Topic: European Health Data Network (EHDN)

All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

Topic details

Action type	Research and Innovation Actions (RIA)
Submission & evaluation process	2 Stages

Part of the Big Data for Better Outcomes Programme (BD4BO)

Introduction to the BD4BO programme and problem statement

The IMI2 Big Data for Better Outcomes (BD4BO) programme aims to catalyse and support the evolution towards value-based, more outcomes-focused, sustainable and therefore better quality healthcare systems in Europe. Exploiting the opportunities offered by the wealth of emerging data from many evolving data sources via the generation of methodologies with real world data - will inform European decision-making in healthcare and policy debates. The programme's objectives are to maximise the potential of large-scale, harmonised data from variable, quickly-developing digital and non-digital sources which will be referred to as 'big data' in the context of this initiative.

This programme will provide a platform and resources for defining and developing enablers of the outcomes transparency evolution, together with patients, payers, physicians, regulators, academic researchers, healthcare decision makers, etc. The key enablers are:

- definition of outcome metrics;
- protocols, processes and tools to access high quality data;
- methodologies and analytics to drive improvements, digital and other solutions that increase patient engagement.

The following topic (the European Health Data Network) sits within the BD4BO Programme.

BD4BO Programme structure

The programme is composed of several topics which will be key enablers for the transition of healthcare systems towards more outcomes transparency, including an over-arching coordination structure (through a Coordination and Support Action (CSA) implemented by the DO-> IT consortium), several disease/therapeutic area (TA) topics focusing on a specific disease, population, therapeutic area or technology (HARMONY (http://www.imi.europa.eu/content/harmony), ROADMAP (http://roadmap-alzheimer.org/), BigData@Heart) and this European Health Data Network topic.

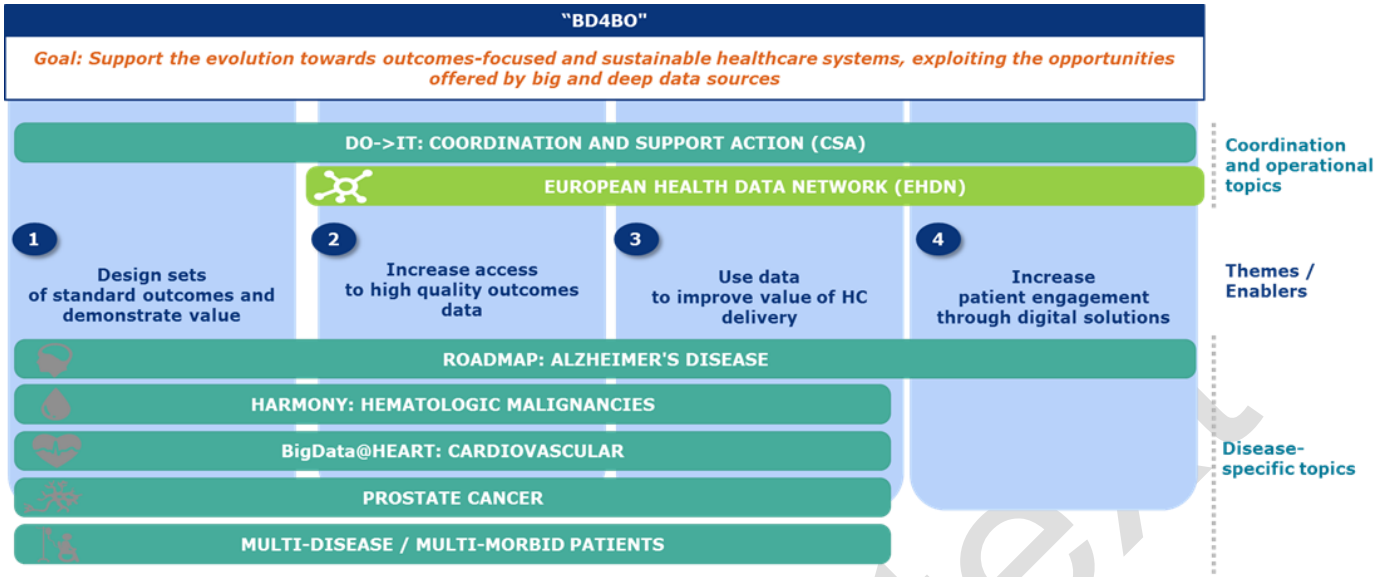


Figure 1: Programme structure, themes / enablers and CSA

The success of the overall BD4BO programme will rely on a coordinated approach across projects to ensure strategic alignment and consistency and to define new business and health funding models (including incentive models) that will allow for healthcare systems transformation. In addition, integration of areas of expertise which are common to most projects (such as legal, ethics, data privacy, sustainability or collaboration with payers/HTAs) will yield higher quality results, consistency and increased efficiency by avoiding duplication of work.

