Webinar | IMI2 – Call 12
European Health Data Network

13.07.2017 • 11:30 CEST

Webinar | IMI2 - Call 12
European Health Data Network (EHDN)

Iwona Jablonska
IMI webinar • 13.07.2017

Today's webinar

Will cover all aspects of the Call topic

- Introduction to IMI programme
- Proposed project
  - Objectives, Need for public-private collaborative research
  - Key deliverables
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium

Will not cover rules and procedures

- A webinar on rules and procedures will take place on
  Monday 17 July, 14:30-16:00
- Register here

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IMI – Europe's partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

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IMI 2 budget (2014 – 2024)

EU funding goes to:

- Universities
- Hospitals
- SMEs
- Mid-sized companies
- Patient groups

€1.638 bn

efpia

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other €213 m

Associated Partners e.g. charities, non-EFPIA companies

IMI 2 total budget €3.276 billion

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IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients' lives

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges**.

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How a topic is generated

Industrial partners align themselves around a real challenge for industry and agree to work together **and commit resources**

New ideas from public sector, universities, SMEs etc. are needed to address the challenge

Scale is a key to success and is provided through IMI funding

Outcomes should be transformative for the industry as well as having a clear “public” value

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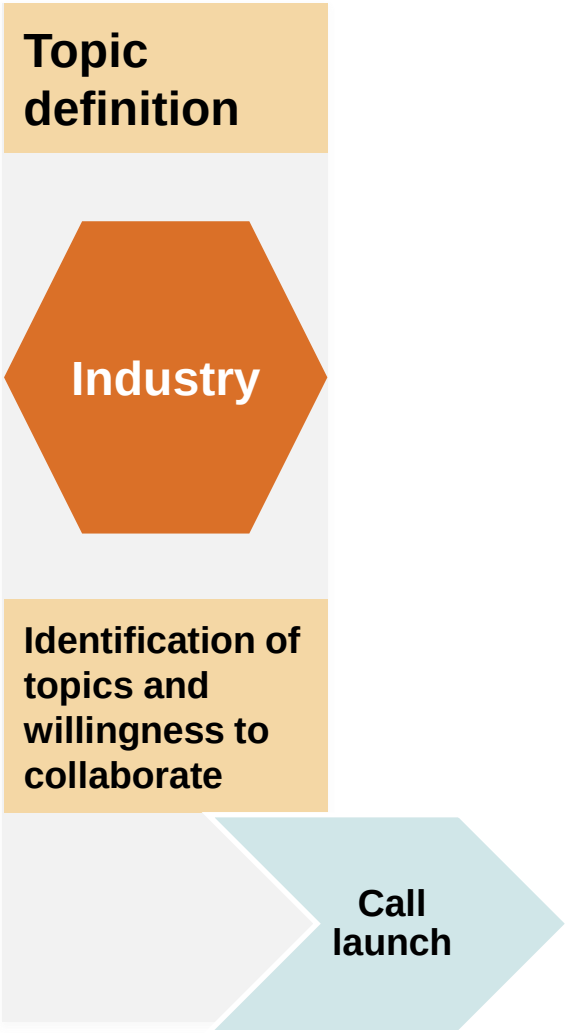
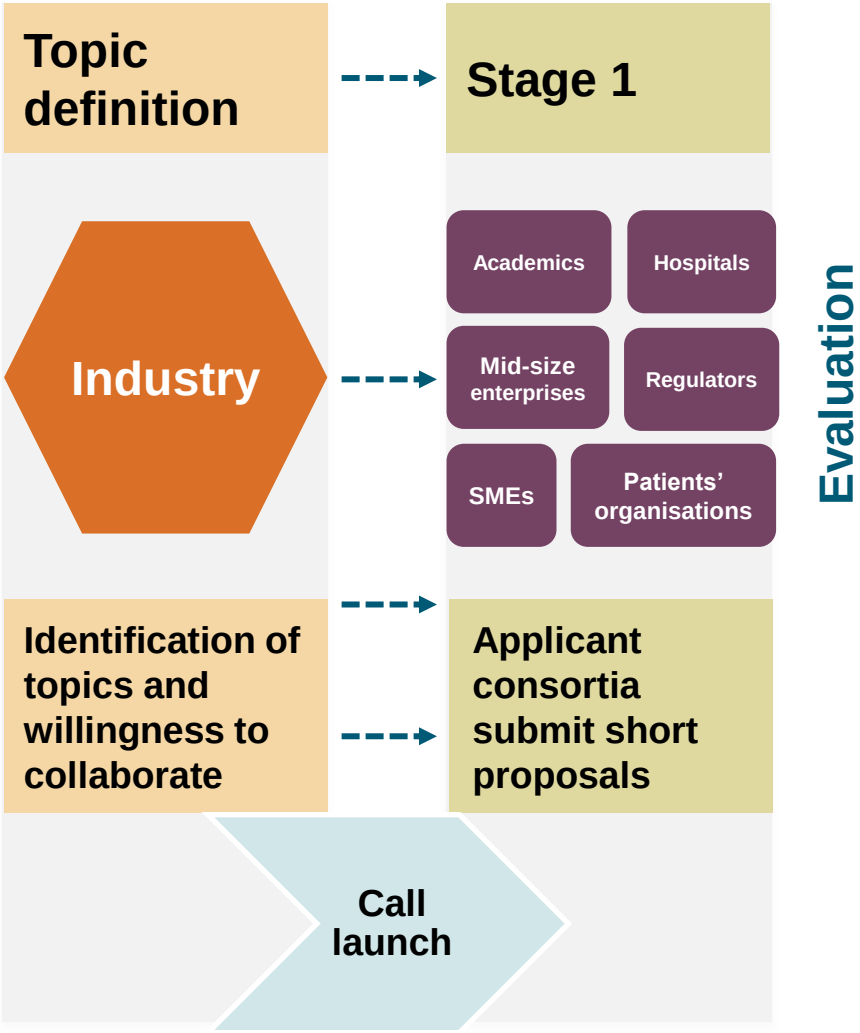
Typical IMI project life cycle



