Introduction to registries

From vision to impact: Building registries that truly serve rare disease communities

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A registry is a means to an end.
Not the end itself.

Registries are transformative

From shaping the path to new treatments, providing critical data for researching real-world outcomes, informing doctor treatment behavior and improving evidence-based practice.

A guided approach to understanding registries

Current landscape
Why are registries important?

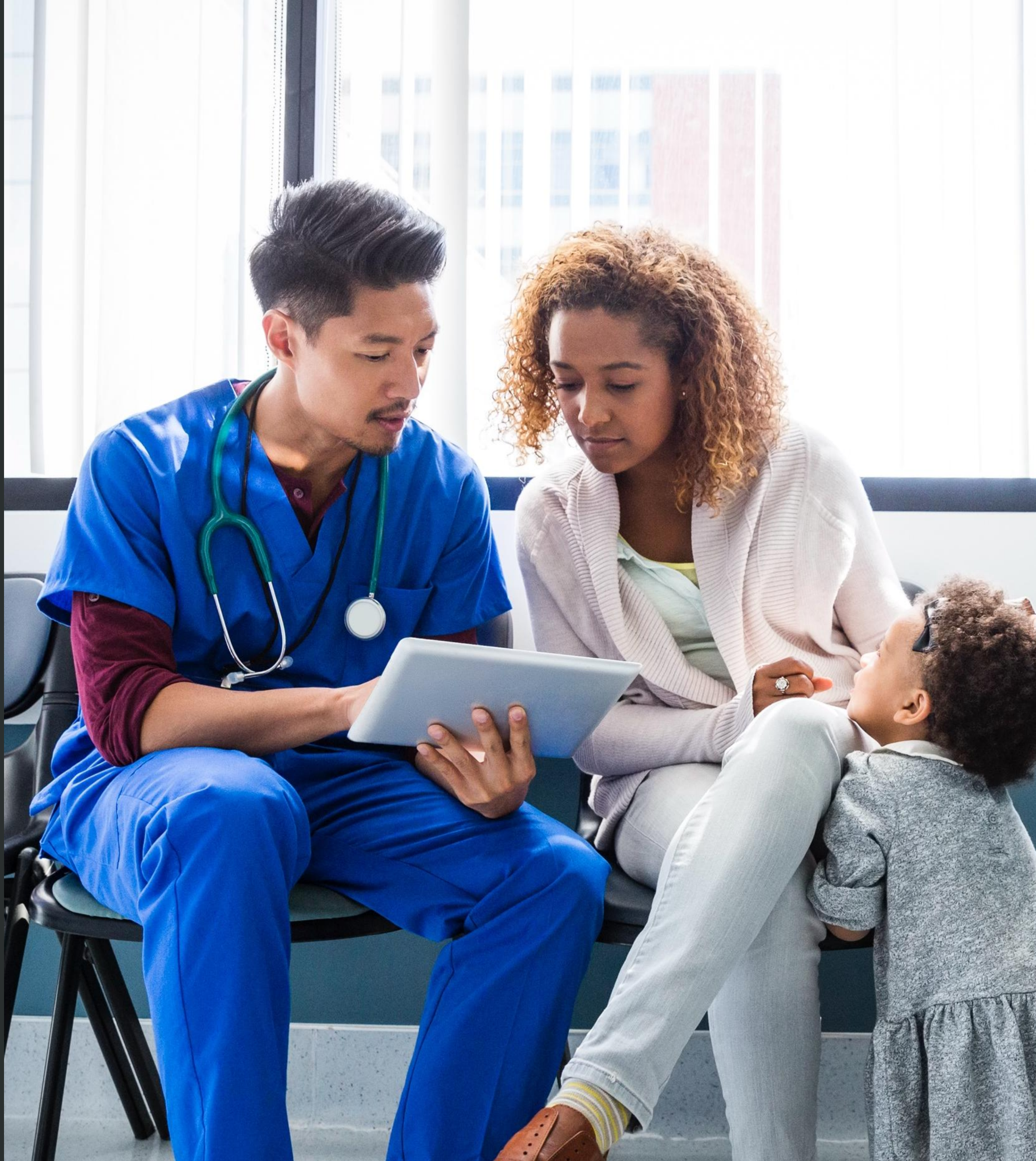
What is a registry ?
Back to basics

Ownership
Do we need to own the registry ?

