnancy and breastfeeding women, ensuring that regulatory approvals reflect real-world needs.

    - Supporting collaborative paediatric clinical trials
        - Gilead is working closely with global research networks to advance paediatric-specific HIV prevention and treatment studies.
        - Providing support for collaborative trials that integrate paediatric-specific needs in both prevention and treatment regimens.
    - Ensuring availability for paediatric research and implementation science
        - Commitment to providing the necessary drug supply for paediatric trials and supporting implementation science research to optimize real-world delivery of paediatric formulations.

Asks to other Stakeholders

- Gilead calls on research networks, regulators, and global health partners to work together in expediting paediatric and maternal clinical trials.
- Encourages researchers and policymakers to adopt inclusive study designs that prioritize pregnant and breastfeeding women earlier in the development cycle.
- Greater focus is needed on implementation science research to ensure new therapies reach the most affected communities.
- Governments, funding agencies, and partners should prioritize the introduction of innovative treatment options within national HIV programs.

Recent advancements in investigational compounds for HIV treatment hold promise for improving care and expanding access to more effective therapies. Current research has led to a new investigational compound showing promising results in Phase 2 studies, prompting preparations for a Phase 3 clinical trial set to begin this year. These developments mark a significant step forward in enhancing treatment options and ensuring that new innovations reach those in need.

- Phase 3 Clinical Trial Preparation
    - Following positive outcomes in Phase 2 studies, efforts are now focused on launching Phase 3 trials to evaluate safety, efficacy, and long-term impact.
    - This research aims to support the development of a robust, optimized treatment regimen, particularly for vulnerable populations, including children.
    - Collaboration with key global partners has been instrumental in refining trial protocols and ensuring regulatory alignment.
- Ensuring Paediatric Inclusion in Trials
    - Recognizing the historical gap in paediatric HIV treatment research, ongoing efforts are prioritizing preparing for paediatric studies in parallel with adult trials.
    - Engaging with key stakeholders, including regulatory authorities, research networks, and global health organizations, to ensure that children are not left behind in the drug development process.
- Technology Transfer for Affordability and Accessibility
    - Technology transfer initiatives are underway to support local manufacturing and enhance affordabilityin low- and middle-income countries (LMICs).

- Ensuring that newly developed treatments are accessible and cost-effective is central to the commitment to equitable access.
- Collaborating with pharmaceutical partners and procurement agencies to facilitate early adoption and streamlined distribution.

Asks to Stakeholders

- Regulatory Authorities: Fast-Tracking Approvals and Harmonizing Processes
  - Regulatory delays remain a major bottleneck in ensuring that children and adults receive timely access to new HIV treatments.
  - Calls for accelerated regulatory reviews and harmonized approval processes to prevent unnecessary delays in rolling out new treatments.
  - Encouragement for parallel regulatory submissions across agencies to improve efficiency and reduce approval timelines.
- Global Health Partners: Strengthening Collaborative Efforts
  - Appeal to research networks and funding agencies to support paediatric research efforts and ensure that clinical trials are adequately resourced.
  - Greater engagement from policymakers and multilateral organizations to streamline the introduction of new therapies into national HIV programs.
- Pharmaceutical and Industry Partners: Sustaining R&D Commitments
  - Urging industry stakeholders to maintain a strong focus on HIV R&D and prevent deprioritization of paediatric and maternal treatment options.
  - Encouraging continued investments in paediatric formulations and ensuring that new treatments are developed with equitable access in mind.

Prof. Anthony Garcia-Prats, Stellenbosch University and the Therapeutic Research Community

Stellenbosch University and the Therapeutic Research Community has a strong commitment to advancing TB drug development through collaboration, innovation, and strategic research design. As co-leaders of paediatric TB therapeutic research, the focus remains on ensuring that new treatments are efficiently developed, tested, and made accessible to children. Progress in paediatric TB treatment requires urgent action and a fundamental shift in approach. Investments in research, regulatory support, and cross-sector collaboration must be scaled up to ensure that children receive timely access to optimized TB therapies. Stellenbosch University and the Therapeutic Research Community asked funders, pharmaceutical companies, and global health stakeholders to move beyond rhetoric and take meaningful action to close the gap in paediatric TB care.

Current Challenges in Paediatric TB Research

- Limited Innovation in Childhood TB Therapy
    - Despite advances in adult TB drug development, paediatric TB treatment options remain stagnant.
    - There is no scientific reason why progress in childhood TB treatments should lag behind.
    - Without a shift in approach, history will continue to repeat itself, delaying access to life-saving therapies for children.
- Funding and Investment Gaps
    - Significant underinvestment in paediatric TB research has resulted in limited progress.
    - Although some investments have been made, they are insufficient to sustain comprehensive research initiatives.
    - There is a need for dedicated funding streams to accelerate innovation in childhood TB treatment.

Asks and Recommendations

- Increased Investment from Funders and Research Platforms
    - Urging funders and global health partners to actively contribute to research platforms dedicated to paediatric TB.
    - Encouraging stakeholders to move beyond discussions and translate commitments into concrete action.
    - Strengthening investment in collaborative research platforms like Cheetah to drive clinical trials and innovative treatment strategies.
- Commitment from Pharmaceutical and Industry Partners
    - Encouraging sustained engagement from industry leaders, including those who have made prior commitments.
    - Requesting clear, actionable commitments from pharmaceutical companies to ensure that TB drug development includes paediatric formulations from the outset.
    - Holding companies accountable for commitments made at global health meetings, ensuring that future discussions focus on measurable progress rather than repeated promises.
- A Collaborative Approach to Paediatric TB Trials
    - Advocating for stronger partnerships between researchers, industry, and regulatory bodies to design and implement paediatric TB trials more effectively.
    - Ensuring that regulatory pathways support simultaneous adult and paediatric TB drug approvals, rather than treating children as an afterthought.
    - Leveraging global research networks to facilitate data sharing, optimize study designs, and accelerate access to new TB treatments.

ANNEX 5 – MINUTES: STRATEGIZING FOR THE FUTURE

3 February, 12:15 – 13:15 CET: Strategizing for the Future

Moderator: Chip Lyons, President and CEO, EGPAF

- Monsignor Robert J. Vitillo, Advisor, Dicastery for Promoting Integral Human Development
- The Honorable Dr. Mark Dybul, Professor in the Department of Medicine at Georgetown University Medical Center where he serves as Chief Strategy Officer of the Center for Global Health Practice and Impact, Executive Chair of Platform Life Sciences, and CEO of Enochian BioSciences
- Dr. Joy Phumaphi, Board Member, Partnership for Maternal, Newborn and Child Health (PMNCH); Executive Secretary, ALMA
- Dr. Angeli Achrekar, Deputy Executive Director of the Programme Branch at the Joint United Nations Programme on HIV/AIDS (UNAIDS) and an Assistant Secretary-General of the United Nations, UNAIDS

Strategizing for the Future: A Call for Transformation in Global Health

- As global health faces an era of unprecedented change, there is an urgent need to rethink, restructure, and reform how institutions, partnerships, and strategies are designed to serve the most vulnerable, children, mothers, and communities. This discussion is not about incremental improvements but about fundamental transformation.
- The time for minor adjustments has passed. Global health structures as we know them today were not built for the world we live in now. If we were to start from scratch, would we recreate the same institutions, funding mechanisms, and operational models? The answer is no. This moment presents an opportunity to break apart outdated systems and rebuild them with inclusivity, efficiency, and sustainability at the core.

The Need for a Paradigm Shift

- The current global health system, fragmented, duplicative, and inefficient, was built over decades, with organizations working in silos and responding reactively to emerging crises. This approach has led to wasted resources, slow response times, and a disconnect between the solutions designed in global capitals and the realities faced in high-burden countries.

- However, disruption creates opportunity. We are now at a defining moment where health leaders, policymakers, industry, faith groups, and communities must come together to rethink the future. The question is not whether we should change, but whether we are willing to give up outdated ways of working to create something radically more effective and equitable.

Strategic Directions for the Future

1. Shifting Power to Countries and Communities
   - Re-centering global health leadership in high-burden countries instead of Geneva, Washington, and donor capitals.
   - Empowering national governments, community organizations, and local leaders to take ownership of their health responses.
   - Transitioning from top-down funding models to approaches that support national self-sufficiency and long-term sustainability.
   - Ensuring that decisions about children's health are made closer to where children live, by those who understand their realities.
2. Consolidating and Streamlining Efforts
   - Breaking down institutional silos, health is one interconnected system, yet programs for HIV, TB, malaria, and maternal health remain fragmented.
   - Aligning funding, procurement, and supply chains across diseases to create integrated service delivery models.
   - Rethinking global health architecture by consolidating redundant structures and investing in strong, multi-sectoral, and country-led platforms.
3. Redefining Partnerships Beyond Traditional Actors
   - Moving beyond health-sector-only partnerships to include finance ministers, private sector leaders, and technology innovators.
   - Faith leaders and civil society must play a more central role in advocacy and implementation.
   - Engaging with the broader private sector, not just pharmaceutical companies, but also digital health firms, AI developers, and logistics providers.
4. Embracing Technology and Innovation for Systemic Change
   - Artificial intelligence, digital health, and real-time data analytics must become integral to global health decision-making.
   - National health data platforms should ensure real-time monitoring of outbreaks, supply chains, and patient outcomes.
   - Investment in innovation for paediatric and maternal health must be prioritized, ensuring children and pregnant women are included in clinical trials from the start.
5. Strengthening Accountability for Real Results
   - Holding countries accountable for commitments made to prioritize children's health and end AIDS as a public health threat by 2030.
   - Ensuring funding is tied to measurable impact, not just program outputs.

- Building new mechanisms to track country performance and service delivery efficiency, leveraging both governments and non-state actors to ensure accountability.

Are We Ready to Let Go?

- A fundamental question was raised: Are we ready to give up the power and influence we have accumulated over the past two decades?
- The reality is that institutional inertia is strong, and many organizations are designed to sustain themselves rather than solve problems efficiently. Reform is not just about building new structures: it requires the courage to dismantle outdated ones.
- However, change does not mean abrupt interruption of services or programs. The transition must be managed carefully to ensure that as we redesign systems, vulnerable populations are not left without care.

A Moral and Strategic Imperative

- Pope Francis has often reminded us that global health is not just about science or funding: it is a moral responsibility. His leadership during COVID-19, ensuring equal vaccine access for the most marginalized, is a testament to the power of faith-driven advocacy for health equity.
- As we move forward, the sacred goal remains clear: ensuring that every child, mother, and family has access to the healthcare they need, not in fragmented, piecemeal interventions, but as part of a cohesive, people-centered system.
- Seizing the Opportunity for Change
- The global health system was not built for today's challenges, but we now have the opportunity to rebuild it for tomorrow's realities. This requires bravery, innovation, and a willingness to let go of past models that no longer serve us.
- As we navigate this transition, the guiding principle must be inclusion: ensuring that those historically left out of decision-making processes, particularly leaders from high-burden countries and community-based organizations, are at the forefront of shaping the future of global health.
- The train of change has arrived. Will we be passengers watching it pass, or will we be engineers shaping its course?The choice is ours.
-

ANNEX 6 – MINUTES SOLUTIONS AND ACTIONS ON GLOBAL, REGIONAL AND NATIONAL REGULATORY PROCESSES FOR HIV AND TB DIAGNOSTICS AND MEDICINES FOR CHILDREN, PREGNANT AND BREASTFEEDING WOMEN

Objective: Address regulatory inefficiencies preventing life-saving medicines from reaching children and pregnant women, discuss bottlenecks, and propose actionable solutions.

Challenges; Opportunities, Solutions; and Recommendations

1. Challenges

- Regulatory Delays and Fragmentation
  - Lack of harmonization among global, regional, and national regulatory agencies causes inefficiencies.
  - Different approval pathways lead to prolonged timelines, even after WHO prequalification.
  - Country-specific regulatory processes delay medicine availability in low-income settings.
- Exclusion from Clinical Trials
  - Children, pregnant, and breastfeeding women are often excluded from clinical trials, delaying safety and efficacy data.
  - Additional paediatric studies required by regulators extend approval timelines.
- Weak Supply Chains
  - Even when medicines are approved, distribution challenges prevent them from reaching patients.
  - Rural areas suffer from stockouts and logistical barriers.
- Lack of Investment in Local Manufacturing and Capacity
  - Many African nations rely on international manufacturers due to limited domestic production capacity.
  - National regulatory systems are underfunded, slowing the approval process.
- Inequities in Innovation Access
  - New HIV and TB medicines reach low-income regions years after wealthier countries due to cost and regulatory barriers.
  - Despite scientific advancements, regulatory bottlenecks create disparities in treatment availability.