Typical IMI project life cycle



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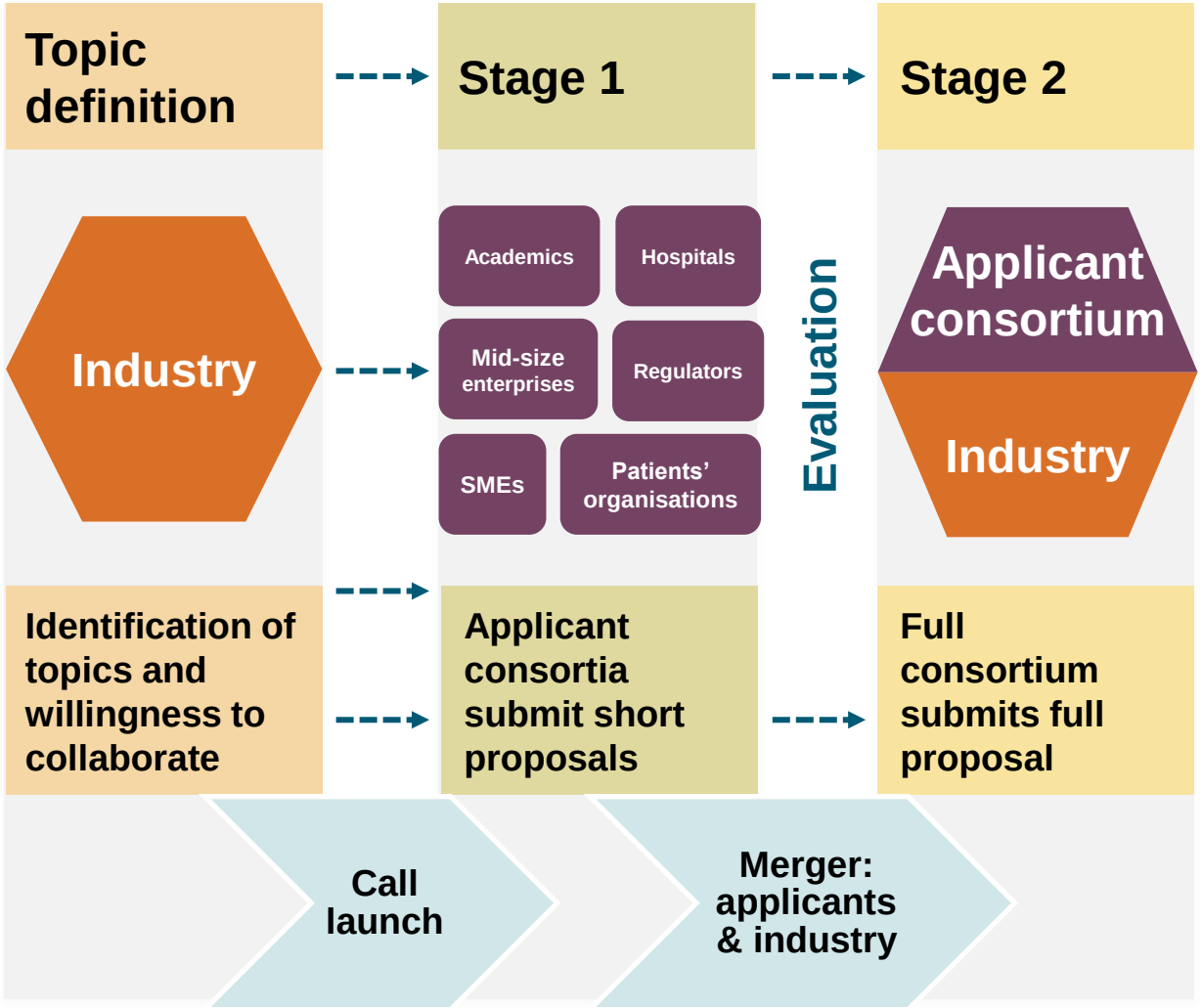
Typical IMI project life cycle



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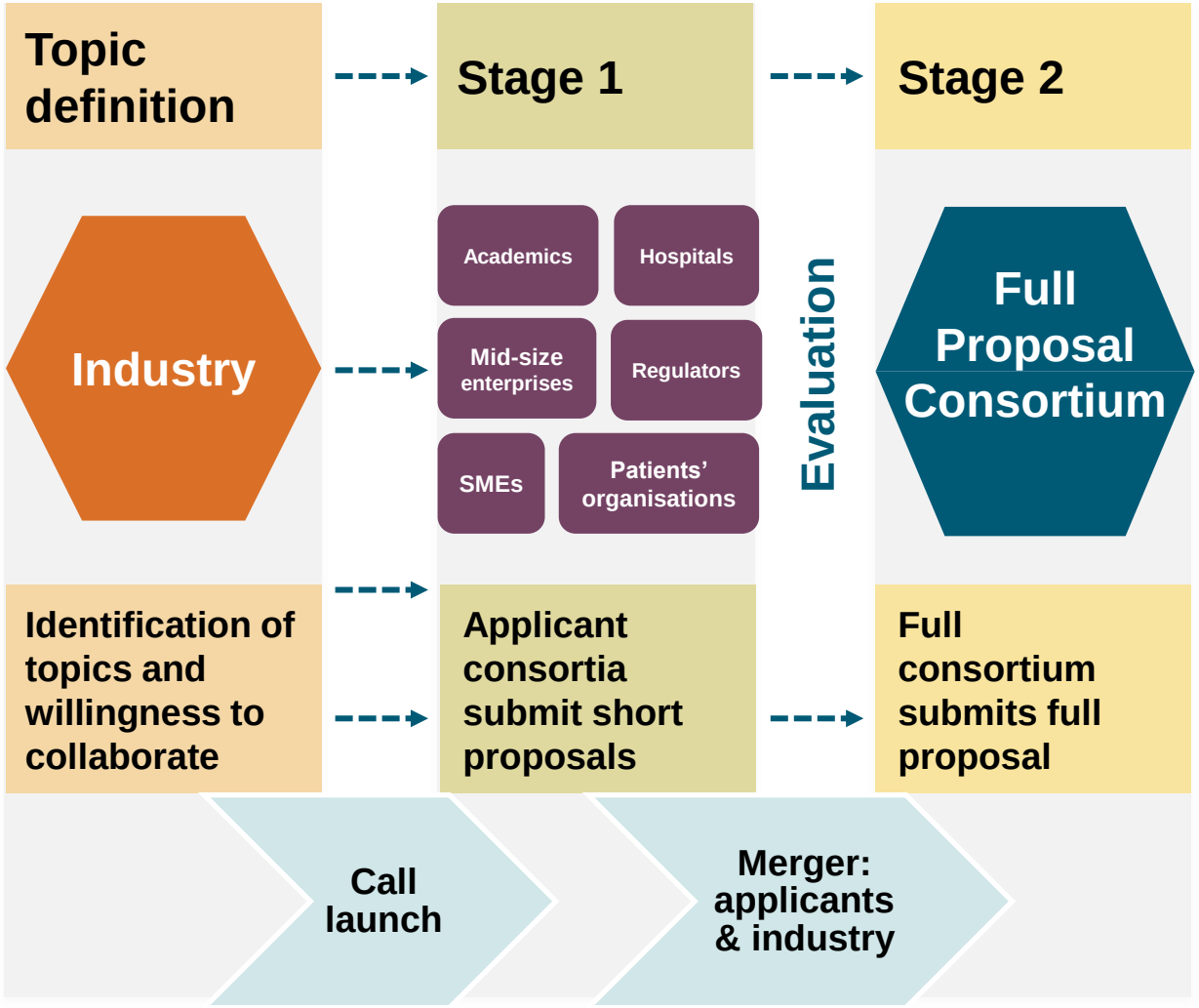