Planning with purpose
What to think before you start ?

Best practices
Actionable tips and takeaways

Have you ever launched or been closely involved in a registry?



Current landscape

Why are registries important?

Patients with rare conditions are facing a lack of good data and evidence resulting in:

- No clear understanding of disease progression
- No consensus on which outcomes matter most to patients
- Few or no clinical trials
- Little guidance for care or access decisions

Gathering evidence with registries

Understanding

Understanding natural history of the disease

Support clinical trial design

Support the design of clinical trials by better understanding the population, disease evolution, outcomes that matter to patients

Tracking

Track treatment impact in the real world

Influence

Influence policy or care guidelines

Reimbursement

Build a case for reimbursement or access

What is a registry ?

Back to basics

Collecting structured data information over time, including:

1
A defined purpose

2
A specific population

3
Standardized data collection

4
Governance plan

5
Analyze and share findings

A **registry is a system that collects information over time** about individuals living with a particular condition or exposure to a drug or a device. It's not just a list of patients. It's a structured, intentional collection of data, designed to answer specific questions.

Type of registries

We are usually dividing registries into two main categories :

Disease or Condition Registries

- Individuals **suffering from a disease** *(either they always have it and at it at a for a certain period of time like infectious diseases, some cancers or obesity.)*

Product Registries

- Individuals **exposed to a healthcare product, such as a drug or a device, or other potential risk factor** *(personal, environmental or exposure).*

In some cases, health authorities mandate such registries to ensure safe use of medications.

Pregnancy registries represent a separate class of product registries.

Registry ownership

Do we need to own the registry ?