Collaboration agreements

To ensure the interactions between the projects under the BD4BO programme, the therapeutic area/disease (TA) projects are expected to actively contribute key results to the Coordination and Support Action (CSA) which will provide direct support to the TA projects, and collaborate with, this, the European Health Data Network (EHDN) project. Therefore, the grant awarded for the EHDN will be complementary to the Grant Agreements already awarded under the BD4BO programme. The respective options of Article 2, Article 31.6 and Article 41.4 of the IMI2 Model Grant Agreement will be applied.

Expected impact of the BD4BO Programme

The expected impact of the programme will be a network of different health data sources to support the growing requirement for evidence to support expanding value-based and outcomes-focused healthcare delivery in Europe. Technological development will accompany the network based on prior programmes to support the relationship between data users and data providers, but a key driver for success will be active collaboration within the network. The programme will also enable evolution and management of R&D portfolios and prioritisation of research methodologies in line with outcomes focused healthcare services in Europe. We also need to recognise the growing use of multi-centre observational studies, with its increasing complexity, which require organisation and a broader European-wide strategy in response.

Specific challenges to be addressed

The central theme for the BD4BO Programme is the prospect of outcomes-driven, sustainable healthcare systems. At the same time, it is recognized that reuse and analysis of healthcare data holds the key to the transition to these systems (see http://www.efpia.eu/topics/innovation/outcomes), under the maxim that, 'you cannot change, what you do not measure'.

The EHDN initiative seeks to address this critical challenge by converting relevant datasets across Europe to a common format and standard so that they can be more efficiently used to their full potential within a federated network to achieve the objectives as mentioned above, while respecting patient privacy, local data provenance, governance and applicable regulations. Achieving this is pivotal and implies addressing the following challenges:

1. ***Technical*:** healthcare data are very fragmented. Even data within one healthcare centre are typically spread across different repositories. Across entities, different standards are used to code diagnosis, lab results, drugs or procedures. In most of the healthcare systems a majority of the core clinical data is buried in unstructured (text) notes, making data analysis even more challenging. The EHDN will provide a harmonised model to address the structural heterogeneity and the use of different coding standards, expediting efficiencies in the research process
2. ***Socio-ethical*:** Besides the technical heterogeneity amongst data sources, a similar diversity in governance processes to perform studies using data collected by healthcare providers, can be seen. The project should specifically seek to provide a pragmatic governance framework that can be used to accommodate cross-centre studies, within the confines of societal parameters that manage data use in the EU.

To obtain concrete results, it is important to note that the EHDN project's ambition will need to be sharply focused on providing pragmatic solutions in this respect, thereby maximally reusing results and solutions from prior IMI projects. To achieve this focus, thereby enabling the long-term EFPIA strategic agenda, EHDN will focus on three "Application Domains".

Application Domain 1: Research: e.g. from discovery, pharmacovigilance, ongoing monitoring of effectiveness / safety of compounds, outcomes research, identification of variability in care delivery, disease background related info or epidemiology of disease.

Application Domain 2: Health services efficiency: e.g. outcomes based contracting, optimizing patient pathways, quality improvement of health services (dashboard driven / financial incentives / driving changes to health care systems). Regulatory applications will also be covered within this domain. Recent experience in e.g. GetReal (https://www.imi-getreal.eu/) and EMIF (http://www.emif.eu/) point to the growing interest and support for real world data (RWD) by the European Medicines Agency (EMA) and the Health Technology Assessment (HTA) bodies.

Application Domain 3: Individual patient care: e.g. providing an interoperable data standard to facilitate and stimulate a market in digital health solutions, expert systems, predictive algorithms, etc., integration with mobile health.

Need and opportunity for public-private collaborative research

To achieve above mentioned objectives, health care systems are challenged with (1) lack of definition and alignment on outcomes that are relevant to all stakeholders and patients, (2) policy makers having limited benchmark data to evaluate the risk/benefit ratio and value, (3) Personalised medicine allowing for more focused treatment options thus increasing the difficulty of demonstrating the risk/benefit in the real world, driven by rapid technological and biological innovation (4) clinicians having to make treatment choices based on short-term, surrogate and often not comparable data, (5) patients not having access to the right treatment at the right time, and (6) payers having the need to make reimbursement decisions on life prolonging options with limited data and finite budgets.

Collaboration among healthcare systems and relevant stakeholders is necessary to capture and aggregate data, analyse it and extract relevant insights. Engagement of payers, providers and regulators will ensure these outcomes and clinical endpoints are measured and used in healthcare systems (e.g. for reimbursement or assessments). A critical element in achieving a more outcomes based healthcare system is the adoption of

well-suited standards. EHDN will apply two important standards, the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) and the International Consortium for Health Outcomes Measurement (ICHOM) standards[1].

The OMOP CDM is the result of a public-private collaboration, currently under the umbrella of the Observational Health Data Sciences and Informatics (OHDSI, pronounced "Odyssey", https://ohdsi.org/) project[i]. OHDSI is an international collaboration of more than 120 researchers (public and private) from 12 countries that contributes expertise at all levels, from infrastructure to clinical research, ensuring that the developed infrastructure meets clinical research needs. OHDSI's Common Data Model[ii], originally developed as part of the Observational Medical Outcomes Partnership (OMOP)[iii], is a deep information model that specifies how to encode and store clinical data at a fine-grained level, ensuring that the same query can be applied consistently to databases around the world. OHDSI has chosen data standards that dovetail with those of the United States government and the international community, and it also supplies tools and mapping tables for converting data from other standards. At last count, 52 databases, with a total of 682 million patient records, had been created using the Common Data Model[i]; this number may include duplicate records for databases with overlapping populations. As such the OHDSI suite of standards and tools is rapidly becoming a de facto international standard for working with real world data.

Besides standardisation and technical aspects, there is also a paramount need for further shaping a trusted environment for data sharing in Europe. To move the data sharing agenda forward, creating benefits for all stakeholders in the eco-system, several non-technical dimensions are of critical importance. These are, for example legislative aspects, data security and privacy or data quality improvement.

Scope

The EHDN project is a critical enabling component of the IMI BD4BO program and it is responsible for delivering the vision for large scale medical outcomes research. As the EHDN is part of the larger BD4BO programme, the research aspects of the BD4BO project will be supported by the respective research projects. This suggests that the *EHDN should fully focus on being an enabling project* and aim to deliver more pragmatic goals. The European landscape for secondary use of medical data is fragmented across different nations and providers, meaning a lack of standards. Several initiatives such as the FP7 project EU-ADR, TRANSFORM, IMI projects EH4CR (http://www.ehr4cr.eu/) and EMIF (http://www.emif.eu/)and the US based OHDSI project have demonstrated methodologies that can be used to perform outcomes based research across Europe.

The first goal of this project is to "reduce to practice" the approaches pioneered in these earlier research projects and develop a standard methodology.

The European "market" for health outcomes research is limited to commercial providers and a limited number of Academic Health Science Centres with funds available to develop secondary use platforms for research. This both biases the research that can be undertaken as only data collected by these providers can be used and in some cases, creates a monopolistic environment that prevents health outcomes research from gaining more traction. It would likely be true to say that not one data source provides the whole truth in the real world, and as such collaboration is critical to supporting quality evidence.

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 adoption of common enabling technology across all nodes in the EHDN will stimulate a new generation of (digital) providers to develop and deliver services in data transformation, data semantics and analytical capabilities. This will be achieved through the implementation of a certification process for SMEs and other providers. This has the halo effect of creating a second generation of practitioners and services who can further reap the benefits of health outcomes research, ensuring a common stewardship to the use of health data.

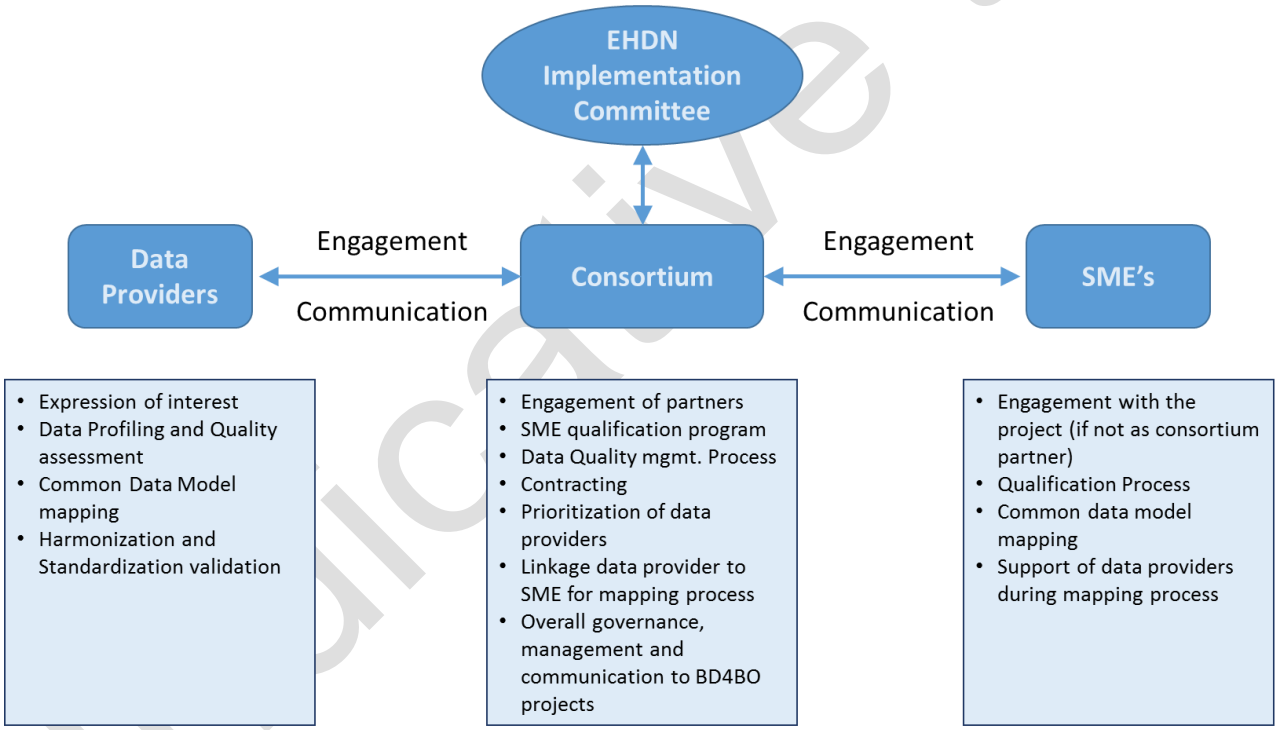
[1] http://www.ichom.org/

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.

The EHDN will implement a Federated Data Network, the implementation of which is based on the OMOP Common Data Model and utilise solutions and methodology approaches of EMIF. No further development or research is needed: the use of the OHDSI toolsets and EMIF contributions have already validated this approach and method. By doing this, EHDN will fully adhere to the FAIR principles of data networks. Via technical and governance solutions, data will be made Findable, Accessible, Interoperable and Reusable. For more information on the FAIR principles, see http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

Implementing the EHDN will stimulate the business ecosystem, matching data consumers with data providers (via a data set catalogue) by a standardised governance process, with an upfront agreed and transparent business model; and offer additional services in the form of a platform being built on open source components with public standards. Small and Medium Enterprises (SMEs), both within and outside the consortium, can develop and offer commercial services to data providers or consumers (see section on Applicant consortium for the distinction of SME's in- and outside of the consortium).

The Process is summarised as follows:



Collaboration agreements

Tthe grant awarded for the EHDN will be complementary to the Grant Agreements already awarded under the BD4BO programme. The respective options of Article 2, Article 31.6 and Article 41.4 of the IMI2 Model Grant Agreement will be applied.

