



INDUSTRY
LIAISON
FORUM



ILF/CIPHER Thematic Roundtable on Paediatric ARVs:
*Stimulating development of
the most needed formulations*

Room St. Moritz, Starling Hotel, Geneva, Switzerland

Monday, 7 March 2016, 13:00 – 16:30 CET



Existing innovative models of collaboration

Objective for these slides: Complement the presentations on existing innovative models of collaboration, and feed the roundtable discussion on fast tracking the development of the most needed paediatric ARVs. Models presented:

- DNDi/Cipla Collaboration (4-in-1 LPV/r-based FDCs)
- Antiretroviral Pregnancy Registry
- HIV Cure Initiative
- Vaccine Adverse Event Reporting System
- Critical Path to TB Drug Regimens
- Medicines for Malaria Venture



DNDi/Cipla Collaboration

(4-in-1 LPV/r-based FDCs)

Funding



Objective

Develop and register two solid taste-masked first-line LPV/r-based fixed-dose formulations with two NRTIs (3TC + ABC or AZT)

- LPV/r + 3TC+ ABC
- LPV/r + 3TC + AZT



Cipla

Industrial scale-up, validation, manufacturing, registration, pharmacovigilance, distribution, recalls of the 4-in-1s

DNDi

Drugs for Neglected Diseases *initiative*

Clinical studies (Phase II/III and implementation studies), certain access activities of the 4-in-1s.

Joint Steering committee – members from DNDi and Cipla working on R&D formulations



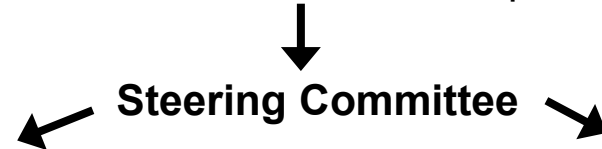
Antiretroviral Pregnancy Registry (APR)

Objectives

- Provide early warning signal of major teratogenicity
- Estimate risk of major birth defects and compare to that of general population
- Supplement data from animal toxicology, clinical, and epidemiological studies
- Designed to assist clinicians and patients in weighing potential risks and benefits of treatment

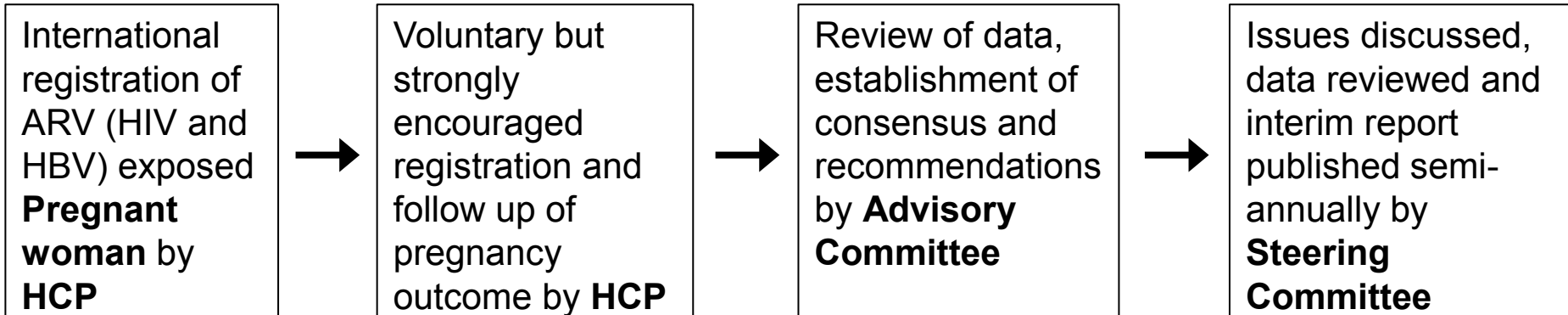


MANAGEMENT
(conduct clinical research and pharma consulting)



SPONSORSHIP
26 pharmaceutical companies representing 94 products

Advisory Committee
CDC, FDA, NIH, Office of the Global AIDS Coordinator, and practicing physician specialists
Review the Registry data; develop the Consensus Statement; provide enhancements to the Registry; communication





HIV Cure Initiative

Objectives

Bring interested parties together so that HIV cure can be most rapidly achieved

The initiative is developing:

1. An **investment case** justifying the development of an HIV cure through a multi-stakeholder initiative
2. An **initiative framework** that sets out a high-level set of stakeholder commitments and benefits associated with their involvement
3. A **long-term roadmap** of activities and priorities

