



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?



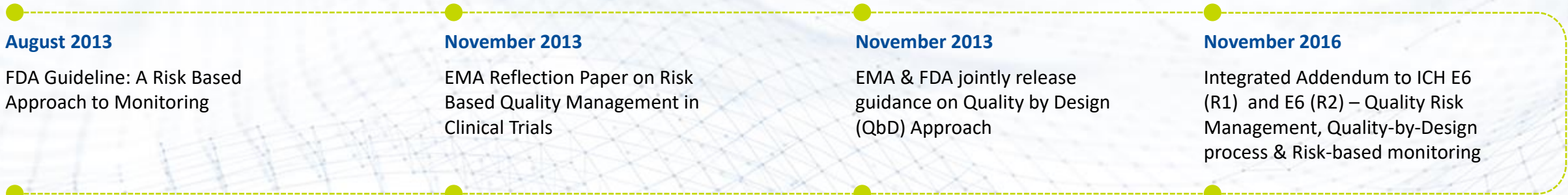
Pandemic as Tipping Point  
for RBQM Adoption



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



# Regulatory Agencies & RBM/RBQM Guidelines

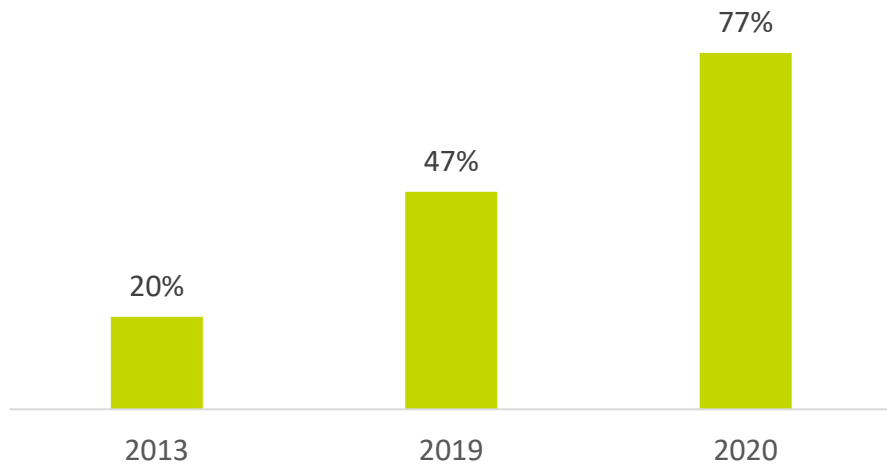


# Contrasting Before & After RBQM Guidelines

| + 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)

