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GLOBAL ANNUAL MEETING

CHICAGO, IL
JUNE 19-23

Risk-Based Monitoring in Clinical Trials: An Evolution of Practices During the COVID Pandemic

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RBQM Working Group Members & Leads

Association of Clinical Research Organizations (ACRO)



@ACROhealth

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About ACRO

- ▶ The Association of Clinical Research Organizations (ACRO) is a trade association that brings together the leading global CROs and technology companies
- ▶ Currently 15 member companies
- ▶ ACRO hosts several committees including:
 - Risk-Based Quality Management (RBQM) Working Group, Decentralized Clinical Trials (DCT) Working Party, Diversity & Inclusion (D&I) Committee



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Drug Development

ORACLE®

premier
research

 **SIGNANT** HEALTH

verily

ICON

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About ACRO's RBQM Working Group

- ▶ Today's speakers are all members of the RBQM Working Group (founded in 2015)
 - Collaborative effort to promote and advance the adoption of Risk-Based Monitoring (RBM) and RBQM principles in clinical trials
 - CROs and technology companies coming together to support sponsors, sites, regulators and each other
 - Pursuing our annual landscape project
 - Brought about by frustration within regulatory authorities, sponsors and CROs that RBM and RBQM components were not being implemented to their fullest potential
 - DCT components added to the project over the last two years



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ACRO's Annual Landscape Survey

▶ PRIOR YEAR'S SURVEY // **2019 Landscape Data**

- **6,513 studies** ongoing in 2019 from 7 different CROs

▶ LAST YEAR'S SURVEY // **2020 Landscape Data**

- **5,987 studies** ongoing in 2020 from 6 different CROs
- 908 of these studies were new study starts in 2020

▶ THIS YEAR'S SURVEY // **2021 Landscape Data**

- **4,889 studies** ongoing in 2021 from 7 different CROs
- 1,270 of these studies were new study starts in 2021



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RBQM Components Included in Survey

- Initial Cross-functional Risk Assessment
- Ongoing Cross-functional Risk Assessment
- Quality Tolerance Limits (QTLs)
- Key Risk Indicators (KRIs) Specific to Data Quality / Subject Safety
- Centralized Monitoring
- Off-site / Remote-site Monitoring
- Reduced SDV
- Reduced SDR



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Considerations in our Dataset

- ▶ Dataset is made up of outsourced clinical trials
- ▶ Sponsors maintain oversight of some components (QTLs, for example) – which would not show up in our dataset
- ▶ Results may be an underestimate of RBM and RBQM uptake, but they are valuable indicators and still show adoption trends
- ▶ Each year, we are working to improve tracking capabilities



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The Changing Landscape Over Time

