High level dialogue to scale up service for children living with HIV and TB
The Vatican platform for High-Level Dialogues

- **Rome 1**
  - April 2016
  - High-Level Meeting with representatives of Pharmaceutical and Diagnostic Industries Regarding Paediatric

- **Rome 2**
  - May 2016
  - Consultation organized by Pontifical Council for Justice and Peace, Caritas Internationalis, UNAIDS, PEPFAR on “Fast-Tracking Paediatric HIV Diagnosis and Treatment”

- **Rome 3**
  - Nov 2017
  - High-Level Dialogue on Scaling Up Early Diagnosis and Treatment of Children and Adolescents with a focus on accelerating development and introduction of medicines

- **Rome 4**
  - Dec 2018
  - High level dialogue to address remaining bottlenecks to quickly identify HIV-infected children and link them to testing and treatment with optimal regimens.
Paediatric HIV: Rome Action Plan

The Rome Action Plan is a compilation of commitments by key stakeholders to accelerate research, development, registration, introduction and uptake of HIV diagnostics and optimal antiretroviral drugs (ARVs) for children living with HIV, with the ultimate objective of reducing morbidity and mortality among this highly vulnerable group.

The Rome Action Plan is the product of a series of High Level Dialogues convened by His Eminence Peter Kodwo Appiah Cardinal Turkson, Prefect of the Dicastery for the Promotion of Integral Human Development, and organized by the World Health Organization (WHO), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), PEPFAR, UNAIDS, Caritas Internationals, the World Council of Churches – Ecumenical Advocacy Alliance (WCC-EAA), and global partner organizations.

The co-chairs of the AIDS Free Working Group have the responsibility to monitor progress on the Action Plan and to promote full and timely implementation of the action points, including tracking progress towards milestones, and communicating regularly with participants about progress on their commitments and overall implementation of the Plan.

This website tracks the commitments of the Rome Action Plan.

https://www.paediatricrichivactionplan.org/
A few “success” stories

• In 2017 US FDA made strong statement of support to **PSP submissions developed according principles of acceleration** as described by WHO-convened PAWG. EMA endorsed the same principles in 2018

• In 2018 USFDA-WHOPQ agreement led to the launch of **CRPlite** to accelerate in country registration of products approved by USFDA. Innovators and generics exploring CRP to accelerate in country registration

• **CRP for diagnostics** being initiated and donors are not funding repetitive country-by-country registrational studies for diagnostics

• **Innovators commitment to accelerate timelines and partner with key stakeholders to enable more rapid access**
  - ie ViiV and research networks committed to accelerate completion of clinical studies on DTG and rapidly share data to inform WHO guidelines and are now on track for submission at the end of the month. In addition, ViiV/CHAI/Unitaid partnership to accelerate generic development of a 10 mg scored DTG dispersible tablet

• **First all-in cost** (reagent rental) for a point-of-care nucleic acid test announced

• Better **alignment between implementing partners** on key steps (tools development, transition strategies, ...)

• More **resources mobilized** to support key implementers (ie FBOs), impactful interventions (ie. POC EID)
Vatican 5: Purpose and specific objectives

• To assess **progress** on the commitments documented in the November 2017 and December 2018 Pediatric HIV Rome Action Plan;

• To highlight **remaining gaps and solutions** on paediatric HIV and diagnostics;

• To highlight **current gaps in TB prevention, diagnosis, treatment and care for children living with HIV**;

• To identify **solutions and commit to actions** that enable improved access to innovative, high quality, TB preventive therapy and affordable TB drugs and diagnostics for children exposed to or living with HIV;
High level dialogue to Dialogue to Assess Progress on and Intensify Commitment to Scaling Up Diagnosis of Paediatric HIV and TB/HIV (April 2020)

Bilateral meetings with stakeholder to firm up commitments and gather additional suggestions (Feb-March 2020)

TPMAT (Jan 2020)

Subgroup calls: R&D, Regulatory, Uptake (Jan 2020)

Countries engagement at ICASA (Dec 2019)

WHO Paeds regulatory network meeting (Dec 2019)

Joint partners TC to explore issues and solution (November 2019)

Awareness raising union (October 2019)

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**Identifying new commitments on HIV/TB**

- Work with **other stakeholders** (manufacturers, regulatory authorities, donors, etc.) to help identify and **take on further commitments**
- Work with partners to help **identify commitments they would like other stakeholders to make**
- Commitments should be **SMART**
  - Particularly important to be able to measure and document progress
  - Timebound commitments ideal

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Share your thoughts with us!

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