

**High-Level Dialogue to Assess Progress on and Intensify Commitment
To Scaling Up Diagnosis and Treatment of
Paediatric HIV and TB in Children Living with HIV**

ROME ACTION PLAN 2020

Introduction

On 5-6 November 2020, His Eminence Peter Cardinal Turkson, Prefect of the Dicastery for the Promotion of Integral Human Development, convened, with the President's Emergency Plan for AIDS Relief (PEPFAR), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), and in collaboration with the Stop TB Partnership and Faith-Based Organizations, the High-Level Dialogue to Assess Progress on and Intensify Commitment to Scaling Up Diagnosis and Treatment of Paediatric HIV and TB in Children Living with HIV (Rome 5).

The purpose of the High-Level Dialogue to Assess Progress on and Intensify Commitment to Scaling Up Diagnosis and Treatment of Paediatric HIV and TB in Children Living with HIV was to identify solutions to bottlenecks in the development, introduction, and scale-up of optimized diagnostics, preventive treatment, and treatment for TB among children living with HIV, as well as further steps to improve access to paediatric HIV diagnostics and optimal ARVs. Participants in the High-Level Dialogue agreed to the following Plan of Action that lays out commitments to be taken by individual organizations or groups of stakeholders to redress the challenges raised during discussions. The commitments are part of a set of "Rome Action Plans" that have been adopted during similar High-Level Dialogues in 2017 and 2018. Commitments from previous Rome Action Plans are still valid for the stakeholders who undertook them until completed. Progress on all Action Plan commitments is monitored through a collaborative accountability mechanism led by the co-organizers of the Dialogues.

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TB TREATMENT

I. Focus on and accelerating research and development of priority TB drugs and formulations for children living with HIV

Stop TB Partnership's Global Drug Facility (STBP/GDF) commits to:

1. Ensure priority formulations are appropriately communicated to suppliers, including in regular meetings with suppliers, GDF tenders, and at GDF's supplier meetings.
2. Include priority formulations in the TB Medicines Dashboard.
3. Identify and implement mechanisms to derisk suppliers who invest in development of child-friendly formulations.
4. Continuously monitor and project demand for pediatric formulations to identify when the market would benefit from additional suppliers.

TB Procurement and Market Shaping Action Team (TPMAT) commits to:

5. Assess proposed formulations against the intended use(s), available research results, and the market to ensure the final formulation will fulfill as many intended uses as possible minimizing market and supply chain barriers to introduction and scale-up.
6. Review the TB Medicines Dashboard and facilitate coordination and alignment across all stakeholders contributing lists and guidance documents to the dashboard.

WHO commits to:

7. Convene technical discussions to provide advice to innovators prior to submission of PSPs/PIPs, communicate technical opinions to SRAs in a timely manner, and provide dosing and ratio recommendations to generics for development of new formulations.
8. Update treatment guidelines in a timely manner to ensure that more effective drugs are recommended for children as soon as pharmacokinetic (PK) and safety data is available.
9. In collaboration with Stop TB Partnership (STBP)/Global Drug Facility (GDF) and the TB Procurement and Market-Shaping Action Team (TPMAT), continue to revise the minimum set of pediatric formulations to guide national procurement and ensure their inclusion in Essential Medicine List for Children (EML-C).
10. As convener of the Paediatric Drug Optimization for TB (PADO TB) process, set the research agenda for product development, update the list of priority products as needed; communicate outcomes to industry and regulators in a timely manner; and ensure inclusion of PADO priority products in the WHO PQ Expression of Interest list as soon as dosing is identified.

IMPAACT and PENTA commit to:

11. Focus research efforts and rapidly disseminate research findings on optimal drugs and regimens as defined by the PADO TB priorities list.
12. Optimize clinical research in line with PADO priorities, including:
 - Use state of the art population PK methods to design and analyze paediatric PK studies allowing for inclusion of clinically relevant factors such as age, weight, formulations, HIV, malnutrition, etc.
 - Complete palatability and acceptability work on new formulations early on in the field, ideally in diverse populations.
 - Ensure coinfecting patients are included to explore drug-drug interactions.
 - Rapid dissemination of findings with WHO and key stakeholders to inform policy, practice, and field guides.
13. Use the following best practices for the design and implementation of research studies:

- Initiate preparation for paediatric studies as soon as a given drug shows promising efficacy and safety in Phase IIa adult studies.
 - Always include adolescents when conducting initial adult efficacy trials, or conduct parallel trials with the goal of providing information to support licensing for adolescents at the same time as adults.
 - In the design of paediatric PK and safety studies, study weight-based dosing and enroll all children above 4 weeks of age concurrently (i.e no age de-escalation), unless a strong rationale exists for not doing so.
 - Assess acceptability and palatability of formulations, including for use in low-resource settings, at early stages of the formulation's development.
14. Develop drug susceptibility testing (DST) and methods in parallel to new molecule development and make pure drug substance available for DST at the same time as the introduction of a new molecule.

GAP-f partners commit to:

15. Provide a platform to coordinate and support work led by key TB stakeholders in order to accelerate investigation, development, introduction and roll out of paediatric TB priority formulations.
16. Promote donor coordination and collaboration to cover the full spectrum of activities required to ensure accelerated research, development, registration, commercialization, roll-out, sustainable access, and appropriate monitoring of paediatric TB priority formulations.
17. When needed, review effectiveness of, identify and facilitate the most suitable incentive for TB priority formulations to be rapidly developed.

GAP-f partners and other researchers commit to:

18. Seek and direct funding to support the additional clinical research required to inform development of priority products.
19. Expand clinical trials site capacity to accelerate enrolment in paediatric TB studies (especially for Drug-Resistant TB) and for operational research

Generics [Lupin, Macleods, Micro Labs, Viartis] commit to:

20. Prioritize the development and commercialization of products on the Global Fund Expert Review Panel (ERP) Expression of Interest (EOI) and the WHO PQ EOI.
21. Develop paediatric formulations in line with the PADO TB, GF ERP EOI and the WHO PQ EOI lists, including:
- Rifapentine 150mg scored dispersible tablet by 2021
 - Linezolid 150mg dispersible tablet by 2021
 - A second supplier of rifampicin/isoniazid/pyrazinamide 75/50/150mg FDC dispersible tablet
 - A second supplier of isoniazid 100mg dispersible tablet
 - A second supplier of ethambutol 100mg dispersible tablet.

Donors commit to:

22. Support, strengthen, and expand clinical and implementation research to inform development, approval and use of paediatric formulations included in the priority list, including early PK modelling and palatability studies.

Sanofi commits to:

23. Continue to support research networks conducting studies to confirm rifapentine dosing in young children, including children living with HIV.

