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
### 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**

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### What are Decentralized trials?
Trials executed through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model

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### DCT

#### Core DCT
- E-Consent
- Telemedicine
- ePRO / eCOA
- Wearables / Remote Monitoring

#### Auxiliary DCT
- Patient Registry & Identification
- Patient Recruitment / Enrollment
- Patient Screening
- Home Healthcare
- Direct to Patient IP Supply
- Data Interoperability & Management
- Patient Concierge / Engagement
- EHR Review / Integration
- Mobile Lab / Imaging
- Hardware Provisioning & Logistics
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
**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

Source: informa: Survey indicating reliability is major considerations in DCT
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

DCT Components by Country
- eConsent
- eSignature
- ePRO
- IP Supply
- Telemedicine
- Wearables
- Home nursing

regulations overview table

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Collaboration

On Demand Support Centre

Home Health and Nursing

Mobiles and Devices

Direct to Patient

Labs, Imaging, eCOA Devices

Telemedicine, Virtual Visits

IMP, Labs, Pharmacy, Site/HCPs

For Site staff, Patients for Technical and Care support

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

Verify appropriateness Feasibility Scaling Remote Patient Monitoring

Robust Data Collection and Transfer Plan Standardization

Tele visit, Telemedicine, Secure Data Archiving, Remote Monitoring
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

eConsent

Human Centric design

Protect rights and privacy

Understand and their rights
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