Expected key deliverables

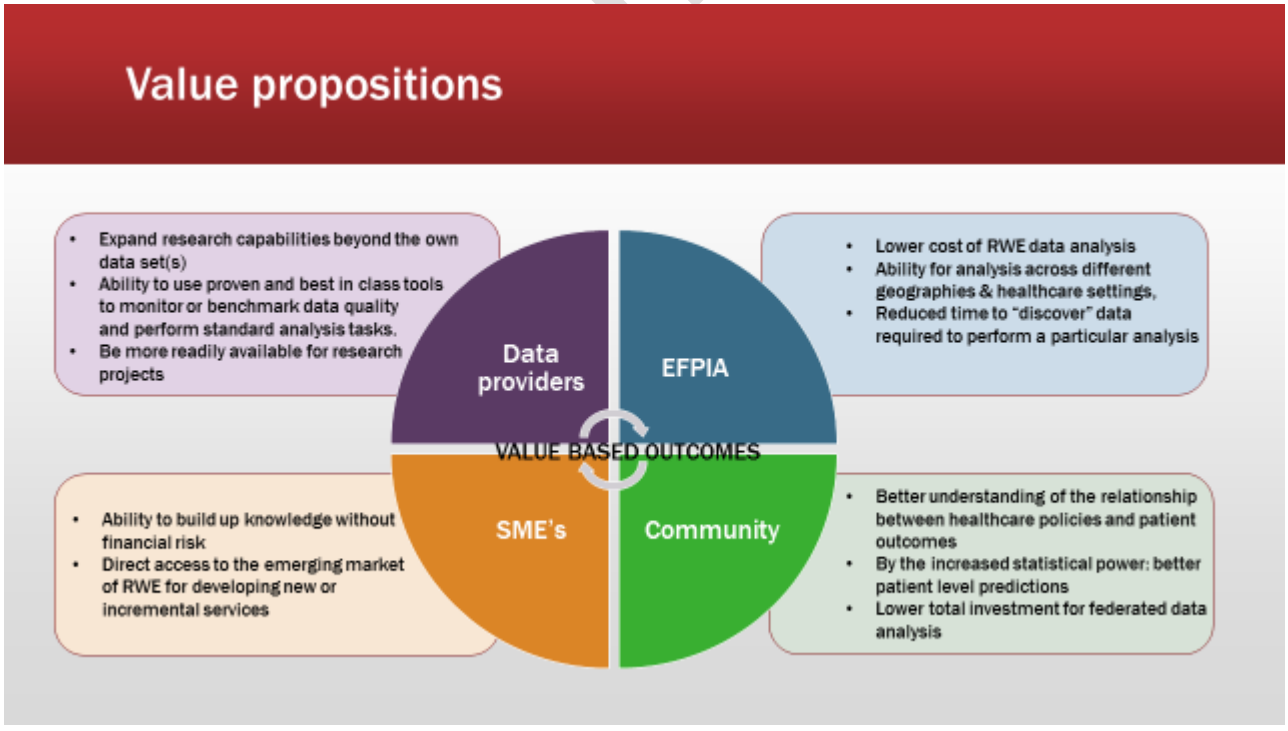
Suitable third party data providers will be identified for the selected priorities (disease areas, type of data, data quality requirements etc).

The suitable third party data providers (e.g. Hospitals, Regional data sets, Disease registries) that have the ambition to be part of the EHDN can subsequently apply to have the OMOP common data model constructed and deployed within their firewall, and also ensure their staff receive the necessary training.

It is envisaged that the IT technical services to provide this transformation will be provided by a number of EU based SMEs. These SMEs will normally not be part of the applicant consortium. The ultimate outcome will be a set of harmonised and validated data sets (within the firewall of the respective data owners' organisation), compliant with the EHDN suite of tools for reusing data. This will enable the data providers to successfully carry out BD4BO and other outcomes focused research projects. The EHDN project executive will administer the process for candidate data providers to apply to the fund and the subsequent awarding of financial support. Overall this undertaking will support:

- An operational network of data sets covering up to 20% of the EU population or approximately 100 million persons (estimated around 200 data sets) in support of existing and new BD4BO or other health outcome related initiatives. The project will support the implementation of the OMOP common data model within data provider firewalls. Key performance indicators will be developed to monitor the progress in terms of absolute number of data sources covered, diversity across different disease areas, geographical coverage and breadth of coverage across different types of data sets.
- The validation of mapped data sets as compliant with the EHDN suite of tools for accessing data and the possibility to participate in BD4BO research projects by the respective data owners. This will imply the existence of an operational data quality management framework for real world data. This data quality management framework (definition of criteria, applicable procedures, technical implementation) will be operational by the end of year 1
- European SMEs experienced in building innovative services for data providers and/or consumers. This will be incentivised by organizing hackathons and targeted competitions
- Certification of the IT technical services of EU SMEs where the technical services relate to the preparation, execution, testing, deployment and documentation of the transformation from source to harmonised data sets.
- EHDN project governance with a focused approach to manage the recruitment and approval of third party datasets, to oversee the data harmonisation and to interact with other BD4BO projects

Expected impact



The EHDN project aims to improve Europe's (technical) capabilities to undertake systematic health outcomes research at an unprecedented scale across the entire region. It will achieve this aim by taking advantage of and implementing the validated and robust OHDSI collaboration and common data model; supporting data providers with the transition to the common model for easier reuse of data and consistency across data

platforms; ensuring full compliance and governance is in place to protect integrity of the data; and offering the BD4BO projects a platform for successful and compliant data reuse and analysis.

It is not sufficient to just create a network of data providers that are making data available, we must also ensure there is research to be performed by one part of the EHDN node that permits all network partners to participate for some additional value, working towards a value based outcome mandate.

