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

SCDM Live
India conference
2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru
Decentralized Clinical Trials:

- Also known as hybrid, virtual, remote or Direct to Patients (DtP) trials, where part of or all of the trial happens outside a traditional physical clinic or trial site

Never done or known before:

- Though the term Decentralized Trials was more used during this pandemic that hit us in 2020, it was first time initiated in 2011, when entirely web-based trial, REMOTE, under an Investigational New Drug application, was carried out by Pfizer
- COVID-19 pandemic significantly catalyzed the adoption of decentralized clinical trials due to physical distancing and health-system resources packed in COVID-19-related care
Why ‘YES’ to DCT ??? What are the Pros.....

- **Controlling Clinical Study attrition**
  - Helping in Patient recruitment and retention
  - Use of digital technology for recruitment help participants to identify trials for which they are eligible and researchers or healthcare professionals to identify potentially suitable participants for their trial
  - **Examples of Digital Technologies used:** automated SMS; audio and video messages; radio and television advertising; online advertising; social media, smartphone apps, pop-up computer screen reminders and emails

- **More Flexibility:**
  - Provides patient-centered approach by allowing used of virtual tools such as telemedicine and wearable devices to carry out remote visits and monitor data
  - Regulatory committees have created guidance/instructions to follow the use of alternative clinical-trial approaches (such as remote monitoring, drug shipments to patient homes, home nursing, and alternative sites)

- **Management of therapy:**
  - Direct-to-patient shipment of the therapy (drug or medical device)
  - Time required for distribution, inventories and storage-related logistics for study supplies
  - Will always be compliant to with Good Clinical Practice (GCP)

- **Improved data diversity:**
  - Decrease geographic barriers
  - Diverse populations can be included, thus enhancing integrity of study
  - Gathering more diverse and applicable data by monitoring patients remotely in real-time
Why ‘YES’ to DCT ??? What are the Pros.....

• Real-time communication with patients
  ➢ Improves relationship between the patient and the researcher/clinician
  ➢ Using ePRO, telemedicine, eReminders, made Patients life burden free (travel, getting appointments, Physicians availability etc.)

• Improved reliability and accuracy of data:
  ➢ Collecting data using technology keeps data organized and safe
  ➢ Tools are validated and used as standard
  ➢ Digital end points can be primary end points

• Easier reporting and analysis of results:
  ➢ Validated tools enable data collection and sharing to be standardized
  ➢ Real time data would make Rapid identification and reporting of adverse events
  ➢ Enabling a speedy medical intervention in case of need.
Graphic Representation of Decentralized Clinical Trial
## Activities in Clinical Trial that can be handled Remotely

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<th>Site Activation</th>
<th>Patient Enrollment</th>
<th>Conduct</th>
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<td><strong>Digital site engagement</strong></td>
<td><strong>Patient online identification and recruitment</strong></td>
<td><strong>Trial decentralization to homes and alternative sites</strong></td>
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<td>Remote and central-site monitoring</td>
<td>Patient preidentification and identification²</td>
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<td>Digital trial marketing and patient activation</td>
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<td>Digitized investigator engagement and payment</td>
<td>Online-recruitment portals</td>
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<td>Patient concierge services and navigation help</td>
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<td><strong>Digital patient engagement and assessment</strong></td>
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<td>Telemedicine (Health Insurance Portability and Accountability Act [HIPAA] compliant)</td>
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<td>Remote patient monitoring, including efficacy</td>
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<td>Electronic clinical-outcome assessment and electronic patient-reported outcome</td>
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Why ‘No’ to DCT ??? What are the Cons.....

- **Complex digital technologies**
  - Limits the possibilities of enrolment and retention

- **Digital health data collection**
  - Critical issues in data collected as data are collected in a less protected environment

- **Personal data protection and cyber security**
  - Problems related to any accidental leaks of sensitive data or cyber attacks

- **Managing and processing higher volume of patient data**
  - Issues in collecting and processing data received from digital tools

- **Relationship between the patient and the doctor/ research team**
  - Cannot provide a full and systematic substitute for the doctor/ patient relationship and for direct clinical assessment
  - Can prove relatively ineffective in terms of patient involvement or incorrect use of Instruments

- **Continuity of patient care**
  - Inconsistency of visiting HCPs could potentially be distressing

- **Management of therapy**
  - Logistic problems (e.g., failure to deliver, or delay in doing so)
  - Not all medications can be delivered in direct-to-patient mode
  - Some of study procedures require doctor’s intervention.
Why ‘No’ to DCT ??? What are the Cons.....

• **Time management**
  - Visiting multiple patients in one day
  - Travelling between locations efficiently and on time while maintaining the high standard of care they would deliver on-site

• **Data analysis:**
  - Complex procedure of standardization of results received from local clinical laboratories and diagnostic facilities

• **Technological failure**
  - Error Bugs would result in a loss of patient data, as there will be no expert on hand to provide immediate guidance or fixes
  - Disrupt or delay the trial progression by corrupting results
  - Technologies fail to provide adequate health services or recent updates as per regulatory requirements.
  - Inadequate telecommunications infrastructure. Clinicians/researchers become the help desk for resolving technical/logistic difficulties (expected supplies not reaching the patient’s home or being delivered late, technical problems with sensors or wearables, etc.)

• **Logistics:**
  - Non-availability of suitable, certified laboratories and healthcare services
  - Finding specially-trained couriers to deliver medication and other medical supplies and equipment safely and legally

• **Finding new technology vendors**
  - Difficult to find and approve vendors in a timely way to avoid delay in trials

• **Patient attitude**
  - Some patients may be more comfortable being seen in person, especially where they are unsure about administering tests or using technology.
Possible Solutions to Overcome Challenges

• Tool/Device validation
  ➢ Tool/Device should be robust and validated to 100% accuracy
  ➢ Data accuracy checks should be implemented at the time of collection of data.
  ➢ The programming of gate keeper checks would also be very helpful in maintaining the data accuracy and limiting the errors to happen during collection of useful data via various devices.

• Tool/Device usability:
  ➢ Need to create device/tool as simple as possible for the subjects to understand and use it and able to enter the data.
  ➢ Sponsors/CROs should train subjects/trial personnel
  ➢ Manuals should be created for subject’s reference
  ➢ Should have support always ready and contingency plan in place for cases of device/tool malfunction.

• Tool/Device Privacy:
  ➢ Implement biometrics to operate tool/device by the subject so no one else can access the device/tool or data.
  ➢ Data should be collected and transferred to a centralized platform having capability to distinguish unblinded data is accessible by unblinded team only and not available for blinded team.
  ➢ There can be a threat detector implanted in device to alarm if it is being hacked

• Tool/Device data format
  ➢ Ensure even if data coming from multiple source to standardize the data at a centralized platform so data is useable for analysis and submission.
  ➢ Ensure the data collected is having same dimensions and device/tool have ability to convert the data into standard format.
Possible Solutions to Overcome Challenges

**External Data:**
- Ability to integrate/import external data received in any format (sas, excel, txt, etc.)
- Ability to convert multiple external vendor datasets into a standard dataset.
- Ability to join external datasets using unique identified such as Subject, Site, Visit, DEMOG data etc.

**EDC integration with external tool:**
- Ability to convert multiple studies datasets into standard dataset using simple function or with minimal programming support to run standard DM manual listings on standard datasets.
- Ability to integrate EDC with external tool to track all study data (Clinical Data) as well as operational data (Study Metrics).
- Ability to integrate EDC with the external tool to facilitate raising query within the tool to reflect in EDC.

**Data Review:**
- Notification or pop-up for real time data review as soon as date is entered
- Dataset /EDC integration to review and raise the queries within the tool to avoid opening EDC.
- Ability to give output category per Country, Site, Subject, Visit, Subject Status, Data Compliance, Data Completeness etc.
- Ability to combine 2 or more than 2 datasets using simple drag-drop function.
- Tool should have the pre-defined checks in place and should be deployed in less time for team to start their work.
- Tool support excel, word, graph and other analytics / data visualization.

**Running Study Metrics:**
- Ability to perform query/CRF trend analysis within tool.
- Integration with EDC to help generate standard study metrics reports to have a consistent structure of reports.
- Ability to generate study reports on ad-hoc basis.
- Ability to integrate with EDC and import external data to populate CPT within the tool.
Collaboration: Working Together For a Better Future

“Alone we can do so little; together we can do so much”

Collaboration: In common terms is the action of working with someone to produce or create something.

Healthcare Professionals from different platforms / roles, stakeholders from different industries cooperatively working together, sharing responsibility for problem-solving and making decisions to formulate and carry out plans for patient care.

Importance of Collaboration:
- Helps to prevent medication errors
- Improve the patient experience
- Reduce time for Drug Development
- Deliver better patient outcomes
- Can reduce healthcare costs
Collaboration: Is Working Together helping Mitigate Challenges?

• Sanofi and Insilico Medicine
  ➢ Sanofi using Insilico’s ‘Pharma.AI’ platform to advance drug development process

• Google Cloud and Epic
  ➢ Enabling customers to run their Epic workloads on Google Cloud
  ➢ Gains in Efficiency, Innovation, and Security.

• Google Cloud with Hackensack Meridian Health, LifePoint Health, and Mayo Clinic and Others
  ➢ Develop “accelerators”, will help healthcare leaders and administrators find the data they need much more easily
  ➢ Google technology is also providing clinicians with more precise image technology to help determine if patients are at higher risk for tumor

• Oracle’s acquisition with Cerner
  ➢ Oracle utilizing electronic health records and improves everything from claims processing to managing the supply chain

• PPD collaborated with Medable and Science 37
  ➢ Direct-to-patient and direct-from-patient models
  ➢ Incorporating home health care nursing,
  ➢ Study drug administration,
  ➢ Sample collection
  ➢ Pickup and return of study materials
  ➢ Digital solutions such as eConsent, telemedicine, devices/wearables, eCOA, ePRO
**Collaboration: Is Working Together helping Mitigate Challenges?**

- **Datavant with Medable**
  - Datavant to integrate its tech into Medable’s decentralized trials platform, which will see trial teams combine real-world health records, claims, diagnostic and other sources with their clinical trial data.

- **Covance + Medable**
  - Covance, Patient and Site Interface with Medable’s modular software platform
  - Provide access to applications encourage patients in study participation – eConsent, ePRO, eCOA
  - Enable remote data collection
  - Increase engagement between Patients, sites and Investigators

- **Covance acquires GlobalCare**

  ![Key Service Areas Supporting DCTs](#)

  **Central and Local Pharmacy Services**
  - Secure, temperature-controlled, limited-access storage
  - Compounding, mixing and dispensing
  - Shipping to sites/patients following cold chain logistics
  - Sourcing of commercial products and devices (infusion pumps)
  - Pharmacy supplies

  **Site Support Services**
  - "Just-in-time" support on site
  - Chart review for potential patients
  - Scheduling patients for screening visits
  - Assistance with on-site tests and assessment
  - Data entry

  **Mobile Healthcare Services**
  - Study drug administration (infusion, injection, topical)
  - Blood draws (safety labs, pharmacokinetics, genomics)
  - Other biologic sampling (nasopharyngeal and oral mucosal swabs, urine)
  - Clinical assessments (vital signs, body weight, ECGs, concomitant medications, signs/symptoms)
  - Patient training and education (e.g., self-administration, devices)
  - Study compliance checks (patient diary, drug storage)
  - Patient questionnaires
  - Patient chaperoning services to sites
  - Call center services
Collaboration: Is Working Together helping Mitigate Challenges?

• **Signant Health acquisition of VirTrial**
  ➢ VirTrial’s tele-research platform, which includes secure video, audio, chat, and connected medical device capabilities for decentralized patient-site interaction and assessments
  ➢ Signant with a solution to address remote site startup and monitoring
  ➢ Remotely conduct site evaluation, initiation, and monitoring visits

• **ERT and Bioclinica become Clario**
  ➢ Trial Anywhere™ offers sites and sponsors more clinical trial options, empowers patient choice, and provides the means to create diversity within clinical trials improving health equity

• **Syneos Health and Illingworth Research Group**
  ➢ Illingworth Research Group, a leading provider of clinical research home health services

• **ICON and PRA**
  ➢ World’s most advanced healthcare intelligence and clinical research organization

• **Collaboration for fighting against cyberattacks**
  ➢ Hospitals have suffered hundreds of cyberattacks in 2022. Two out of three healthcare IT professionals (67%) said their organizations had a significant cybersecurity incident in the past 12 months. As per Cybersecurity analysts' healthcare industry lags in terms of strengthening their defenses.
  ➢ Clearwater and CynergisTek, who are cybersecurity firm join with healthcare industry and other highly regulated industries
Collaboration Is Redefining The Future Of Healthcare… especially for Decentralized Clinical Trials