



EXPERTISE

SAFETY

SOLUTIONS

RBM: PAIN OR PLEASURE?

TIPS FOR AN EFFECTIVE IMPLEMENTATION

Steven THYS, PharmD, MSc – Director Global Clinical Operations, SGS

PHUSE EU Connect 2020 | 9-13 November 2020

WHEN YOU NEED TO BE SURE

SGS



RBM

Contents

- Background
- Practical considerations for implementing RBM
 - Getting started
 - Roll out
 - Measuring effectiveness
- RBM today
 - Current status
 - Challenges and benefits
- Conclusion

RBM

BACKGROUND

Risk based monitoring



- Risk based approaches have been promoted since 2009 through several initiatives (CTTI, OECD, TransCelerate...)



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINE · HEALTH

- Regulatory guidance published in 2013
 - “A Risk-Based Approach to Monitoring” (FDA)
 - “Reflection paper on risk based quality management in clinical trials” (EMA)

- RBM included in ICH-GCP (R2) in 2016
 - The methods used to assure and control the quality of the trial should be proportionate to the risks inherent in the trial and the importance of the information collected
 - The sponsor should identify risks to critical trial processes and data
 - The sponsor should develop a systematic, prioritized, risk-based approach to monitoring clinical trials



Adapted to **risk**, tailored to trial needs

- Risk assessment
- Quality = fit for purpose

Focus on what really matters

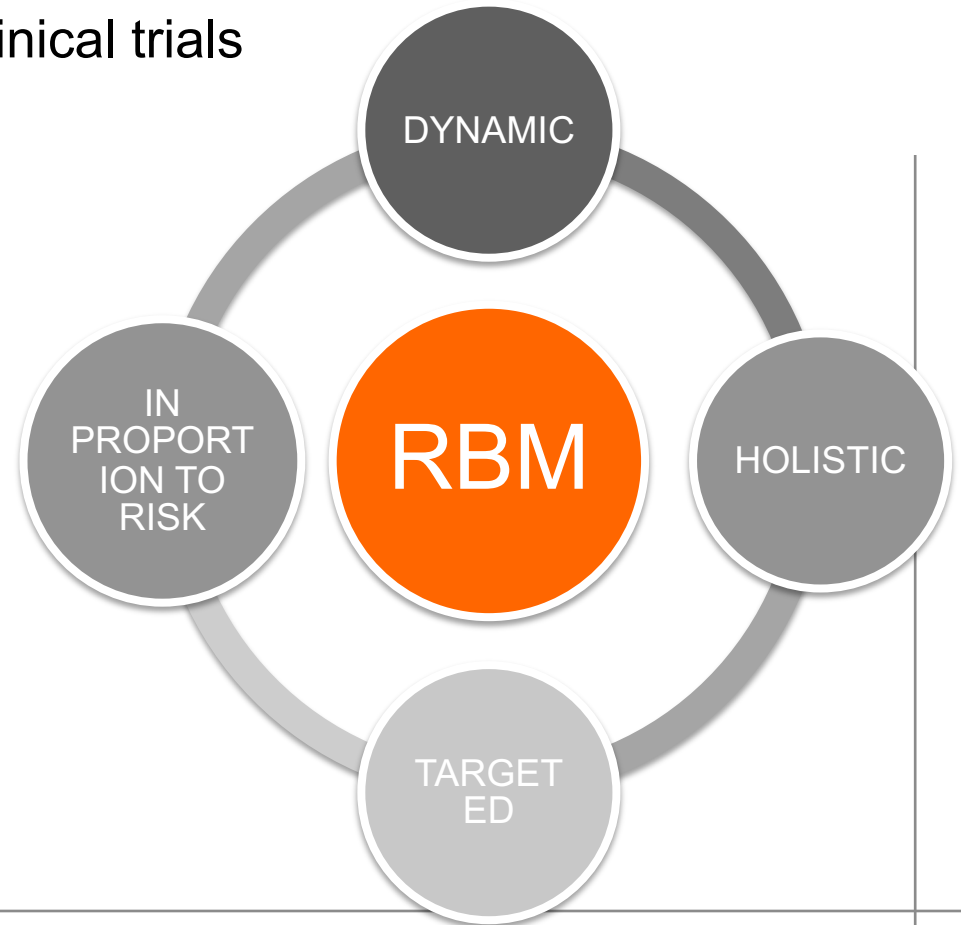
- Critical data & processes

Multidisciplinary approach

- Central & onsite monitoring
- Better use of technology

Ongoing **adjustments**

- Risk review
- Triggered monitoring



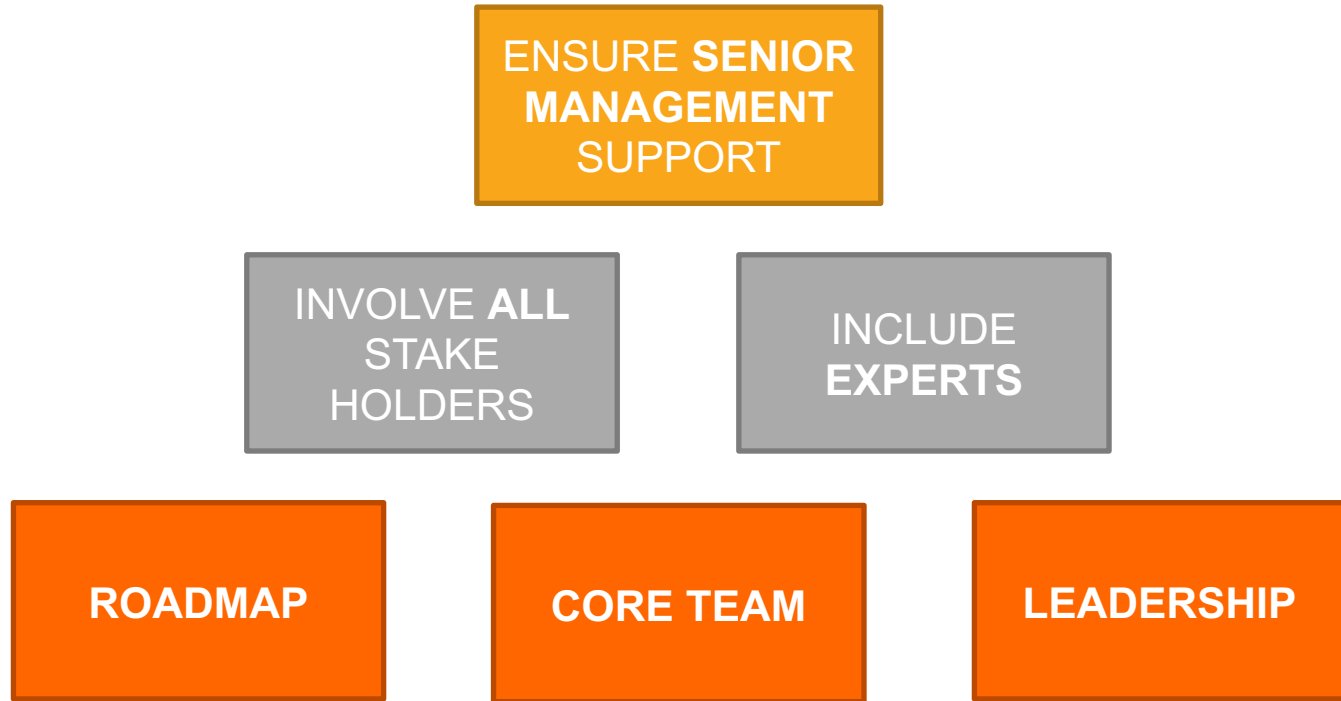
RBM

IMPLEMENTING RBM

Getting started

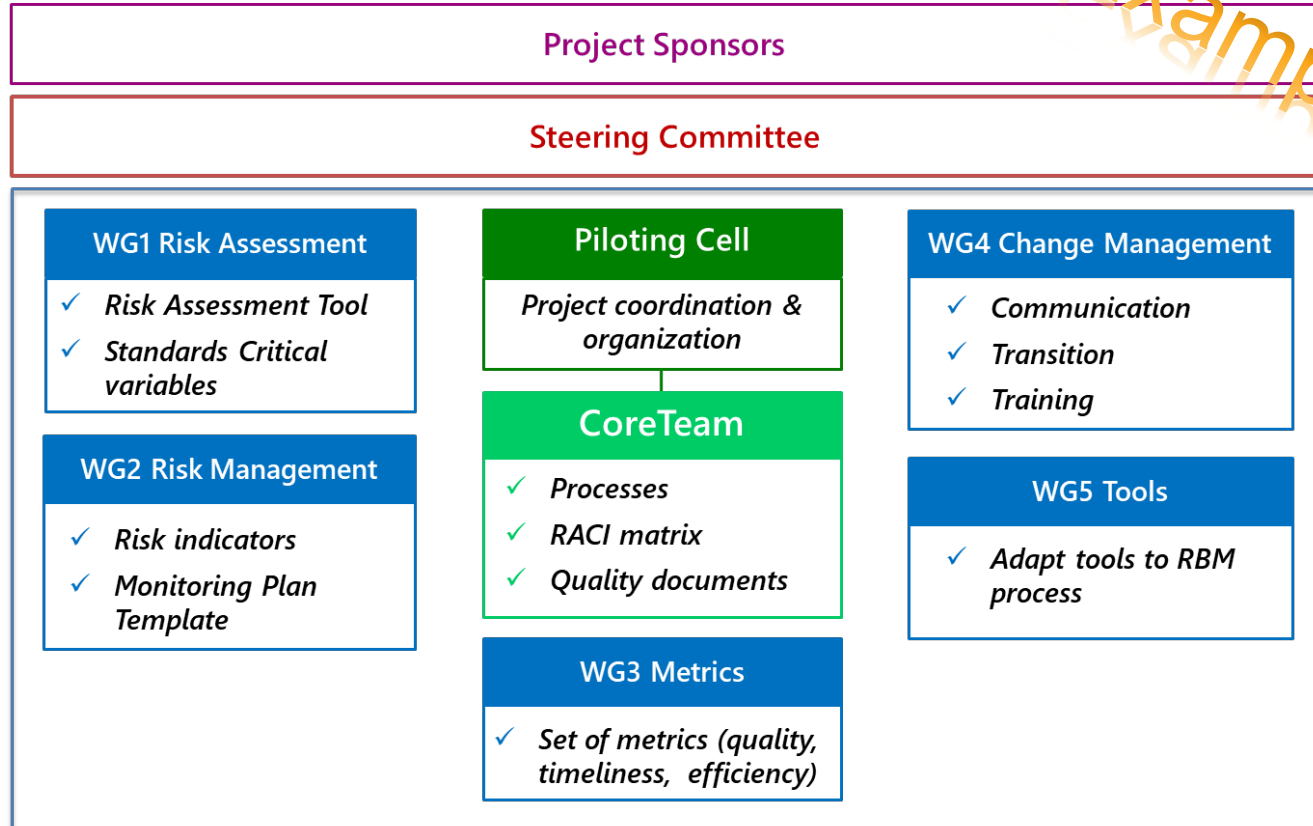
GETTING STARTED

Key Success Factors



GETTING STARTED Project Organization

Example



GETTING STARTED

Defining a high level RBM process

Figure 1 TransCelerate Methodology for Risk-Based Monitoring - High Level Process and Associated Tools

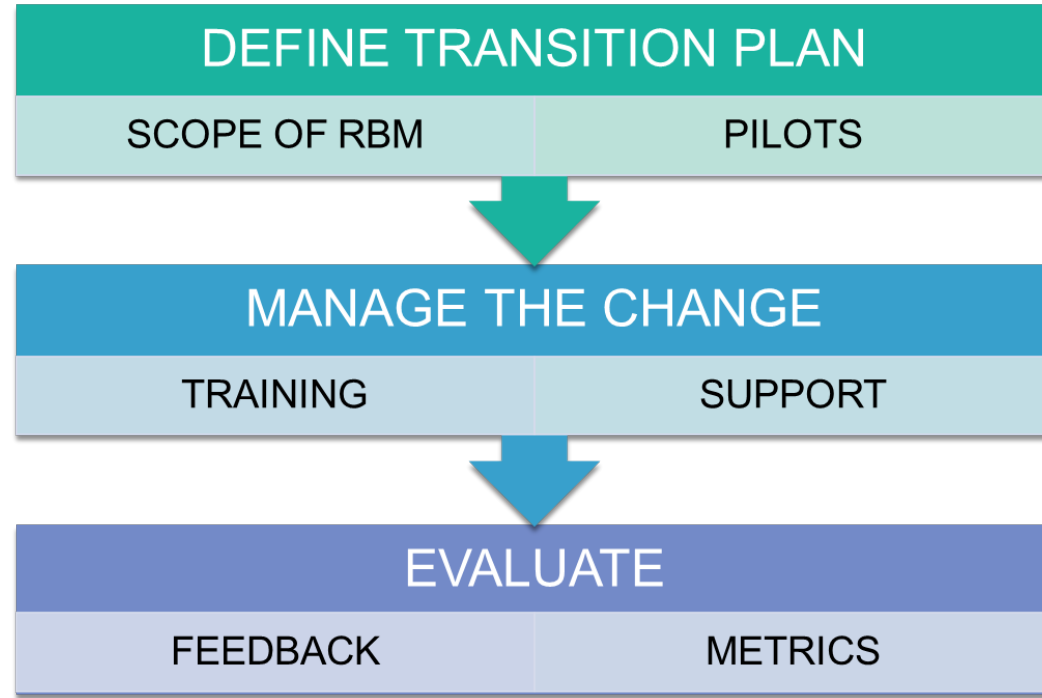


Source: Transcelerate RBM Position paper 2013

RBM

IMPLEMENTING RBM

Roll out



IMPLEMENTING RBM

Managing the change



IMPLEMENTING RBM

Common misconceptions

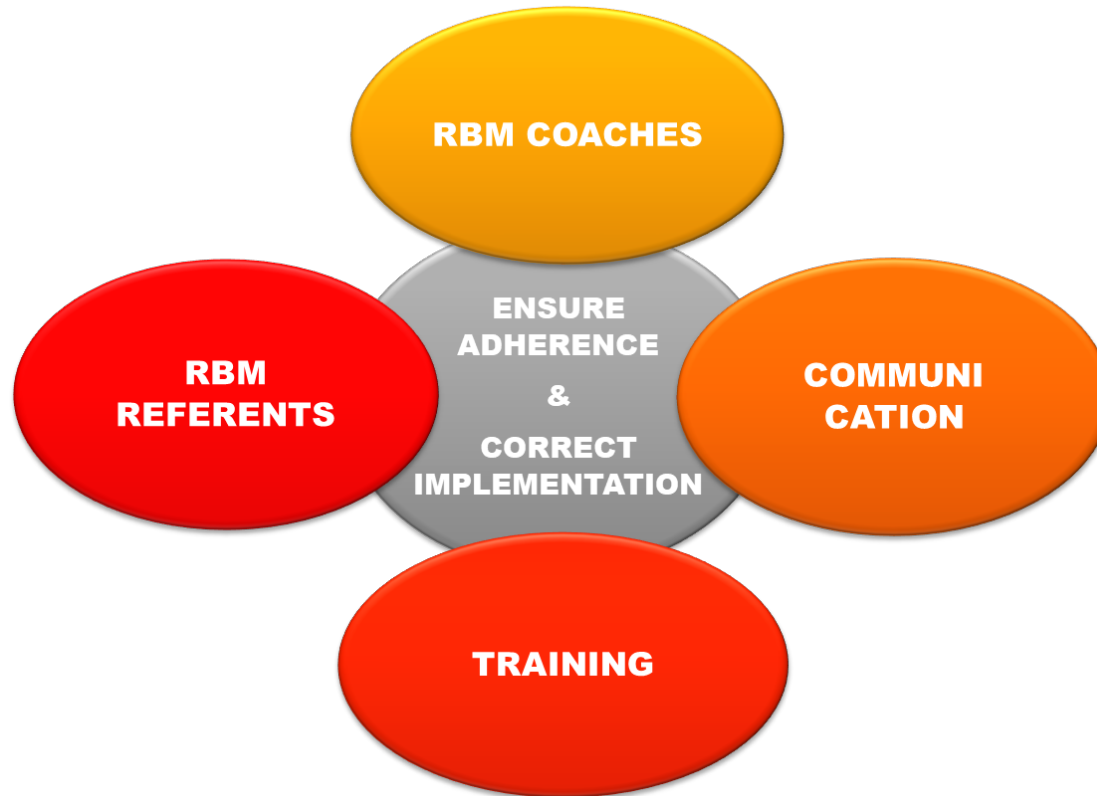
Risk Based Monitoring is...

- aiming for cost reductions
- only about reducing SDV
- putting quality of data at risk
- a clinical operation topic
- only working in large phase III trials
- about taking more risks

FAKE NEWS

IMPLEMENTING RBM

Change management strategies



STEP 1

SOP training

STEP 2

RBM e-learning
per type of actor

STEP 3

Practical workshops
Per type of key actor

STEP 4

Study specific training for
monitoring teams

IMPLEMENTING RBM

The role of the RBM coach



Mission

- Ensure the successful implementation of the RBM model by providing adequate support, guidance and training to key stakeholders.

Tasks and responsibilities

- Organizing workshops around risk assessment and risk management for key actors
- Facilitating the preparation of RACT and the writing of the monitoring plan by being present during team discussions/meetings
- Collecting questions and feedback and ensure coordinated reporting to the RBM Core Team



Role of the RBM referent

- Act as an ambassador for the RBM project
- Point of contact in their department in case of need and of questions
- Provide feedback and share regularly with RBM team

Informal voluntary network of people well-known to RBM

15



VISUAL AIDS

**INFO
SESSIONS**



**CRA
SURVEY**



SEMINARS



ROLLING OUT RBM

Main challenges



Table 3 Perceived problems associated with the implementation of centralised monitoring ($n = 114$)

Factor	Very important	Moderately important	Not important
Lack of education and training in centralised monitoring	71 (62%)	36 (31%)	8 (7%)
Cost associated with centralised monitoring	45 (40%)	54 (48%)	13 (12%)
Information Technology (IT) demands of centralised monitoring	53 (46%)	53 (46%)	9 (8%)
Workload associated with centralised monitoring	47 (41%)	48 (16%)	18 (16%)

Source: Hurley et al. *Trials* (2017)

RBM

IMPLEMENTING RBM

Measuring effectiveness



METRICS

- Objective: evaluate the effectiveness of the RBM model regarding quality, timeliness, efficiency and compliance.
- Set of predefined metrics (including audit findings) to be compared with relevant internal + external (e.g. Transcelerate) benchmarks at several time points during the study

SURVEYS

- Objective: identify areas of improvement for preparing and implementing the RBM methodology successfully
- Multiple surveys addressed to concerned study actors at different time points (before, during and after study)

MEASURING EFFECTIVENESS

RBM metrics



Average number
of major/critical
audit findings 🔍



Percentage of
unreported,
confirmed SAEs as
compared to total
SAEs as discovered
through any method 🔍