The primary beneficiaries will be the different BD4BO projects – EHDN can focus on ongoing and forthcoming BD4BO projects (e.g. Harmony, Roadmap, BigData@Heart, the forthcoming prostate cancer project). Other "enabled data sets" could more easily participate in future BD4BO projects. The model outlined in this proposal will make it easier for data providers to participate in research studies by implementing a common framework.

For the community at large, the research enabled through this platform will contribute to the BD4BO objective of an outcomes-driven and sustainable healthcare. This project should therefore also result in an increased use of outcomes based models in actual healthcare delivery and regulatory/HTA decision making.

Potential synergies with existing consortia

Applicants should consider incorporating technologies , experience and insights from previous/ongoing projects including:

- EMIF (http://www.emif.eu/)
- EHR4CR (http://www.ehr4cr.eu/)
- GetReal (https://www.imi-getreal.eu/)
- ENABLE (http://nd4bb-enable.eu/)
- eTRIKS (https://www.etriks.org/)
- OHDSI (https://ohdsi.org/)

Indicative duration of the project

The indicative duration of the project is 60 months.

Following an initial three-year period, a project review will be held to ensure the project is on track to deliver the expected impacts within the 5 year period.

Potential applicants must be aware that the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking may, if exceptionally needed, publish at a later stage another Call for proposals restricted to the consortium already selected under this topic, in order to enhance their results and achievements by extending their duration and funding. The consortium will be entitled to open to other beneficiaries as they see fit.

Such further work could include, but is not limited to, additional extension of the data network and further development and refinement of tools. The decision for this will be based on progress of the project and decision envisioned to be made in the sustainability work stream of the project.

Applicant consortium

The applicant consortium will be selected on basis of the submitted short proposals.

The applicant consortium is expected to address all the objectives and make key contributions to the defined deliverables in synergy with the industry consortium which will join the selected applicant consortium in preparation of the full proposal for stage 2.

As described above, the prime focus of the EHDN project is on implementation of established data standards to facilitate outcomes research in Europe. The ideal consortium therefore will contain a limited number of partners with proven expertise in the domain of real world data management and analysis, focusing on very

specific goals. Data sources will not be part of the consortium, but will be 'supplementary partners', mainly due to their diversity and significant expected number.

While the focus is on implementation, the EHDN project also wants to illustrate the value of the approach via a limited number of research "use cases" that will illustrate the societal value of the network. The applicant consortium is therefore also expected to have experience in the practical use of a federated network of data sets. Other guidelines on composition and expertise required for the application consortium are as follows:

The applicant consortium should mobilise the following expertise:

- A limited number (ideally up to three) leading academic centres in this domain:
  - They will serve as evangelists and key stakeholders. Ideally, these centres represent various European geographies (North, Central, South). These centres have practical expertise in working with RWD and the mentioned data standards e.g. OMOP CDM, ICHOM. As the EHDN project will also provide support for the OHDSI community in Europe,it is expected that the leading academic centres will have active on-going or previous collaborations within this community. This will serve as an important additional "validation" of the approach of working with a network of harmonised data sets.
  - The centres are expected to contribute specific domain knowledge on applicable standards in medical coding and terminologies in the relevant disease areas. Decisions need to be made on how to implement the OMOP CDM in the identified disease areas and possible extensions to the applicable standards will need to be agreed upon.
  - An important element in the selection of relevant data sets is the data quality evaluation (considering the research question envisioned). Expertise in the deployment of data quality evaluation is necessary. Ideally, the EHDN project will develop a "Data Quality benchmark" approach, allowing for a standardised and routine way of measuring data quality. As described above, EHDN will adhere to the FAIR principles.
  - Having led similar initiatives on a local, regional or disease level across a significant set of data sources where a substantial harmonisation effort was required, is recommended.
- A limited number (ideally up to three) technical SMEs with the following capabilities:
  - technical skills necessary to maintain and further develop the key infrastructural components, including the data catalogue solution, the central platform components and quality assessment solutions. Having developed or supported one or more of these applications in a public partnership is required.
  - the technical knowledge to support extensions of the vocabulary mappings. Experience in different healthcare coding systems, master data management systems and/or terminology services is expected. This would include either existing commercial product offerings or services in this area by the respective SME or previous delivery of such solutions in other public private partnerships.
  - the technical capability to develop and improve interoperability solutions. EHDN may consider the development of "inflow or outflows" from several common data formats instead of doing this for every data source independently. As an example, one could consider an outflow to i2b2 / TranSMART or to the backend of the hospitals data warehouse (e.g. i2b2) of institutions participating in the Champion Programme (follow-up from IMI-EHR4CR). Requests for interoperability with CDISC (SDTM, BRIDG) could also be expected. Experience in developing interoperability solutions and in one or more of the mentioned standards is required.

