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RBM & ICH E6(R2) Implementation Survey

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Evolution of Risk Based Monitoring

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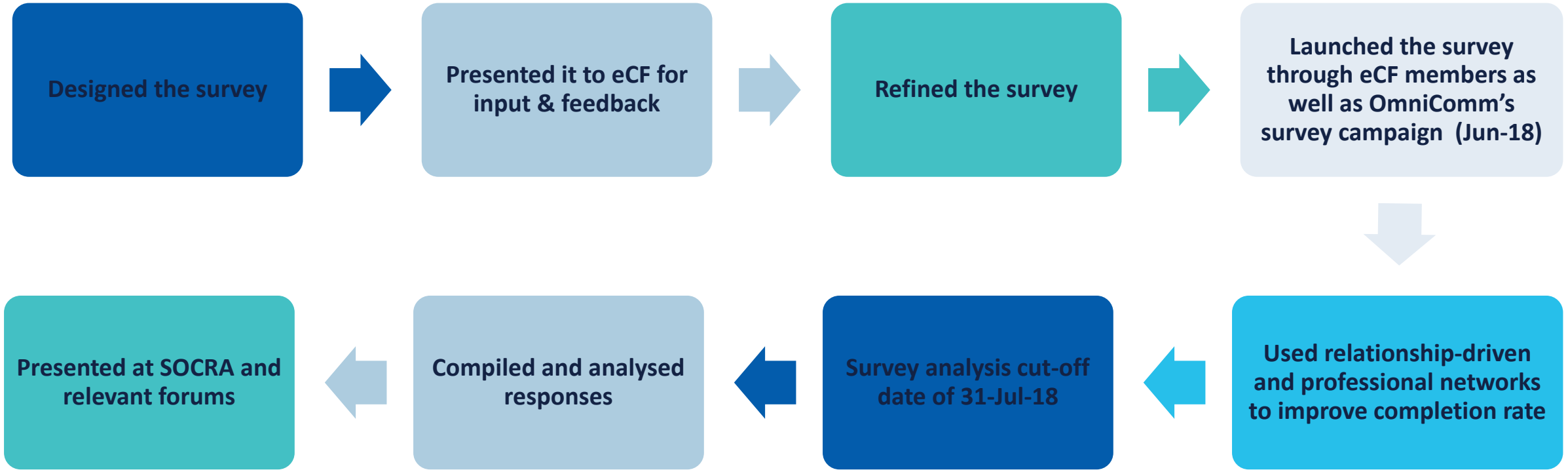
- Background
  - Risk based monitoring (RBM)has been widely discussed since 2012
  - Risk based approaches to monitoring and reduced source data verification have been employed within our industry for quite some time
- Regulatory Guidance
  - AUG-2013: FDA Guidance: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring
  - NOV-2013: EMA Reflection Paper: Risk-based quality management in clinical trials
- TransCelerate
  - 2013 position paper: Risk-based monitoring methodology
  - Risk Assessment Categorization Tool (RACT) & Protocol-level risks and Integrated Quality Risk Management Plan (IQRMP)
  - 4 Updates and FAQs from 2013 to 2015
- Industry Adoption
  - Adoption of RBM has been mixed and only in certain sections of the industry; many pilots
  - Numerous perspectives and approaches to the new model have been implemented by organizations
  - Some companies use TransCelerate approach, but other approaches are also used
  - Unlike other clinical research processes, the standard approach for RBM is still evolving

Survey Background

- eClinical Forum (eCF) endeavors to provide a forum for discussion and help enable implementation within the industry
- eCF RBM task force had published a publicly available white paper, and then an article in Applied Clinical Trials entitled “Risk-Based Approaches: Best practices for ensuring clinical data quality”
- OmniComm volunteered to run a survey and present results at SOCRA annual meeting in September 27-29th, 2018 in New Orleans
- Survey intent is to be comprehensive enough to provide insights into how organizations are approaching ICH-E6(R2) compliance and adoption efforts by assessing:
  - Current state & outlook of ICH-E6(R2) implementation
  - Industry approach and implementation
  - Major implementation challenges
  - Role of technology