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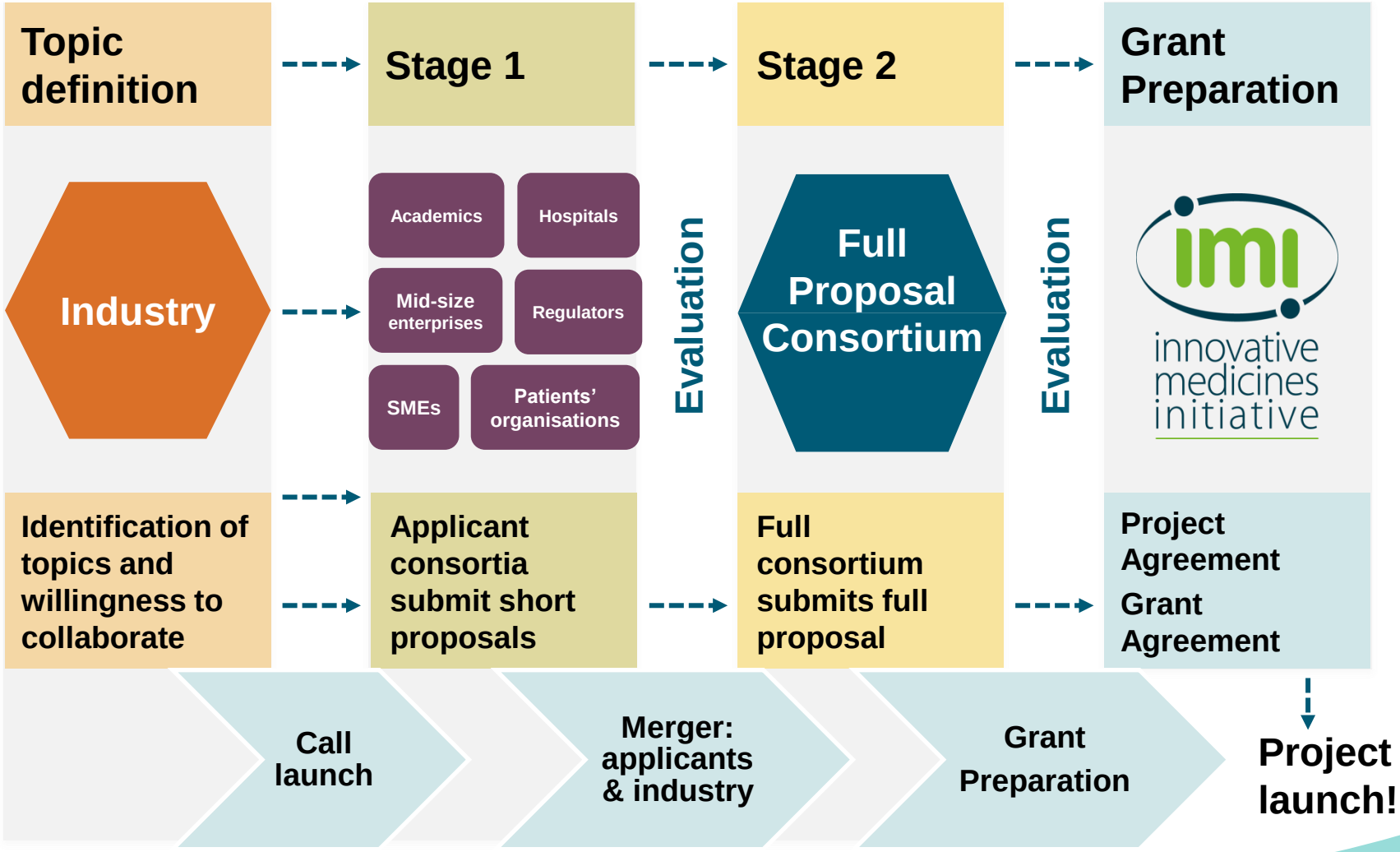
Typical IMI project life cycle



