Biospecimen Management Benchmarking Survey

Research Report 2024

Conducted by TrendCandy

Sponsored by Biospecimen Management Consortium

Biospecimen Management Consortium

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EXECUTIVE SUMMARY

The Status Quo of Biospecimen Management in Clinical Trials

The **Biospecimen Management Consortium (BMC)** conducted a comprehensive benchmarking survey in Q3 2024 to assess current biospecimen management practices in the biopharma and medical device industries. This initiative aimed to inform the development of industry best practices and standards, ultimately shaping the future of clinical research.

The survey gathered insights from 164 biopharma and medical device professionals across the U.S. and Europe on existing processes and challenges with different aspects of biospecimen management - including study start-up, sample tracking, queries and reconciliation, kitting design, informed consent, sample shipping, data transfers, and reporting.

Findings highlight the pain felt by the lack of up-front study start-up planning, the sheer amount of manual work still being required of all stakeholders, the clinical trial risk caused by delays in clean sample data, the lack of defined metrics being tracked, as well as the lack of priority that the site experience plays in clinical trial decisions.

The survey results will inform the BMC's future initiatives, focusing on addressing the identified challenges and developing standardized practices to enhance biospecimen management in clinical research. The BMC encourages the industry to leverage these results within their own organizations as well.

To learn more about this report or the BMC, visit Biospecimen-Consortium.org.

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Key Findings

PLANNING

A **lack of up-front study start-up planning** causes downstream issues.

MANUAL WORK

The biospecimen lifecycle process **still requires significant manual work.**

QUALITY

Delays in QC'd sample data are putting trials at risk.

METRICS

Metrics are not being tracked consistently, or not tracked at all.

SITE CENTRICITY

Site experience is considered, **but not a top priority.**

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By Region

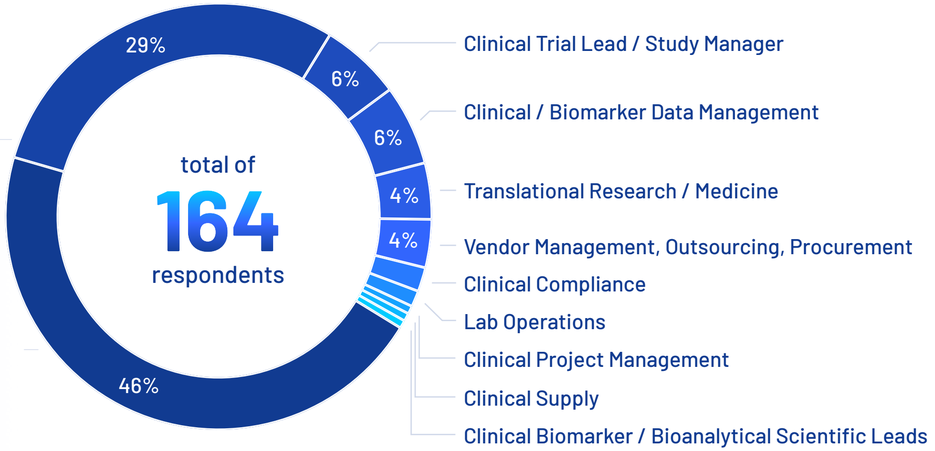
65% United States

35% Europe

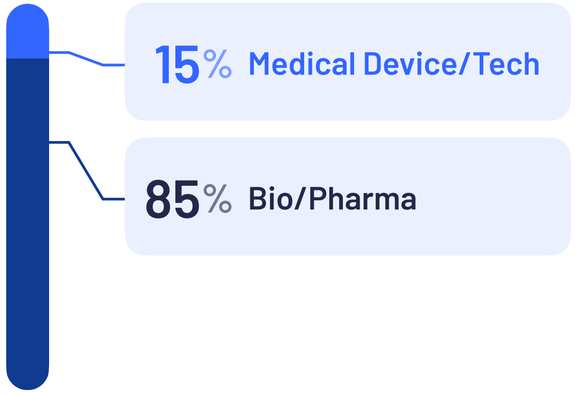
By Role at Company

29% Clinical Operations / Trial Management

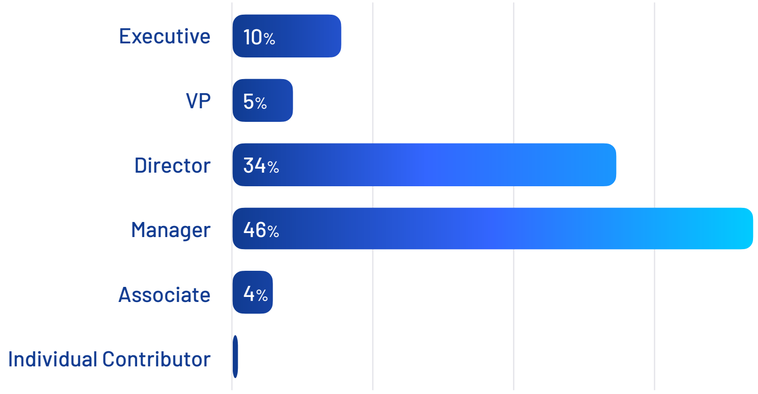
46% Biomarker/Biospecimen Ops, Bioanalytical Sciences



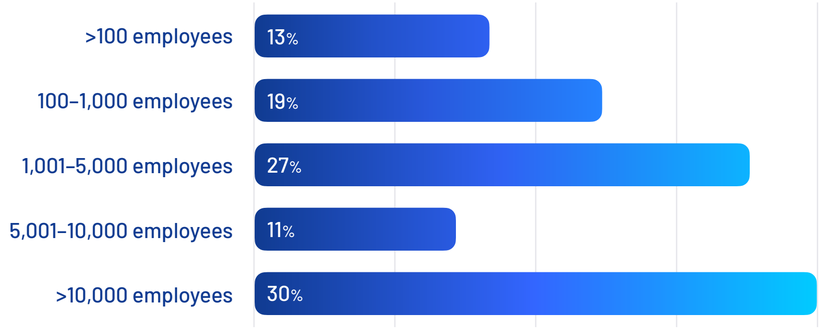
By Company Type



By Seniority at Company



By Company Size



The research was conducted by TrendCandy through an online survey in Q3 2024. The sample was drawn from BMC member organizations as well as TrendCandy databases.

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Results and Insights

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Study Startup

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Schedule of assessments may not be informing accurate lab manuals

Only

51%

agree that the schedule of assessments within the protocol informs accurate lab manuals.

To what extent do you agree or disagree with the following statement? “The schedule of assessments in the clinical protocol informs accurate lab manual development.”

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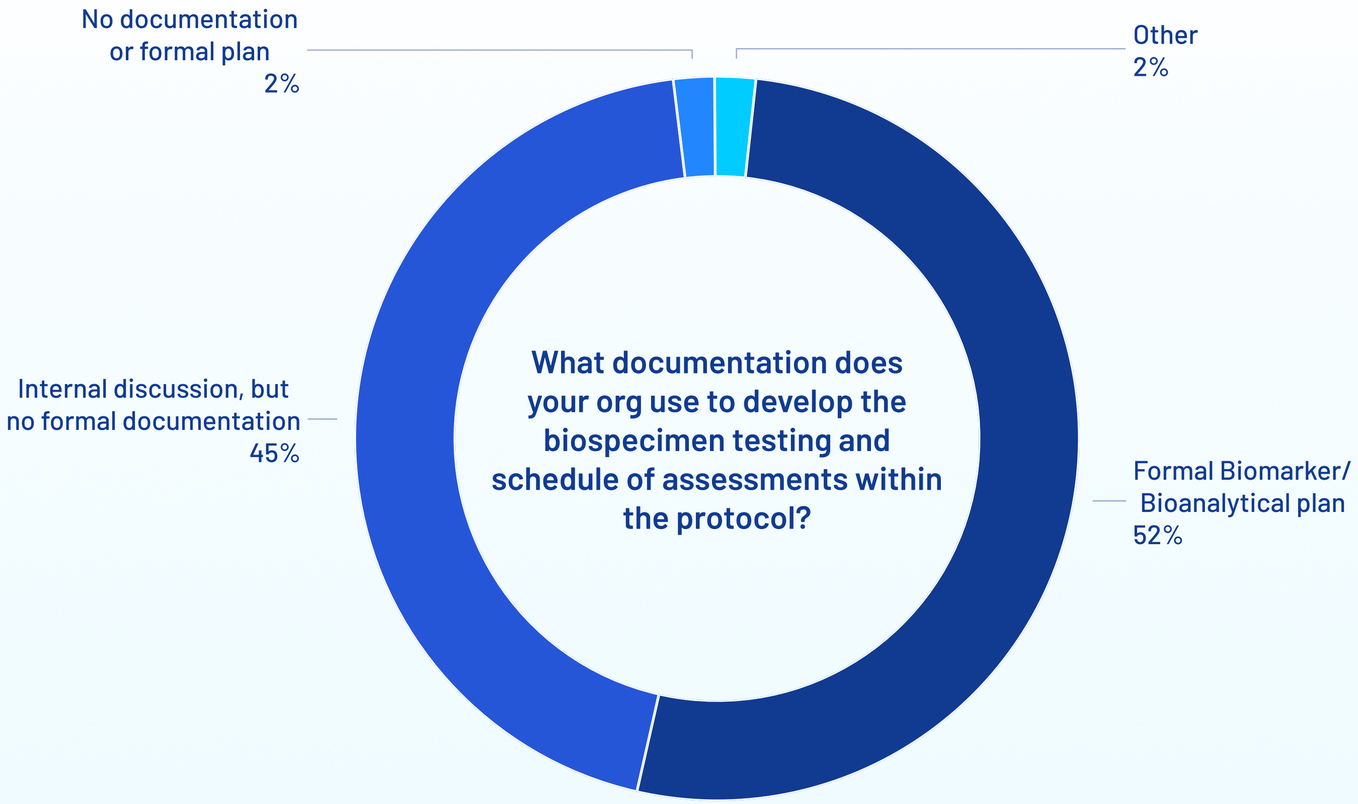
Formal biomarker & bioanalytical plans
are not yet standard



45% respondents have internal discussions, but no formal documentation

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Testing & biospecimen collection strategies require clarity

Only

45%

agree that their testing strategy and biospecimen collection hierarchy is well defined.

To what extent do you agree or disagree with the following statement? “My org’s testing strategy and biospecimen collection hierarchy is well defined.”

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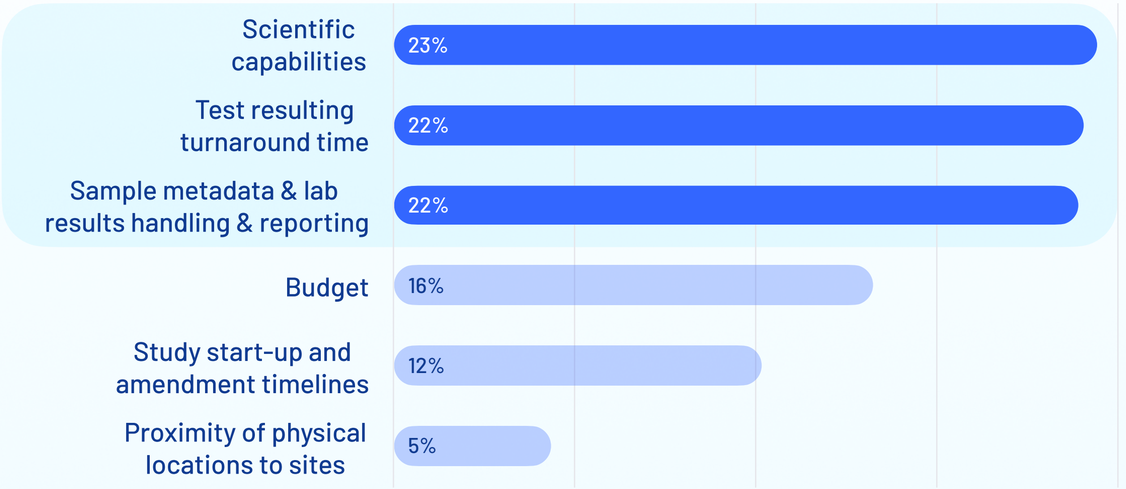
Scientific capabilities
are driving lab strategy

23% scientific capabilities

22% test results turnaround time

22% sample metadata & lab results handling & reporting

Which are most important when you are developing your lab strategy? Select your top 3.