Survey Methodology



Analysis Methodology

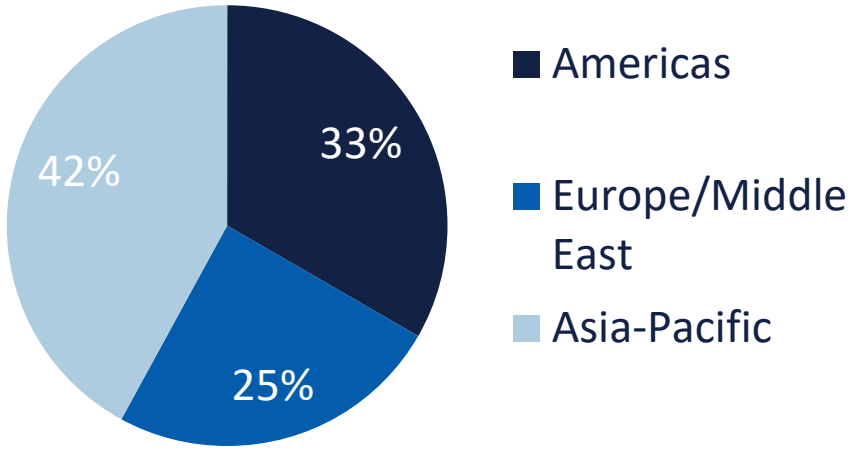
- Overall survey responses grouped by:
  - Size of organization, by manpower:
    - Large-sized organizations: > 2000 people
    - Small & mid-size organizations: Up to 2000 people
  - Type of organization:
    - Sponsor: Pharma, Biotech & Medical devices
    - CROs
    - Academic & Others (AROs, Consultants, SMOs, eClinical Vendor)
- Compiled observations where significant trend, pattern, or inference is seen

