



Society for Clinical Data Management
DATA DRIVEN

Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

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Radisson Blu Hotel, Bengaluru

Are we at the tipping point of
RBQM widespread adoption?



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Disclaimer

- 01** This presentation is based on publicly available data
- 02** The views presented are the views of presenter, not necessarily those of Premier Research
- 03** These slides are intended for educational purpose only and for the personal use of the audience
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- 05** The content of this deck is accurate to the best of the presenter's knowledge at the time of production

Content



Regulatory landscape
and RBM/RBQM



Why RBQM Adoption is
the Need of the Hour?



Clinical Trials
Management – RBQM &
Non-RBQM Approach



Lessons from Covid-19
vaccine development, for
embracing RBQM in Post-
Pandemic times?



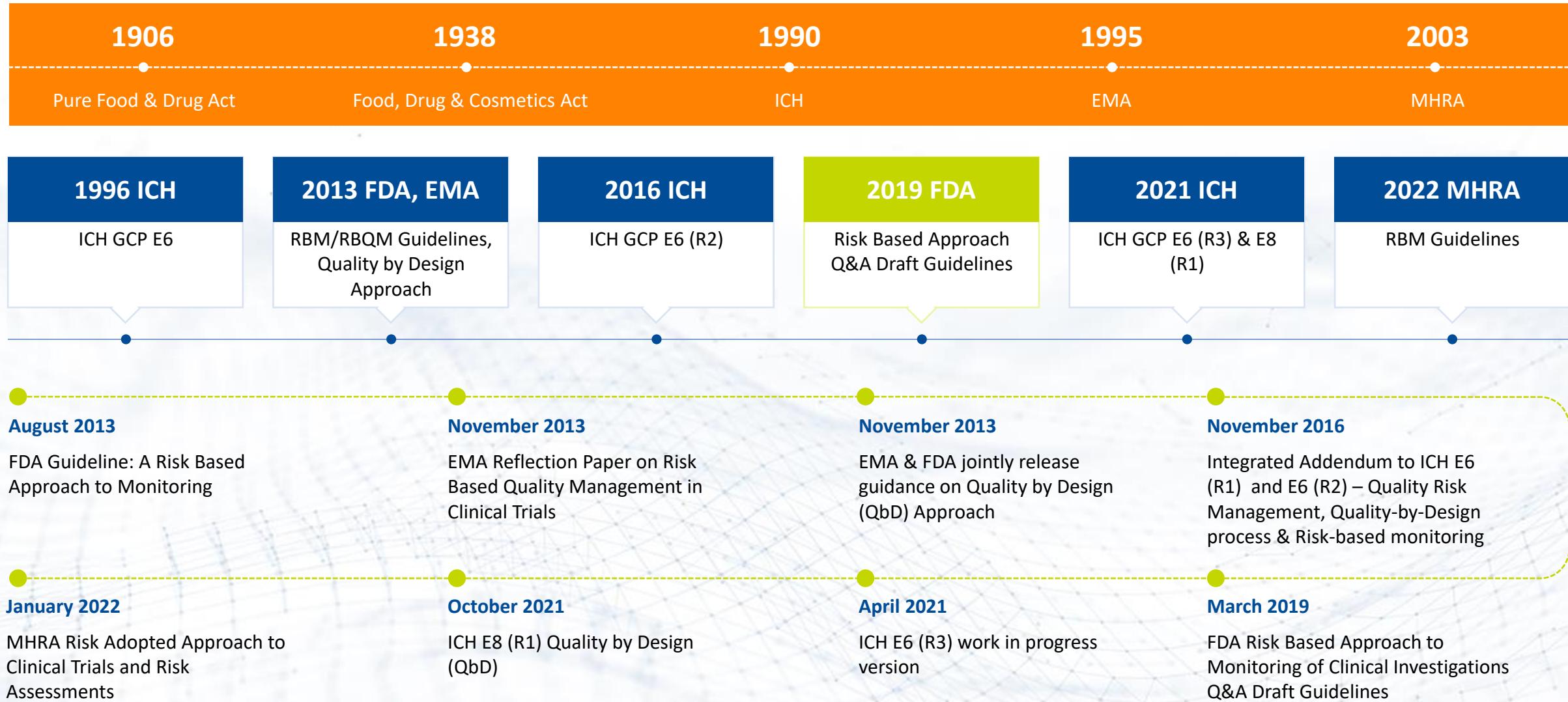
Pandemic as Tipping Point
for RBQM Adoption



Post Pandemic will RBQM
Adoption keep up it's
momentum?



Regulatory Agencies & RBM/RBQM Guidelines

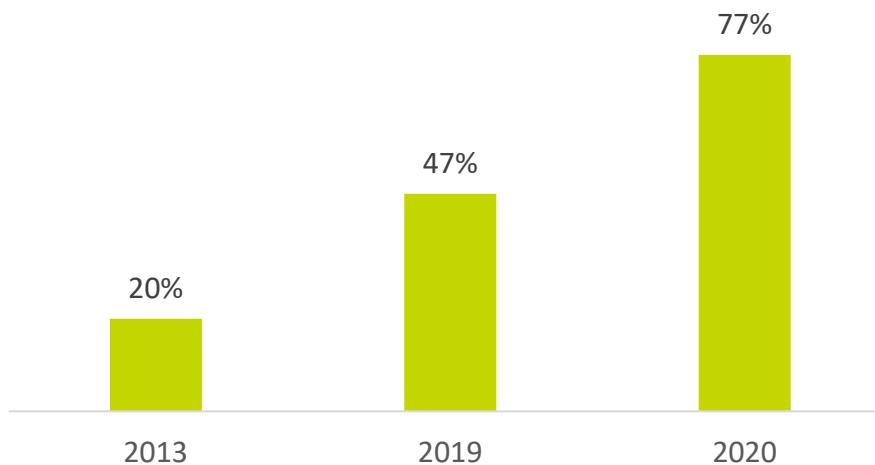


Contrasting Before & After RBQM Guidelines

 RBQM Guidelines	 Before RBQM Guidelines
Proactive Risk Management (Cross-functional)	Frequent Site Visits
Quality Tolerance Limits (QTLs)	100% SDV
Key Risk Indicators (KRIs)	Reactive Issue Management, Lag indicators
Quality-by-Design (Protocol, CRF, Sites, Personnel)	Systematic errors, Trends not identified
Leveraging Technology	No customization of time & efforts, based on trials
Optimization — Focus monitoring activities on critical study parameters	High labour hours (resource intensive trials)
Centralized Monitoring	
Off-site/Remote-site Monitoring	
Reduced SDV & SDR	

RBM/RBQM Adoption Trend during Pandemic

Ongoing Clinical Trials Using at least One RBM/RBQM Component



Reasons for slow adoption of RBM between 2013 till 2019:

- Resistance to change (maintain status quo)
- Challenges in understanding, implementation, execution
- Misconception about RBM

Reason for faster adoption of RBM between 2019 to 2020:

- Pandemic – tipping point
- Need (Necessity is the mother of all invention)