24. Prioritize the development, registration, and commercialization of priority TB products in research and development plans
25. Engage in early and regular consultations with GAP-f and other WHO-convened expert groups on PIP/PSPs
26. Engage with the Medicines Patent Pool to enter into open, voluntary licensing agreements in preference to exclusive licensing agreements.
27. Facilitate technology transfer and knowledge sharing that can promote faster paediatric formulation development by generic companies.
28. Make pediatric formulations and data available to research networks advancing pediatric PK and safety studies.
29. Rapidly submit data to regulatory authorities and the WHO to facilitate updating of labelling and recommendations.
30. Use the following best practices for the design and implementation of research studies:
 - Initiate preparation for paediatric studies as soon as a given drug shows promising efficacy and safety in Phase IIa adult studies.
 - Always include adolescents when conducting initial adult efficacy trials, or conduct parallel trials with the goal of providing information to support licensing for adolescents at the same time as adults.
 - In the design of paediatric PK and safety studies, study weight-based dosing and enroll all children above 4 weeks of age concurrently (i.e no age de-escalation), unless a strong rationale exists for not doing so.
 - Assess acceptability and palatability of formulations, including for use in low-resource settings, at early stages of the formulation's development.
31. Develop drug susceptibility testing (DST) and methods in parallel to new molecule development and make pure drug substance available for DST at the same time as the introduction of a new molecule.

Johnson & Johnson commits to:

32. Ensuring ongoing access to the 20mg bedaquiline tablet, which Johnson & Johnson, in partnership with Stop TB Partnership's GDF Pediatric DR-TB Initiative, has already made available for over 130 countries, following US FDA approval in May 2020.
33. Continue efforts in exploring additional clinical trial sites to ensure timely completion of study investigating the use of bedaquiline in children below 5 years of age.
34. Engage early and regularly with GAP-f and other WHO-convened expert groups on pediatric indication development.
35. Engage with the Medicines Patent Pool and/or generic companies to evaluate licensing agreements for pediatric formulations, where appropriate.
36. Make pediatric formulations and data available to research networks advancing pediatric PK and safety studies, where appropriate under collaborative agreements. Rapidly submit data to regulatory authorities and the WHO to facilitate updating of labelling and recommendations.
37. Use the following best practices for the design and implementation of research studies:
 - Engage with regulators to explore options for pediatric studies as soon as a given drug shows promising efficacy and safety in Phase IIa adult studies.
 - Consider Including adolescents when conducting initial adult efficacy trials or conduct parallel trials with the goal of providing information to support licensing for adolescents at or near the same time as adults, when appropriate from a scientific and ethical perspective and allowed by regulations.
 - In the design of paediatric PK and safety studies, when appropriate from a scientific and ethical perspective and allowed by regulations, consider studying weight-based dosing and enrolling all children above 4 weeks of age concurrently (i.e., no age de-escalation).

- Assess acceptability and palatability of formulations, including for use in low-resource settings, at the earliest appropriate stage of the formulation's development.
38. Support the development of drug susceptibility testing (DST) and methods in parallel to new molecule development and make pure drug substance available for DST at the same time as the introduction of a new molecule.

Otsuka commits to:

39. Ensuring global access to its child-friendly delamanid formulation in collaboration with the Stop TB Partnership's GDF Pediatric DR-TB Initiative, national TB programmes, and other stakeholders.
40. Performing technology transfer for child-friendly delamanid formulations used to treat DR-TB, to be completed shortly after first stringent regulatory authority approval of the formulation.
41. Expedite development and regulatory submission of pediatric versions of new TB compounds already in the Otsuka R&D pipeline, with an aim to have pediatric versions available shortly after regulatory approval of the adult formulation.
42. Prioritize the development, registration, and commercialization of priority TB products in research and development plans.
43. Facilitate technology transfer and knowledge sharing that can promote faster paediatric formulation development by generic companies.
44. Make pediatric formulations and data available to research networks advancing pediatric PK and safety studies.
45. Rapidly submit data to regulatory authorities and the WHO to facilitate updating of labelling and recommendations.
46. Use the following best practices for the design and implementation of research studies:
- Initiate preparation for paediatric studies as soon as a given drug shows promising efficacy and safety in Phase IIa adult studies.
 - Assess acceptability and palatability of formulations, including for use in low-resource settings, at early stages of the formulation's development.
47. Develop drug susceptibility testing (DST) and methods in parallel to new molecule development and make pure drug substance available for DST at the same time as the introduction of a new molecule.

Micro Labs commits to:

48. Finalize the development of child-friendly linezolid for the treatment of drug-resistant TB, with an aim of submitting a dossier to WHO PQ and GF ERP by the 3rd quarter of 2021.
49. Finalize the development of child-friendly ethambutol 100mg for the treatment of drug-sensitive and drug-resistant TB, by finalizing any remaining items with GF ERP in Q1-2021.

Lupin commits to:

50. Finalize the development of 3-medicine pediatric fixed-dose combination product for treatment of drug-sensitive TB, with an aim of submitting dossier to PQ and ERP by July/August 2021.

Viatrix commits to:

51. Develop child-friendly formulation(s) for novel MDR-TB medicines for which Viatrix has the requisite license(s).
52. Provide regular updates on pediatric pretomanid development plans and timelines alongside the TB Alliance.
53. Evaluate pediatric TB formulations that are not being developed by other partners and are identified by WHO and others partners as priorities to determine if there are any which can be developed and supplied by Viatrix.

II. Expedite regulatory review of priority TB drugs and formulations for children

WHO PQ and National Regulatory Authorities commit to:

54. Expand use of the Collaborative Registration Procedure based on PQ or SRA approval to expedite national review of paediatric TB drugs and formulations.
55. Use the Paediatric Regulatory Network for advocacy of use of the Collaborative Registration Procedure and to explore models of regulatory reliance to promote equitable access to paediatric TB formulations.

National Regulatory Authorities commit to:

56. Expedite and simplify the review of priority paediatric formulations including by:
 - Making better use of sub-regional collaborative regulatory approval processes and the WHO Collaborative Registration Procedure for accelerated registration;
 - Increasing reliance on evaluations and opinions of SRAs and the WHO PQ programme.
57. End requirements for local clinical trials when sufficient PK and safety data exists, even when no equivalent innovator product exists.
58. Minimize/remove country-specific packaging and labelling requirements for paediatric formulations.

WHO PQ commits to:

59. Prioritize PQ review of key TB drugs for children, for example Rifapentine dispersible single tablets and Bedaquiline dispersible single tablets.

SAHPRA commits to:

60. Continue to apply priority review of all TB drugs in alignment with the national strategy
61. Conduct priority review for priority TB paediatric medicines (as defined in the TB PADO List).
62. Use reliance approaches and collaborative regulatory review processes, including WHO Prequalification and “Zazibona,” a sub-regional collaborative platform that allows joint review to expedite the review of TB drugs.