    Please note that SMEs charged solely with the actual data harmonisation tasks are NOT expected to be part of the applicant consortium. Such activities are expected to be covered by the financial support to third parties described below.

- experience in data governance aspects privacy and ethical aspects of secondary data use.
- The involvement of regulatory and HTA organisations is recommended:
  - Given the important regulatory and/or HTA context of the BD4BO projects, a strong link to EMA and/or an HTA body is a requirement. Ideally as part of the consortium, otherwise, these partners should be engaged in an advisory role. Experience from IMI projects like GetReal should be leveraged.

- At least one partner should be a pan-European patient advocacy group, in order to build trust and engage them proactively in definition of health outcomes driven use case selection.

It would be advantageous to include:

- Expertise in development of distributed statistical analysis or machine learning methods. A current limitation of the current federated network is that a particular data analysis is performed at a single data set. A "short-term engagement" could be considered that explores the feasibility for executing data analysis methods across an entire set of data sources while preserving the applicable constraints of the federated network.
- Ability to render structured content, mapped to the applicable data standards from unstructured text (text mining).

Financial support to third parties[2] (supplementary partners) for the provision of data-sets

The EHDN project requires the recruitment, mapping and OMOP data model implementation of a EU-wide operational network of data sets. These data providers will become supplementary partners, i.e. external consortium third parties, that would be recruited during the project lifetime through open call(s) and would agree that their data is mapped to the common data model. This will be normally done by qualified SME(s) hired by the same data-providers. Becoming a supplementary partner would allow the respective organization to participate in the network of data sources and as such engage in different research initiatives but also requires the data source to:

- Provide aggregate statistics on their data for inclusion in a data catalogue (e.g. number of patients per year of birth, gender distribution, distribution of person years covered, outcomes measured etc)
- Agree to the publication of this metadata in a data set catalogue
- Have a documented governance process for engaging and / or reviewing research questions from participants in the consortium (including other supplementary partners).

In order to cover the related costs for the above mentioned activities (i.e. hiring qualified SMEs for OMOP implementation), the EHDN consortium will provide financial support to the supplementary partners of up to EUR 100 000 per third party[3], selected under an open call launched by the selected consortium in the form of reimbursement of actual costs.

Therefore, in their full proposal, at stage 2, the applicant consortium must clearly detail the objective and the results to be obtained and include at least the following elements:

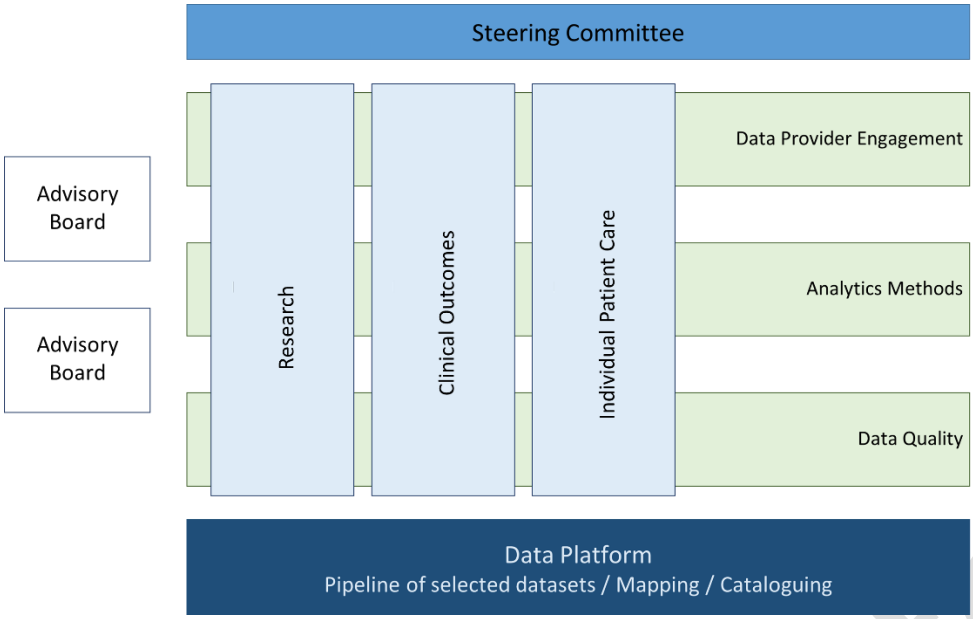
- a fixed and exhaustive list of the different types of activities for which a third party may receive financial support,
- the definition of the categories of legal entities which may receive financial support,
- the criteria for awarding financial support
- the criteria for calculating the exact amount of the financial support,
- the maximum amount to be granted to each third party and the criteria for determining it.

