Diagnostics to Address Antimicrobial Resistance (AMR)

Consultative workshop for the establishment of a call within the IMI framework

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Today’s goals

- Present the idea of a diagnostics-focused initiative to address AMR which could be proposed within the IMI framework

- To discuss the content and objectives of the proposed call

- To obtain feedback and input from as many diverse stakeholders as possible, in order to create a robust IMI call to address the important issues around AMR diagnostics

- To encourage the participation of as many companies, agencies, and foundations as possible in this initiative
Why is bioMérieux coordinating this workshop with IMI?

- bioMérieux has been a “Partner in Research” of EFPIA since mid-2016

- bioMérieux is an active member of MedTech Europe

- bioMérieux believes that diagnostics are under-appreciated and under-valued in healthcare, and specifically in Infectious Diseases

- bioMérieux believes that now is the time to highlight the role of DIAGNOSTICS in preventing and controlling global AMR, and has committed resources for assisting to create a call within the IMI framework
The global push and support for diagnostics to address AMR

- Extolling the virtues of DIAGNOSTICS to the audience at today’s consultative workshop is unnecessary
- Unanimous recognition that diagnostics are relatively under-valued and under-appreciated in healthcare, with most of the emphasis on therapeutics and vaccines
- The value of diagnostics in addressing AMR is potentially enormous
UK Five Year Antimicrobial Resistance Strategy 2013 to 2018

We need to get to a point where:

- good infection prevention and control measures to help prevent infections occurring become the norm in all sectors of human and animal health,
- infections can be diagnosed quickly and the right treatment used,
- patients and animal keepers fully understand the importance of antibiotic treatment regimens and adhere to them,
- surveillance is in place which quickly identifies new threats or changing patterns in resistance,
- there is a sustainable supply of new, effective antimicrobials.

Professor Dame Sally C. Davies
Chief Medical Officer
Chief Scientific Adviser
Department of Health
RAPID DIAGNOSTICS:
STOPPING UNNECESSARY USE OF ANTIBIOTICS

THE REVIEW ON ANTIMICROBIAL RESISTANCE
CHAIR ED BY JIM O’NEILL

OCTOBER 2015
UN General Assembly (2016) repeatedly mentioned:

“……..antimicrobial medicines, diagnostic tools, vaccines and other interventions…..”
**ROADMAP**

<table>
<thead>
<tr>
<th><strong>TITLE OF THE INITIATIVE</strong></th>
<th>Commission's Communication on a One-Health Action Plan to support Member States in the fight against Antimicrobial Resistance (AMR)</th>
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<tbody>
<tr>
<td><strong>LEAD DG – RESPONSIBLE UNIT – AP NUMBER</strong></td>
<td>SANTE – AMR TASK-FORCE (G4, D3, 01)</td>
</tr>
<tr>
<td><strong>LIKELY TYPE OF INITIATIVE</strong></td>
<td>Inter-institutional non-legislative file: Communication from the Commission to the European Parliament and the Council</td>
</tr>
<tr>
<td><strong>INDICATIVE PLANNING</strong></td>
<td>Adoption foreseen first semester 2017</td>
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This Roadmap aims to inform stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Stakeholders are in particular invited to provide views on the Commission’s understanding of the problem and possible solutions and to make available any relevant information that they may have. The Roadmap is provided for information purposes only and its content may change. This Roadmap does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content.
How did we get to this consultative workshop?

- Discussion of “diagnostics and AMR” at the IMI “Infection Control Strategic Governing Group (SGG)” (June 2016)

- Birth of an idea to create an IMI call on how to increase the value and appreciation of diagnostics for addressing AMR

- Webinar to inform potential stakeholders about intention of creating the call (Sept. 2016)

- Companies and agencies working in the AMR field at an in-person workshop to brainstorm on creating the call (Dec 2016)
  (bioMerieux, Thermo Fisher, Alere, Biocartis, Bio-Rad, BD, BMGF, Cepheid, Janssen, MedTech Europe, Philips, Roche, Wellcome Trust)

- Based on workshop input, a draft call idea has been formulated

- Invited input from stakeholders (today) on the draft call for submission to IMI (June 2017)
This is where we are now
Possible objectives of the IMI call (1)

- Improving **technical aspects** of diagnostics for AMR
  - Phenotypic vs. genotypic AST methods
  - High level of performance (sens, spec)
  - “Pathogen targets” vs. “host susceptibility” assays
  - Rapidity of results
  - Ease of use
  - Low cost
  - Connectivity
Possible objectives of the IMI call (2)

