Emerging Best Practices of Hybrid & Virtual Decentralized Approach and Risk-Based Quality Management (RBQM) to optimize prospective Real-World Evidence (RWE) Studies (Observational Studies)

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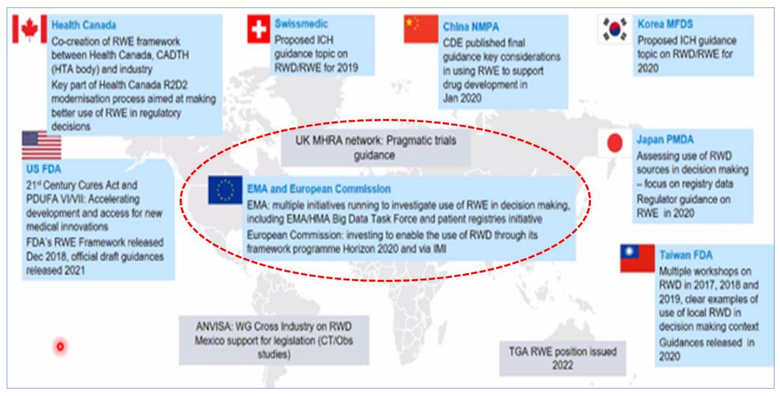
RWE Regulatory Landscape and Emerging Trends in Prospective Observational Studies [1, 2]

Evolution of RWE Regulatory Landscape

- RWE identified as key area of focus in medical devices and digital health, in rare diseases per NICE five-year strategy plan on April 19, 2021.
- In June 2022, EMA, FDA, and HC co-chaired ICMRA workshop to share experience on accomplishments and challenges of RWE in medicines regulation, and to identify opportunities for future regulatory collaboration. [1]
  1. Harmonization of RWD and RWE technologies
  2. Convergence of RWD and RWE guidance
  3. Readiness
  4. Transparency
- In December 2021, MHRA (UK) released guidance on the use of real-world data in clinical studies to support regulatory decision making and requirements for gaining approval

ICMRA*: International Coalition of Medicines Regulatory Authorities

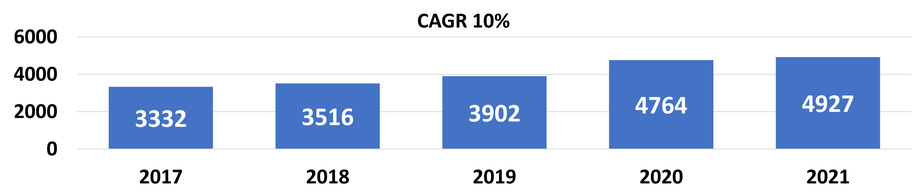


Significant contribution from RWE to support recent US FDA regulatory approvals

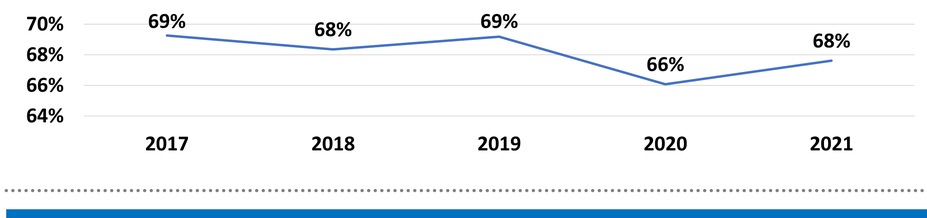
- 70 % increase (YoY) from 2019 to 2020 in RWE contribution for generating evidence of safety and/or effectiveness.
- RWE study played a key role in 78% of FDA approvals related to NDA and BLAs in 2020, as compared to 53% in 2019.
- 75% of all the FDA approvals in infectious diseases in 2020 included RWE study as substantial, primary or supportive evidence.
- 90% of Oncology approvals in 2020, included an RWE Study
- 59% of the decisions specific to product labels follow RWE studies and their findings
- Growing demand of Platforms that integrate clinical study data with RWD, such as health insurance claims, electronic medical records (EMRs), genomic data, patient-reported outcomes (PROs) etc.

Emerging Trends in Prospective Observational Studies [2, 3, 4, 5]

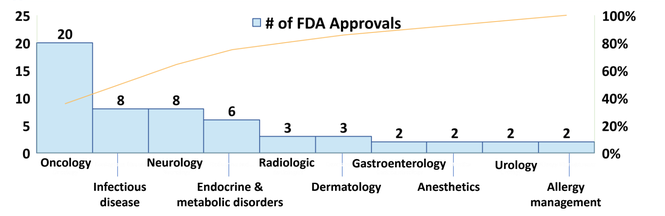
Demonstrable Consistent Growth of Prospective Observational Studies, 2017-2021



Consistent Dominance of Prospective Observational Studies with > 65% of Observational Studies (Retrospective & Prospective)

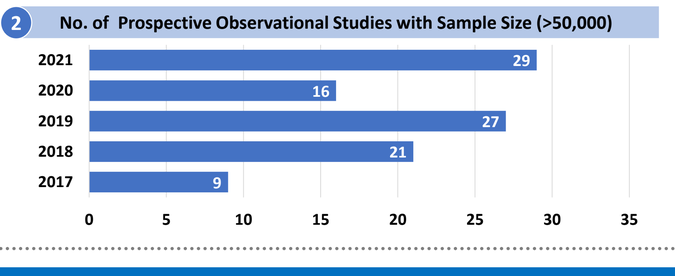


1 Research Objective (for supporting regulatory approval or HTA approval)



Therapeutic Area

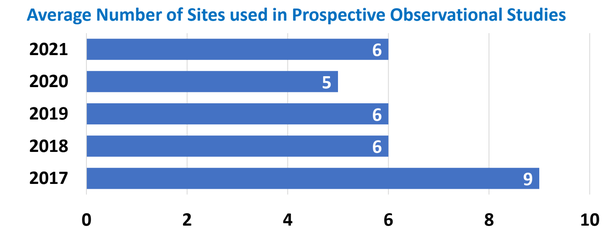
2 No. of Prospective Observational Studies with Sample Size (>50,000)



Complexity Criteria for Prospective Observational Studies

3 Number of Sites

Average Number of Sites used in Prospective Observational Studies



4 Avg study duration in months

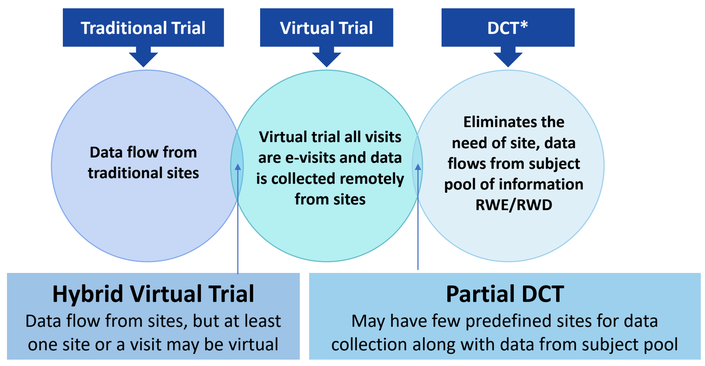
60 months

5 Types of RWD source (Single source or integration of multiple sources)

Our research indicates significant trend of prospective observational study design leveraging integration of multiple Real World Data sources

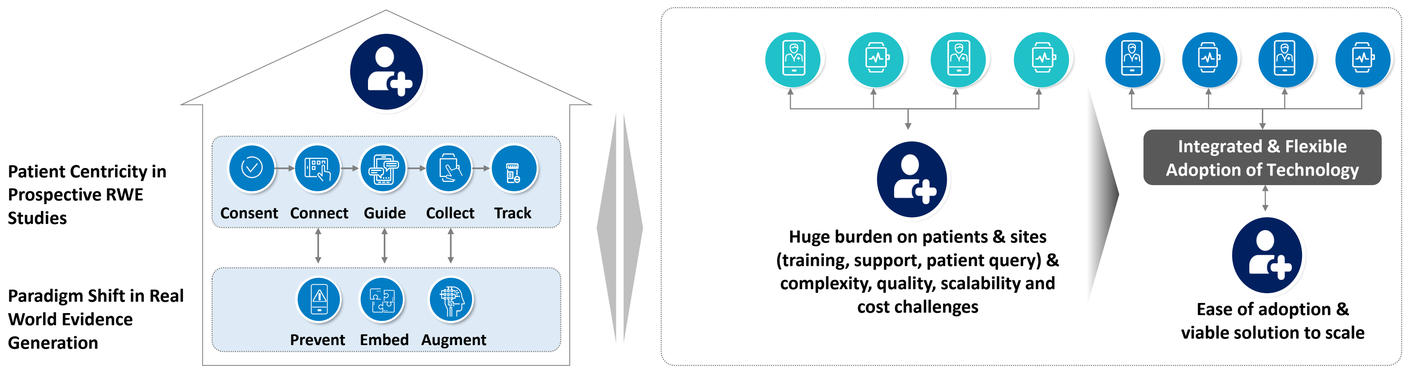
Adopting Best Practices of Decentralized Trials for Optimizing Prospective Observational Studies [6]

What is Decentralized Approach?



DCT* - Decentralized Trial

Enabling Evolution of Patient Centric Prospective RWE Studies: From Few pilots to Mainstream Adoption



Adopting Best Practices of Risk Based Monitoring and Predictive Analytics for Optimizing Prospective Observational Studies [6]

Context of Dynamic Risk Based Monitoring in Clinical Trials

Effective onsite monitoring is important to ensure timely SDV* & SDR*. Delays in correction of data, capture of missing data, quality issues and deviations leads to delayed milestones.

Traditional Site Monitoring	Dynamic Risk Based Monitoring
Pre-determined and fixed schedule of site monitoring	Implement dynamic monitoring strategies using Predictive Analytics driven by AI/ ML
Static schedule of monitoring frequency	Identify 'high focus' sites
Manual, time intensive process of resource allocation	Eliminate human intervention
Lagging indicators in RBM processes & tools	Intelligent integration of lagging and leading indicators with predictive analytics
Reactive approach	Proactive monitoring

*SDV - Source Data Verification, *SDR - Source Data Review

Efficiencies and Quality improvement in clinical trials monitoring through predictive analytics and dynamic risk-based quality management

Strategic Drivers

Time
- Predict sites with potential issues using AI/ ML
- Proactive actions

Quality
- Proactively identify and manage issues and risks

1 PREDICT
2 OPTIMIZE
3 MANAGE RISKS
4 COLLABORATE

Cost
- Remote Data Driven monitoring
- Focused site visits

Sponsor of Choice
- Improve investigator site experience

Proven outcomes of adopting predictive analytics and dynamic risk-based quality management

- **Simplified Decisions** — 30% operational efficiency gains
- **Predicted Outcomes** — 100% elimination of manual allocation
- **Pandemic Support** — Remote monitoring of 200+ studies

300+ Clinical Trials
7 Therapeutic Areas: Onco, Immuno, Resp, CVD, Neuro
20+ Covid 19 studies

Improved cross functional collaboration, quicker decisions resulting in accelerating approval timeline

Case Study

Global Pharma Redesigns Its Operational Analytics Framework

Challenges
- Site/study operations
- Prediction of site/study performance outcomes
- Data silos and disparity
- Disjoint communication

Solution
- Data Model
- Key Risk Indicators
- Predictive Analytics
- Actionable Insights

Benefits
- Reduced monitoring cost
- Actionable insights
- Reduced workload
- Accelerated approval pathway

LIVE FOR 3000+ GLOBAL USERS , 30000+ SITES & 300+ STUDIES

Proposed Value Creation by Adoption of Best Practices [6]

Existing Adoption and Regulatory Perspective

	Adoption in Clinical Trials (Phase I, II,III & IV)	Adoption in Prospective RWE Studies	Regulatory Guidance /Mandate
Hybrid & Virtual Decentralized Technology	Significant	Not Significant	Emerging
Risk Based Quality Management	Significant	Not Significant	Mandated (ICH E6R2 - with context to Phase I , II,III & IV trials)

Proposed Value Outcomes

Activities in Product Development	Value Creation Contribution by Adopting Hybrid & Decentralized & RBM Approach
Complimentary Regulatory Evidence Generation Support	30% upside
Productivity and Cost Savings of Trial/Study	30% reduction
HTA Approvals	20% upside

References

1: Indian Society for Clinical Research Webinar – May 2022

2: The Role of RWE in FDA Approvals- eBoook by Aetion, 2021

3&4: Clinicaltrials.gov

5: Indian Society for Clinical Research Webinar – May 2022

6 : TCS Proprietary Research & Case Study