Building Smarter Patient Registries

A report from FasterCures’ Patients Count: The Science of Patient Input program
The collection of patient data, via tools like patient registries, allows for various applications to enhance patient-centered research; however, patient registries vary immensely in rigor and capabilities.

bit.ly/FCPatientData
FasterCures examined the landscape of patient registries created or held in trust by patient-led foundations with three objectives.
1. **Assess** (through a survey and individual interviews) the state of patient-led patient registries as a robust source of patient insights and actionable data to meet emerging opportunities.
2. Evaluate use of patient registries by patient-led organizations as a surrogate measure of readiness for the expanding emphasis on patient centricity
3. Identify information and practices that would enhance existing patient registries and could inform the creation of new ones.
### Why have a patient registry?
Registry data can produce valuable outcomes

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of Respondents</th>
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<tbody>
<tr>
<td>Formed the basis of research presented at a conference</td>
<td>18</td>
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<tr>
<td>Helped recruit subjects to participate in research</td>
<td>18</td>
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<tr>
<td>Informed research priorities for our organization or another institution</td>
<td>16</td>
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<tr>
<td>Formed the basis of unpublished research</td>
<td>15</td>
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<tr>
<td>Formed the basis of published research</td>
<td>10</td>
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<tr>
<td>Attracted new investigators to the field</td>
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<tr>
<td>Attracted new sources of support/investment to the field</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
</tr>
<tr>
<td>Informed policy positions for our organization or another institution</td>
<td>8</td>
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</tbody>
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Source: 2016 Survey of 45 Patient Registry Leaders
Key Learnings

1. Patient registries evolve rapidly.
2. Success = careful planning + active upkeep.
3. Trust is essential, but not enough.
4. Patients expect to be partners.
5. Opportunity will knock. Be prepared.
Top advice & principles

1. Begin with the end in mind
2. Patient organizations are trusted partners
3. Engagement & funding are major challenges
4. Outcomes are fully based on direct patient input
Critical steps for building and maintaining an effective patient registry:

“Building Smarter Patient Registries” presents key issues at each of these important steps.
Identifying a Purpose

Anchor the registry with a single purpose or a small set of purposes. Having a **clear purpose** will help inform all other necessary decisions and lead to more effective stakeholder engagement.
## Conducting a Landscape Assessment

### Key Questions to Answer to Assess the Landscape

1. Does starting and maintaining a patient registry align with our mission and goals? What other organizational priorities might be enhanced or undermined by committing to a registry?

2. Do we have the necessary staff, volunteer and financial resources to build and maintain a registry?

3. Does our organization occupy a position of trust with the patient community that we wish to engage?

4. How much community education about the research enterprise will we need to do in order to support the need for and benefits of a registry?

5. Do we have constructive relationships with key influencers that can help to promote registry participation?

6. What threats to building a successful registry are we most concerned about? How can we mitigate these threats?

7. Do any registries (including international ones) already exist within our disease space? Be sure to investigate registries housed in clinical settings, academic centers and by industry. And if registries exist, are they collecting all of the information necessary to facilitate patient-centered research?

8. Might collaboration with an existing registry be possible or preferable to starting a new registry?

9. What end users would we hope to engage with registry data and how strong are our existing relationships to them? Will they be likely to value patient-reported data?

10. What data standards might end users have in order for registry data to be useful to their decision-making?
Evaluating Technology Platform Options

A variety of platform options exist, depending on your organization’s technical expertise, financial resources and registry purpose. Consider the following questions when selecting a platform.
Planning for Good Governance

Patient registries should develop and follow a written registry **governance plan** that articulates what expertise is needed and how decisions will be made, executed and monitored.
Planning for Good Governance

Consider including representatives from the following stakeholder groups:

• End user representatives (often from industry or academia)
• Patient and caregiver representatives
• Field experts
• Representatives with legal and ethical training.
Determining What Information to Collect When

Balancing burdening registry participants and efforts to document the complete patient experience is a major registry challenge. Registry data entry should be simple at the point of registration, to preserve a low barrier of entry. It should also allow for the collections of data over time by including an initial informed consent process.
Use the registry purpose, the governing board, and input from registry stakeholders to determine the data to collect and the format in which to collect it.

