

Exposé: Data Infrastructures and RWD for efficient clinical trials

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Short Description

We aim to implement a solution that makes it possible to conduct clinical trials based on real data (RWD). While clinical trials are typically conducted in controlled settings, more realistic data that considers real-world patient environments can be beneficial for both pharmaceutical development and healthcare by collecting real-world sample and patient data. Our goal is to implement solutions that are combined in decentralized data health spaces that ensure data sovereignty and thus meet the conditions of data protection; With this architecture, patients can share their data in a secure way while maintaining their privacy and sovereignty.

Exposé

The European Commission has recently introduced several regulations to standardize digital transformation. The Data Act¹ is a crucial component of the EU's efforts to harmonize data access and use. As a result of the establishment of this framework, organizations and individuals will be able to share data more effectively. In accordance with the act, citizen or customer data (directly produced or collected through connected devices) may and should be shared with businesses and social organizations².

Due to the possibility to record data directly from the patient using wearables, this technical and legal framework offers interesting possibilities to record Real-World-Data (RWD) directly from the patients; impacting and disrupting the way clinical trials will be implemented in the next future. Here it is relevant to observe that decentralized and hybrid trial models are gaining momentum, especially for remote patient engagement and adaptive study designs. In this case the Regulatory enhancements, such as the implementation of the Clinical Trials Regulation and the CTIS platform, are streamlining multi-country trial approvals and administration.

¹ <https://www.bmv.de/SharedDocs/DE/Anlage/DG/Digitales/eu-data-act-englische-fassung-22-12-23.pdf>

² <https://www.deloitte.com/lu/en/Industries/technology/perspectives/the-eu-data-act-what-does-it-mean-for-you.html>

The market size for clinical trials in Europe in 2025 is estimated to be between USD 22 billion and USD 24 billion, with forecasts suggesting growth to approximately USD 32–43 billion by 2033–2034. Europe’s clinical trials market is advancing at a compound annual growth rate (CAGR) ranging from 6.8% to 7.6% throughout the next decade. Growth Drivers and Trends of this market are:

- Accelerated pharmaceutical and biotech R&D spending in major countries such as Germany, the UK, and France is a key driver.
- Prevalence of chronic diseases like cancer. For instance, oncology remains the largest segment, making up more than 36% of trial activity in the region.
- Germany holds the leading share, accounting for 18.5% of Europe’s clinical trial market in 2024

We are aiming to implement a solution that makes it possible to conduct clinical trials based on real-world data (RWD). While clinical trials are typically conducted in controlled environments, more realistic data that takes into account real-world patient environments (registered in short time intervals, like each minute or even each second) can be beneficial for both pharmaceutical development and healthcare by collecting real-world subject and patient data. To this end, we aim to implement solutions that are combined in decentralized Data Health Spaces that ensure data sovereignty and thus meet the conditions of data protection; with this architecture, patients can share their data in a secure way while maintaining their privacy and sovereignty.

Such implementation offers the option to develop not only AI tools for the integration and analysis of different data types (including structured and unstructured data), but also the design and implementation of digital twins for safe clinical trials.

[HRSE365AT](#) and [PerMediQ](#)³, together with [VITO](#), offers a solution to this problem by providing both data sharing infrastructure for data streams as well as static data that is compliant with FAIR rules as well as data protection policies and EU data regulations. Therefore, the platform provides a harmonized framework for specifying who may use product data or related service data, under which conditions, and on what basis. As a result, such an infrastructure can provide solutions for connected devices, data repositories, and customers, including data owners and data recipients.

What we offer

- Data Interoperability in Medicine
- Product Certification in Medicine
- Experience in management, integration, analysis and AI modelling of structured and unstructured data
- Language processing
- Product design
- AI deployment
- Development of decentralized data structures based on [Solid](#)
- Use-case application (e.g., PGx, or digital twin)
- Regulatory testing of AI applications
- Structured management of medical data
- Airway digital twins

We are seeking for

- **Project coordination for EU-Horizon program**

³ See portfolio: https://jgdopod.solidweb.org/Permediq/2025_Referenz_Projekte_En.pdf

- Partners are willing to apply this technology for clinical tests (medical products or pharmacology)
- Producent of medical devices willing to adopt data-management schemes conform to the EU-data act
- Investors willing to support the development of this technology