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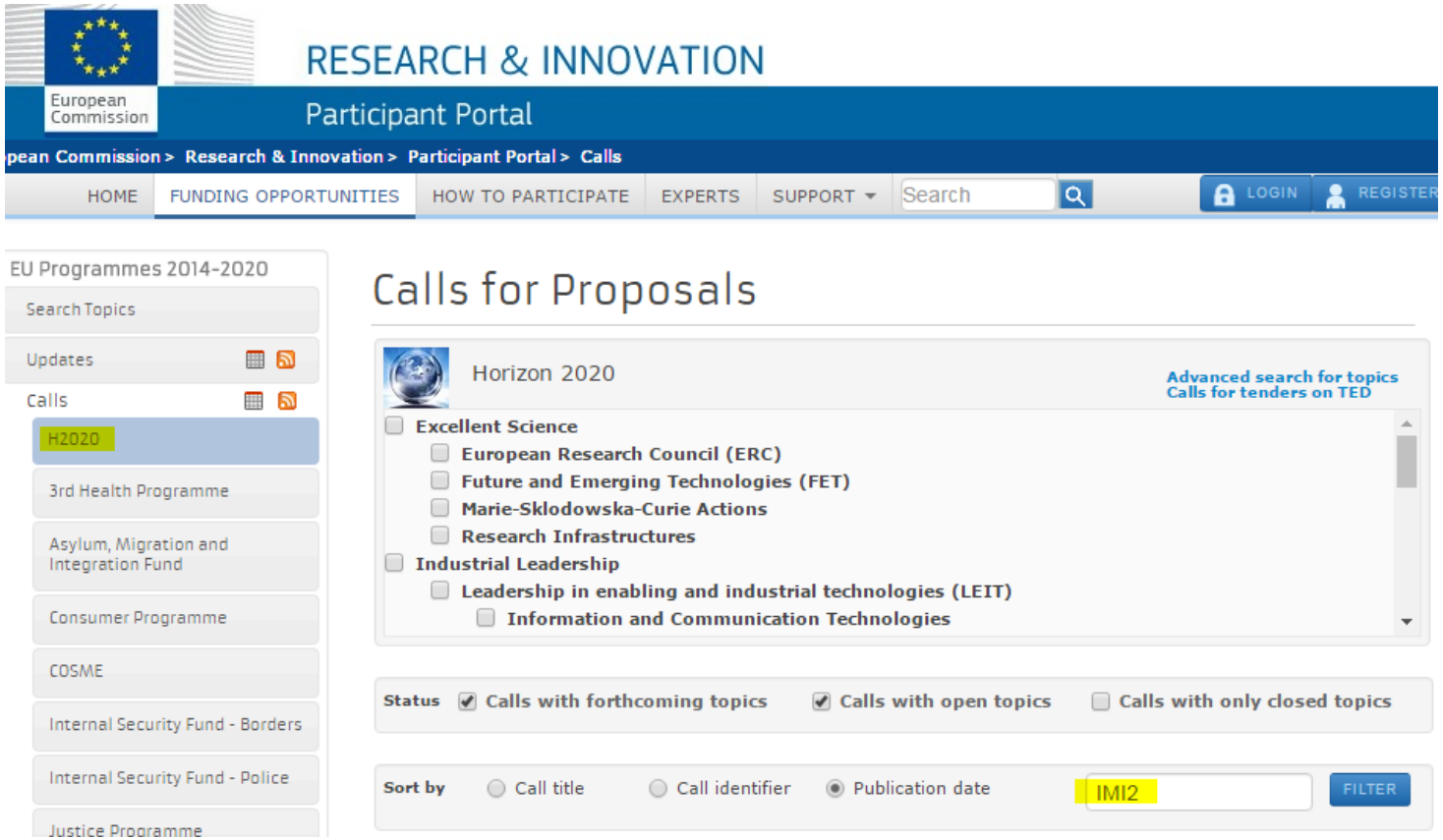
Submitting a proposal

- https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/index.html



Proposal Template

- Available on IMI website & H2020 submission tool
- For first stage proposals, the page limit is **30 pages**.

Title of Proposal

List of participants

Table of Contents

1.	**EXCELLENCE**	**3.**	**IMPLEMENTATION**
1.1	Objectives	3.1	Outline of project plan — Work packages, and major deliverables
1.2	Relation to the call topic text.	3.2	Management structure and procedures
1.3	Concept and approach	3.3	Consortium as a whole
1.4	Ambition	3.4	Table 3.1a: List of work packages
2.	**IMPACT**	**4.**	**PARTICIPANTS**
1	Expected impacts	4.1.	Participants (applicants)

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Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the proposal to meet all key objectives of the topic;
  - Credibility of the proposed approach;
  - Soundness of the concept, including trans-disciplinary considerations, where relevant;
  - Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art;
  - Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.
- **Impact**
  - The expected impacts of the proposed approach as mentioned in the Call for proposals;
  - Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant;
  - Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
  - Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget;
  - Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal;
  - Appropriateness of the proposed management structures and procedures, including manageability of the consortium.

Tips for writing a successful proposal

- Read **all the call-relevant material:**
  www.imi.europa.eu
- Begin forming your consortium **early**
  Partner search tools & networking events
- Provide **reviewers** with all the information requested to allow them to evaluate your proposal
- **Finalise and submit your proposal early**
- Contact the **Programme Office** (**NOT** topic writers):
  infodesk@imi.europa.eu

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Common mistakes

- Admissibility/Eligibility criteria not met**:**
  - submission **deadline** missed
  - minimum of **3 legal entities** from **3 H2020 member & associated states** not met
- The proposal does **not address all the objectives** of the topic
- A proposal is **scientifically excellent** but will have **limited impact**
- **Complementarity** with Industry consortium not well described.

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Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools:**
  - IMI http://www.imi.europa.eu/content/partner-search
  - German NCP version: http://www.imi-partnering.eu
  - Fit for health: http://www.fitforhealth.eu/
- Get in touch with your **local IMI contact point**: www.imi.europa.eu/content/states-representatives-groups
- Talk to your **Health National Contact Point** (NCP)
- Network on **social media** (e.g. IMI LinkedIn group)

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SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

For example, being closer to the market, SMEs can drive the tangible outputs of the project, and help ensure these outputs are sustained beyond the project lifetime and therefore help lead to faster impact on healthcare.

Therefore, where possible, include SMEs in your Short Proposal

Topic IMI2-2017-12-04: European Health Data Network (EHDN)

Nigel Hughes & Michel Van Speybroeck

13.07.2017 • IMI webinar

Need for public-private collaboration

- To work and connect with real world data is necessarily collaborative and multidimensional in challenges
- In an increasing value and outcome-focused domain in healthcare, evidence is the critical enabler to an informed process of care delivery and optimal outcomes for patients
  - There are many and varied actors in this
  - Building on IMI1 programmes, e.g. EHR4CR, EMIF, ADVANCE, GetReal and other FP7 programmes, we will be utilising the outputs of those PPPs, the relationships and their contributions
- There is a complex relationship between data custodians and data users, 80% of which is sociological, and 20% technological
- EHDN will be supporting the PPP BD4BO initiative programmes
- *Not one data source is the whole truth in the real world*

