Strategic priority for AMR
launching a new program

ASM / ESCMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance

Boston 07 September 201
Wellcome’s framework for supporting science

Advancing ideas
We support great ideas and inspired thinking

Seizing opportunities
We bring ideas together to make a difference

Driving reform
We change ways of working so more ideas can flourish
Wellcome’s new strategic framework

Seizing opportunities

We bring ideas together to make a big difference.

We identify times when our concerted intervention can accelerate progress towards better health.

We identify a critical need and set ambitious goals.

We connect experts from different disciplines, build partnerships, and lead advocacy, policy development, communications and public engagement.

We do this by providing focused, intensive support that creates a step change over five to ten years.
Drug Resistant Infections Why a priority area?

The thoughtless person playing with penicillin is morally responsible for the death of the man from penicillin-resistant organism.

I hope this evil can be averted.

Drug-resistant infections are a challenge on the scale of climate change.

Antimicrobial resistance is a slow-motion tsunami. It is a global crisis that must be managed with the utmost urgency.

Alexander Fleming 1945

Jeremy Farrar 2016

Margaret Chan 2016
Wellcome’s priority area focused on AMR

Will be

- Outcome / objective led
- Targeting research activities to deliver outcomes
- Commissioning work and inviting requests for proposals
- Influencing & advocating
- Building and catalysing partnerships

Response-mode funding (*Advancing Ideas*) will still support AMR research as it always has

Not a broad funding scheme for AMR

Not pulling all AMR activities under one umbrella
A look at Wellcome’s support to advance ideas
Funding research globally to tackle AMR

The UK has invested £287m in AMR activities since 2004, including:
- Basic science (£108m)
- Translation (£122m)
- Surveillance/epidemiology (£34m)
Significant investment in translational research for therapeutics in a smaller number of projects compared to basic science.

Notably there has been little support for diagnostic development and almost nothing in public engagement.

Outcomes relating to Wellcome-funded activities were not captured making it difficult to conclude the impact of investment.
Funding has been heavily weighted toward malaria and to a lesser extent TB.
The opportunity to be seized
A complex problem with multiple drivers

- **ANIMALS**
  - agriculture
  - aquaculture
  - veterinary

- **MEdICINE**
  - prescription
  - OTC
  - diagnosis
  - clinical practise
  - community use

- **ENVIRONMENT**
  - water
  - soil
  - wildlife

- **GLOBALISATION**
  - travel
  - trade
  - migration

- **STRUCTURAL FACTORS**
  - economic drivers
  - regulation
  - access

- **Antimicrobial Resistance**
Global Call to Action

Concerted efforts to tackle drug-resistance threat world-wide

World Health Organization
- WHO Strategic and Technical Advisory Group on AMR (2013-2016)
- Global Action Plan WHA68.7 (2015)

United Nations
- High-Level Meeting at UNGA (2016)
- Political Declaration 16-16108 (2016)
- IACG (2016 – present)

Trans-Atlantic Task Force on AMR (TATFAR) (2009-present)

Joint Programming Initiative on AMR (JPIAMR) (2014-present)
WHO Global Action Plan

To ensure treatment and prevention of infectious diseases with quality-assured, safe and effective medicines

GLOBAL ACTION PLAN

- Improve awareness and understanding of antimicrobial resistance
- Strengthen knowledge through surveillance and research
- Reduce the incidence of infection
- Optimize the use of antimicrobial agents
- Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions
Recommendations for tackling AMR on ten fronts

- Public awareness
- Sanitation and hygiene
- Antibiotics in agriculture and the environment
- Surveillance
- Rapid diagnostics
- Vaccines and alternatives
- Human capital
- Drugs
- Global Innovation Fund
- International coalition for antimicrobial resistance review
Developing Wellcome Trust’s strategic priority

Seeking to transform the response to the threat of AMR by improving treatments, enabling policy and engaging communities

Near-term goals

Understanding emergence and transmission of AMR

Increased pipeline of new therapeutics and diagnostics, and optimisation of existing Tx

Accelerating development of new treatments for patients

Coordinating activities toward common goals

Long-term goals

• Paradigm shift in preventing and treating infections

• Coordinated international response to make healthcare systems resilient to threat of resistance

• Public mandate for change
The moment to act is now

Drug-Resistant Infection is a global health threat that undermines the progress made in the fight against infectious disease in the last century.