Funding

- Annenberg Foundation Trust
- NIH Office of AIDS Research
- Infectious Disease Research Institute
- Argos Therapeutics
- Gilead Sciences
- Merck
- ViiV Healthcare

Provide

Scientific guidance and peer review to HIV cure R&D stakeholders

Augment

Existing HIV cure efforts, develop stronger relations among all stakeholders

Facilitate

Public-private partnerships/other collaborations among stakeholders

Advocate

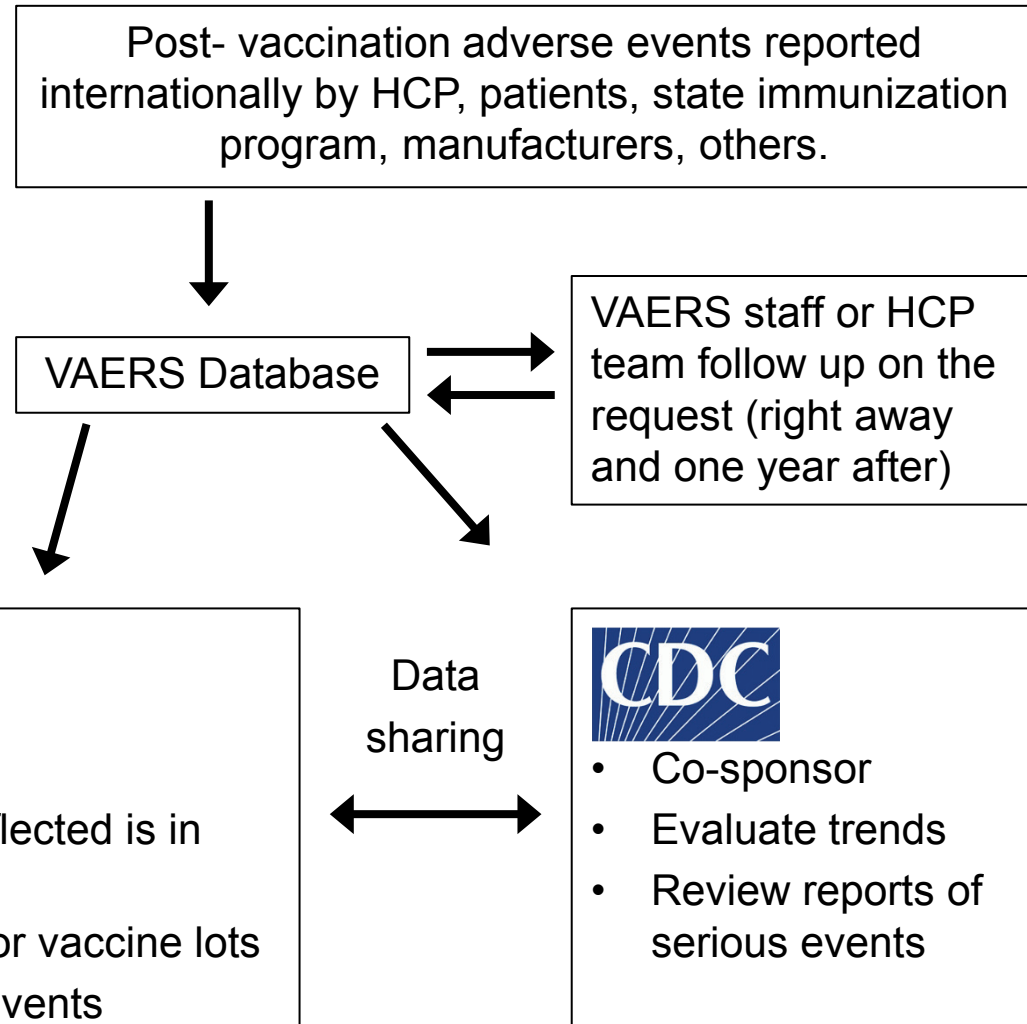
For access to sufficient funding for the stakeholders to support HIV cure efforts



