EU funded research projects and the link with authorisation of new antimicrobials

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Research and Innovation

EU research funding to combat AMR

€800 million for projects on antimicrobial resistance FP5 – FP7(1999-2013)

- Priorities:
  - developing new strategies for prudent/rational antibiotics use in medicine and agriculture
  - understanding how antimicrobial resistance develops
  - developing diagnostic tests to determine whether and which antimicrobials to prescribe
  - developing new antimicrobial drugs and alternatives to antimicrobials

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Research to combat antimicrobial resistance - key actions in the action plan

Action plan against the rising threats from antimicrobial resistance, launched on 17 November 2011

- **Action 6:**
  to promote unprecedented public-private collaborative research and development to bring new antibiotics to patients

→ Innovative Medicines Initiative

- **Action 11:**
  Reinforcing and co-ordinating research efforts

→
- **~€90M new projects from last FP7 calls**
- **JPIAMR**

jpiamr Joint Programming Initiative on Antimicrobial Resistance

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Co-operation with the industry: Innovative Medicines Initiative (IMI)

- An opportunity to combine public and private resources for new antimicrobials
- 2011 funding a €14.5 million project to improve rapid point-of-care tests for appropriate use of antibiotics (www.rapp-id.eu)
- May 2012: Launched a €223.7 million programme **New Drugs for Bad Bugs (ND4BB)** to develop and speed up the delivery of new antibiotics
- 2013 start of the first two ND4BB projects and launch of several additional calls

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Research funding

Research is the foundation for novel products

The foundation has to be well suited to the final product….

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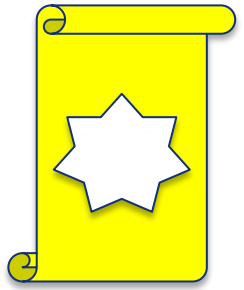
Research

Innovative Medicines Initiative

ND4BB TOPIC 1: COMBACTE - Enabling Clinical Collaboration and refining clinical trial design

Innovative Medicines Initiative

ND4BB TOPIC 3: Discovery & development of new drugs combating Gram-neg. infections



communication

Regulation / authorisation

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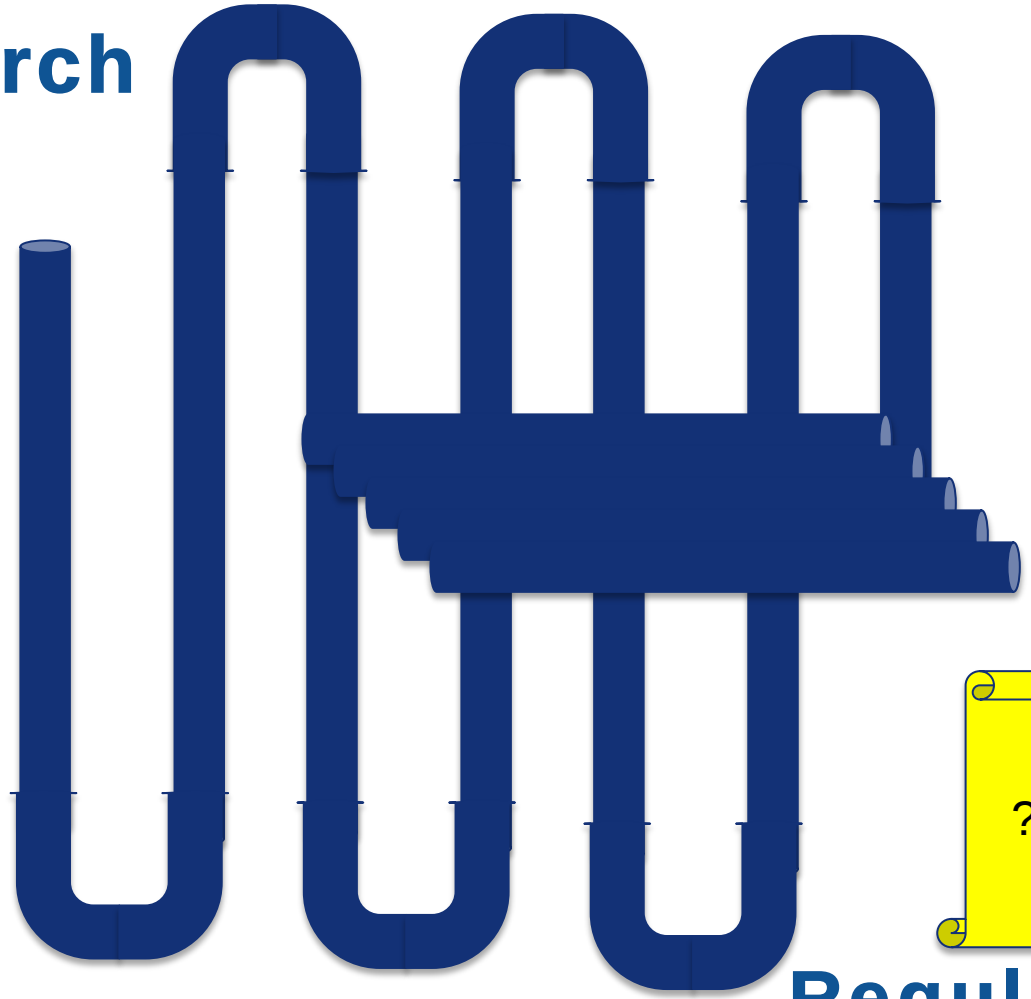
Research



