AFCROs

LES ENTREPRISES DE LA RECHERCHE CLINIQUE

REUSE OF RWE DATA IN DECENTRALIZED CLINICAL TRIALS

Written by

Alexandre Malouvier, ICON
Lise Radoszycki, CARENITY
Members of the AFCROs RWD working group

05/2023

Decentralized clinical trials (DCTs) based exclusively on the reuse of secondary data coupled with the collection of primary data collection directly from patients (ePRO, and connected devices) have already taken place in the USA [1]. While totally decentralized and dematerialised studies are not yet possible in France, there are solutions to get closer to this goal while we wait for the regulations to change.

Four Key Concepts that Make Possible the Reuse of Real Word Data

1. Interoperability

In healthcare industries, interoperability is the ability for different information systems and software to communicate, exchange data, and use that exchanged data[2].

There are two main types of interoperability:

- "Technical" interoperability allows the interconnection of two computer systems using technological interfaces, shared standards and protocols guaranteeing security and confidentiality;
- "Semantic" interoperability is based on interoperability repositories, allowing two systems to use a "common language" (vocabulary and syntax) to produce and use the data exchanged.

[1] Spertus, J.A., Birmingham, M.C., Nassif, M. et al. The SGLT2 inhibitor canagliflozin in heart failure: the CHIEF-HF remote, patient-centered randomized trial. Nat Med 28, 809–813 (2022). https://doi.org/10.1038/s41591-022-01703-8

[2] HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 2nd Edition, 2010, Appendix B, p190

2. Coding (and data standardization)

The use of data exchange standards and models makes it easier to share information between the different players in the health system, regardless of the application used.
Many standards exist to define the format and structure of data, for example: HL7 V2.X, HL7 V3 (demographic data and clinical and administrative data) or DICOM (medical imaging).
International terminology systems make it possible to standardize the semantics and coding of medical terms, for example: ICD-10 (classification of clinical diagnoses and procedures), or LOINC (laboratory examination, measurements and clinical observations).

3. Portability

The Data Protection Regulation (GDPR) defines the right to data portability. This means that individuals have the right to receive the personal data provided by them to a controller, in a structured, commonly used and machine-readable format, and have the right to transmit this data to another controller without the controller to whom the personal data have been communicated obstructing it.
Data portability represents both the ability to export personal data collected and stored digitally as well as the possibility of obtaining personal data in a commonly used structured format and authorizing another data controller to receive portable data.

4. Data Linkage

Data linkage is the ability to match data from two, or more, sources and identify pairs that belong to the same individual[3]. These data sources can be of different types: medico-administrative databases, cohort, connected objects, medical devices, patient surveys, etc.
Direct matching methods use an identifier common to the different data sources (e.g., the NIRPP) to identify data belonging to the same individual. Indirect matching methods are based on procedures aimed at finding data for the same individual from a combination of variables that are not directly identifying him/her.

[3] Winglee M, Valliant R, Schuren F. A case study in record linkage. Survey Methodol. 2005; 31(1): 3–11

Reuse of Real World Data: What are the Challenges for Clinical Research ?

The growth in the collection and analysis of real world data is opening up interesting prospects for clinical research, in particular:

- Enrichment of primary data (information specifically collected to study a phenomenon) with secondary data (information that has already been collected for a purpose different from the study conducted) or even the use of secondary data instead of primary data collection.
- The constitution of synthetic control arms (control groups from randomized trials already carried out). This approach has several advantages, in particular that of improving patient access to promising products in the evaluation phase.
- The decentralization and dematerialization of clinical trials such as the Janssen CHIEF HF study, which is a completely decentralized randomized clinical trial. It was conducted without any physical interaction between patients and doctors.

Nevertheless, there are still many technical and operational challenges to be met in order to generalize the use of real-world data in clinical research, in particular: improving the quality of data and their coding, the development of interoperable systems guaranteeing the data security, integrity and portability, etc.

The "Mon espace Santé"[4] portal deployed in France at the start of 2022 allows all users of the healthcare system to access a secure storage and sharing space for health data and documents. Ultimately, this system could constitute a secure solution for the portability of health data on a national scale.

[4] "My Health Space" in English

Three Examples of Innovative Solutions Based on the Reuse of Real World Data

The Use of Electronic Medical Records to Identify Patients Eligible for a Clinical Trial

Clinerion (recently acquired by TriNet-X) is a Swiss company that has developed technologies for analyzing electronic health record (EHR) data from a global network of partner hospitals. These data can be used for the study of disease epidemiology, the evaluation care pathways, as well as clinical research.

The platform Patient Network Explorer offers tools to optimize protocols, perform site feasibility studies, and identify patients potentially eligible for a clinical trial. This solution can be used to increase diversity in clinical trials and facilitate the identification of patients with rare diseases.

The Use of Data Generated in Community Laboratories to Recruit Patients in Clinical Trials

Biokortex is a French start-up that develops interoperable IT solutions to connect players in the medical world such as medical laboratories, pharmaceutical and diagnostic companies, CROs, healthcare establishments and healthcare professionals.

The applications developed by Biokortex structure the data according to international standards in order to allow the identification of patients eligible for a clinical trial. During sampling, the patient profile can be supplemented by an interview conducted by the nurse as well as by biological data. The tools also make it possible to monitor recruitment and optimize the selection of investigation centers.

A Data Portability Solution that Allows Patients to Share their Data

Andaman7 is a mobile application that allows patients to collect all of their health data from electronic medical records, connected devices or documents on their mobile phone. Thanks to its network of healthcare establishments interconnected with the application, patients can easily download their data.
Patients can also complete ePROs (self-assessment questionnaires).
Patients can choose to share their file with their caregivers, relatives, or with organizations that contribute to medical research. The patient therefore becomes the gateway to access multi-source and quality data.

*Many thanks to **Andaman7** for the translation of this article. You can access the original article in French here.*