

Webinar | IMI2 - Call 7
‘Increase access and use of high quality data to improve clinical outcomes in heart failure (HF), atrial fibrillation (AF), and acute coronary syndrome (ACS) patients’

Gunnar Brobert; Maureen Cronin
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Background and outlook for IMI2 'Big Data to Improve CV Outcomes' Programme

- The Innovative Medicines Initiative (IMI), the world's largest public-private partnership in the life sciences, is a joint undertaking between the European Commission and EFPIA
- Long term goal: Re-invigorate the European bio-pharmaceutical sector and foster European pharmaceutical R&D
- One programme aims at using 'Big Data' to improve patient outcomes
- This proposal has been planned in cooperation with several EFPIA partners and approved by the European Commission

Need for public-private collaboration

Generating new knowledge to improve outcomes in individuals suffering from atrial fibrillation (AF), heart failure (HF) or acute coronary syndrome (ACS) requires a broad collaboration

- Private and public organisations as well as patients have to define what is needed from the partnership
 - Both private and public partners have relevant data
 - Public representation in particular ensures adequate governance to deal with ethical and legal issues
 - Input from patients and patient organisations into the governance, use of data and definition of meaningful outcomes is essential

Pre-competitive nature

- The neutral platform of IMI design allows pharma companies to collaborate with academia, payer, regulatory, patient organisations and other important stakeholder partners to facilitate discussions and recommendations on how to improve cardiovascular patient outcomes

Objectives of the full project

The main goal of this initiative is to improve AF, HF, and ACS patient outcomes through better access and use of data by:

1. Defining, identifying and analysing relevant information on:
 - Patient outcomes
 - Access and analysis of morbidity and mortality data from publically available sources
 - Collection of new and/or analysis of data from not yet publically available sources e.g.: clinical studies (both interventional and observational), genomic, protein biomarkers, and quality-of-life information

Objectives of the full project

2. Use advanced analytics to define algorithms/tools that combine traditional and newer sources of data to improve our ability to:
 - Assess the risk for relevant cardiovascular outcomes
 - Characterise patient subtypes (e.g biological drivers, risk factors & comorbidities)
 - Identify most effective treatments for these patient risk groups
 - Monitor & predict progression or regression of disease

3. Translate these insights into disease management concepts and guidelines, as well as innovative drug development projects

Expected impact

- The expected impact of this work are more effective and safer treatment paradigms for patients with AF, HF, and ACS
- This impact should be achieved by providing evidence which will make it easier for HCPs and other stakeholders:
 - *to provide the right treatment*
 - *to the right patient*
 - *at the right time*

Suggested architecture of the project

- The applicant consortium is expected to have a strategy on how to translate the relevant project outputs into healthcare practice
- It is expected that both private and public partners will have leading roles in the consortium
- The industry and public partners will jointly define the final architecture of the full proposal in the Full Proposal phase (Stage 2)
- Applicants should include their proposed expertise and activities for the overall strategy on how to translate the project outputs into healthcare practice, Work Packages¹ -7, and recommendations on the architecture of the project

Suggested architecture of the project

- Proposed work packages:
 - **1: Project coordination**
 - **2: Disease understanding and outcomes definition**
 - **3: Mapping, selecting and curating existing data**
 - **4: Data collection**
 - **5: Data analysis**
 - **6: Dissemination and communication**
 - **7: Ethics, legal aspects and data privacy**

Expected contributions of the applicants (1/2)

- Knowledge about and access to key cardiovascular relevant stakeholders: health care providers, patient groups, regulators, payers, HTA bodies, academia, and healthcare policy makers
- The applicant consortium is expected to be multidisciplinary and to enable effective collaboration between key stakeholders with the ability to engage with extended audiences
- The applicant consortium is expected to have programme management experience, such as project tracking and reporting, meetings, internal communication, and budget management
- The applicant consortium is expected to develop outreach and communication strategies for the stakeholders and the public at large

Expected contributions of the applicants (2/2)

- Expertise in:
 - Defining validated outcomes metrics and measurement tools
 - Population based research including data collection, informatics architecture, programming and data analysis techniques
 - Conducting research with large data sets from diverse databases
 - Integration and analysis of 'omic characterisation data together with relevant outcomes information
 - HTA/regulatory: drug approval and reimbursement procedure input, and comparative analyses of relevance

Expected contributions of EFPIA members

- Contribution of knowledge and expertise in the following areas:
 - Epidemiology, HEOR, biostatistics, health outcomes definitions & measurement tools, proteomics, genomics and analytical skills
 - Regulatory, HTA, payers, health care providers, patient groups incl. engagement via digital solutions
 - Project management
 - Pharmacovigilance, benefit/risk assessment, pricing and reimbursement
 - Data privacy law and related legal aspects
 - Medical affairs and health care communication, website mgmt.
 - Data/knowledge management, repository of knowledge
 - Public policy and governmental affairs

What's in it for you?

- Researchers/SMEs: Define algorithms to assess the risk for relevant cardiovascular outcomes, to characterise patient subtypes and biological drivers (e.g.; risk factors & comorbidities) of those risks, to identify most effective treatments for these patient risk groups, and to monitor for progression or regression of disease. Conceiving and writing relevant publications in peer reviewed journals
- Patient Organisations: Define patient relevant real world outcomes and help provide improved, reimbursed medications and prevention strategies
- Regulatory/HTA/Payers/Policy Makers: Generate outcome evidence to drive health care decisions

Key deliverables of the full project

- Definition of relevant cardiovascular patient outcomes in alignment with relevant stakeholders
- Identification of relevant data sources, strategy to access including coverage of data privacy and legal aspects and combine information for meaningful results
- Collect relevant missing data possibly including genomic and proteomic characterisation
- Advanced analyses of the data to develop algorithms to better target treatments to patients who would benefit the most from interventions
- Translate these insights into disease management concepts and guidelines, as well as innovative drug development projects
- Endorsement of these results by key stakeholders
- Implement a diverse communication programme on the results

Next Steps

- Applicants need to apply to IMI by 17 March 2016 – 17:00 Brussels time
- Evaluation of proposals: March to April 2016
- Selection: May 2016
- Final Proposal creation: May to August 2016
- Evaluation of Final Proposal: September to October 2016
- Approval: October 2016
- Grant Preparation: October to December 2016
- Grant Agreement signature: December 2016
- Project start: mid December 2016

Questions?

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infodesk@imi.europa.eu • www.imi.europa.eu

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