Market
Patients

???

Regulation / authorisation

Research and Innovation

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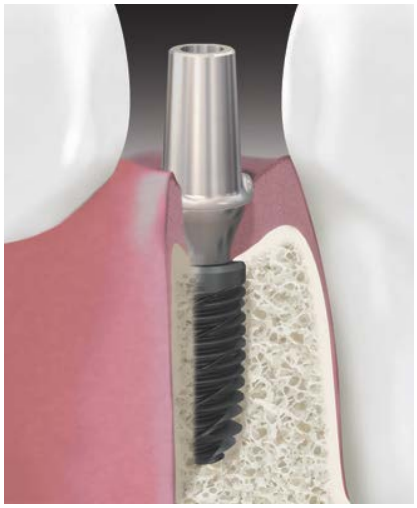
Medical devices with antibacterial properties

COOPERATION

dental implants



hip implants

coated catheters

Five EU funded projects are developing medical devices with antimicrobial coatings or devices manufactured from polymers releasing antimicrobials

There is high SME participation in such projects

This is both market-driven and responds to a high medical need

Regulatory requirements?

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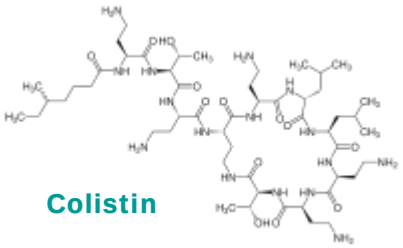
Clinical trials of off-patent antibiotics



Colistin

Two EU funded projects are performing clinical trials to determine the clinical effectiveness and optimal dosing of off-patent antibiotics like Colistin

Due to rising multidrug resistance old antibiotics are increasingly being prescribed -> medical need

The projects might identify a need for a different use

Effect on regulatory approval?

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Alternative treatments

PhagoBurn

An EU funded project aims to evaluate phage therapy for treatment of burn wounds infected with *E. coli* and or *Pseudomonas aeruginosa*. This project will implement a phase I-II clinical trial.

Modern clinical trial data are expected to provide a basis for further development and optimisation of phage therapy

Development of a regulatory approval pathway?

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Conclusion

It is crucial that there is a good communication between (early stage) research and regulation / legislation

- **Researchers and their funders want to develop novel medicines / medical devices that have a real potential to reach the markets.... and the patients**
- **Regulators need solid science for approval**
- **Everyone needs effective antimicrobials and the best use of money**

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The EU Framework Programme for Research and Innovation 2014-2020

Societal challenge "health demographic change and wellbeing"

- **planned support for identification and control of new / resistant pathogens**

IMI-2 continued support for AMR research

- **develop at least 2 new medicines that could be antibiotics**

Joint programming initiative on AMR

- **support for the launch of transnational research call on AMR**