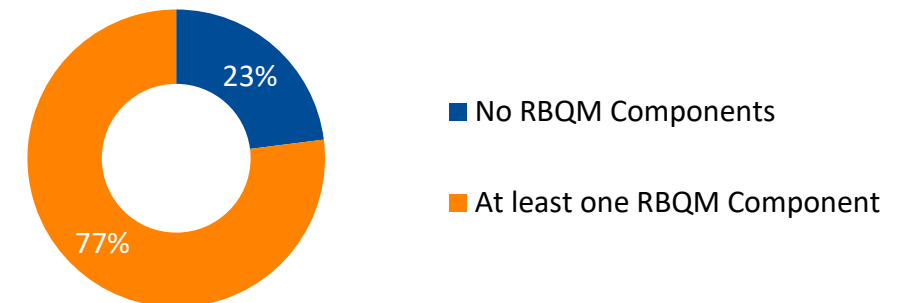
## 2019 ACRO Landscape Survey Results

6513 ongoing studies, 7 CROs in 2019



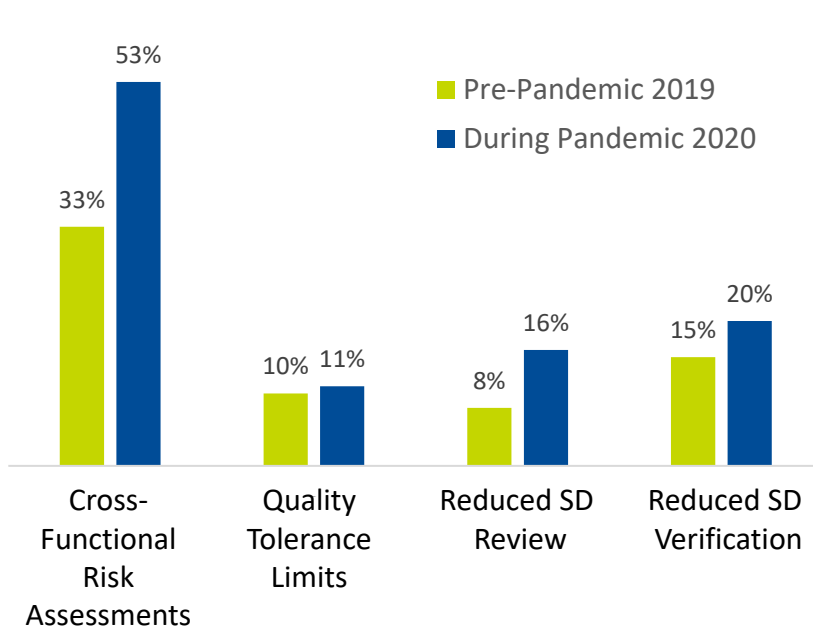
## 2020 ACRO Landscape Survey Results

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

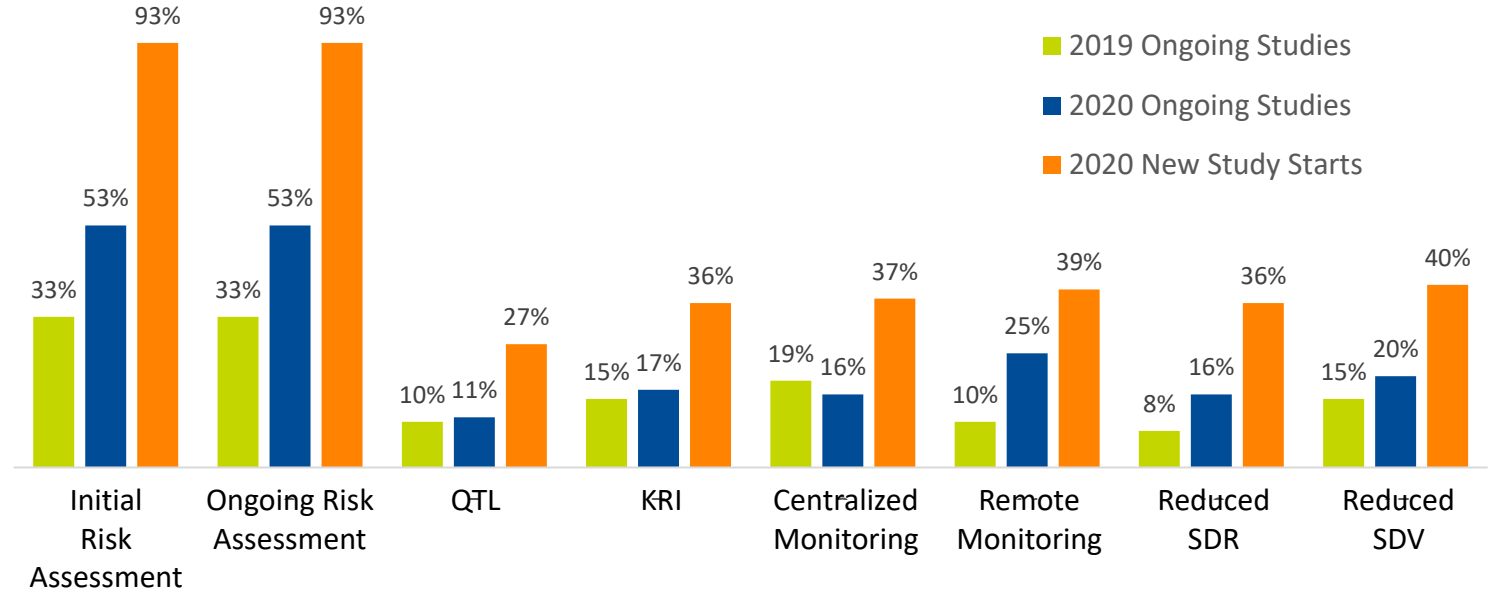


# RBM/RBQM Adoption Trend During Pandemic

## Adoption of Individual RBM/RBQM Components

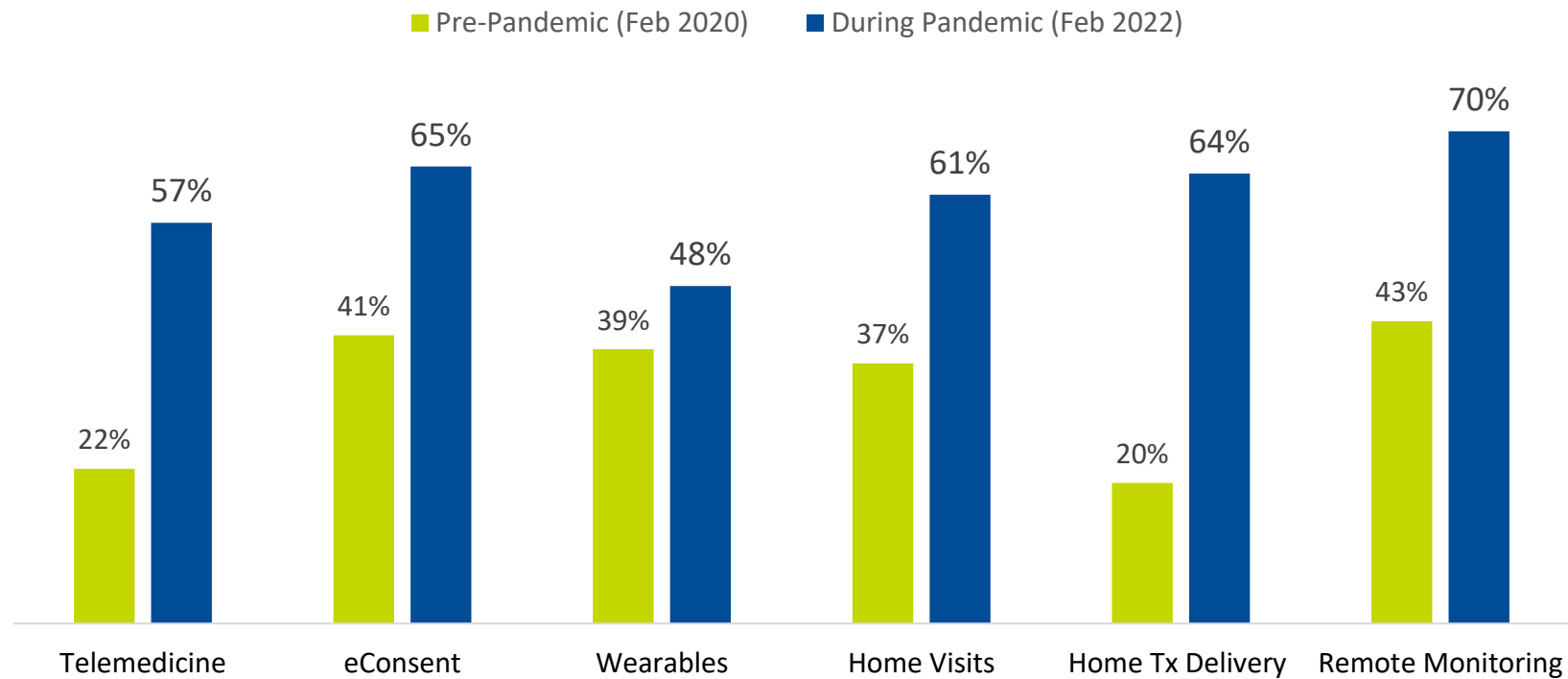


## 2019 - 2020 ACRO Landscape of RBM/RBQM Implementation



# Mirroring DCT Solutions Adoption During Pandemic

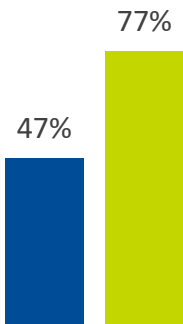
## DCT Solutions Adoption



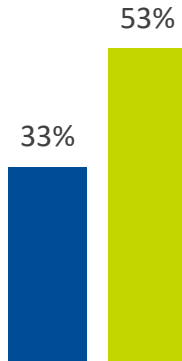
**Source:** Tufts CSDD May 2022, N = 54 Companies Keynote Speaker Ken Gentz, Executive Director & Professor Tufts CSDD, RBQM Live 2022, Keynote: How the Evolving RBQM Landscape Will Reinforce The Way We Improve Efficiencies The Way We Improve Efficiencies And Add Value.