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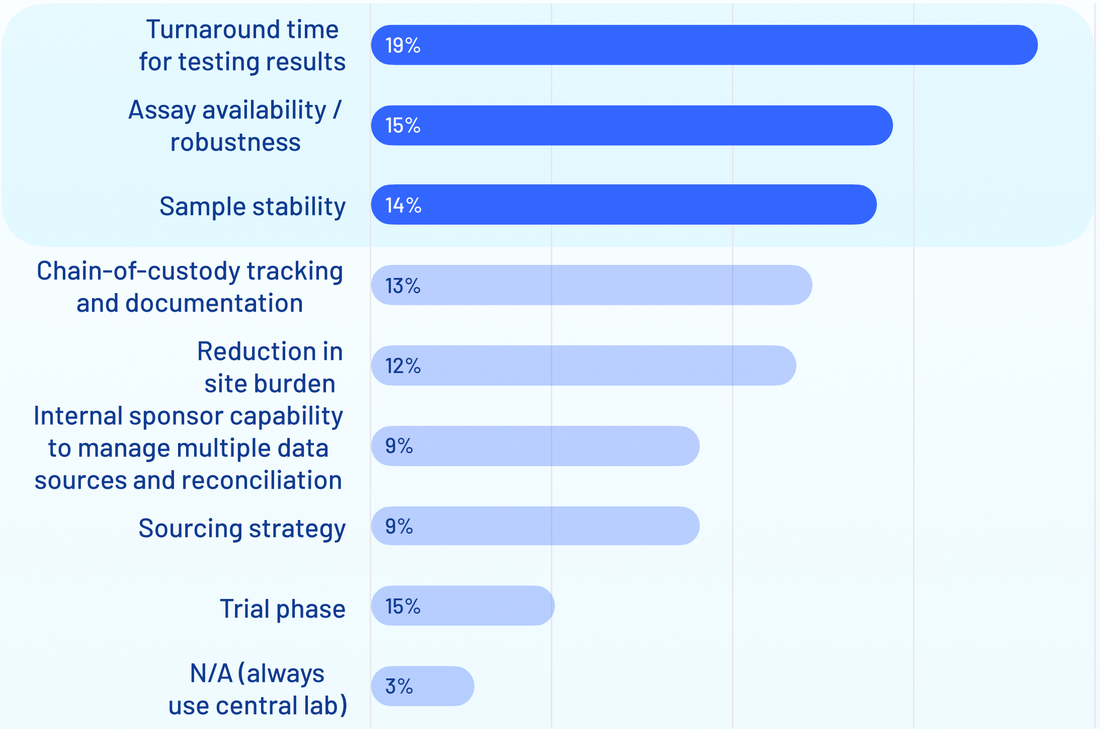
Turnaround time for testing results drives the choice between central and specialty labs

19% turnaround time for testing results

15% assay availability / robustness

14% sample stability

Which factors impact your decisions to use central labs vs direct to specialty labs? Select your top 3.



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Sample Tracking

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Manual and internally developed sample trackers are the norm

38% of respondents use manual methods, while 36% use internally developed trackers

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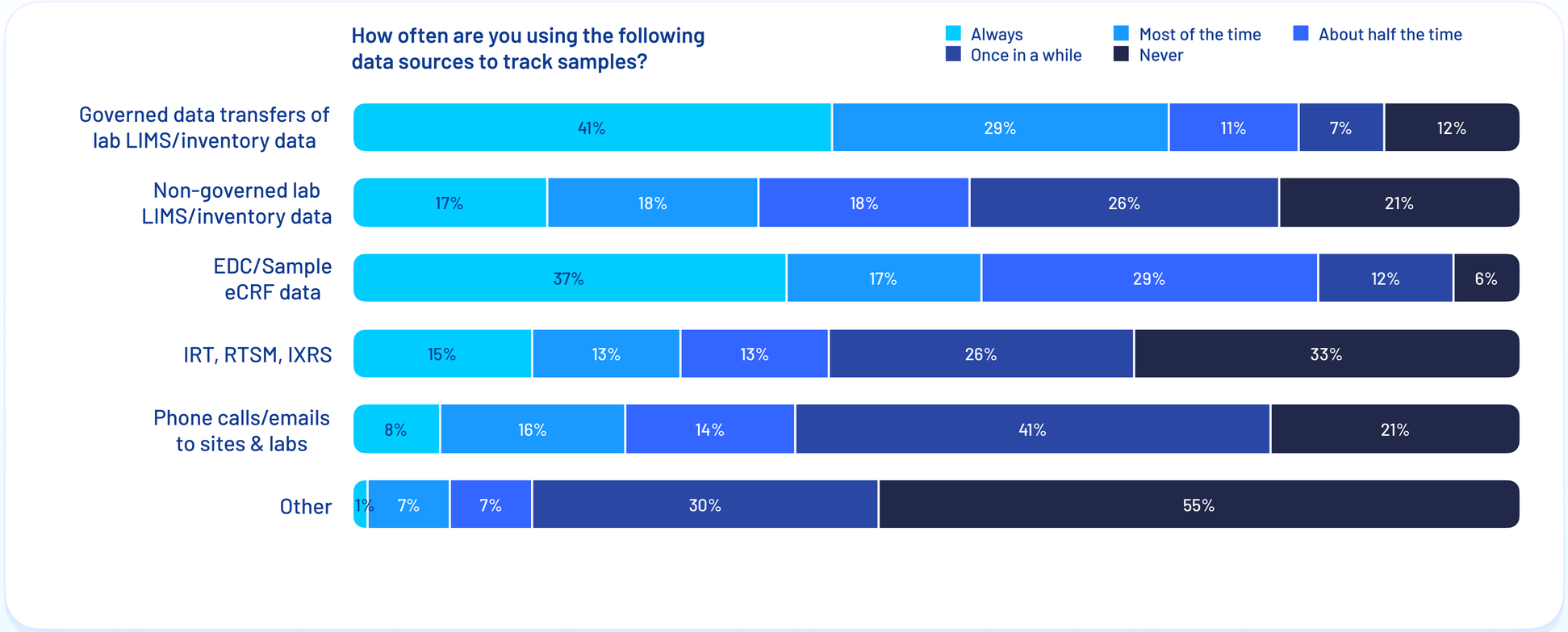
Disparate sources are used to track samples with a majority using non-governed data



79% of respondents are using non-governed data transfers to track samples

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Biosample Operations ranked highest as responsible for sample tracking

40% of organizations reported that Biosample Operations groups were responsible for sample tracking.

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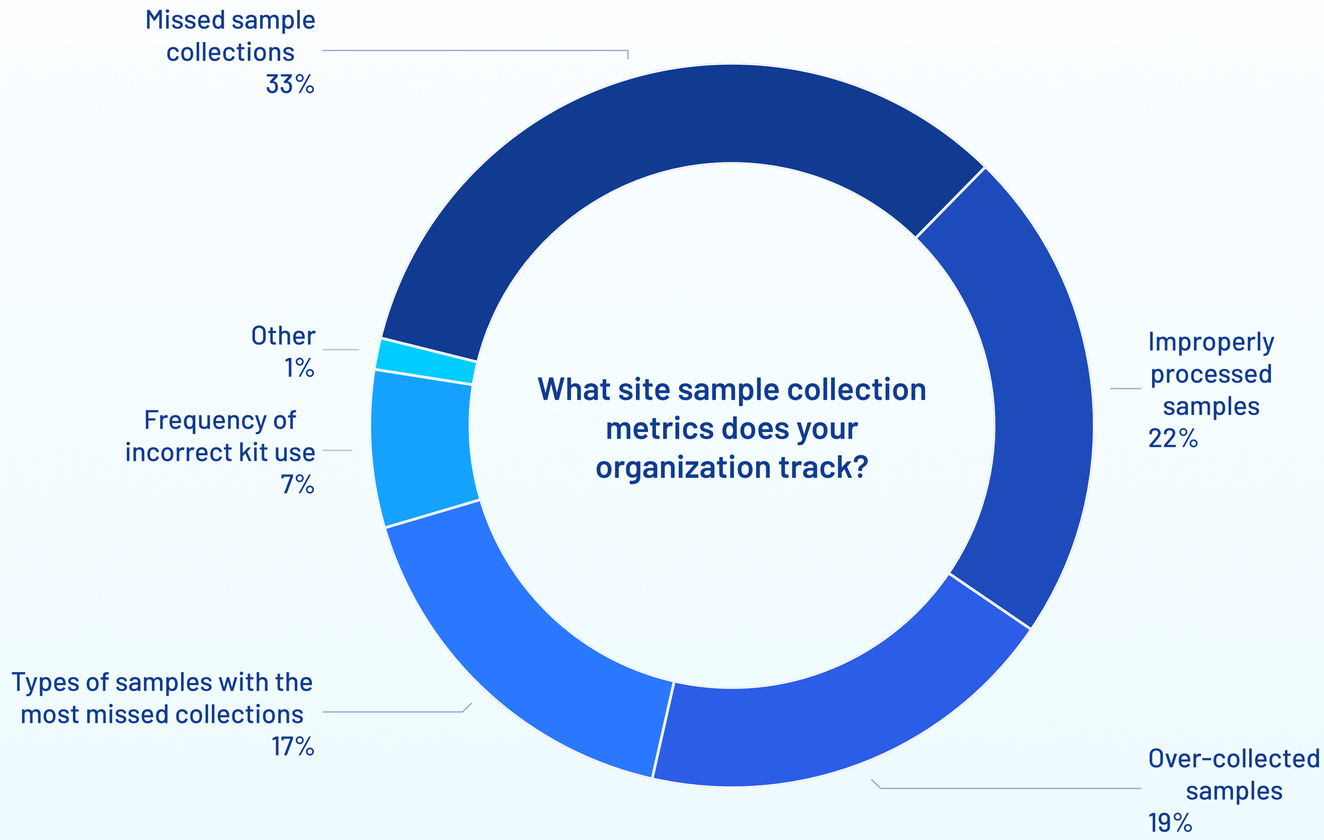
Sample collection metrics
are not readily tracked