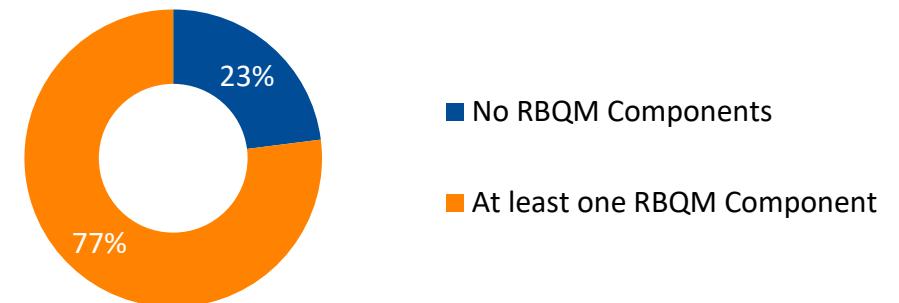
2019 ACRO Landscape Survey Results

6513 ongoing studies, 7 CROs in 2019



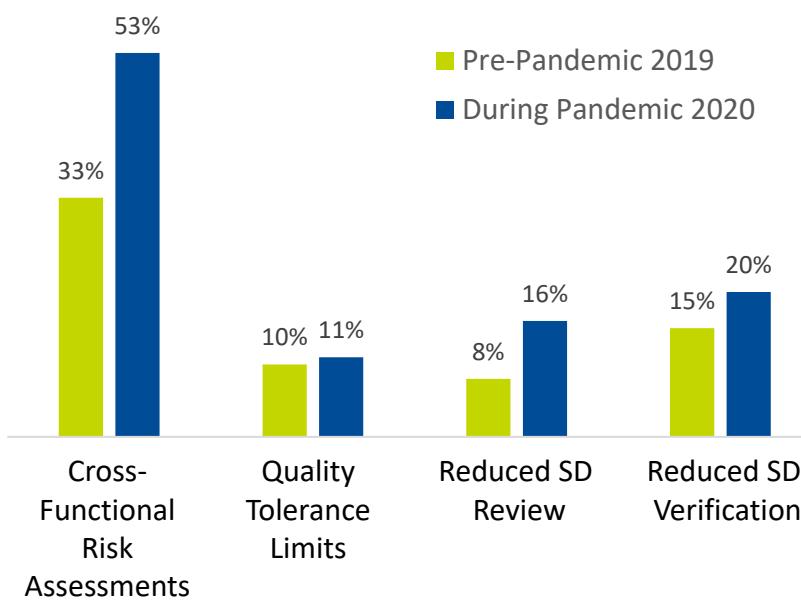
2020 ACRO Landscape Survey Results

