



RbQM: An Intersection of Cross-Functional Collaboration of Clinical, Analytics, Statistics and Technology Domains for Better Clinical Trial Governance

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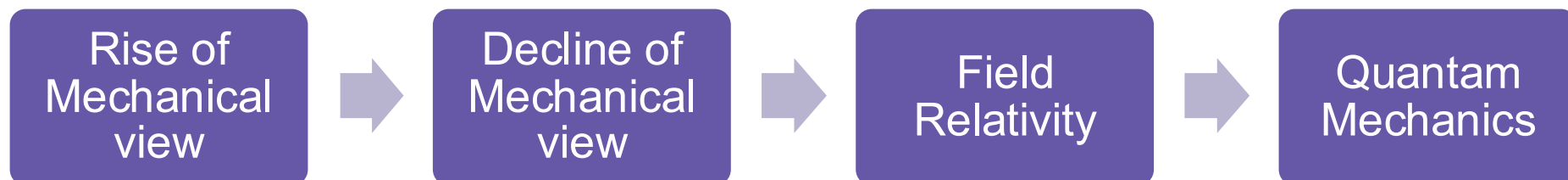
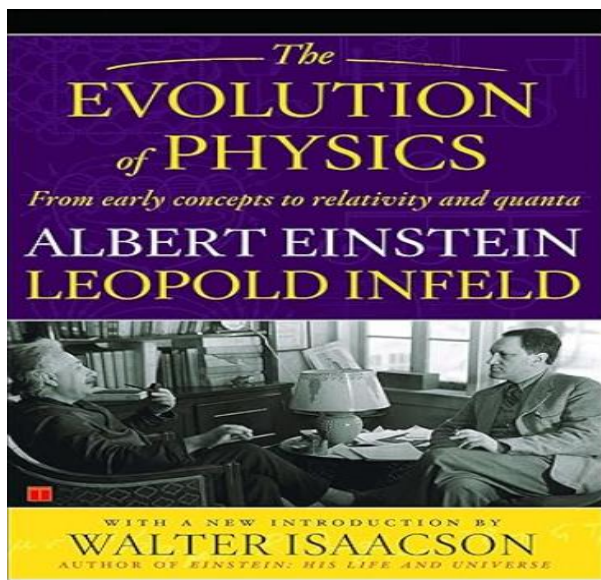
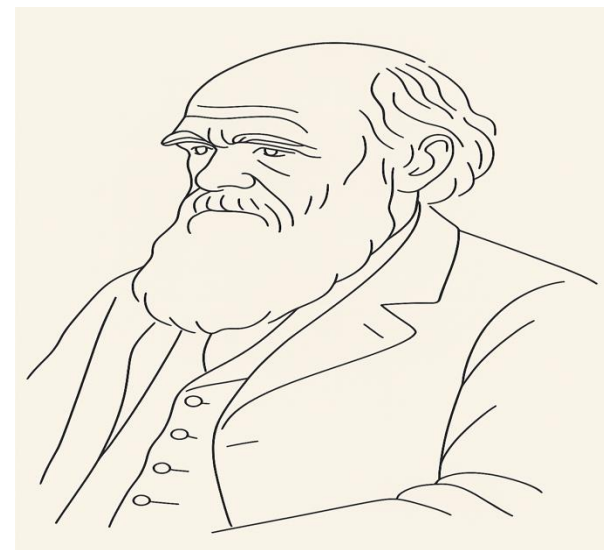
- Evolution: Traditional Monitoring to RBM to RbQM
- How it all Started?
- Four Corner Stones of Clinical Trial Quality
- How BioPharma Industry responded?
- Paradigm Shift: RbQM – Cross-functional, Interdisciplinary
- Challenge: Change Management
- Solution: Effective Change Management
- ADKAR model for effective Change Management
- Call for Action!



