Summary Report:

A Survey of ACRO Member Companies Shows How Risk-Based Approaches Are Used in Clinical Trials

ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

In early 2022, ACRO conducted the third 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.

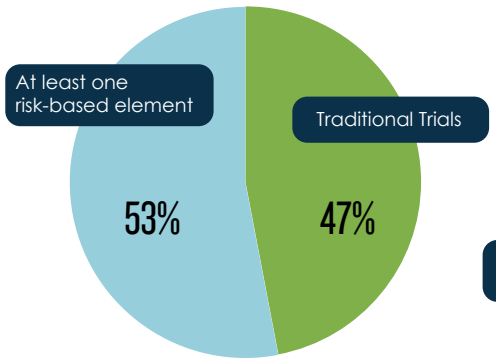
You can find full results and in-depth discussion in ACRO's January 2023 publication, **Risk-Based Monitoring in Clinical Trials: 2021 Update.**

OVERVIEW OF TRIALS IN THE SURVEY & ADOPTION OVER TIME:

Below is a quick look at the number of trials included in the survey. The dataset is limited to clinical trials that were outsourced to CROs. It does not include components that may be maintained by sponsor companies.

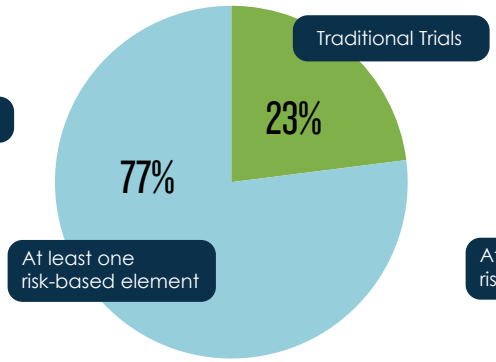
In 2021, 88% of clinical trials had at least one RBM or RBQM component included, a massive improvement from 2019, when this figure was only 53%.

2019 Landscape



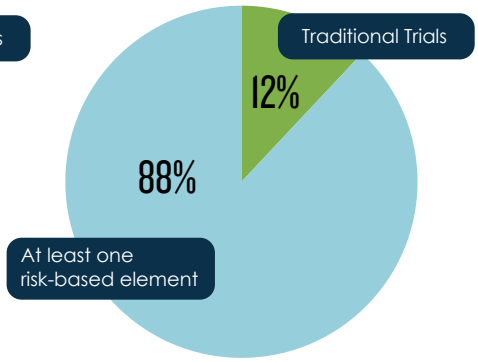
n=6,513 ongoing studies in 2019

2020 Landscape



n=5,987 ongoing studies in 2020

2021 Landscape



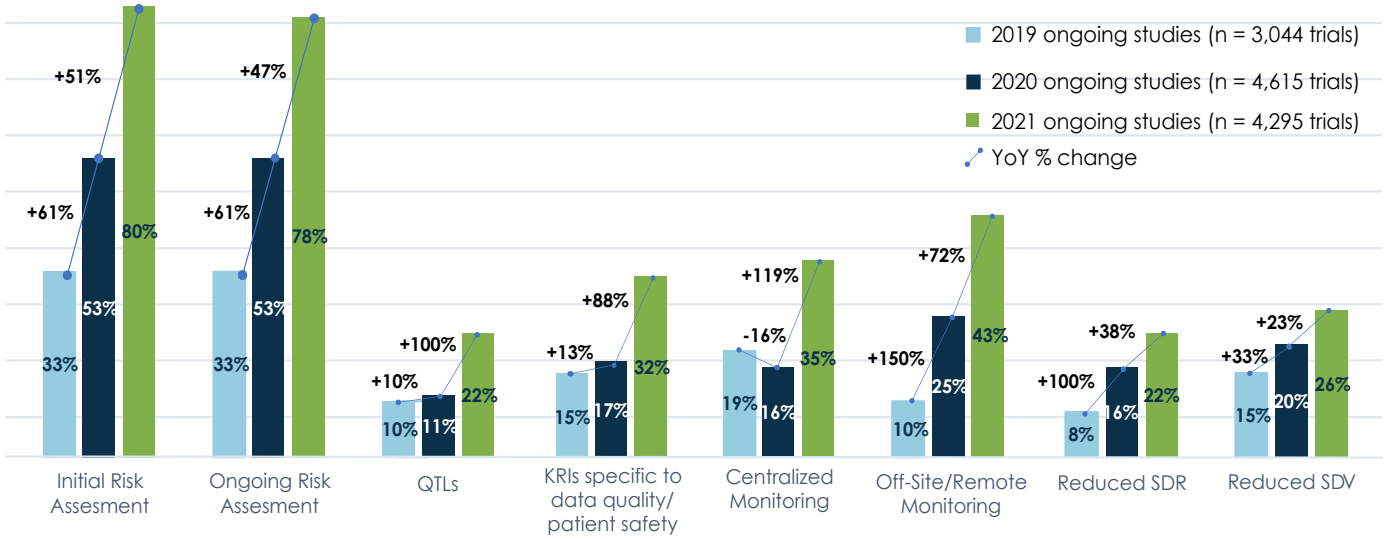
n=4,889 ongoing studies in 2021

Key Takeaways:

- This data shows that industry adoption of RBM and RBQM components has steadily grown from 2019 to 2021.
- The clinical trial industry welcomes the April 2023 finalization of FDA's **A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers**. In addition, the industry eagerly awaits the planned release of ICH E6(R3).
- These guidance documents will help advance adoption even further. RBQM is a critical component to further adoption of more complex and decentralized clinical trials (DCTs). RBQM supports holistic data quality oversight and participant safety.