Number of
Significant Protocol
Deviations 🔍



Average Monitoring
(all types) 🔍



Average interval
between on-site
monitoring visits 🔍



Median number
of days from issue
open to close 🔍



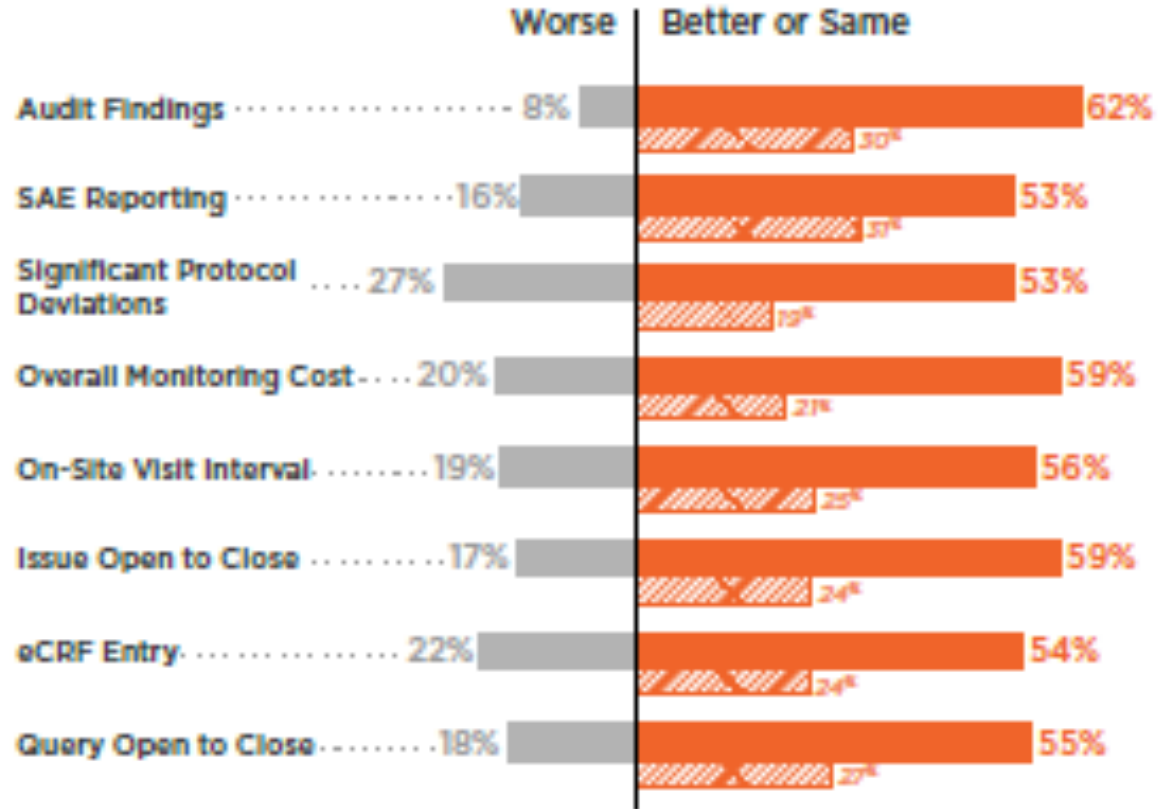
Median number
of days from
patient visit to
eCRF data entry 🔍



Median number
of days from query
open to close 🔍

MEASURING EFFECTIVENESS

RBM metrics





Question site staff and clin ops teams about:

- Impact of RBM on their workload
- Perception on data quality
- Understanding of RBM
- Impact on the relationship with the sites/sponsor
- Usefulness of remote visits