The European Medicines Agency (EMA) agrees to:

63. Continue the review of Paediatric Investigation Plans (PIPs) specifically taking into account the following points, always bearing in mind that PIPs are evaluated on a scientific case-by-case basis:
 - Paediatric formulation development must be considered in an integrated way right from the beginning of the planning process together with the whole paediatric drug development after completion of phase 1 studies in adults, taking into account dose finding and clinical studies.
 - Adolescents should be included in adult trials or adolescent trials should be conducted in parallel with adults unless scientifically justified.
 - Studies of medicines across the paediatric spectrum of ages/weights should be conducted in parallel rather than in serial age-staggered approach, taking into account for example the pharmacological characteristics of the particular medicinal product, e.g. specific safety or drug disposition factors which may warrant a different approach.
 - PIPs for new TB medicines should consider including systematically children with HIV and other common co-infections found in children affected by TB, taking into account safety or drug-drug interaction issues.
64. Provide guidance about when clinical trials for efficacy have to be done in children and when extrapolation of efficacy based on PK is sufficient.
65. For planned regulatory submissions to provide guidance on pathways for paediatric drug development programmes without reference products and/or TB indication in adults.

66. Continue to work with other non-EU regulatory authorities and WHO to foster alignment on development programmes for TB in children.
67. Identify specific mechanisms as defined by the legal framework to facilitate access to WHO Prequalified paediatric TB formulations in their countries/regions through specific mechanisms as defined by the legal framework.
68. Continue to offer the opportunity to target countries to participate as observers in the EMA evaluation.

The US Food and Drug Administration (USFDA) commits to:

69. Observing the following principles in its regulatory review process:
 - Extrapolating efficacy from adults to children is acceptable for most children with TB. Extrapolation of adult efficacy to paediatric populations for the treatment of pulmonary TB may be appropriate for most paediatric populations, other than the very young as they can have different clinical and pathophysiologic characteristics. Pharmacokinetic (PK) and safety information in paediatric patients will be needed to support the appropriate dose for treatment of children.
 - Adolescents with pulmonary TB can be included in phase 3 clinical trials, if appropriate.
 - Paediatric patients can be enrolled in trials if sufficient safety and antimycobacterial activity data in adults are available and appropriate dosing regimens have been characterized.
 - Studies of drugs across the paediatric spectrum of ages/weights can be conducted in parallel rather than sequentially unless there is a specific safety or pharmacokinetic properties that warrants a different approach.
 - Paediatric development plans for new TB medicines could include children living with HIV and other common co-infections provided there are no safety or drug-drug interaction issues.
 - Cohorts for paediatric studies can be defined based on chronological age or weight-based criteria, particularly for oral drugs.
 - Paediatric formulation development should begin soon after adult Phase 2-b trials and dose selection.
70. Continue to work with other regulatory authorities to seek alignment on development of products for TB in children.
71. Continuing engagement on development of products and age appropriate formulations for treatment of TB in children

Stop TB/GDF commits to:

72. Lead the external review of the Global Fund's Expert Review Panel Expression of Interest (GF ERP EOI) through TPMAT and suggest prioritization of formulations for expedited review.
73. Monitor the development pipeline and work with the Global Fund to expedite access to new formulations and medicines.
74. Develop a strategy/roadmap for countries on TB paediatric drug registration that is linked to procurements and procurement goals.

Sanofi commits to:

75. Explore regulatory options to allow access to TB paediatric formulations in other regions and countries currently without access (e.g. EU, US, Canada, Australia etc.).
76. Consider the use of the CRP for national registration of paediatric TB products.
77. 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.
78. Consider facilitating existing joint assessment procedures by planning the submission in different countries/regions to allow for joint assessment in existing networks.

79. Provide multilingual Patient Information Leaflets or Instructions for Use to facilitate appropriate use by Healthcare workers and caregivers
80. Register new TB paediatric products quickly in countries where registration is required and import waivers cannot be granted for procurement (regardless of source of funding)

Otsuka commits to:

81. Explore regulatory options to allow access to TB paediatric formulations in other regions and countries currently without access (e.g. EU, US, Canada, Australia etc.).
82. Consider the use of the CRP for national registration of paediatric TB products.
83. 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.
84. Consider facilitating existing joint assessment procedures by planning the submission in different countries/regions to allow for joint assessment in existing networks.
85. Provide multilingual Patient Information Leaflets or Instructions for Use to facilitate appropriate use by Healthcare workers and caregivers
86. Register new TB paediatric products quickly in countries where registration is required and import waivers cannot be granted for procurement (regardless of source of funding)

Johnson & Johnson commits to:

87. Consider the use of the CRP for national registration of paediatric TB products.
88. 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.
89. Consider facilitating existing joint assessment procedures by planning the submission in different countries/regions to allow for joint assessment in existing networks.
90. Provide multilingual Patient Information Leaflets or Instructions for Use to facilitate appropriate use by Healthcare workers and caregivers
91. Consider prioritizing registration submission of new TB pediatric products in high burden countries where import waivers cannot be granted.

III. Introduction, Uptake and Procurement

Ministries of Health commit to:

92. Accelerate transition to more optimal regimens and formulations as described in WHO Guidelines by:
 - Adopting and implementing new WHO TB guidelines relevant for children within one year of their release
 - Revising national procurement plans to align with WHO recommended regimens and the EML-C
 - Scaling-up use of dispersible fixed-dose combinations and single drug formulations for drug-sensitive and drug-resistant TB (including rifampicin + isoniazid + pyrazinamide [RHZ] and rifampicin + isoniazid [RH], INH dispersible single, ethambutol dispersible single and child-friendly second-line formulations)
 - Supporting the provision of shorter TB Prevention Treatment regimens for children when these regimens have appropriate data and are available in child-friendly formulations (i.e., 3RH, 3HP, 1 HP)
 - Strengthening reporting and recording systems for TB infection, contact tracing and provision and completion of TPT for children
 - Strengthening PSM systems for TPT medicines.

93. Prioritize funding for paediatric TB prevention, diagnosis (including DST), and treatment in national budgets and requests to donors, including to provide these services free of charge and to support improved models of care for children and for training of HCWs.
94. Create a plan of action to reduce stigma and discrimination in health care systems and communities and support civil society and community generated initiatives focused on pediatric TB.
95. Collect data on TB-HIV co-infection and TB treatment outcomes in children living with HIV.

Generic companies commit to:

96. Manufacture paediatric products at a scale that aligns with market demand as provided by GDF.
97. Ensure new products are available for supply at time of approval or prequalification, including validation of manufacturing process during regulatory review.

Unitaid commits to:

98. Supporting the TB treatment agenda through our grants (TB Speed – Université de Bordeaux, Cap-TB – EGPAF, Benefit Kids – Stellenbosch University, IMPAACT4TB – Aurum Institute, and WHO).
99. Identify and establish effective collaboration and funding support to advance the application of new technologies for delivery of improved paediatric formulations for TB treatment for susceptible and resistant TB.
100. Promote integration of different services to increase detection and treatment of children with TB.
101. Continue to support, with WHO and partners, the introduction of optimal paediatric formulations for treatment, and also preventive treatment (3RH and 3HP).

Global Fund commits to:

102. When negotiating grants, encourage countries to address health product management and domestic procurement challenges that may negatively affect the procurement of quality, affordable health products, including the procurement of small volume or small market products, such as pediatric DS and DRTB drugs.
103. Continue to use a flexible approach in the implementation of the co-financing policy, particularly related to small volume, small market products that might be more challenging to procure effectively via domestic procurement.
104. With partners, support and encourage countries to adequately prepare to procure small volume, small market products as they increase their role in domestic procurement and encourage the use of international pooled procurement platforms. In alignment with recommendations from the United Nations High Level Meeting on Tuberculosis in 2018, encourage the use of STBP/GDF when countries are unable to efficiently procure such products directly from suppliers.

