ACRO

Summary Report

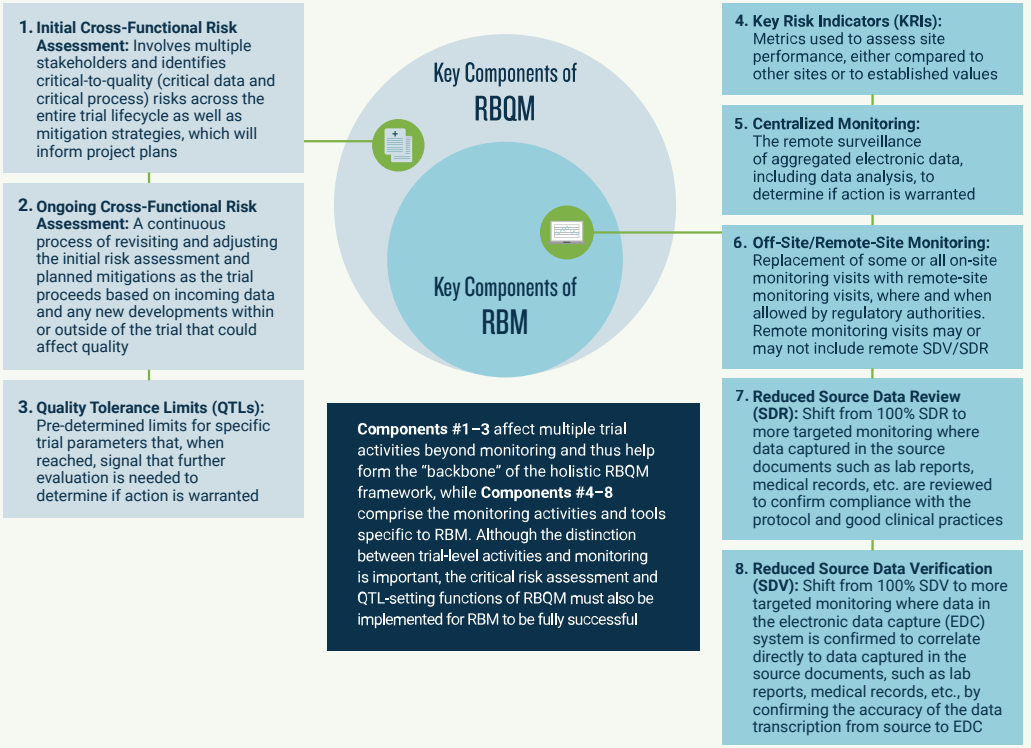
A 5-year survey project of ACRO member company CROs shows how risk-based approaches are used in clinical trials

Overview of Trials in the Survey & Adoption Over Time:

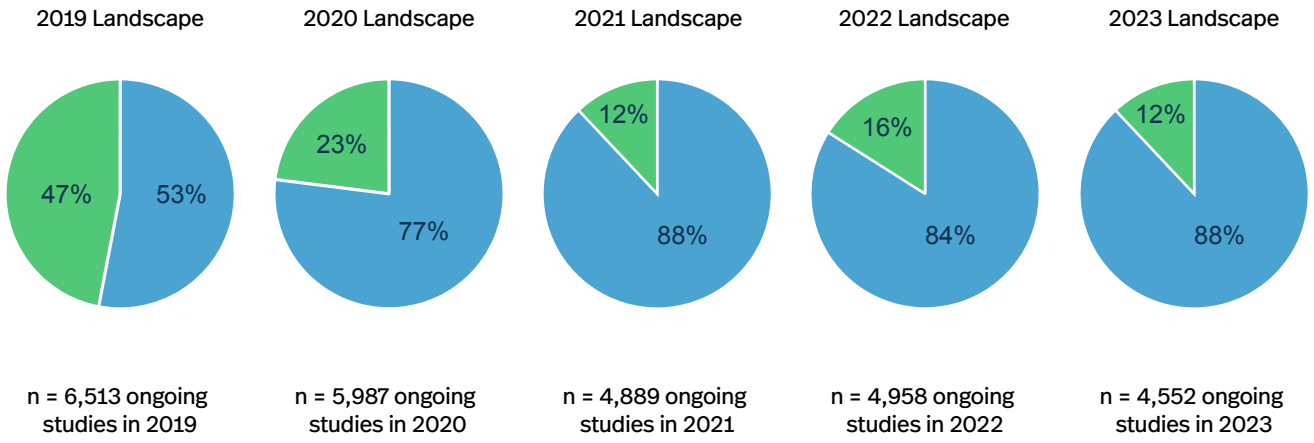
In early 2024, ACRO conducted the fifth consecutive year of its annual landscape survey, and this report highlights key findings. The aim of the survey is to answer ACRO member companies' and global regulators' interest in understanding how risk-based monitoring (RBM) and the larger framework of risk-based quality management (RBQM) are being adopted across the clinical trial industry. Conversations with FDA helped inform survey content and development. You can find an in-depth discussion on how ACRO member companies are adopting some of these practices in ACRO's December 2024 publication, Risk-Based Quality Management: A Case for Centralized Monitoring. This paper will walk you through a case example of how you can implement an effective centralized monitoring strategy within your organization.

In 2023, 88% of clinical trials had at least one RBM or RBQM component included, a massive improvement from 2019, when this figure was only 53%.

RBM & RBQM Components Looked at in the Survey

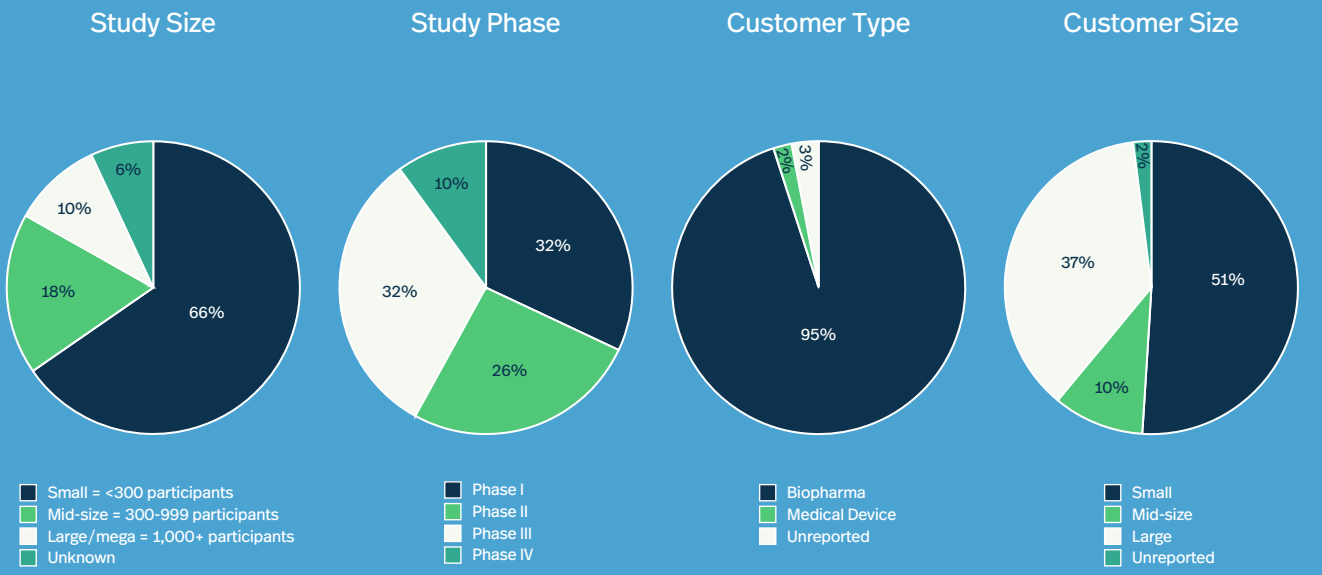


Over the past five years, ACRO members have seen an increase in the number of trials that utilized remote or risk-based components. "Traditional" clinical trials are being phased out in favor of more efficient and effective approaches.