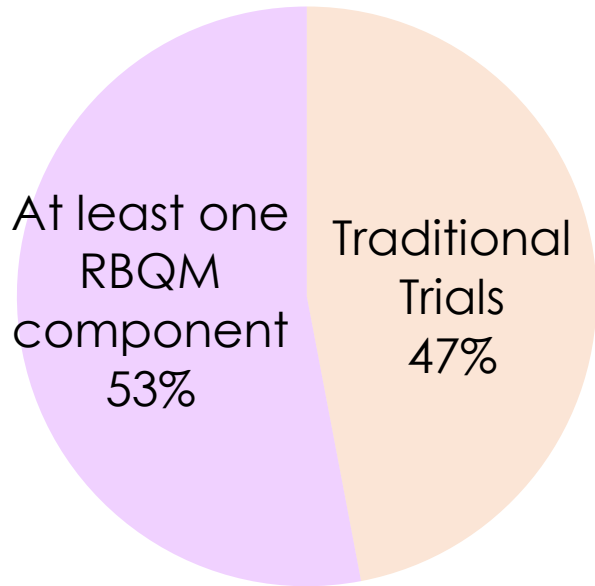


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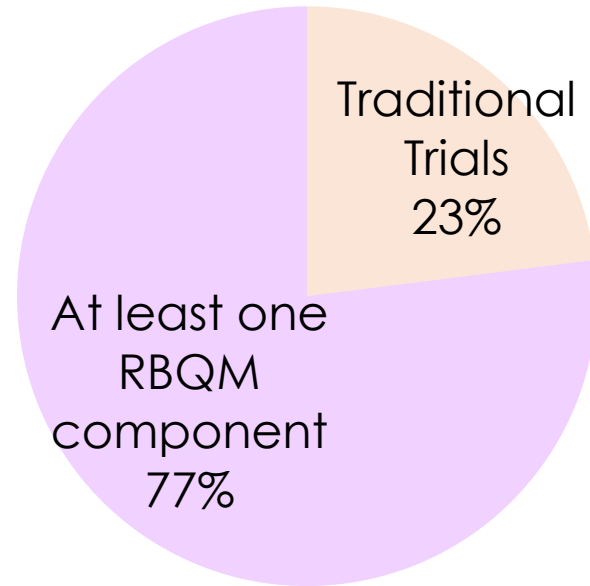
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2019 Landscape



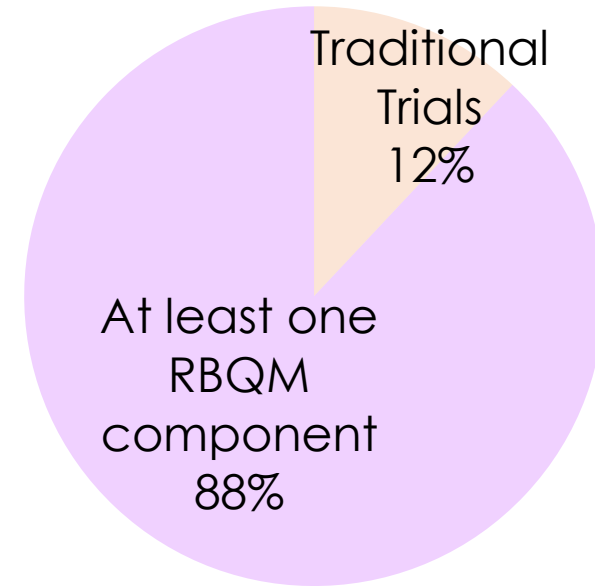
n=6,513 ongoing studies in 2019

2020 Landscape



n=5,987 ongoing studies in 2020

2021 Landscape



n=4,889 ongoing studies in 2021

A Closer Look at the 2021 Dataset

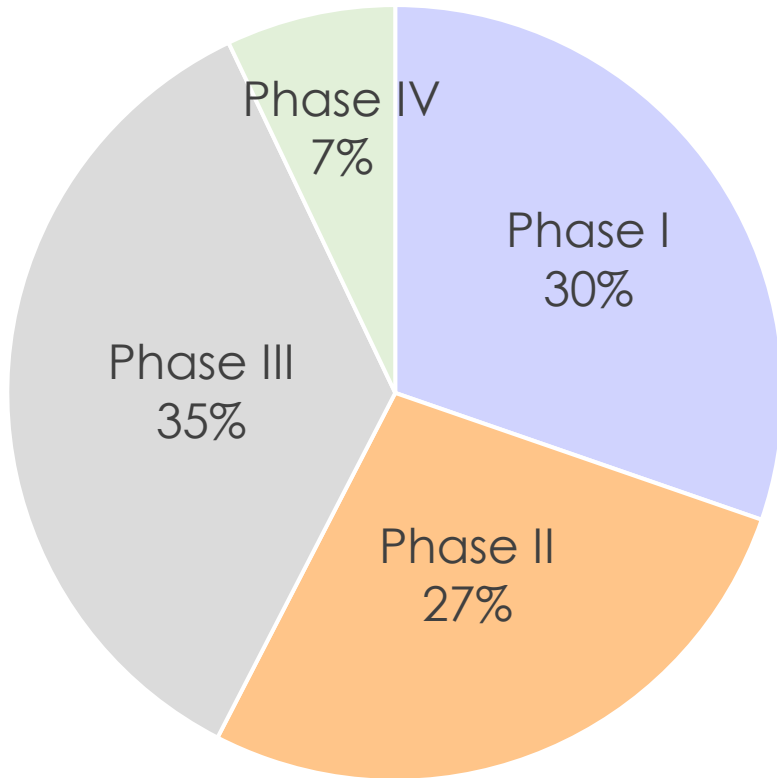


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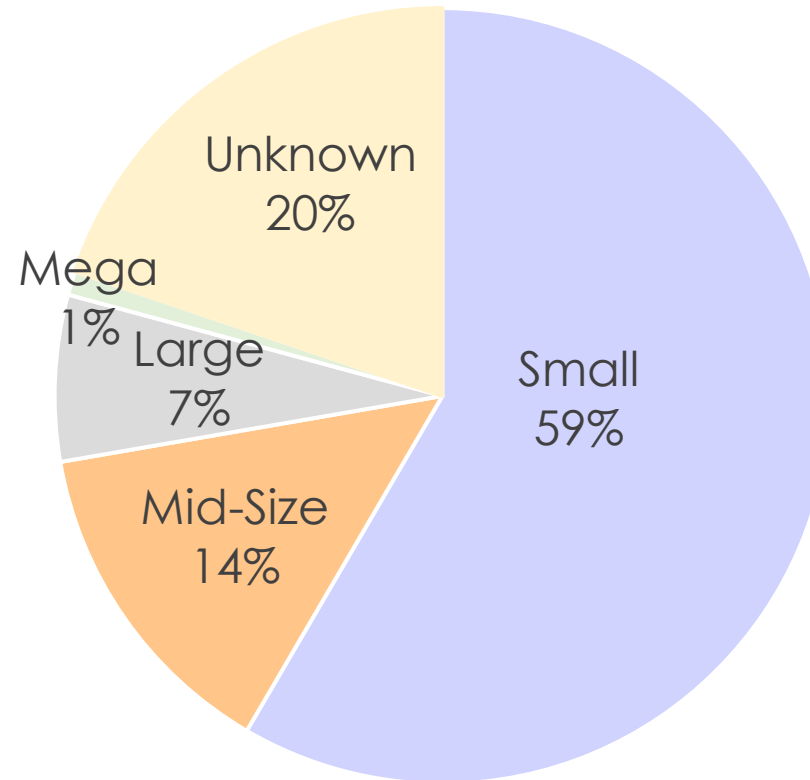
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Study Phase



Study Size Based on # of Patients



Small: less than 300 patients
Mid-sized: 300-999 patients
Large: 1,000-5,000 patients
Mega: More than 5,000 patients

