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

Overview

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What is GARDP?

- The Global Antibiotic Research and Development Partnership is a not-for-profit R&D organization that will develop new treatments for bacterial infections.
- GARDP is a joint initiative of the World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi).
- The current team of 10 people is currently hosted by DNDi.

2023 Objectives:

- Develop four new treatments through improvement of existing antibiotics and new chemical entities.
- Build a robust pipeline of pre-clinical and clinical candidates.
- Actively support appropriate use and access of new antibiotic treatments.
GARDP from conception to date

2014
- DNDi consultations
- Business Plan scope – AMR suggested
- May 2014 WHA
- May 2015 WHO-DNDi
- Dec. 2014
- Meeting to explore
- PDP for antibiotics

2015
- 13 Nov. 2015
- DNDi-WHO consultation
- support for PDP
- Oct. 2015 G7
- Declaration: explore
- PDP for AMR

2016
- 1 Dec. 2015 DNDi
- Board approves
- incubation
- 1st Scientific consultation
- Institut Pasteur
- 24 May 2016
- GARDP Launch

2017
- GARDP Business Plan

May-Dec. Expert Meetings:
- Stewardship and Access (May)
- Gonorrhoea (June)
- Neonatal Sepsis (Aug.)
- Memory Recovery (Aug.)
- Combination Platform (Aug.)
- South Africa Regional Meeting, SAMRC (Sept.)
- 2015 G7 Follow up, Berlin (Oct.)
- Sustainable Access (Nov.)
- India Regional Meeting, ICMR (Dec.)
- Enteric Fevers Expert Meeting (Dec.)

5.8 M EUR up to 2018 secured:
- 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
Respective GARDP Roles of DNDi & WHO

**WHO**
- Priority setting & technical input
- Convening of international experts
- Support stewardship & access approaches
- Report to Member States on GAP-AMR
- Input from AMR Secretariat, disease departments, Essential Medicines Programme, & Global Health R&D Observatory

**DNDi**
- Hosting GARDP
- Governance through Board of Directors
- Business support through fundraising, communication, HR, finance, administration
- Provide scientific environment, while GARDP has dedicated R&D team, GARDP Scientific Advisory Committee
A comprehensive mission

Impact for patients’ & global public health needs

- R&D programmes
  From any starting point in pipeline to patients

- Prioritization
  Pathogens, populations, syndromes and diseases

- Sustainable access
  Including innovation, access, and stewardship

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Role GARDP can play globally in AMR R&D

- **Priority TPPs**: Work with WHO to develop specific TPPs for key programmes

- **AMR R&D ecosystem**: Help build tools and resources that will support drug developers especially in academia and small and medium-sized enterprises (SMEs) (e.g. ‘Memory Recovery’)

- **R&D Implementation**: Develop and execute programmes for key global health antimicrobial resistance (AMR) priorities receiving insufficient investment (e.g. neonatal sepsis, sexually-transmitted infections - STIs)

- **Effective funding and partnering**: Directly support and fund the work of developers, including SMEs, in developing new chemical entities (NCEs) of relevance through a direct partnership model

- **Embedding access**: Proactively work to ensure affordability, availability and stewardship according to public health needs
**Priority pathogens**
Focus on Gram-negative bacteria and multidrug-resistant pathogens. Certain fungal pathogens may also be considered.
*WHO Priority Pathogens List

**Priority populations**
Include neonates and children, immunocompromised patients, marginalized and underserved populations.

**Pathogens**

**Diseases and syndromes**
Include sepsis, sexually-transmitted infections and potentially enteric infections.
*WHO Infectious Disease Syndromes Review
* WHO Review of Antibiotic Pipeline

**Following Prioritization – Selection Criteria:**
- Global health need, relevance for developing countries;
- R&D gap and opportunity to partner
- Potential for short to medium-term fruition
- Ability to test and/or apply access and stewardship strategies.
Scientific strategy approaches

GARDP’s strategy comprises **short, medium and long-term approaches**, utilizing existing, forgotten, abandoned and new technologies by:

**High priority, immediately actionable**

- **Optimizing the use of antibiotics**, by improving dosing, treatment duration, formulation, drug repurposing, and new combinations (with old, new, and non-antibiotics), to improve treatment for important and drug-resistant bacterial infections

- **Accelerating, re-starting, and recovering** the development of new and abandoned drug candidates that address public health priorities and vulnerable populations (e.g. people living with STIs, newborns)

**Long-term, exploratory**

- **Exploring novel and innovative drug development approaches** leading to creative and durable solutions with a view to meeting patient needs in the long term. Scoping conducted to determine areas where GARDP could add value to the current R&D landscape.
**R&D Priorities and Pilot Programmes**

**Neonatal Sepsis**: Global consortium to conduct preclinical/clinical studies. By 2023, develop 1 treatment for empiric use, and 1 treatment for highly drug-resistant infections to clinical development.

**Sexually-transmitted Infections**: Portfolio with private and academic partners. By 2023, develop 1 new treatment for gonorrhoea (incl. MDR) and explore use for syndromic management of STIs.

**Paediatric Antibiotic Platform**: To optimize current and new antibiotics for children through dose, duration of treatment, formulation, or combinations. By 2023, develop 1 new treatment.

**Exploratory/Upstream/Memory Recovery**: Antibiotic Memory Recovery Initiative; combinations; carbapenem-resistant organisms; ESBLs; possibly fungal infections & enteric infections; other upstream opportunities.
Comprehensive approach to access
Operational models for GARDP

GARDP works as a virtual R&D organization through partnership and multi-stakeholder collaboration, and develops its overall strategy and policies.

Funds / Resources will be directed in two ways:

**Active R&D programmes driven, sponsored and directly executed by GARDP:**

- internally developed covering areas of acute need
- where very few external actors active

**Equal partnerships to which GARDP brings appropriate funding, direction, and support:**

- GARDP may seek out, or receive request for partnership
- GARDP works to ensure sustainable access is embedded, and global public health needs are met, through appropriate business models
Initial budget for ‘core’ R&D programmes EUR 270m
Leveraging our network

Being hosted in DNDi offers a unique opportunity to build a new dedicated entity for AMR through:

- Starting within an existing governance structure, allows time to build a strategy, programmes/projects, and a longer term governance
- Utilizing existing support structures of DNDi that ensure our funding is directed to start up of core R&D business
- Extensive regional presence and networks to help implement trials (7 regional offices – high, middle, and low income countries)
- Building strong links with AMR networks, including microbiology and trial networks in HICs
Thank You

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