Stop TB Partnership (STBP)/Global Drug Facility (GDF) commits to:

105. Lead the TB Procurement and Market-Shaping Action Team (TPMAT) to coordinate global TB stakeholders and develop implementation roadmaps for new formulations.
106. Work to build, stabilize and maintain access to small-volume products including child-friendly formulations for drug-resistant TB.
107. Continue to use the Launchpad Approach to support the introduction and scale-up of paediatric formulations in programmes.

All GAP-f partners commit to:

108. Lead efforts to facilitate and strengthen collaboration among relevant stakeholders to ensure the most efficient development and uptake of optimal paediatric TB drug formulations and regimens, in close consultation with the community of people living with and at risk of TB

EGPAF commits to:

109. Through its Unitaid-funded project CAP-TB, improve pediatric TB care, finding more children, and putting them in treatment, including improving the increased access and use of TB preventive Treatment in the high risk population of child contacts < 5 and CLHIV.

KNCV commits to:

110. Work with country stakeholders to develop a platform and mechanism to ensure all commitments turn into action
111. Support countries to develop national strategic plans and Global Fund concept notes that are data driven and addressing the needs of children in the entire patient pathway.
112. Collaborate and coordinate with in-country professional and regulatory bodies to ensure countries are prepared for early uptake of new innovations/medicines and develop a plan for scale up.
113. Produce high quality documentation of our best practices and evidence to share at global platforms to guide global policies and guidelines.
114. Engage with civil society to create sense of urgency at country level to ensure all children needs related to TB/HIV are implemented
115. Support countries in scaling up the stool test with GeneXpert for TB diagnosis in children including development of generic SOP's and training materials.

The Union commits to:

116. Continue to support countries to prioritize the identification, diagnosis, and scale-up of TB preventive treatment, including children living with HIV, including 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
117. Support the scale-up of access to priority formulations and diagnostics and to take steps to facilitate their wider roll-out including by performing operational research via The Union's Centre of Operational research, 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.
118. 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; to urge governments to ensure that all children have access to the latest formulations and models of care for TB prevention and care; and to work together to reduce stigma and discrimination that stops children from accessing care that they need.

Implementing Partners and Faith-Based Organizations commit to:

119. Advocate for and support Ministries of Health to rapidly transition to optimal paediatric formulations as outlined by the latest WHO guidelines, provide coordinated support for the development and implementation of transition plans, inform clinicians and patients of the value of transitioning to new formulations, and ensure communication of reliable information on the availability of new formulations in-country.
120. Support the scale up of access to priority formulations and diagnostics and take steps to facilitate their wider roll-out, including by performing operational research, developing introductory guidance and education, materials, and other tools for health facilities and local community health structures.
121. Promote the revision of national procurement plans to align with WHO recommended regimens and the EML-C, and support the provision of reliable forecasts and the consolidation of orders.

Networks of persons living with or affected by TB, Implementing Partners, and Faith-Based Organizations commit to:

122. Mobilize their networks and work with communities to help build treatment literacy, generate demand, and expand access to TB diagnosis and treatment among children in close collaboration with other stakeholders.
123. Raise awareness in local, national, and global fora about the unmet diagnostic and treatment and prevention needs of children with or at risk for TB.
124. Foster and more actively participate in coordinated and collaborative advocacy to:
 - Increase funding for TB research & development, introduction and scale-up of priority paediatric drugs and formulations;
 - Accelerate regulatory processes for rapid adoption and uptake of optimal paediatric TB drugs and formulations; and
 - Ensure sustainable access to optimal TB testing and treatment for infants and children.
125. Tackle the TB stigma and discrimination in communities, schools, and healthcare settings that prevent children and adolescents living with TB or at risk of TB from accessing testing and treatment, including promotion of awareness of the difference between infection and disease and include messages of hope regarding treatment of both HIV and TB.
126. Promote uptake by mobilizing their networks of hospitals and community structures to distribute paediatric medicines in hard to reach places and in situations of conflict and crisis.

Faith Based Organizations commit to:

127. Support and increase TB treatment initiation and retention for children, adolescents, and families by:
 - Identifying all TB-exposed children and connecting them to treatment and preventive TB treatment through FBO clinics and within communities of faith;
 - Reducing TB stigma and discrimination through mobilization and evidence-based education and training of faith leaders and faith communities

WHO, UNICEF, and UNAIDS commit to:

128. Support countries to collect and report data on TB-HIV co-infection and TB treatment initiation and outcomes in children living with HIV.

UNICEF commits to:

129. Advocate for increased pediatric TB case-finding and access to child-friendly treatment as a core member of the TB Child and Adolescent Working Group and the TB PADO.
130. Support national governments to optimize the integration of TB with child health, HIV, and nutrition services.

HIV TREATMENT

I. Focus on and accelerate research and development of priority ARV drugs and formulations for children living with HIV

WHO commits to:

1. Undertake and launch appropriate update of WHO consolidated guidelines in Q1/2 2021 to reflect approval of new formulations, including dosing recommendations as endorsed by PAWG.
2. Convene PADO5 in Q2 2021 and, in collaboration with GAP-f members, ensure rapid dissemination of its outcomes
3. Follow generation of ongoing research and consider revision of 2nd and 3rd line recommendations, as needed, by the end of 2021.

GAP-f partners commit to:

4. Facilitate revision of the 2018 Pediatric ARV Optimal Formulary and Limited-use List for submission to the 2021 WHO EML for Children edition.
5. With the support of Unitaid, CHAI will partner with Janssen and generic manufacturers to develop and register DRV/r 120/20 mg.
6. With the support of EDCTP, PENTA will partner with Gilead and CHAI to implement the UNIVERSAL project to inform development and use of DRVr FDC and TAF-containing FDC as prioritized by PADO.
7. CHAI, with support of Unitaid, will collaborate with PENTA and Gilead to advance the development of generic versions of TAF-containing paediatric formulations.
8. Enhance collaboration and facilitate knowledge-sharing to promote development of new technologies to enhance effectiveness and acceptability of paediatric medicines.

CHAI commits to:

9. Advance the field of research in collaboration with Monell, MMV, and donors to identify a universal bitter blocker that can be used in pediatric formulations to improve palatability.

DNDi commits to:

10. Set up a clinical study to determine in young children co-infected with HIV and TB to determine if dose adjustments are needed when the 4-in-1 is used with a rifampicin-containing regimen.
11. Facilitate a clinical study to determine safe and efficacious dosage of the 4-in-1 in neonates.

IMPAACT commits to:

12. A scientific agenda that focuses on PADO priorities and to undertake studies employing best practices to rapidly determine safety and dosing for new agents for infants, children, and adolescents.
13. Determine dosing and safety of DTG in newborns as well as in pediatric specific fixed dose combinations.
14. Determine safety, dosing, and acceptability of long-acting injectable ART with cabotegravir and rilpivirine in adolescents and children.
15. Accelerate work on its commitments despite the challenges posed by the COVID pandemic to ensure that optimal products are available to this vulnerable without added delay.