RBQM Components in 2019-2021 Ongoing Studies

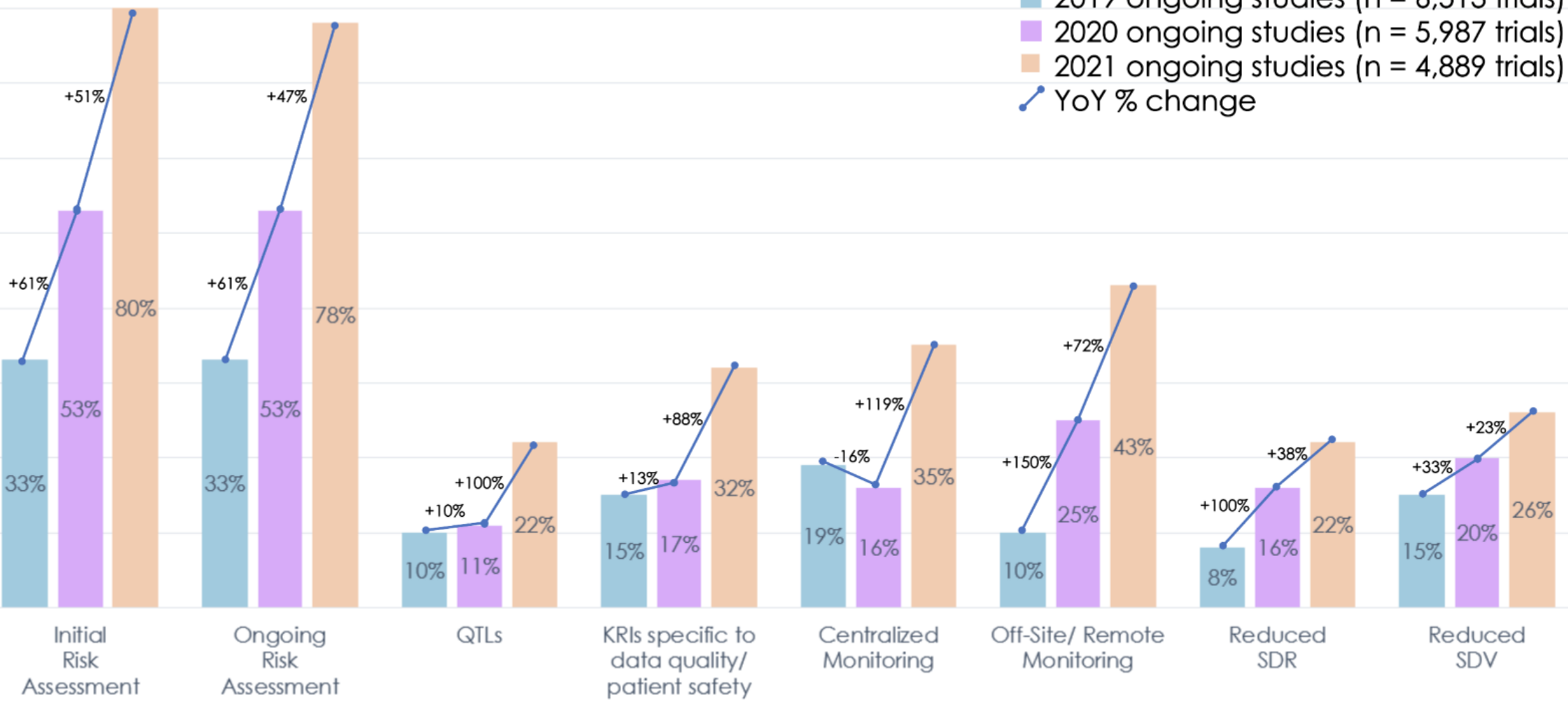


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■ 2019 ongoing studies (n = 6,513 trials)
 ■ 2020 ongoing studies (n = 5,987 trials)
 ■ 2021 ongoing studies (n = 4,889 trials)
 ● YoY % change