2. Opportunities and Solutions

- Global and Regional Regulatory Harmonization
  - WHO's Prequalification (PQ) Program enables national regulators to rely on its assessments, streamlining approvals.
  - African Medicines Agency (AMA) should be fully operational to unify regulatory processes across Africa.
  - Countries should adopt regulatory reliance models to avoid redundant, country-by-country approvals.
- Fast-Tracking Paediatric Drug Approvals
  - National agencies must align paediatric approvals with adult medicines to avoid unnecessary delays.

    - WHO should strengthen fast-track mechanisms for paediatric HIV and TB treatments and diagnostics.
- Expanding Clinical Research for Children and Pregnant Women
    - Parallel regulatory submissions should be adopted globally to shorten approval timelines.
    - Companies must ensure inclusion of pregnant women in clinical trials without unnecessary restrictions.
- Strengthening Supply Chains and Last-Mile Distribution
    - Governments must improve procurement systems to ensure medicines reach rural communities.
    - Faith-based organizations should be formally integrated into supply chain planning.
- Building Local Manufacturing and Regulatory Capacity
    - Increased investment in regional pharmaceutical manufacturing to reduce reliance on international suppliers.
    - Strengthening national regulatory bodies with adequate funding and technical support.

3. Recommendations

- Accelerate Regulatory Harmonization
    - Support full implementation of the African Medicines Agency (AMA) to unify approval processes across African nations.
    - Strengthen WHO's Prequalification Program to enable broader regulatory reliance.
- Commit to Fast-Track Approvals for Paediatric Medicines
    - Align national regulatory frameworks with WHO recommendations to expedite paediatric drug approvals.
    - Ensure that paediatric formulations are reviewed alongside adult medicines.
- Expand Investment in Local and Regional Manufacturing
    - Build sustainable incentives for regional manufacturers to produce paediatric HIV and TB medicines.
    - Increase funding for national regulatory agencies to process approvals efficiently.
- Ensure Paediatric Inclusion in Clinical Trials
    - Require global pharmaceutical companies to integrate children and pregnant women into adult clinical trials.
    - Reform regulatory requirements to reduce unnecessary additional studies for paediatric populations.
- Strengthen Supply Chain Coordination and Last-Mile Delivery
    - Improve coordination between faith-based health networks, government agencies, and supply chain actors to ensure medicines reach underserved communities.
    - Scale up the use of rapid test kits and mobile clinics to increase treatment access in rural areas.
- Improve Coordination Between Regulatory Authorities
    - Standardize global regulatory guidelines for HIV medicines in pregnancy and breastfeeding.

- Align regulatory expectations between WHO, national agencies, and industry stakeholders to eliminate inefficiencies.

Detailed Minutes of the Regulatory Session

14:30 – 15:15 CET: Solutions and actions on global, regional, and national regulatory processes for diagnostics and medicines for children and for pregnant and breastfeeding women (HIV and TB)

Panel, Facilitator: *Monsignor Robert J. Vitillo,* Advisor, Dicastery for Promoting Integral Human Development

- **Setting the Scene** on regulatory processes for TB and HIV diagnostics and medicines for children, pregnant and breastfeeding women:
  - Dr. Hiiti Sillo, Unit Head, Regulation and Safety, Department of Regulation and Prequalification at World Health Organization
- **Vision Forward:** In the current global health landscape, where efficiency is paramount, how can regulatory authorities further collaborate to harmonize processes, thereby improving the introduction and access to safe, optimal products and medicines for children and their mothers? Additionally, from the private sector's perspective, what strategies can enhance regulatory efficiency amidst competing priorities and limited resources? What systematic changes are necessary to support advancements in products' introduction and access?
  - Dr. Michel Sidibé, African Union Special Envoy for the African Medicines Agency (video)
  - Dr. Moupali Das, Vice President, Clinical Development, HIV Prevention & Paediatrics, Franchise Head, HIV Prevention, Gilead Sciences
  - Dr. Richard Neci Cizungu, Executive Director, Ecumenical Pharmaceutical Network (EPN)
- **Discussion:**
  - Moderator: Dr. Carmen Perez, Senior Strategy Lead & Pandemic Preparedness Head, Unitaid
  - Questions for participants:
    - **Priority actions, commitments and opportunities:**
      As you share your organization's commitments, please also reflect on how regulatory authorities could further collaborate to harmonize processes, improving the introduction and access to safe, optimal products and medicines for children and their mothers? Additionally, from the private sector's perspective, what strategies can enhance regulatory efficiency amidst competing priorities and limited resources? What systematic changes are necessary to support advancements in product introduction and access? What opportunities exist/or should be created to accelerate progress and avoid stagnation?
    - **Questions to Other Stakeholders:**
      What are your asks to other stakeholders? What specific support would you like to request from other stakeholders that could

facilitate and accelerate the actions your organization is prioritizing? The "asks/requests" are an opportunity to clarify and address some of the most pressing bottlenecks in the paediatric HIV and TB response while fostering opportunities for collaboration.

Dr. Hiiti Sillo, Unit Head, Regulation and Safety, Department of Regulation and Prequalification at World Health Organization

The session began with a WHO Prequalification (PQ) Programme presentation, outlining:

- WHO's role in accelerating regulatory approvals by allowing national agencies to rely on its assessments.
- Regulatory challenges delaying paediatric medicines despite adult approvals.
- Fragmented national pathways and differing requirements slowing access in low-income countries.
- Harmonization and regulatory reliance as key solutions to speed up approvals and distribution.
- WHO's commitment to integrating paediatric HIV and TB medicines into fast-track approval processes.

Urgency of Addressing Regulatory Bottlenecks

- Paediatric HIV and TB medicines take 3-5 years longer to reach LMICs than adult versions.
- Delays cost lives: A mother in rural Africa may know the drug her child needs, but regulatory approval processes block access.
- WHO stressed the need for synchronized regulatory submissions globally rather than country-by-country approvals.

Key Barriers Identified

A. Regulatory Delays and Fragmentation

- Lack of harmonization between global, regional, and national regulatory agencies.
- Different approval processes across countries cause inefficiencies.
- Even after WHO prequalification, national approvals can take years.
- Inconsistent regulatory requirements between agencies create confusion and delays.

B. Exclusion from Clinical Trials

- Children and pregnant women are often excluded from drug trials, delaying critical safety and efficacy data.
- Regulatory agencies require additional paediatric studies, extending approval timelines.

C. Weak Supply Chains

- Even when medicines are approved, they do not reach patients due to logistical barriers.

- Rural areas suffer the most, with stockouts and delayed distribution.

D. Lack of Investment in Local Manufacturing and Capacity
- Many African nations still rely on international manufacturers.
- Local regulatory systems lack funding and infrastructure to process approvals quickly.

E. Inequities in Innovation Access
- Despite scientific advancements, social inequalities persist in accessing treatments.
- Low-income regions receive innovations years later due to cost and regulatory barriers.

Dr. Michel Sidibé, African Union Special Envoy for the African Medicines Agency

"Every regulatory delay is a death sentence for children."
- Proposed urgent actions at three levels:
  - Global Level:
    - Strengthen WHO Prequalification Program to accelerate paediatric approvals.
    - Regulatory reliance and harmonization must be widely adopted.
  - Regional Level:
    - Make AMA fully operational to harmonize approvals across Africa.
    - Ensure sustainable funding for AMA's independence and effectiveness.
  - National Level:
    - Governments must implement fast-track approvals for paediatric formulations.
    - Align national regulatory frameworks with WHO recommendations.

Dr. Moupali Das, Vice President, Clinical Development, HIV Prevention & Paediatrics, Franchise Head, HIV Prevention, Gilead Sciences

Health Equity Approach – Four Pillars:
- Partnerships with community organizations.
- Listening to affected communities to shape interventions.
- Person-centric design ensuring real-world access.
- Equity and inclusion to prevent disparities.

Commitments:
- First company to include adolescents in adult HIV prevention trials.

- Pregnant women included in research without requiring contraception.
- Parallel regulatory submissions across global agencies for faster access.

Asks:

- Align global regulatory processes to avoid inefficiencies.
- Prioritize paediatric drug approvals alongside adult formulations.
- Expand investment in equitable access programs.

Dr. Richard Neci Cizungu, Executive Director, Ecumenical Pharmaceutical Network (EPN)

- Faith-based organizations (FBOs) serve over 300 million people in Africa, especially in rural areas.

Key Challenges Identified:

- Lack of trained pharmaceutical staff in rural areas.
- Regulatory authorities mainly focus on cities, leaving rural areas vulnerable to counterfeit drugs.

Commitments:

- Expand healthcare worker training in rural areas.
- Introduce rapid test kits for paediatric HIV and TB medicines.
- Engage faith leaders to promote awareness and adherence to treatment.

Asks:

- Investment in last-mile drug quality control.
- Ensure faith-based networks are systematically included in regulatory and supply chain planning.

African Union Commission

Progress:

- 29 countries ratified AMA; Zambia joined on January 21, 2024.
- AMA aims to harmonize African regulations covering research, manufacturing, supply chains, and pharmacovigilance.

Asks:

- Support advocacy to ensure all African Union members ratify AMA.
- Secure funding to sustain AMA's operations.

Dr. Carmen Perez, Senior Strategy Lead & Pandemic Preparedness Head, Unitaid

The moderator highlighted the following takeaways from the discussion:

- Regulatory inefficiencies must be addressed systematically, not case-by-case.

Commitments from Global Stakeholders:

- WHO's parallel development approach for paediatric drugs must be widely adopted.
- Expert Review Panels (ERP) must be strengthened to accelerate access.
- Regional manufacturing must be expanded for greater availability of paediatric formulations.

Call for Systematic Approaches:

- We cannot continue addressing regulatory issues product by product, case by case.
- Systematic action is needed to align regulatory processes, innovation pathways, and implementation efforts.

Support for AMA's Full Implementation

- AMA must ensure regulatory harmonization across Africa.
- Governments should streamline regional approval pathways.

Helen McDowell, ViiV Healthcare, GSK

Specific Asks to Regulatory Authorities:

- Standardized Regulatory Guidelines for HIV Medicines in Pregnancy & Breastfeeding
  - Regulators must adopt consistent global standards for paediatric HIV and pregnancy studies.
- Reforming Paediatric TB Drug Approvals
  - Move away from inefficient efficacy trials and instead rely on pharmacokinetics & safety data.
- Global Regulatory Alignment
  - WHO, national regulators, and pharmaceutical companies must harmonize approval processes.
- Avoid Additional Regulatory Burdens
  - Ensure new drug approval requirements do not introduce unnecessary delays for paediatric formulations.
- Improve Coordination Between Regulatory Authorities
  - Differences between WHO guidance and national agency requirements create inefficiencies in drug approvals.
  - Regulatory reliance must be scaled up for more predictable and synchronized processes.

Recommendations

Engage regulatory agencies to fast-track approvals.

Ensure paediatric drugs are included in global approval pathways.
Commit to AMA's full operationalization and support regulatory harmonization.

ANNEX 7 – MINUTES SOLUTIONS AND ACTIONS RELATED TO R&D OF HIV AND TB DIAGNOSTICS FOR CHILDREN

Objective: The session focused on key challenges and opportunities in paediatric TB diagnostics, emphasizing the need for faster regulatory approvals, increased collaboration among stakeholders, and innovations tailored to children. Discussions covered gaps in research, industry commitments, and ethical considerations surrounding AI-powered diagnostics.

Challenges; Opportunities, Solutions; and Recommendations

1. Challenges

Regulatory and Access Barriers

- Fragmented regulatory systems delay WHO-prequalified TB and HIV diagnostic tests in low- and middle-income countries (LMICs).
- Even after WHO prequalification, national approval processes delay access by up to two years or more.
- Lack of regulatory harmonization prevents rapid scale-up and delays the introduction of new diagnostic tools.

