Diagnostics – gathering intelligence to fight antimicrobial resistance

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EU Research to combat AMR since 1999

Tackling the growing resistance to antimicrobials by

- taking a One Health approach
- addressing bacteria, viruses, parasites and fungi
- with special attention on:
  - understanding how AMR develops
  - developing novel therapies
  - developing detection methods/diagnostics
  - new strategies to prevent infection/transmission
  - new strategies to improve prudent use

>€ 350 m so far
Investments so far in the area of diagnostics

**2011** Development of multi-analyte diagnostic tests (for AMR)

**2013** Diagnostics for infectious diseases in humans

**2014** Improving the control of infectious epidemics and foodborne outbreaks through rapid identification of pathogens

**2014** Development of new diagnostic tools and technologies: in vitro devices assays and platforms

**2014-2015** Clinical research for the validation of biomarkers and/or diagnostic medical devices → continued until **2017**
Examples of projects on Diagnostic test development

**C4L** developed **rapid diagnostic tests** to link antibiotic prescription with evidence-based diagnosis. Combining the Multiplex Ligation-dependent Probe Amplification (MLPA) and microfluidic technologies allows determination of **viral or bacterial origin**, as well as bacterial **resistance** mechanisms.

**PARCIVAL** developed an integrated and automated multi-analyte lab-on-a-disk platform for the fast and reliable sample-in → answer-out diagnosis of **highly infectious respiratory pathogens**, **resistance patterns** and **biomarkers for individual severity** of the infection.
Examples of projects on Diagnostic test development

**ROUTINE** developed a test that integrates sample preparation, DNA amplification and a fluorescent-based read-out on one platform to allow direct detection of bacteria causing **Upper Respiratory Tract Infection** and the associated antibiotic resistances within 30 min.

**RiD-RTI** developed and evaluated diagnostic tools for the rapid (< 2 hrs) diagnosis of **pneumonia**. The diagnostics products are ‘near patient’, reliable, cost-effective and user friendly allowing for detection, identification, and quantification (for selected targets) and molecular drug susceptibility testing of RTIs.
The "ecosystem"

Risk level

Discovery → Development → Validation → Commercialization

"Valley of Death"

FP7/H2020 Grants

EDCTP: PRD, NID

Horizon Prize

InnovFin ID

IMI-ND4BB

SME-Instrument

ERCP MSCA

JPIAMR

H2020 pillars
- Excellent Science
- Industrial Leadership
- Societal Challenges

The "ecosystem" supports projects through various stages of development, highlighting the "Valley of Death" as a critical challenge. Resources required for these stages include grants from FP7/H2020 and other programs under the H2020 pillars.
A new financial instrument for infectious diseases R&D

- Jointly developed by the European Commission and European Investment Bank and launched on 15 June 2015
- Provides loans between EUR 7.5m and EUR 75m to innovative players active in developing vaccines, drugs, medical and diagnostic devices, and research infrastructures for combatting infectious diseases.
- 4 deals signed so far

3 projects on diagnostics signed so far

**CAVIDI** (Swedish SME)
- €10 million loan
- Loan will allow Cavidi to develop an automated, high-throughput low-cost HIV viral load testing device that was developed in a FP7 EU project

**MOBIDIA**G (Finnish SME)
- €15 million loan
- Loan will allow to finalise and scale up manufacturing, validation and commercialisation of a diagnostic tool for Infectious Diseases

**STAT-Diagnostica & Innovation**, (Spanish SME)
- €20 million loan
- Loan will support the development of a new molecular diagnostics device capable of identifying a wide range of infectious pathogens, such as meningitis, respiratory or gastro-intestinal infections.
The Horizon Prize - Better use of Antibiotics

is offering a cash reward of €1 million to the person or team who can most effectively develop a rapid test that will allow healthcare providers to distinguish at the point-of-care between patients with upper respiratory tract infections that require antibiotics and those that can be treated safely without them.

Upper Respiratory Tract Infections include pharyngitis, sinusitis, otitis and bronchitis.

Website: www.ec.europa.eu/horizonprize/antibiotics
WINNER AND RUNNERS UP

Prize Award ceremony
6 February 2017

Winner:

• **Minicare HNL**
  Partners: Philips Electronics, Handheld Diagnostics, The Netherlands and P&M Venge AB, a Swedish R&D Performing SME

Runners up:

• **ImmunoPoC**
  Partners: MeMed Diagnostics, Israel, University Medical Centre Utrecht, The Netherlands, and Frog Design, Italy

• **PulmoCheck**
  Partners: Di Dr Andreas Paar kg, Austria and Synovo GmbH, Germany and Stichting Medisch Centrum Twente, The Netherlands

Research and Innovation
Minicare HNL

- Is a unique solution to reliably detect bacterial infection at the point of care using a fast and easy to use test.

- The assay is based on the detection of the biomarker Human Neutrophil Lipocalin (HNL) on the Minicare platform from a single droplet of blood.

- Finger prick test = minimally invasive.

- Less than ten minutes to result.

- The HNL assay has been transferred onto the CE marked Philips Minicare system consisting of a point of care analyzer and cartridges.

- The device is affordable for the physician's office as well as for the emergency department or primary care setting.
New One-Health AMR Action Plan

The Commission will continue and scale up its fight against AMR with the launch of a second Action Plan

Format: Commission communication to the European Parliament and the Council

3 strategic pillars:
1) Supporting Member States and making the EU a best-practice region
2) Boosting research, development and innovation
3) Shaping the global agenda on AMR

- Adoption foreseen for end of June
Pillar 2 Boosting research, development and innovation

• Improve knowledge on infection control and surveillance
• New therapeutics and alternatives
• New preventive vaccines
• New diagnostics
• New economic models and incentives
• Close knowledge gaps on AMR in the environment and prevent transmission
A roadmap for diagnostics

- Boost diagnostic development
- Understand what is needed to help patients
- Boost uptake of diagnostics
- Address the economic challenges
- Understand the diagnostics "ecosystem"
Thank you for your attention