ADVARRA

BRAID

Frequently Asked Questions

What is Braid?

Braid is Advarra's data and AI engine that transforms complex trial plans and scattered, hidden data into clear, connected insights—helping study teams design smarter studies, automate key workflows, and run trials more efficiently. Advarra developed Braid to address a pervasive challenge in our industry: Trial plans often don't reflect how studies actually operate. Critical operational data is scattered, hidden, or locked in static documents, making it hard to plan accurately. Braid unlocks this data to help teams design more efficient trials and avoid pitfalls that slow trials down.

How does it work?

Operational data has long been buried in static documents and fragmented eClinical systems—too unstructured to access or scale. Braid changes that. It unlocks operational data across the entire trial lifecycle, capturing the full progression of the study including any modifications that are made, not just a single point in time. This allows us to generate intelligence that improves how research is planned, executed, and scaled. Over time, Braid becomes smarter—accelerating performance, reducing burden, and driving greater precision at scale.

As the AI engine that underpins Advarra's technology, Braid acts as an interoperable intelligence layer that powers automation and turns data into actionable insights. It is powered by a uniquely rich and comprehensive set of operational data.

What types of protocol and operational data does Braid leverage?

Braid draws from a comprehensive set of protocol and operational data sources across the clinical trial lifecycle. This includes structured and unstructured information from documents including, but not limited to:

- Protocol attributes (study objectives, design elements, inclusion/exclusion criteria)
- Amendments and deviations (including rationale and impact)
- Schedules of Assessments (SoAs)
- Eligibility criteria and patient burden indicators
- Enrollment trends and screening metrics
- Startup milestones like IRB submissions, site activations, and document timelines
- Site feasibility assessments and capability surveys
- Additional operational inputs such as dropout rates, protocol deviations, and performance benchmarks

Who owns the data you're using to power Braid?

It's important to distinguish the type of data Braid leverages for its model: It isn't clinical data, PHI data derived from EDC systems or identifiable information from clinical studies; rather, it's system metadata, aggregated operational data—like cycle times, enrollment trends, and modifications made to study protocols, to name a few—which sponsors, CROs, and sites can combine with their own proprietary data to gain deeper insight into the performance of their trial operations. This is made possible by Braid's secure and confidential data clean room architecture, which is a controlled environment where multiple parties can bring data together for analysis without revealing the source or displaying identifiable information.

How does Braid ensure privacy and trust?

For decades, Advarra has helped sponsors, CROs, and sites navigate clinical research with integrity and confidence. Advarra brings deep institutional knowledge and a proven track record of delivering reliable services and solutions at scale. And we're doing the same with AI. Every piece of data Braid touches is encrypted and handled in a secure, validated environment. We're also transparent about our governance, sharing it with clients to support their compliance and best practices. Trust with clients, partners, and the broader research community has always been at Advarra's core.

Has Braid been reviewed or approved by the FDA?

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We developed Braid independently, grounded in our team's expertise and informed by feedback from clients who are deeply engaged in the challenges we aim to solve. At the same time, we actively welcome dialogue and engagement with regulatory bodies—including the FDA, EMA, and others—to ensure our approach aligns with evolving standards and best supports the broader goals of safety, efficacy, and innovation across the industry.

To complement this, Advarra recently established the Council for Responsible Use of AI in Clinical Trials—a cross-industry initiative bringing together sponsors, CROs, academic researchers, and study sites to define shared standards and guardrails for the ethical and effective use of AI in research. The Council reinforces our commitment to collaboration and transparency and is a critical step in helping the industry align on best practices as AI becomes more embedded in trial operations.

Advarra is known for its IRB. Are you leveraging AI to perform IRB reviews?

No, Advarra does not use AI to perform IRB services. Ethical oversight remains a fundamentally human responsibility—rooted in judgment, experience, and rigorous regulatory frameworks. While we believe in the promise of AI to streamline workflows and reduce administrative burden across the clinical trial lifecycle, core ethical decisions remain firmly in the hands of board members. All decisions related to ethical review and participant protection are—and always will be—made by people, not AI.

Is Braid relevant for global trials and diverse populations?

Yes, data feeding into Braid reflects global studies. Non-US studies are submitted to Advarra's US IRB, and global sites use our clinical trial systems.