Insufficient Research and Development for Paediatric Diagnostics

- Most TB and HIV diagnostics are first developed for adults, with paediatric versions coming much later or not at all.
- Validation studies rarely include children, particularly for non-sputum-based samples, limiting diagnostic options.
- No clear "gold standard" for paediatric TB diagnostics makes evaluation and adoption of new tests challenging.
- AI-powered diagnostics and molecular assays are still not adapted for paediatric use.

Operational Challenges and Siloed Approaches

- GeneXpert and other diagnostic platforms are underutilized due to poor integration across programs (e.g., HIV programs cannot access TB testing infrastructure, and vice versa).
- High maintenance and service issues render many machines non-functional when needed most.
- Limited access to training and resources for health workers, especially in rural settings, reduces diagnostic capacity.

Ethical and Equity Concerns in AI-Powered Diagnostics

- AI-driven diagnostics perform differently across settings, requiring local adaptation.
- Private sector investments primarily target high-resource settings, leaving LMICs behind.
- Ethical dilemma: Should AI-driven diagnostics be restricted due to lower sensitivity/specificity even if they are the only available option in LMICs?

Funding Constraints and Global Health Disruptions

- Global health priorities are shifting, and TB and HIV programs are at risk of reduced funding.
- COVID-19 caused severe setbacks, with childhood TB diagnoses declining by 28% in 2020.
- Malnutrition is a major driver of TB, yet nutrition programs are not integrated into TB/HIV strategies.

2. Opportunities and Solutions

A. Strengthening Research and Development

- Mandate paediatric inclusion in all TB and HIV diagnostic R&D trials from the start.
- Develop and validate non-sputum-based TB diagnostics, such as:
    - Stool-based testing
    - Tongue swabs
    - Blood-based biomarkers
- Expand validation studies beyond sputum samples, ensuring:
    - Paediatric-focused AI-driven diagnostic research
    - Digital X-ray AI validation for children
    - Accelerate research on molecular-based assays for paediatric TB and HIV detection.

B. Fast-Tracking Regulatory Approvals and Market Access

- Harmonize global regulatory processes to enable faster national approvals.
- Expand regional manufacturing to reduce cost and accelerate access.
- Implement a "fast-track" approval mechanism for paediatric diagnostics in high-burden countries.

C. Optimizing Existing Diagnostic Platforms and Breaking Silos

- Fully utilize GeneXpert and other multiplex diagnostic platforms by allowing:
- Cross-program use between TB, HIV, and maternal-child health services.
- Introduction of multiplex testing for co-infections (HIV, syphilis, hepatitis, TB) in antenatal care settings.
- Ensure diagnostic machines remain operational by:
    - Introducing monthly multi-stakeholder service meetings to prevent maintenance failures.

    - Expanding training programs for frontline health workers.

D. Leveraging AI & Digital Health Innovations

- Ensure AI-based diagnostics are tested and validated in real-world conditions.
- Develop paediatric-specific AI training datasets to improve diagnostic accuracy.
- Encourage private sector investment in AI-driven diagnostics tailored for LMICs.

E. Expanding Access & Improving Service Delivery

- Promote the use of treatment decision algorithms to support early and accurate TB diagnosis.
- Ensure routine diagnostics are available in non-TB programs:
    - Nutrition programs
    - HIV clinics
    - Maternal and child health settings
- Encourage pooled and collaborative funding mechanisms to maintain research momentum despite budget cuts.

3. Recommendations:

A. Strengthen Research and Development for Child-Friendly Diagnostics

- Require paediatric inclusion in all TB & HIV diagnostic R&D efforts.
- Mandate non-sputum-based diagnostic validation (stool, tongue swabs, blood-based biomarkers).
- Expand AI-driven research for paediatric TB detection using cost signatures, digital X-rays, and clinical algorithms, conducting research in high-burden, malnourished, and rural populations to ensure real-world relevance.

B. Accelerate Regulatory Approvals and Scale-Up Efforts

- Implement a fast-track approval mechanism for paediatric diagnostics in LMICs.
- Expand regional manufacturing capacity for rapid production and distribution.
- Harmonize national regulatory requirements to facilitate faster access.
  Support governments in scaling up WHO-recommended paediatric TB and HIV diagnostics.

C. Optimize Diagnostic Platforms and Improve Integration

- Break siloed approaches and enable cross-program usage of diagnostic tools (TB, HIV, maternal-child health).
- Scale up multiplex diagnostic platforms for TB, HIV, syphilis, hepatitis, and other co-infections.
- Ensure TB diagnostics are fully operational at all health facilities through proactive service coordination.

D. Promote Ethical & Equitable AI-Powered Diagnostics

- Ensure AI-driven diagnostics are adapted and validated locally before large-scale rollout.

- Invest in AI-powered diagnostic tools specifically for paediatric TB detection.
- Develop regulations that balance quality assurance with ethical access in LMICs.

E. Secure Sustainable Funding & Strengthen Partnerships

- Advocate for sustained financial commitments from global health donors.
- Encourage pooled funding mechanisms to support paediatric TB & HIV R&D.
- Integrate TB, HIV, and nutrition programs to optimize resources and improve child health outcomes.

Key takeaways

- Prioritization, partnerships, and innovation are essential moving forward.
- Children must be at the center of TB and HIV research and funding strategies.
- R&D must shift the focus from simply adapting adult diagnostic tools to developing child-specific solutions.
- Regulatory barriers must be removed to allow faster access to diagnostics.
- AI-driven and digital diagnostic tools must be rigorously tested and adapted for LMICs.
- Funding and advocacy efforts must remain steadfast to sustain progress and scale up effective solutions.

Detailed Minutes of the R&D Diagnostics Session

3 February, 15:45 – 16:30 CET: Solutions and actions related to research and development of diagnostics for children (HIV and TB)

Facilitator: *Monsignor Robert J. Vitillo,* Advisor, Dicastery for Promoting Integral Human Development

- **Vision Forward**: *How do we strike the right balance between prioritization of interventions in a landscape of reduced resources and maintaining focus on innovations to ensure novel diagnostics can improve the wellbeing of children and their mothers? What are the opportunities to accelerate the R&D for children and their mothers in today's global health landscape?*
    - Dr. Rachel O'Shea, Vice President, Cepheid
    - Dr. Kerri Viney, Team Lead, People-centred services, Communities and Determinants Unit, Global Tuberculosis Programme, WHO
- **Setting the Scene** on HIV and TB R&D Diagnostics:
    - Dr Cathy Hewison, TB Advisor and TB working group leader, Médecins Sans Frontières, Operational Section Paris

- Discussion:
    - Moderator: Meg Doherty, Director Global HIV, Hepatitis and STI Programmes, World Health Organization
    - Questions for participants:
- **Priority actions, commitments and opportunities:**
  As you share your organization's commitments, please also reflect on and share your thoughts on how we can effectively balance the prioritization of interventions in a landscape of reduced resources, with the need to maintain innovations that ensure progress in tools and strategies. What opportunities exist/or should we create to accelerate progress and avoid stagnation?
- **Asks to Other Stakeholders:**
  What are your asks to other stakeholders? What specific support would you like to request from other stakeholders that could facilitate and accelerate the actions your organization is prioritizing? The "asks/requests" are an opportunity to clarify and address some of the most pressing bottlenecks in the paediatric HIV and TB response while fostering opportunities for collaboration.

Dr. Rachel O'Shea, Vice President, Cepheid

In these challenging times, Cepheid wants to take this moment to shine a light on some significant innovations and progress in R&D that are making a real impact. Advancements in TB Diagnostics & WHO Prequalification: At Cepheid, we remain committed to improving access to diagnostics. One of the most significant achievements is that the GeneXpert TB Ultra cartridge is now offered at cost, with zero profit to Cepheid and its parent company, Danaher. This commitment extends through our public-private partnership mechanism, allowing private sector laboratories to use the technology while sharing data directly with Ministries of Health.

Cepheid continues to investing in GeneXpert technology:

- The Expert Ultra TB test is now WHO prequalified, fulfilling a commitment we made in the Rome Paediatric HIV and TB Action Plan years ago.
- The Expert XDR TB cartridge is currently undergoing WHO prequalification, with approval anticipated in the first half of this year.
- The GeneXpert platform is now included in WHO guidelines for use in children and for non-sputum samples, which is a critical step in improving access to accurate TB testing.

Investing in Sustainable Manufacturing and R&D in India: Over the past two years, we have also opened a manufacturing facility in India. As discussed earlier, the link between healthcare and society is undeniable, and this new facility is not only supplying cartridges for India and Southeast Asia but is also serving as an R&D hub to drive further innovation.

Breakthroughs in Early Infant Diagnosis and Green Innovation: In 2024, we launched XC (Extended Coverage), a new cartridge for early infant diagnosis (EID) and viral load testing. Another major breakthrough is the removal of ITC (isothiocyanate) from EID testing, eliminating the need for high-temperature incineration and reducing the environmental footprint. This "green step forward" contributes to a healthier future for children.

Regulatory Fragmentation and Access Delays: Despite these WHO prequalified tests, fragmented regulatory systems remain a significant barrier to timely access. As someone overseeing the Global Access Program at Cepheid, I know firsthand that even with WHO prequalification, it may still take two years or more for these tests to reach certain Asia-Pacific and South American countries. This delay is unacceptable, and regulatory harmonization is urgently needed to ensure life-saving innovations reach those who need them most, without unnecessary delays.

Operational Challenges and Systemic Silos in Diagnostics: Innovation isn't just about new products; it's also about how we operate and function. A critical issue we identified is the inefficiency in platform functionality:

- The GeneXpert system is one of the most widely used molecular diagnostic platforms, with 22,000 units across high-burden countries.
- Yet, a major challenge has been ensuring that these machines remain operational.
- To address this, we introduced monthly multi-stakeholder service meetings to ensure that when a mother and child arrive at a site, the GeneXpert machine is working and accessible.

Call for Integration: Ending Siloed Approaches: One of the most frustrating systemic inefficiencies is the lack of integration between disease programs.

- The GeneXpert platform operates like an espresso machine: you simply change the cartridge.
- However, in many countries, TB programs refuse to let HIV programs use the machines, and vice versa, despite the technology being capable of running multiple disease tests.
- This siloed approach is a huge barrier to efficiency, and in this time of uncertainty, we must ensure existing innovations are fully utilized to serve public health.
- We have the technology. We have the partnerships. We have the commitment from manufacturers. Now, we need all stakeholders, governments, regulators, funders, and policymakers, to step up and break down barriers so we can fully realize the potential of innovation in saving lives.

Dr. Kerri Viney, Team Lead, People-centred services, Communities and Determinants Unit, Global Tuberculosis Programme, WHO

The Urgent Need for Advocacy and Funding: As we consider the challenges ahead, one thing remains clear: advocacy must continue and intensify. Ensuring adequate funding for TB research, diagnosis, and treatment is critical, especially for children, who face disproportionately high TB-related morbidity and mortality.

Since the last Rome meeting in 2022, WHO has published the third edition of the Roadmap Towards Ending TB Among Children and Adolescents, outlining 10 key actions to improve the lives of children, their families, and at-risk communities.

Key Research Priorities in Paediatric TB Diagnosis: One of the key actions in the Roadmap focuses on supporting TB research, development, and innovation. Under this, WHO has identified priority areas for TB diagnostic research, including:

- Treatment Decision Algorithms, enhancing algorithms to improve early and accurate TB diagnosis, particularly in low-resource settings.
- Advancing Molecular-Based Assays, generating evidence for the next generation of WHO-recommended rapid molecular diagnostics using minimally invasive sample types.
- Artificial Intelligence for Chest X-Ray Diagnosis, expanding research into AI-powered computer-aided detection (CAD) software for interpreting chest X-rays in TB diagnosis.
- Biomarker Research, identifying and validating host and pathogen biomarkers for TB disease to improve early detection.
- Non-Sputum-Based Approaches, scaling up diagnostic techniques that do not rely on sputum, which is particularly difficult to collect from young children.

These research priorities aim to overcome limitations in current diagnostic tools, which often lead to delays or even failure in diagnosing children with TB.

Strengthening Adoption of WHO-Recommended TB Diagnostics: Beyond research, it is crucial to support countries in adopting and scaling up existing WHO-endorsed diagnostic tools for children. This includes:

- Expanding the use of treatment decision algorithms, particularly at primary healthcare levels.
- Promoting molecular tests on respiratory specimens and stool samples for TB diagnosis in children.
- Ensuring access to LF-LAM (lateral flow urine assay) for children living with HIV, as recommended by WHO.

