Data Saves Lives

Toolkit

Part Three: Establishing a Community-Led Patient Registry

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ESTABLISHING A COMMUNITY-LED PATIENT REGISTRY

Introduction

Patient registries are powerful tools that play a crucial role in advancing medical research and patient care. These structured databases collect, store, and manage health-related information about individuals with specific health conditions or characteristics in a real-world setting. Through analysing this information, registries can connect clinical research with the real world, offering deeper insights into disease patterns, patient outcomes, and the impact of interventions over time.

Unlike traditional registries often set up and run by institutions or industry stakeholders, a community-led registry places patients' interests at the forefront, from determining what data is collected to how the impact is communicated back to participants.

This section of the toolkit aims to provide some simple tools that patient organisations can use to start or continue taking steps towards establishing a community-led registry. It is important to remember that however you choose to progress, you will not be expected to have all the expertise needed to establish a successful and sustainable patient registry by yourself – it will be a collaborative process involving technical, legal and data specialists to ensure that your project is robust and meets the necessary compliance measures.

What are the benefits of a patient registry being community-led as opposed to other stakeholders?

As a basic definition, a community-led patient registry is a centralised database or platform that is managed, controlled, and governed by a community-led group. It serves as a repository of health-related data voluntarily provided by individuals (people living with a condition, their caregivers or healthcare professionals) within a specific community.

Some of the key features include:

- The registry is fully independent from any one sponsor and can be owned by multiple stakeholders
- Data contribution is based on the voluntary consent of individuals
- The community determines what specific health-related information is collected

The key benefits include:

- **Increased community empowerment:** those living with health conditions can actively participate in managing their health data which can lead to a greater sense of control and ownership over their health
- **Enhanced trust and transparency:** as the registry is owned and managed by the community there is greater transparency in governance and decision-making processes which can ultimately build trust among community members
- **Tailored research priorities:** data collection is more likely to focus on the specific needs of the community which can lead to research initiatives and studies that can improve patient outcomes
- **Improved accuracy and completeness:** the community has first-hand knowledge of their medical history and experiences. Through patient-reported outcomes (PROs), this information can contribute to more accurate and comprehensive data

COMMUNICATING THE BENEFITS OF A COMMUNITY-LED PATIENT REGISTRY

There are many different types of patient registries run by different types of stakeholders. In this section, we provide examples of some of the benefits of having a registry that is led by a community organisation specifically. The benefits that you communicate will need to be tailored by audience. Here we set out some of the common benefits for four different core audiences:

- **People living with disease and their caregivers**
- **Healthcare professionals**
- **Pharmaceutical and biotechnology companies**
- **Payers and healthcare regulators**

Benefits to people living with disease and their caregivers

- Support scientific research and discovery
- Drive improvements in care, including existing and new treatments
- Support greater health equity and improve access to best practice care
- Ensure the patient experience and perspective is at the centre of understanding of disease (holistic view of disease)
- Increase disease awareness, knowledge and understanding
- Highlight inequality in health outcomes globally
- Support healthcare regulators in decision-making
- Inform the design of clinical trials; improving the effectiveness and long-term safety of future therapies
- Balance the 'power' between industry and community

Benefits to healthcare professionals

- Support systematic and consistent collection of data to drive real change
- Increase understanding of natural history of disease and impact of medical intervention
- Inspire research into new interventions
- Improve standards of care and the patient experience
- Support impactful research publications
- Inform development of national and international clinical care guidelines
- Support local drug reimbursement decisions
- Support relationships with patients: can help to build trust

Benefits to pharmaceutical and biotechnology companies

- Access comprehensive data resource that is independent of commercial influence, holding value with healthcare authorities in the development of clinical guidelines, drug approvals and reimbursement decisions
- Support pharmacovigilance requirements
- Help to identify meaningful clinical endpoints
- Understand the 'true burden of disease'
- Support black triangle requirements due to regular adverse event reporting
- Provide evidence of adherence to medicines/interventions

Benefits to payers and healthcare regulators

- Understand the natural history of disease and the impact of different management approaches
- Effectively monitor treatment impact for disease
- Support the development of evidence-based, clinical guidelines
- Inform the efficient use of resources by pairing the 'right' intervention with the 'right' patient population that has the potential to benefit most
- Ultimately save money as able to reimburse more effective drugs over drugs without RWE

KEY REGULATIONS/ GUIDELINES IN THE EU

When setting up a community-led patient registry in the EU, there are two sets of key regulations and guidelines to be aware of regarding data management and protection. These are: **General Data Protection Regulation (GDPR)** and the proposed **European Health Data Space (EHDS)**. Although data management and protection may seem like daunting concepts, with a little time and investment into learning, we are confident you will develop an understanding of the key principles and steps needed to set up a compliant patient registry. Below we provide background information on each of these regulations, and outline some of the guiding principles of data management.

