



Society for Clinical Data Management  
DATA DRIVEN

# Decentralized Clinical Trials: Opportunities and Challenges

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

# Meet Your Presenters



**Garun Yadav**

- Director, Data Management, Syneos FSP 360
- 16 Years CDM Experience
- Oncology SME/InForm/Veeva
- Follows DCT, Presented in SCDM, ISCR and European Clinical Research Conference
- Leads SCDM partnership from Syneos



**Agatha Moses**

- Program Lead, Pfizer
- 18 Years IT and Pharma Experience
- Technology and Innovation
- Data Analytics, