Global Antibiotic R&D Partnership
A Joint DNDi / WHO initiative

Dr Jean-Pierre Paccaud, PhD
Corporate Strategy and Business Development Director, GARDP
A Global Public Health Vision

The Global Antibiotic R&D Partnership (GARDP):

• A not-for-profit Product Development Partnership

• GARDP works in partnership with the public and private sectors to develop new antibiotic treatments for important infections where drug resistance is present or emerging, and are of low priority for the private sector

• It promotes sustainable access for antimicrobial treatments by balancing responsible use for optimal conservation, while ensuring equitable access for all, with a focus on global health needs.
A comprehensive mission

- Bridge R&D gaps & address priority medical needs: disease-specific and cross-cutting drug discovery and development approaches

- Develop new antibiotic treatments for important and significant bacterial infections and syndromes that represent a public health problem and have a global impact

- Sustainable access and conservation are ongoing embedded endeavours in all projects undertaken by GARDP
**GARDP: from the initial concept to launch**

- **2014**
  - DNDi consultations Business Plan scope – AMR suggested
  - May 2014 WHO-DNDi meeting to explore PDP for antibiotics

- **2015**
  - May 2015 WHA adopts GAP-AMR + resolution
  - Oct. 2015 G7 Declaration: explore PDP for AMR

- **2016**
  - 13 Nov. 2015 DNDi-WHO consultation support for PDP
  - 1 Dec. 2015 DNDi Board approves incubation
  - 29 Feb. 2016 1st Scientific consultation Institut Pasteur

- **2017**
  - 24 May 2016 GARDP Launch
  - May-Sept. Expert Meetings:
    - Stewardship & Access (May)
    - Gonorrhoea (June)
    - Neonatal Sepsis (Aug.)
    - Memory Recovery (Aug.)
    - Combination Platform (Aug.)
    - South Africa Regional Meeting – SAMRC (Sept.)

**EUR 2.2 M (of EUR 3 M) of required seed funding:**
- Federal Ministry of Health of Germany
- The Netherlands’ Ministry of Health Welfare and Sports
- South African Medical Research Council
- United Kingdom Department for International Development
- Swiss Federal Office of Public Health
- Médecins Sans Frontières

GARDP dedicated entity / Governance & Structure / Launch projects
Scientific Strategy Approaches

GARDP’s strategy comprises short and long-term approaches, utilizing existing, forgotten, abandoned and new technologies such as:

- **Improving** dosing, duration, formulations, and drug repurposing to optimize existing antibiotics
- **Combining** old antibiotics, new antibiotics, and non-antibiotics to overcome drug-resistant bacteria
- Working with former antibiotic researchers to bridge generational knowledge gaps and recover/redevelop abandoned and forgotten drug candidates from previous decades
- Accelerating development of new drug candidates, targeting public health priorities and vulnerable populations (e.g. STIs, newborns), unpursued for commercial reasons
- Exploring novel drug development approaches leading to creative and durable solutions
Potential Pilot Projects

- **Neonatal sepsis**
  - *NeoAMR - A global consortium to conduct preclinical/clinical studies to develop two new treatments for neonatal sepsis (empiric use and highly drug-resistant infections) (2016)*

- **Memory Recovery**
  - *Antimicrobial Memory Recovery Initiative - An imaginative approach to rediscover the knowledge, contacts, data, and assets of ‘forgotten’ antibiotics to identify new drug candidates (2016)*

- **Sexually transmitted diseases**
  - *A portfolio with private and academic partners to develop two new treatments for STI syndromic management and confirmed drug-resistant cases of gonorrhoea (2017)*

- **Antibiotic Drug Combinations**
  - *Drug Combination Platform - Standardized platforms linking expertise for in vitro and in vivo studies to optimize combination regimens of existing/new antibiotics and non-antibiotics (2017)*
Sustainable Business Models for Public Health Returns

Key elements:

• **Diverse and sustainable** financial resources to enable development of innovative solutions to address resistance to antibiotics at a global level

• **Suitable economics** for products developed through GARDP to guarantee production and distribution, but also **affordability** for all patients

• Build strong **partnerships** with all public and private actors to ensure access and **promote optimal/appropriate** usage of new treatments

• Interventions **complementary** to other actors, when economics does not provide enough financial incentives
Sustainable Business Models for Public Health Returns

Applicable models:

- **Push**: fully subsidized by GARDP => identify partner(s) for next steps
- **Push/Pull**: subsidized by GARDP + pull incentives for partner(s)
- **Joint-venture**: co-investment/development with GARDP => shared risks, responsibilities and benefits

Economics:

- Must insure **sustainability** but also **affordability**:
  => e.g. price commensurate to patient’s financial capacity
- Explore **role of IP**: impact on access, sustainability of production and on over marketing
- **Fair pricing** to be developed based on Gross National Income (GNI)
- Commensurate to the level of GARDP investments, **revenue streams** can be considered for GARDP as long as compatible with affordability.
Sustainable access: what does it mean?

Sustainable Access = Innovation + access + conservation + stewardship

Key factors to consider:

- Need to navigate wide range of contexts: LIC – HIC (Global)
- Strategies require integration with other healthcare interventions (e.g. IPC)
- Dependent upon on TPP / Product(s): *New vs Old / Patented vs Off patent; where product will be deployed in the healthcare system*
- Approach will need to be different to conventional PDP approach: product development **and** product management
- Strategies must complement other broader interventions and policy frameworks (e.g. global/local public health campaigns; Development and Stewardship Framework)
Holistic approach to sustainable access

- Training / Capacity building / Product packaging / Pilot implementation programmes / Monitoring studies
- Registration / policy and guidelines / fair pricing / responsible licencing
- Pull mechanisms with sustainable access embedded (e.g. facility to support country scale up with appropriate use and access, milestone prizes)

GARDP will as appropriate:
- Conduct
- Support
- Drive
- Promote
- Finance
Objectives for 2023

GARDP aims to:

• develop **4-5 new treatments** targeting serious drug-resistant infections
• build a **robust pipeline** with a focus on gram-negative infections
• pilot **incentive mechanisms** that promote sustainable access
• test alternatives not-for-profit **business models**
Thank you