5,987 ongoing studies, 6 CROs in 2020. 908 study started in 2020

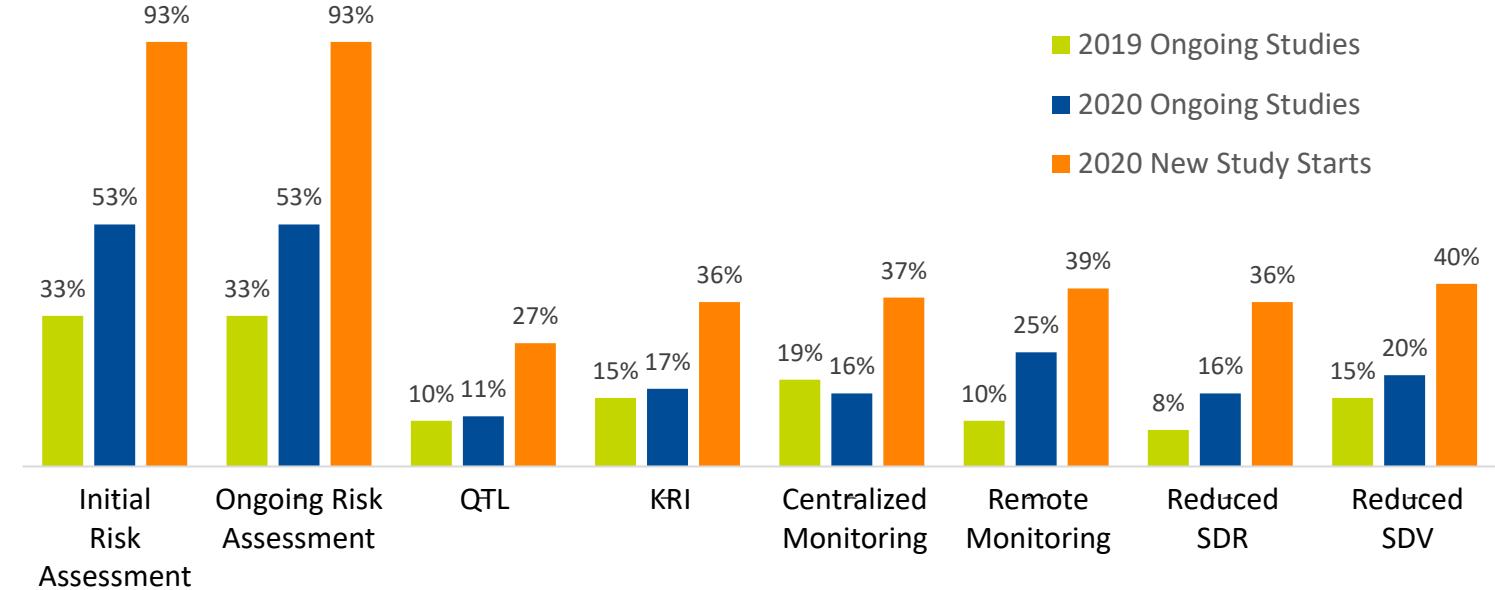


RBM/RBQM Adoption Trend During Pandemic

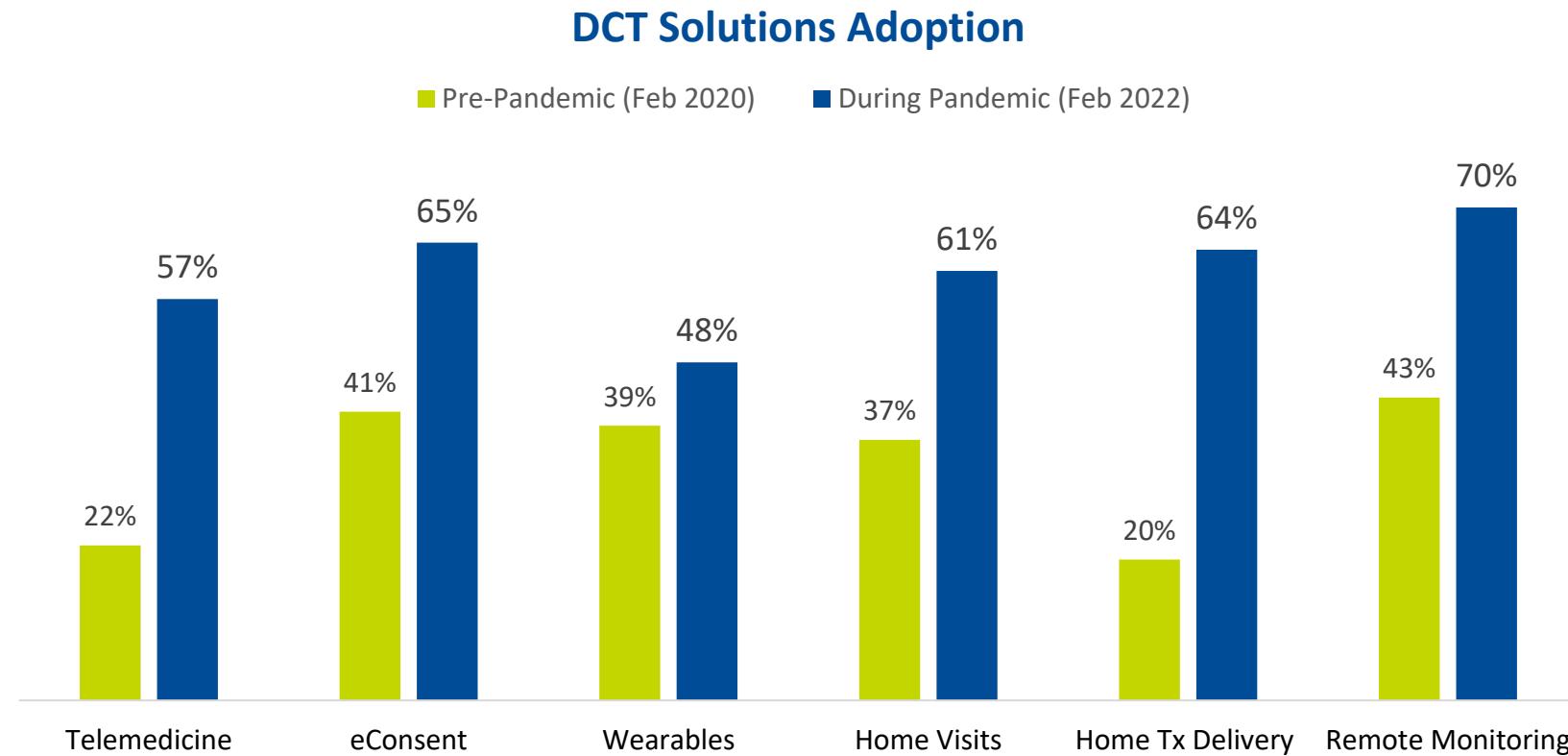
Adoption of Individual RBM/RBQM Components



2019 - 2020 ACRO Landscape of RBM/RBQM Implementation

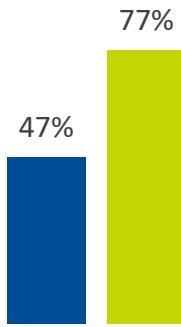


Mirroring DCT Solutions Adoption During Pandemic

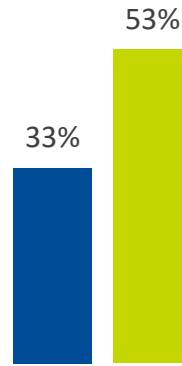


Source: Tufts CSDD May 2022, N = 54 Companies Keynote Speaker Ken Gentz, Executive Director & Professor Tufts CSDD, RBQM Live 2022, Keynote: How the Evolving RBQM Landscape Will Reinforce The Way We Improve Efficiencies The Way We Improve Efficiencies And Add Value.

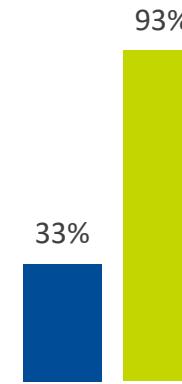
Pandemic The Tipping Point for RBQM Adoption!



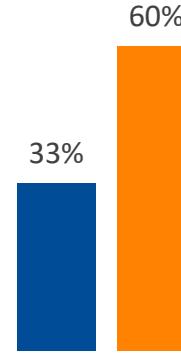
47% to 77% jump in at least one RBM component from 2019 to 2020