Vaccine Adverse Event Reporting System

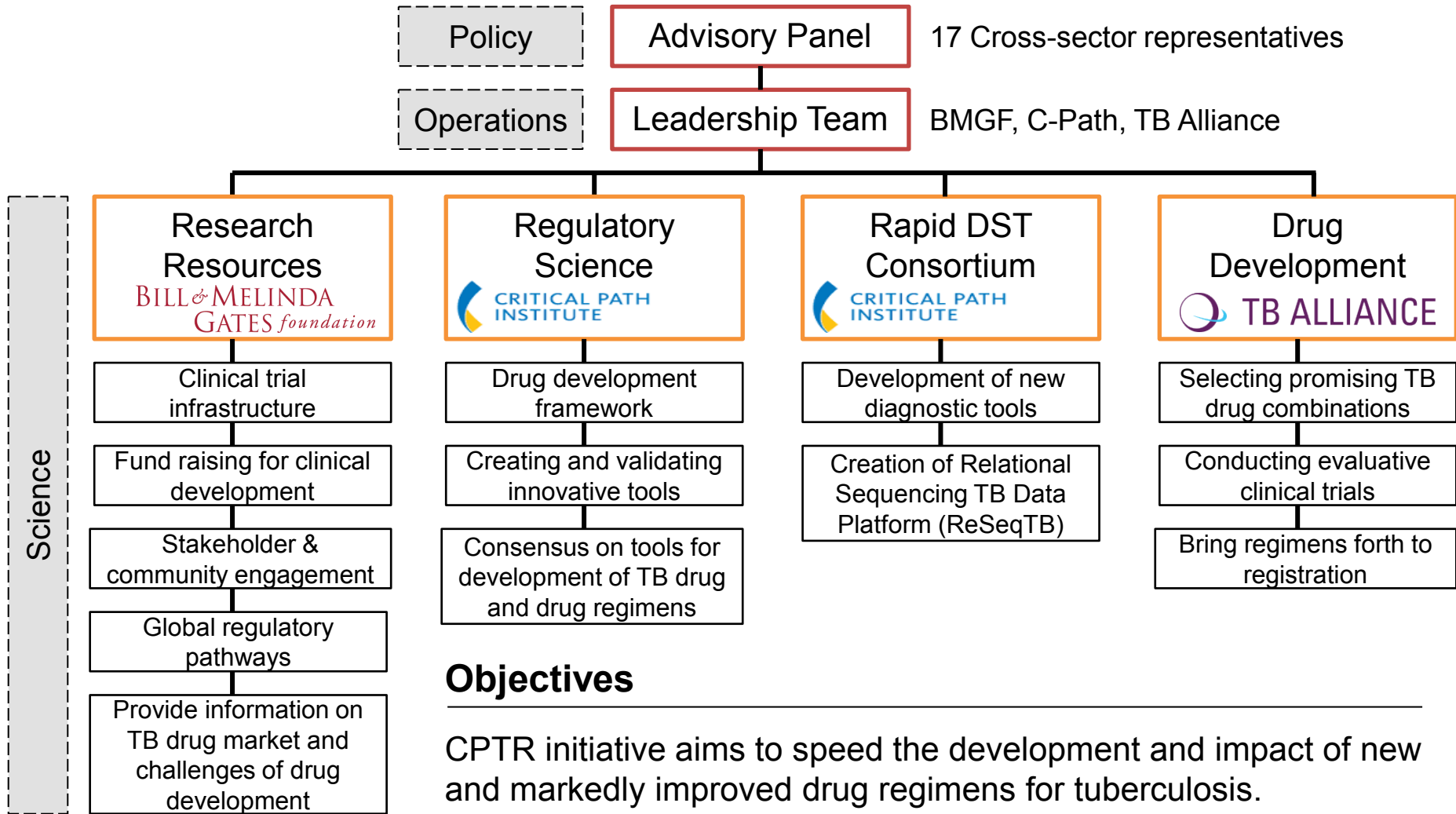
Objectives

- Detect new, unusual, or rare vaccine adverse events
- Monitor increases in and identify potential patient risk factors for particular types of adverse events
- Identify vaccine lots with increased numbers or types of reported adverse events;
- Assess the safety of newly licensed vaccines





Critical Path to TB Drug Regimens



Objectives

CPTR initiative aims to speed the development and impact of new and markedly improved drug regimens for tuberculosis.



Medicines for Malaria Venture

Private Sector (Biotech & Pharma)

1. Knowledge and expertise of drug development
2. Access to novel and proprietary compound libraries

Clinical centres in endemic and non endemic countries

1. Safety and efficacy of drugs
2. Training in clinical practice
3. Regulatory requirements of trial sites

Donors

1. Funding and support for R&D projects
2. Supporting specific interventions

Public Sector, Research & Academic Institutions, Governments, International organizations

1. Sharing of knowledge
2. Carrying out research
3. Advertising malaria treatment
4. Dialogue to shape the malaria agenda and policy implementation

MMV 
Medicines for Malaria Venture

NGOs and non profit organizations

1. Bridging together the private and public sector
2. Advocacy initiatives
3. Product development partnerships

Objectives

Reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs.