EMIF Deliverable 15.5: First Draft Business Plan

Executive summary

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Today, research (re)using health data from diverse sources is a challenging process, illustrated by a lack of accessibility to possible data sources, potentially as they are unknown to the researcher, as well as numerous technological, administrative, regulatory and process hurdles which can slow or inhibit research outcomes.

Working outside of the confines of the randomised clinical trial setting, in more naturalistic or observational clinical practice environments, or with derived data in claims or regional databases requires differing approaches to identifying, accessing, evaluating and (re)using health data. Predominately the life sciences and pharmaceutical industry is the largest player within this arena, but governments and payers, academics and clinicians, patient organisations and numerous data management companies and consultancies have an increasing vested interest in working with Real World Data (RWD) and Real World Evidence (RWE).

The European Medical Information Framework, EMIF, was initiated via the IMI programme to respond to these challenges and needs. It is attempting during the lifetime of its public and EFPIA funding to develop a technology, governance and process management platform that would improve the efficacy and efficiency of such research within the EU, as well as introduce more harmonisation and consistency in both the experience and the outcomes of health research using RWD/RWE. The principles of EMIF are being further evaluated through two vertical disease-specific research initiatives identifying early biomarkers, in Alzheimer's disease, and metabolic disorders (e.g. diabetes mellitus type 2, and obesity).

With the end of its current five year funding, in December 2017, there is a need to develop a sustainable business model to ensure longevity of the project legacy longer term, while building from a start up to a demonstrably useful and efficacious Data Research Organisation (DRO; analogous to a Clinical Research Organisation, but for research (re)using health data).

Work to date has been in collaboration with EMIF partners, from Data Custodians (DCs) responsible for approximately 40 million patient records across fourteen countries within the EU, to EFPIA partners, academic partners, patient organisations, Small to Medium Enterprises (SMEs) and vendors, and relevant consultants. The business planning process has focused on addressing market analysis, improving understanding of the unmet needs and possible opportunities, as well as deriving insights in which to direct technical and architectural decisions, as well as governance, process and financial considerations.

Most challenging has been the positioning of an EMIF-like DRO post-IMI funding in an already competitive and rapidly evolving data market, while being able to demonstrate its unique proposition and niche. Furthermore, this is complicated by the diversity of needs and agendas within the EU. Three dimensions that go beyond any

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one DC are (1) innovation on data standardisation, (2) permitting combination and scale over multiple DCs, and (3) innovation on analytics supported.

Other IMI programmes, such as EHR4CR, GETREAL, et al, are already working through the start to their sustainability challenge with some synergies, and EMIF will learn much from this, as well as potentially collaborating for mutual success.

The EMIF platform is being developed to facilitate data identification, via a catalogue, suitability evaluation through specific tools and dashboards, feasibility work and ultimately access to the required variables and values from prior-described patient profiles from sources such as EHRs or cohorts, for analytical work within a secure and privacy protected environment. Ultimately, this is via a federated versus centralised approach, due to the requirement of most DCs to retain provenance of their own databases, and also ensuring meeting local guidelines and practice. Utilisation of common data models (e.g. the Observational Medical Outcomes Partnership (OMOP)) and linked tools (e.g. Observational Health Data Sciences and Informatics (OHDSI)) is also seen as a both a requirement for at least suitability availability evaluation, as well as strong legacy for the EU research community.

Against this backdrop, WP15 in concert with members of other relevant work packages has been developing scenarios to address potential commercial and/or not-for-profit approaches to sustaining the EMIF platform post-IMI. Key elements of this are summarised within this D15.5 document, but have been investigating possible organisational and financial models. Clearly, such scenarios and models are based on assumptions, which need to be tested against the evidence currently available, as well as future insights between now and 2017.

It is a primary assumption that the life science and pharmaceutical industry will be the key user of the EMIF sustainable model, but willingness-to-pay remains a key area of assumptions to be challenged, whilst the willingness-to-share data from DCs, also needs to be confirmed. Overall, this would support the IMI goal of accelerating access to novel therapeutics for EU citizens, based on access to real world data/real world evidence to derive biological and clinical insights, as well as generating insights into actual outcomes of therapies.

Revenue models based on subscriptions to commissioned research charges, as well as public and private sector funding or grant sources are being evaluated, and stakeholder mapping is a next phase in the work programme.

In summary, EMIF proposes to develop the technology, data understanding, governance and process management platform to support the use of health-related data sources from across Europe in the creation of federated, digital, virtual cohorts for discovery, R&D, and outcomes in the EU health sector across therapeutic areas, engendering collaboration between all key stakeholders. As the business modelling

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work and sustainability question is addressed further, the opportunity and cost will become more concrete.

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