- **Addressing the “Market access” issues of diagnostics for AMR**
  - *Regulatory pathway for AMR diagnostics*
    - Increasingly complex, costly, not favorable to innovative AMR diagnostics and region-specific (CE marking, FDA, CFDA); not harmonized
  - *Capturing the “true value” of AMR diagnostics (HTAs)*
    - HTA methodology for diagnostics not well established and implemented; country-specific; not standardized
  - *Reimbursement issues to reflect “medical value”*
    - Reimbursement not based on “medical value” nor on the ability to decrease antibiotic use; country- and payor-specific
  - *Lack of R&D incentives for innovation of AMR diagnostics*
  - *Inadequate education of healthcare providers re: AMR diagnostics*
    - Many providers unaware of tests available & evidence supporting their use
    - Personalized medicine not as evolved in Infectious Diseases as with Oncology
  - *Behavior of healthcare providers limiting uptake of AMR diagnostics*
    - Low adoption of AMR diagnostics, even when available
    - Social, ethical, economic and psychological factors affecting perception/uptake
Possible objectives of the IMI call

- **Technical aspects of diagnostics for AMR**
  - Phenotypic vs. genotypic AST methods
  - High level of performance (sens, spec)
  - “Pathogen targets” vs. “host susceptibility” assays
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**Why?**
Current obstacles to AMR diagnostics

- Not really technological

- Much more related to “market access” issues

- An innovative revolutionary diagnostic to address AMR, if available today, would have enormous difficulties with market penetration because of the long list of “market access issues”

  - R&D costs for market readiness
  - Regulatory pathway
  - HTA methodology
  - Reimbursement price & criteria
  - Healthcare provider education
  - Healthcare provider adoption
The value of an IMI project

- To address the “market access” issues which can facilitate market entry and penetration of innovative diagnostics to address AMR

- Addresses the key components of market access for “AMR diagnostics” which the diagnostic & pharmaceutical industries cannot tackle on their own

- “Pre-competitive” space:
  - Improve the creation, development and deployment of all types of diagnostics addressing AMR
  - Improve the use of diagnostics in the validation and deployment of new antibiotics
Benefits of the IMI call

**Diagnostic industry**
- Address “generic” issues of Market Access for diagnostics addressing AMR
- Improve the environment for developing and deploying AMR diagnostics (R&D, regulatory, reimbursement, adoption, education, etc.)

**Pharmaceutical industry**
- Improve availability of innovative diagnostics to facilitate & support new antibiotic clinical trials:
  - Faster & more efficient patient recruitment
  - Homogeneous patients with targeted pathogen of interest
  - Lower costs of clinical trials
  - Higher probability of success
- Access to improved diagnostics after antibiotic approval to better target patients (“personalized”)
The IMI call

Objective (what do we want to achieve?)

- Demonstrate the value of diagnostics for the optimal use of antimicrobials and healthcare resources in a standardized care environment*, thereby reducing AMR

Method (how can we achieve this?)

- Standardized care setting* for a selected disease (e.g. acute RTI)
- Biobanking and relevant data collection
- Care maps of when and how to use diagnostic tests
  - "Standard" diagnostics; "Innovative" diagnostics
- Health economics and outcomes research (HEOR) analytics
- Regulatory aspects
- Economic incentives
- Reimbursement aspects
- Educational approaches for healthcare providers & general public
- Psychosocial factors underlying behavior of healthcare providers

*Standardized care setting/environment: the full spectrum of care, from primary care to hospitalization to post-acute care (home/rehabilitation)
One important caveat........

This IMI call does not address the need for AMR diagnostics in LMICs

LMICs are often the source of MDRO and, in this increasingly connected world, should also be the beneficiaries of AMR diagnostics

But.....currently very little innovation in diagnostics for LMICs because:

- Unknown or diminished financial return
- Unknown or limited market size
- Substantial additional “Market Access” difficulties
- Target sale price very low
- Sale price mark-ups due to distributors, corruption
- Supply chain issues (cold chain, customs, storage conditions)
- Support for installation, training, maintenance, customer service
- ...etc
Today’s Agenda

- Briefly present the political landscape surrounding the role of diagnostics for addressing AMR (WHO, Wellcome Trust, European Commission)
- Presentation of the draft proposal for the IMI call
- Discussion of the difficulties in conducting clinical research on AMR diagnostics (round-table)
- Short presentations by various stakeholders, sharing their perspective on AMR diagnostics
- Open discussion
- Summary/closure