Survey Results

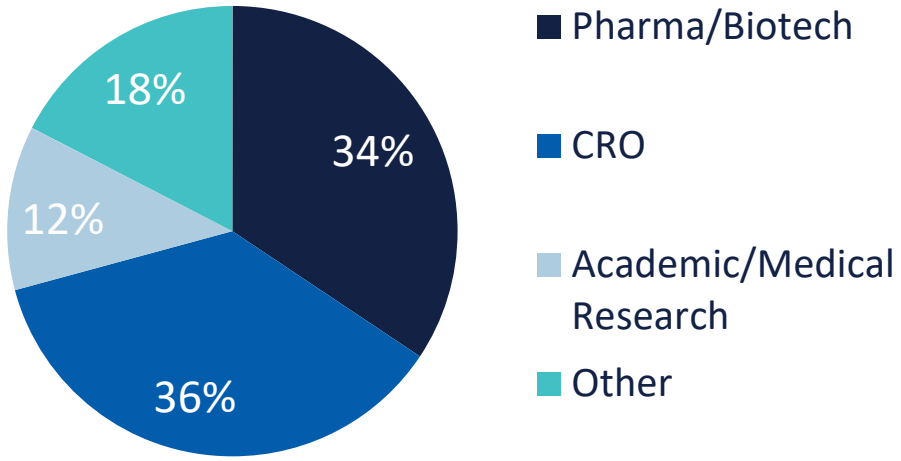
Respondent Demographics

195 Total Responses

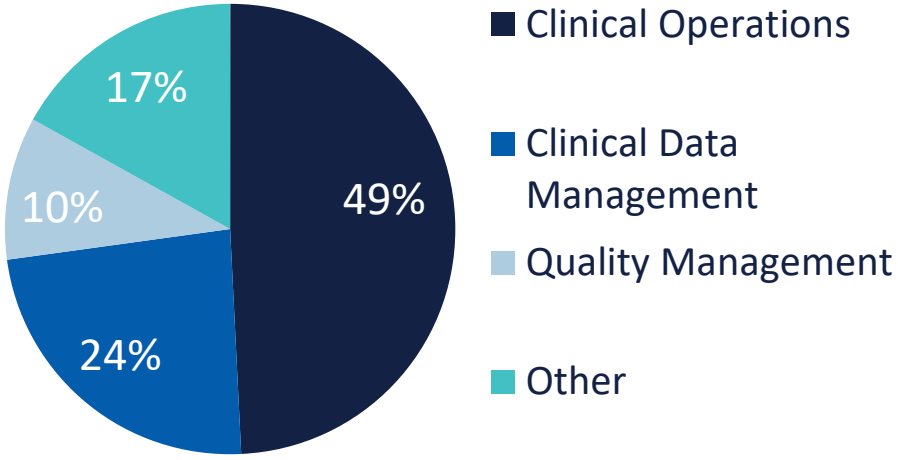
Location



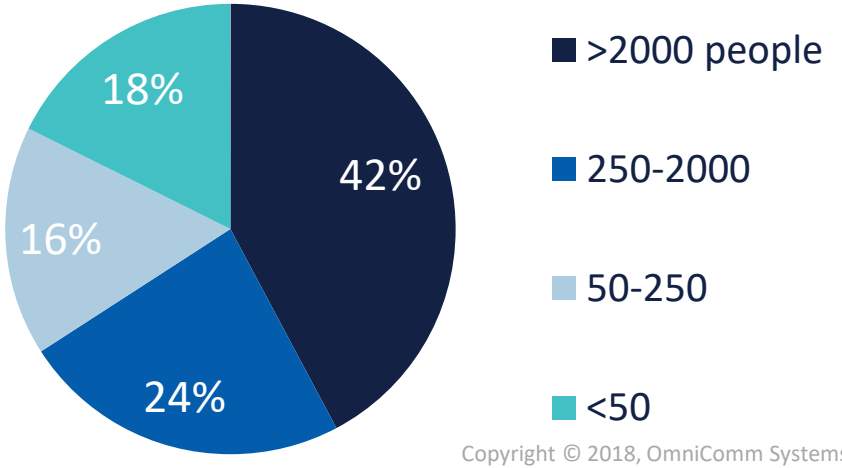
Company Type



Department/Function



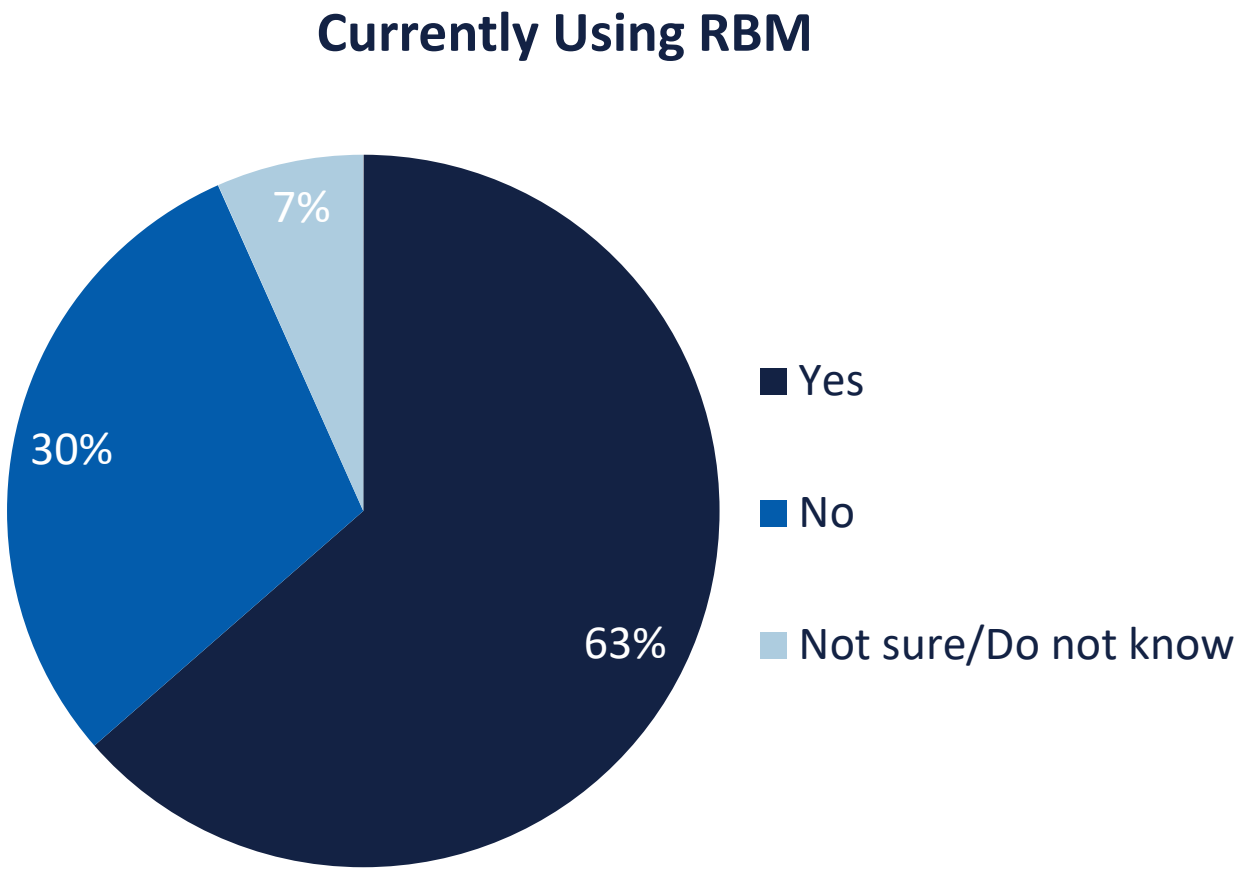
Company Size



Survey Results

Select Questions and Responses

Is your company currently using RBM?

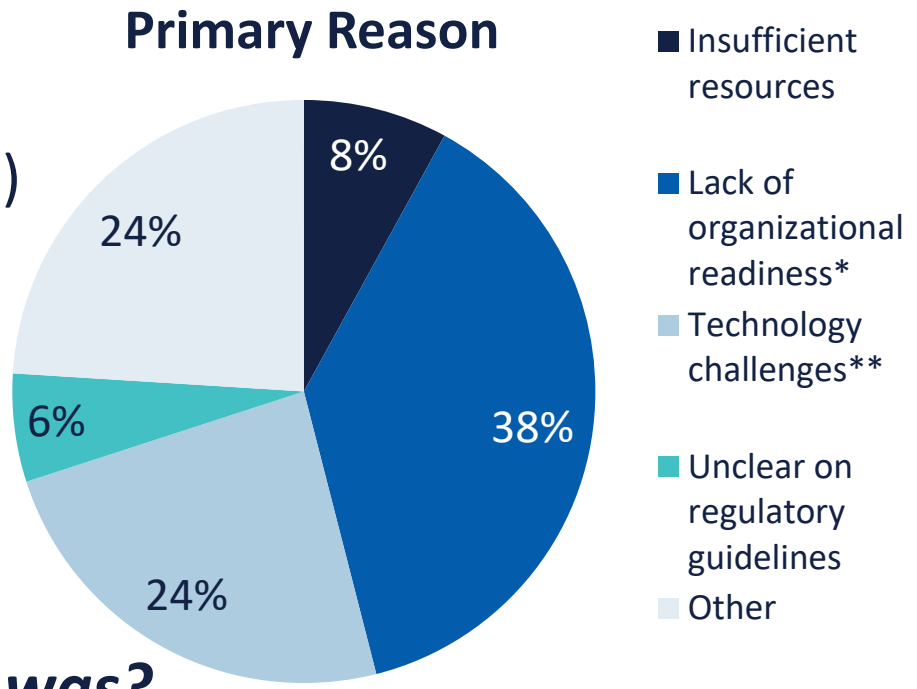


Of those currently using RBM:

- Majority are large, sponsor organizations
- CROs: ~40%
- Some utilization in small- and mid-size academic research centers
- Highest adoption in Europe (76%)

If NO, why?

- If responders answered NO (n=50), they were asked “What do you perceive to be the primary reason your company or organization has not yet implemented RBM?”
- Possible responses:
  - Insufficient resources
  - Lack of organizational readiness (SOPs, org. structure)
  - Technology challenges
  - Unclear understanding of regulatory guidelines
  - Other