Unitaid commits to:

16. Continue supporting the paediatric agenda as per the Plan of Action through the grants with different partners (including, for year 2021, CHAI, EGPAF, Medicines Patent Pool, Research-

institutions such as University of Liverpool or Stellenbosch, WHO's Prequalification Program and WHO HIV/Hepatitis/STIs department).

17. Identify and establish effective collaboration and funding support to advance the application of new technologies for delivery of improved pediatric formulations.
18. Support GAP-f partners' plan for the accelerated introduction and rollout of the generic DTG 10mg dispersible tablet formulation in 13 priority countries.
19. Provide funding for the development, regulatory review, and accelerated introduction of generic formulations of a TAF-containing pediatric FDC, in collaboration with Gilead, and advance on the work on DRV/r f and ALD pediatric formulation.

Cipla commits to:

20. Develop ALD pediatric formulation by end of 2021.

Gilead commits to:

21. Using feedback from the Vatican platform to leverage best practices and make earlier changes to development plans.
22. Sharing clinical development and regulatory plans, as well as enabling generic formulations of a TAF containing pediatric fixed-dose combinations, with submission of a formulation for low-dose f/TAF with unboosted third agents for children over 2 years (14-25kg) by end 2020 and continuing to develop a formulation for 3-25kg older than 4 weeks children.
23. Fulfilling ongoing PSPs and PIPs for capsid inhibitors with collaboration and feedback from the GAP-f partners.
24. Advancing discussions with CHAI and Monell to identify a universal bitter blocker appropriate for pediatric formulations.

MSD commits to:

25. Explore collaborations with GAP-f partners to accelerate the generation of evidence on child-friendly formulations of DOR and ISL, using weight bands and with concurrent testing of age groups making use of GAP-f input on PSPs and PIPs.

Johnson & Johnson commits to:

26. Ensure innovation to improve the health of children by supporting CHAI and PENTA in their commitment to accelerate development, registration and catalytic launch of DRV/r 120/20 mg optimal pediatric fixed dose combination and provide DRV API from 2021-23.
27. Support approaches that track access to pediatric patients and to continued transparency around its HIV & TB pediatric work.
28. Enhance collaboration and facilitate knowledge-sharing to promote development of new technologies to enhance effectiveness and acceptability of paediatric medicines, including long-acting injectables for infants and adolescents (Rilpivirine).

ViiV commits to:

29. Support and facilitate long-term follow up in the ODYSSEY trial, including long-term safety profile data.
30. Support the Impaact P2019 study to evaluate ABC/3TC/DTG for children under 12 years including new dispersible tablet formulation.
31. With CHAI and Unitaid, expedite development of a dispersible fixed dose combination of pediatric ABC/3TC/DTG with Aurobindo and Viatrix.
32. Supporting rapid product introduction and broad access post-registration for both originator and generic versions of dispersible paediatric DTG.

The Access to Medicine Foundation commits to:

33. Include paediatric R&D and product deployment research and analysis in the next Access to Medicine Index, highlighting critical paediatric treatment R&D issues and actions pharmaceutical companies are taking to address those, by January 2021.
34. Explore additional methods of including paediatric access issues in the following editions of the Access to Medicine Index and to do so as part of the next Access to Medicine Index Methodology review process, by December 2021.

II. Expedite regulatory review of priority ARVs and formulations for children

WHO PQ commits to:

35. Conduct priority review and facilitate national registration of Lopinavir/Ritonavir 4-in-1 solid formulations and Dolutegravir 5mg and 10mg dispersible tablet formulations.

SAHPRA commits to:

36. Continue to apply priority review of all HIV therapies in alignment to the national strategy of accelerated access.
37. Conduct priority review for priority HIV paediatric medicines (as defined in the PADO List), for example for paediatric DTG formulations.

EMA and WHO commit to:

38. Continue to include target countries NRAs as observers in the EMA assessment procedure for new paediatric ARVs.

USFDA commits to:

39. Continue supporting the pediatric HIV priority ARV drugs research and development agenda, as outlined in Rome Action Plan.

ViiV commits to:

40. Through novel collaborative approaches, enable marketing authorisation applications in target NRA countries (Botswana, Malawi, Namibia and Zimbabwe) in parallel to the EMA assessment to accelerate national registration of DTG 5mg dispersible tablets
41. Utilise the WHO CRP process in other African countries to enable quickest possible registration of DTG 5mg dispersible tablets.

III. Introduction, Uptake, Procurement and Monitoring

WHO commits to:

42. Work with GAP-f partners to implement a coordinated plan to provide technical assistance in support of DTG and 4in1 introduction to ensure rapid policy update and effective uptake in the 21 AIDS FREE priority countries.

Pharmaceutical companies, donors, and GAP-f partners commit to:

43. Through PENTA and IAS CIPHER, work together to develop an enhanced monitoring and safety data platform for new and existing paediatric ARV drugs.
44. Convene or participate in a series of virtual consultations of key stakeholders in 2020-2021 to develop a model and mobilize resources for the platform.

Johnson & Johnson commits to:

45. In collaboration with EGPAF and other key partners, broaden the impact of the New Horizons Advancing Pediatric HIV Care Collaborative (NHC). The NHC currently provides support to its participating countries with health systems strengthening and access to Darunavir (DRV) & Etravirine (ETR) through donations (from Johnson & Johnson subsidiary Janssen Products LP). Starting in 2021, these two pillars of the program will be enhanced through further expansion of technical assistance in identifying and managing HIV treatment failure in children and adolescents, capacity building, evidence generation, supply chain management, and support for harmonized TB co-infection screening. Johnson & Johnson and the NHC team commit to seek additional stakeholders to support the expansion of these critical initiatives.
46. Continue to work with PEPFAR on catalytic procurement of DRV 75mg for children in the developing world.

Generic companies commit to:

47. Rapidly scale up the manufacture of new PADO priority pediatric ARV products (4-in-1 and DTG 10mg dispersible tablets) at a scale that will fully meet market demand as forecast by GAP-f partners and procurement agencies within 6 months of approval.

ARV manufacturers commit to:

48. Guarantee transparency on current and anticipated capacity of all generic formulations listed in the optimal formulary and limited use list as well as notification to APWG within one week of all anticipated supply disruptions.

GAP-f partners commit to:

49. Work with MOHs to coordinate accelerated introduction and rollout of the DTG 10mg dispersible tablet formulation in the context of broader optimization efforts and strategic sequencing of improved pediatric products

Unitaid commits to:

50. Support stakeholders involved in accelerated introduction and rollout of the 4-in-1 formulation as an alternative regimen for young children in priority countries.
51. Continue to support, with WHO and partners, the introduction of optimal ARV formulations, the roll out of a pediatric Advanced HIV DISEASE (AHD) package of care – including associated treatment literacy and training, and enhanced monitoring & safety data platform for new and existing paediatric ARV drugs.

PEPFAR commits to:

52. Support DTG global roll-out plan in collaboration with GAP-f partners by placing orders to enable early procurement of the DTG 10mg dispersible tablet formulation to ensure early and widespread roll-out .
53. Provide additional support for country programs to transition, including wastage of legacy products (e.g., NNRTIs) and funds to procure optimal formulations including pediatric DTG, and as needed, LPV/r formulations.

Global Fund commits to:

54. Support GAP-f partners' plan for the accelerated introduction and rollout of the DTG 10mg dispersible tablet formulation in priority countries to ensure early and wide uptake.
55. Support stakeholders involved in accelerated introduction and rollout of the 4-in-1 formulation as an alternative regimen for young children.

CHAI and EGPAF commit to:

56. Through the Unitaid Optimal grant, accelerating access to optimal pediatric ARVs for children, including DTG 10 mg dispersible tablets, across focal countries.

CHAI commits to:

57. With the support of Unitaid, support catalytic procurement of generic DTG 10 mg dispersible tablets across several focal countries to rapidly bring this optimal product to children by late Q1 2021.

DNDi, EGPAF, ICAP and EVA commit to

58. Support MOHs to accelerate the introduction and roll out of optimized formulations in at least 6 countries: Kenya, Uganda, Tanzania, Senegal, Burkina Faso and Cameroon.

EGPAF commits to:

59. Support health system strengthening and access to DRV and ETR as part of the New Horizons Advancing Pediatric HIV Care Collaborative (NHC) supported by J&J. This will be achieved through technical assistance in identifying and managing HIV treatment failure in children and adolescents, capacity building, evidence generation, supply chain management, and support for harmonized TB co-infection screening.

ICAP commits to:

60. Collaboratively scale-up optimal pediatric antiretroviral multi-month dispensing and to contribute to the development tools, materials, and guidance to enhance home-based case management and support for ART.
61. Support select countries to rapidly complete the transition to currently available optimal pediatric ARVs (LPV/r and DTG 50 mg) and accelerate the scale-up of new pediatric ARV formulations as they become available in country.
62. Continue the collaboration with DNDi, EGPAF and EVA to develop resources for the introduction of the 4-in-1 including trainings, webinars and country specific technical assistance.

DNDi and Cipla commit to:

63. Work with ARV Procurement Working Group to ensure coordination of demand and supply of 4-in-1 and LPV/r pellets.

Cipla commits to:

64. Once 4-in-1 is approved by FDA, ensure it is widely available and rapidly scale up production.
65. Move towards 4-in-1 at \$15 per pack of 120's.

Viatris commits to:

66. Coordinate with APWG to ensure LPVr pellets and granules are not scaled down prematurely based on APWG forecasts.
67. Supplying 100,000 packs of DTG 10mg dispersible tablets in Q1 2021 to support catalytic procurement by CHAI and Unitaid.

UNICEF commits to:

68. Expand the demand for optimal paediatric ARVs in Western and Central Africa, increasing coverage of ART from 24% to 30% by adding 3,000 children on treatment by end of 2021 through enhanced case identification of children and expanded provider capacity.

69. Through dialogue and negotiation with manufacturers to implement flat pricing for pediatric drugs and to issue voluntary licenses or commitment to non-enforcement of patents with respect to pediatric ARVs.
70. Support national governments to implement targeted and differentiated services deliveries for children and adolescents anchored in continuous quality improvement through the rollout of the service delivery framework.

Faith Based Organizations commit to:

71. Equip, mobilize, and support faith leaders, FBOs, people in places of worship, and the wider community to create awareness of the importance of HIV testing of infants and children of people living with HIV. Demand that national school curricula include scientifically appropriate information on HIV prevention, testing and treatment.
72. Combat stigma and discrimination among faith leaders and within communities of faith around HIV prevention, testing and treatment. Create demand for client-centered and stigma-free care within health facilities as well as access to community-based treatment.
73. Further collaborate and coordinate community mobilization, education and outreach to find otherwise hard-to-reach children, adolescents, youth and adults for age appropriate prevention education, testing, and linkage to and continuity of treatment, health, psycho-social and spiritual support services and integrate into the national system.

TB DIAGNOSTICS

National governments, with support from implementing partners and FBOs, commit to:

1. Adopt and implement WHO TB guidelines as relevant for infants and children in case-finding, screening, and testing.
2. Scale up available, appropriate, timely, quality assured pediatric TB diagnostics, using comprehensive diagnostic network mapping and optimized use of all diagnostic resources to maximise paediatric case detection.
3. Ensure follow-up, screening and appropriate care for children who are a household contact of a person living with TB, and that pediatric case-finding is prioritized.
4. Implement rapid molecular assays for detection of TB in infants and children, including use of stool and other non-sputum specimens endorsed by WHO.
5. Implement the TB-LAM assay and/or similar urine-based lateral flow assays for routine use in both TB and HIV national programs in line with the latest WHO recommendations to support identification of TB in all HIV-infected infants and children.
6. Incorporate costed and budgeted requests for interventions for pediatric TB diagnosis, including procurement, training, and case-finding interventions, into Global Fund and PEPFAR requests.
7. Optimize infant and children case-finding approaches to ensure increased and equitable access to screening and testing as well as linkage to treatment, including preventive treatment.
8. Work with researchers and relevant experts to develop pediatric specimen banks/repositories to support faster studies of new TB diagnostics and ensure open access to academic groups and manufacturers.
9. Work with national regulatory authorities to register diagnostic assays and streamline procedures while ensuring the use of WHO approved products when considering national regulatory approval.
10. Support sharing of available diagnostic platforms and associated networks across programs to attain wider access to testing, for more optimal utilization of available platforms, more efficient systems, and improved sustainability.

11. Remove barriers to accessing screening and preventive treatment for healthy children who are exposed to TB (e.g. provide transport vouchers, home-based screening and treatment, etc.).

Ministries of Health and other partners commit to work with National regulatory authorities to:

12. Support optimal access and supply to TB diagnostics through efficient registration of WHO recommended diagnostics and not taxing public goods.
13. Implement pre-qualification assessments of TB in vitro diagnostics to assess quality, safety and performance of specific products, as a quality assurance mechanism complementing WHO policy recommendations.
14. Streamline national regulatory approval of TB diagnostic products that have been assessed according to stringent standards for quality, safety and performance.
15. Develop and implement post market surveillance of diagnostic products.