33% track missed samples

22% track improperly processed samples

19% track over-collected samples

17% track types of samples with the most missed collections



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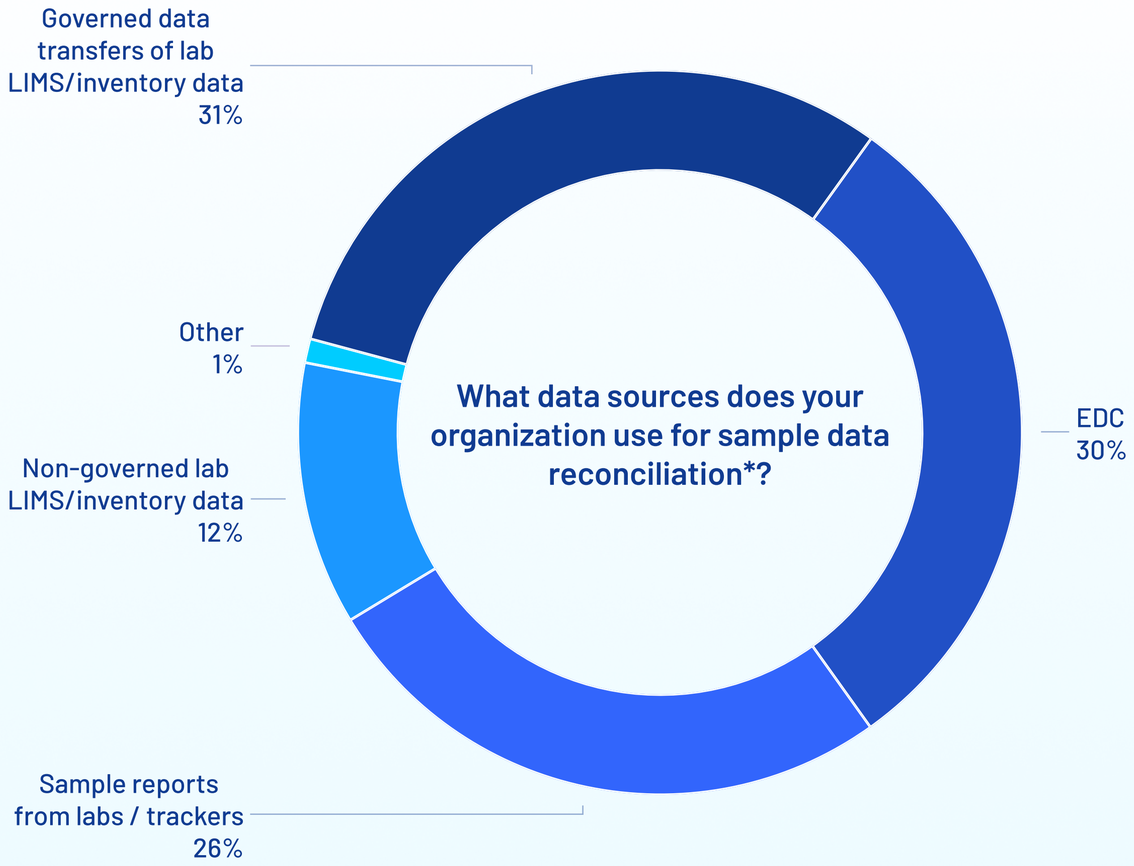
Queries & Reconciliation

Sample data reconciliation data sources could put trials at risk

12%

are still using non-governed LIMS inventory data for reconciliation



* comparison between eCRF and LIMS / inventory data

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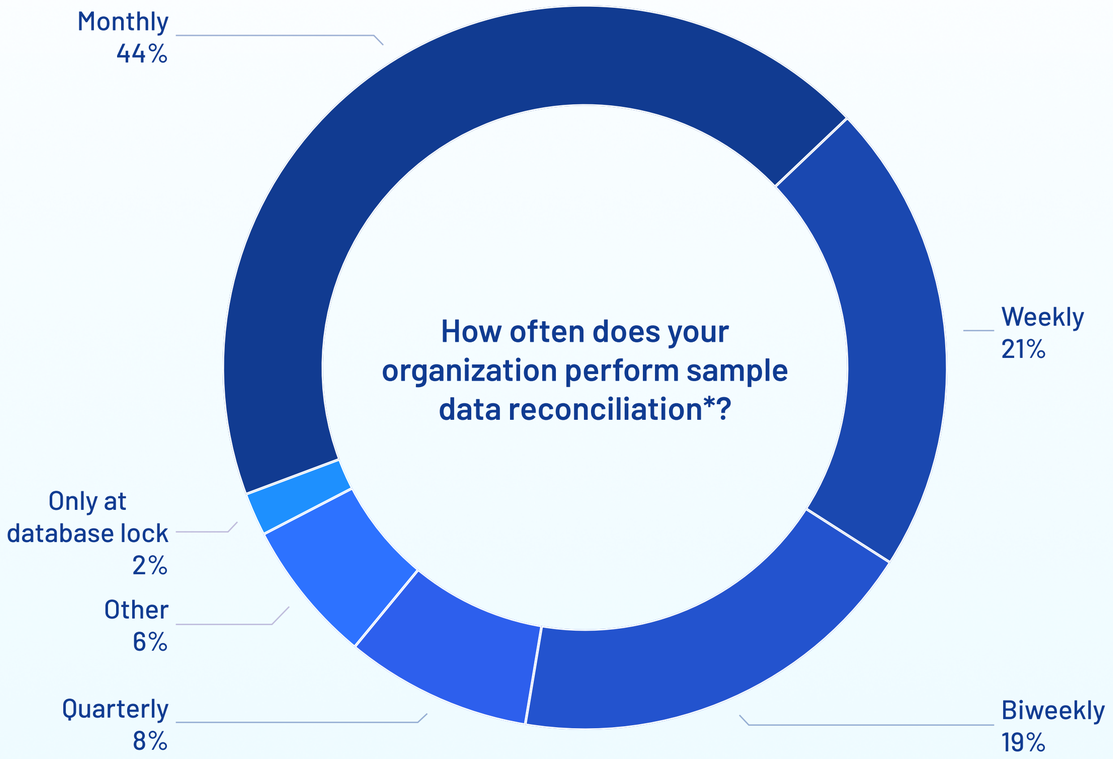
Monthly sample data reconciliation is most common

44%

reconcile sample data between eCRF and LIMS/ inventory data monthly



* comparison between eCRF and LIMS / inventory data

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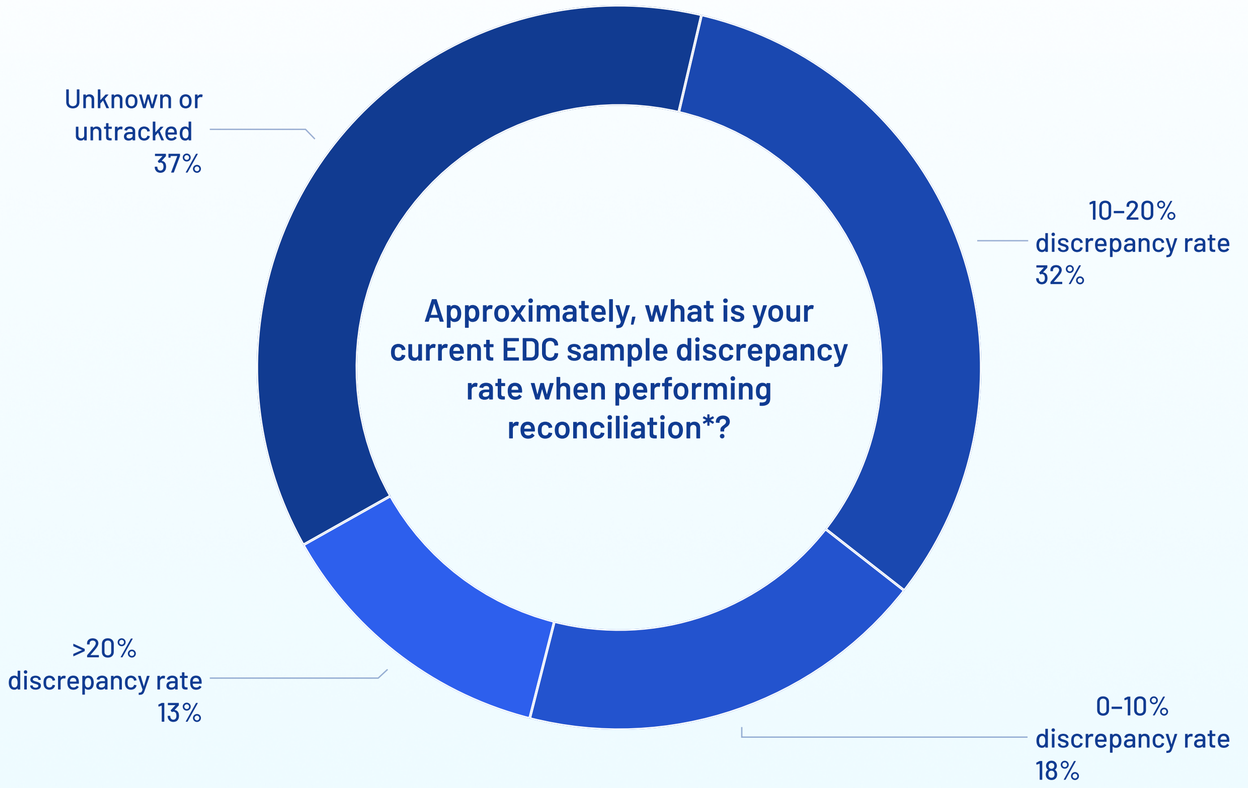
Most don’t know or don’t track their current EDC discrepancy rates

37%

don’t know or don’t track EDC discrepancy rates.

Of what was tracked, 32% cited discrepancy rates of 10–20%, and 13% cited rates greater than 20%.



* comparison between eCRF and LIMS / inventory data

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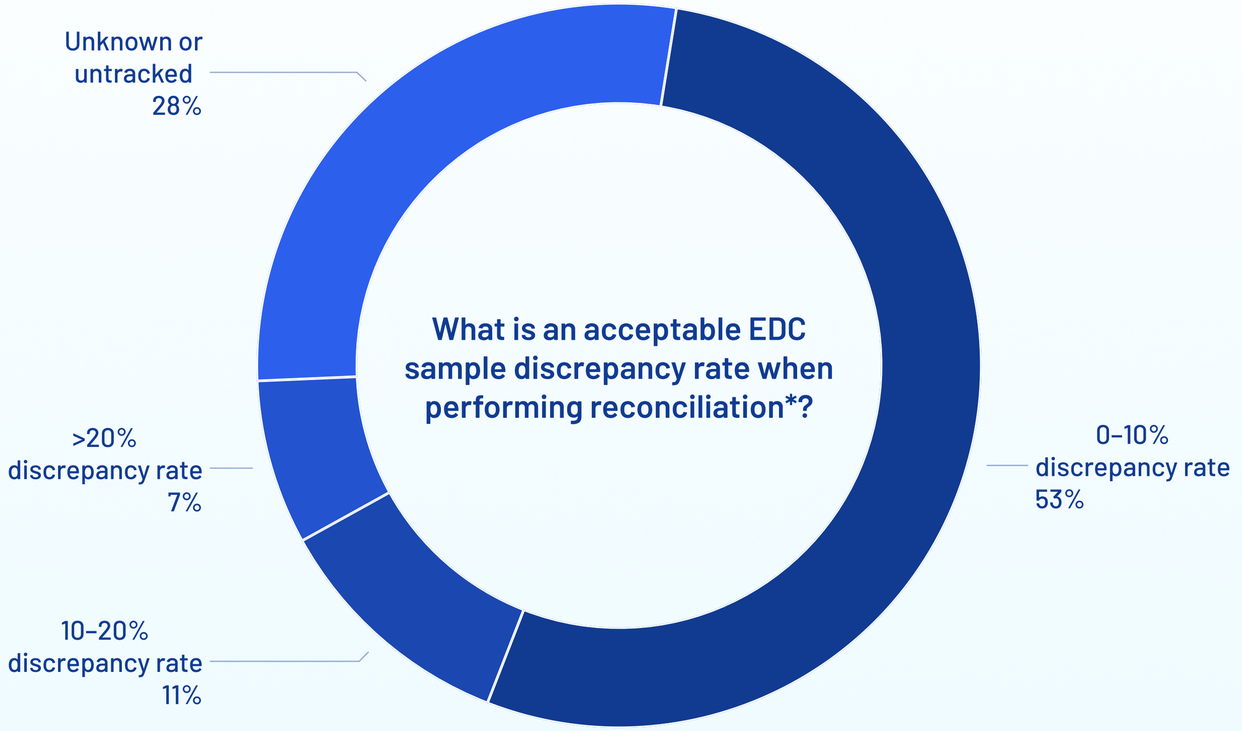
Acceptable EDC discrepancy rate
is much lower than reported rates

53%

report an acceptable EDC discrepancy rate to be <10%.