Disclaimer:

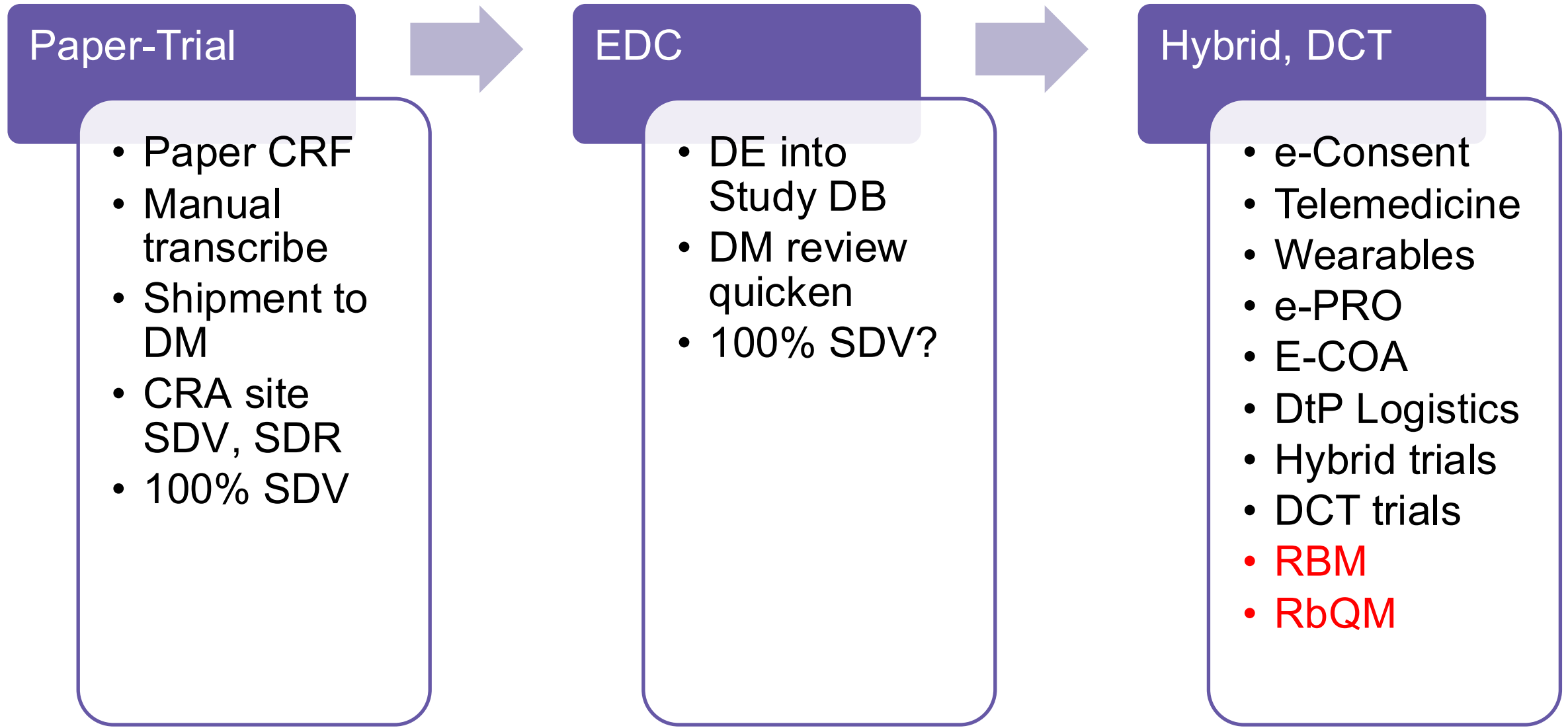
The views expressed here are mine in my personal capacity and not my organization's views.

Evolution Change is Inevitable, Growth is Optional



N examples: IR 1.0 to IR 4.0; Paper Money to Digital Payment; Computers to AI

Evolution Clinical Research



How?

Duke Clinical Research Institute, TIMI Study Group conducted trials and over the years, highlighted, 100% Monitoring didn't seem to have a profound effect on study quality.

Swedish Assoc. of Pharma 2005: 50% GCP activities related costs was for SDV. 71% responded did not perceive any increase in scientific reliability of trials.