"The key is to make GDPR and EHDS your friend!"

Petra Wilson, Health Connect Partners, Information Governance Expert

What is GDPR and EHDS?

GDPR is a set of rules and regulations designed to protect the privacy and personal data of individuals in the EU. It's a law that aims to give people more control over their personal information and how it's collected, used, and stored by companies and organisations.

It's very important to implement GDPR practices at the start of building a registry as it can establish a robust framework for protecting an individual's privacy, ensuring transparency, and promoting responsible and ethical handling of personal data.

Click here for more information on GDPR

The proposed **EHDS** – which is not in place yet but expected to be introduced imminently – is an initiative by the EU that aims to create a secure and interconnected environment for sharing and accessing health-related data across the EU. Think of it like a digital platform designed to make it easier for healthcare organisations, researchers, and authorities to share and use health data for the benefit of public health.

The proposed EHDS is a framework for the inoperability of data and ethical data use, which is a vital component of any registry. It's important to keep up to date with this proposed legislation to remain compliant under EU law.

Click here for more information on EHDS

What are the guiding principles of lawful data processing?

Below we have summarised some of the guiding principles of lawful data processing to give you a flavour of the kinds of things to consider and implement, to ensure any patient database or registry you set up is compliant.

Of course, there are more considerations around setting up a patient registry and general data management, for in-depth information on GDPR and EHDS please click on the links above.

When data are collected, used or stored (e.g. patient information) it must be done…

Lawfully, fairly and transparently; and for explicit and specific purposes	• Establish a legal base • Know why you are collecting the data and what you will do with it
Accurately, adequately, it must be relevant and limited; and stored only for as long as necessary	• Only collect as much data as needed for your purpose • Keep it only as long as needed for that purpose
Securely, with the data 'controller' or 'processor' accountable for this (under GDPR)*	• Security includes physical and virtual data storage • Know who is accountable if something goes wrong/there are questions

* A data 'controller' or 'processor' are specific roles under GDPR. The 'controller' determines the purposes and means of processing personal data, while the 'processor' does the actual data processing on behalf of the data controller

TECHNICAL CONSIDERATIONS AND QUESTIONS FOR SOFTWARE DEVELOPERS

Typically, you will need to involve someone to actually build the platform to host the registry for you and allow participants to securely input their data. Here are some of the key questions that you will need to think about when choosing a technical partner and the technical considerations for developing a registry.

- **Recruiting registry users and onboarding –** how will the registry users be identified and engaged? What process will they need to follow to register and sign-up to the registry? How will they be onboarded to the platform and its functionality once they sign-up?
- **Registry questions –** what kind of data can the registry collect? In what format can questions be asked/ information be submitted e.g. multiple choice/free text/images uploaded etc.? Is there value or risks associated with certain data being collected? How often can data be input, and recommendation regarding this? Recommendations on how to structure the questions asked e.g. order, number of questions, themes to cover?

Something to consider when developing the registry questions is how they'll be perceived and may impact the registry user. For example, the user may feel disheartened if they are logging 'negative' symptoms over a long period of time, or it may draw their attention to an aspect of their health journey that makes them feel upset or discouraged.

Keep in mind how the questions are asked and how frequently, and if there are ways to support registry users e.g. signposting to a patient group who can provide support.

- **User experience and accessibility –** how will the registry be accessible for all e.g. device agnostic, font size, use of subtitles, images, translations? What are some top tips for optimal user experience e.g. limit on number of questions, types of questions asked etc.?
- **Ongoing engagement –** will there be a minimum requirement for engagement e.g. if data isn't input every 6 months will the platform still be able to send notifications (a consideration for some platforms e.g. Apple store apps)? How will user engagement be encouraged? Will a summary report be shared with the user?
- **Data management and protection –** will the registry be compliant with relevant data protection legislation? What protection and privacy measures will be in place and what functionality will and won't be allowed e.g. will face/fingerprint-recognition be possible to login? How will the registry verify the patient or caregiver using it? Where is the server access and will this need to be reported to an ethics committee?

IMPORTANT: Remember to read the terms and conditions of any contract put in place very carefully and question anything you don't understand or are unsure of. You may also want to ask the technical provider questions about the legal parameters of the contract in case they stop operating e.g. they go bankrupt or other eventualities, to ensure you are equipped with as much information as possible

When choosing a partner, cost will be an important factor. Be wary of providers that have very low costs compared to others and make sure you're clear on what's included in the offer. Some companies entice with a lower price but then as your project continues there will be lots of hidden costs that come up along the way, which can be much harder to plan for from a budgetary perspective.