

2025 Annual State of Observational Research Report

The industry's progress toward modern approaches to observational research

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Key findings from life sciences leaders

The life sciences industry in the United States is currently facing an uncertain environment, particularly regarding FDA regulations, market access, and payer reimbursement. These factors, coupled with a surge in technological innovation, have accelerated the industry's search for measures to simplify research and reduce costs.¹

Clinical development, medical affairs, and real-world evidence teams are under growing pressure to conduct observational research more efficiently. Traditional methods, like site-based prospective studies or retrospective chart reviews, fail to answer many research questions and can be expensive, cumbersome, or limited by missing data. Innovative approaches exist to overcome these challenges, but they have been implemented sparingly. This report examines the industry's current priorities and challenges and reveals the growing adoption and openness to modern, technology-driven approaches to research.

61%

utilize **AI or other advanced technologies** to support their research

78%

use or are open to using **virtual observational study models** with engaged patients

60%

indicate **long-term follow-up studies** as 2025's top research focus

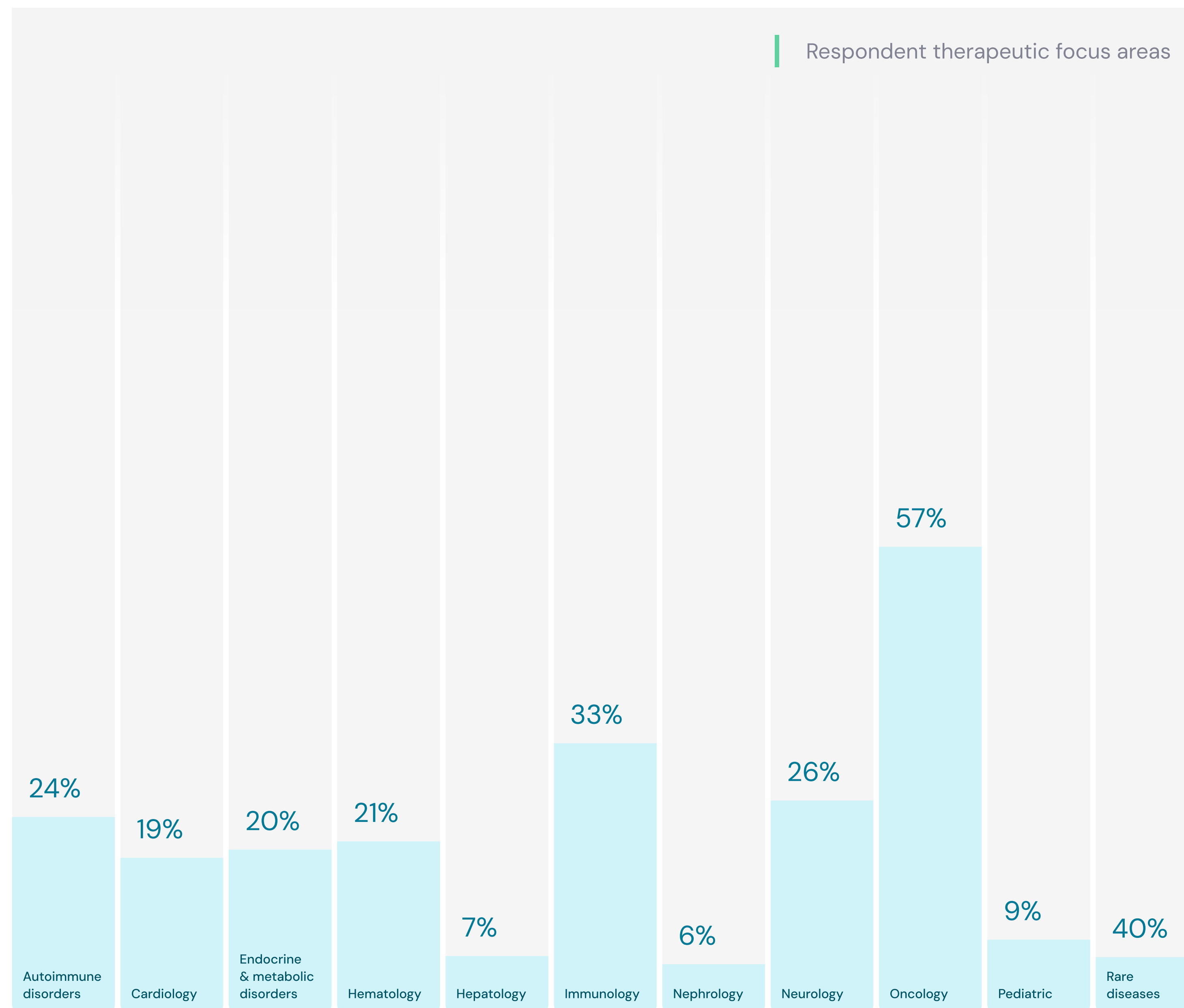
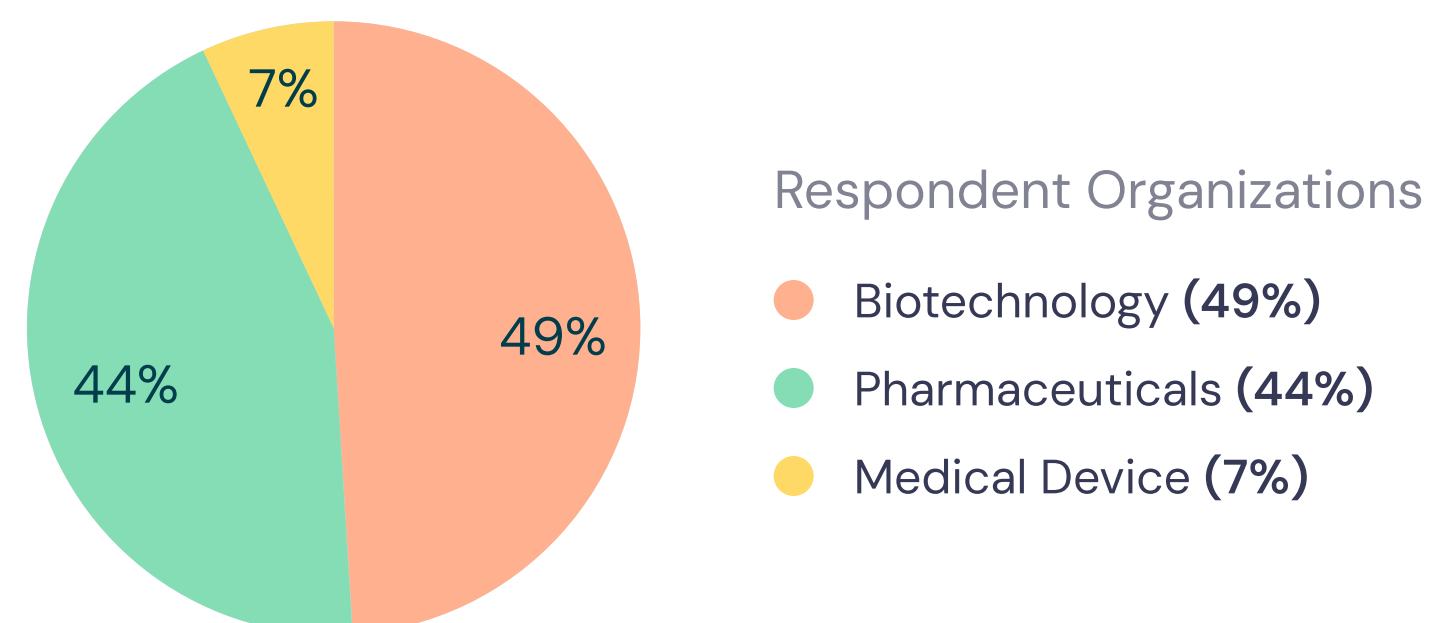
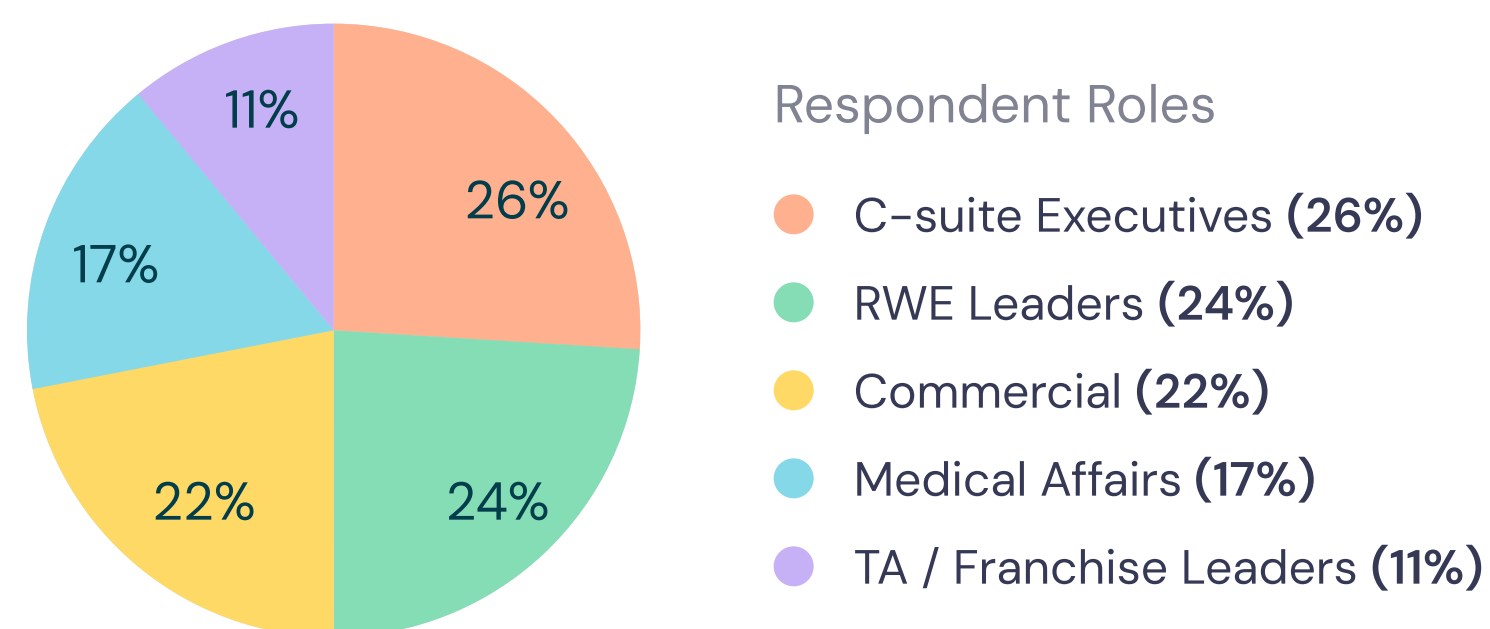
64%

note **incomplete data** as the most significant challenge when running a study



About the respondents

In January 2025, PicnicHealth collaborated with Guidepoint to survey 100 U.S.-based life sciences leaders. Respondents spanned all therapeutic areas and held various leadership roles, with 77% of respondents directly owning budgets for observational research.