ADOPTION OF COMPONENTS IN ONGOING TRIALS:

ACRO analyzed the subset of clinical trials that had at least one RBM or RBQM component. The following graph shows how each component was adopted in ongoing clinical trials in 2019, 2020 and in 2021.



Highlights for Ongoing Clinical Trials:

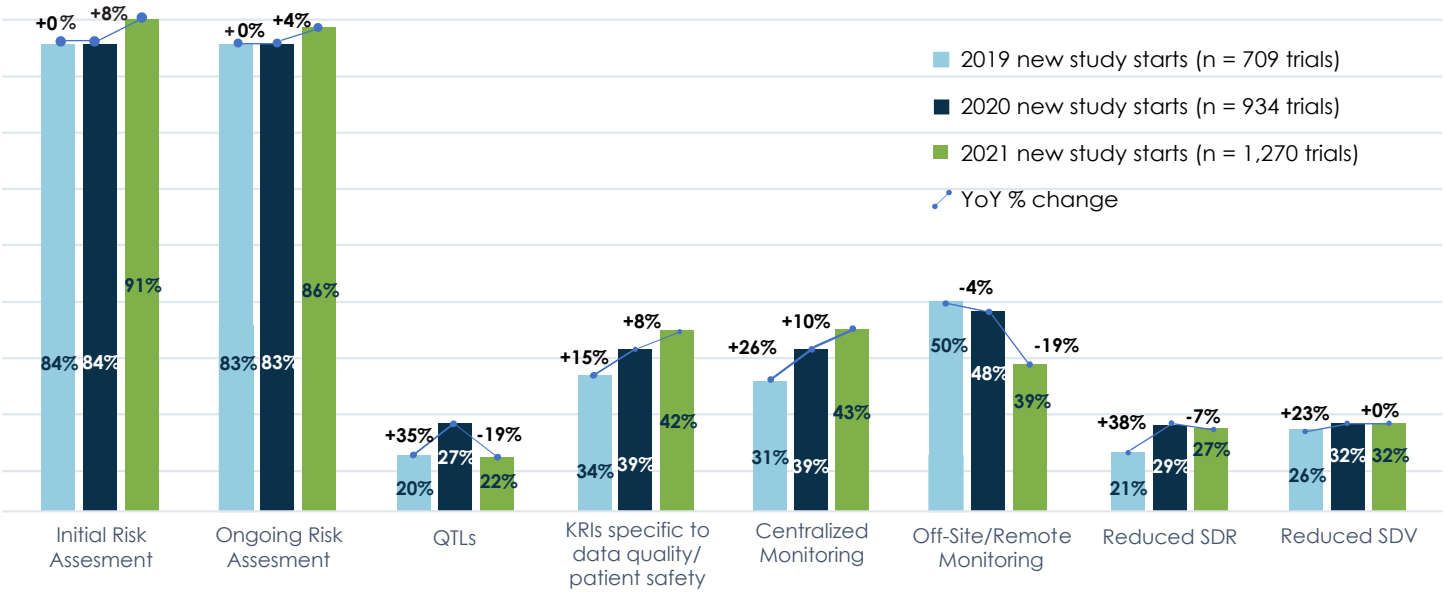
- Initial and ongoing risk assessments are in almost every study.
- Significant increases year-over-year in QTLs, KRIs, centralized monitoring, and off-site/ remote monitoring. Overall adoption of these components is still lower than ideal, though rates are trending in the right direction.
- 100% SDR/SDV is still used on a majority of trials, despite the large increase in centralized monitoring. Although this increase was notable for ongoing trials, the adoption in new study starts remained relatively flat between 2020-2021 (see the graph on the next page).

CENTRALIZED MONITORING IS THE KEY:

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.

ADOPTION OF COMPONENTS IN NEW STUDY STARTS:

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



Highlights for New Study Starts:

- Off-site remote monitoring decreased in 2021 new study starts. This likely demonstrates the normalization after the initial COVID pandemic peak, when off-site monitoring was added by necessity to a large portion of trials. This may reflect the hesitation from clinical trial sponsors and sites to keep remote technologies in place as trial sites resumed more normal activities in 2021.
- There was a small decrease in the use of QTLs in studies that started in 2021. It is possible that some sponsors managed QTLs in-house using their own methods in 2021, as opposed to outsourcing QTL management to CROs. There is also a lack of regulatory feedback and clarity around QTLs which has contributed to variability in how CROs are applying them.

ABOUT ACRO:

The Association of Clinical Research Organizations (ACRO) represents clinical research and technology companies that provide a variety of specialized services to support the development of new pharmaceuticals, biologics, and medical devices. ACRO member companies operate across the globe and support or operationalize the conduct of the majority of industry-sponsored clinical trials worldwide. ACRO hosts a Risk-Based Quality Management (RBQM) Working Group that developed the survey projects and this report. For more information on our team and to read our past publications, visit: **www.acrohealth.org/risk-based-quality-management/.**

Special thanks to Industry Standard Research (ISR), an independent third-party vendor, for administering all three surveys.
Results were reported in aggregate, and each individual submission was blinded and protected for privacy