Demystifying Real-World Data – Insights for Patients - Workshop Protocol

The Real4Reg Consortium aims to ensure high visibility of the project and the promotion of active interaction with key stakeholders. As stated in the Dissemination, Exploitation and Communication Plan, Real4Reg organises "major symposiums within the RWD workshops aimed at patients and the general public. These will be organised in close cooperation with patients' organisations (EIWH[1] and EUpALS[2]), who will be directly involved in the design of these events.

The first event aimed at patients took place in October 2024, the details are provided below.

Workshop Title: Demystifying Real-World Data - Insights for Patients

Date: 14th October

Time: 11:30 - 13:00 CEST

Online Platform: WebEx

Agenda:

11:30-11:35 **Introduction**

11:35-12:00 **Session 1: Understanding real-world data (RWD) and its potential**

Presentation: RWD and its uses - Nicolas Thurin (University of Bordeaux)

Presentation: Real4Reg - Britta Haenisch (BfArM)[3]

12:00-12:55 **Session 2: perspectives of patients regarding data privacy, security and ethical considerations**

Presentation: Data privacy - Chloé Antoine (University of Namur)

Roundtable with patient representatives
Moderation: Rebecca Moore (EIWH)

Participants: Antonella Cardore (Cancer Patients Europe), Elsa Frazão Mateus (EUPATI)[4], Ywan Dierick (EUpALS)

12:55-13:00 **Closing**

[1] EIWH - European Institute of Women's Health
[2] EUpALS – European Organisation for Professionals and People with ALS
[3] Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte)
[4] European Patients' Academy on Therapeutic Innovation

The workshop was publicised through email invitations sent to a list of stakeholders, as well as via publications on the Real4Reg website, social media, and promotion by Real4Reg partners on their websites and social media channels.

Participants:

The workshop had a total of 54 participants from 13 European countries. Participants were not only representatives of patients associations, but a diverse group of participants - including universities, healthcare institutions, pharmaceutical R&D organisations, regulatory agencies, and private companies.

The audience also included members of the Real4Reg consortium and advisory board.

Workshop recording and materials

The recording of the workshop is available on Real4Reg website, as well as the presentations of the speakers. (Click here)

Summary of the activities:

Presentation: RWD and its uses - Nicolas Thurin (University of Bordeaux)

Outline:

- Definitions: RWD, RWE
- Pyramid of evidence
- RWE vs clinical trials
- Generalisability of results
- Examples – SIGMA Consortium; COVID-19 federated studies (VAC4EU)

Presentation: Real4Reg - Britta Haenisch (BfArM)

Outline:

- The Real4Reg project and its impact
- Methods: use cases, datasets, work packages
- First results
- Outlook

Presentation: Data privacy, Security and Ethical considerations - Chloé Antoine (University of Namur)

Outline:

- The RWD journey (from the data protection point of view)
- How may RWD be collected?
- What “safeguards” apply to the use of RWD? GDPR principles
- What are your rights?

Roundtable

The roundtable session was moderated by Real4Reg partner Rebecca Moore (RM, EIWH), with the following participants: Antonella Cardore (AC, Cancer Patients Europe), Elsa Frazão Mateus (EM, EUPATI), Ywan Dierick (YD, EUpALS), and Chloé Antoine (CA, University of Namur).

Patients are a diverse group. Their opinions about the use of their data and concerns about privacy can be distinct.

EM believes that transparency and clear communication are essential to building trust across patient communities. Using the appropriate language is essential in fostering this trust, and with this, the patients will consent to the use of their data.

AC commented on CA's presentation, emphasizing that information from her presentation should be more publicly accessible. AC also acknowledged that patients are individuals with unique ethics and knowledge. However, patient organisations, such as Cancer Patients Europe, are invaluable in capturing patient perspectives through surveys and focus groups. It is important to ask the opinions to the individual patients, not just the representative of the category. AC agreed with EM on the importance of building trust, achievable only through transparency.

YD supported the importance of understanding individual patient perspectives, and noting that each patient's background is a valuable and rich source of information.

CA also underscored the importance of individual perspectives. While incorporating all individual views into legal provisions can be challenging, legislators try to consider a broad range of views and implement them in legal texts. The GDPR provisions can address individuals' concerns by providing explicit consent options and rights, such as the right to data erasure.

From the Real4Reg survey, privacy and security are major concerns of the patients, regarding the use of RWD/E

EM emphasised that much of the information related to informed consent and data use is presented in complex language, hard to understand. EM suggests that researchers collaborate with patient organisations to simplify this information, as researchers, scientists, and legal professionals tend to rely on technical jargon.