Suggested architecture of the full proposal

To ensure the project stays focussed on the end-users, the driving force of the project should come from the identified 'application domains'. These application domains (WP1 through 3) share a set of cross cutting concerns (e.g. data provider engagement, quality management, analysis methods) while the actual implementation of these concerns might be different. It's expected that the consortium will set up the necessary mechanisms to provide the coordination across these shared 'concerns'.

[2] In accordance with Annex K of the Horizon 2020 Work Programme and the article 15 of the IMI2 Model Grant Agreement.

[3] The costs of mapping can vary greatly between different data sources. Mapping existing, highly structured and integrated research databases may be relatively cheap, while mapping unstructured or semi-structured data will be a resource-intensive effort. Therefore, the cost to perform such a conversion are estimated to vary between EUR 30 000 and EUR 100 000 per data source.



The applicant consortium should submit a short proposal which includes their suggestions for creating a full proposal architecture.

Work Packages 1 to 3 – Application Domains

Each application domain focuses on a specific domain but shares common 'process' elements. These common elements include:

- Data provider engagement: Attracting relevant data sets through an open call for recipients of financial support based on needs of the other BD4BO projects and other criteria to be developed in the Full Proposal[4]. Contact and coordination with IMI-2 (BD4BO) and other projects to understand their data needs and /or to engage data sets in the respective BD4BO projects
- Data quality evaluation
- Requirements for the analytical methods: while it's not the objective of EHDN to perform the analysis (this should rather be performed in the BD4BO projects that are being supported) the EHDN will define the requirements that the analytical methods should adhere to and will provide input in how analytical methods can be shared / distributed across the network
- Identification and engagement with the relevant internal and external stakeholders (EMA, HTA's, …)

The specifics for WP1 to 3 are as follows:

Work package 1: Application domain 'Research'.

Work package 1 focuses on setting up a network of organisations who on basis of a shared data model can execute research questions at an unprecedented scale. WP 1 will lead and shape that community, engage with the relevant data sources and the broader (global) community. The analysis methods and the method to share or deploy them across the community is one of the key deliverables from this work package

Work package 2: Application Domain 'Clinical Outcomes'

The central theme to work package 2 will be the concrete implementation of transitioning to an outcomes driven healthcare system. This includes: a specific collaboration with disease specific projects on:

- applicable outcome measures;

[4] In compliance with article 15.1 of the IMI2 Grant Agreement.

- data source engagement to provide the appropriate outcome measures;
- translating the clinical outcomes to the common data model;
- defining quality criteria for applicable data sets;
- input and definition from regulatory and HTA to what constitutes valid real world evidence as it relates to applicable data input as well as the required analytical methods.

WP2 will also consider what other requirements might apply to outcomes based contracts and how RWD can be used in regulatory pathways.

Work package 3: Application Domain 'Individual Patient Care'

The focus of WP3 is how big data collected across the entire spectrum of data sources can contribute to the health of individuals. This WP will provide input on how to integrate digital health solutions and patient reported outcomes into the model. The Work package will also define the appropriate analytical methods to enable subject level (predictive) modelling in a distributed network – without impacting data privacy.

Work Package 4 – Technical implementation

This work package will focus on:

- Set up, maintenance and gradual improvements to the data catalogue
- Data harmonisation and standardisation of selected data sets
- Coordination of work with the use cases

Work Package 5 –Governance, Adoption, Dissemination and Sustainability

This work package will focus on:

- Shaping of governance
- Ensuring optimal adoption among each of the stakeholders, given legal/data privacy context
- Dissemination to the greater research community
- Exploration of sustainability models

Work Package 6 – Overall project governance and PMO

This work package will focus on:

- Governance ensuring close alignment and collaboration across work packages
- Project Management Office
- Internal and external communication

References

1. Hripcsak G, et al. (2015) Observational Health Data Sciences and Informatics (OHDSI): Opportunities for observational researchers. Stud Health Technol Inform 216:574–578.

2. Observational Health Data Sciences and Informatics (OHDSI) OMOP Common Data Model V5.0. Available at www.ohdsi.org/web/wiki/doku.php?id=documentation: cdm:single-page. Accessed June 1, 2015.

3. Overhage JM, Ryan PB, Reich CG, Hartzema AG, Stang PE (2012) Validation of a common data model for active safety surveillance research. J Am Med Inform Assoc 19(1):54–60.