- Standard demographic information
- Personal medical history
- Family medical history
- Current and past medication use (consider providing a list of commonly prescribed medications with branded and generic names)
- Physical examination findings
- Symptom questionnaires
- Results of laboratory, imaging and/or functional tests
- Standard function and/or quality-of-life measures
- Disease-specific function and/or quality-of-life measures
- Information about social, behavioral and environmental factors
- Electronic health record (EHR) (possibly by providing one-time authorization via a health-care provider’s electronic portal)
- Costs associated with care

See also the National Health Council’s “Patient Perspectives on Disease Impact and Treatment Options: A Stratification Tool.”
Conquering Common Challenges

The biggest challenges that patient foundations face throughout the lifespan of a registry center on patient engagement and funding.
Conquering Common Challenges

- Initial participant enthusiasm can wane over time; refresh the registry to combat fatigue.
- Be realistic in your expectations for the amount of revenue a registry will generate.
Maximizing Participant Engagement

Tips to maximize patient engagement:

✓ Use gamification, badge or reward systems to incentivize participation and profile completion/updates
✓ Borrow principles from user-centered design like “personas”
✓ Leverage social communities to keep participants involved
✓ Connect registry involvement to the big picture
  Integrate multiple data sources to create a “one-stop-shop” for patients and caregivers
✓ Return results to participants early and often, even if only status updates or process measures
Allocating Resources

Identify direct and indirect costs at start-up and over the lifetime of the registry.

**KEY COSTS TO CONSIDER**

- Technical costs: platform access, data storage, platform and Web changes
- Staffing: organization staff and consultant costs
- Marketing and communications resources: outreach to both potential and active patient participants as well as potential end users
- Legal counsel: review of terms and conditions of data use agreements and compliance with federal and state laws
- Data quality assurance: administrative support and technical expertise to monitor and curate data
- Globalization: translation into various languages and compliance with international regulatory bodies
Attracting “Customers”

Engaging end users ensures that registry data serve a purpose beyond sitting in a repository. Recommendations for engaging end users:

- Publishing periodic data summaries
- Promoting and advertising the ability for external parties to direct queries or surveys
- Exhibiting at professional society/trade conferences about the availability of registry data
- Contracting with external researchers to conduct studies the organization sees as important
- Issuing funding opportunities for projects that utilize registry data
- Posting data sets on open research platforms
- Issuing data challenges or prizes to stimulate data analysis
Revealing Patient-Centered Registry Outcomes

With these complex considerations, it may be easy to lose sight of patient registries’ immense potential to accelerate and improve research outcomes – outcomes that are fully based on patient perspectives.

Patient registry data can reveal disease burden, the patient journey, unmet medical needs, patient preferences, natural history, subgroups and patient-centered outcomes and endpoints.
Sharing Results

Communicating registry outcomes keeps participants engaged and maintains the organization’s position as a trusted, honest broker within a patient community. Consider providing real-time data, releasing outcomes on a regular schedule (monthly, quarterly or annually), and issuing public updates as soon as outcomes are presented at conferences or published in journals.
Connecting to a Data Network

Connecting to a network allows researchers to look across diseases to identify patterns and shared features.
Going Global

Globalizing a registry is often warranted, particularly for rare disease registries where patients are few and geographically dispersed around the world.

To globalize a registry efficiently and effectively, seek out partner organizations active in countries where you’d like to expand. Working with international nonprofits can help you ensure global versions of your registry are culturally appropriate and in compliance with international laws. Partnering can also help with outreach, fundraising and services delivered in those individual countries.
Patient foundations are ideally suited to capitalize on growing interest in patient data by building high-impact patient registries. Registries give patients a direct means to participate in the research process, leveraging their input and insights to focus priorities and outcomes across the discovery-development-delivery continuum.
For more on patient registries...

- Showcase your organization and registry and find others to learn from and partner with by joining [Patients Count Network](#).
- Watch our Partnering for Cures session - [Building smarter registries](#).
- Check out our webinar - [Building research ready communities: A closer look at patient registries](#).
- Learn from registry case studies on our blog
  - [Friedreich’s Ataxia Research Alliance on the importance of investing in a natural history study](#).
  - [Innovator Spotlight: Crohn’s & Colitis Foundation of America](#).
- Access the [Patients Count Resource Library](#) to find broader patient registry resources, other case studies, toolkits, and more.
Learn more at fastercures.org/programs/patients-count