



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

2<sup>nd</sup> - 3<sup>rd</sup> 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

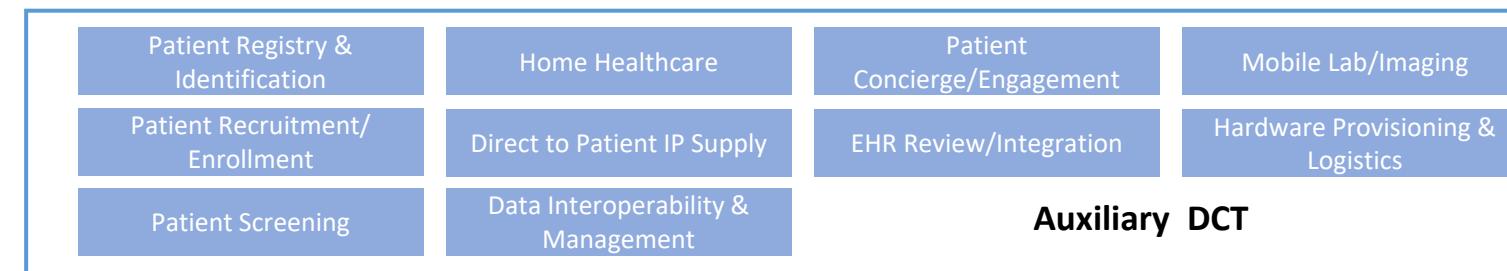
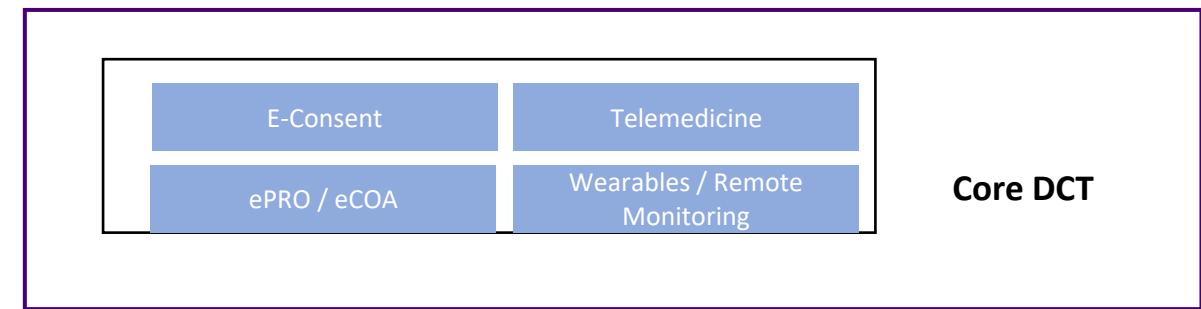
# DCT

## Regulatory Guidance

- 2016 | 21<sup>st</sup> 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?

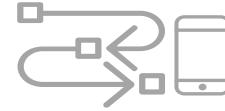
Trials executed through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model



# Opportunities



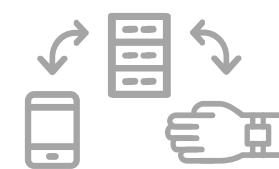
**Diversification**  
Identify patients from diverse population that are eligible for studies



**eConsent/Device**  
eConsent  
Patient  
Enrollment and  
Device  
provisioning



**Delivery of Medicines**  
Direct shipment of IMP to Patients

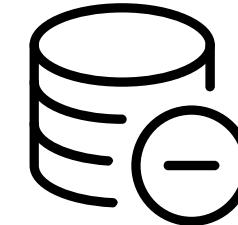
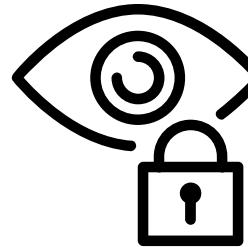
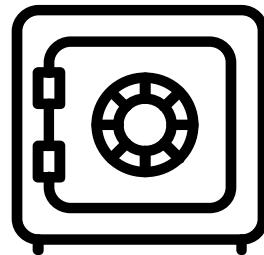


**Collection**  
Collection of data from multiple sources  
Mobile applications  
Smart wearables



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

# Threats



## Reliable Data

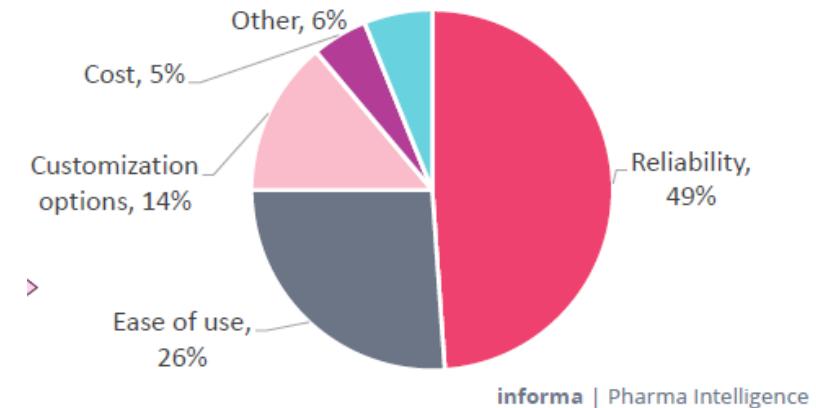
Concerns on Data Origin  
Consistency and reproducibility  
of the data  
Person with access to devices  
can enter data on behalf of  
patients

