Decentralized Clinical Trials: Opportunities and Challenges
Meet Your Presenters

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- Director, Data Management, Syneos FSP 360
- 16 Years CDM Experience
- Oncology SME/InForm/Veeva
- Follows DCT, Presented in SCDM, ISCR and European Clinical Research Conference
- Leads SCDM partnership from Syneos

Agatha Moses
- Program Lead, Pfizer
- 18 Years IT and Pharma Experience
- Technology and Innovation
- Data Analytics, Reporting, UAT, Operations
- M. Tech, From Chennai

Priyanka Pandhare
- General Manager, Accenture
- 13 years CDM Experience
- E2E DM, Start-up SME
- Oncology, Autoimmune, Vaccines
- M. Pharm, From Bengaluru

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Decentralized Clinical Trials (DCT), also known as Hybrid, Virtual, Remote or Direct to Patients (DtP) trials, are the ones where part of or all of the trial happens outside a traditional physical clinic or trial site.
Graphical Representation of DCT

Opportunities

Site Activation
- Site Pre-activation and remote activation
- Remote and Central-site monitoring
- Digitized investigator engagement and payment

Patient Enrollment
- Online Patient Identification
- Online Patient Recruitment
- Online Patient Enrollment
- Electronic Informed Consent

Study Conduct
- Direct –To-Patient clinical supply from site or depot
- In-house clinician / nurse visit for assessments & infusions
- Remote Patient Monitoring including efficacy
- Data Collection and Analysis
- RBM, RBQM, Centralized Monitoring
Key Considerations for DCT

**SIZE, PHASE and INDICATION**
Patient population size, Study Phase and indication

**INFRASTRUCTURE**
Maturity and capabilities of the sponsor and its trial infrastructure

**INVESTIGATIONAL PRODUCT**
Storage and administration at patient home

**DATA SOURCES**
Data from eConsent, ePRO, eDiaries, eCOA, wearables and/or sensors, Televisit and lab data

**TECHNOLOGY RELIABILITY**
The trial population’s access and familiarity with health technology and the reliability of internet connections

**DIGITAL HEALTH TECHNOLOGY**
Sufficient to support its use and interpretability in the clinical investigation
DCT Threats

Complexity
- Protocol and Technology complexity
- Multiple systems with complex data flows and integrations

Regulatory Obligations
- Novel clinical endpoint
- Global / Local regulations

Data Reliability
- Concerns on Data Origin
- Consistency and reproducibility of the data

Privacy and security
- Unauthorized access to blinded and patient PHI
- Threat to patient safety, ethical conduct and patient privacy

Unknown Risk Factors
- DCT modalities can raise new risks for GCP compliance
- Risk types and magnitude vary for different DCT modalities

- Phase III protocols undergo an average of 3 substantial amendments
- Phase III clinical trials generate an average of 3.6 million data points, three times the data collected by late-stage trials 10 years ago
- Data Reliability contributes to 49% of the DCT threat
- Direct-to-patient medication comes with risk, increased four-fold from 5% to 20%
Challenges in DCT Adoption

- **Cost**: Premium technology might increase the cost of clinical trial (Unclear ROI)
- **Right Technology**: To collect, organize, secure & transfer patient data from modalities -> site -> sponsor / CROs
- **Technology Literacy**: Challenges in learning new technology by Participants & Clinical research professional
- **Protocol Deviation**: High risk of protocol deviation. Patients could use a device wrong or record incorrect data
- **Oversight & Attrition**: Oversight and coordination between Site, Sponsor, CRO, Tech vendor
- **Participant Accessibility**: Access to smartphones / computers and reliable internet access could be an issue
Mitigating the Challenges

1. Tools and Technology
   - Select the right tools and technology to adopt a digital transformation
   - Real use cases to implement DCT
   - On Demand Support Center

2. Flexible Solutions
   - Configuration of the CDMS to distinguish the different data sources
   - Real time integration and DM verification
   - Mobile Units/Local Site, Pharmacy

3. Privacy and Security
   - Identify and assess the risk to participant safety and privacy (as per General Data Protection Regulation (GDPR))
   - Secure Data Archiving at Site with their own infrastructure

4. Training and Adoption
   - Journey Maps for Patients, HCPs
   - Custom tools, technology and process training materials
   - Surveys to check the adoption
   - Patient Advocates

5. Project Management and Oversight
   - Cross collaboration
   - Monitoring of progress, resolving issues, Governance
   - Reduce the cycle time of processing at each stage of data collection

6. Resources
   - Flexible and scalable resource supply
   - Manage turn over
   - Expand the skillset of site staff to meet the technology demand

Sponsor, CRO, Site, Regulators, Tech vendor, Third party vendors – Works as ONE TEAM
Home health services
Mobile Units Labs, Pharmacy, Site/HCPs
Remote Patient Monitoring

For Site staff, Patients for Technical and Care support

On Demand Support Centre
Remote Data Collection, Site Monitoring
Cyber security
Direct to Patient

Wearable Technology

Direct-to-patient and direct-from-patient models

Technology companies enabling remote data collection, and Site monitoring

Secure Data Archiving, Preventing Cyber attacks
DCT is transforming the philosophy for the conduct of clinical trials by offering opportunities with use of Digitalization and giving Patient Centric approach.

Robust processes, guidance documents with advanced statistical monitoring, analytic tool, AI and ML to identify patterns and anomalies is the way ahead.

Collaboration is redefining The Future Of Healthcare. Specially for Decentralized Clinical Trials.
Questions?