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Designing Trials With Sites, Not Just for Them

How AbbVie is Turning Real-World Site Experience Into Better-Informed Study Design

Clinical trials are built long before the first patient is enrolled. Protocol requirements are established, feasibility is assessed, processes are developed, and patient-facing materials are created.

But decisions made early in that process ultimately have to work in the real world.

For AbbVie, that makes the perspectives of sites, patients, and other stakeholders an important part of study development. By bringing those perspectives into the process earlier, AbbVie teams can identify potential burdens, uncover blind spots, and make more informed decisions before challenges reach the field.

"Sites bring a real-world perspective that is difficult to replicate through data alone," said Michael Dawson, Director II, Clinical Acceleration & Performance, Oncology and Clinical Insights at AbbVie. "Engaging them earlier helps us understand what may work in practice and where we may need to think differently."

This is one example of how AbbVie is working to operationalize collaboration. Here, that culture of collaboration is helping bring site and stakeholder perspectives into protocol design, feasibility, and ultimately, the patient experience. In a follow-up Collaborate Forward InterVIEW, we'll explore how AbbVie extends that approach through ongoing site engagement, turning feedback into organizational intelligence and action.

Bringing Real-World Experience Into Study Design

AbbVie views sites as key partners in developing trials that can successfully recruit and enroll appropriate and representative patient populations.

Sites understand what works in practice. They also see firsthand the requirements that create operational burden, make recruitment more difficult, or make a study less attractive to patients.

Sites bring a different kind of expertise to study design: the experience of translating a protocol from what is written on paper into what can actually be executed with patients.

AbbVie has looked for ways to incorporate those perspectives into study feasibility assessments through early engagement with sites with relevant therapeutic-area experience.

Part of this work grew from an initiative focused on reducing avoidable protocol amendments. But the opportunity became broader: What could AbbVie learn earlier that might improve the study before an amendment was ever necessary?

That meant looking beyond traditional study feasibility. AbbVie expanded its outreach when appropriate to include patients, pharmacists, community sites, healthcare professionals, and other stakeholders. Their perspectives can provide additional context about potential operational and patient burdens before a study is underway.

Study teams can ask a more useful question:

Does each element of the protocol have a clear reason to be there?

Some monitoring, safety, laboratory, and other requirements are necessary to generate the evidence a study needs. But AbbVie also took a closer look at what was truly necessary and what might be superfluous, irrelevant, or confusing.

Finding the Blind Spots

Data can show how a proposed study compares with similar trials, but it cannot show everything that may make the study difficult to run.

That is where site and stakeholder input adds value. Sites can flag requirements that look reasonable on paper but may create recruitment and execution challenges, add unnecessary operational burden, or make participation less feasible for patients. Those conversations can surface issues that study teams did not identify through data or standard feasibility assessments alone.

The earlier those issues emerge, the more useful the feedback becomes. AbbVie's goal is to bring site and stakeholder perspectives into study development while teams can still adjust the design, rather than waiting until a problem appears during execution.

AbbVie is also measuring indicators such as protocol amendments and site decline rates to assess whether earlier input is helping teams make more workable decisions. Over time, site willingness to participate may provide another signal of whether study designs are working for the organizations being asked to execute them.

This is where **Operational Impact**, one of the four pillars identified in the Collaborate Forward Playbook, becomes particularly important. Collaboration becomes meaningful when the perspectives shared early in the process help shape the decisions that follow.

From Site Feedback to the Patient Experience

The impact of AbbVie's approach can extend beyond protocol design.

AbbVie has also applied a collaborative approach to its informed consent process, with patient centricity as a core objective.

AbbVie team members around the world provide an important connection to site feedback and help identify needs and trends in each local geography. Institutional Review Boards (IRBs) or Ethics Committees (ECs) offer another perspective, informed by their understanding of both site and patient needs.

Together, those perspectives can reveal an important tension: global consistency is valuable, but a process designed globally still needs to work locally.