The roles of a patient association

You don’t need to own the registry to have a voice or represent the patient

Owner / Sponsor

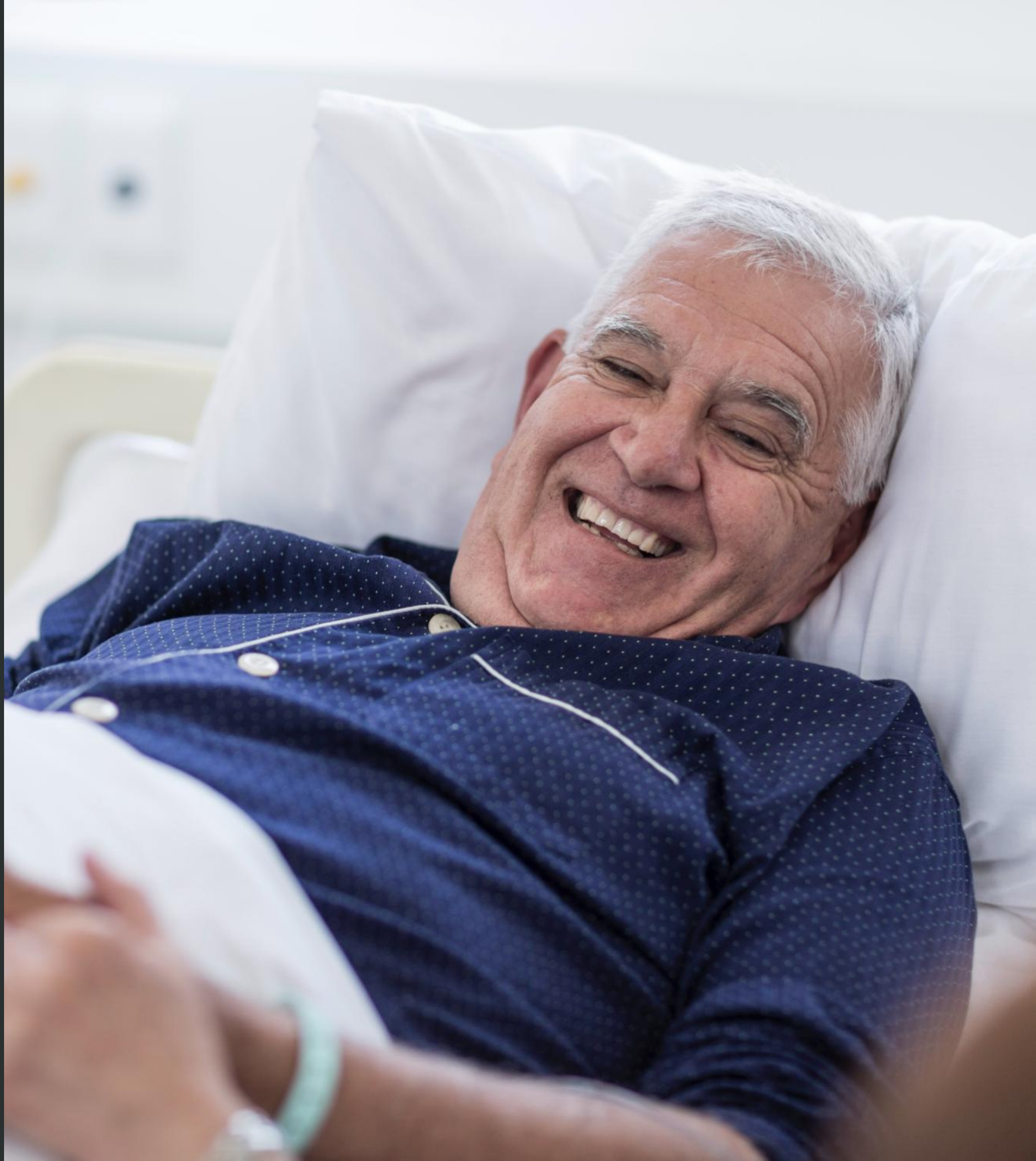
This is where you lead the initiative — you fund it, manage it, define the governance, and select the technology and partners.

Co-leader

This is a shared model where you partner with other stakeholders and jointly defines the registry’s purpose, design, and use of data.

Contributor / Advisor

Your group might contribute by advising on which data matters most to patients, helping with recruitment, or shaping how findings are shared with your community.



Considerations with different roles

Owner / Sponsor

Ownership brings control, but also responsibility and cost

Co-leader

Partnering bring reach and sustainability, but may require negotiation and compromise

Contributor / Advisor

Contributing allows you to focus on impact, but you will need to be clear on boundaries and influence

Key considerations

The point is: there's no one-size-fits-all model

Pre-launch, it is worth considering the following:

Funding

Who will fund the registry at the launch and after ?

Sustainability

If we build something, do we have the long-term capacity to sustain it?

Contribution

Is there an existing effort we can join or strengthen?

Patient voice

And whatever our role - how do we ensure patients are not just in the database, but at the table?

Planning with purpose

What to think before you start ?

A registry isn’t just a database.
It’s a strategy.

Planning with purpose

Purpose and vision

Governance and ownership

Design and data collection

Launch, operations and sustainability

Planning with purpose

Purpose and vision

Governance and ownership

Design and data collection

Launch, operations and sustainability

Purpose and vision

What's the goal of the registry, who is it for, and what will success look like?

What is this registry for?

Be specific.

Supporting research is not enough.
Consider what kind of research? To answer what question? And to support what decision?

Who will use this data? And how?

Designing for your audience, whether it's researchers, companies, clinicians, or patients themselves, helps ensure your data is not just collected, but used.

Long-term vision

What would success look like in 5 years?

Will your registry support trial readiness? Change care guidelines ? Empower patients?

Fit-for-purpose

The design must match the goal.