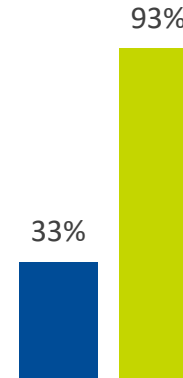
# Pandemic The Tipping Point for RBQM Adoption!



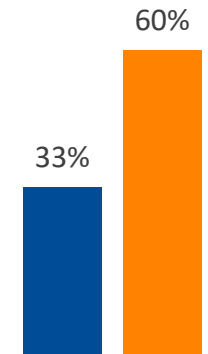
**47% to 77%** jump in at least one RBM component from 2019 to 2020



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



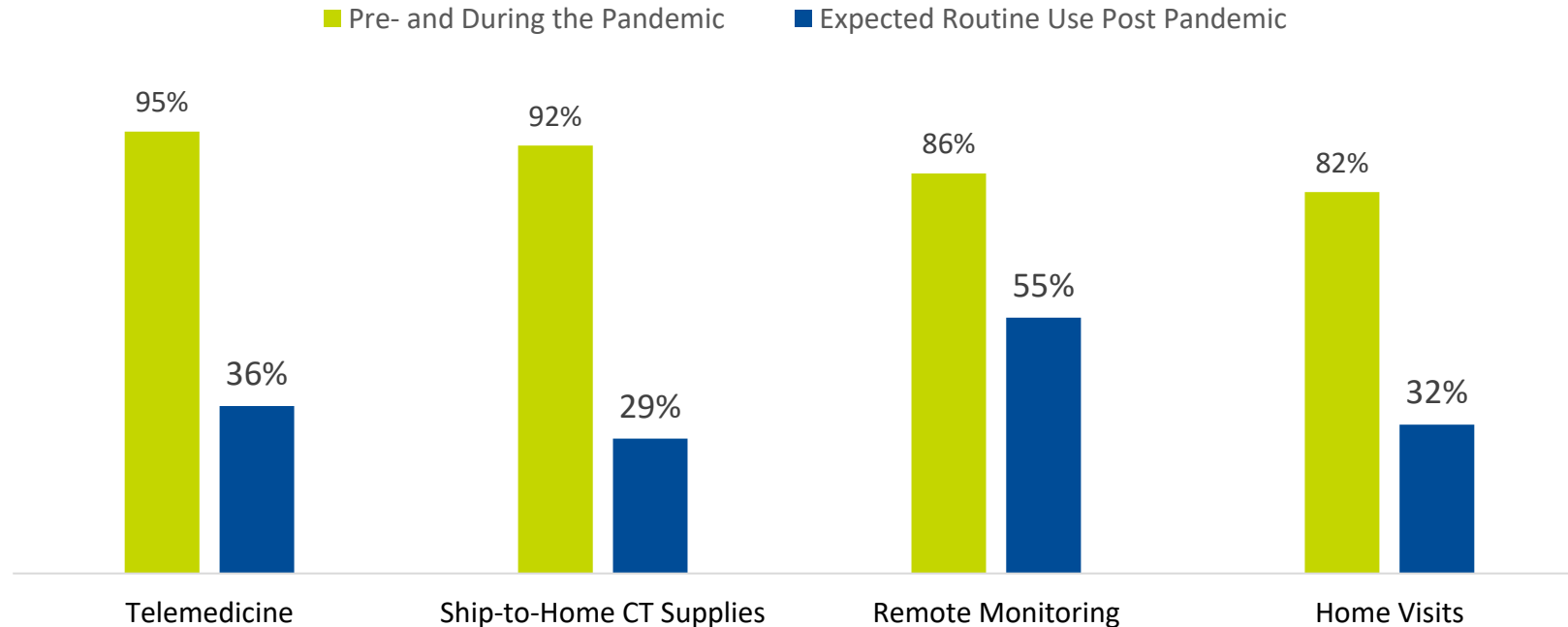
**33% to 93%** jump in Initial & Ongoing Risk Assessment from 2019 to 2020