Metadata study, Sheetz et al, 2014. 1% of e-CRF data corrected by SDV. 3.7% corrected by any data-cleaning method. 96.3% not corrected by any methods. 11% major & 0.65% critical audit findings were related to SDV.

Evolution Regulators Nudge

USFDA 2013 Oversight of clinical investigations – A risk-based approach to monitoring

EMA 2013 Risk based quality management in clinical trials

ICH 2018 Integrated Addendum to ICH E6(R1), (R2), E8 (R1). Risk-based monitoring & clinical trial quality management system (QMS).

What really Matters! Four Pillars of Clinical Trial Quality

Areas of Focus	Failures	Most frequent reasons
Population	Recruited population is not the intended trial population	Insufficient disease severity – no need for additional treatments
Intervention	Population not exposed to the intervention as planned/intended	Low compliance, premature discontinuation of treatments
Data collection/ Endpoints	Data to prove effectiveness of intervention is incomplete/inaccurate	Missing assessments, LTFU, variability of assessments
Bias	Something influences the study arms differently	Management of adverse events changes patient readout.

Reference: RBQM training, Marcin Makowski

Evolution Change is Inevitable, Growth is Optional

BIOPHARMA Industry proactively embraced the Change

TransCelerate 2013: Evaluating Source Data Verification as a Quality Control Measure in Clinical Trials.

Defining a Central Monitoring Capability: Sharing the experience of TransCelerate BioPharma, Part 1 (2014)

Technology considerations to enable risk-based monitoring methodology, Part 1 (2014)

Evaluating Source Data Verification as a quality control measure in clinical trials (2014)

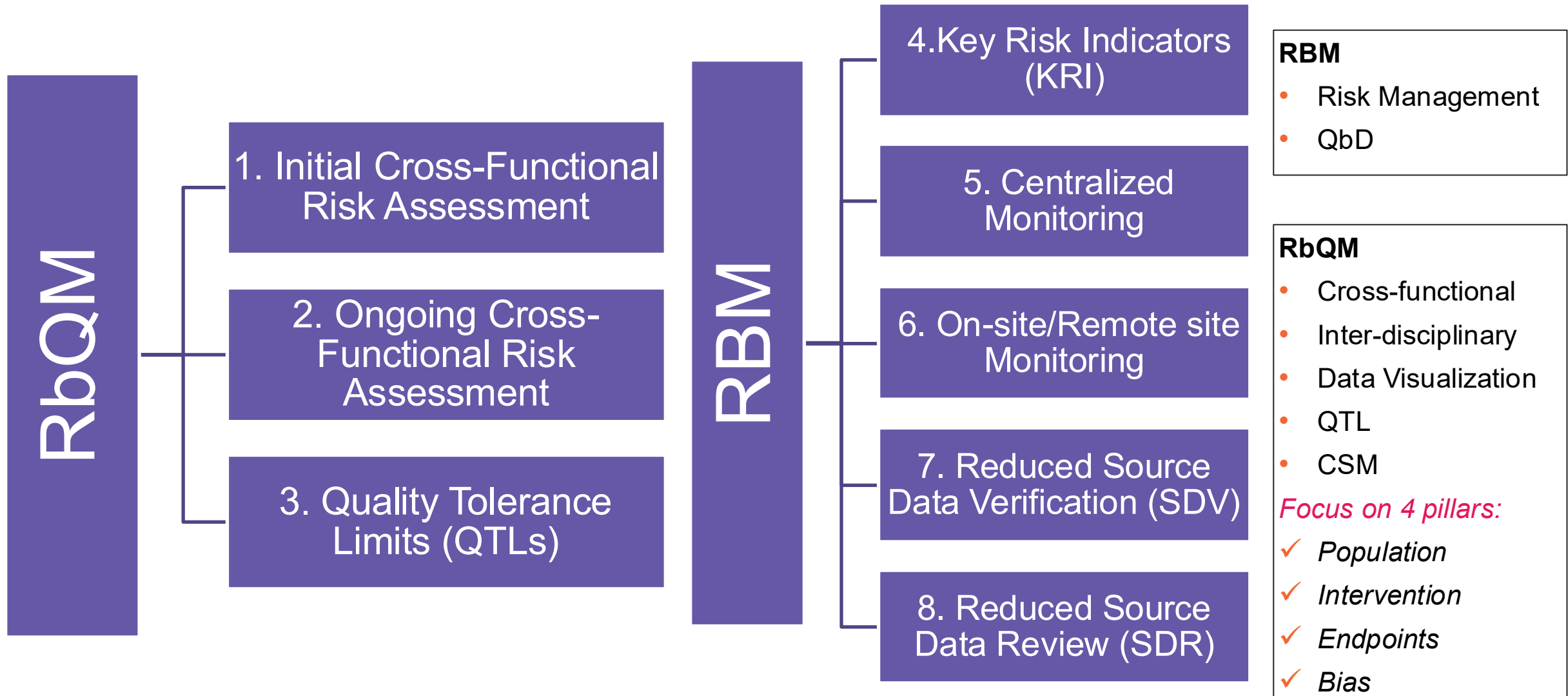
TransCelerate Risk-based monitoring technology considerations, Part 2 (2015)