Our strategy will deliver a reduction in the impact of AMR

- Epidemiology of Drug-Resistant Infection
- New treatments
- Accelerating clinical assessment
- Global governance
Epidemiology of AMR

Outcome
Robust epidemiology generated and used in global and national strategies

Activities proposed:
Global analysis of surveillance and mapping data
Levers for global change

Epidemiology and surveillance DATA are currently INSUFFICIENT to inform interventions

- Data collection & sharing
- Data analysis
  - Map of antibiotic use
  - Models of transmission
  - Map of disease burden

Inform public health interventions

- Tools to engage public and policy makers
- Conservation strategies driven by data

Impact & Change
New treatments

Outcome
Accelerated discovery of new treatments

The current PIPELINE is INADEQUATE to meet future needs

Activities proposed:
- CARB-X with partner commitments $250 million from BARDA, NIH, FDA
- Other areas to address access and conservation, e.g. GARDP
Accelerating clinical assessment

Outcome
Accelerated clinical development of new drugs and improved use of existing drugs

Activities proposed:
- **Global clinical trial networks (GCTN)** to support design, operation and interpretation
- **Continuous master protocols (CMP)** to accelerate registration of new treatments

Clinical DEVELOPMENT is a significant BOTTLENECK in the delivery of new treatments

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**Diagram:**
- Basic Science
- Preclinical Research
- Clinical Assessment
- Registration
- Patients
- New Drugs
- Discovery
- Optimise
- Candidate selection
- Prototype
- Optimise
- Manufacture
- P1
- P2
- P3

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Global governance

Outcome
Effective global governance framework for DRI

Activities proposed:
- Coordinate global action
- Support multilateral action
- Incentivise R&D

LACK of an effective global GOVERNANCE and coordination framework
CARB-X and accelerating development of new treatments
Accelerating projects globally

CARB-X

Accelerating global antibacterial innovation

Investing to develop new antibiotics and other life-saving products to treat drug-resistant bacteria
What is CARB-X?

**Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator**

Created in response to US government’s 2015 Combating Antibiotic Resistant Bacteria (CARB) initiative and UK government’s call in 2016 for concerted global effort to tackle antibiotic resistance

Headquartered at Boston University

Launched July 28, 2016, by the US Department of Health and Human Services

- Biomedical Advanced Research and Development Authority, a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR/BARDA)
- National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIAID/NIH)

Mission: Accelerate a portfolio of high-quality antibacterial products towards clinical development, focusing on the priority drug-resistant bacteria identified by the WHO and CDC

Funded over 5 years by Wellcome Trust ($155M) and BARDA ($250M). NIAID provides preclinical services ($50M)

Partners include the Broad Institute of MIT and Harvard, the Massachusetts Biotechnology Council (MassBio), the California Life Sciences Institute (CLSI), and RTI International
New Treatments

CARB-X accelerating R&D
to combat the rising threat of serious drug-resistant bacterial infections

Urgent public health need
Antibiotic resistance kills an estimated 700,000 people each year worldwide. No new classes for drug-resistant Gram-negative bacteria have been approved in decades.

New global partnership model
CARB-X represents a new non-profit public-private partnership model to accelerate the development of life-saving antibiotics, vaccines and rapid diagnostics.

Turning science into products
Non-dilutive funding and accelerator support help companies with promising early research become life-saving antibiotics, vaccines and rapid diagnostics to treat serious drug-resistant bacterial infections.

CARB-X’s first year results
18 companies in 6 countries; 8 are pursuing new classes against Gram-negative bacteria; 10 new molecular targets; 5 non-traditional products; one rapid POC diagnostic.
Reinvigorating the pipeline

Focused on supporting early stage projects to get them to a stage when they can attract new private or public investment.
Global reach: CARB-X funds 18 projects in 6 countries

North America
Forge Therapeutics
San Diego, CA
Cidara Therapeutics Inc.
San Diego, CA
Achaogen Inc.
South San Francisco, CA
Contafect Corporation
Yonkers, NY
VenatorRx Pharmaceuticals
Malvern, PA

Spero Therapeutics LLC
Cambridge, MA
Visterra Inc.
Cambridge, MA
Tetraphase Pharmaceuticals Inc.
Watertown, MA
Entasis Therapeutics Inc.
Waltham, MA
Microbiotix Inc.
Worcester, MA

Europe and Asia
Iterum Therapeutics Ltd.
Dublin, Ireland
Proteus IRC
Edinburgh, Scotland
Redx Pharma Plc
Alderley Park, UK
Oppilotech Ltd.
London, UK
Eligochem Ltd.
Sandwich, UK
Antabio
Labège, France
Debiopharm International S.A.
Lausanne, Switzerland
Bugworks Research India Pvt Ltd.
Bangalore, India

Great science knows no boundaries
18 early stage R&D projects investigating 8 new classes of antibiotics, 5 non-traditional antibiotics, 10 new molecular targets and a rapid diagnostic
Wellcome Trust priority on AMR

Wellcome seeks to achieve a TRANSFORMATIVE IMPACT on AMR through the delivery of a coordinated and interconnected set of activities

Wellcome has:

- Invested over £287m in DRI-related research since 2004
- Shown capacity to integrate and coordinate activities of disparate stakeholders

We are building:

- **In-house team** dedicated to the Wellcome DRI Priority Platform
- A joint Strategic approach with Vaccines initiative

Projected budget £175m
Thank you