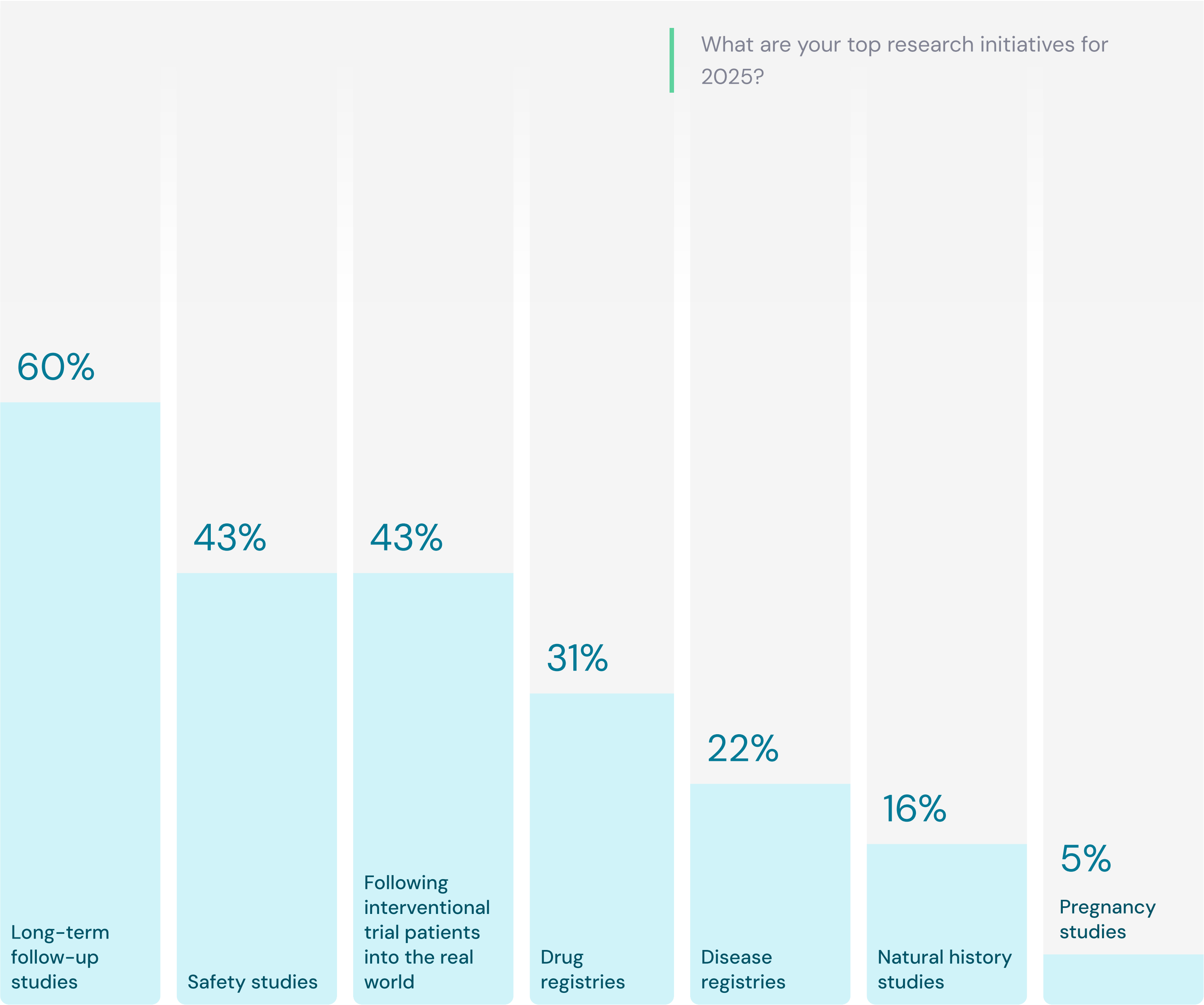


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Industry sentiments in 2025

Assessing long-term safety & efficacy is the top research priority.