Only 18% are operating at an acceptable discrepancy rate, highlighting the gap.



* comparison between eCRF and LIMS / inventory data

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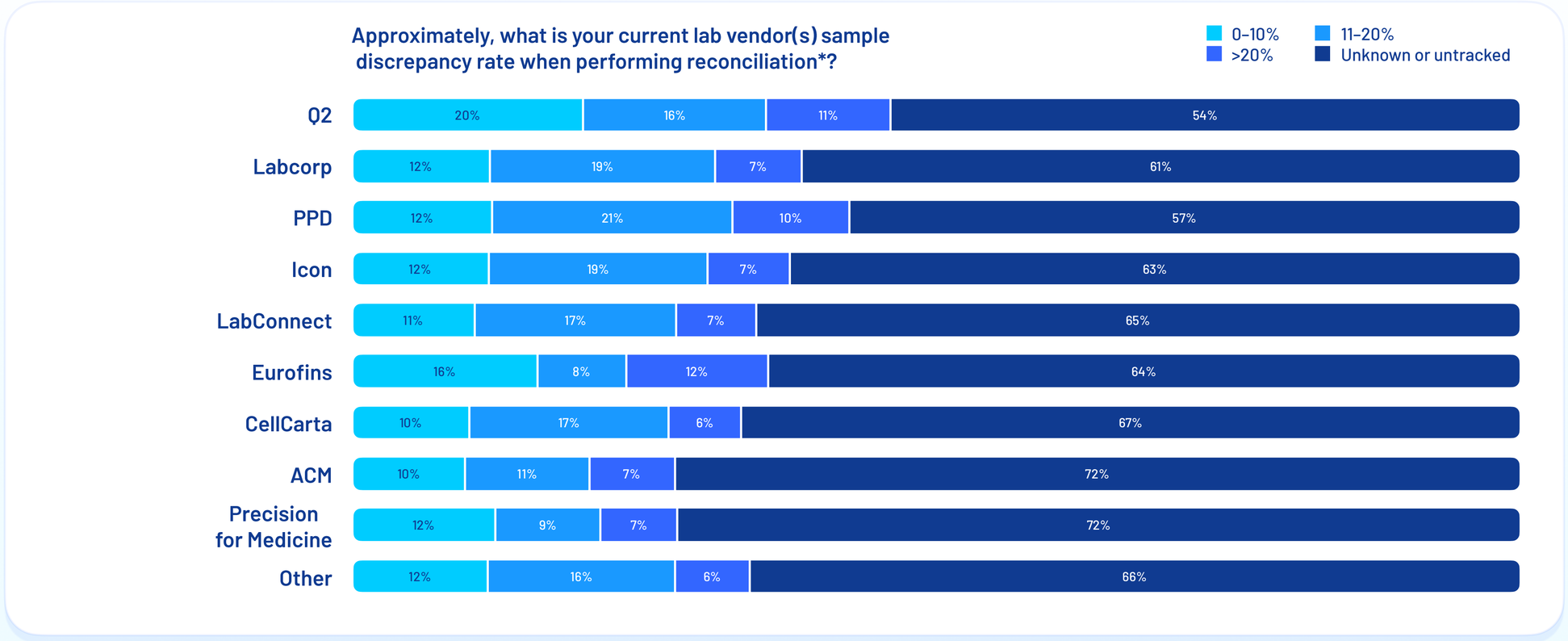
Most don't know or don't track their current lab discrepancy rates when performing reconciliation



64% don't know the lab discrepancy rates. Of what was tracked 14% cited discrepancy rates of 10–20%, and 8% cited discrepancy rates over 20%.

* comparison between eCRF and LIMS / inventory data

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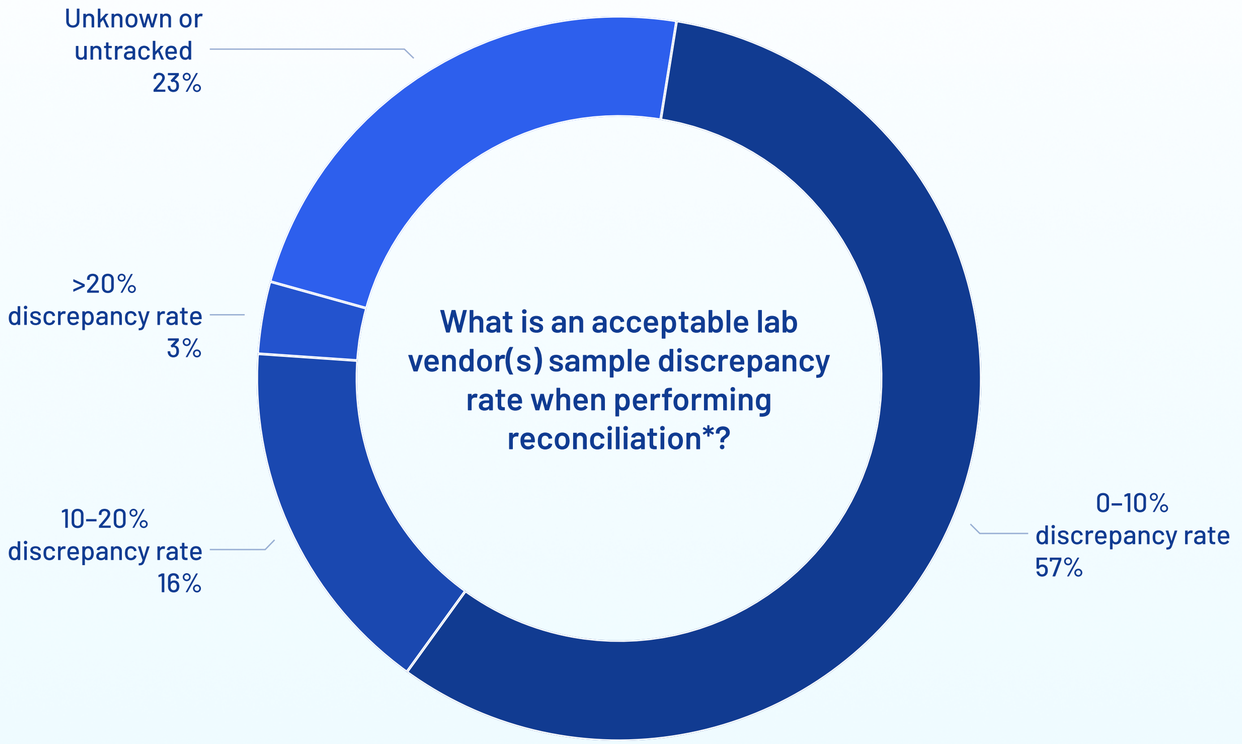
Acceptable lab discrepancy rate when performing reconciliation is much lower than reported rates

57%

report an acceptable lab discrepancy rate to be <10%.

Of note, 23% are unsure what an acceptable rate would be.



* comparison between eCRF and LIMS / inventory data

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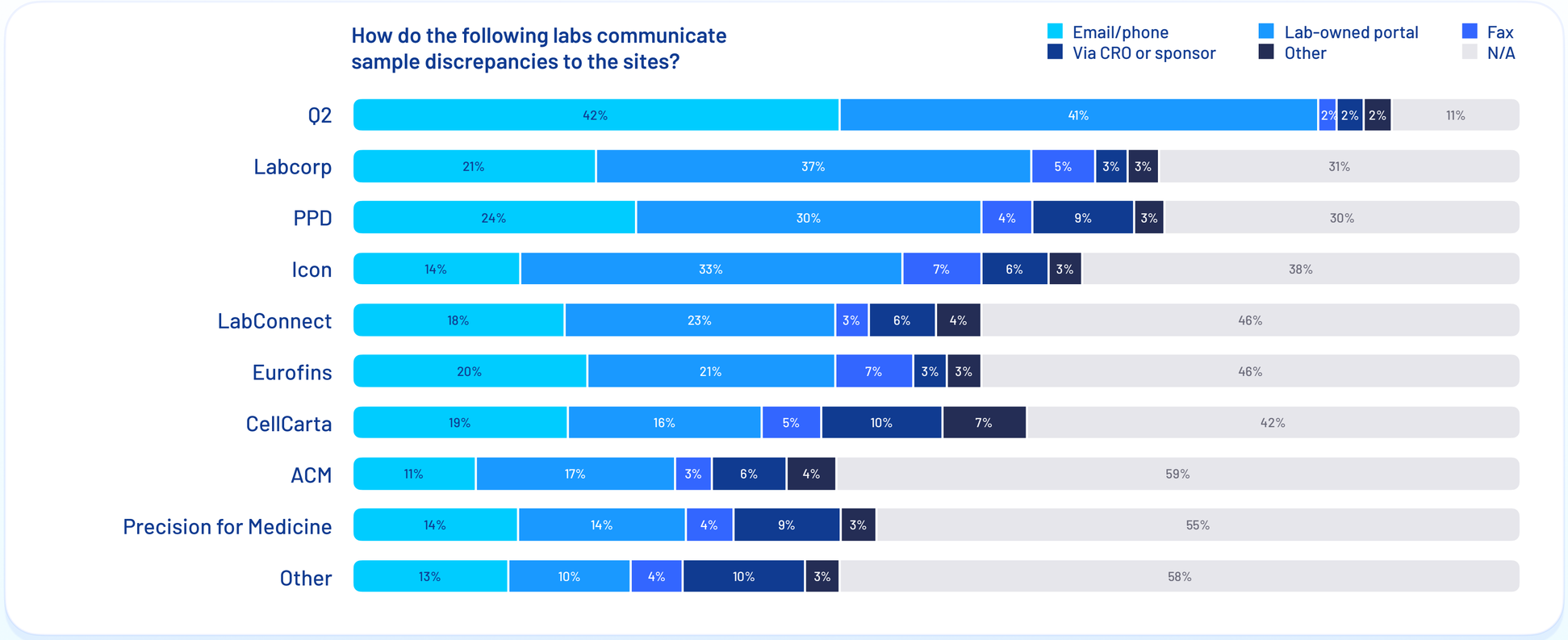
Labs still rely on email & phone calls to communicate discrepancies to sites



20% reported that labs call / email sites to resolve queries, while 25% rely on lab-owned portals.

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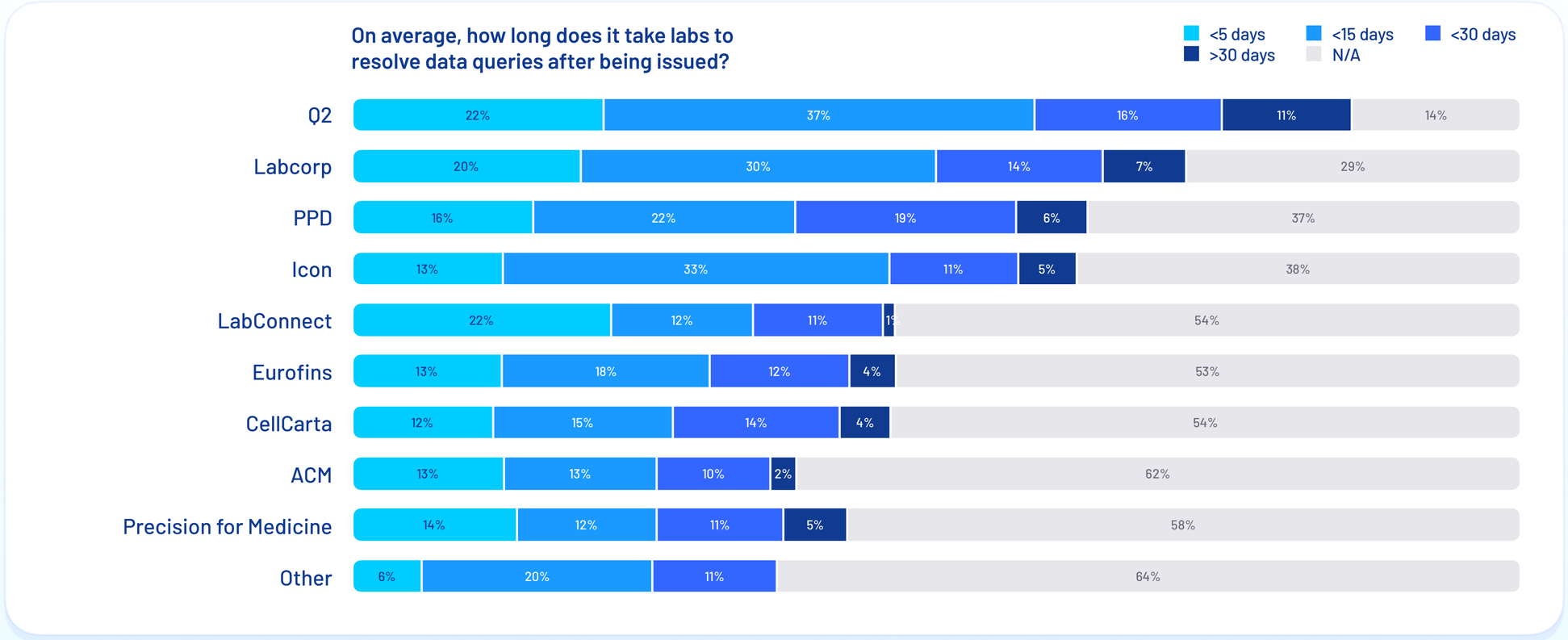
Lab queries are slow to resolve



38% of respondents cite that it takes over 5 days to resolve a query, with 20% taking >15 days, 13% taking >30 days, and 5% taking 30 days. Only 15% cite resolution in under 5 days.

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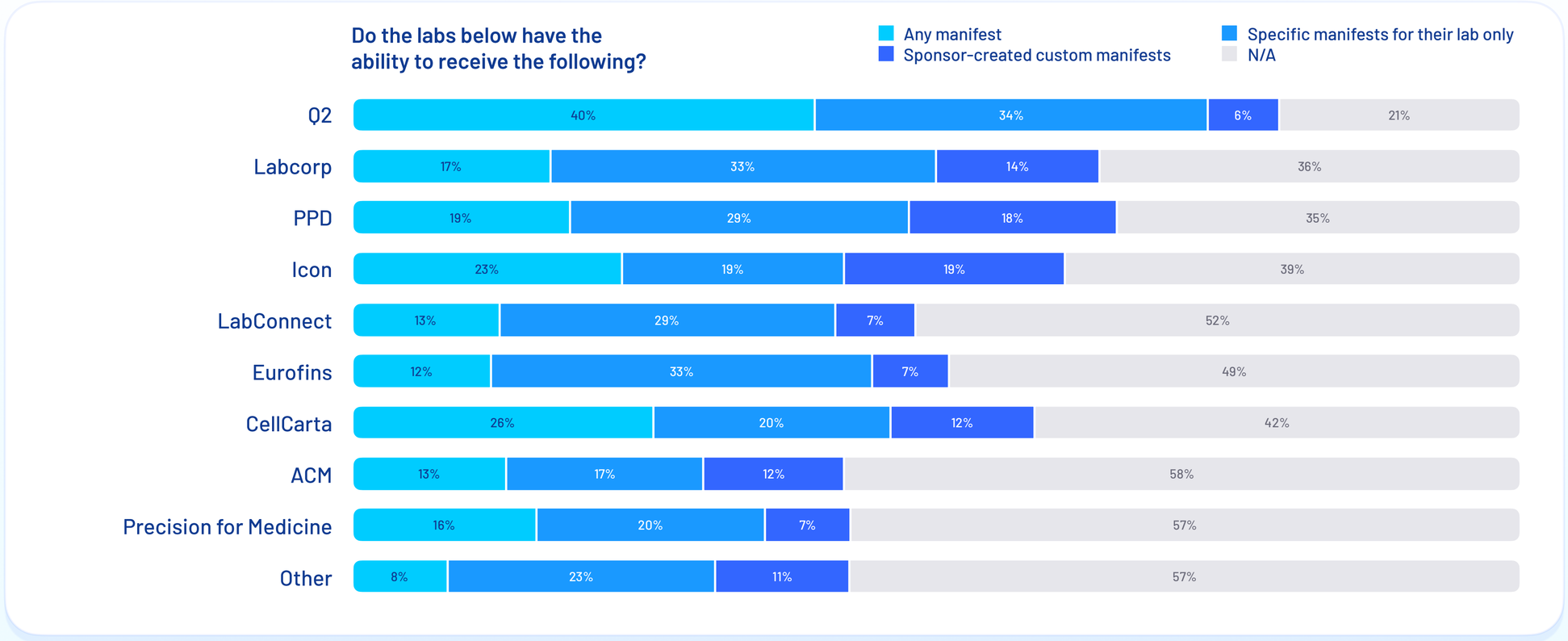
Majority of labs require use of their manifests



26% of respondents report that their labs require use of their specific manifests, followed by 19% using any manifest, and 10% will use sponsor created custom manifests

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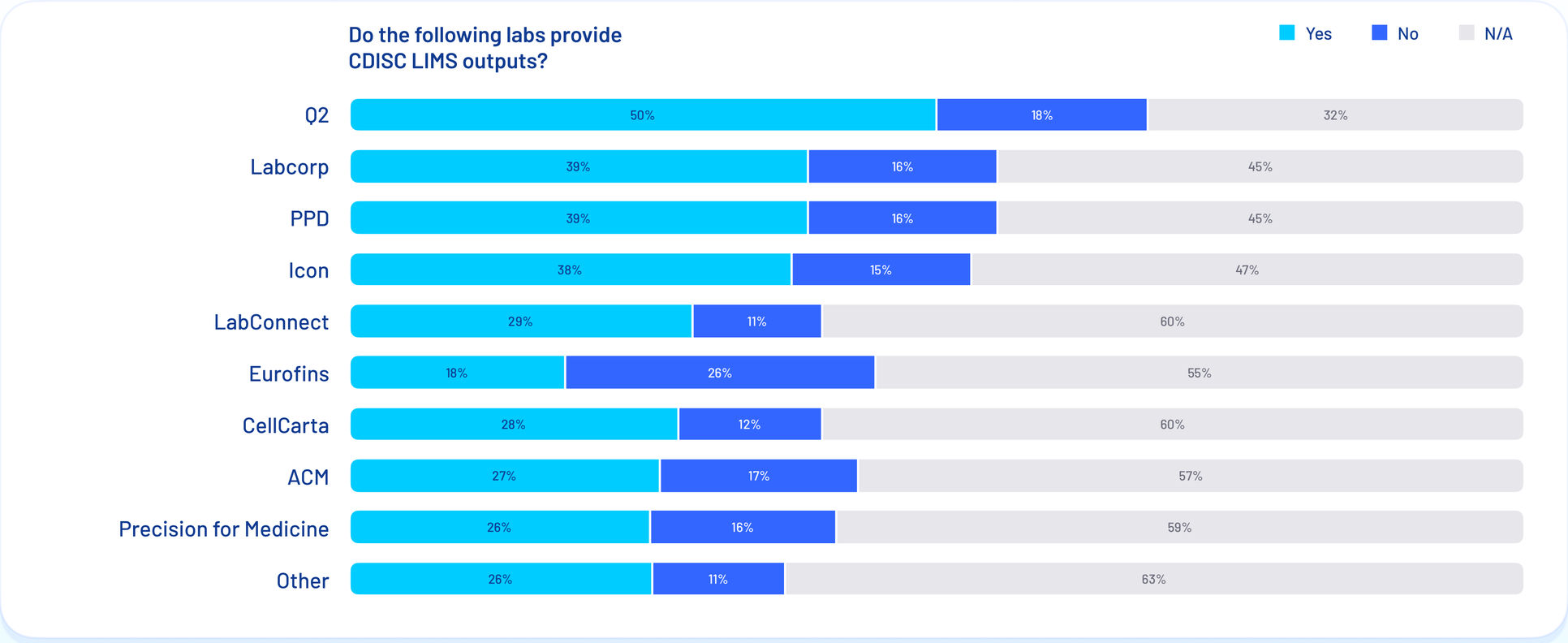
Majority unsure if labs use CDISC LIMS outputs



32% indicated their labs use CDISC LIMS outputs, while 15% indicated no. 53% selected *not applicable*, indicating that they may not know.

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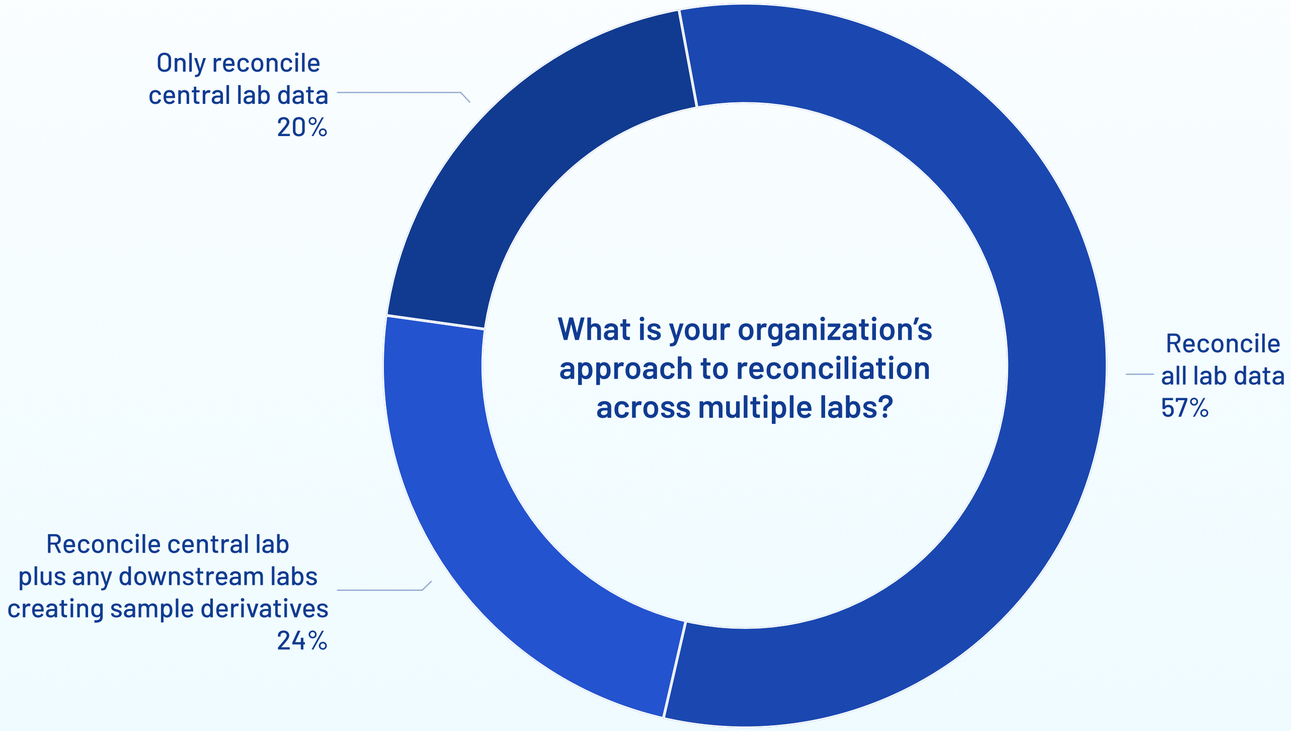
Majority of organizations **reconcile all lab data**

57%

indicated they reconcile all lab data, while 24% reconcile central lab data plus any downstream labs creating sample derivatives.