Resource Constraints and The Impact of Disruptions: In the current global health funding landscape, we must remain vigilant to ensure children are not deprioritized in TB diagnostic programs. During the COVID-19 pandemic, TB notifications fell by 18% between 2019 and 2020, but

for children under five, the decline was even worse—28%.While trends have improved in recent years, further funding cuts or healthcare disruptions could again disproportionately impact children.

Key Actions to Address Resource Constraints: In light of funding challenges, we must optimize resources and streamline approaches to sustain and accelerate progress:

- Include children in research and clinical trials
- Ensure children are actively enrolled in TB research studies and their samples are tested to generate paediatric-specific evidence.
- Avoid delays in adapting new technologies for children by integrating paediatric considerations early in R&D.
- Enhance collaborative funding and data-sharing
- Encourage pooled and collaborative funding mechanisms across global health programs.
- Improve coordination between TB, HIV, maternal and child health, and nutrition programs to maximize efficiency.
- Strengthen coordination between innovation and implementation
- Ensure that new diagnostics are not only developed but also effectively integrated into national TB programs.
- Reduce resource burdens by aligning diagnostic service delivery with existing health system infrastructures.

Even amid uncertainties, our commitment to improving paediatric TB diagnosis must remain unwavering. Key words moving forward are Prioritization, Partnerships, and Innovation:

- Advocacy must continue, ensuring sustained funding for TB research, development, and innovation.
- WHO-recommended diagnostics must be scaled up, especially at peripheral healthcare levels.
- Ongoing research must be completed, even if funding constraints require strategic prioritization of evidence.
- New research efforts should focus on the most impactful diagnostic approaches to reach more children with TBusing innovative study designs.

Prioritization, partnerships, and new ways of working are essential as we move forward.

Setting the Scene on TB R&D Diagnostics

Dr Cathy Hewison, TB Advisor and TB working group leader, Médecins Sans Frontières, Operational Section Paris

Médecins Sans Frontières (MSF) / Doctors Without Borders is a humanitarian medical organization, often operating in war zones, conflict zones, refugee camps, and epidemic settings. No matter where we work, we always find children with TB. This is a reality that underscores the daily challenges of diagnosing, treating, and preventing TB in children.
Recognizing this, we launched the Test, Avoid, Cure TB in Children (TACTIC) initiative, focusing on: 1. Testing to improve TB diagnosis in children; 2. Avoiding TB through better prevention; 3. Curing children with effective treatment.
This is an urgent issue. We need to move beyond discussions and take real action to improve TB care for children worldwide.

The Problem: Why Are We Failing to Diagnose Children with TB?

- We are not diagnosing enough children.
- Nearly half of children under 15 with TB remain undiagnosed.
- The situation is even worse for children under 5.
- Only 14% of children with multidrug-resistant TB (MDR-TB) receive treatment.
- Every three minutes, a child dies from TB.
- Children under 5 are the most affected.
- Most TB deaths in HIV-negative children occur in this age group.
- 96% of children who die from TB were never put on treatment.
- The issue is clear: We have a diagnosis problem, not a treatment problem.
- What happens to the children we fail to diagnose? They die.
- This is not just a problem in low-resource settings; it is a global issue.
- Even in Europe, the U.S., and Australia, diagnosing TB in children is difficult because there is no reliable test specifically for them.

Why is TB Diagnosis So Different for Children?

- Unlike adults, diagnosing TB in children is not difficult; it is different.
- TB presents differently in children due to their immature immune systems.
- Children have fewer TB bacteria (paucibacillary disease), making confirmation through tests harder.
- Most TB tests are designed for adults, not children.
- Even with the best tools (GeneXpert, culture, etc.), confirmation rates remain low.
- Challenges in TB Testing for Children
- Sputum collection is NOT the biggest problem—the real issue is that children's TB is different and harder to detect.
- Testing doesn't always provide answers.

- In resource-limited settings, it is difficult to justify expensive TB tests when positivity rates are low.
- Sample collection challenges.
- We need non-sputum-based tests.
- Manufacturers and researchers must expand validation studies beyond sputum samples.
- X-ray limitations
- Current AI-based chest X-ray detection tools (CAD) are not validated for children.
- Most TB-endemic areas lack access to X-ray machines.
- Pathogenesis and host response.
- TB in children does not follow the same disease progression as in adults, making it harder to diagnose using standard approaches.

Where do we find children with TB?

- Not just in TB programs!
- Most are found in nutrition programs, HIV clinics, intensive feeding centers, displaced persons camps.
- Malnutrition is a major risk factor for TB.
- Food is the best TB vaccine we already have.
- The India study confirmed that nutritional support reduces TB risk.

The Solution: What Needs to Change? - Reccomendations

- Develop Child-Specific TB Diagnostic Tools
- Non-sputum-based, point-of-care, affordable, and widely available tests.
- Current TB tests are designed for adults first, and children are only considered later.
- Prioritize Children in TB R&D
- Children must be included in target product profiles (TPPs).
- We must ensure R&D trials prioritize paediatric TB.
- Validation studies should not require sputum samples only.
- Invest in Better Tools and Smarter Use of Existing Ones
- Expand treatment decision algorithms.
- Ensure clinicians are trained to diagnose TB clinically, even without test confirmation.
- Scale up stool-based testing and alternative sample methods.
- Recognize that TB in Children is Everywhere

- TB isn't confined to TB programs—children with TB are found in nutrition, HIV, and displacement settings.
- Programs must integrate TB screening across sectors.
- Recognize the uniqueness of TB in children.
- Prioritize non-sputum-based TB tests.
- Ensure children are included in all TB R&D initiatives.
- Invest in better diagnostic tools specifically for children.
- Improve the use of current tools through training and integration across healthcare programs.
- TB is the leading infectious cause of death in children, yet it remains neglected.

- If we are serious about reducing child mortality, we must act NOW.

Discussion

Moderator: Dr. Meg Doherty, Director Global HIV, Hepatitis and STI Programmes, World Health Organization

Post-COVID Innovations and the Need for Integration: COVID made clear that diagnostic innovations must be better integrated. A 2023 World Health Assembly resolution emphasized the need to improve diagnostics capacity, leading to an ongoing working group. This group includes multiple WHO departments and external partners, forming a technical working group to explore Multiplex cross-platform diagnostics. The goal is to streamline diagnostic processes to:

- Improve efficiency
- Defragment diagnostics
- Ensure timely access to essential tests

An upcoming Multiplex diagnostic recommendation is expected soon. Prequalification efforts are also aligning with upcoming innovations, such as combining HIV, syphilis, hepatitis B, and hepatitis C testing in antenatal care (ANC) settings.

There is no reason why TB diagnostics should not also be included in this process. This is a clear opportunity to integrate expert TB tests into broader diagnostics for maternal and child health.

Molbio Diagnostics

Developing Effective TB Diagnostic Tools for Children - The key question we face is: How do we effectively use and validate diagnostic tools for children? While we have developed portable and affordable diagnostic systems for use in field settings, the challenge remains in developing child-specific diagnostic algorithms and ensuring they are properly validated. This is an area where we are actively collaborating with partners.

Concerns About TB Test Delays: A major issue in TB testing is the extended timeframe for results, often taking months or even years to reach patients. In many cases:

- TB tests are not the first point of diagnosis, leading to delays.
- Patients must navigate multiple steps before receiving quality-assured test results.
- Only 10-12% of cases in hybrid settings test positive. What happens to the remaining 85-90% of symptomatic individuals?
- The question remains: Are we treating the disease, or are we treating people suffering from the disease?

The Need for Low-Cost, Rapid Multiplex Testing: To address these issues, we are focused on developing lower-cost, rapid, multiplex tests that can provide timely and accurate TB diagnosis. However, there is not enough discussion in the global TB community about accelerating patient recovery by ensuring faster access to diagnosis and treatment.

A New Approach: Molecular Diagnostics in the Field: From a research perspective, we have created a platform called True Life, which allows TB diagnosis through tongue swab samples with high sensitivity. We have also developed an ultra-portable, affordable system that enables molecular diagnostics in field settings. When coupled with tagging technology, this system has the potential to revolutionize access to diagnostics.

However, critical questions remain:

- How do we adapt these technologies for children?
- How do we develop validation protocols for paediatric TB testing?
- How do we integrate these tools into existing TB diagnostic frameworks?

Rethinking TB Diagnosis Beyond Traditional Approaches: The broader challenge in TB diagnostics is that we focus only on identifying the disease rather than addressing all underlying causes of symptoms. We need to:

- Develop integrated diagnostic platforms that detect multiple diseases and co-infections.
- Introduce fever-based diagnostic pathways for TB and other common infections.

- Encourage other diagnostic manufacturers to take on these challenges and contribute innovative solutions.
- This discussion is not just about committing to multiple diagnostic platforms but also about rethinking how we diagnose TB and other diseases in children. The question remains: How can we enable a faster return to wellness for people who are seeking care?

We invite other stakeholders, manufacturers, and researchers to join the effort and push for faster, more inclusive, and child-friendly TB diagnostics.

Additional key discussion points by participants:

- Exploring AI and Cost Signatures for TB Screening
- Call for Innovation in Handheld and AI-Based Technologies
- Challenges in Adapting AI and Imaging for Paediatric TB
- The Challenge of Diagnosing Paediatric TB Without a Gold Standard
- The Importance of Conducting Research in High-Burden Areas

- A research organization from Denver proposed using cost signatures for diagnosing TB. However, it remains unclear whether this method is applicable to children. Can we leverage AI-driven cost signature analysis for TB screening, especially in children? While TB confirmation requires bacterial identification, could this approach offer a new way to improve screening and early detection?
- AI and digital diagnostic tools have the potential to enhance TB screening and early detection in children. However, the practical field application of these technologies must be rigorously tested.
- Data performance in real-world settings must be validated, ensuring they are reliable for frontline health workers.
- Currently, AI-driven tools such as ultralight digital X-rays and computer-assisted detection (CAD) softwarehave shown promise.
- However, directly applying adult-based AI models to children is problematic. We need child-specific validation studies to ensure accuracy.
- One of the key issues is the lack of a clear gold standard for paediatric TB diagnosis. In many cases, TB in children is diagnosed clinically rather than through confirmatory tests, making it difficult to evaluate new diagnostic methods.
- Studies often rely on composite definitions that consider clinical response and other indirect indicators. However, applying these composite definitions consistently across different settings remains challenging, adding a layer of subjectivity.

- To improve TB diagnosis in children, we must conduct studies in high-burden countries, where the majority of cases occur. However, research in these settings remains difficult, particularly in malnourished populations, where TB rates are high.
- Nutrition is a key driver of paediatric TB: there are more malnourished children with TB than those co-infected with TB and HIV, a fact that is often overlooked.
- Expanding research in these vulnerable populations is essential to developing effective diagnostic strategies.

Mr. Ricardo Baptista Leite, President, Unite

- The increasing use of artificial intelligence in digital diagnostics introduces challenges related to sensitivity and specificity of results.
- A recent study published in Nature highlighted that an imaging technology approved by the US FDA with extremely high sensitivity and specificity performed dramatically worse when applied in a different context.
- This underscores the need to evaluate AI-based diagnostic tools across diverse settings before assuming global applicability.
- Unlike medical devices and pharmaceutical products, AI-based technologies cannot simply be distributed globally without local adaptation.
- The effectiveness of AI-powered diagnostic tools depends on training with local data, ensuring that they work in different healthcare environments.
- A key challenge is that many low- and middle-income countries (LMICs) lack the necessary data to adapt these technologies effectively.
- Private sector investment in AI-driven healthcare solutions tends to focus on high-resource settings, leaving underserved regions at a disadvantage.
- There is an urgent need to address equity in access to digital diagnostics.
- Current regulatory approaches compare digital tools to traditional "gold standard" diagnostics, but this method may not always be appropriate.
- An ethical dilemma arises:
- If a gold standard diagnostic is unavailable in certain regions, should AI-driven alternatives still be restricted due to lower sensitivity/specificity?
- Would it be ethical to deny these technologies to underserved populations simply because they do not meet the highest possible accuracy standards?
- These issues require open discussion among regulators, manufacturers, researchers, and implementers.
- The conversation must prioritize access and equity, ensuring that digital innovations do not widen existing healthcare disparities.