Donors commit to:

16. Support the development of a competitive, healthy, and sustainable market for point-of-care and laboratory-based testing for TB infection and disease as well as digital x-ray technologies.
17. Consider increasing investments in diagnostic research and development, case-finding, and scale-up of product procurement in high TB burden countries.
18. Support country level roll-out of new tools for pediatric TB detection, including testing of nasopharyngeal aspirates, stool, urine, and other non-sputum specimens.
19. Consider support to build evidence base for product development, evaluation, and WHO guidance.
20. Add paediatric-specific diagnostics and associated specimen collection devices/consumables to available diagnostics catalogues.
21. Include TB-LAM and other urine-based lateral flow assays in procurement considerations in all countries but especially for high HIV burden countries.
22. Support the development of pediatric X-ray libraries to facilitate the development of machine learning algorithms for the interpretation of pediatric chest X-rays.
23. Support more coordinated diagnostic network strengthening and optimization exercises, led by national governments, across diseases (TB and HIV as well as other key diagnostics).
24. Support the development of biomarker-based tests for infants and children, as well as tests and/or testing procedures that use alternative (non-sputum-based) specimens.
25. Facilitate appropriate budgeting and access to quality-assured TB diagnostics at affordable prices and ensure a sustainable market and supplier accountability.

WHO commits to:

26. Provide guidance to manufacturers, donors, and other stakeholders on the diagnostic approval processes to ensure a consistent baseline level of evidence for WHO-convened expert reviews.
27. With appropriate evidence, prioritize the timely review of additional urine-based lateral flow assays, molecular technologies (both point-of care and laboratory-based), alternative (non-sputum-based) specimen types, and novel testing approaches to provide better tools for pediatric TB detection and encourage and introduce market competition.
28. Support national regulatory bodies to develop or leverage regulatory procedures based on WHO assessments.
29. Develop more simplified pediatric case-finding algorithms and implementation guidance for collecting, processing and testing various non-sputum specimens, in collaboration with the Global Laboratory Initiative and Child and Adolescent TB Working Group.
30. Generate target product profiles for diagnostic assays needed for children.
31. Consider clinical scoring and symptom-based diagnostic algorithms while awaiting bacteriologic confirmation.

Diagnostic manufacturers commit to:

32. Prioritize the pediatric TB diagnostic space to ensure there are improved tools for pediatric TB infection and disease detection to reach and maintain targets.
33. Develop quality-assured, affordable, less invasive alternative specimen processing methods or products (not based only on sputum) that can be used for the pediatric population, such as urine, stool or saliva.
34. Ensure diagnostic studies include children and alternative (non-sputum-based) sample types.
35. Expedite development of point-of-care biomarker-based tests for infants and children.
36. Consider moving from separate instrument, consumable, and service procurement towards more consolidated, all-inclusive pricing models, for both laboratory-based and point-of-care technologies.
37. Provide service level agreements that clearly spell out key performance indicators for all technology types and their offered service plans, plus a mitigation plan when the threshold is exceeded.

Faith Based Organizations commit to:

38. Support and participate in national efforts to improve and integrate the use and impact of pediatric diagnostics for TB and HIV and develop national strategies to optimize the use of new technologies and interventions.

All partners commit to:

39. Support rational and coordinated integration, network optimization and scale up of point of care molecular and TB-LAM technologies within diagnostic networks for timely identification and monitoring of infants and children with TB and HIV.
40. Develop pediatric sample banks/repositories to support faster studies of new TB diagnostics and ensure open access to academic groups and manufacturers.
41. Train skilled and confident health workers at all levels to execute recommended screening and testing approaches and algorithms and promote the capacity of community health workers or other community cadres to conduct household contact tracing, screening of identified paediatric contacts of TB index cases, counselling, initiation of TB preventive treatment (if permitted by national guidelines), and monitoring of treatment adherence.

Academic groups commit to:

42. Incorporate the development of pediatric specimen banks/repositories into studies to support faster clinical trials of new TB diagnostics and ensure open access to academic groups and manufacturers.
43. Support pediatric sample repositories, including non-sputum less invasive samples, for more expeditious technical evaluations of new diagnostics and regulatory approval processes.
44. Incorporate the development of pediatric chest X-ray image libraries into studies to develop and support improved machine learning algorithms for computer-assisted X-ray interpretation and ensure open access to other research groups and manufacturers.

Global Fund commits to:

45. Support countries' TB case finding strategies that address children and country-level uptake and scaling up of new tools for TB diagnosis in children, as per international guidance.
46. Support more coordinated diagnostic network strengthening and optimization exercises, led by national governments, across diseases (TB and HIV as well as other key diagnostics).

Unitaid commits to:

47. Supporting the TB diagnostic agenda through our grants (TB Speed – Université de Bordeaux and all consortium members and target countries, Seq&Treat – FIND, and WHO).
48. Identify and establish effective collaboration and funding support to advance the application of new technologies for delivery of improved paediatric diagnosis, using other samples than sputum, such as stools and nasopharyngeal aspirate.
49. Promote integration of different services to increase detection and treatment of children with TB.

EGPAF commits to:

50. Through its Unitaaid-funded project CAP-TB, improve pediatric TB care, finding more children with latent or active TB, and putting them on appropriate treatment. This includes improving the increased access and use of TB preventive Treatment in the high-risk population of child contacts <5 and CLHIV.

Abbott commits to:

51. Develop a new, more sensitive lateral flow TB LAM RDT with a broader indication for use including in TB without HIV co-infection in both adults and children.
52. Offer access pricing for TB testing for laboratory-based, high-throughput devices to complement decentralized testing, which will include pursuing WHO PQ (when relevant for TB) as well as the WHO guidance and recommendation process.

Cepheid commits to:

53. Support further decentralization of testing through release of the GeneXpert Omni technology in 2021 in a limited set of countries; broader market release in 2022.
54. Continue development of a blood-based assay for TB.
55. Continue the work on the stool sample validation with FIND for MTB/RIF assay with an estimated launch in 2021.

FujiFilm commits to:

56. Accelerate introduction of the SILVAMP TB LAM test in limited-resource settings through technology transfer to a new manufacturing site that can allow for transparent, lower, and fair pricing in line with affordable pricing of TB diagnostics and ensure capacity of the manufacturing site can support potential volumes.
57. Accelerate performance study for assay in HIV-positive and HIV-negative pediatric populations.
58. Offer access pricing and prospective reductions based on global volume thresholds; publish the volumes procured quarterly.
59. Prepare a roadmap towards WHO endorsement/prequalification.

Hain commits to:

60. Prioritize attainment of WHO recommendation of the FluoroType MTBDR assay.
61. Prioritize obtaining waivers for GenoType and FluoroType assay technologies for countries under US embargo.
62. Offer access pricing and prospective reductions based on global volume thresholds; publish the volumes procured quarterly.
63. Consider introduction of a diagnostic connectivity solution that is API-capable for automatic reporting of line probe assay test results to users and other information management systems.

Hologic commits to:

64. Prioritize the development of a TB assay for the Aptima technology.
65. Incorporate a future TB assay into the all-inclusive, transparent price of \$12 across molecular assays.

Molbio commits to:

66. Prioritize regulatory approvals where required for introduction of Truenat TB tests in additional high TB burden countries.
67. Share a plan for service and other forms of technical support in international settings with international partners for comment and transparent review/ implementation.
68. Proactively define standardized Key Performance Indicators for system and test performance.
69. Prioritize the regulatory processes of HIV assays for infant diagnosis and viral load.
70. Offer access pricing and prospective reductions based on global volume thresholds; publish the volumes procured quarterly.
71. Prioritise the development of resistance markers for TB as well as multiple sample types and to work on a TB +COVID test.