Defining a central monitoring capability: sharing the experience of TransCelerate BioPharma's approach Part 2 (2015)

Detecting data quality issues in clinical trials: current practices and recommendations (2015)

Statistical monitoring in clinical trials: best practices for detecting data anomalies suggestive of fabrication of misconduct (2016)

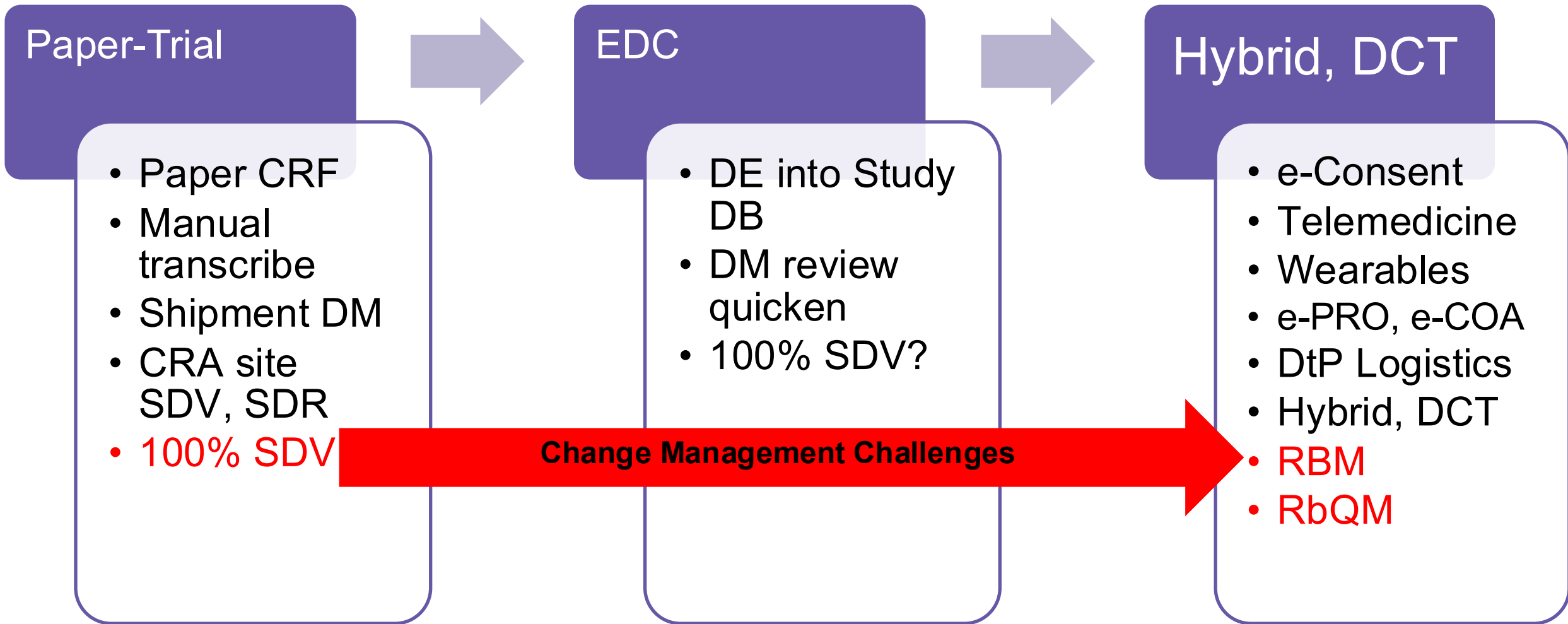
Paradigm Shift Traditional Monitoring > RBM > RbQM