If your purpose is regulatory, the data structure and rigor need to match that.
If it's community empowerment, accessibility and patient relevance matter more

Planning with purpose

Purpose and vision

Governance and ownership

Design and data collection

Launch, operations and sustainability

Governance and ownership

How are decisions made and by whom ?

Ownership

Ownership refers to legal control: who owns the data, the infrastructure, the brand?

Governance

Governance is broader and refers to how decisions are made, who is involved, what processes exist to decide on access, priorities, or partnerships.

Building trust

Good governance builds trust — and avoids future conflicts. It also touches on important ethical and regulatory questions, like consent, privacy (GDPR), and secondary data use.

Governance and ownership

How are decisions made and by whom ?

Partnership

Industry are **key stakeholders**, but you need to ask yourselves how you want to partner with them.

Conflict of interest is a key point.

Who sits at the table ?

Building your **governance committee** is essential, but who are the right stakeholders ?

Planning with purpose

Purpose and vision

Governance and ownership

Design and data collection

Launch, operations and sustainability

Design and data collection

Once your purpose and governance are clear, only then should you define what data to collect.

The question is not: what might be interesting?
It’s: What do we absolutely need to answer our purpose?

Purpose

Collecting “everything just in case” may feel safe, but it backfires. Too much data = lower participation, more missing values, harder maintenance.

Consideration

How is the data collected?
How often?
How burdensome it is for the patient or caregiver?

And critically: can you align with existing efforts?

Duplication

Duplication is a big issue in rare diseases — where data is scarce to begin with. Fragmentation only makes things harder for everyone.

Planning with purpose

Purpose and vision

Governance and ownership

Design and data collection

Launch, operations and sustainability

Launch, operations and sustainability

Launch & operations

Funding

You will need investment at launch and even earlier, during the planning phase.

Thinking through your funding model from day one is essential.

Operations

You'll need **ongoing operational capacity** — to collect, clean, manage, and monitor data.

A major aspect here is **putting your governance into action.**
That means having clear rules for:

- **Privacy and data protection**
- **Data access**
- **Security**

Launch, operations and sustainability

What happens after launch ?

Long term use plan

Who will use the data — and for what ?

What partnerships might be needed to make that happen ?

What happens in 2 years, 5 years?

Funding

Is there funding for maintenance, not just set-up, who’s responsible for updates, compliance, user support.

Community engagement

How do you give back to the community?

This closes the loop, builds trust, and keeps people engaged.

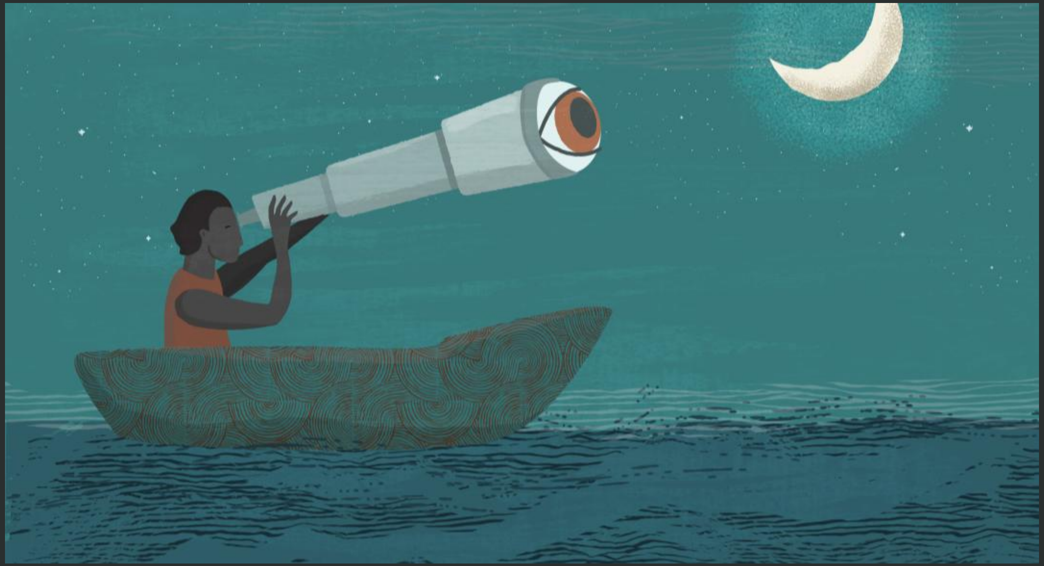
Sites engagement is also critical.