- The rapid expansion of AI and digital diagnostics presents both opportunities and risks, and the global health community must navigate these challenges responsibly.

This discussion highlights the urgent need for:

- AI-driven diagnostic innovations tailored for children. Gather additional insights from stakeholders working in AI-driven diagnostics and paediatric TB research.
- Rigorous validation of AI and digital TB screening tools in real-world settings.
- Increased research in malnourished and high-TB burden populations.
- A shift in focus from simply adapting adult diagnostic tools to developing child-specific solutions.

ANNEX 8 – MINUTES CLOSING SESSION DAY 1: Prioritizing Paediatric HIV and TB

Objective: Reflect on key themes and opportunities from the day's discussions to effectively address paediatric HIV and TB within the broader context of children's health and integral human development.

"We cannot let politics, bureaucracy, or inefficiency continue to cost lives. We have seen what happens when systems fail, but we have also seen what happens when innovation and accountability drive impact. We urge all partners here to take decisive action, ensuring equitable healthcare access for children, mothers, and families." Echo Vanderwal, The Luke Commission (TLC)

"We need a clear, data-driven plan based on science and collaboration. We can no longer afford parallel efforts: our success depends on an integrated, focused strategy that prioritizes children in global health efforts" David Ripin from the Clinton Health Access Initiative (CHAI).

"We are at a turning point. What we do now will determine whether paediatric HIV and TB are eliminated, or whether we continue to see preventable deaths. Let's commit to real action."

The session opened with a reflection on the day's discussions, acknowledging the creative and strategic thinking that had emerged. It was noted that while new ideas and innovative solutions were explored, many of the core challenges remain similar to those identified in earlier dialogues on paediatric HIV and TB.

A key takeaway was the need to integrate bioethical considerations into the conversation, ensuring that AI and technological advancements respect human dignity, diversity, and core ethical principles in healthcare decision-making.

The session then moved to two key interventions, starting with Echo Vanderwal, The Luke Commission (TLC), followed by David Ripin from the Clinton Health Access Initiative (CHAI).

Echo Vanderwal, Executive Director, The Luke Commission: Addressing Systemic Failures in Paediatric HIV & TB Response

Background & Achievements

- Founded 20 years ago in Eswatini (then Swaziland), the country with the highest HIV prevalence rate in the world.
- Expanded from a team of 10 to 700 healthcare workers, serving 300,000 patients annually.
- Leading provider of HIV and TB care in the country, including:
- Highest number of ART initiations and TB cases treated per year.
- Only admitting facility for critical MDR/XDR-TB patients.
- Largest PreP initiator and highest uptake of IPTV.
- Largest provider of cervical cancer screenings and treatment.
- Use of digitalization to integrate care and prevent missed opportunities.

COVID-19 Response & Innovation

- Built Eswatini's first medical oxygen plant during the pandemic, addressing national shortages.
- Developed a national digital system for vaccine tracking, ensuring 100% vaccine utilization.
- Reduced national case fatality rates by 50%, demonstrating the power of technology, accountability, and innovation in healthcare.

Systemic Challenges and Inequities in Funding

- Despite these achievements, TLC has faced chronic underfunding and systemic barriers:

- TLC carries 28% of Eswatini's healthcare burden but receives less than 2% of national resources.
- Faith-based healthcare institutions provide nearly 50% of national health services but receive only 12% of resources.
- Recurring stockouts of essential HIV and TB medicines, including paediatric formulations.
- Ongoing supply chain failures exacerbated since COVID-19, costing thousands of lives.

Accountability and Transparency Failures in Global Health Systems

- Repeated calls for urgent intervention internationally have gone unheard.
- Despite external audits confirming TLC's efficiency, additional funding has not materialized.
- Local corruption in global health investments resulted in duplicative infrastructure projects (e.g., a redundant oxygen plant funded without coordination with TLC).

CHAI's Perspective: Addressing Paediatric HIV & TB in a Changing Global Landscape

The Urgency of the Moment

- 120,000 new paediatric HIV infections per year.
- 76,000 child deaths annually from HIV—15,000 in Nigeria alone.
- Global health funding shifts are creating uncertainty and threatening progress.
- Without targeted donor investment, children will continue to be deprioritized.

Key Questions Moving Forward

- How will health be prioritized in an era of competing global crises?
- Within health, how will HIV and TB remain a priority?
- How do we ensure children are not left behind in integrated health responses?

The Need for Strategic Investment & Collaboration

- Past successes were driven by major targeted investments (e.g., UNITAID, FASTER initiative).
- Without similar funding mechanisms, paediatric HIV and TB will fall through the cracks.
- Parallel programming (where each actor works in isolation) is inefficient.
- Donors must prioritize high-impact, integrated investments to sustain progress.

Key Takeaways: Day 1 of the Dialogue

1. Actionable solutions exist: we must now focus on execution.
2. Funding gaps and inefficiencies threaten progress: global health actors must urgently realign priorities:
    a. Global health financing must prioritize effectiveness over bureaucracy.
    b. Existing resources must be leveraged efficiently to avoid duplication and waste.
    c. Supply chain systems must be overhauled to prevent medicine shortages.
    d. Global partners must disrupt inefficiencies and invest in sustainable models that prioritize outcomes.
3. Regulatory barriers must be dismantled to ensure new innovations reach children in LMICs.
4. Long-acting HIV prevention tools must be prioritized to end paediatric HIV transmission: new prevention tools have the potential to eliminate vertical transmission:
    a. Northern countries have nearly eliminated paediatric HIV by ending mother-to-child transmission.
    b. New long-acting PrEP and HIV prevention tools offer the potential to close the gap in LMICs.
    c. If these innovations are prioritized, paediatric HIV can be eliminated within a generation.
5. A shift toward efficiency and accountability is non-negotiable in the current global health landscape: accountability and transparency must be non-negotiable in funding and implementation decisions.

Path Forward and Next Steps

- Discussions must focus on HOW we implement these solutions.
- A roadmap for ongoing collaboration must be established: this conversation cannot end here.
- Partners must commit to sustained engagement and action beyond this meeting.

ANNEX 9 – MINUTES SOLUTIONS AND ACTIONS – IDENTIFYING AND DIAGNOSING CHILDREN WITH HIV AND TB

Challenges; Opportunities, Solutions; and Recommendations

Challenges

1. Persistent Diagnostic Gaps and Treatment Inequities

- A significant gap remains in identifying and diagnosing children exposed to HIV and TB, with an estimated 400,000 undiagnosed children living with HIV.
- Paediatric ART coverage lags behind adult treatment rates (77% for adults vs. 57% for children), translating to approximately 450,000 children in urgent need of treatment.
- Only 63% of children with TB have an HIV test result available, leaving many undiagnosed and untreated.
- Limited provider-initiated testing, outpatient testing, and family-based index testing restrict early identification.

2. Barriers in Laboratory Systems and Diagnostic Tools
   - Inconsistent sample transport systems lead to delays in processing and unusable test results.
   - Weak quality control mechanisms in laboratory networks limit the reliability of test results.
   - Limited availability of point-of-care diagnostic tools for both HIV and TB prevents timely testing and case identification.
   - Challenges in specimen collection, particularly for infants and young children, further hinder diagnosis (e.g., lack of accessible respiratory samples for TB).
3. Integration and Service Delivery Barriers
   - Fragmented healthcare services result in missed opportunities to diagnose children during routine health visits.
   - Weak integration of HIV and TB screening within broader maternal and child health programs reduces efficiency.
   - Drop-off rates in follow-up care after birth and postnatal services prevent consistent early infant diagnosis.
4. Weak Policy Implementation and Resource Constraints
   - Despite WHO's updated guidance and Road Map Towards Ending TB in Children, national implementation remains inconsistent.
   - Only 5 out of 13 surveyed countries have incorporated treatment decision algorithms into policies.
   - Funding for paediatric HIV and TB diagnostics remains insufficient, limiting scale-up efforts.
   - MDR-TB detection rates remain low (only 4,000 cases reported annually), due to limited testing capacity.

Opportunities and Solutions

1. Strengthening Diagnostic and Laboratory Systems
   - Expanding point-of-care diagnostics, including multiplex nucleic acid amplification tests and digital chest radiography, will improve early detection rates.
   - New WHO recommendations for concurrent testing using both respiratory and stool samples, along with LF-LAM tests for HIV-positive children, offer promising solutions for diagnosing TB in children.
   - Enhancing sample transport systems and quality control processes will minimize delays and improve reliability.
2. Expanding Integration and Community-Based Testing

- Implementing universal 18-month HIV testing, integrated with routine childhood vaccinations (e.g., South Africa's MMR-linked testing approach), could significantly increase early case detection.
- Strengthening community-led approaches, such as family-centered models in Tanzania and outreach programsin Mozambique, will improve service reach.
- Expanding home-based and self-testing approaches for caregivers could facilitate earlier identification of HIV-exposed infants.

3. Policy and Health System Strengthening
   - Fully integrating paediatric case finding into national HIV and TB strategic plans will improve focus on children's health outcomes.
   - Expanding task-shifting to community health workers for TB and HIV screening will enhance accessibility, particularly in rural areas.
   - Adopting clinical decision algorithms for TB will help ensure that paediatric cases are diagnosed and treated earlier, even in settings where microbiological confirmation is not possible.
4. Innovative Approaches for Accelerating Case Finding and Linkage to Care
   - Digital health solutions can enhance data tracking, case management, and early detection efforts.
   - Rapid scaling of new diagnostic technologies will help overcome traditional barriers in testing accessibility.
   - Public-private partnerships should be leveraged to accelerate multiple testing methods and facilitate the introduction of new TB diagnostics in high-burden settings.

Recommendations

1. Strengthen Diagnostic Systems and Laboratory Efficiency
   - Scale up point-of-care testing technologies, such as multiplex NAAT and digital radiography, to improve TB and HIV case detection.
   - Improve sample transport networks and laboratory quality assurance mechanisms to ensure timely and accurate results.
   - Standardize laboratory protocols to ensure alignment with updated WHO recommendations on paediatric TB and HIV diagnosis.
2. Expand Service Integration to Improve Early Diagnosis
   - Ensure universal HIV testing at 18 months is integrated with routine childhood vaccinations and maternal and child health visits.
   - Link HIV and TB screening with broader child health services, including nutrition and vaccination programs, to create a holistic, patient-centered approach.
   - Scale up community-based and outreach testing models, prioritizing rural and high-risk populations.
3. Strengthen National Policies and Funding for Paediatric HIV and TB
   - Ensure children are fully included in national HIV and TB policies, strategic plans, and funding applications.
   - Scale up the inclusion of paediatric treatment decision algorithms across national TB programs.
   - Advocate for increased domestic and donor funding to expand diagnostic capacity and innovative testing methods.

4. Leverage Digital Technology and Data-Driven Decision Making
   - Implement AI-driven data systems to track diagnostic gaps, monitor new product pipelines, and optimize resource allocation.
   - Expand the use of digital chest radiography and innovative TB screening tools to enhance early detection and treatment initiation.
   - Improve health system coordination through digital platforms, ensuring better integration of TB and HIV services.
5. Build Stronger Community Engagement and Multisectoral Collaboration
   - Strengthen task-sharing with community health workers to improve case finding, linkage to care, and adherence support.
   - Address stigma, gender inequality, and social barriers that hinder care-seeking behavior among women and children.
   - Expand partnerships with faith-based organizations, civil society, and private sector stakeholders to accelerate innovations and ensure last-mile access.
6. Scale Up Procurement and New Product Introduction
   - Ensure rapid introduction of new HIV and TB formulations, with immediate technical assistance for country-level adoption.
   - Expand regional manufacturing of paediatric HIV and TB medicines, reducing reliance on international suppliers and ensuring a sustainable supply chain.
   - Improve coordination between donors, governments, and procurement agencies to streamline drug and diagnostic supply chains.

Detailed Minutes Identifying and Diagnosing Children with HIV and TB

This session focused on scaling up diagnostics, medicines, and case finding to address the critical gaps in identifying children living with or affected by HIV and TB. The moderator introduced the session talking about "Fixing the Most Important Problem for Children Living with HIV," setting the stage to review current challenges, data gaps, and potential solutions.

