



Diagnosics – gathering intelligence to fight antimicrobial resistance

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Advancing Public Health'

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

>€ 1 billion in
FP5 – FP7
(1999-2013)



>€ 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

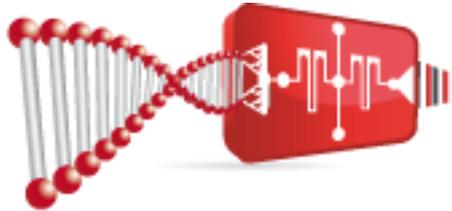
2014 Improving the control of infectious epidemics and foodborne outbreaks through rapid identification of pathogens

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



Chips 4 Life

Rapid Microbiologic Diagnostics

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



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.

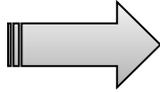
Rid RTI

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"



PUSH



Resources
required



PULL

"Valley of Death"

Risk level

Discovery

Development

Validation

Commercialization

FP7/H2020 Grants

EDCTP: PRD, NID

Horizon
Prize

SME-Instrument

ERC
MSCA

InnovFin ID

IMI-ND4BB

H2020 pillars

Excellent
Science

Industrial
Leadership

Societal
Challenges

JPIAMR

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

<http://www.eib.org/products/blending/innovfin/products/infectious-diseases.htm>

3 projects on diagnostics signed so far

CAVIDI (Swedish SME)

- €10 million loan
- Loan will allow Cavidu to develop an automated, high-throughput low-cost HIV viral load testing device that was developed in a FP7 EU project

MOBIDIAG (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.



BETTER USE OF ANTIBIOTICS

#HorizonPrize

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



BETTER USE OF ANTIBIOTICS

#HorizonPrize

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



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"





European
Commission



**Thank you for your
attention**