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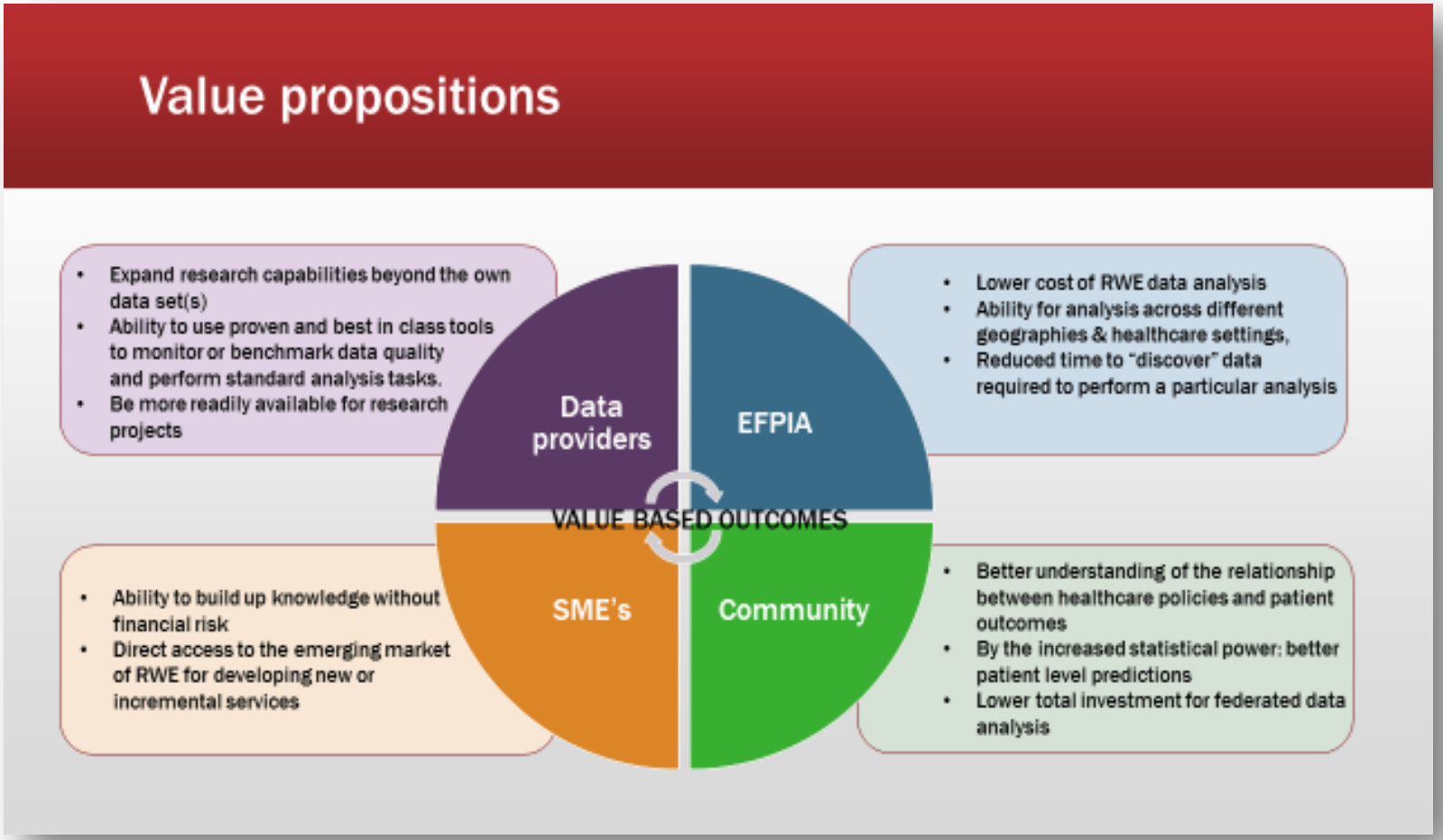
Need for public-private collaboration



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Objectives of the full project:

'You cannot change, what you do not measure'

- *The first goal of the EHDN is to implement the approaches pioneered in these earlier research projects and develop a standard methodology*

- *The second goal of EHDN is to help mature both the supply side and the demand side of this 'health data eco-system' in compliance with robust privacy and ethics governance*

- *The third goal of EHDN is to stimulate* development of new and augmented health services through available and expanded technologies, in the interest of health outcomes

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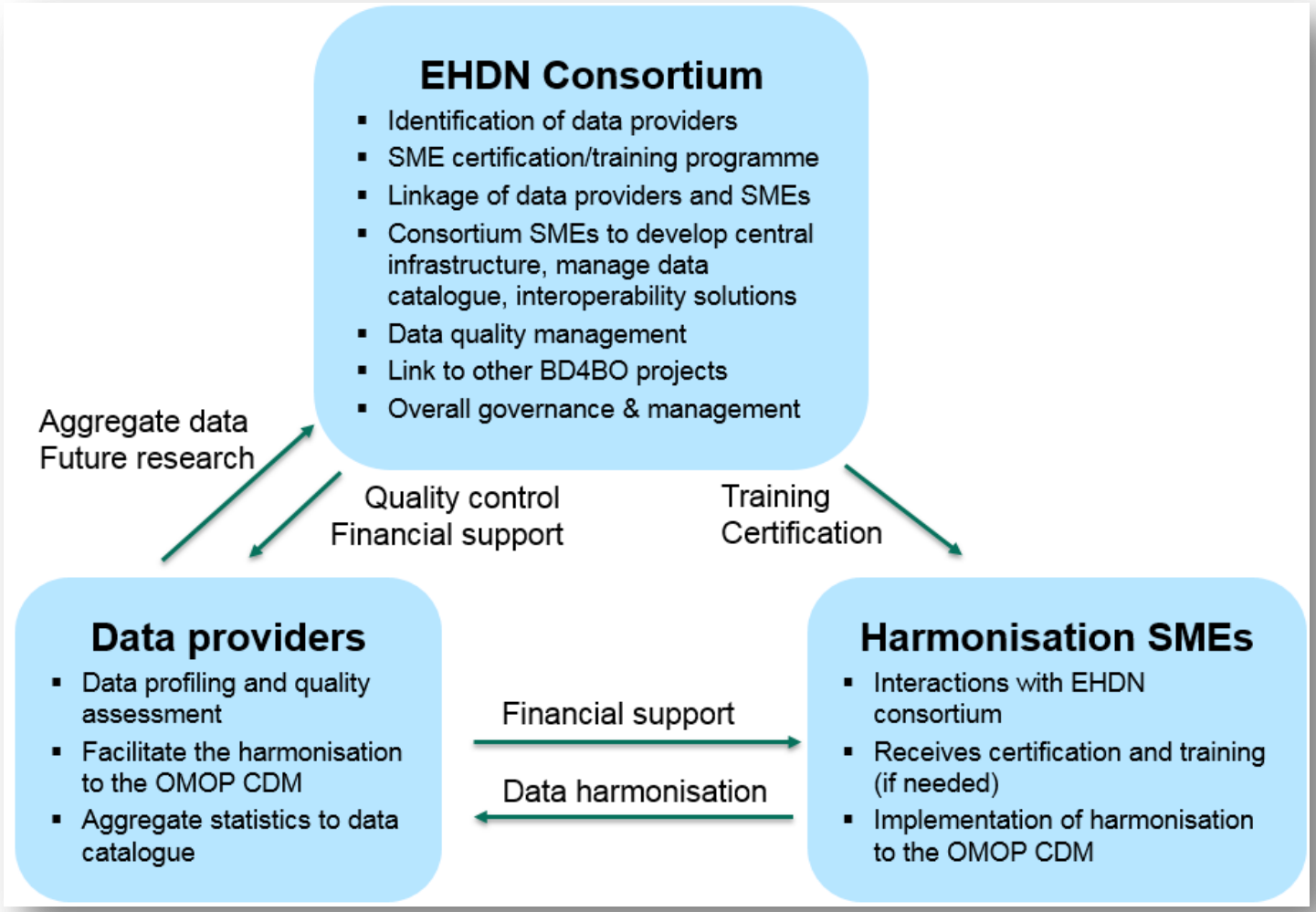
Objectives of the full project