## 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



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

#### Color Code

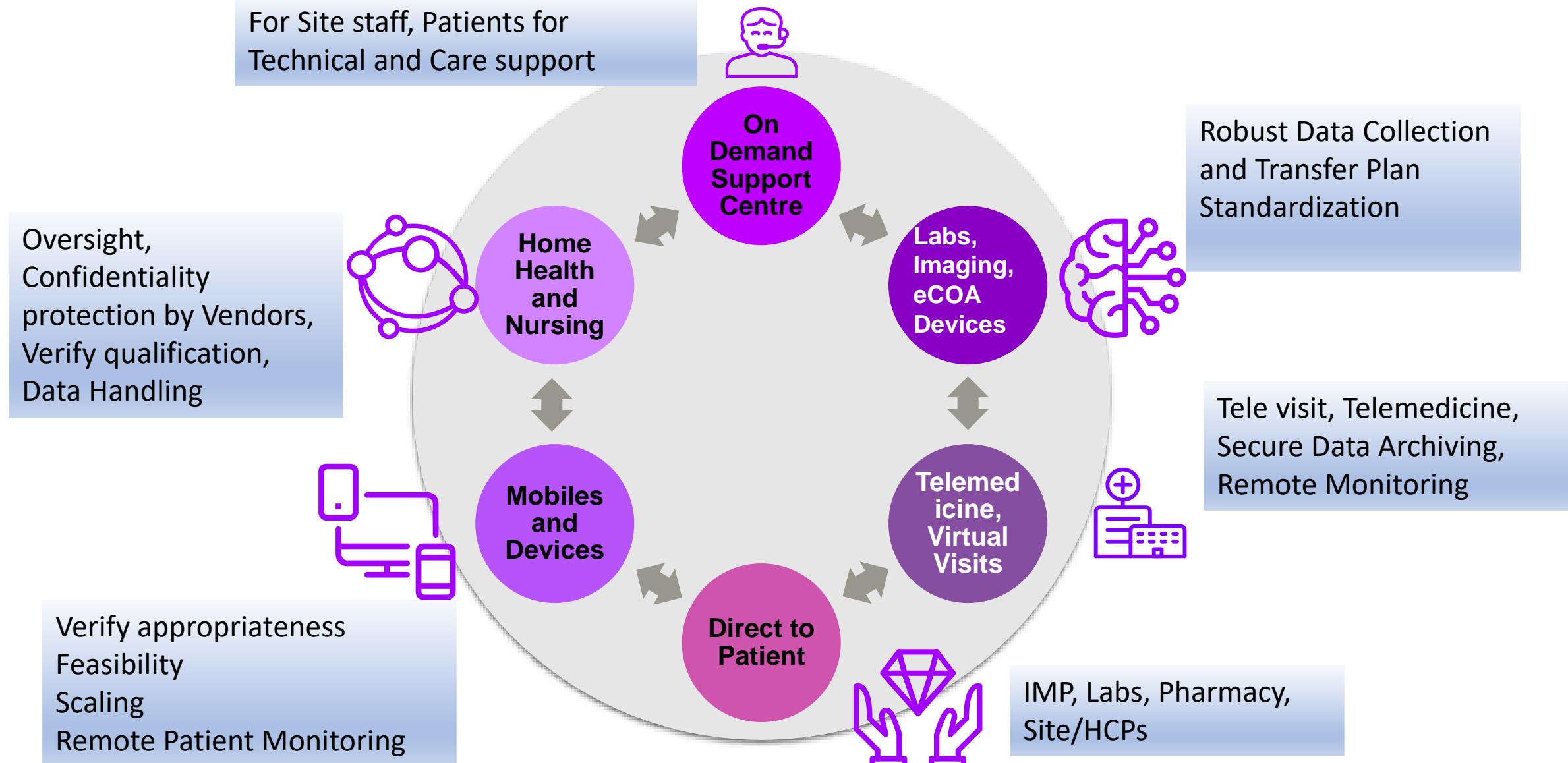


#### DCT Components by Country

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing
AU	Green	Green	Yellow	Green	Yellow	Yellow	Yellow
BE	Green	Green	Yellow	Green	Green	Yellow	Yellow
BR	Green	Yellow	Green	Green	Green	Yellow	Yellow
CA	Green	Yellow	Yellow	Green	Yellow	Yellow	Yellow
CN	Green	Red	Yellow	Green	Green	Yellow	Yellow

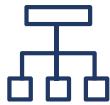
regulations overview table

# Collaboration



# 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

Human Centric design

eConsent

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