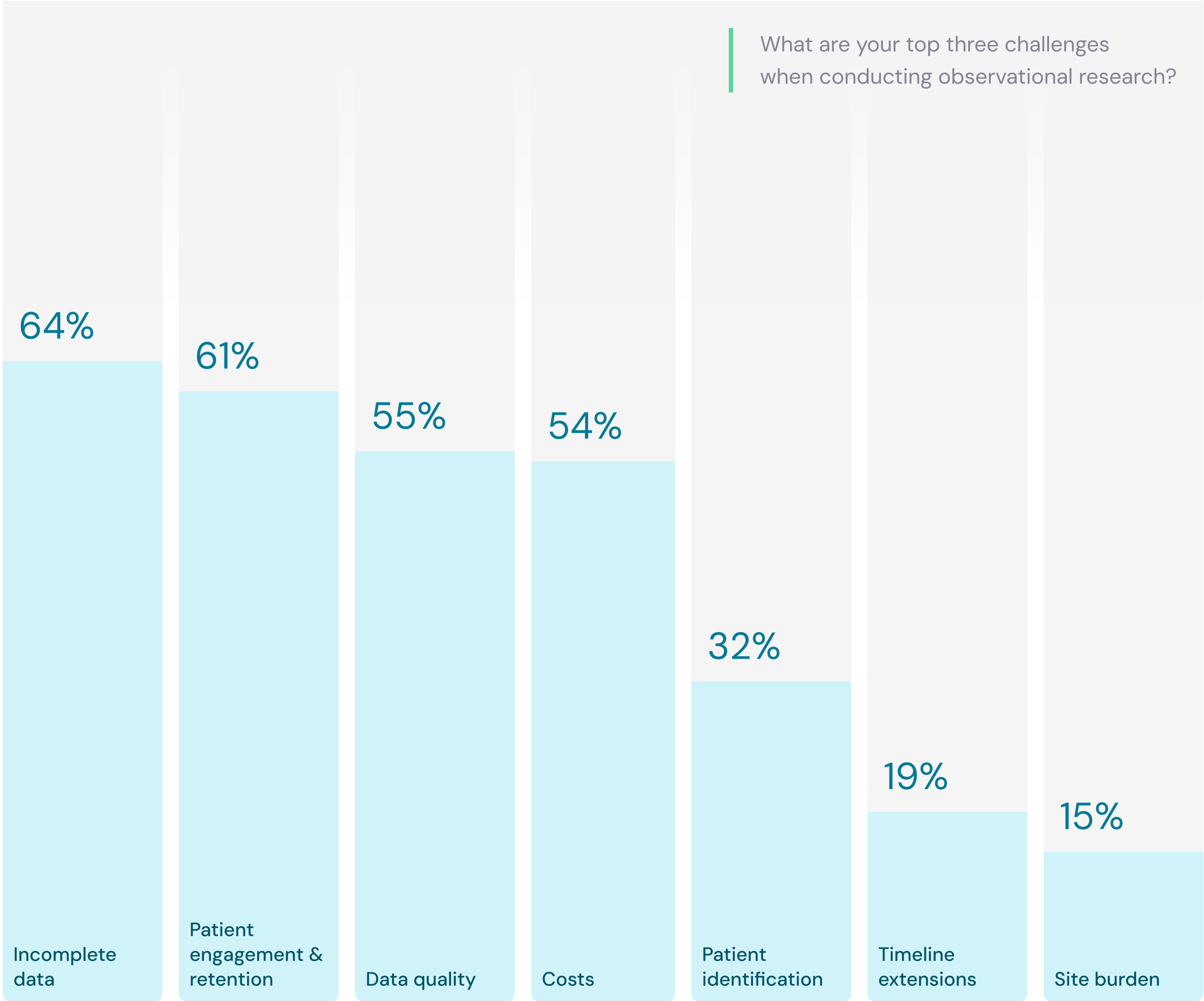
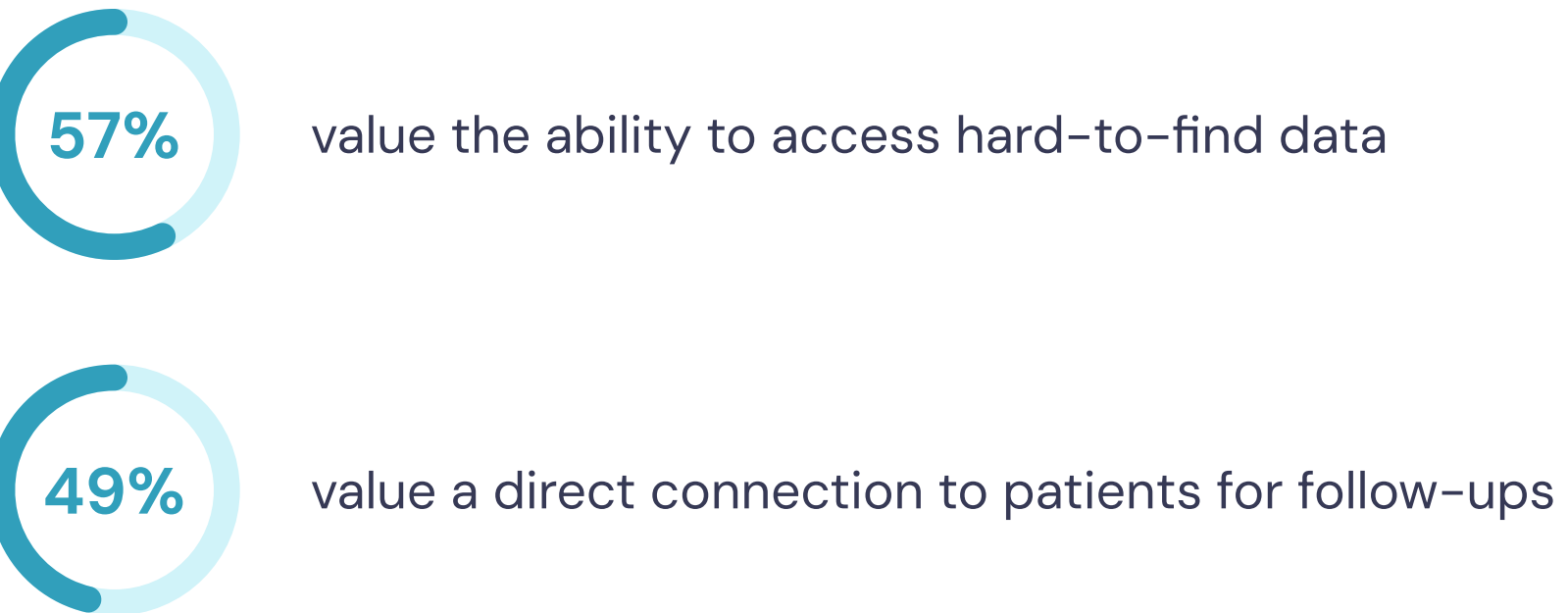
Life sciences companies are responding to growing demands from regulators, payers, and patients for insights into the real-world safety and efficacy of approved treatments. Respondents revealed their top research priority for 2025 is long-term follow-up studies, with safety studies and studies following interventional patients into the real world ranked as second priorities.



Data completeness is the greatest challenge.