Only 20% reconcile central lab data only.



* comparison between eCRF and LIMS / inventory data

Kitting Design

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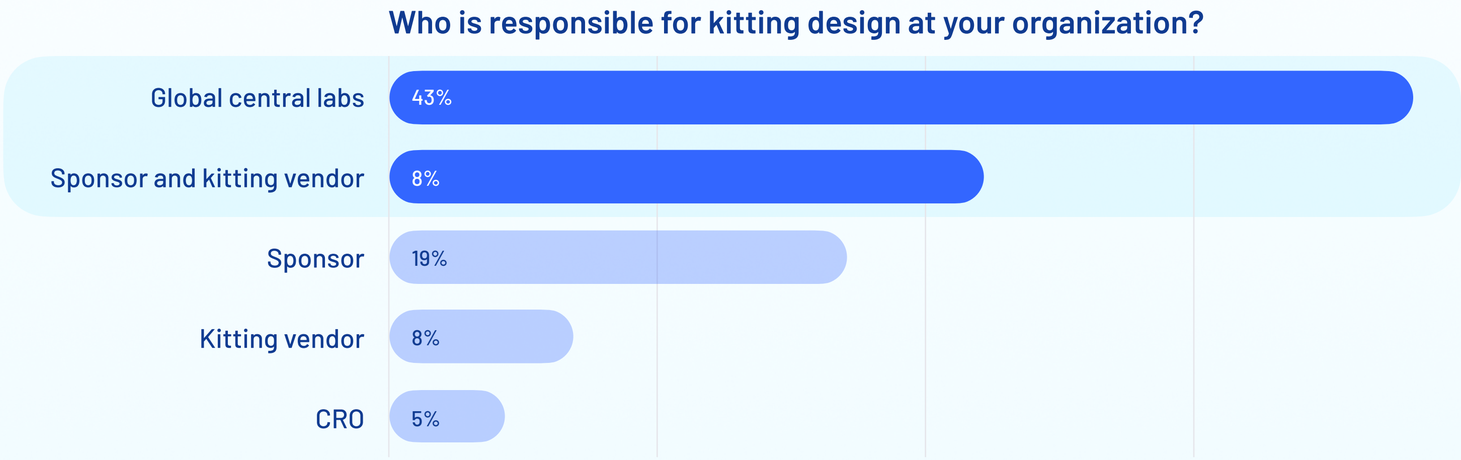
Global central labs
dictate kitting design



43% of respondents indicate that global central labs are responsible for kitting design; followed by 25% collaboration between sponsor and kitting vendors

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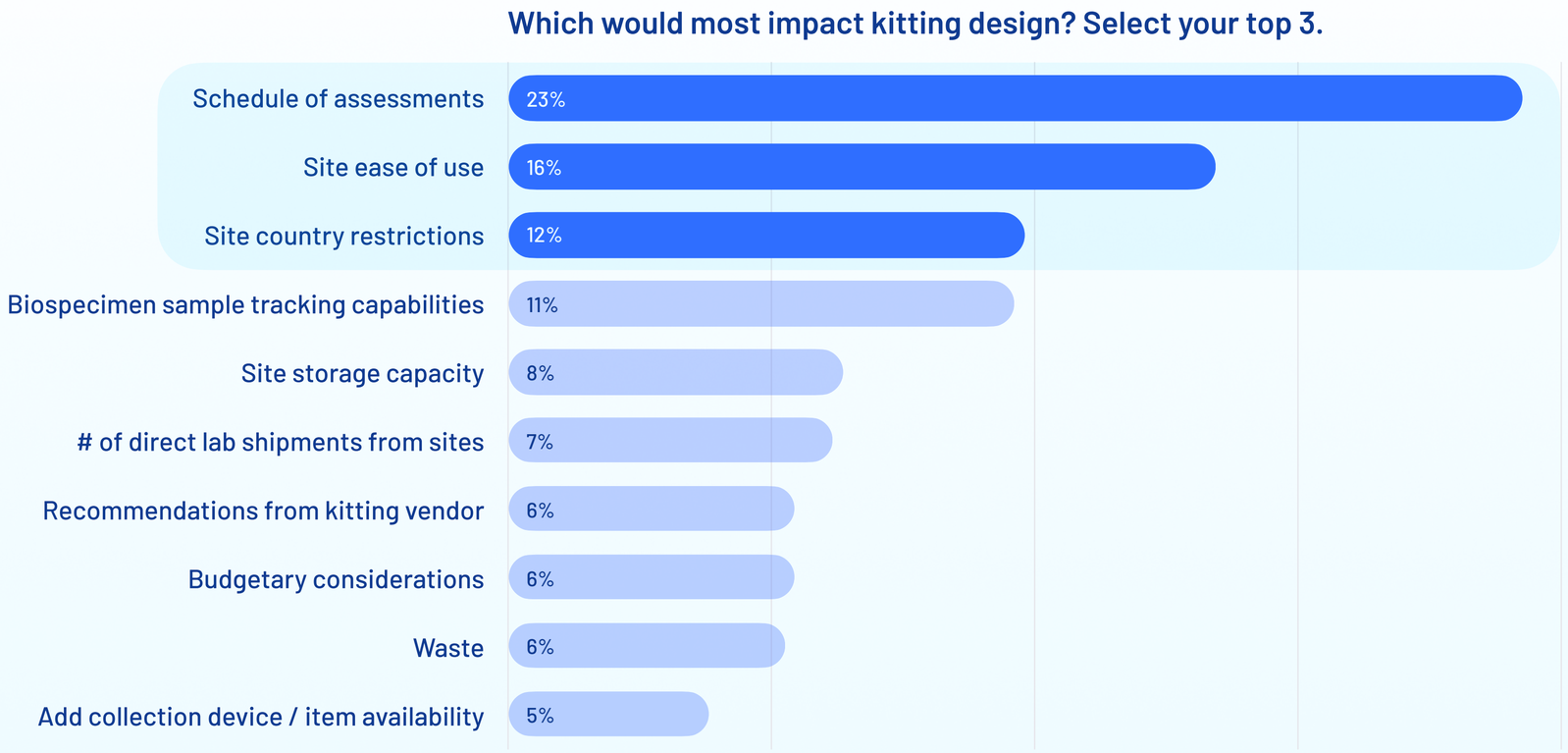
Schedule of assessments is the driving factor for kitting design



Top three factors that impact kitting design include schedule of assessments (23%), site ease of use (16%), and site country restrictions (12%)

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Informed Consent

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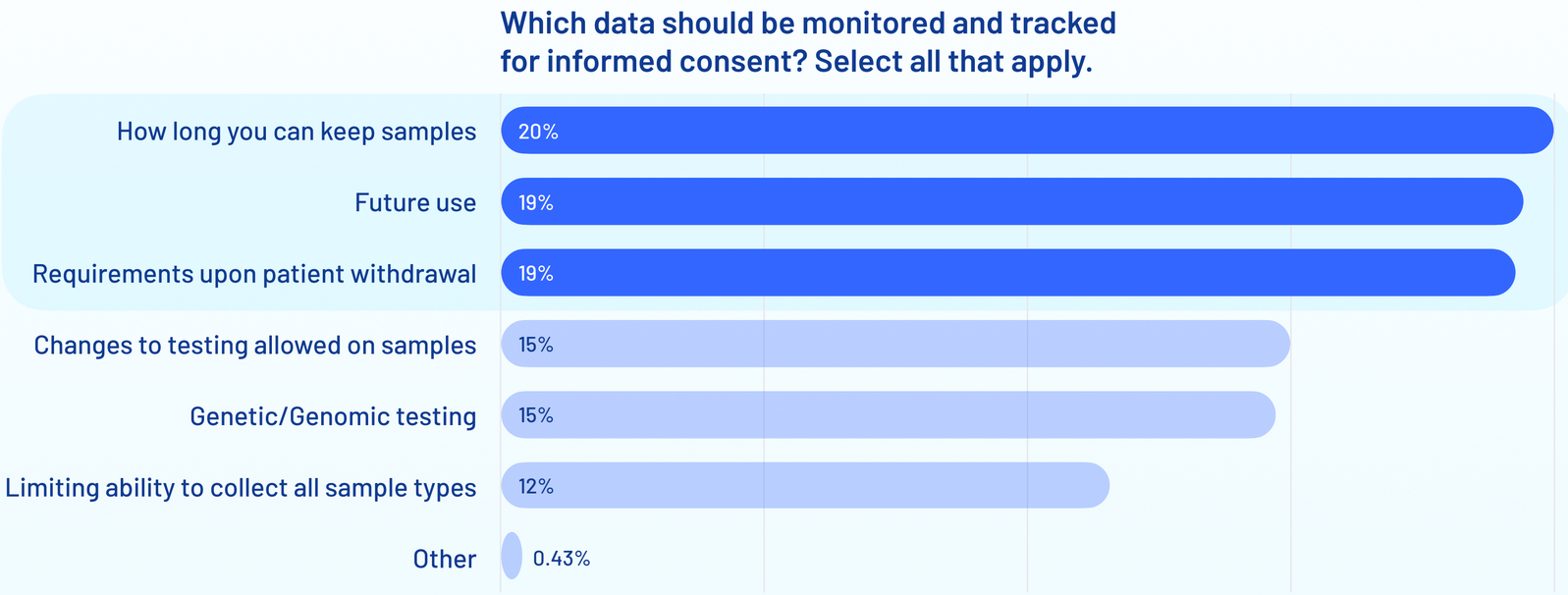
Length of time, future use, and patient withdrawal are all key informed consent metrics



Top three data points that should be monitored and tracked for informed consent are how long you can keep samples (20%), future use (19%), and requirements upon patient withdrawal (19%)

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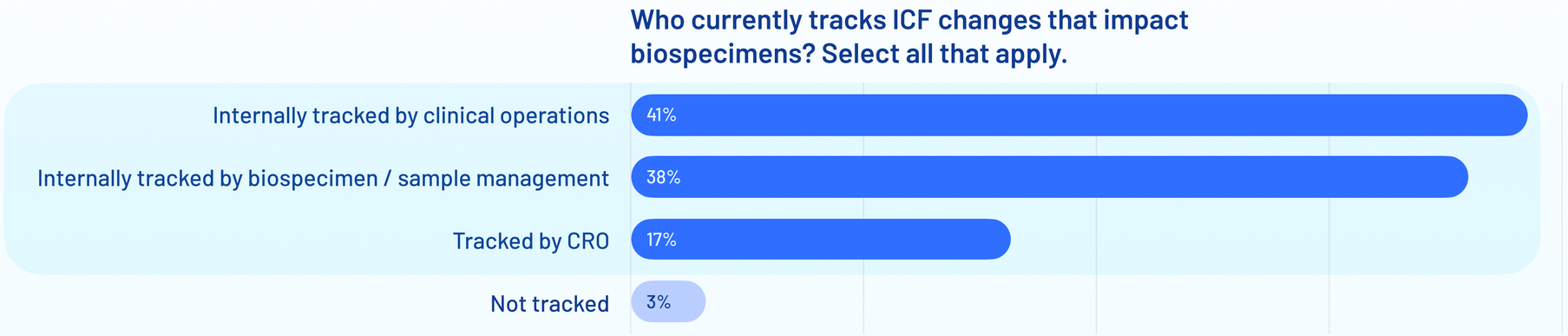
ICF changes primarily tracked by the sponsor



Only 17% cited as tracked by CRO; while the majority was tracked by clinical operations (41%), followed by sample management (38%)