DAY 2, 4 February
09:00 – 10:00 CET: Solutions and actions on identifying and diagnosing children (HIV and TB)

Scene, Facilitator: *Monsignor Robert J. Vitillo,* Advisor, Dicastery for Promoting Integral Human Development

- **Setting the Scene** on identifying and diagnosing children exposed to and/or living HIV and TB:
  - Dr. Shaffiq Essajee, Senior Advisor in HIV, UNICEF
  - Dr. Kerri Viney, Team Lead, People-centred services, Communities and Determinants Unit, Global Tuberculosis Programme, WHO

- **Vision forward:** In today's increasingly complex healthcare environment, how can we enhance the efficiency and effectiveness of case finding, ensure access to optimal diagnostics, and foster integration?
    - Mrs. Marijke Wijnroks, Head, Strategic Investment & Impact Division (SIID), the Global Fund to Fight HIV, TB and Malaria
    - Mrs. Florence Riako Anam, Co-Executive Director, The Global Network of People Living with HIV (GNP+)
    - Dr. Claudia Llanten, Senior Manager Maternal and Child Health, Catholic Medical Mission Board (CMMB)
    - Dr. Gabriele Fontana, Regional Adviser, Health, UNICEF
- **Discussion:**
    - Moderator: *Dr Shaffiq Essajee, Senior Advisor in HIV, UNICEF*
    - Questions for participants:
- **Priority actions, commitments and opportunities:**
  As you share your organization's commitments, please also share your thoughts on how we could enhance efficiency and effectiveness in case finding and ensure access to optimal diagnostics. What opportunities exist/or should we create to accelerate progress and avoid stagnation?
- **Asks to Other Stakeholders:**
  What are your asks to other stakeholders? What specific support would you like to request from other stakeholders that could facilitate and accelerate the actions your organization is prioritizing? The "asks/requests" are an opportunity to clarify and address some of the most pressing bottlenecks in the paediatric HIV and TB response while fostering opportunities for collaboration.

Dr. Shaffiq Essajee, Senior Advisor in HIV, UNICEF

A. Setting the Scene and Data Overview on Identifying and Diagnosing Children with HIV

The presentation began by highlighting the stark inequity in treatment coverage using the "3-95" framework. While 77% of adults are on antiretroviral therapy (ART), only 57% of children receive treatment, a 20-percentage-point gap. This disparity translates to an estimated 450,000 additional children needing treatment, driven primarily by a diagnostic gap of around 400,000 missing diagnoses. The speaker stressed that closing this diagnostic gap is key to achieving treatment equity.

Diagnostic Testing Challenges

The current guidelines outline three primary stages for testing in the continuum of care:

- Infant Diagnosis:
    - Timing: Testing at birth, again at 4–6 weeks (or 2 months), and at 9 months using biological tests.

    - Challenges: Although access has improved, coverage has plateaued due to issues such as inadequate end-to-end support, unreliable sample transport (with delays rendering samples unusable), and insufficient quality control systems.
- Final Status Testing at 18 Months & Provider-Initiated Testing:
    - Timing: Final status testing is recommended at around 18 months, alongside testing for sick children initiated by providers.
    - Challenges: Despite long-standing guidance, there is minimal data reporting in global monitoring systems. Weak postal services and a significant drop-off in follow-up after birth and the first six weeks have been observed.
    - Innovative Approach: South Africa's recent policy now recommends universal HIV testing at 18 months, integrated with the MMR vaccine for all children, which represents a promising model for broader implementation.
- Outpatient and Catch-Up Testing:
    - Scope: This category includes provider-initiated testing for symptomatic children, outpatient-based testing, and outreach efforts such as index testing.
    - Challenges and Opportunities: While guidelines exist, scale-up remains limited. Successful community-based approaches were highlighted, including Tanzania's family-centered model, where trained community members address HIV testing alongside nutrition and vaccination, and similar strategies in Mozambique that effectively reach remote populations.

Dr. Kerri Viney, Team Lead, People-centred services, Communities and Determinants Unit, Global Tuberculosis Programme, WHO

B. Setting the Scene and Presenting Data on Identifying and Diagnosing Children with TB

The speaker introduced the session by stating its focus on identifying and diagnosing children exposed to or living with TB. Key data were presented using a slide that tracked trends in TB among children and young adolescents (ages 0–14) from 2011 to 2023 (slides available to participants).

Diagnostic and Treatment Gaps

The speaker highlighted several critical gaps:

- **HIV Testing in TB Cases:** Only about 63% of children with TB have an HIV test result available, meaning roughly one-third remain untested.
- **Treatment Coverage:** Among those tested, 3.6% are HIV positive (compared to nearly 7% in adults), and 91% of HIV-positive children receive ART, which is comparable to adult coverage (89%).

- **MDR-TB Detection:** Only about 4,000 cases of multidrug-resistant TB (MDR-TB) in children are notified each year, just 14% of estimated cases.

A slide presented by a colleague from MSF illustrated programmatic gaps in detection by age groups:

- For children under 15, only about 55% are detected, compared to 77% among adults.
- The lower detection rate among younger children (especially those under 5) was attributed to the nature of the disease, lack of sensitive point-of-care tests, difficulties in collecting suitable samples (such as respiratory specimens), and various health system challenges.

Policy Landscape and New Guidelines

The speaker then discussed the policy framework:

- In 2022, WHO launched the 3rd edition of the Road Map Towards Ending TB in children and adolescents, outlining key actions for reducing morbidity and mortality among children, adolescents, and pregnant/postpartum women.
- This Road Map aligns with targets from the UN meeting on TB in 2023 and includes priorities such as funding, accountability, and social protection.
- Additionally, WHO's updated consolidated guidelines on TB management in children, along with an operational handbook, provide recommendations on screening, diagnostic approaches, and models of care.
- A rapid communication issued in September last year introduced new recommendations for concurrent testing using two specimens, one respiratory sample and one stool sample, with an additional LF-LAM test for children living with HI, to improve the accuracy of TB diagnosis.

Implementation Considerations and Operational Research

The speaker noted that these recommendations must be implemented within decentralized and integrated care systems:

- Implementation considerations include cost (due to the requirement for two specimens), logistical challenges in sample collection, and the need for capacity building in clinical diagnosis where microbiological confirmation isn't always possible.
- The new testing recommendations must be integrated with treatment decision algorithms.
- Ongoing operational research, conducted in collaboration with TDR and involving over 15 groups and an expected 20,000 records, is aimed at externally validating and harmonizing treatment decision algorithms across TB programs.

Reccomendations

1. Optimizing Laboratory Systems and Delivery

The discussion emphasized the need to improve laboratory systems to:

- Enhance sample transport and maintenance.
- Establish robust quality control.
- Expedite the return of diagnostic results.

Innovative diagnostic methods, such as point-of-care testing, multiplex nucleic acid amplification tests, and assisted self-testing, were identified as crucial to overcoming operational challenges, especially in settings where obtaining standard respiratory samples is difficult, necessitating alternative specimen types like stool.

2. **Integrating Diagnostics with Service Delivery**

The discussion underscored that diagnostic improvements must be integrated into a comprehensive care model. Key strategies include:

- Integration with HIV and TB Programs: Linking TB screening with HIV prevention, treatment, and diagnostic evaluation to ensure seamless care.
- Capacity Building: Investing in training, mentoring, and supportive supervision for healthcare staff to enhance the overall quality of service delivery.
- Decentralized and Community-Based Approaches: Strengthening contact investigation and outreach efforts, ensuring that innovations in diagnostics translate into real-world impact through effective, community-centered delivery systems.
- Digital Health Integration: Leveraging digital chest radiography and new diagnostic tools to improve early detection and treatment initiation.

3. Key programmatic interventions to scale up identification and diagnosis include:

- Ensuring that children are included in national TB strategic plans, guidelines, and funding requests for capacity building, monitoring, mentoring, and supportive supervision.
- Strengthening contact investigations and linking TB screening to HIV prevention, treatment, and diagnostic evaluation.
- Enhancing access to digital chest radiography and integrating diagnostics with treatment care services, including access to the latest TB preventive and treatment regimens.

Mrs. Marijke Wijnroks, Head, Strategic Investment & Impact Division (SIID), the Global Fund to Fight HIV, TB and Malaria

- **Moral Imperative and Focus on Children's Health**
  - There is a critical moral imperative to ensure that every child receives the treatment they need.

- If we do not address the health needs of children, HIV and TB will continue to pose significant public health threats.

- **Addressing the Diagnostic and Treatment Gap**
  - An estimated 590,000 children are living with HIV, and nearly 500,000 remain undiagnosed, a diagnostic gap that must be closed to achieve treatment equity.
  - Historically, child-friendly treatment options have been delayed, and existing guidelines have not effectively translated into practice.
- **Challenges in Traditional Case Finding**
  - Traditional HIV and TB programs often fail to identify children.
  - Every interaction with a healthcare facility should be seen as an opportunity for early diagnosis, yet current systems miss many children.
- **Innovative Approaches and Service Integration**
  - There is a need to integrate case finding into broader healthcare platforms.
  - Examples from South Africa illustrate how service integration can strengthen sustainable health systems.
  - Partnerships with the private sector are essential, particularly for accelerating innovations such as multiple testing methods and the use of alternative samples for TB diagnosis.
- **Enhancing Procurement and New Product Introduction**
  - Recent efforts in procuring new formulations for HIV and TB treatments have made these treatments available in over 50 countries.
  - Ongoing collaboration is necessary to provide technical assistance for new product introductions, ensuring that innovations reach children promptly.
- **Overcoming Structural Barriers and Inequities**
  - It is crucial to address the inequities and structural barriers that prevent marginalized populations from accessing essential healthcare.
  - All stakeholders must work collaboratively with communities to ensure that the health of children and adolescents remains a top priority.

Mrs. Florence Riako Anam, Co-Executive Director, The Global Network of People Living with HIV (GNP+)

The speaker emphasized a "back to the basics" approach from the community's point of view. She highlighted the following:

- **Evolving Focus on Treatment Access:**

- While significant progress has been made in expanding treatment access for children living with HIV, the focus now must shift toward strengthening treatment literacy among people living with HIV.
- In the past five years, paediatric treatment has undergone major changes in policy and regimens. However, mothers are struggling to keep pace, and safe, supportive environments for treatment and testing remain inadequate.

- **Addressing Social Barriers:**
  - Persistent stigma, discrimination, and gender inequalities hinder mothers from seeking care and bringing their children for testing.
  - GNP+ noted that delayed turnaround times for test results generate anxiety among young mothers, 12% of respondents in a recent global report indicated they did not return to facilities because of these issues.
- **Policy Influence and Prioritization:**
  - There is an urgent need to influence policies to prioritize children's health and ensure that treatment access becomes a key focus.
  - GNP+ is encouraged by emerging policy expectations for paediatric HIV and sees opportunities to advocate at forums like the COP for enhanced services for children.
  - GNP+ recalled that shortages of essential tests (e.g., viral load assays during 2020–2021) have contributed to missed opportunities, underscoring the need for sustained commitment.
- **Building Community Champions:**
  - GNP+ stressed that champions for children should extend beyond mothers. Teachers, religious leaders, nurses, and doctors can play a vital role in educating and advocating within their communities.
  - Addressing internal stigma and supporting mental health are critical, as nearly 89% of individuals report experiencing internal stigma, which negatively impacts their healthcare engagement.
- **Leveraging Multisectoral Tools:**
  - GNP+ highlighted the WHO validation process for ending HIV and syphilis, now referred to as triple elimination, as an effective multisectoral tool.
  - This process guides the development of PMTCT guidelines and engages communities to tackle social and human rights barriers.
  - Kenya is targeting triple elimination by 2027-2025.

Strengthening treatment access for children requires ongoing collaboration, community engagement, and renewed policy focus.

Dr. Claudia Llanten, Senior Manager Maternal and Child Health, Catholic Medical Mission Board (CMMB)

CMMB started by highlighting the longstanding mission of the organization, noting that for over a century, the organization has worked

tirelessly to support women and children in low-income countries, striving to overcome historical marginalization. Despite existing guidelines recommending screening for infants born to HIV-positive mothers, many challenges persist. These include:

- **Operational and Logistical Barriers:** In humanitarian settings such as Haiti and Sudan, geographical obstacles, inadequate transportation facilities, security concerns, and high mobilization costs severely limit access to essential healthcare.
- **Gaps in Testing and Follow-Up:** Although screening is recommended, many infants are not consistently tested due to a lack of robust systems. In some instances, children receive injections without proper HIV testing because of limited testing kits and insufficient training of healthcare providers.
- **Stigma and Discrimination:** Social barriers remain significant. Children not living with their biological parents face heightened stigma and discrimination, which further impede access to timely care.
- **The Need for Community Engagement:** CMMB emphasized that education and spiritual programs can play a vital role in bringing hope and changing attitudes. By working closely with community-based organizations and the broader health system, messages can be tailored to resonate within communities, ultimately leading to improved outcomes.

