A European Medical Information Framework (EMIF) of patient-level data to support a wide range of medical research

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Need for public-private collaboration

• An increasing amount and detail of patient health data is required to advance research into disease including the study of special patient subgroups and rare events.

• Such data is currently fragmented across populations, healthcare providers and systems in Europe and data linkage is needed to form the required large and integrated data pool.

• Public-private collaboration is needed because of the scale of the task, the multitude of stakeholders involved as well as the range of skills and backgrounds needed. Furthermore, such integrated patient health data and disease insights will benefit organisations in both the public and private sector.
Objectives of the full project

• Three distinct topics
  1. Information Framework of patient health data
  2. Metabolic complications of obesity
  3. Predictors of Alzheimer’s Disease (AD)

• Topic 1 to provide the patient health data for research topics 2 and 3

• Topic 1 also to serve as the information base for other research into patient health

• Further research topics, supported by the Information Framework, to be put forward in subsequent IMI Calls
The EMIF framework has 2 dimensions:

- Vertical, the research projects
- Horizontal, the common service layer
Pre-competitive nature

• Project objective is to further the understanding of disease and disease management in support of drug development as well as clinical practice and public health.

• Discovery and development of new molecules is not within the scope of this project.

• Availability and access to project output to be governed by a clearly defined governance model.
Information Framework - Objectives

Develop the Information Framework that:

- provides access to the required patient level data in adults and children for the specific research topics;

- is sustainable and scalable to serve as the information base for further research projects that use patient health data following completion of this project;

- offers a governance model for all ethical and privacy related aspects.
A picture is worth a thousand words …
Specific objectives of Information Framework (2)

• In paediatrics provide
  – Detailed inventory and description of different data sources
  – Access to paediatric patient level data for the research project in obesity
  – Future platform for further research projects
  – Governance model for ethics

• For
  – Better insight in paediatric epidemiology
  – Better targeted therapeutics in paediatrics
Information Framework - Architecture

EMIF governance

TA- workstream
- Metabolic
  - Complications of obesity
  - Patient generated data
  - Risk stratification
- AD markers of onset
  - Risk factor analysis
  - Prevention algorithms
  - Predictive screening

TA- workstream
- CNS
  - Call 5
- Call 5
- TBD

IMI Structure and Network

Research activities focusing on application of specific methodologies

Data Privacy
Analytical tools
Semantic Technology
Information standards
Data access / mgmt

Common Service layer
Information Framework – project structure: Work Packages (WPs)

- WP1  Governance and Business model
- WP2  Landscape exploration
- WP3  Legal context
- WP4  Architecture and Solution development
- WP5  Data protection, privacy and security
- WP6  Data preparation and integration
- WP7  Analytical methodologies
Information Framework – Expectations Consortium

• Access to Patient-level health data sources, including adult and paediatric data and access to patients if possible

• Planning, design & execution of work activities including lead in specific areas

• Expertise and capabilities in
  – evaluating patient health data quality
  – health-related research informatics
  – electronic health data linkage (semantic interoperability)
  – patient health data management and analysis
  – governance of access to linked-up patient-level health data including solutions in the domains of data privacy, ethics.
Information Framework – EFPIA Contributions

- Business model knowledge
- Vision development (Future Sketching)
- Programme management
- Overview of existing data-networks
- Available patient-level data relevant to research projects
- Leverage of contacts leading to patient-level data
- Legal support
- Experience in working with ethical committees
- Leverage from other IMI projects
- Expertise in data management and in data standards
- IT architecture expertise
- Expertise in analysis of longitudinal patient records
- Analytical platforms that could be embedded in EMIF framework
Specific objectives and deliverables of the obesity research topic

Objectives

• To discover predictors of the metabolic complications diabetes and fatty liver in childhood/adult obesity by using an extreme phenotype approach

