IHI Call Days | Call 9

Therapeutic and non-therapeutic interventions for addressing anti-microbial resistance (AMR)

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Challenges and objectives

- **Challenge:** To tackle Bacterial antimicrobial resistance (AMR) there is a need to move towards more personalised treatment of infections through better integration of diagnostics into the patient care pathway combined with increased availability of a range of alternative treatments for tackling infectious disease.
- **Addresses:** TS2 (SO2): Integrate fragmented health research and innovation efforts by bringing together health industry sectors and other stakeholders to enable the development of tools, data, platforms, technologies and processes that will in turn facilitate the prevention, diagnosis, treatment and management of diseases, especially in areas where there is an unmet public health need.
- **Public Health Need:** AMR has emerged as a serious global burden and threat to public health. It is estimated that bacterial AMR was directly responsible for 1.27 million deaths in 2019, and a contributing factor to

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Your approach to solve the problem

- Champion the development of innovative diagnostics and emerging therapeutics to ultimately provide an integrated suite of diagnostic/therapeutic candidates to tackle a specific bacterial infection.
- Accelerate process development with modality specific collaborators to provide guidance in areas such as regulation, digitalisation, CMC and pre-clinical testing.This will encompass modalities from traditional recombinant proteins and monoclonal antibodies to phage, live biotherapeutic products and RNA.
- The project would consist of three fundamental pillars:
  1) Advancement of diagnostic tools for rapid diagnosis of bacterial infection
  2) Therapeutic development across a breadth of modalities for pre-clinical demonstration of emerging AMR candidates
  3) Integration within healthcare systems across Europe

- The project would be divided into modality/diagnostic streams which would run in parallel towards a pre-clinical end point. Estimated duration – 5 years

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Is your project suitable for IHI?

- **Need for public private collaboration:** The topic of better integration of diagnostic tests with treatment plans for infections is especially suited to pre-competitive collaboration due to the complexity and interconnectivity of the challenges. To make significant progress on this systemic challenge requires collaboration across a wide range of stakeholders to address a shared problem.
- **Industry Contribution:** Industry can play a key role in supporting novel therapeutics and diagnostics which are derived from academia, SMEs, and large organisations, translating their therapeutic/diagnostic to market

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Outcomes and Impact

- **Results/outcomes and impact**
  - Precision treatment of infections. Integration of diagnostics with targeted treatment
  - Integration of the pharmaceutical sector with healthcare systems and regulators across Europe to create a roadmap for AMR therapeutics and diagnostic adoption.
  - Reduced reliance on antibiotic use and ultimately hospitalisation rates/mortality
  - Enhanced public health and pandemic preparedness
  - Social benefits e.g. workforce productivity
- **Translation**
  - Industry will gain expertise and support universities, SMEs and other organisations translate their therapeutic/diagnostic to market
  - Development of regulation and precedence for translating novel modalities towards clinical development
  - Promotion of innovation in the pharma sector for AMR therapeutics
- **Strengthening the competitiveness of the Union's health industry**
  - Greater access within Europe to a suite of therapeutics to tackle the WHO priority pathogens (ESKAPE)
  - European health equity and access
  - Improved adoption in healthcare systems and global markets
- **Benefits for patients**
  - Improved patient outcomes
  - Reduced spread of resistant infections through early detection and treatment
  - Faster and more accurate diagnosis to provide early detection, leading to prompt treatment
  - Reduction in misdiagnosis and reducing misuse of antibiotics

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Expertise and resources

- **We have**:
  - CPI: Process development, CMC & scale-up
  - MHRA: Regulatory support, UK
  - University of Southampton: Raman based diagnostic for bacterial identification
  - UCL: Phage manufacture and regulation

- **We are looking for:**
  - Organisations with emerging modalities towards the prevention/treatment of antimicrobial resistance
  - Organisations with novel diagnostic methodologies for rapid, real-time identification of pathogens
  - Organisations with digital technologies to accelerate process development of one of more AMR relevant modalities
  - Healthcare groups within Europe (e.g. hospitals and clinical groups)
  - European regulators and surveillance groups

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