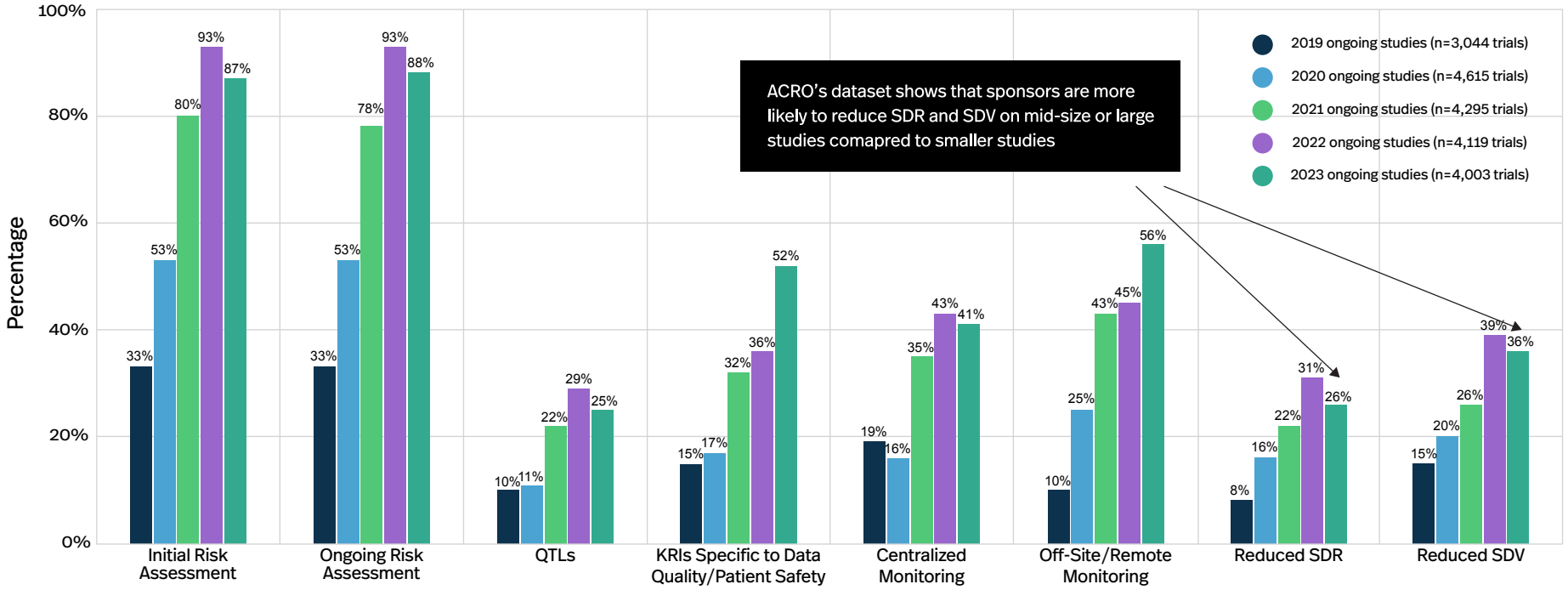
A Closer Look At The Studies In Our Dataset

The 4,552 studies we looked at in 2023 were mostly small studies, outsourced from either small or large biopharma customers. Keep in mind that the data we are presenting came from 7 CROs, but we believe it is representative and reflective of sponsors' willingness to adopt these components.



Adoption of components in ongoing trials:

The following graph shows how each RBM or RBQM component was adopted in ongoing clinical trials in each year 2019-2023:

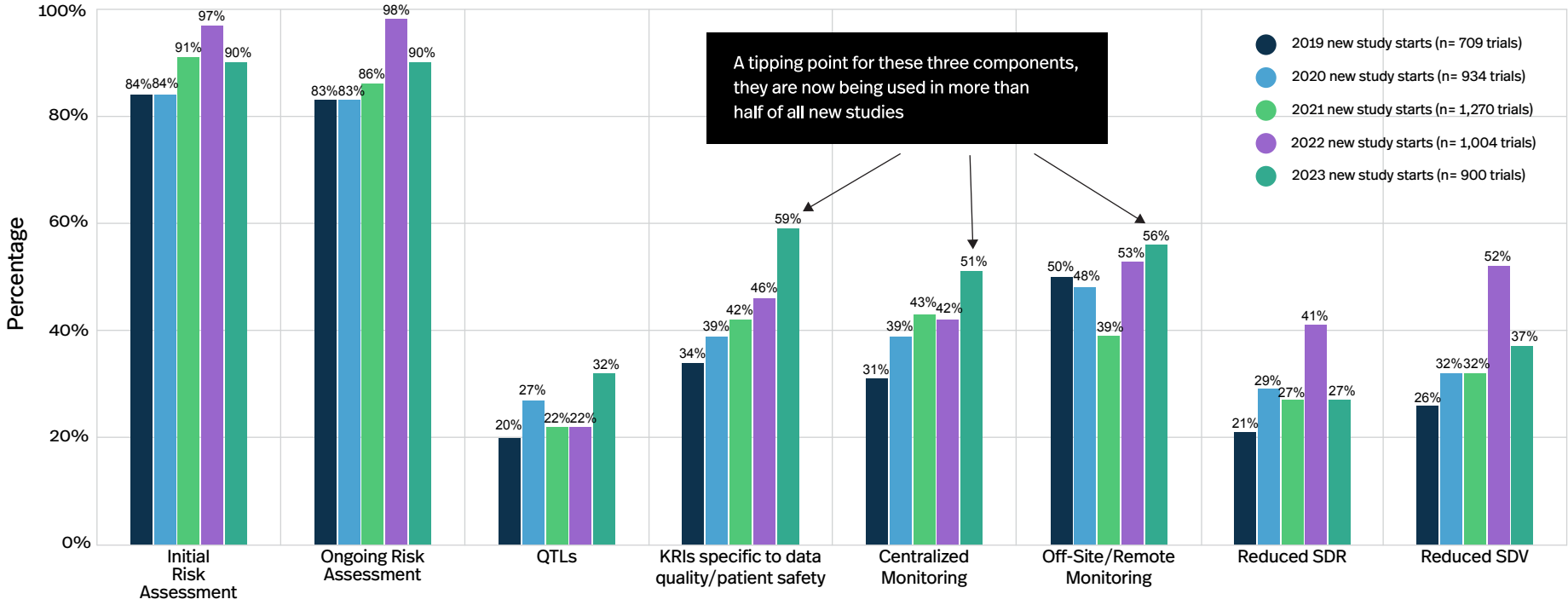


Highlights for Ongoing Studies:

- Initial and ongoing risk assessments are in almost every study. We do see a slight dip in 2023, but we believe that many sponsors are bringing risk assessments in-house, and this data is only looking at the services that CROs provide.
- After the COVID-19 global pandemic, we saw huge jumps in centralized monitoring and off-site/remote monitoring. This "new normal" of utilizing more remote approaches is evident in the data.
- ACRO conducted an informal poll of sponsors at the 2023 DIA Annual Meeting and the respondents said that if the industry could adopt centralized monitoring and reduce SDR/SDV on 60-80% of trials, that would be a success. While adoption of many of the components is still lower than ideal, the industry is making progress each year and adoption is trending in the right direction overall.
- More than half of the ongoing clinical trials have risk assessments, KRIs, and off-site remote monitoring. Despite this progress, 100% SDR/SDV is still used in a majority of trials. This is an area for improvement, especially as increasing study complexity necessitates greater use of centralized monitoring.

Adoption of components in new study starts:

The same analysis was run based on new study starts each year.



Highlights for New Study Starts:

- The industry is at a tipping point. More than half of new studies utilize risk assessments, KRIs, centralized monitoring and remote monitoring.
- There was a small decrease in risk assessments as some sponsors have taken this in-house.
- Mid-size sponsors had higher adoption rates compared to large or small sponsors. Generally, in our experience, smaller sponsors are more reluctant to invest in centralized monitoring when designing a study, but we believe by doing so, the cost of monitoring could drastically be reduced through reductions in SDR/SDV and on-site monitoring. Routine site communications can continue to occur remotely for relationship and critical site management activities.
- Unfortunately, we're still seeing 100% SDR/SDV on the majority of studies. In large/mega-sized studies, 100% SDR/SDV is being used 32-53% of the time. This is costing the industry a lot of time, cost, and human resources for little return.

Does Adoption Differ by Sponsor Size?

When looking at new study starts, ACRO's data shows that large sponsors were more likely to conduct their own risk assessments in-house than small or mid-size sponsors, who were more likely to outsource the risk assessment to CRO partners. Similarly with QTLs, large sponsors often take these in-house.

Large and mid-size sponsors were more likely to reduce SDR/SDV as compared to small sponsors. Mid-size and large sponsors were more likely to implement centralized monitoring and off-site remote monitoring as compared to small sponsors.

Why are risk assessments not on every study?

We believe risk assessments are happening on every study. The reason our data does not show 100% risk assessment rates is because it is only reflective of when CROs conduct the risk assessment. If a sponsor does the risk assessment in-house, but outsources other parts of a clinical trial, that risk assessment would not show up in our CRO dataset. Thanks to ICH E6(R2) and recognition from the industry of risk assessments as a best practice, we do believe they are being used consistently.

Centralized monitoring is the key to quality:

Centralized monitoring gives sponsors and CROs a better view of the data compared to 100% SDR/SDV. This makes it possible to analyze the data in real-time, increasing trial efficiency and participant safety. Read more about how centralized monitoring can be implemented in ACRO's publication, Risk-Based Quality Management: A Case for Centralized Monitoring.

Key Takeaways:

- ACRO's dataset shows that industry adoption of RBM and RBQM components has steadily grown from 2019 to 2023.
- With millions of data points across multiple sources, aggregating data and deploying centralized monitoring can improve issue detection and safety observations. It is imperative that the industry utilizes centralized monitoring.
- The clinical trial industry welcomes the finalization of ICH E6(R3), which will further help the industry take risk-based and quality-forward approaches to clinical trial management.
- Sponsors and CROs cannot just reduce SDR or SDV alone, this must be done after centralized monitoring has been initiated. This will save costs and increase data quality in the long run.

To learn more about how you can apply central monitoring techniques to increase RBQM adoption within your organization, click here to read ACRO's latest publication "Risk-Based Quality Management: A Case for Centralized Monitoring."