



EMIF Deliverable 15.2: Market Analysis: usage models and data sources characterization

Executive summary

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Typical users of an EMIF-like platform include (Bio-)Pharmaceutical companies, Academic researchers, Payers / Governments, CRO's (Contract Research Organisations) and Patient Organisations. Albeit on different levels and in different forms, all are already using Real World Data (RWD). Some of the most urgent needs of EFPIA, academics and CRO's coincide and can be summed up as follows: there is a clear need for linked data with great granularity and quality, geographical spread, knowledge exchange platforms to exchange methodology and know-how and unified and simplified contracting processes. Real world data has already been introduced in some member states in the form of adaptive licensing and risk-sharing agreements and its importance is expected to grow due to the evolving concept of established medical science and the scalable benefits of cost reduction due to the use of RWD.

There are many types of real world data sources such as registries, administrative or claims data, electronic health records, etc. These can then be further subdivided depending on whether they are viewed prospectively or retrospectively and according to whether they collect information for administrative purposes or serve as the patient's medical record. Though all have their specific strengths and weaknesses they share common needs: data standards and mapping services, optimised data processing for studies implemented in networks such as EMIF, tools to efficiently access and analyse their data and governance to comply with privacy and confidentiality rules. Remarkably they share a major business need with the EMIF users namely wanting access to more data. This is explained by the fact that many data custodians have dual roles: they provide access to data and at the same time they do research with RWD. Showcasing their databases and analytical tools to analyse their own data are considered the principal benefits of EMIF for providers. With regards to differing levels of access between data sources, the overarching principle in the EMIF consortium is such that each data custodian is defining their own limitations and data use. Data custodians retain their freedom to decide whether or not they want to participate in a specific activity or not and they keep control over the level of sharing of data and results. Data sharing is subject to limitations due to local governance procedures, privacy regulations or legislation.

EMIF plans to be both a data (i.e. data broker, data management tool provider) and a solution (i.e. remote research environment, study designs) provider. The complex landscape EMIF will be entering already houses a large number of initiatives that can be seen as competitors, possible collaborators or both. However EMIF could fulfil a role in this landscape. Further study will conclude whether its positioning will evolve in the direction of data provider, solution provider or both.

Due to the leveraging opportunities this landscape provides EMIF has already started reaching out to similar or interesting initiatives such as OHDSI, EHR4CR, ENCEPP, e-Labs,



GAAIN, Get Real and SALUS. Processes for this outreach have been established and validated and the first steps towards collaboration have already been made.

Contacts

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