Dr. Gabriele Fontana, Regional Adviser, Health, UNICEF

UNICEF stressed that one of the primary reasons for low treatment rates and poorer outcomes in children compared to adults is the failure to diagnose children in a timely manner. Key points from the intervention included:

- **Leveraging Existing Health Platforms:** UNICEF advocated for the use of primary healthcare delivery platforms, which are closer to the communities in need, to enhance the identification and diagnosis of children living with HIV.
- **Role of Community Health Workers:** UNICEF highlighted that community health workers are uniquely positioned to reach households, identify children due for vaccinations, and detect signs of malnutrition or illness. Their regular engagement with communities builds trust and creates opportunities for early HIV testing.
- **Integration of HIV Services:** Integrating HIV identification into primary healthcare, as UNICEF has been doing in several countries, can extend the reach of the health system beyond traditional facilities. This integration is essential for achieving timely diagnosis and treatment, particularly in resource-constrained settings.
- **Expanding Successful Practices:** UNICEF concluded by emphasizing the importance of adopting and scaling up successful models of care. By transforming these good practices into the new norm, we can ensure that children receive the timely care they deserve and that the health systems become more resilient and inclusive.

Discussion

- The moderator emphasized the importance of integrated testing as a vital opportunity to not only improve performance but also enhance the overall quality of our work by leveraging community engagement.
- It was noted that stigma remains a critical barrier, as it prevents women and people living with HIV from returning for care. Addressing these structural barriers is essential for effective case finding and diagnostics.

- Challenges in Documentation and Strategic Planning:
  - There is an acknowledged gap in the documentation and characterization of effective community approaches. Although these approaches are often cost-effective, the lack of robust evidence sometimes hinders their prioritization in strategic planning.
- Industry Engagement and Opportunities:
  - The moderator called on colleagues from the private sector to share opportunities and commitments related to optimizing diagnostics and enhancing case finding for HIV and TB.
  - It was stressed that this topic will form a key area of commitment within the new Rome Plan.
- Specific Areas for Improvement:
  - Prevention Gaps:
    - There is a significant gap in TB preventive treatment for children under five years old who are household contacts. One reason for this gap is that TB prevention is not viewed as a health center activity; it must be taken to the communities, where people often have other priorities.
  - Resource Needs:
    - The need for additional resources to support community-based initiatives was highlighted.
  - Holistic, Patient-Centered Approach:
    - Emphasized the importance of integrating services (including vaccination and nutrition) with HIV and TB case finding, ensuring a holistic approach that is patient-centered.
  - Policy and Funding:
    - The moderator noted that only 5 out of 13 countries surveyed have incorporated treatment decision algorithms for TB in their policies. Increased funding for diagnostics—such as additional testing cartridges and tools—is essential.
    - The treatment decision algorithm, which relies on clinical diagnosis, is crucial because approximately 80% of children are diagnosed based on clinical features rather than laboratory confirmation.
  - Next Steps and Support Measures:
    - The panel will continue to support proposals aimed at improving diagnostic systems, monitoring the pipeline for new tools, and integrating diagnostics with treatment strategies.

- Emphasis was placed on ensuring the availability of innovative tools and exploring local manufacturing opportunities to secure the supply of essential screening tools for children.
- Polyvalent community health workers were recognized for their critical role in expanding outreach and ensuring effective case finding.

Key Recommendations from the Session

1. Enhance Diagnostic Systems and Laboratory Efficiency
    - Improve sample transport, maintenance, and quality control to expedite diagnostic turnaround times.
    - Implement innovative diagnostic methods, including point-of-care testing, multiplex nucleic acid amplification tests, and concurrent testing (using both respiratory and stool samples, with additional LF-LAM for HIV-positive children), to close the gap of approximately 400,000 missed diagnoses.
2. Integrate Diagnostics with Comprehensive Service Delivery
    - Link TB screening with HIV prevention, treatment, and diagnostic evaluation within a unified care model.
    - Strengthen capacity through targeted training, mentoring, and supportive supervision for healthcare staff, ensuring early and accurate detection.
    - Expand decentralized, community-based approaches (such as family-centered models and index testing) to reach underserved and remote populations.
3. Strengthen Policy, Funding, and National Ownership
    - Ensure children are included in national TB strategic plans, guidelines, and funding requests, addressing the estimated treatment gap of 450,000 additional children in need.
    - Advocate for increased and innovative funding, engaging both traditional donors and the private sector, to sustain diagnostics and treatment initiatives.
    - Align policy strategies with updated WHO guidelines (including the Road Map Towards Ending TB in children and adolescents) to transform guidelines into actionable, country-led programs.
4. Leverage Digital Technologies and Data
    - Utilize digital platforms, artificial intelligence, and data analytics to monitor diagnostic pipelines in real time and optimize resource allocation.
    - Enhance the use of digital chest radiography and other novel diagnostic tools to support early detection and prompt treatment initiation.

5. **Foster Community Engagement and Multisectoral Partnerships**
    - Empower community health workers and collaborate with community-based organizations to ensure every healthcare interaction is an opportunity for early diagnosis.
    - Address social barriers, such as stigma and discrimination, through integrated educational, advocacy, and support initiatives.
    - Build and sustain partnerships among governments, the private sector, faith-based organizations, and civil society to drive a coordinated and impactful response.

The presentations and discussions recognized that, although the challenges in paediatric HIV and TB diagnosis are significant, they are not insurmountable. By scaling up diagnostic capabilities, streamlining laboratory systems, and integrating innovative case-finding strategies with robust treatment linkages, we can close the diagnostic gap and achieve treatment equity for children. It was emphasized that these recommendations must be implemented within a strong, functioning health system. All speakers underscored that a concerted effort, combining improved diagnostic capacity, streamlined service delivery, and robust community engagement, is essential to bridge the gap in paediatric HIV care and to overcome the persistent challenges in reaching vulnerable children.

In today's complex healthcare environment, with reduced funding, we must continue to improve case finding, optimize diagnostics, and achieve greater integration. However, concerns and questions persist regarding our future direction.

ANNEX 10 – MINUTES SOLUTIONS AND ACTIONS – ON INTRODUCTION AND SCALE UP OF HIV AND TB MEDICINES FOR CHILDREN AND THEIR MOTHERS

Challenges; Solutions, Opportunities; and Recommendations on Introduction and Scale up of HIV and TB Medicines for Children and their Mothers

Day 2: 4 February
10:00 – 11:0 CET: Solutions and actions on introduction and scale-up of medicines for children and their mothers (HIV and TB) (60 minutes)

Panel, Facilitator: Monsignor Robert J. Vitillo, Advisor, Dicastery for Promoting Integral Human Development

Setting the Scene, Dr Nandita Sugandhi, Paediatric Lead for Global HIV, Hepatitis, and STIs Programmes, World Health Organization

Dr. Nandita Sugandhi provided a historical overview of paediatric HIV treatment, emphasizing the importance of transitioning to integrase-based regimens. She highlighted the significant reduction in paediatric HIV mortality over the years due to improved treatment protocols but stressed that treatment access remains a major barrier.
She also presented procurement data, showing rapid adoption of new paediatric formulations but also pointing to disparities in implementation across different countries.

Barriers to Scale-Up:

- Regulatory delays: Some countries have slow approval processes for paediatric formulations.
- Supply chain inefficiencies: Persistent stock-outs and uneven distribution hinder access.
- Need for second-line regimens: Current gaps in alternative treatment options for children failing on first-line therapy.

Vision forward: Given the increasingly complex global health landscape, how do we consolidate progress and find greater efficiency in the way we roll-out and sustain drug optimization in the grounds? What are the key opportunities forward for improving access?

- **Mr. Esteban Burrone**, Director for Policy, Strategy and Market Access, and a member of MPP's Executive Leadership Team, Medicines Patent Pool (MPP): highlighted how licensing partnerships have accelerated access to paediatric HIV medicines. He stressed the need for better coordination among stakeholders and increased data sharing to track implementation progress.
- **Dr. David H. Brown Ripin,** Executive Vice President, Infectious Diseases; Chief Science Officer, Clinton Health Access Initiative (CHAI) provided an in-depth analysis of the supply chain challenges and inefficiencies that still exist in paediatric HIV treatment access. He pointed out:
  - The need for greater coordination between manufacturers, procurement agencies, and country programs to ensure timely drug delivery.
  - Concerns over the impact of supply chain disruptions on treatment continuity for children.
  - The importance of planning for sustainable second-line treatment options as resistance to first-line regimens grows.
  - Market challenges for paediatric HIV medicines, including the risk of treatment shortages if procurement commitments decline.

- **Dr. Angeli Achrekar**, Deputy Executive Director of the Programme Branch at the Joint United Nations Programme on HIV/AIDS (UNAIDS) and an Assistant Secretary-General of the United Nations, UNAIDS: emphasized the critical role of political accountability in ensuring sustained investment in paediatric HIV programs. She called for:
  - Stronger commitments from governments to prioritize paediatric treatment.
  - More proactive country-level implementation of WHO guidelines.
  - Better integration of paediatric HIV treatment within primary healthcare to reach children in remote areas.
  - Strengthening policy frameworks to integrate paediatric HIV into broader health and development agendas.
  - Ensuring continuous advocacy at national and global levels to keep paediatric HIV on policymakers' radar.
  - Mobilizing resources through innovative public-private partnerships and domestic financing mechanisms.
  - She also referenced the Global Alliance to End AIDS in Children, stressing the importance of leveraging this platform to track progress and address gaps in service delivery.

- Discussion:
  - Moderator: Dr. Sébastien Morin, Policy, Strategy and Market Access, Medicines Patent Pool (MPP)
  - Questions for participants:
- **Priority actions, commitments and opportunities:**
  As you share your organization's commitments, please also share your thoughts on how we could consolidate progress and find greater efficiency in the way we roll-out and sustain drug optimization in the grounds? What are the key opportunities forward, given the increasingly complex global health landscape? What opportunities exist/or should we create to accelerate progress and avoid stagnation?
- **Asks to Other Stakeholders:**
  What are your asks to other stakeholders? What specific support would you like to request from other stakeholders that could facilitate and accelerate the actions your organization is prioritizing? The "asks/requests" are an opportunity to clarify and address some of the most pressing bottlenecks in the paediatric HIV and TB response while fostering opportunities for collaboration.

UNICEF and Global Fund Representatives reaffirmed their commitment to supporting national programs by:

- Ensuring new paediatric drug formulations are readily available for procurement.
- Providing technical assistance for rollout and implementation.
- Addressing market constraints and ensuring the sustainability of paediatric treatment supply chains.

CHAI spoke about Advanced HIV Desease in children and presented case studies from the Thrive Project, which focuses on reducing childhood mortality due to HIV. She underscored the importance of integrating paediatric HIV treatment into broader child health frameworks. She also spoke on case finding and retention strategies for children with HIV. She discussed community-led initiatives such as Last Mile Plus, which increases case identification in remote regions. Last Mile Plus initiative seeks to:

- Increase paediatric case identification in underserved regions.
- Strengthen community awareness on HIV prevention and treatment.
- Leverage social and cultural networks to improve treatment retention.

GNP+ called for stronger community participation in paediatric HIV programs, emphasizing the role of traditional birth attendants and local health workers in linking mothers and children to care.

The Global Fund reiterated the need to scale up child-friendly TB and HIV treatments, emphasizing that addressing co-infections like TB is critical to reducing childhood mortality.

Closing refloection:
Dr Joy Phumaphi stressed the need for structural reforms in health systems to improve service delivery for children. She proposed:

- Decentralizing paediatric HIV care to bring services closer to families.
- Developing targeted interventions for high-risk populations, including children of key affected groups.
- Integrating digital health tools to enhance monitoring, supply chain efficiency, and treatment adherence.