Deliverables

• A detailed understanding of the variability of metabolic complications in the childhood and adult obese population including identification of the subgroups on either extremes of the distributions
• Effects of constitutional, environmental and obesity-specific risk factors
• Genetic, epigenetic and metagenomic susceptibility markers
• Identification of high-risk individuals and development of an algorithm for a diagnostic test
• Possibly novel targets for future therapeutic interventions
Specific objectives of the obesity research topic – additional focus on paediatrics

- Specify criteria for overweight and obesity for all classes of ages from birth to adolescence

- Discover biomarkers (including omics) to predict metabolic complications of obesity in paediatrics
Expected contributions of the applicants for the obesity research topic

- Access to relevant patient-level health data and access to patients if possible
- Planning, design & execution of studies including lead in specific areas
- Expertise and capabilities in
  - (molecular) epidemiology
  - clinical practice and research in the metabolic therapy area
  - genetics and the extreme phenotype approach
  - metabolomics and other ‘omic sciences
  - paediatrics, in particular in metabolic diseases, and design of relevant research studies
  - analysis of patient-level health data
  - development of relevant diagnostic tests
  - clinical trial execution.
Expected (in kind) contributions of EFPIA members for the obesity topic

- Identification and evaluation of relevant patient-level health data sources
- Planning, design & execution of studies including lead in specific areas
- Expertise and capabilities in
  - (molecular) epidemiology and statistical methodology
  - research in the metabolic therapy area
  - genetics and the extreme phenotype approach
  - ‘omic sciences including access to ‘omic technology platforms
  - paediatrics and design of relevant research studies
  - management and analysis of patient-level health data
  - planning, design and conduct of clinical trials
  - project coordination and management including governance model
  - communication strategy and dissemination of results.
Specific objectives and deliverables of the Alzheimer’s Disease research topic

Objectives

• To discover predictors of Alzheimer’s Disease (AD) including AD progression by using an extreme phenotype approach

Deliverables

• A detailed understanding of the variability of AD onset and progression in the general population and in patients with mild cognitive impairment, including identification of patients on either extremes of the distributions
• Effects of constitutional, environmental and disease-specific risk factors
• Genetic, epigenetic and metagenomic susceptibility markers
• Identification of high-risk individuals and development of an algorithm for a diagnostic test
• Possibly novel targets for future therapeutic interventions
Expected contributions of the applicants for the Alzheimer’s research topic

- Access to relevant patient-level health data and access to patients if possible
- Planning, design & execution of studies including lead in specific areas
- Expertise and capabilities in
  - (molecular) epidemiology
  - clinical practice and research in the Dementia therapy area
  - genetics and the extreme phenotype approach
  - metabolomics and other ‘omic sciences
  - CNS imaging
  - analysis of patient-level health data
  - development of relevant diagnostic tests
  - clinical trial execution.
Expected (in kind) contributions of EFPIA members for the AD topic

- Identification and evaluation of relevant patient-level health data sources
- Planning, design & execution of studies including lead in specific areas
- Expertise and capabilities in
  - (molecular) epidemiology and statistical methodology
  - research in the Dementia therapy area
  - genetics and the extreme phenotype approach
  - ‘omic sciences including access to ‘omic technology platforms
  - management and analysis of patient-level health data
  - planning, design and conduct of clinical trials
  - project coordination and management including governance model
  - communication strategy and dissemination of results.
Research topics – project structure: Work Packages (WPs)

WP1 Define data requirements & evaluate suitable data sources
WP2 Characterise the study population
WP3 Identify extreme phenotypes
WP4 Characterise extreme phenotypes
WP5 Validate findings in the general population
WP6 Identify and select individuals for treatment
WP7 Project management and communication
What’s in it for you?

- Access to a broader network of researchers and data users within a clearly-defined, safe and sustainable governance model
- Provides additional opportunities for research collaborations covering a range of areas including paediatrics
- Collaborations with a wide range of subject matter experts
- Common standards may enhance data collection, validation and management processes for the individual data sources
- Access to a large patient pool with integrated and in-depth health information
- The number and range of stakeholders involved enables research projects, including future projects, that would not be possible in smaller settings.
Thank You!

For further questions, please contact the IMI central office

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