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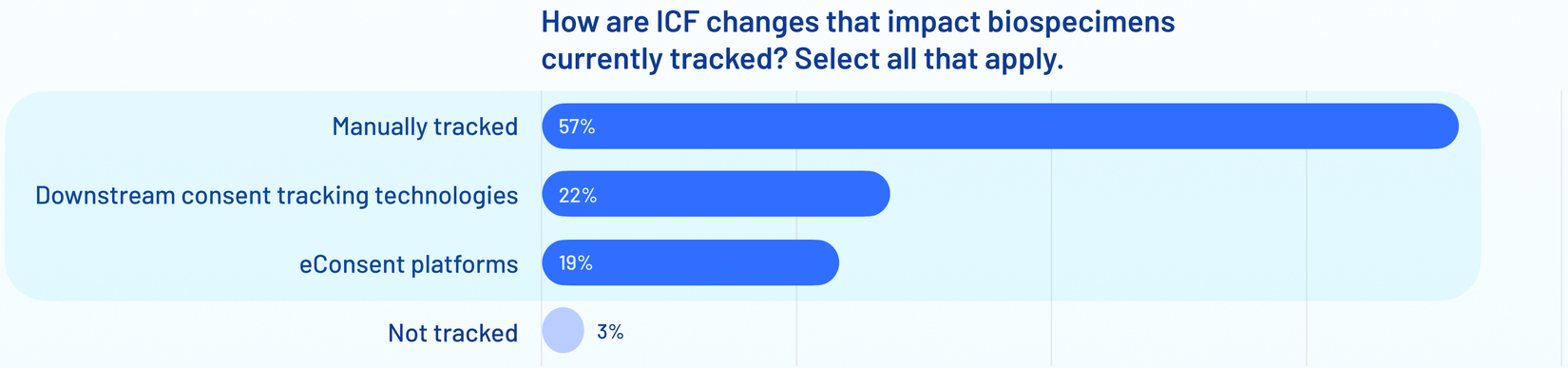
Manual tracking still the norm for informed consent



57% of respondents manually track ICF changes, while 40% use downstream consent platforms

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Sample Shipping

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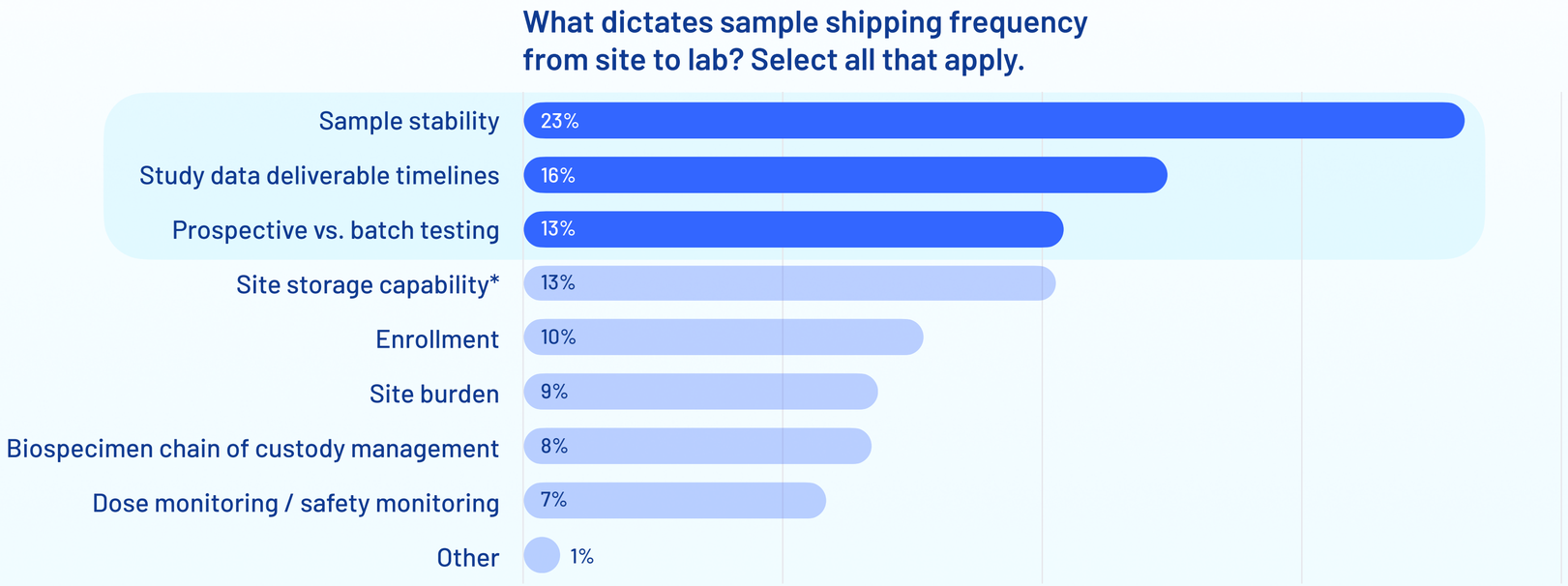
Sample shipping frequency from site to lab driven by **sample stability**



Sample stability was the highest factor that dictates sample shipping frequency (23%), followed by study data deliverable timelines (16%) and prospective vs. batch testing (13%)

* pre-rounding, *site storage capability* ranked slightly below *batch testing*

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Sample shipment progress monitored by central labs / kitting vendors

32% of respondents rely on central labs and kitting vendors to monitor sample shipment progress, followed by courier tracking technology (28%)

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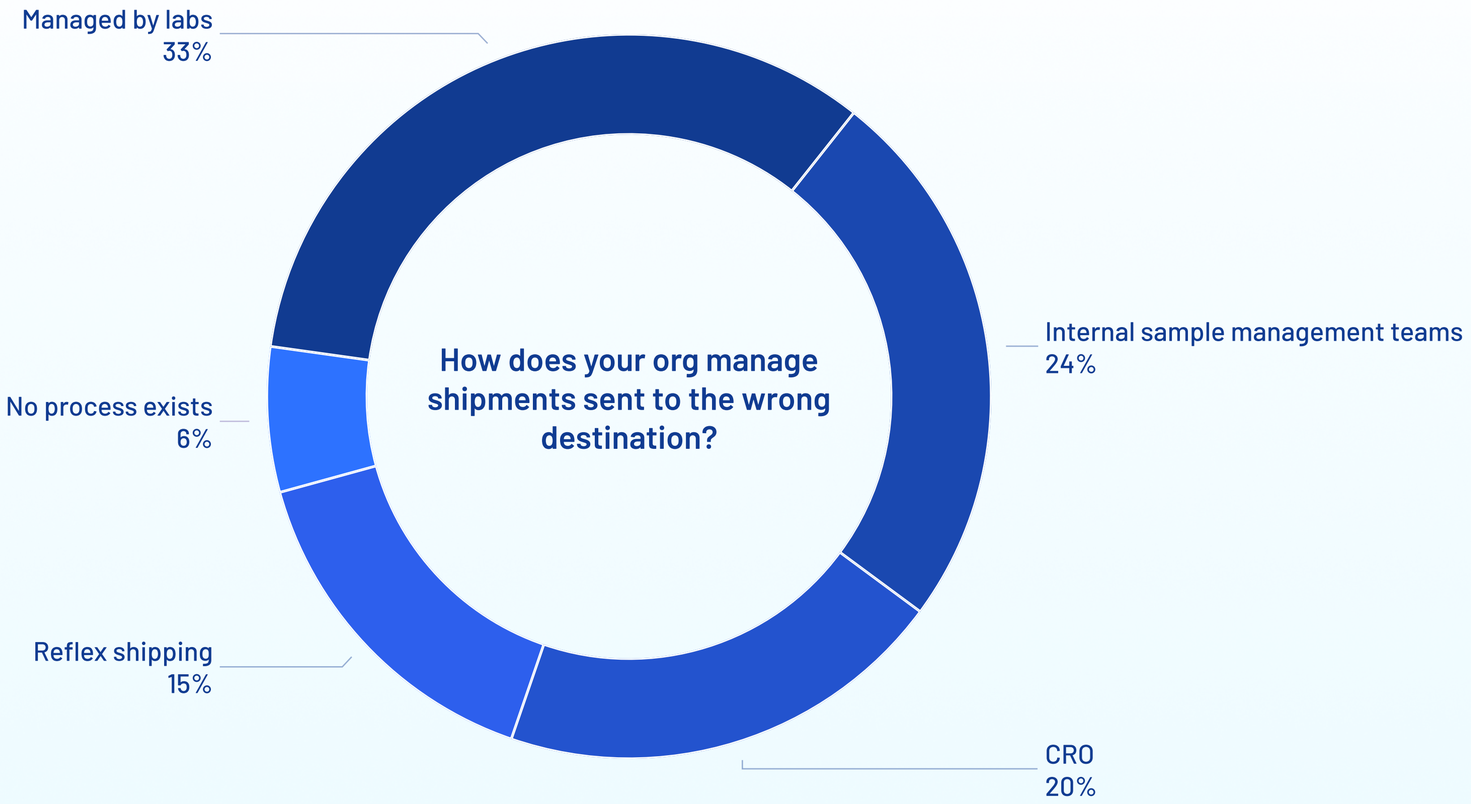
Sample shipments sent to the wrong destination also managed by labs



33% of respondents indicated their labs are responsible for managing shipments sent to the wrong destination; in contrast to 24% of internal sample management teams

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Sample Accessioning, Data Transfers, & Reports

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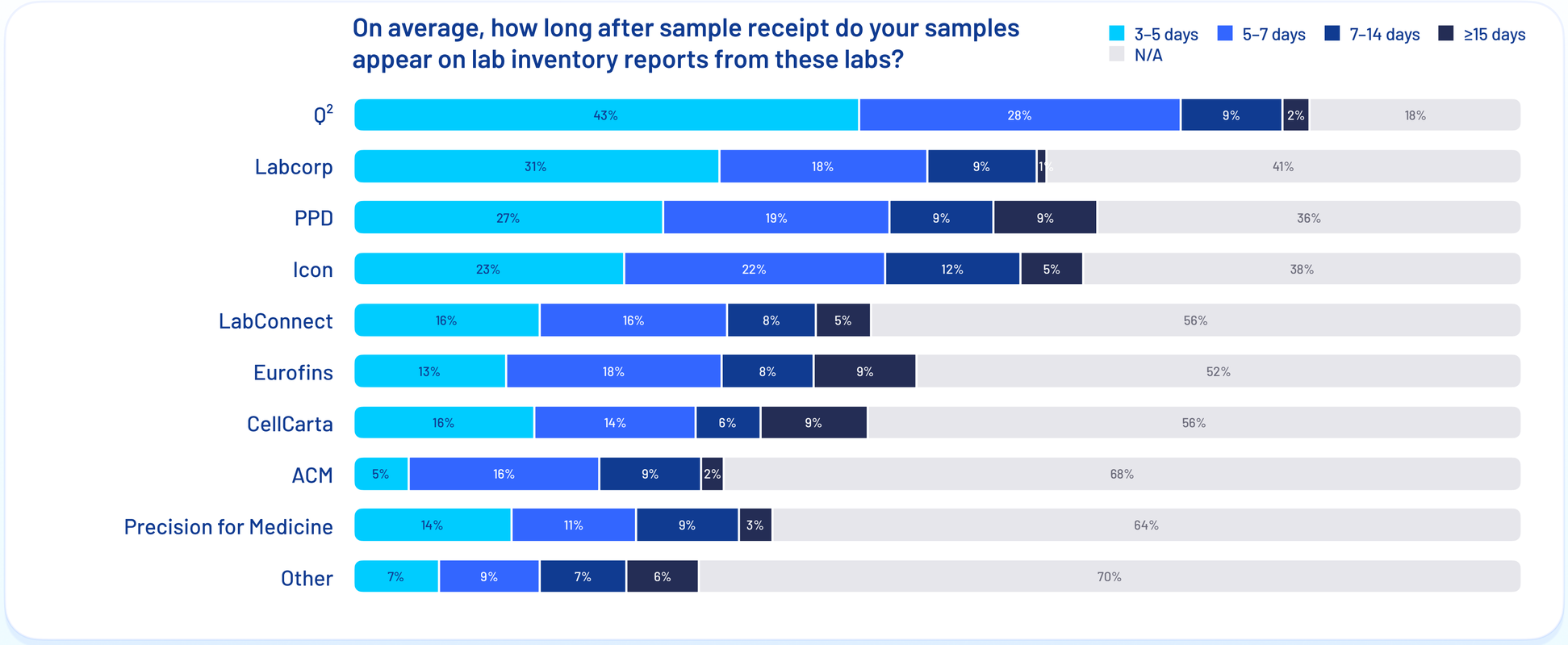
Lab sample accessioning is delayed



While it varies by lab, on average only 20% of respondents reporting accessing in under 5 days. 18% reported 5–7 days, 8% was 7–14 days, and 5% was over 2 weeks.