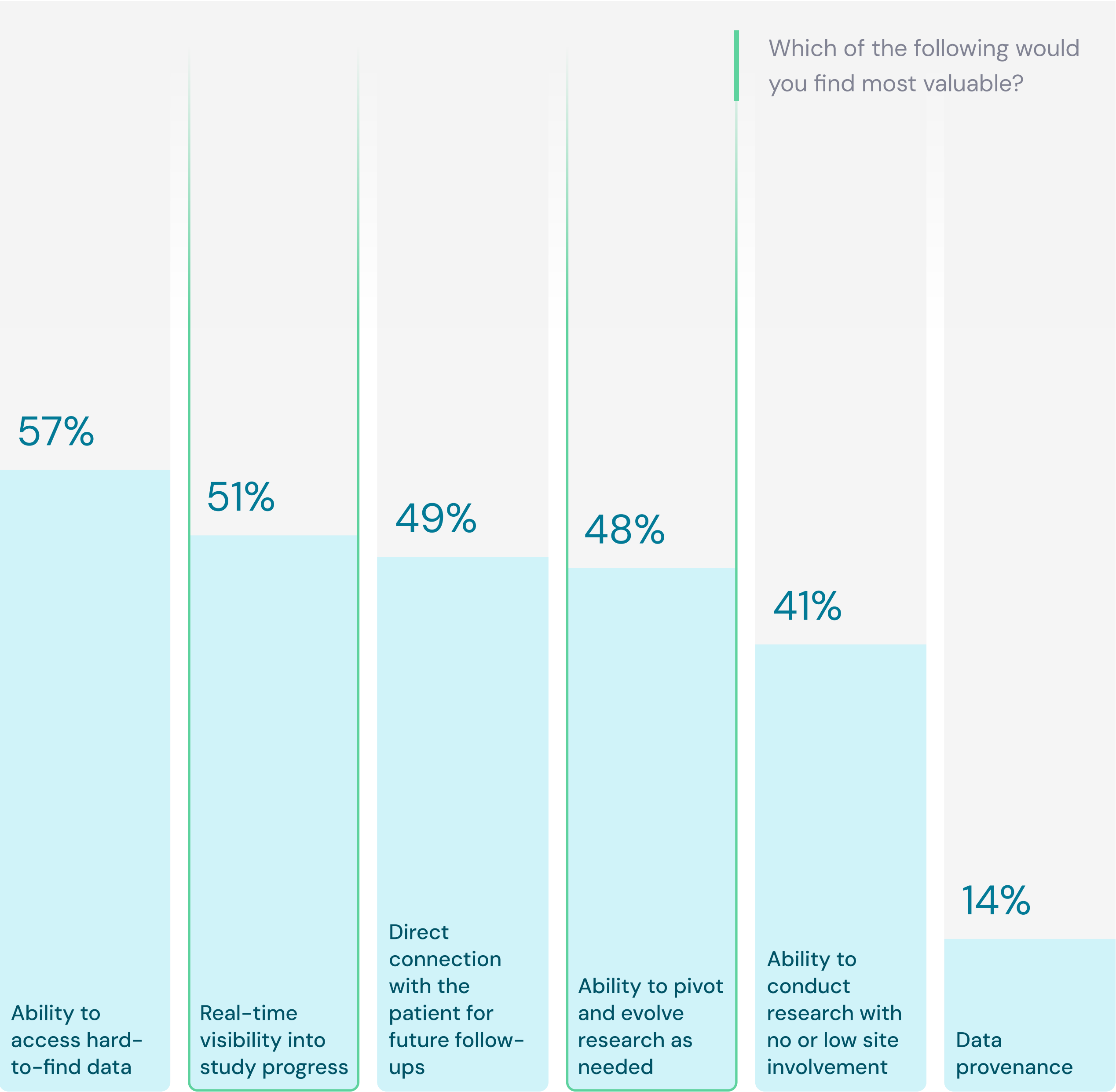
Observational research, especially when meeting regulatory requirements, necessitates capturing complete endpoint data, but traditional methods cannot always deliver. Survey respondents indicated that their top challenge when conducting observational research was incomplete data. Patient retention, data quality, and costs followed closely behind.

Similarly, when it comes to research partners, respondents most value the ability to provide complete data.



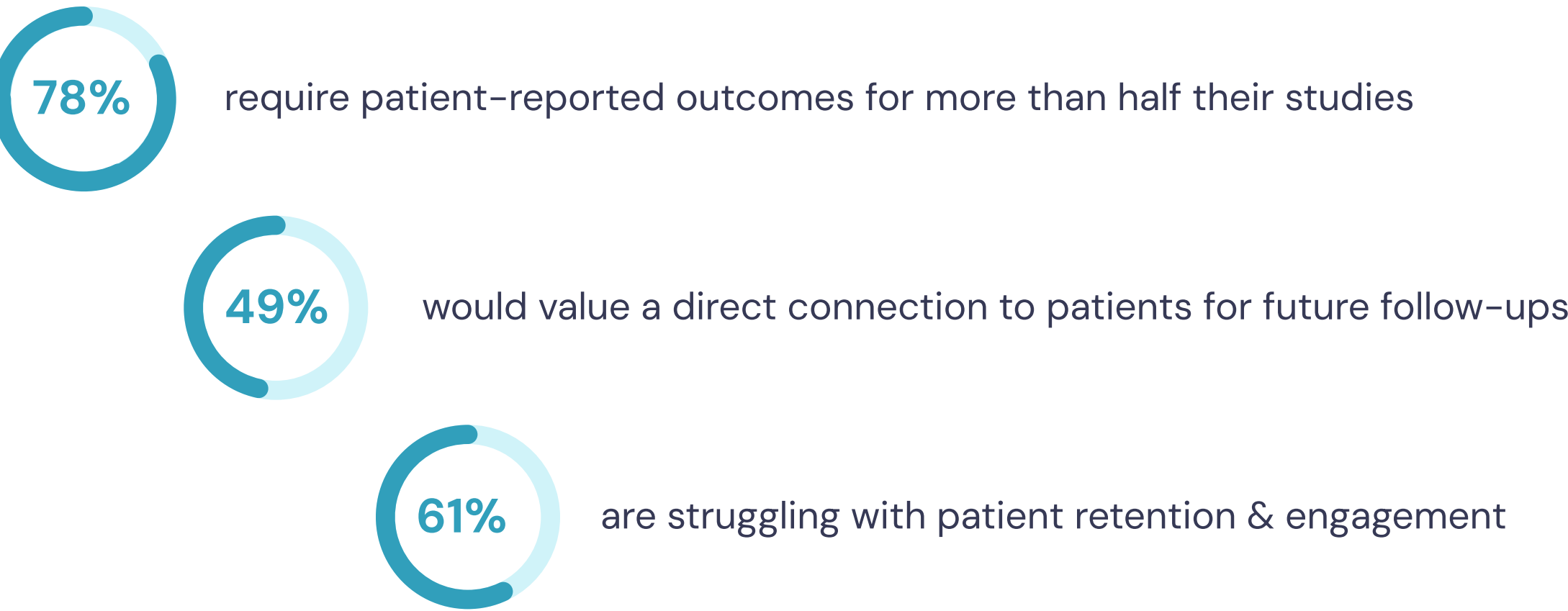
Leaders want flexibility and visibility into study progress.