**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



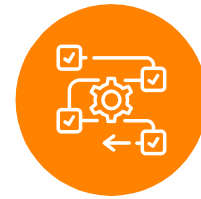
**Technological Advancement**  
(opportunities for alternative monitoring & data analysis)

03



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

04



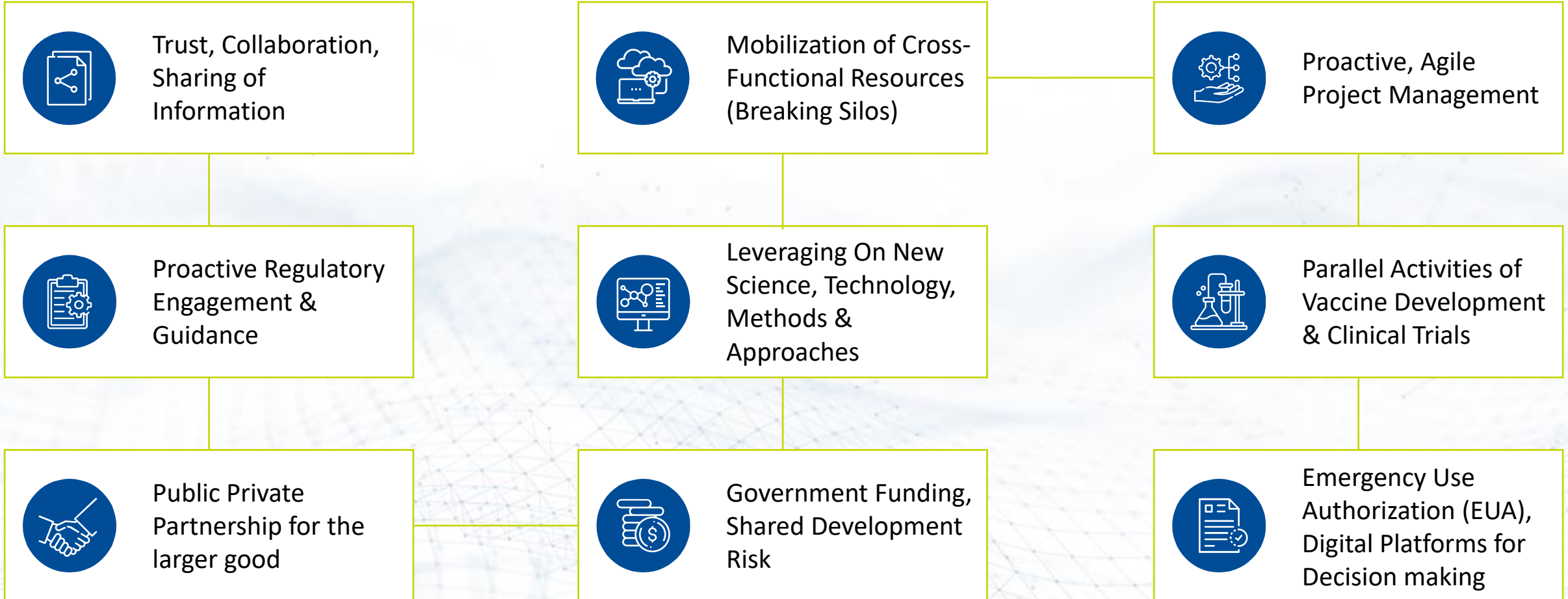
**Integrated Risk Identification & Mitigation**  
(Holistic, Proactive Project Management)

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) |
| <b>Coronavirus (Covid-19)</b> | <b>Jan 2020 – Dec 2020</b>        | <b>11 months</b>   |

# 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)



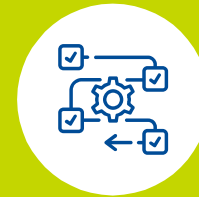
**Increasing Number of CT**  
(y-o-y registered CT is growing in numbers)



**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**