A registry is a means to an end. Not the end itself.

Best practices

Actionable tips and takeaways

Best practices



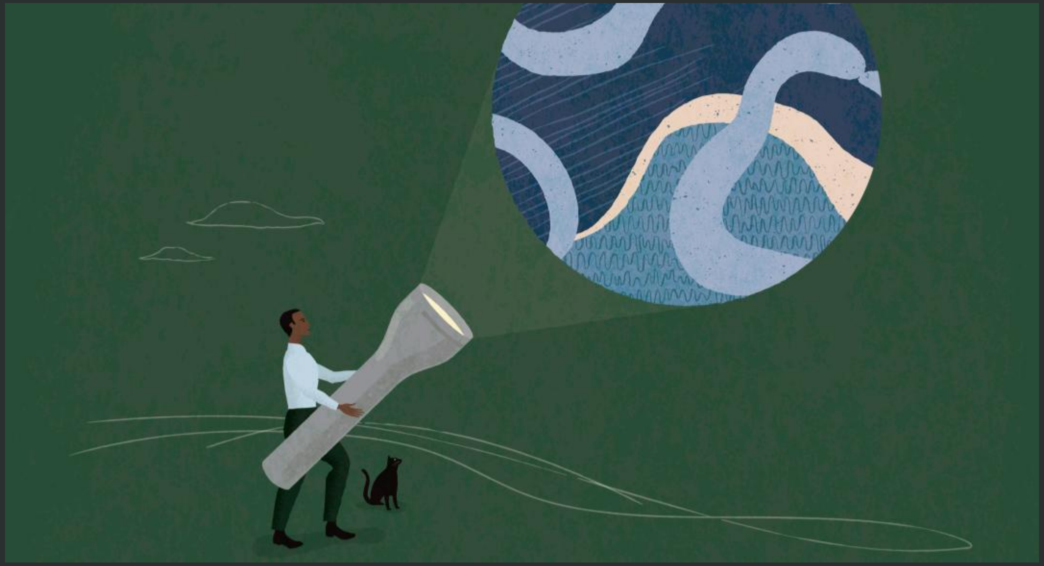
Start with “why” and keep it in focus

- Come back to your goal constantly. Why are you building this? Who will benefit?
- This will help you make the right choices in design, data, governance, and partnerships.
- And it helps you say no to things that don’t serve your core mission.

Co-design with others

- Don’t build in a vacuum.
- Engage early with patients, clinicians, researchers, regulators, industry — they’ll help identify what’s needed and what’s realistic.
- Build in patient perspectives not just as contributors, but as decision-makers.

Best practices



Start simple and you can scale

- Many registries fail by trying to do too much, too fast.
- It's better to start with a focused core dataset and grow over time. Don't let perfection delay progress.
- Your registry can evolve — but if it's too heavy at the start, people won't stick with it.

Plan for the long run

- Sustainability isn't just about funding — it's about ownership, relevance, and trust.
- Think early about what happens in year 2, 5, and beyond.

Best practices

Communicate Results Back to the Community

- Show participants how their data made a difference.
- Whether it's improving care, informing research, or guiding decisions — report back.