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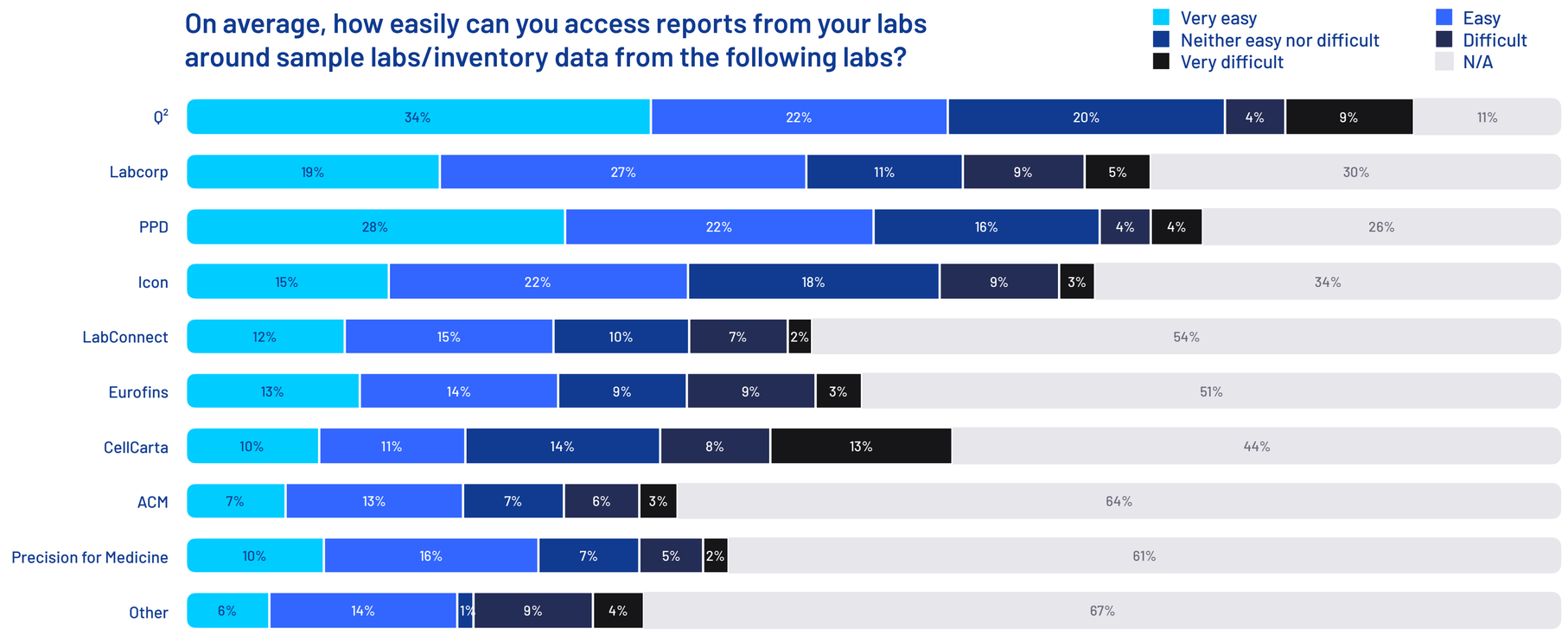
Access to reports from labs is perceived as easy



55% of respondents said that it is very easy/easy to access reports from labs

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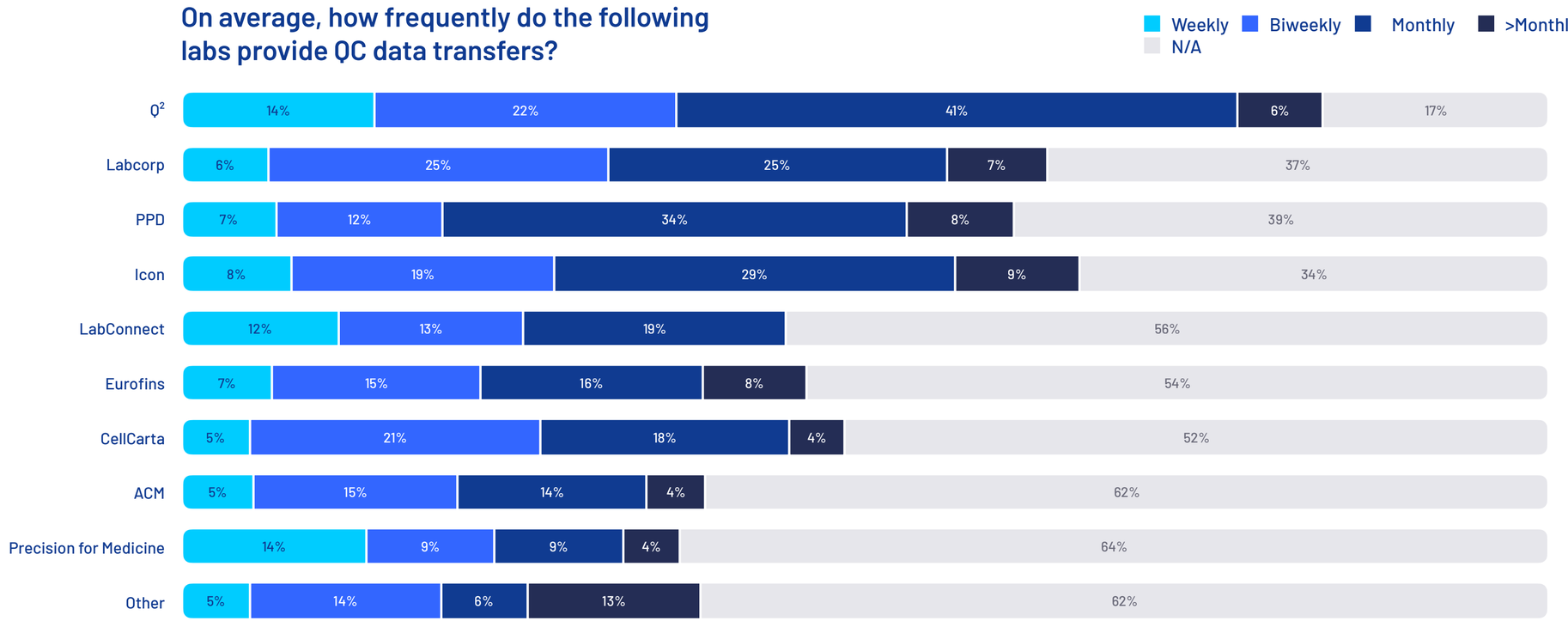
QC sample data transfers are available monthly



41% of respondents report getting access to QC'd data transfers on a monthly basis

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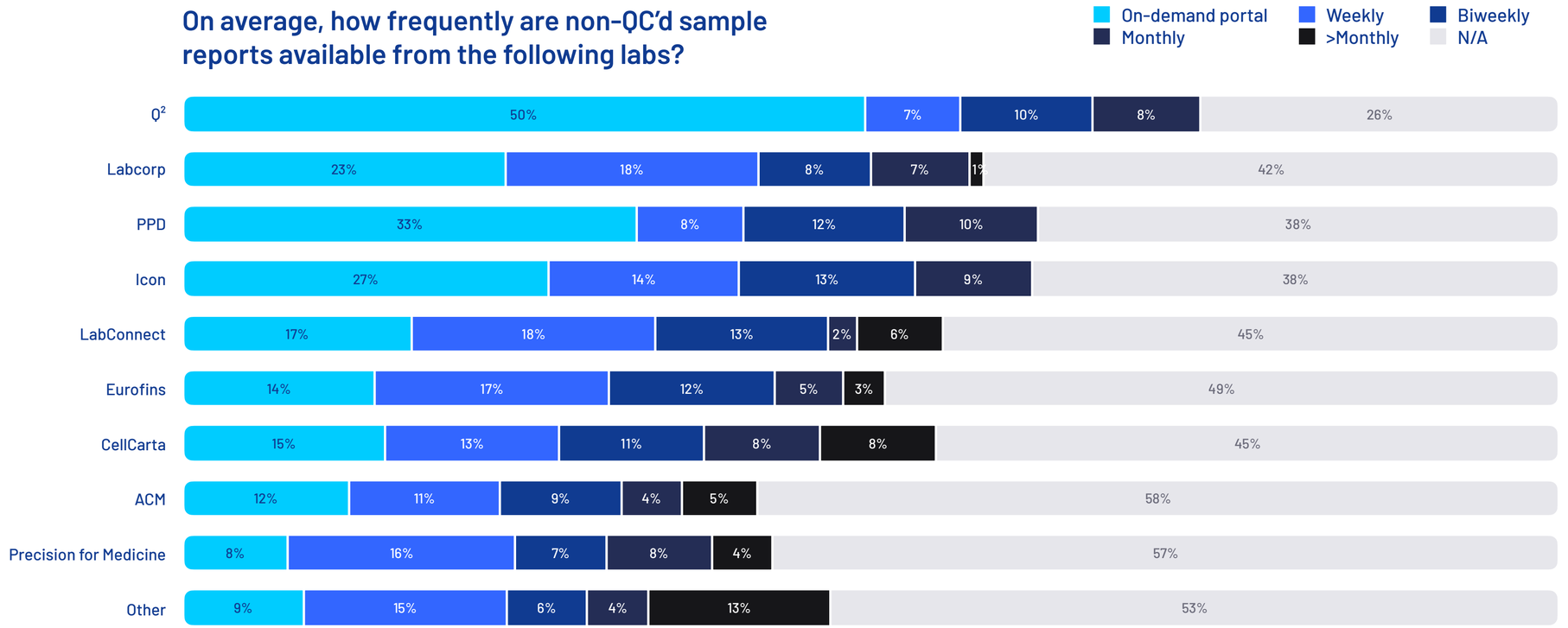
Non-QC'd sample reports from labs are available in near real-time



50% of respondents leverage on-demand lab portals to access non-QC'd sample reports

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Sample metadata is mostly transferred directly from the lab to the sponsor

38% of respondents report that sample metadata is transferred from lab to the sponsor, followed by 28% from lab to CRO

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Conclusion

The initial BMC benchmarking survey results support the realization that there is no standardization or best practices for biospecimen management, and that there is much work to be done to improve clinical research.

Several results also indicate that a majority of the industry doesn't have a formal process for biospecimen planning, relies on manual processes, and either doesn't track or is unsure of the performance of their sample management processes or vendors.

The BMC is using this data to inform its initiatives and openly encourages the industry to reach out to the BMC with feedback, ideas, and their own experiences through the BMC website.

About the BMC

The Biospecimen Management Consortium (BMC) is a clinical trial industry partnership dedicated to driving sample excellence in clinical research. Founded in June 2024, the BMC mission is to raise awareness of the importance and criticality of biospecimen management, develop industry standards and best practices, and advocate for change within the clinical trial ecosystem through standardization, policy, and thought leadership.

To learn more about the BMC, or to inquire about membership, please visit Biospecimen-Consortium.org.