

# Diagnostics to Address Antimicrobial Resistance (AMR)

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

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Mark Miller, MD  
Corporate VP, Chief Medical Officer  
bioMérieux



efpia



innovative  
medicines  
initiative

# 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?

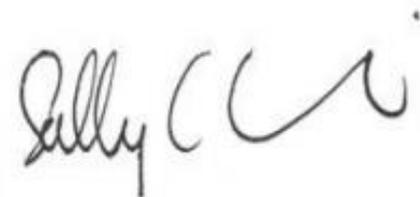
- bioMérieux has been a “Partner in Research” of EFPIA since mid-2016
- bioMérieux is an active member of MedTech Europe
- bioMérieux believes that diagnostics are under-appreciated and under-valued in healthcare, and specifically in Infectious Diseases
- bioMérieux believes that now is the time to highlight the role of DIAGNOSTICS in preventing and controlling global AMR, and has committed resources for assisting to create a call within the IMI framework

*“Without diagnostics, medicine is blind”*  
*ALAIN MÉRIEUX, President, Fondation Mérieux*

# 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



Professor Dame Sally C. Davies  
Chief Medical Officer  
Chief Scientific Adviser  
Department of Health

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.



Review on  
Antimicrobial  
Resistance

*Tackling drug-resistant infections globally*

## **RAPID DIAGNOSTICS:**

# STOPPING UNNECESSARY USE OF ANTIBIOTICS

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THE REVIEW ON  
ANTIMICROBIAL RESISTANCE

*CHAIR*ED BY JIM O'NEILL

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OCTOBER 2015

# NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

## PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

MARCH 2015



**Goal 3:** Advance Development  
and Use of Rapid and Innovative  
Diagnostic Tests for Identification and  
Characterization of Resistant Bacteria



### HIGH-LEVEL MEETING ON ANTIMICROBIAL RESISTANCE



21 SEPTEMBER 2016, UN HEADQUARTERS, NEW YORK

UN General Assembly (2016) repeatedly mentioned:

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

ROADMAP			
TITLE OF THE INITIATIVE	Commission's Communication on a One-Health Action Plan to support Member States in the fight against Antimicrobial Resistance (AMR)		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	SANTE – AMR TASK-FORCE (G4, D3, 01)	DATE OF ROADMAP	24/10/2016
LIKELY TYPE OF INITIATIVE	Inter-institutional non-legislative file: Communication from the Commission to the European Parliament and the Council		
INDICATIVE PLANNING	Adoption foreseen first semester 2017		
ADDITIONAL INFORMATION			
<p><b>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 prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content.</b></p>			

# 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  

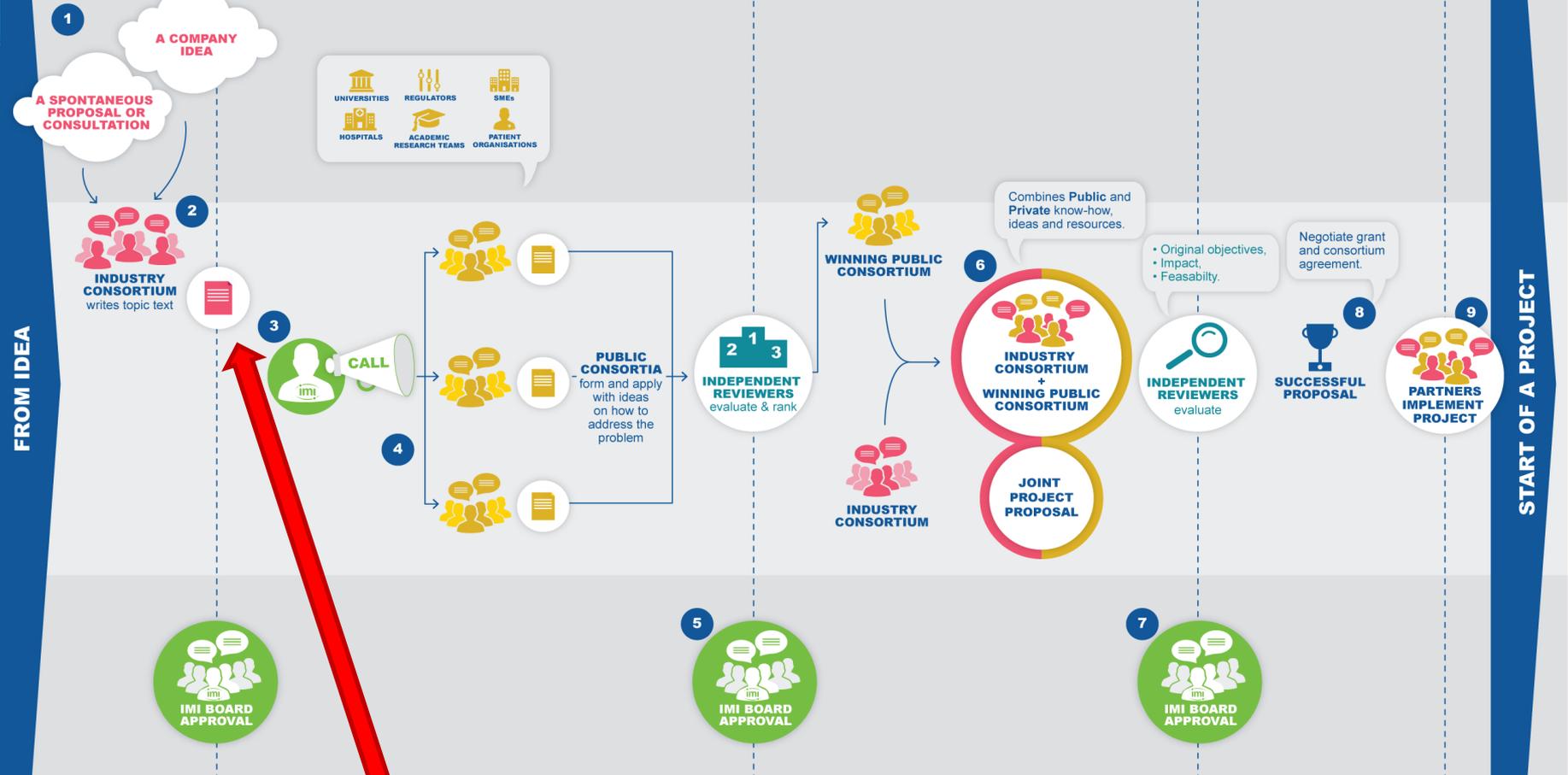
- **Webinar** to inform potential stakeholders about intention of creating the call (Sept. 2016)  

- 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)

# IMI: FROM IDEA TO PROJECT



FROM IDEA

START OF A PROJECT

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-specific” vs “pan-antigenicity” assays
  - Rapidity of results
  - Ease of use
  - Low cost
  - Connectivity

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**