That is particularly apparent in informed consent. Expectations can differ significantly across countries and cultures, including preferences around language, tone, document length, structure, and how information is presented.

AbbVie has used feedback to improve readability and simplify informed consent documents. That includes shortening materials and using addenda, bullet points, and tables where appropriate.

At the same time, AbbVie maintains local informed consent templates for the applicable countries in which studies are conducted that incorporate relevant local legal requirements alongside a global template.

The approach allows teams to maintain important consistency while still recognizing that one global format may not meet every local need.

Listening for Patterns, Not Just Comments

Individual feedback is valuable, but determining what it means requires context.

Ongoing communication helps AbbVie understand whether feedback represents an isolated preference or signals a broader trend that may require action.

That distinction is important when designing global processes. A comment from one country, site, or IRB/EC may identify a specific local need. Similar feedback appearing across multiple sources may point to a larger opportunity for improvement.

This reflects two additional Collaborate Forward pillars: **Information Governance and Feedback Loops.**

Information needs to move from the people who hear it to the people who can act on it. And organizations need mechanisms to evaluate what they are hearing, identify meaningful patterns, and determine when a process should evolve. Informed consent provides a tangible example of what that can look like in practice.

Keeping the Patient at the Center

Ultimately, the purpose of informed consent is not the document itself. It is to help a patient understand the clinical trial and what participation involves.

That principle has helped AbbVie focus on simplifying and shortening informed consent materials while maintaining necessary safety and legal information. The work has also included efforts to improve readability.

“Patient centricity has to start with whether the information actually works for the patient,” said Mathias Fallstrom, Director II, Business Process Framework at AbbVie. “The goal is to provide the information patients need to understand the study and their participation as clearly as possible.”

Standardization still has a role. Familiar language and structure across studies can make information easier for both sites and patients to navigate. AbbVie is also considering how eConsent can support the continued evolution of this work.

But the underlying question remains the same one that guides the broader study-design effort:

Does what we have designed work for the people who ultimately have to use it?

Collaboration Earlier in the Process

The four pillars of successful collaboration identified through Collaborate Forward reinforce one another throughout AbbVie's approach.

Executive Leadership Support helps create the environment for collaboration to take hold. AbbVie's One R&D Ways of Working approach supports greater alignment across clinical and medical teams and reinforces site centricity as a shared responsibility. Operational Impact comes from bringing insights into study development while decisions can still be influenced. Information Governance helps teams distinguish individual feedback from broader trends. And Feedback Loops provide opportunities to continually improve processes based on what sites and other stakeholders experience.

The lesson is not that every requirement or source of burden can be removed.

It is that the people who will ultimately execute and experience a clinical trial can provide valuable information about how it will work in the real world.

Bringing those perspectives in earlier creates an opportunity to identify complexity before it becomes a burden, uncover blind spots before they become problems, and design trials that are more workable for sites and more understandable for patients.

In the next Collaborate Forward InterVIEW, we'll explore how AbbVie builds ongoing relationships with sites, creates structure around what it learns, and turns site feedback into action.

Collaborate Forward Takeaways

- **Bring site perspectives in while decisions can still change.** Feedback has greater value when it arrives early enough to influence protocol design, feasibility, and other study decisions.
- **Use data and experience together.** Benchmarking and technology can identify important signals, while sites and other stakeholders can provide the real-world context needed to understand them.
- **Ask whether complexity has a purpose.** Not every burden can or should be eliminated, but every study requirement should have a clear rationale.
- **Balance global consistency with local reality.** Standardization can improve efficiency and familiarity, but flexibility may be necessary to accommodate local, cultural, regulatory, and patient needs.
- **Follow the impact all the way to the patient.** Site collaboration can improve more than site operations. When insights influence patient-facing processes such as informed consent, the benefits of collaboration can extend directly to the people participating in clinical research.

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Let's keep moving forward. Together.

Learn more about Collaborate Forward
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