Addional recommendations from the discussion:

- Expand strategic data sharing to improve visibility on treatment uptake, supply chain gaps, and program performance.
- Accelerate regulatory harmonization to streamline drug approvals in low- and middle-income countries.
- Ensure availability of second-line paediatric treatment options for children who develop resistance to first-line regimens.
- Strengthen supply chain coordination to prevent stock-outs and minimize wastage of paediatric formulations.
- Monitoring the impact of funding disruptions on paediatric treatment access and mobilizing alternative resources.
- Mobilize sustainable funding sources to safeguard paediatric HIV programs amid global funding uncertainties.
- Integrating paediatric HIV treatment with primary health care to ensure broader accessibility.
- Supporting second-line treatment access for children failing on first-line regimens.

Final Recommendations

Scaling Up and Strengthening Implementation

- Urgently expand treatment access and case identification efforts to ensure that all children in need receive timely and effective care.
- Develop and implement practical, measurable strategies to enhance efficiency, streamline service delivery, and ensure sustainable impact.
- Strengthen national health systems to provide comprehensive, long-term support for paediatric HIV and TB programs.
- Leverage digital health solutions to improve patient tracking, reduce loss to follow-up, and enhance supply chain management.
- Increase collaboration with community-based organizations and traditional birth attendants to expand access to services and improve treatment retention.

Advocacy and Policy Reform

- Enhance country-level accountability mechanisms to monitor progress, ensure transparency, and track commitments to paediatric HIV and TB programs.
- Advocate for national policy changes to integrate paediatric HIV into broader child health and social protection frameworks.
- Improve data collection and disaggregation to better track children's health outcomes and inform decision-making.
- Foster greater data transparency and coordination among partners to address implementation challenges and facilitate resource mobilization.

Sustainable Financing and Long-Term Commitment

- Mobilize new funding sources to support paediatric HIV programs, including debt relief initiatives, private sector partnerships, and country-led financing solutions.
- Develop innovative financing mechanisms to ensure the sustainability of paediatric treatment programs, especially in resource-limited settings.
- Plan for long-term sustainability beyond 2030, ensuring that investments and health system improvements remain focused on the needs of children.

Final Commitments and Next Steps

- The session concluded with a firm commitment from stakeholders to follow up on implementation progress in the coming months through high-level discussions and stakeholder engagement forums.
- Urgent focus on closing funding gaps to prevent disruptions in paediatric HIV treatment programs and ensure that children remain at the center of the global health agenda.

- Continued collaboration between governments, multilateral organizations, donors, and community-based organizations to translate commitments into sustained, impactful action.
- Regular progress reviews will be conducted to assess implementation efforts and adjust strategies to improve efficiency and effectiveness.
- Stakeholders agreed to reconvene in future fora to evaluate the progress of these commitments and ensure that all children in need receive access to life-saving treatment and care.

Closing Remarks, Father Renzo Pecoraro, Pontifical Academy for Life

Father Renzo Pecoraro, Chancellor of the Pontifical Academy for Life, delivered a powerful closing address, emphasizing the moral and ethical duty to protect and prioritize the health and well-being of children. He reminded the audience of Pope Francis' recent Summit on Children's Rights (February 2025), highlighting the stark realities faced by vulnerable children worldwide, including those affected by HIV and TB.

He underscored:

- The moral imperative to act decisively, ensuring that no child is left without access to life-saving treatment and care.
- The intersection between faith, ethics, and public health, stressing that religious institutions and faith-based organizations must play a critical role in advocacy, service delivery, and community engagement.
- The need for deeper collaboration between governments, civil society, and religious organizations to mobilize resources and drive real change in paediatric HIV responses.
- The importance of listening to and amplifying the voices of children, ensuring that policies and interventions are shaped by their needs and lived experiences.

He concluded with a call for action, urging all stakeholders to remain steadfast in their commitments and to work together in unity to meet the ambitious targets of ending paediatric AIDS. He emphasized that discussions should translate into concrete steps, accountability, and long-term sustainability.

ANNEX 11 – LIST OF PARTICIPANTS

Jenifer	Healy	**Abbott**	Senior Director International Government Affairs and Policy
Jayasree K.	Iyer	**Access to Medicine Foundation**	CEO
Julio	Rakotonirina	**African Union Commission**	Director for Health and Humanitarian Affairs
Albert	Faye	**ANRS**	
Umesh K.		**Aurobindo**	Global Executive, Leading Key SBUs & Several Geographies
Victor	Genina	**Caritas Internationalis**	Director of Integral Human Development Department
Giulia	Amerio	**Caritas Internationalis**	Health And HIV Advisor
Eugene	ONU	**Caritas Nigeria**	Deputy Director Care and Treatment & TB/HIV Lead
Jean	Munongo	**Caritas Congo Asbl**	Coordinateur National, Service de Promotion de la Santé
Thandiwe	Muzadzi	**Caritas Zimbabwe**	Head of the Health Commission
Dr Jean Bosco	Kanani	**Caritas Rwanda**	
Daniel Somian	Say	**Caritas Cote d'Ivoire**	Responsible MEAL & Renforcement Institutionnel
Rachel	O'SHEA	**Cepheid**	Vice President
Mary-Beth	Powers	**Catholic Medical Mission Board - CMMB**	President & CEO
Claudia	Llanten	**Catholic Medical Mission Board - CMMB**	Senior Specialist Maternal and Child Health
Carolyne	Amole	**CHAI - Clinton Health Access Initiative**	
David H. Brown	Ripin	**CHAI - Clinton Health Access Initiative**	Executive Vice President, Infectious Diseases; Chief Science Officer
Anneke	Hesseling	**Desmond Tutu TB Centre SARcHi Chair in Paediatric Tuberculosis**	*Distinguished Professor in Paediatrics and Child Health*
Allessandra	SMERILLI	**Dicastery for Promoting Integral Human Development**	Secretary
Anthony O.	Ekpo	**Dicastery for Promoting Integral Human Development**	Undersecretary (Monsignor)
Robert J.	VITILLO	**Dicastery for Promoting Integral Human Development**	Senior Advisor (Monsignor)
Luis	Pizarro	**Drug for Neglected Diseases Initiative - DNDI**	Executive Director

Richard	Neci Cizungu	**Ecumenical Pharmaceutical Network (EPN)**	Executive Director
Michael	Makanga	**EDCTP 3**	Executive Director
Chip	LYONS	**Rome Action Plan**	Advisor; Former EGPAF President & CEO
David	Villafranca	**EGPAF**	
Mark	Dybul	**Georgetown University**	Professor and Advisor
Moupali	Das	**Gilead Sciences**	Vice President, Clinical Development, HIV Prevention & Pediatrics, Franchise Head, HIV Prevention
Kathryn	Kersey	**Gilead Sciences**	Executive Director Clinical Development
Florence	RIAKO ANAM	**Global Newtork of People Living with HIV - GNP+**	Executive Director
Sébastien	MORIN	**Medicines Patent Pool - MPP**	Policy and Advocacy Manager
Esteban	Burrone	**Medicines Patent Pool - MPP**	Head of Policy, Strategy and Market Access at Medicines Patent Pool
Cathy	Hewison	**Médecins Sans Frontières, Operational Section Paris**	TB Advisor and TB working group leader
Chandrasekhar	Nair	**Molbio Diagnostics**	Director
Anita	Chandrasekhar	**Molbio Diagnostics, bigtec Labs, the wholly owned R&D subsidiary of Molbio Diagnostics**	Head of Operations at bigtec Labs
Masoud	Dara	**Otsuka Novel**	Senior Director, Global Health & Public Affairs
Federica	Onori	**Parlamentare Italiano**	Chamber of Deputies of the Italian Republic, where she is Member of the III Commission (Foreign and Community Affairs) and President of the "Agenda 2030 Committee". She is also president of the Italy-Spain Interparliamentary Union and a delegate to the Parliamentary Assembly of the Organization for Security and Co-operation in Europe
Carlo	GIAQUINTO	**PENTA Foundation and University of Padova**	President
Rebecca	Bunnel	**PEPFAR**	Principal Deputy Coordinator (PDAS) · PEPFAR, Global Health Security and Diplomacy Bureau, Department of State
Sandy	Thurman	**Emory Rollins School of Public Health**	
Joy	PHUMAPHI	**PMNCH - ALMA**	Chair of the board
Laura	Palazzani	**Pontifical Academy for Life**	Member of the Governing Council of the Pontifical Academy for Life and Professor of Philosophy of Law at LUMSA
Renzo	PEGORARO	**Pontifical Academy for Life**	Prefect (Fr)
Hafsat (Hav-f-i)	Abdullahi		Poet

Francesca	Merico		Consultant
Carol M.	Keehan	**Rome Action Plan**	Advisor
Corinna	Csaky	**The Coalition for Children Affected by AIDS**	Director
Echo	Vanderwal	**The Luke Commission, Eswatini**	Executive Director
Harry	Vanderwal	**The Luke Commission, Eswatini**	
Vindi	Singh	**The Global Fund to Fight AIDS TB and Malaria**	Senior Disease Advisor
Marijke	Wijnroks	**The Global Fund to Fight AIDS TB and Malaria**	Head, Strategic Investment & Impact Division (SIID)
Philippe	DUNETON	**Unitaid**	Executive Director
Carmen	Perez	**Unitaid**	Strategy Senior Lead/PPPR Head
Tony	Garcia-Prats	**University of Wisconsin-Madison & Stellenbosch University**	Professors
Gabriele	Fontana	**UNICEF**	Regional Adviser, Health
Shaffiq	Essajee	**UNICEF**	Senior Advisor HIV
Angeli	Achrekar	**UNAIDS**	Deputy Executive Director
Paula	Dr Paula A. Munderi	**UNAIDS**	Team Lead, Science, HIV Treatment & Pediatricsl UNAIDS
Ricardo	BAPTISTA LEITE	**UNITE**	President
Audrey	Abernathy	**ViiV Health Care and GSK Global Health**	VP and Head of Communications and Government Affairs for ViiV Healthcare and GSK Global Health
Helen	McDowell	**ViiV Health Care and GSK Global Health**	Head of Government Affairs and Global Public Health · ViiV Healthcare
Gracia-Violeta	Quiroga	**WCC**	
Meg	DOHERTY	**WHO**	Director, Global HIV, Hepatitis, STI Programmes
Martina	PENAZZATO	**WHO**	GAPf lead
Nandita	Sughandi	**WHO**	Peadiatric HIV Lead
Françoise	Renaud	**WHO**	
Tiziana	Masini	**WHO**	TB Expert
David Livingstone	Ezekiel	**World Vision International - WVI**	

Michael	Smith	**World Food Programme - WFP**	HIV Advisor
Stefano	Vella		Professor

VIRTUAL PARTICIPATION

Sean	Callahan	**CRS**	President & CEO
Tedros Adhanom	Ghebreyesus	**WHO**	Director General NOTE – VIDEO MESSAGE
Daniela	GARONE	**MSF**	International Medical Coordinator
Ralph	Barx	**EMA**	
Michel	SIDIBE	**African Medicines Agency**	African Union Special Envoy for the African Medicines Agency NOTE – VIDEO MESSAGE
Sweety	Jimmy	**Cipla**	
Tom	McPARTLAND	**The ELMA Philantropies**	CEO
Kerri	Viney	**WHO**	
Anil	Soni	**WHO Foundation**	
Jilian	Sacks	**Roche**	
Mehan	Barathlall	**Roche**	
Linda-Gail	BEKKER	**Desmond Tutu Foundation**	Professor of Medicine and Chief Operating Officer, Desmond Tutu HIV Foundation Director, Desmund Tutu HIV Centre at the University of Cape Town
Henk	den Besten	**Macleods**	
Grania	Bridgen	**The Global Fund**	
Violet	CHIHOTA	**The Aurum Institute**	Chief Specialist Scientist
CHITIMBIRE	VUYELWA TENJIWE	**Zimbabwe Association of Church Related Hospitals (ZACH)**	Executive Director
Hiiti	SILLO	**WHO PQ**	

Marion	LAUMONIER	**WHO PQ**	
Laura	Fregonese	**EMA**	
Roberto	De Lisa	**EMA**	
Emily	Thomson	**EMA**	

ANNEX 12 – LINK TO PRESENTATIONS

https://drive.google.com/drive/folders/1nU2RmK5cHnPYkuVL5Vee7QCqvldCe9SD