Simple can be harder than complex. You have to work hard to get your thinking clean to make it simple. – Steve Jobs

Core Knowledge	Essential Skills	Practice
• Regulatory Compliance • Clinical Trial Design • Risk Management (Risks to Science) • Clinical Data • Technology (End-user)	• Critical Thinking • Analytical Thinking & Analytics • Collaboration (cross-functional) • Data Comprehension • Data Story-telling	• Risk identification • Risk assessment • Risk mitigation • Centralized Monitoring • Continuous Improvement

Change Management Gap between Theory & Practice (execution)



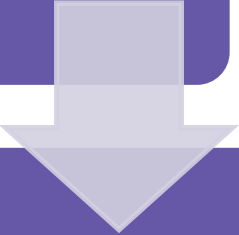
Breaking Silos to Cross-functional/Inter-disciplinary, Integrated Data Review, Organisational changes, Mindset change, L&D, Upskilling, Tech adoption

Effective Change Management Key to RbQM Success

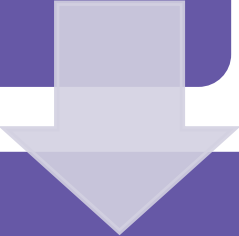
ADKAR element	Definition	What you hear?	Triggers for building
A Awareness	Of the need for change	I understand Why?	Why? Why now? <i>Regulatory Requirement, To reduce Cost & Timeline, Improve Quality.</i> What if we don't? <i>Failure cost for trials will be significantly upwards.</i>
D Desire	To participate & support the change	I have decided to	WIFH (What's In It For Me?) <i>Alignment with Organization's Strategy, New SOPs, Regulators, Industry trend.</i>
K Knowledge	On how to change?	I know how to	Need to know? <i>Knowledge (Clinical, Medical, Statistics, Therapeutic Area, Central Monitoring, Data Management, Trial Design, Risk Management, Project Management) Skills (Critical Thinking, Protocol Interpretation, Clinical Monitoring, Programming, Data Literacy, Data Analysis)</i>
A Ability	To implement required Skills & Behaviors	I am able to	Knowledge - Ability Gap <i>L&D, Upgrading Knowledge, Upskilling Practice (hands-on experience)</i> <i>Growth Mindset, Right Behaviours (Collaboration)</i>
R Reinforcement	To sustain the change	I will continue to	How to Sustain? <i>Measure, Mentor, Guide, Coach, Constructive feedbacks, Recognition & Rewards</i>

Conclusion & Call for Action!

RbQM Intersection of Cross-Functional Collaboration of Clinical, Central Monitors, Data Management, Medical, Analytics, Statistics, Technology etc.



RbQM Paradigm Shift from Traditional Monitoring.
Requires new way of thinking, Upskilling, Soft skills.



Successful Evolution = Effective Change Management.

ADKAR model can raise Awareness, enhance Desire, grow Knowledge, develop Ability and Reinforce cross-functional collaboration, positive attitudes, growth mindset & collaborative behaviours.

If you want to go fast go alone; if you want to go far go together – African Proverb **GSK**

A large, flowing orange shape that starts wide on the left and tapers towards the right, creating a sense of movement and depth.

Thank You

GSK

GSK