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Pre-competitive nature

- EHDN will be conducted as per all IMI programmes in a pre-competitive environment:
  - The programme requires diverse collaboration for the development of an underpinning data network supportive of a value-based research ecosytem for all actors in this domain:
    - It is primarily focused on real world data and infrastructure, and not on explicit health research
    - Data and analytical methodologies for transitioning varied real world data to real world evidence
    - EHDN is an enabler for other BD4BO research projects

Expected impact

- **Pivotal:** Network of diverse data sources facilitating increasing requirement for real world evidence to support expanding value-based and outcomes-focused healthcare delivery in Europe

- **Critical:** Technology deployment based on prior or relevant programmes (e.g. EHR4CR, EMIF, ADVANCE, OHDSI/OMOP) to facilitate the bi-directional relationship between data custodians and data users

- **Enablers:** Evolution of research methodologies, inclusive of harmonisation, to meet the evidence challenge of value and outcomes-based care within the context of multi-centre, real world, observational research

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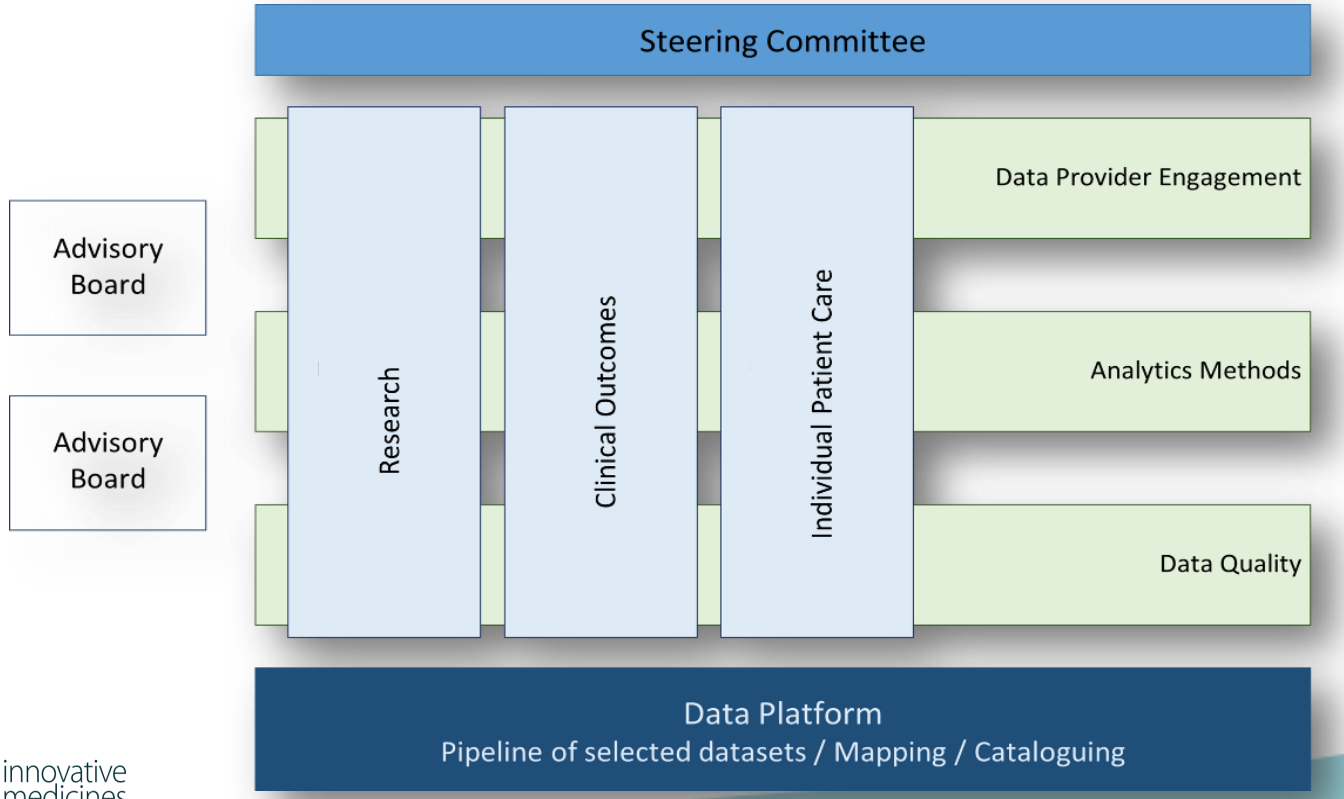
Suggested architecture of the project

- The emphasis within EHDN is focusing on simplicity of structure and activity, with pivotal horizontals supporting the verticals, based on a critical foundation of network data



