



Innovative Medicines Initiative

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

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efpia

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Need for public-private collaboration



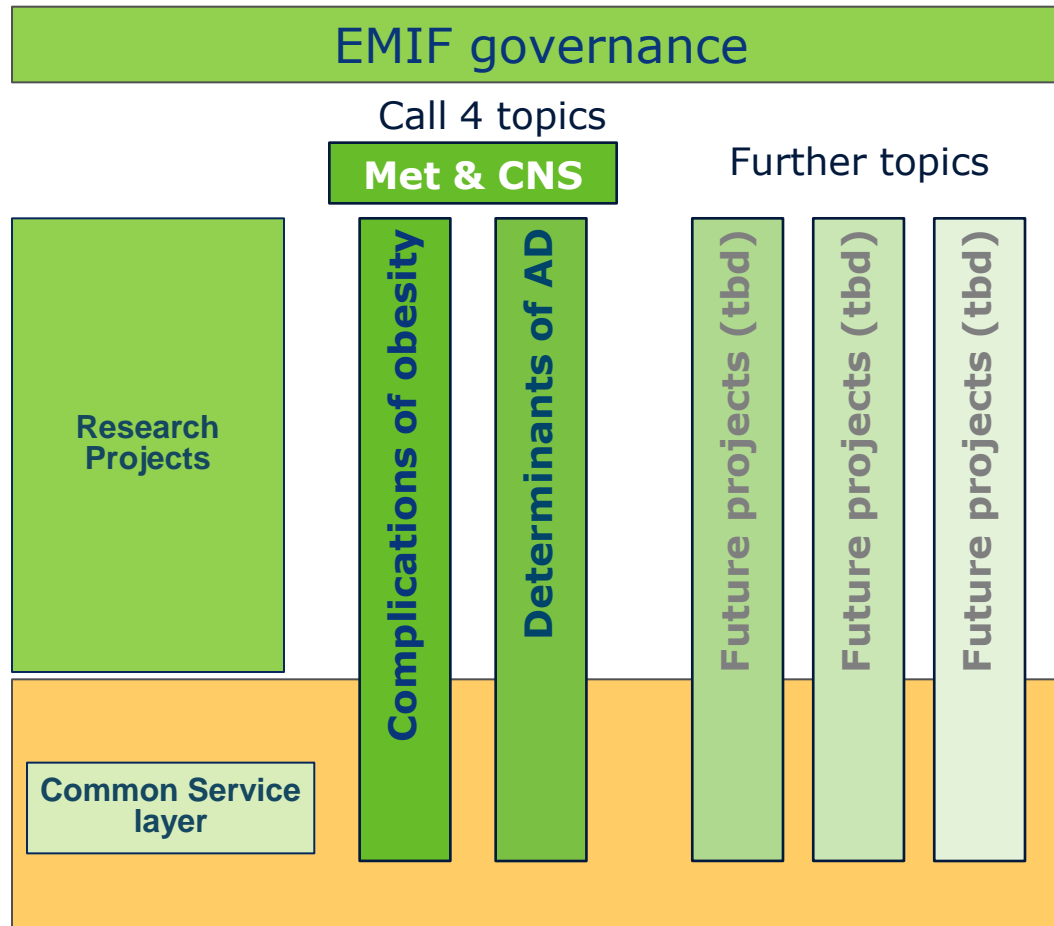
- An increasing amount and detail of patient health data is required to advance research into disease including the study of special patient subgroups and rare events.
- Such data is currently fragmented across populations, healthcare providers and systems in Europe and data linkage is needed to form 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

Information Framework - Structure



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.

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

<ul style="list-style-type: none">– Better insight in paediatric epidemiology– Better targeted therapeutics in paediatrics

Information Framework - Architecture



EMIF governance

TA- workstream TA- workstream TA- workstream

Metabolic Call 5 **CNS** Call 5 **TBD**

Research activities focusing on application of specific methodologies

Complications of obesity

Patient generated data

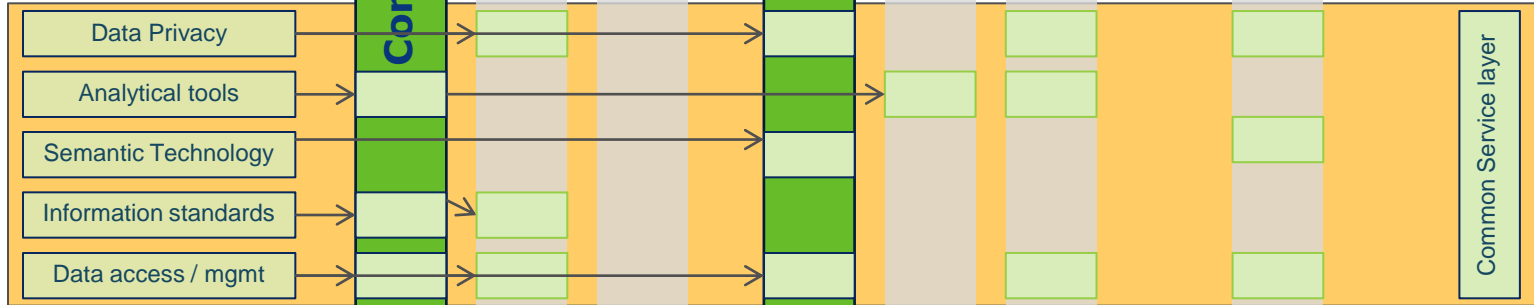
Risk stratification

AD markers of onset

Risk factor analysis

Prevention algorithms

Predictive screening



Common Service layer

IMI Structure and Network

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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