Before, during and after the trial

RBM

RBM today
Current status
Risk and benefits

Uptake of RBM by industry

■ Percent of RBM Studies ■ Percent of Non-RBM Studies

Current Studies Using RBM

29%

71%

© Industry Standard Research

Estimated RBM Utilization in 12 Months

46%

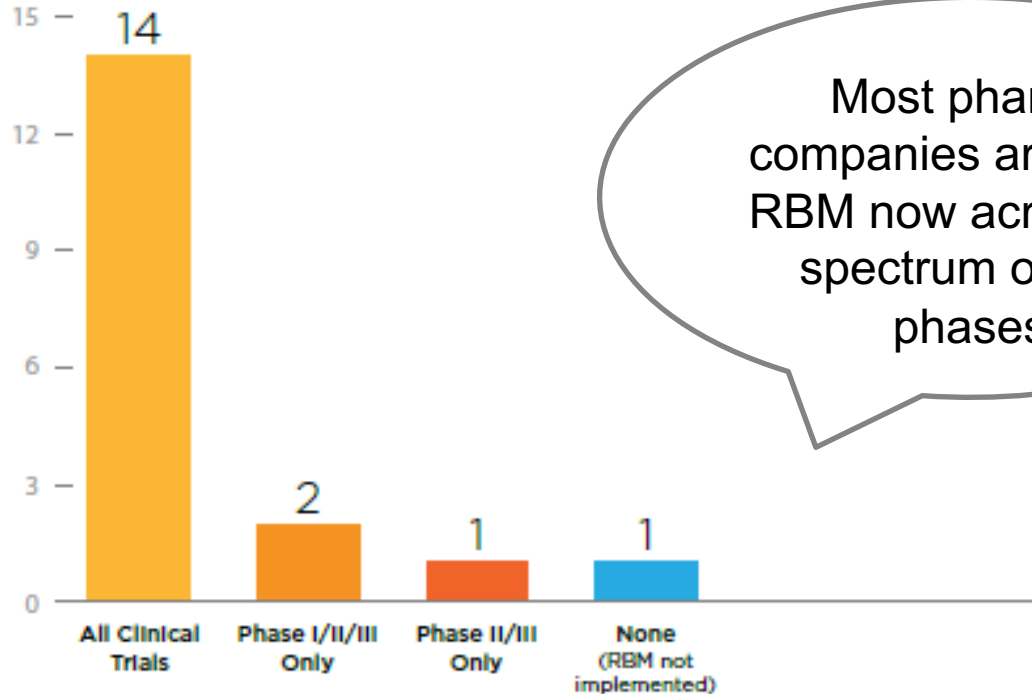
54%

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
% of Studies

Source: ISR Report RBM 2016

Utilization of RBM by type of trial

Number of Member Companies



Source: Transcelerate RBM Metric Report December 2019



- Partial implementation while expecting full benefits
- Unbalance between monitoring modalities
- Misinterpretation of risks
- Limited technological capabilities
- Resourcing : not having the required profiles
- Negative impact on relationship with some investigational sites
- Cultural barriers

QUALITY 

SPEED 

EFFICIENCY 

Table 1. Examples of RBM trial evaluation metrics reported by ACRO survey respondents [ACRO data on file]

Quality in RBM Trials	Efficiency and Speed in RBM Trials
Enhanced ability to identify and manage patient eligibility issues, unreported adverse events and protocol deviations, helping to monitor safety risks	10-day reduction in data management cycle time for a large sponsor implementing a new RBM technology
Central data reviews enabled early detection of quality issues, allowing sites to identify data issues and make early corrections	A smaller biotech has seen database locks go from 30-60 days from Last Patient Visit (LPV) to about 5 days
16% reduction in critical and major findings in site audits	40% faster database lock timeline compared to non-RBM trials
17% better detection of significant deviations	20% reduction in SDV, resulting in more than \$1M savings for a mid-sized sponsor in the first year
4x lower error rate in critical data in a head-to-head comparison of RBM to traditional 100% SDV approach	3-15% savings over traditional monitoring, depending upon the level of SDR/SDV included
45% reduction in the number of missing pages in RBM trials versus traditional trials	21% reduction in subject visit data entry lag

RBM

Conclusion

TAKE HOME MESSAGE

- RBM can be successfully implemented in a reasonable short timeframe
- It requires careful planning and substantial efforts in managing the change
- Cumulative data show RBM reduced cost, improved cycle times and had a neutral to positive impact on quality aspects

It's not an option, it's the new standard!



ADVANCED **CLINICAL** **RESEARCH** SOLUTIONS

LIFE INSPIRED, QUALITY DRIVEN

CONTACT US



clinicalresearch@sgs.com



EUROPE: +32 15 27 32 45
AMERICAS: +1 877 677 2667



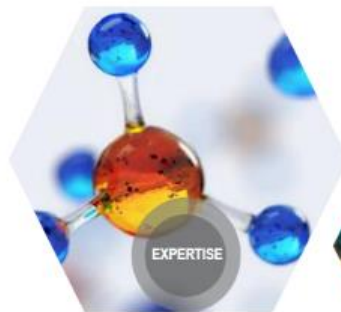
www.sgs.com/cro

JOIN US at the **SGS VIRTUAL BOOTH**
at PHUSE EU Connect 2020



JOIN THE SCIENTIFIC COMMUNITY

Discover R&D market news and events
www.sgs.com/LinkedIn-Life



WWW.SGS.COM

WHEN YOU NEED TO BE SURE

SGS