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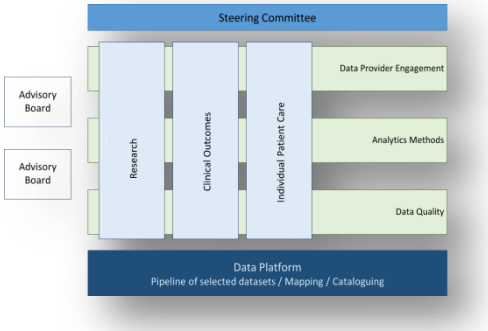
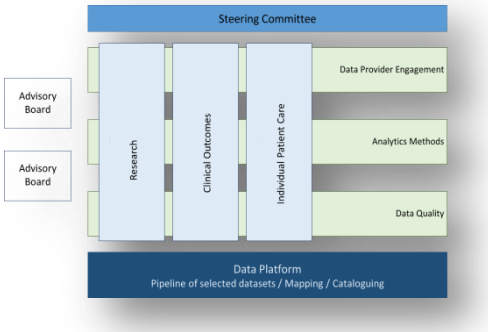
Suggested architecture of the project



- **Work Package 1: Methodological Research**
  - Federated network creation
  - Data harmonisation, evaluation and quality benchmark
  - Evidential linkage with Regulators, HTAs
  - *From technology to RWE*



- **Work Package 2: Health care system efficiency – outcomes based models**
  - Definition/integration of disease specific outcomes in the distributed data network
  - A process for sharing/monitoring defined outcomes
  - Application of outcomes in future business models
  - Coordinate with BD4BO projects
  - Engagement with HTA bodies, Regulators
  - *From RWD to outcomes*

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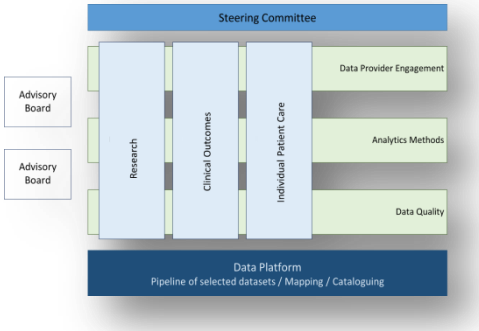
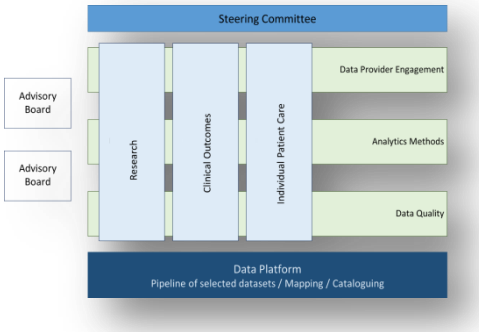
Suggested architecture of the project



- **Work Package 3: Individual patient care**
  - Diversification of representative data sources, e.g. digital health markers, PROs
  - Federated analytics, and clinical-decision making
  - Governance, law, policies and SoPs
  - *Innovation and novelty in engagement & insights*



- **Work Package 4: Technical implementation**
  - Continuation of EMIF Data Catalogue
  - Data harmonisation and dataset standardization
  - Quality management framework to evaluate data sets and harmonisation results
  - Collaborate with BD4BO projects
  - Delivering with outputs from relevant IMI programmes
  - *Technologies deployment to create RWE*

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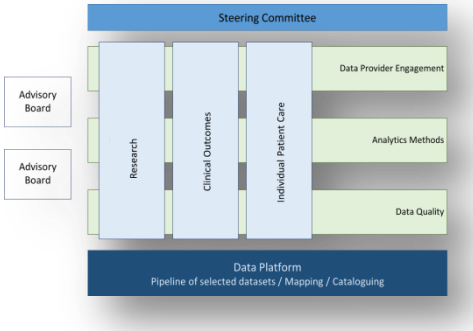
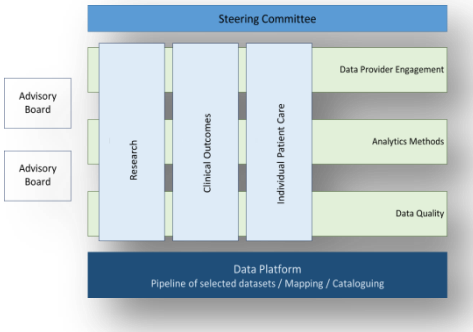
Suggested architecture of the project



- **Work Package 5: Governance and adoption**
  - Shaping of EHDN governance
  - Optimising governance integration (EMIF ECoP)
  - Coordination with BD4BO DO-IT (CSA)
  - *Ensuring RWE with federated provenance*



- **Work Package 6: Overall project governance, project management, dissemination and sustainability**
  - Programme governance across work packages
  - Project Management Office
  - Internal/external communications
  - Development of the EHDN sustainability model
  - *Prudence in EHDN development and delivery*

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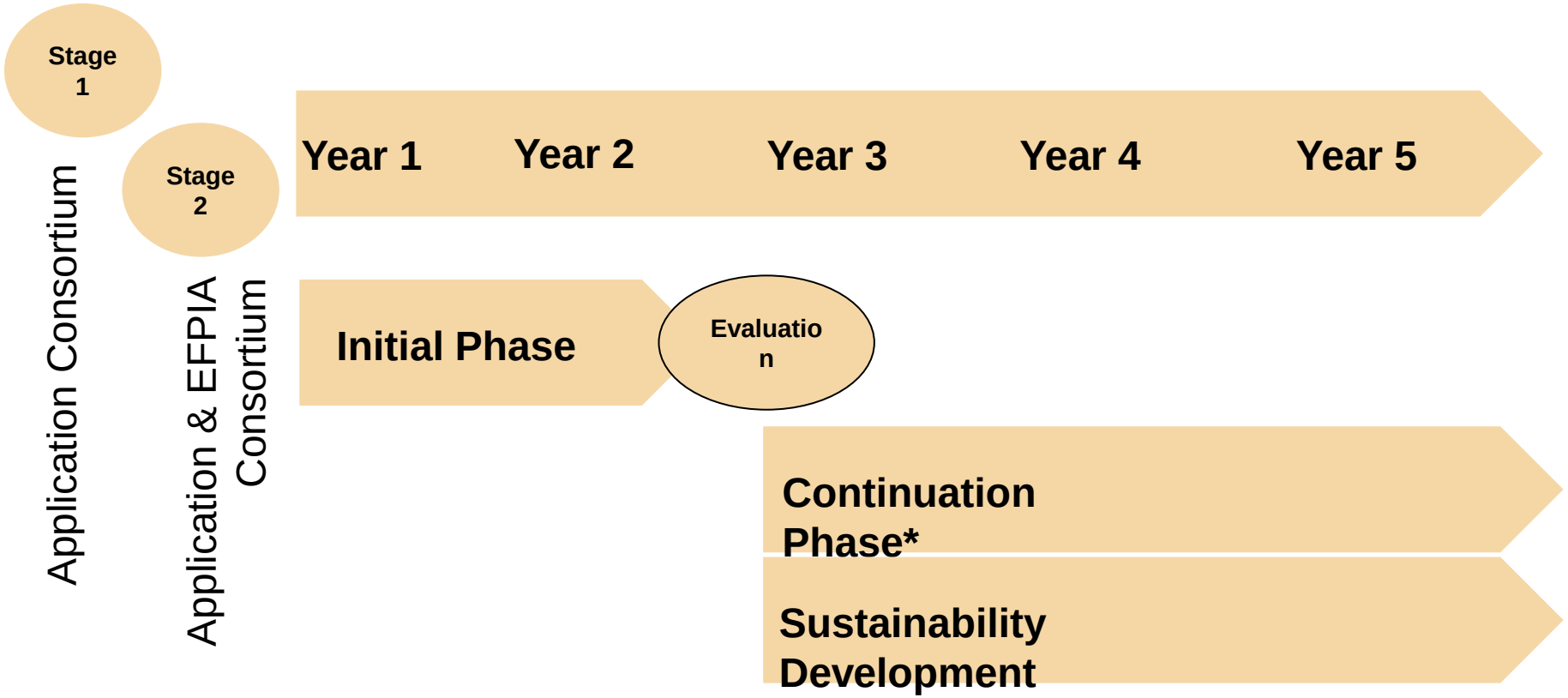
Suggested architecture of the project