Roche commits to:

72. Prioritize attainment of WHO endorsement/prequalification of the Cobas MTB assays.
73. Investigate expanding HIV platforms to use MTB assays.
74. Offer access pricing and prospective reductions based on global volume thresholds.

Manufacturers of Chest X-ray (digital x-ray: FujiFilm, Philipps, Delft, MinXray...) commit to:

75. Ensure the price of devices and comprehensive service and maintenance contracts are defined, transparent, consistent and in place across partners and countries.
76. Early engagement with international and national regulatory and guidance stakeholders to clarify and optimize regulatory processes for digital x-ray and imaging.
77. For manufacturers that offer software for the computer-assisted detection of TB using artificial intelligence, ensure the software is capable of analyzing images from children and adolescents.

HIV DIAGNOSTICS COMMITMENTS

The Ministry of Health of Zimbabwe commits to:

1. Continue funding Early Infant Diagnosis and viral load testing through point-of-care machines.
2. Expand access to urine-based LF-LAM assays for infants and children living with HIV.

PEPFAR commits to:

3. Ensure all children of parents living with HIV are offered HIV testing services in collaboration with implementing partners and faith-based partners.

WHO commits to:

4. Maintain and scale-up a sustainable and affordable collaborative registration procedure for diagnostics and support national regulatory bodies to make use of it to streamline their national regulatory procedures.
5. Develop and disseminate clearer procurement guidance for countries regarding the proposed and suggested remaining shelf-life of molecular diagnostic tests.
6. Expedite release of recent clinical and service delivery diagnostics-related guidance and recommendations in Q2 of 2021.

Diagnostic manufacturers commit to:

7. Commit to making all-in pricing for both laboratory-based and POC technologies more affordable, accessible, and transparent.

USFDA commits to:

8. Work with diagnostics manufactures to use all regulatory tools available, such as breakthrough designations and leveraging existing data from outside the US, to expedite review of early infant diagnostics for HIV.

CHAI commits to:

9. Prioritize integration of systems and device-sharing across HIV and TB programs, including mapping of systems and diagnostic network optimization.
10. Work with Ministries of Health to improve and expand case-finding strategies and focus on priority entry points and index testing.
11. Incorporate LF-LAM and CrAg testing for infants and children with advanced HIV disease.

CRS commits to:

12. Continue to strengthen and expand case-finding through completion of studies of parent-assisted testing intervention in Zambia and Uganda and sharing quickly with WHO and other interested stakeholders.

EGPAF commits to:

13. Work with civil society, communities, governments and multilaterals to scale up access to POC EID through advocacy and technical leadership.
14. Work with governments, FBOs, and health care workers to implement evidence-based strategies for pediatric HIV case finding, especially for older children, and increase demand through community-led education to ensure that all children along the continuum of care are reached.
15. Optimize POC EID by promoting integrated disease testing for childhood HIV and TB on the same platform.

GNP+ commits to:

16. Promoting peer to peer support structures to promote greater use of point of care early infant diagnosis
17. Advocacy of implementation and involvement into the design of the programs of community organizations and advocates.
18. Treatment literacy awareness, building trust, provision of information, encouragement of men to engage in health care needs of their family, and support community based organizations

Unitaid commits to:

19. Continue supporting the pediatric diagnostic agenda as per the Plan of Action through implementing partners (including, for year 2021, CHAI) and WHO's Prequalification Program and WHO HIV/Hepatitis/STIs department.
20. Further generate evidence on optimal deployment models, impact and cost-effectiveness of new and existing technologies.
21. Support optimal use of technologies across different laboratory tiers and disease areas (including integration with TB and coinfections/comorbidities services).
22. Support further discussions with manufacturers of relevant diagnostics products to optimize pricing and supply terms towards affordable and accessible options.

Abbott commits to:

23. Recommit to offering a \$20 all-inclusive price per test (covering instrument, connectivity, service and maintenance) for the m-PIMA qualitative (EID) and viral load assays based on minimum volume thresholds.

Cepheid commits to:

24. Launch an all-inclusive ceiling price (including instrument, cartridges, service and maintenance, etc) of \$14.90 for virology tests, including HIV, HBV, HCV, and HPV, in January 2021.
25. Reduce the price per test for HIV, HBV, HCV, HPV molecular tests in 2021 for those countries unable or not yet ready to access the all-inclusive program.

Hologic commits to:

26. Continue all-inclusive access program across HIV, HBV, HCV, and HPV assays.

Roche commits to:

27. Offering access pricing for technologies that are transparent, consistent, and applicable across assays and donors/procurers and working with donors/procurers to further refine pricing details and transparency.
28. Offer all assays, including HIV, HCV, HBV, HPV and TB on all platforms, including the cobas 4800, 6800, and 8800.
29. Continue to support and strengthen a shared and integrated diagnostic network as well as multi-assay capability on current instrumentation for further optimization and utilization of platform capacity and access to testing.
30. Ensure the plasma separation card is affordable and consider expanding accessibility to other, non-proprietary technologies.

CROSS-CUTTING COMMITMENTS

Stop TB Partnership commits to:

1. Provide high-level political leadership and advocacy at global and country levels to scale-up access to diagnosis and treatment for children with TB in line with targets of the 2018 UN High Level Meeting on TB;
2. Continue to convene and coordinate TB stakeholders at high-level, including manufacturers, faith-based organizations and civil society service providers, national governments and multilateral partners;
3. Work with communities, civil society partners, including organizations of people living with TB and faith partners, to address barriers of stigma and lack of information and increase the uptake of TB testing among children and treatment with the latest regimens;
4. Continue to use the expertise of its Working Groups including the Child and Adolescent TB Working Group and the Global Laboratory Initiative to promote innovations and provide implementation guidance to facilitate their roll-out.

UNAIDS commits to:

5. Set, and report on, ambitious global level testing, treatment, and viral load suppression targets by age group: <1, 1-4, 5-9, 10-14, 15-19 and prevention of HIV mother to child transmission targets in the new UNAIDS Strategy.
6. Support governments in setting and meeting national HIV prevention, testing, treatment, and viral load suppression targets for children
7. In collaboration with partners, support countries to develop the systems to collect age-disaggregated data on HIV testing, treatment, and viral suppression for the age categories currently reported through the Global AIDS Monitoring (GAM) platform.
8. Work with Global TB Programme to develop indicators on age-disaggregated data for HIV and TB co-infection in children

9. Uphold an advocacy plan to mobilize political will, civil society engagement, and resources among the stakeholders to achieve the HIV paediatric and e-MTCT targets, in support of the Rome Action Plan commitments.

The Co-Chairs of the AIDS Free Working Group of the Start Free, Stay Free, AIDS Free framework (WHO and EGPAF) commit to:

10. Take responsibility for monitoring implementation of the Plan and holding actors to account, including regular webinars, tracking the status of all commitments, and regularly communicating with participants about their progress and challenges needing to be addressed.

All partners commit to:

11. Promote awareness of, and advocate for political support for, full implementation of the Plan.