



Single Day Event

DCTs : A New Way of Clinical Trials
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DCTs: A New Way of Clinical Trials

COVID-19 challenging the traditional methods of CTs

Regulators and Industry – New methods of patient care

Continuity Solutions with subject safety and data integrity

Lessons learnt during pandemic

USFDA guidance Nov 2020 – Use of “Digital Health Tech Tools”



DCTs:

The FDA defines **decentralized clinical trials** as those executed through telemedicine and mobile/local healthcare providers, using processes and technologies that differ from the traditional **clinical trial** model.



“Site” to “Patient Centric”

Site Centric

Patient to come to site for –
Med History, Screening, ICF, V2,
V3.....V9 EOT, PD, Follow-up etc.

Lab investigations, Physical Exam, Vital
Signs, drug dispensing, safety and
efficacy procedures etc

Patient Centric

Med History – Tele-visit
E-Consent,
Local Lab Investigations, Eligibility
Drug Supply to patient's residence,
Wearable devices,
Use of Smart Phone and APP to record
data, Home Nursing Visits.



DCT Models

Traditional

Only one or two remote components
E.g., ePRO

Basic Hybrid Trial

Use of DCT Components and study
data collected between site visits.

Advanced Hybrid Trial

Some on-site visits replaced with
remote visits + DCT Components

Full DCT/ Site Less

All visits are completed remotely +
DCT Components.



DCT Components

DCT Components	Process	Comments
Virtual Pre-screening, E-Consent, E-Assent	Compliments AV recording Original + Follow-Up consent.	EC and RA to approve a set process/guideline.
Drug Adherence	Mobile apps to click picture or patients to complete questionnaire and submit. Reminders, Screen sharing, Session Recording	Mobile app user agreement to be available in local languages. (easy for patient)
Direct to patient	Drugs to be shipped to patient's residence.	Patients consent for sharing personal info with courier vendor to be documented. Patient training earlier.
Tele-Health	Schedule appointments early for maximum use of technology.	Patient to be trained to be ready for use of technology.



DCT Components

DCT Components	Process	Comments
eCOA/ePRO/ Patient diaries	Already a part of existing global clinical trials.	Can be used for additional questionnaires.
Home Nursing/ Mobile HCPs	Nurse to visit patient's residence for assessments like Vital Signs, Drug Administration (IV dosing), blood samples collection and other delegated safety procedures.	ICF to be clear with the process. Patient to agree for certain procedures performed by Nurse instead of a doctor/physician.
Local Lab	Patients to get the lab investigations from near by lab. (Sample pick-up arranged)	Reimbursed the patient for the lab investigations. ICF to be clear with process.
Wearables	Use of wearable to track patient's real time data.	Patient training and confirmation is important.



DCTs: Benefits to patients

Easy Access

Convenient Participation

Greater Control

Close/real-time monitoring of patient data



DCTs: Benefits to Sponsors

Faster Recruitment (increased geographic reach)

Better Retention (convenient study participation)

Access to diverse patient population, collected in “real-world” setting.

Improved Data Quality

Improved Monitoring and Analytics



DCTs: Benefits to Investigators

Efficient Visit conduct, more automated, less manual data capture

less transcription

Access patient data in real time or on-demand.

Better overall compliance.

Possibility to flexibly and easily engage patients in studies.



DCTs: Challenges and Barriers

Regulatory Acceptance

Data Protection and Privacy

Technology Functionality

Quality of Data

Ease for use of patients

Staff Training



The Global Healthcare Data Science Community

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Social Media

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