* Potential for further IMI in-programme call for proposals

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Expected contributions of the applicants

- **A limited number of Public Partners (ideally up to 3):**
  - Advocates for RWD, and the rationale for EHDN
  - Geographic representation
  - Practical experience of RWD and relevant data standards
  - Prior and existing networks
  - Validators of EHDN methodologies
  - Expertise and experience with e.g. OHDSI/OMOP CDM, ICHOM standards, FAIR principles
  - Data quality evaluation/benchmarking
  - Prior experience of PPPs or similar collaborative data projects

Expected contributions of the applicants

- **A limited number of technical SMEs (ideally up to 3) require:**
  - Experience of progenitor projects (not necessarily IMI) in developing key components of a federated network
  - Experience with healthcare coding, vocabulary mapping, commercial or open source, or delivery of same in similar projects
  - Technical capability to develop and improve interoperability solutions across providers, standards and structures
  - NOT harmonisation, which is conducted by third party non-partner SMEs

Expected contributions of the applicants

- **Recommended partner representation:**
  - Involvement of Regulatory and HTA organisations
    - Advisory capacity, with learning from e.g. IMI GetReal
  - Pan-European patient advocacy group
    - Participation in relevant work packages (e.g. 2 and 3)
- **Specific proof of concept evaluations (examples)**
  - Federated analytics vs. local analytics (distributed statistical analysis, machine learning)
  - Liberating unstructured data for analysis

Expected (in kind) contributions of industry consortium

- Collaborative full proposal development at Stage 2
- Programme and work package co-leadership
- EFPIA consortia active engagement and participation
- Support for data harmonisation programme
- Expertise:
  - Technical
  - Methodological
  - Market Access & Outcomes Research
  - Regulatory/HTA
  - Governance, law and policy
  - Project Management
  - Communications
- Sustainability/business case development

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Financial Support to Third Parties

- Data providers will mostly be third parties, e.g. hospitals, who are not part of the consortium and that would be recruited during the project lifetime through open calls.
- Data must be harmonised to the common data model. Funding for these activities will be provided via '*financial support for third parties'* to data providers who will ensure data harmonisation. The data harmonisation will be normally done by qualified SMEs hired by the data providers, i.e. primarily third parties.
- In Short Proposals, applicants should allocate the funds needed to such third parties under the 'financial support for third parties' column of the coordinator's budget
- In the Full Proposal, the applicants should develop open, transparent, objective processes for the allocation of this financial support & prizes in accordance the GA clauses 15.1 & 15.2

What's in it for you?

- **Academic Researchers:**
  - Opportunity to collaborate on shaping the European research environment for the 21st century, fit for purpose and fit for outcomes
- **SMEs (partner and third-party):**
  - Driving the European research environment based on cutting edge technologies, methodologies and practices
- **Patient Organisations:**
  - Ensuring the voice of patients/citizens is incorporated in this cornerstone PPP for European health research, impacting from discovery to health outcomes

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What's in it for you?

- **HTA bodies/Regulators**
  - Creation of a RWD federated network with quality assurance to support incorporation of RWE within pre and post authorisation requirements, while shaping the European response to value and outcomes based healthcare

- **Third party data sources**
  - Collaboration within a federated network to facilitate a bi-directional relationship on research, audit and benchmarking, while shaping the European response to value and outcomes based healthcare

Key deliverables of the full project

- An open, transparent call process for third party data providers
- Financial support for mapping to OMOP common data model
- Delivery of an operational, federated network equivalent to a representative 20% of the EU population, or approximately 100 million people (~200 data sets)
- Data quality management framework, supportive of both validation and benchmarking
- European SMEs with relevant experience in innovative services for data providers and/or consumers
  - Certification of these SMEs across the RWE technical continuum
- EHDN project governance for engagement of third party datasets, oversight of data harmonisation and interaction with BD4BO

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Thank you

Contact the IMI Programme Office
infodesk@imi.europa.eu • www.imi.europa.eu

www.imi.europa.eu
@IMI_JU

SME / patient involvement
Financial support to third parties

Iwona Jablonska
IMI webinar • 13.07.2017

SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

In particular, in this topic, SMEs can participate by bringing:

- Technical skills necessary to maintain and further develop the key infrastructural components, including the data catalogue solution
- The technical knowledge to support extensions of the vocabulary mappings

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Patient Participation

There are many ways you can improve project performance by working with your patient partners:

- At least one partner should be a pan-European patient advocacy group, in order to build trust and engage patients proactively in the definition of health outcomes driven use case selection.
- Participation of patient representatives would be very useful in e.g. WP 2 and 3.

"The patient, doctor and researcher – each is a different kind of expert."

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Questions?

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