As the regulatory landscape continues to shift, particularly for long-term data collection, researchers need to be able to maintain visibility into study performance and pivot quickly if needed. After the ability to access hard-to-find data, respondents want real-time visibility into study progress, and about half of respondents value the ability to pivot and evolve their research.



Studies need better patient engagement strategies.

The FDA values the incorporation of patient insights into research, and a significant portion of respondents indicated around half of their studies required patient-reported outcomes.² However, respondents also shared that they are struggling to retain and engage patients, which can impact the ability to capture assessments and generate representative insights. For those who only partner with CROs, patient retention and engagement is the top challenge.



²U.S. Food and Drug Administration. (n.d.). Focus area: Patient-reported outcomes and other clinical outcome assessments.

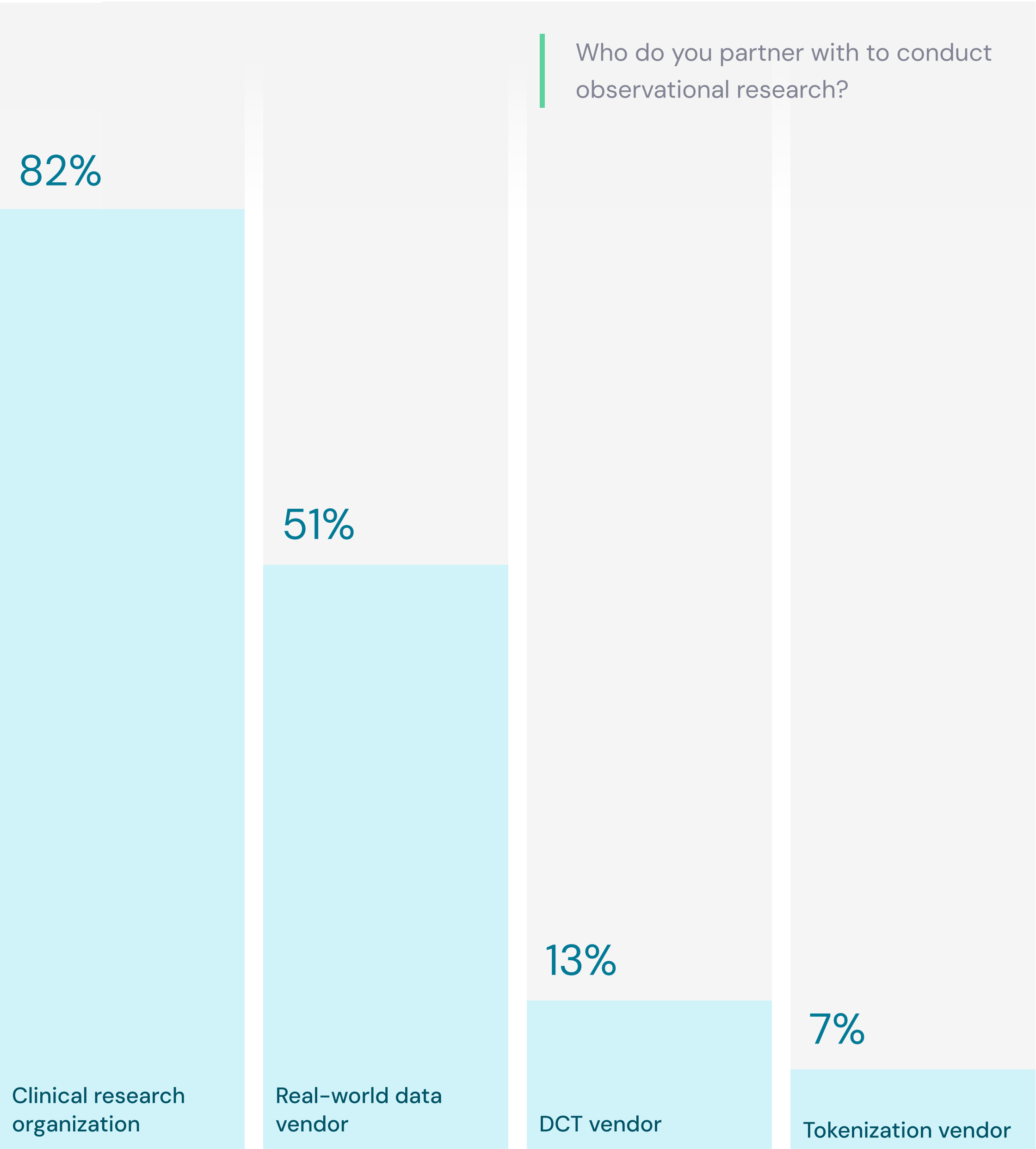
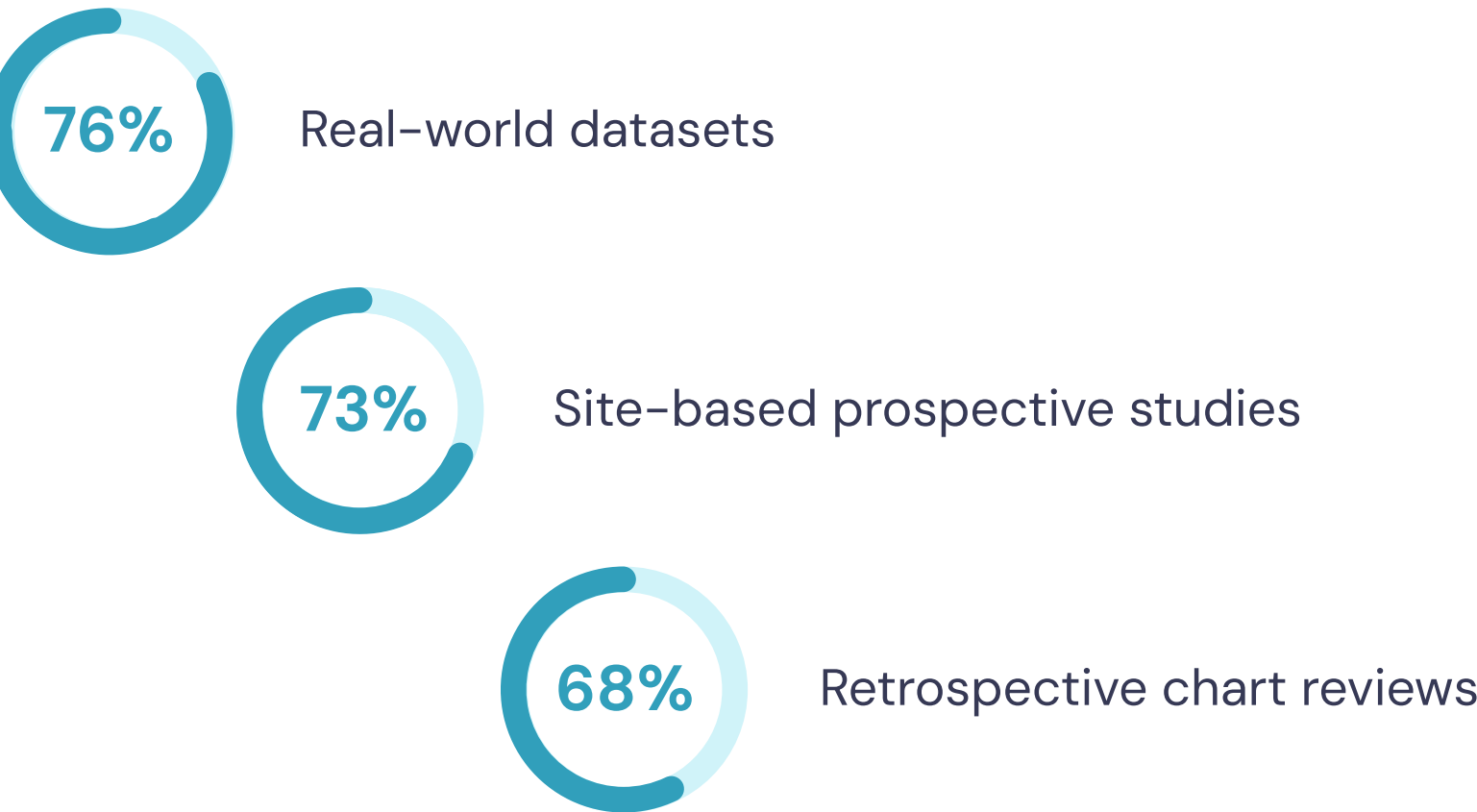
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Industry approaches & new directions