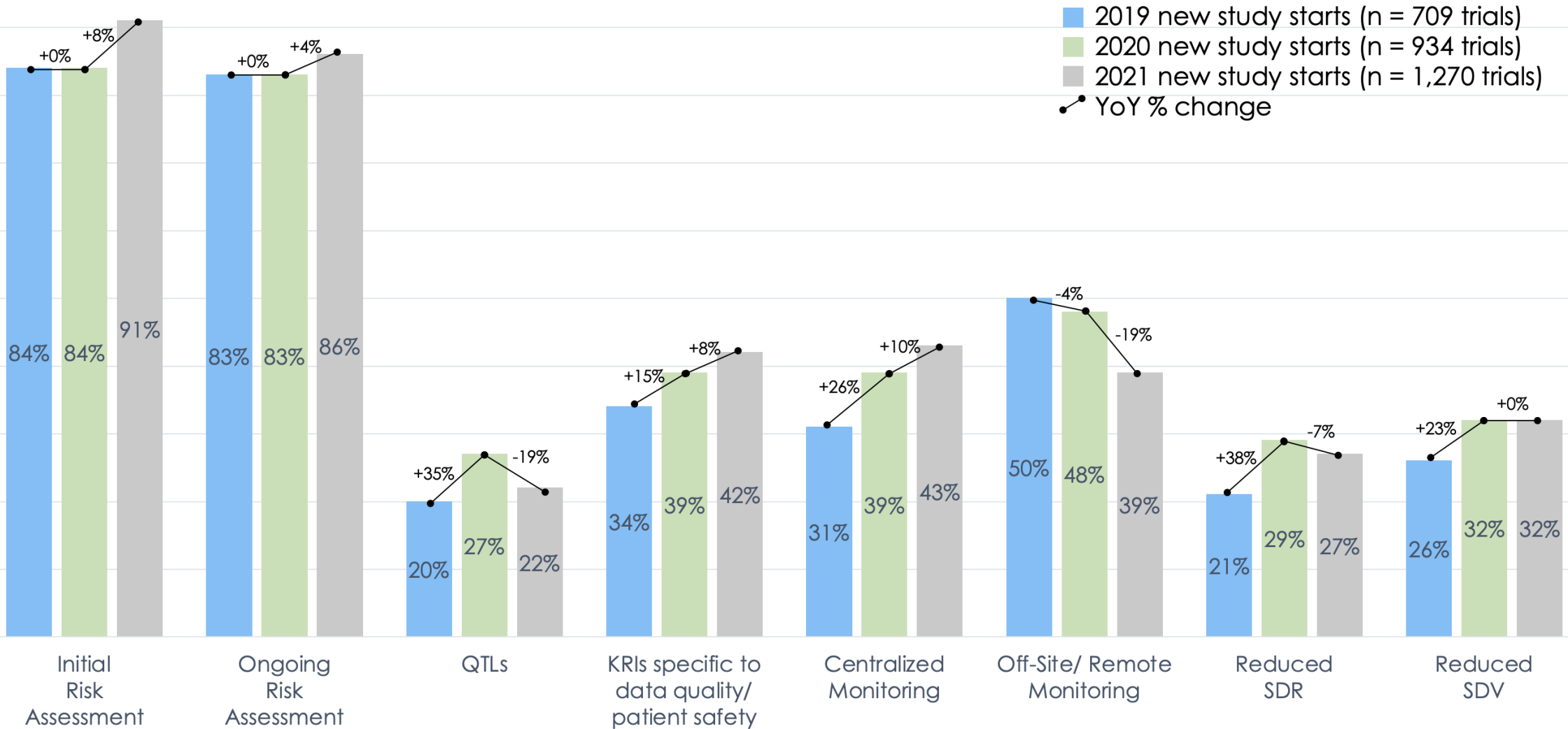
RBQM Components in 2019-2021 New Study Starts



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Observations & Recommendations

► Key observations

- Risk assessments are on almost every study
- Reduced SDV and reduced SDR have potential to increase
- Strong adoption of Centralized Monitoring, combination of reduced SDV/SDR remains paramount

► Top recommendations for how we can support sponsors, sites to increase adoption

- Continued support for risk assessment practices, remain core driver for proper implementation of RBQM components
- Flexibility – there is not a one size fits all approach, each study must be assessed for greatest impacts to participant safety and data quality



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Hopes for Next Year's Survey & Adoption Metrics

- ▶ Increased adoption of reduced SDV and reduced SDR
- ▶ Increased use of centralized monitoring
- ▶ Continue to understand adoption of operationalization of RBQM & DCT – and the evolution of clinical trial operations
- ▶ Interest in success measures, value-driven success metrics
- ▶ Opportunity to collect adoption levels of DCT components
 - eConsent / eConsent eSignature
 - Direct to / from patient shipment
 - Home health visits
 - Telemedicine
 - eCOA / ePRO
 - Connected devices / digital endpoints
 - Local / community labs



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ACRO's Publications on RBQM

- **PRIOR YEAR'S SURVEY // 2019 Landscape Paper**

- RBM in Clinical Trials: Past, Present & Future (TIRS 4/21)



- ▶ **LAST YEAR'S SURVEY // 2020 Landscape Paper**

- RBM in Clinical Trials: Increased Adoption Throughout 2020 (DIA TIRS 3/22)



- ▶ **THIS YEAR'S SURVEY // 2021 Landscape Paper in Progress**

- Today we'll share highlights from the results

- Publications can be found online:

acrohealth.org/risk-based-quality-management



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Thank You

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