33% to 53% jump in Cross-Functional Risk Assessment from 2019 to 2020



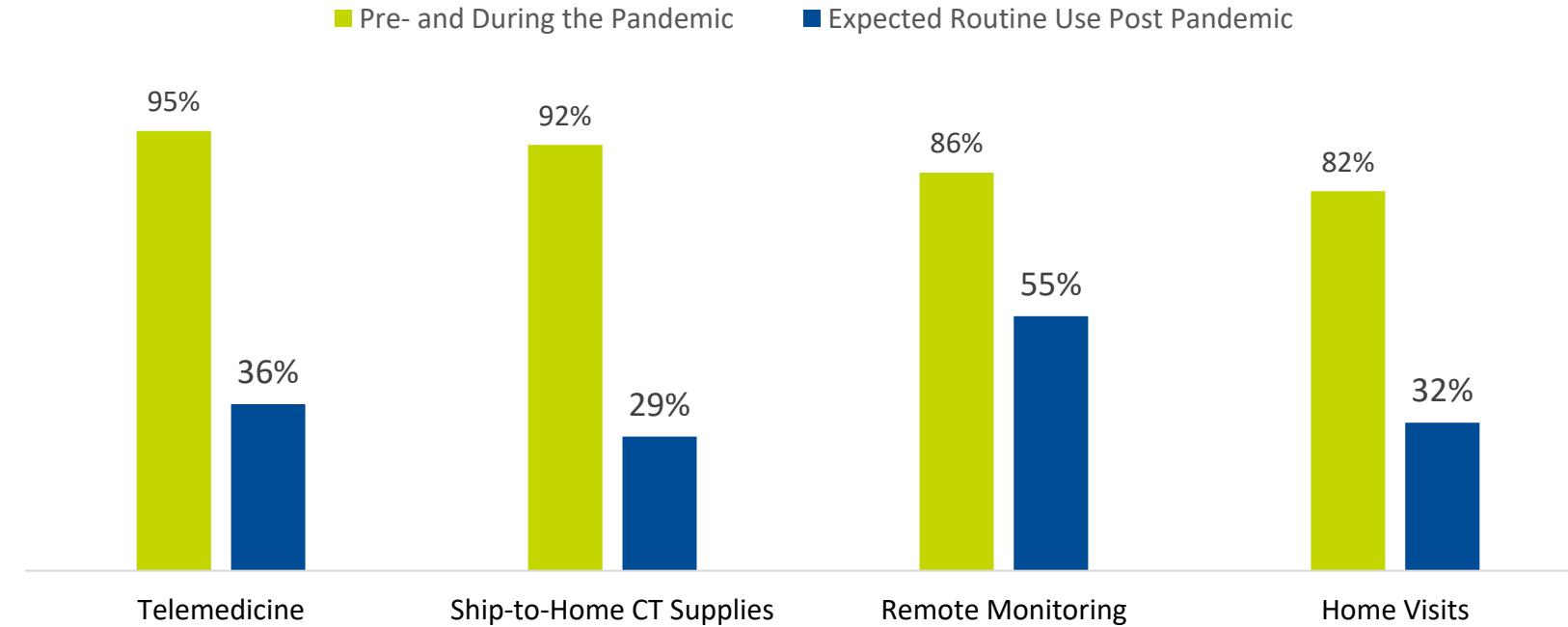
33% to 93% jump in Initial & Ongoing Risk Assessment from 2019 to 2020



33% to 60% jump in DCT adoption during pandemic
(comparison of average of the six DCT components from previous slide)

Forecasting DCT Adoption in Post Pandemic Times

Forecasting Post-Pandemic DCT Adoption



Survey forecasts decline in momentum of DCT adoption post pandemic.

Will similar sentiments mirror for RBM/RBQM adoption post pandemic?

Source: The Avoca Group, 2021 (N = 145 Sponsors and 84 CROs), Keynote Speaker Ken Gentz, Executive Director & Professor Tuffs CSDD, RBQM Live 2022, Keynote: How the Evolving RBQM Landscape Will Reinforce The Way We Improve Efficiencies The Way We Improve Efficiencies And Add Value.

Why Continue to Embrace RBQM in Post Pandemic Times?

- ✓ Pandemic was the Tipping Point for RBQM adoption
- ✓ However, post pandemic momentum of RBQM adoption, may not take an auto-pilot mode!
- ✓ We must take conscious decision to continue embracing RBQM, post pandemic for the following reasons:



Increasing Complexity of CT
(protocol, procedures, endpoints)

01



Increasing Number of CT
(y-o-y registered CT is growing in numbers)

02



Technological Advancement
(opportunities for alternative monitoring & data analysis)

03



Globalization of CT
(customized approach needed across different participating countries)