In summary

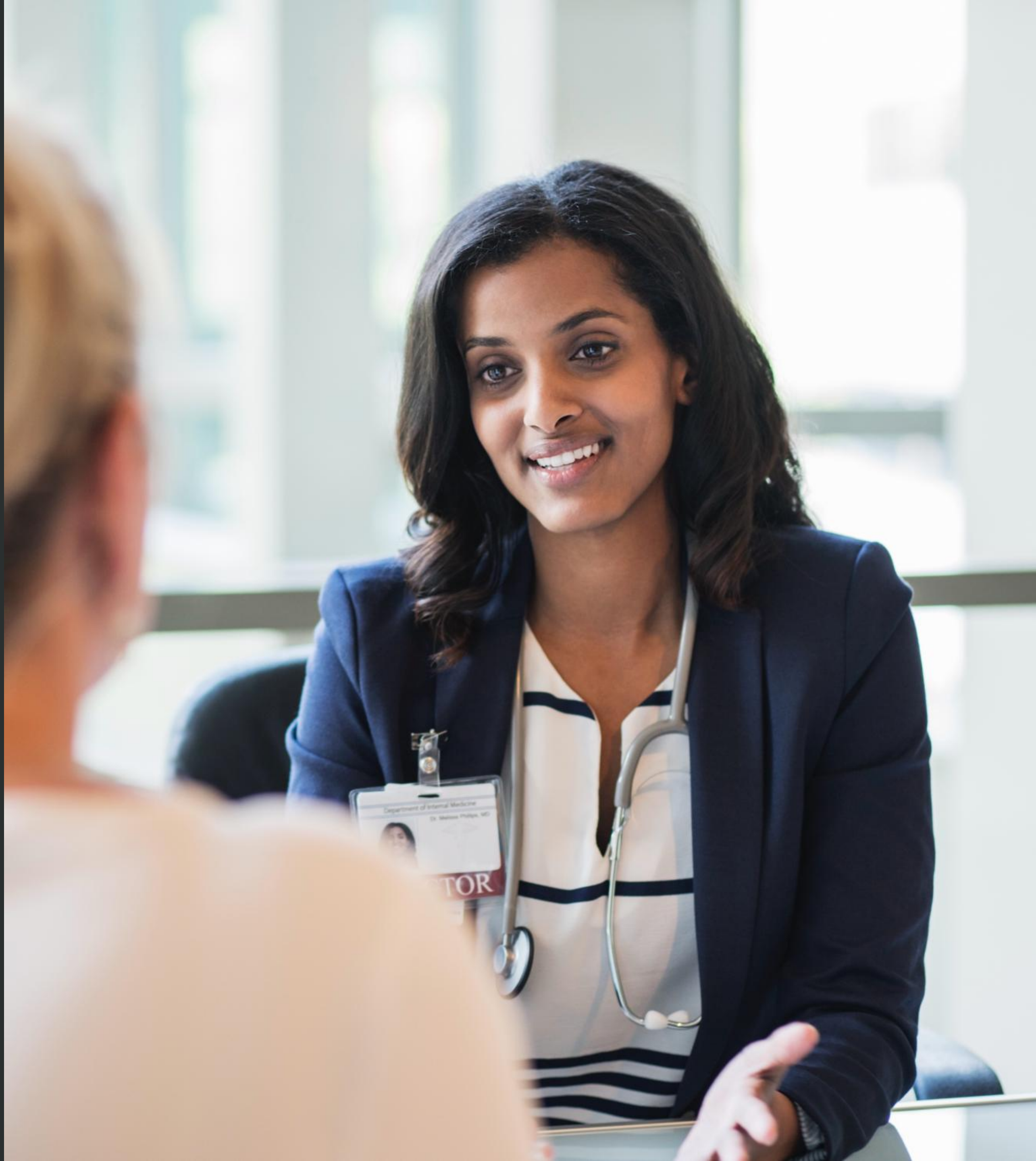
Creating a patient registry is a **big effort — and a powerful one.**
But it only creates value if it's **clear in purpose, carefully designed, and shared with others.**

You have unique insight, deep commitment, and trusted voices.

You **don't need to do everything alone** — but your involvement is what will ensure that these efforts serve the right people

So be bold — but also strategic.

Your data is powerful, but only if it’s **usable, trusted, and seen**.



Thank you

We welcome any questions.

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