



Society for Clinical Data Management
DATA DRIVEN

**Decentralized Clinical
Trials: Opportunities and
Challenges**

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

SCDM **Live**

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

The New Normal

- More Digitalization – in new normal
 - UPI transactions, Apps/QR Code to navigate in public transport
- Tele Health/appointments – video consultations
- Online Pharmacy – possibility of shipment of Medications
- Remote Lab Sample Collection/Swabs/ECG – safety evaluations

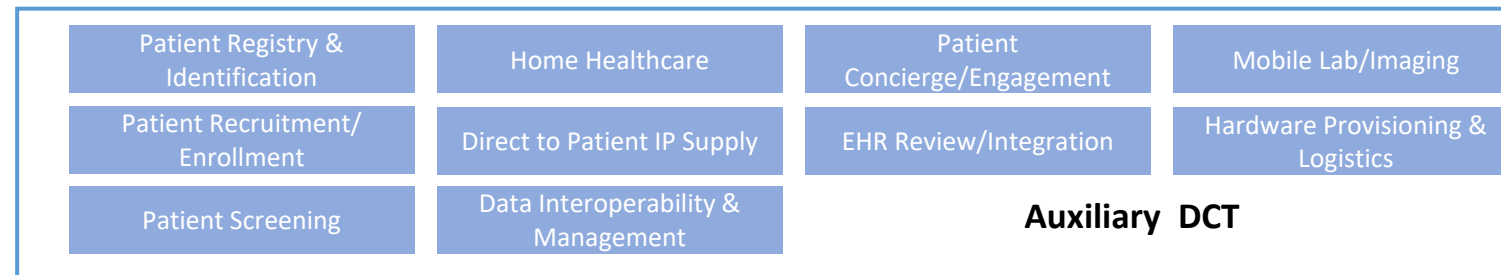
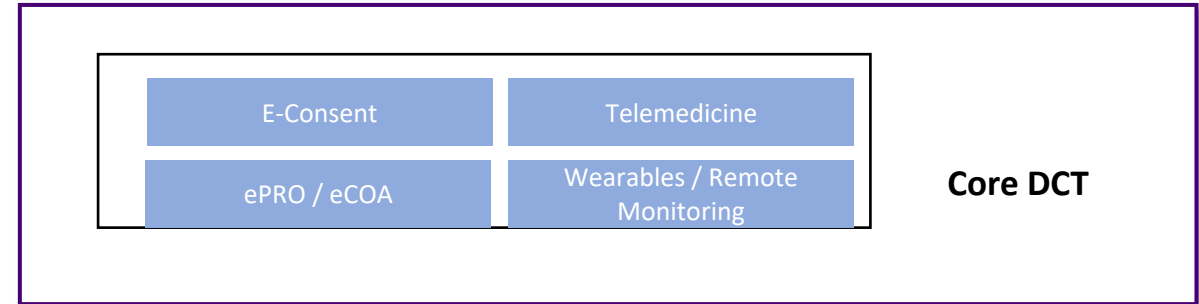
DCT

Regulatory Guidance

- **2016 | 21st Century Cures Act –**
FDA gives Digital Push
- **2019 | FDA affirms interest in**
Decentralized trials
- **2020 | FDA issued guidance to**
virtualize clinical trials in the time
of Covid19

What are Decentralized trials?

Trials executed through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model

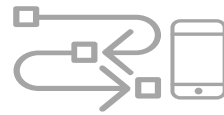


Opportunities



Diversification

Identify patients from diverse population that are eligible for studies



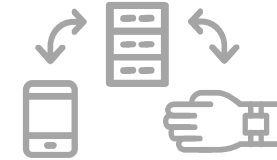
eConsent/Device

eConsent
Patient Enrollment and Device provisioning



Delivery of Medicines

Direct shipment of IMP to Patients



Collection

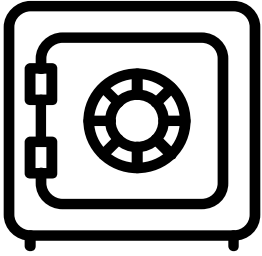
Collection of data from multiple sources
Mobile applications
Smart wearables



Monitoring & Insights

Real time monitoring of the data;
Insights of aggregated data
Track adherence to Protocol

Threats



Reliable Data

Concerns on Data Origin
Consistency and reproducibility
of the data
Person with access to devices
can enter data on behalf of
patients



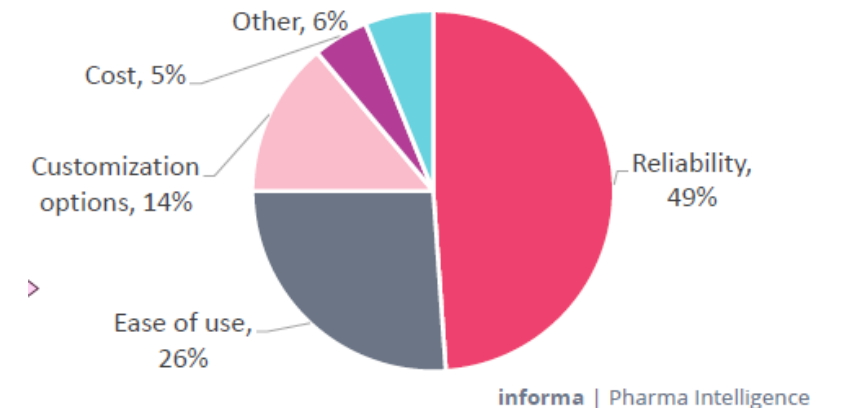
Privacy at risk

Reveal potential identification
of Personal data
Data stored in servers breaching
privacy law of country



Chances of Data loss

Multiple platforms and sources



Challenges

Regulatory guidelines

- Insufficient
- no cross-industry regulatory guidance

Digital literacy

Very low among target patients

Local laws

eConsent
Telemedicine
IP Supply and site monitoring

Multiple platforms

Multiple platforms at site to support a trial

Device Complexity

Accessing high end products at home

Regulations Overview

Color Code

RED: not allowed	YELLOW: no regulation found	GREEN: allowed
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DCT Components by Country

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing
AU	GREEN	GREEN	YELLOW	GREEN	GREEN	YELLOW	YELLOW
BE	GREEN	GREEN	YELLOW	GREEN	GREEN	YELLOW	GREEN
BR	GREEN	YELLOW	GREEN	GREEN	GREEN	YELLOW	YELLOW
CA	GREEN	YELLOW	YELLOW	GREEN	YELLOW	YELLOW	YELLOW
CN	GREEN	RED	YELLOW	GREEN	GREEN	GREEN	YELLOW

regulations overview table

Collaboration

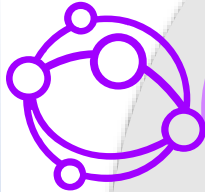
For Site staff, Patients for
Technical and Care support



On
Demand
Support
Centre

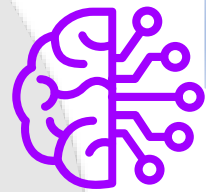
Robust Data Collection
and Transfer Plan
Standardization

Oversight,
Confidentiality
protection by Vendors,
Verify qualification,
Data Handling

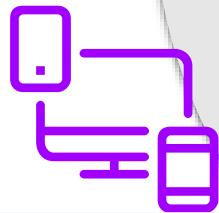


Home
Health
and
Nursing

Labs,
Imaging,
eCOA
Devices



Tele visit, Telemedicine,
Secure Data Archiving,
Remote Monitoring



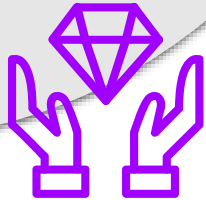
Mobiles
and
Devices

Telemed
icine,
Virtual
Visits



Verify appropriateness
Feasibility
Scaling
Remote Patient Monitoring

Direct to
Patient



IMP, Labs, Pharmacy,
Site/HCPs

Mitigation

DCT RACT



Risk categorization

Identify potential risks
Engage with study team



Impact of the risk

Assess likelihood, detectability
and impact of the risk



Mitigation

Deploy mitigation of the highest risk
categories

Direct to Patient

Depot-to-Patient, Central-Pharmacy-to-Patient, Site-to-Patient and Hybrid

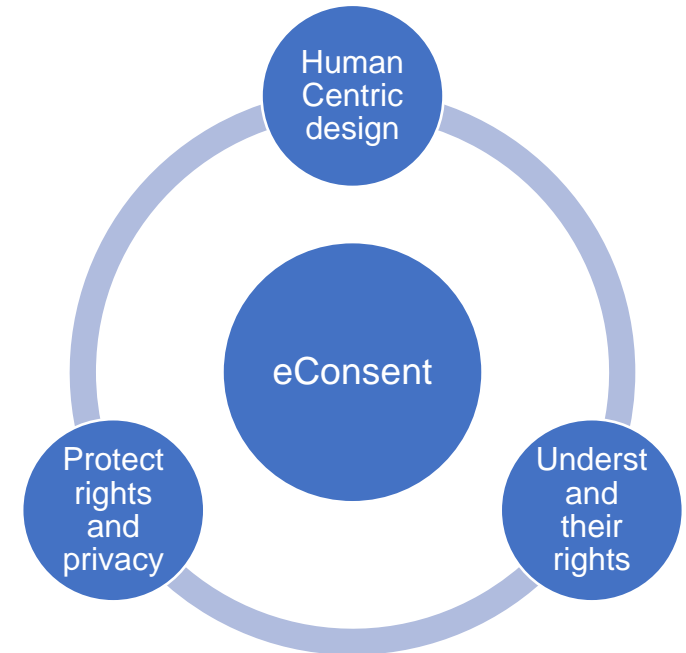
Guidance on the distribution, shipping, disposition, etc. of IMP within the context of remote clinical research

Assess storage conditions, administration of Medications

Instructions to Participants

Hypothesis Testing

Consent



Leads to Improved Patient Experience

- Outcomes measured from the Patients perspectives
 - Not only just reversal of the disease
 - Focus on trial participant improvement and improved Patient experience
 - Quality of life and wellness of the patient
- Indirectly impacting recruitment, engagement and drop out rates
- Advocates for future participants