04



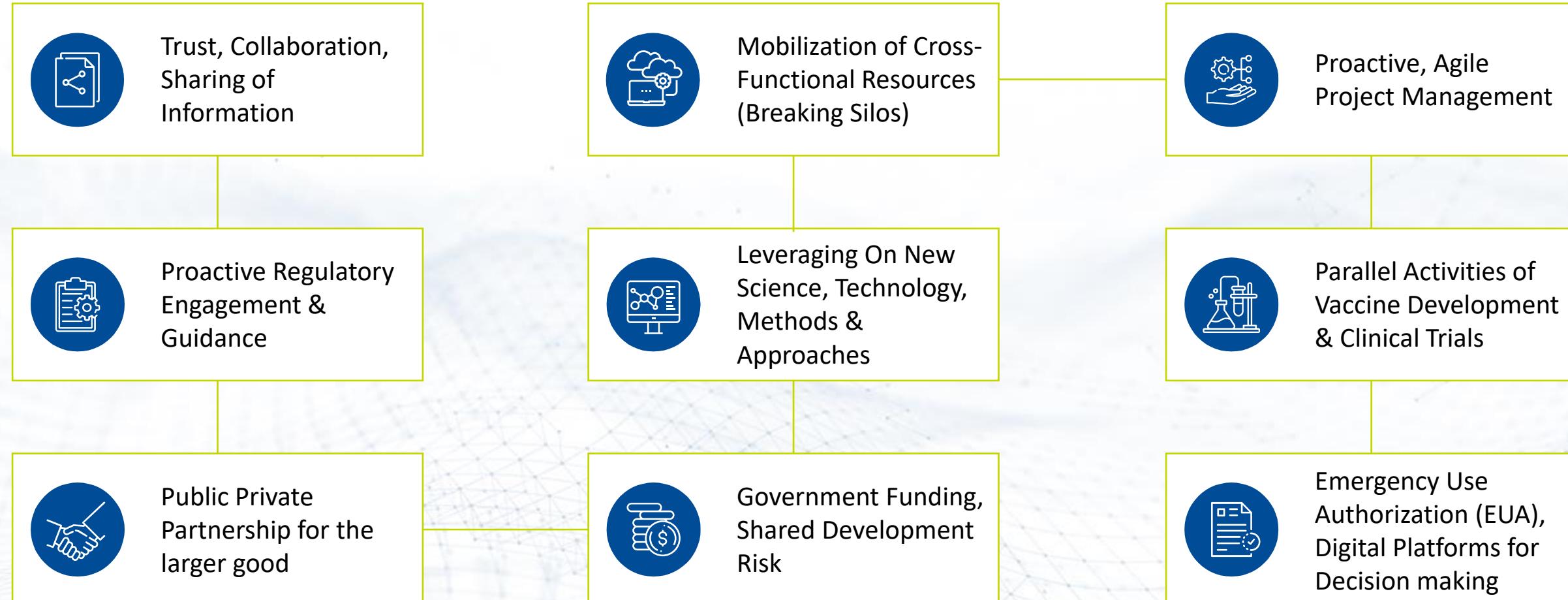
Integrated Risk Identification & Mitigation
(Holistic, Proactive Project Management)

05

Covid-19 Vaccine Development - HOPE & TRIUMPH For RBQM Adoption

Name of Pandemic	Timeframe for Vaccine Development	Duration
Spanish Flu	1917 – 1942	25 years
H2N2 Asian Flu	Feb 1957 – June 1957	< 5 months
H3N2 Hong Kong Flu	July 1968 – Nov 1968	< 5 months
SARS	2003 – present	19 years (ongoing)
Ebola	1976 – 2019	43 years
AIDS	1981 – present	41 years (ongoing)
H1N1 Swine Flu	Apr 2009 – Sep 2009	6 months
MERS	2012 – present	10 years (ongoing)
Coronavirus (Covid-19)	Jan 2020 – Dec 2020	11 months

How We Made Unprecedented Covid-19 Vaccine Development Possible?



Pandemic RBQM's Tipping Point - It's Upon Us Now To Embrace It in - Post Pandemic

Our attributes which made us triumph over the pandemic, can propel us from this Tipping Point towards widespread adoption of RBQM in post-pandemic times for addressing the Needs of Present Day and Future Clinical Trials.



Increasing Complexity of CT
(protocol, procedures, endpoints)



Increasing Number of CT
(y-o-y registered CT is growing in numbers)



Technological Advancement
(opportunities for alternative monitoring & data analysis)



Globalization of CT
(customized approach needed across different participating countries)



Integrated Risk Identification & Mitigation
(Holistic, Proactive Project Management)



THANK YOU