Respondents still rely on traditional methods.

Despite consistent challenges, life sciences companies continue to rely on traditional methods for conducting research. Most respondents stated that they partner with clinical research organizations (CROs) or with real-world data vendors, and they largely employ either site-based prospective methods, retrospective chart reviews, or real-world datasets, all of which have limitations when conducting complex, long-term observational studies.

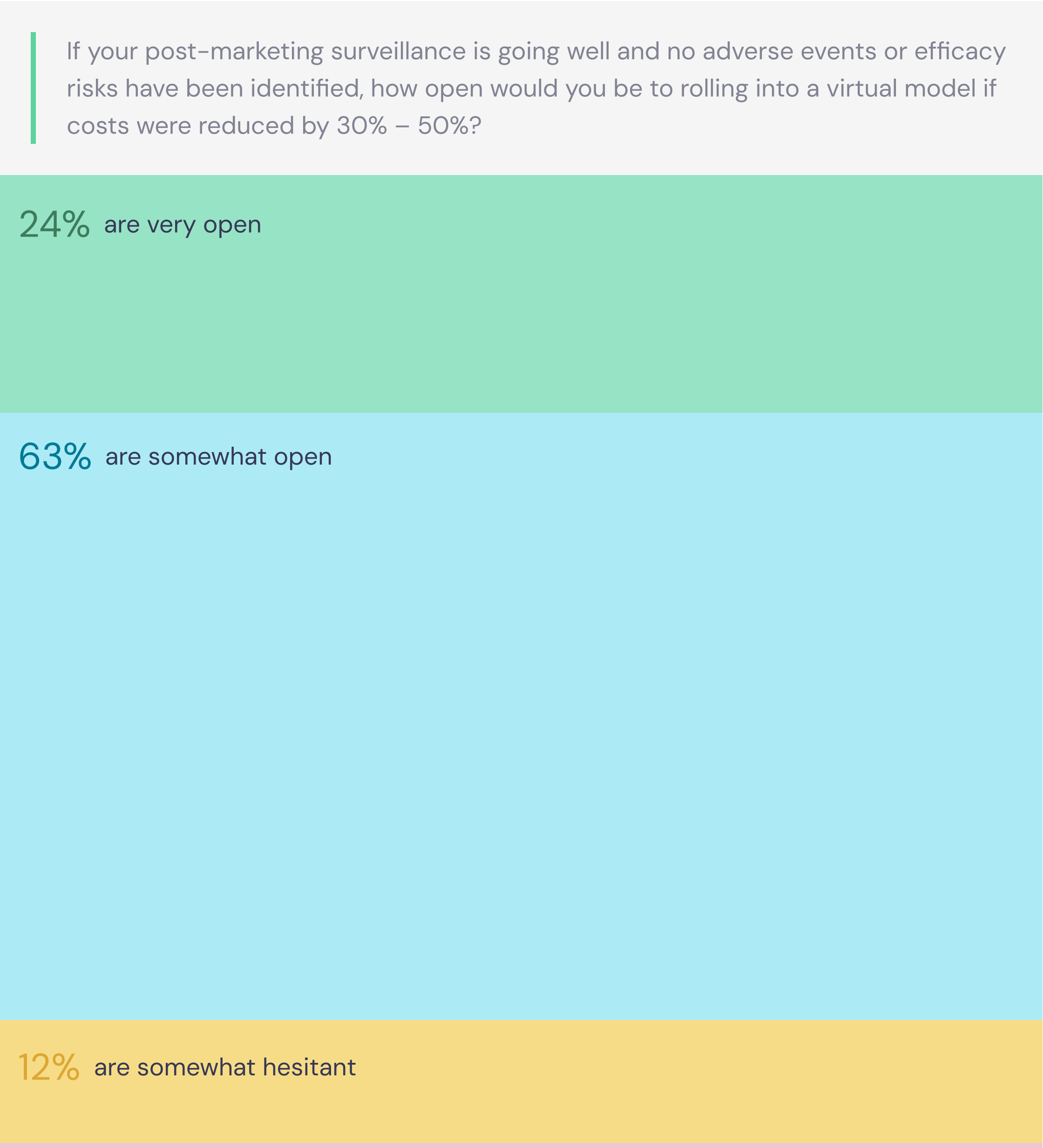
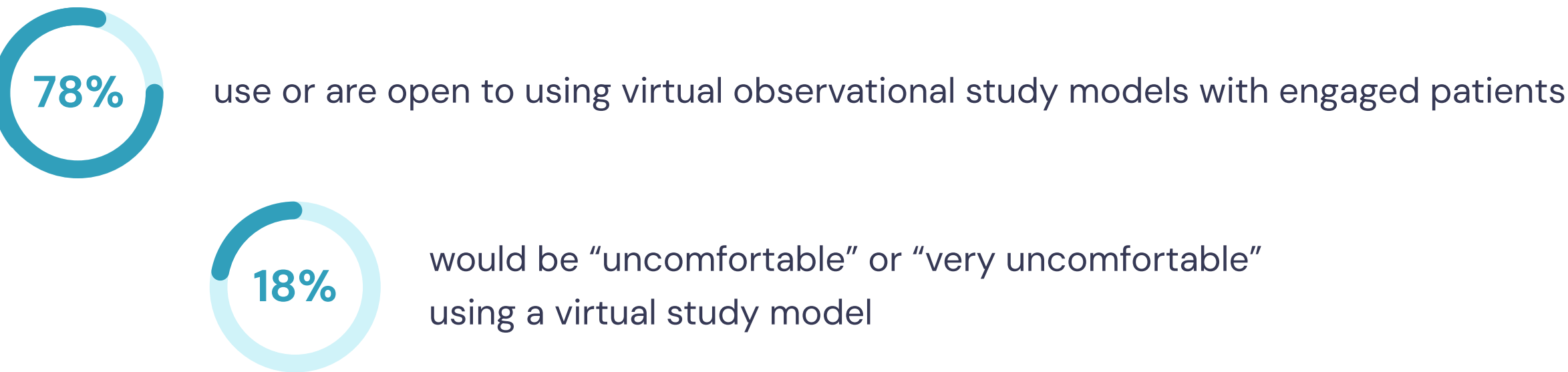
Respondents indicated they use the following traditional approaches in their studies:



Respondents are open to virtual models to conduct research.

In addition to more traditional observational research methods, respondents are also adopting more innovative approaches. Given the challenges many are facing with traditional approaches, it is not surprising that nearly 80% of respondents are already using or are open to using virtual models.

A majority of respondents also indicated an interest in switching to a virtual, cost-effective model if a post-market surveillance study were progressing without incident.



Leaders are beginning to incorporate AI into research.

In pace with the wider adoption of AI across industries, more than half of respondents are utilizing AI and other advanced technologies to support research in some capacity, and only a small portion shared they were reluctant to change. Respondents identified their biggest barrier to adoption was a limited understanding of AI capabilities, presenting an opportunity for research partners to provide increased clarity on how AI enhances research.



What is the biggest barrier to adopting AI in evidence generation?

46% limited understanding of AI capabilities

25% data privacy & concerns

21% resistance to change from traditional models

8% lack of budget or resources



The advent of change

The survey results suggest that as current research methods continue to limit study outcomes and the macroenvironment evolves, life sciences companies are making – and will continue to make – a shift towards more efficient and effective research approaches. By embracing virtual models and leveraging AI, life sciences companies can address data challenges, overcome inefficiencies, and drive innovation in observational research.

About PicnicHealth

PicnicHealth is a leading health technology company dedicated to simplifying healthcare for everyone. To date, the company's direct-to-patient approach and innovative AI and technology platform have enabled 12 of the top 20 largest life science companies to run more efficient observational research.

PicnicHealth has given tens of thousands of patients access to tools and virtual care services to simplify their care journey. PicnicHealth was recently named one of the "World's Best Digital Health Companies" by Newsweek, "Best MedTech Startup" by MedTech Breakthrough, and "Best AI-enabled Life Sciences Solution" by Global Health & Pharma.