AC stressed that trust can only be built if the process is transparent and if patients maintain ownership of their data. Patients should be able to change their minds, with opt-out options strictly regulated. Cancer patients, for example, understand the value of contributing their data to research, so it's essential that the research process remains unaffected by opt-outs. Anonymisation and safeguards are critical to building and maintaining trust.

YD agreed on the importance of clear communication, noting that there is often significant miscommunication. Benefits to patients should be highlighted more explicitly. YD also pointed out that, initially, people were reluctant to share personal data on social media, yet today, data sharing is common. So, why not consider the potential value in sharing health data similarly?

Questions from the chat:

- *Question for Chloé: How do opt-out solutions to Real-World Data collection and processing, for example like the recently passed German law on electronic healthcare records, conform to the requirements of informed consent and what requirements would opt-out approaches need to fulfil to conform to this principle?*

  CA noted that while there is no specific requirement for opt-out in the GDPR, it does state that if consent is given, there should be an easy way to withdraw it. The implementation of an opt-out solution needs to be assessed on a case-by-case basis.

- *Maybe it was already discussed, but what is your opinion on how we can speed up and raise awareness of the public on the literacy in health, cybersecurity and individual rights to privacy and data protection (GDPR, EHDS, Data governance act, AI, MDR etc) and how this can be done industry and pharma independent, to keep the trust of public health at the core of Europe efforts?*

  CA suggested that efforts to improve health literacy and awareness of data rights could be supported by patient associations, governments, e.g. providing information in public hospitals.

AC believes that patient organisations play an important role in increasing health literacy. AC also emphasised the importance of building health literacy before an individual becomes a patient. Cancer patients are very aware of the importance of the research and innovation to save their lives. The civil society normally oppose to the collection of their data, not the patients.

RM stated that it comes back again with health literacy and education.

Conclusions

- Key concepts: Trust and transparency—values also central to Real4Reg's goals.
- Two patient associations involved as partners in Real4Reg, allowing direct patient insights.
- Patients as individuals: RWD mitigates selection bias by including all patients in the analyses.
- Clear language: Essential to encourage patients' willingness to share data.
- Communication efforts on Real4Reg: Commitment to enhancing communication and interaction with patients.

Appendix – comments from the chat

- DDV • Question for Chloé: How close are we to a general Informed Consent Document that has to be signed only once by the patient, allowing the use of its data by a wide range of health care professionals, governmental agencies ...
- LD • Question for Chloé: How do opt-out solutions to Real-World Data collection and processing, for example like the recently passed German law on electronic healthcare records, conform to the requirements of informed consent and what requirements would opt-out approaches need to fulfill to conform to this principle?
- INFARMED • If you have questions or comments, to previous speakers and also to roundtable participants, you can use the chat.
- RA • Maybe it was already discussed, but what is your opinion on how we can speed up and raise awareness of the public on the literacy in health, cybersecurity and individual rights to privacy and data protection (GDPR, EHDS, Data governance act, AI, MDR etc) and how this can be done industry and pharma independent, to keep the trust of public health at the core of Europe efforts?
- IK • i wonder if the rule for not reporting <5 makes sense ? i have been involved with some RWD studies where it can be practically impossible to identify patients ? so can we look at alternative criteria ; some rare subtypes of diseases with even more rare subgroupes will limit in helping treatment outcomes
- IK • where is the proof that reporting in quantities less than 5 leads to identifiability - for example ? why not 6 or 4 ?
- RA • return of results to the patients is also creating value and trust, and is not always happening, especially in trials with negative results
- EM • I fully agree with RA.
- RA • patient's value in research should be recognized and patient representatives should be part of the solution
- LD • For the most part yes, thank you 😊
- CR • in a past project where we investigated whether patients were fast or slow metabolizers of medications resulting in non rapid depletion or increased levels of drugs we actually wanted to share the results of the genetic tests with the patients but could not do so because the results could only have been shared by a doctor in a personal consultation if I remember correctly and we did not have the budget to pay for that
- RA • Last one from my side: what is your advice for managing the incidental findings revealed with health data used in the research?
- EM • Usually the informed consent should already address the incidental findings
- RA • (so it will take into account the national laws, right? as genetic data in one country for instance are managed differently from other coutnries)

- LD • I also agree with Ywan. When patients research their disease on google for example, and maybe type in symptoms they have or write about it on the internet, patients are already (knowingly or unknowlingly) share large amounts of private healthcare data to an US-american company.
- ES • Just as a comment and regarding the idea that subgroups with less than 5 observations lead to identifiability: Some data controllers / permit authorities do not have clear threshold and some 10 or even 20, and some use 5 for regular RWD and 3 for orphan disease RWD – when speaking from international perspective. For me it seems a little arbitrary and hopefully there will be common agreed thresholds.
  Some information how data permit authority here in Finland thinks: https://findata.fi/en/services-and-instructions/producing-anonymous-results/