- ***Audience poll: What do you think the top response was?***

* Primarily among small- to mid-size companies, and also in Europe

** Mostly impacts Asia-Pacific region

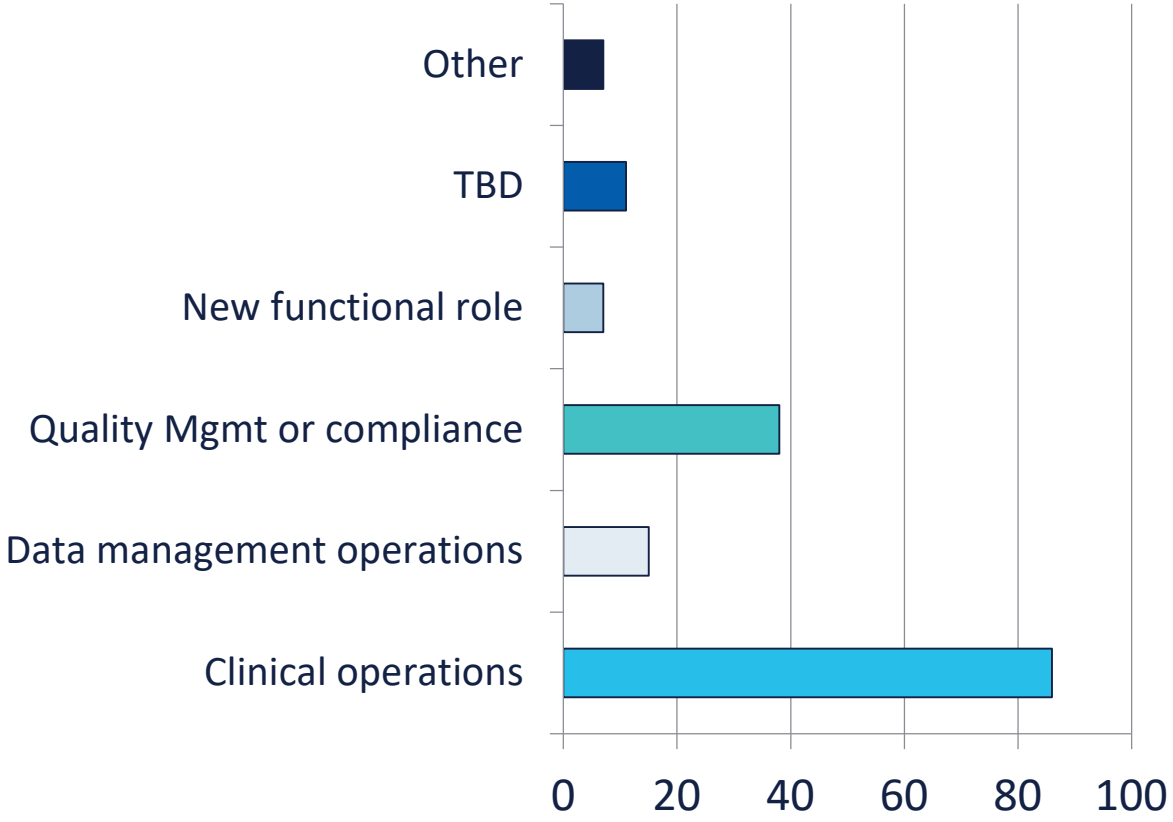
Implementation Progress and Timing

- Significant number (~45%) of organizations (mostly large-sized) have been implementing or piloting ICH E6(R2)
- Small & mid-size organizations are in process mapping and development stages
- Most believe their organization are already compliant with ICH E6(R2) or should be ready within 12 months
- Academic and other organizations were not sure of the time period involved for organizational RBM implementation

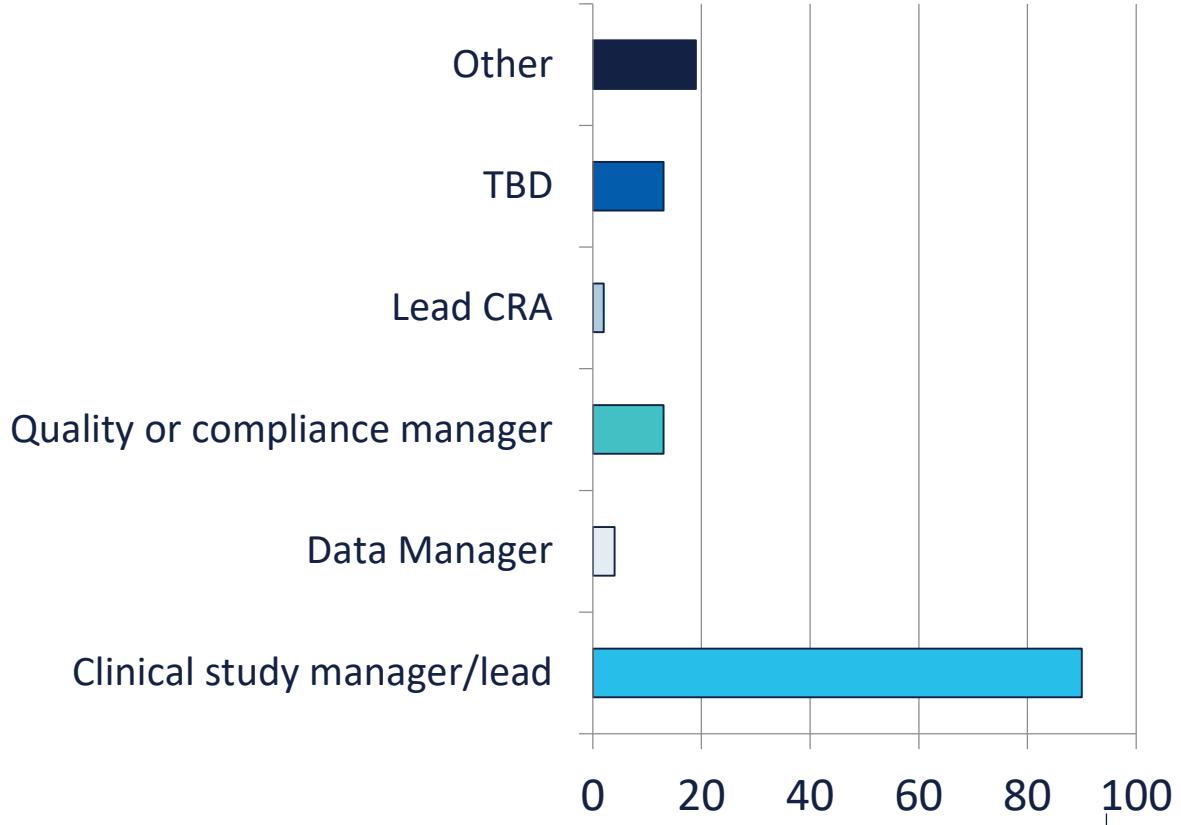
Roles and Responsibilities

Audience poll: What do you think the top responses were to these questions?

Which function within your organization is/will be primarily responsible for implementing ICH E6(R2) compliance?



Who is/will be primarily responsible for performing risk planning on a study?



Strategy

- Significant number of organizations (~27%) are still determining the right tool, but we found that large-sized organizations use a modified RACT
  - Only 12% report using the TransCelerate RACT

- Top 3 requirements of a risk planning tool/technology:
  1. Ability to create key risk indicators from the tool and link them to data visualizations and alerts
  2. Ability to update risk plans on an ongoing basis
  3. Ability to create re-usable library

- 42% report utilizing Targeted Source Data Verification (SDV)
  - 24% of organizations in Asia still use 100% SDV

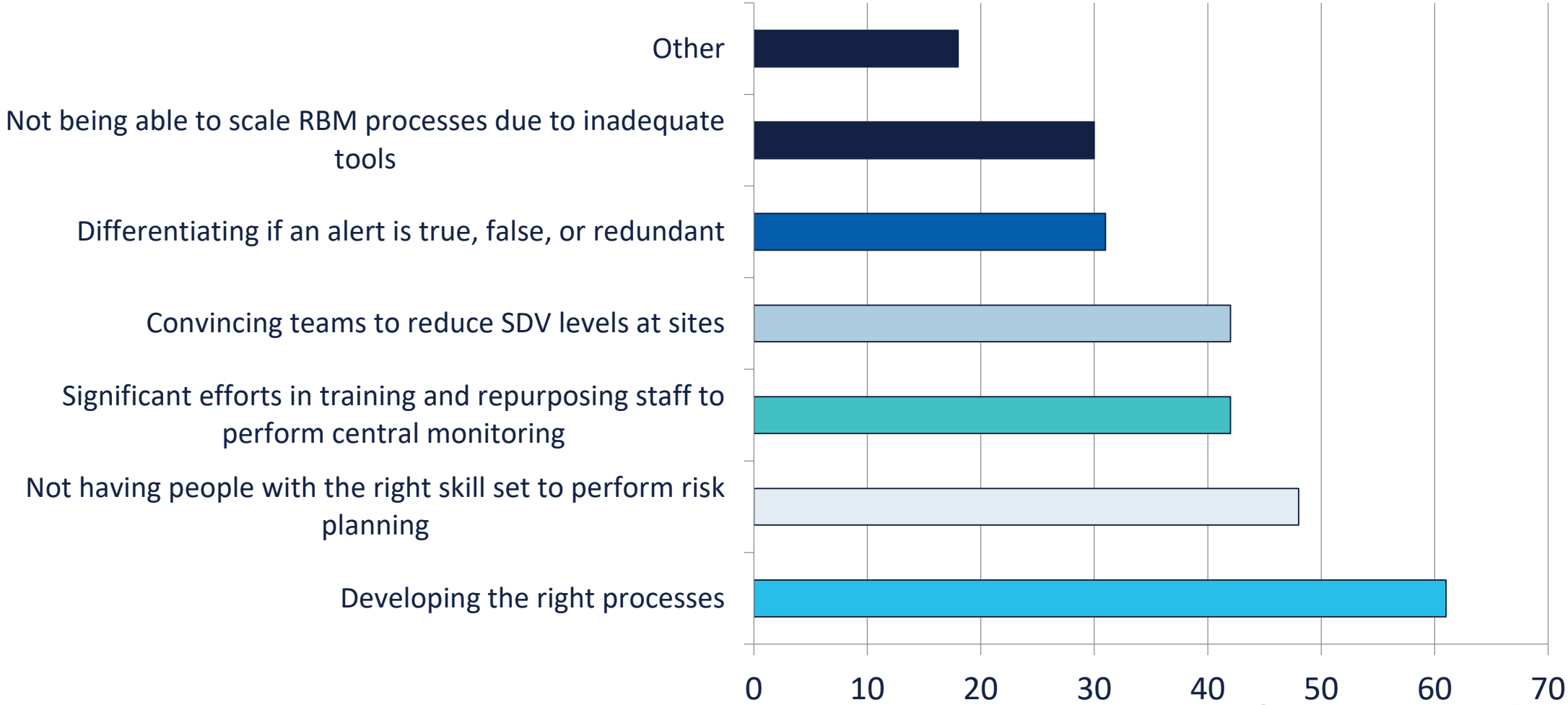
Monitoring and Data Review

- Most common method is combination of clinical data monitoring + stats review (29%)
  - In-house CRAs (19%), Central monitors (18%)
  - Statistician review is least utilized (1.6%)
- EDC continues to be the most utilized source system, followed by CTMS
- Top 4 approaches of central data monitoring:
    - Site level trending and pattern evaluation
    - Aggregate review of KRIs
    - Review automated alerts
    - Comprehensive subject review
- Top 3 approaches for identifying high risk sites
    - Use a combination of outputs from site monitoring visits and central monitoring
    - Analyze central data monitoring outcomes and grade sites
    - Utilize risk scoring framework from aggregate analysis of KRIs
  - These approaches preferred by large-size sponsors and small- and mid-size CROs
  - Academic & other organizations rely more on review of site monitoring visit reports

Top Challenges Facing Organizations

Audience poll: What do you think the top response was?

What are/will be the top challenges facing your organization in implementing RBM?



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Conclusions and Next Steps

Conclusions

ICH-E6(R2) Implementation

PEOPLE

- Clinical Ops in driver's seat
- Study managers: primarily responsible for risk planning
- Central monitors & In-house CRAs being utilized for central monitoring
- Future focus areas will be on upskilling and training, especially among sponsor companies and European organizations

PROCESS

- Small & mid-size organizations beginning to evolve
- Process mapping & development underway
- Targeted SDV to stay
- Central Monitor (CM) + Statistics review is the common strategy
- Site level trends/pattern review + site aggregate risks is common approach

TECHNOLOGY

- Tools being newly sought/ modified
- End-to-end risk planning & monitoring tool is desired
- Data visualizations imperative for monitoring data
- Need recording of CM outcomes
- Need single source of truth to document issues and the actions taken

Next Steps

- Results will be reviewed at upcoming eClinical Forums November 7 & 14
- OmniComm will be producing a publication of the results
- Contact OmniComm to obtain the full survey questionnaire and results presentation
- Add your own insight and experience to the results by taking the survey for yourself!

Scan the QR code on the flyer at your seat to take the survey directly from your mobile device or go to https://www.surveymonkey.com/r/eclinical_rbm

Thank you!

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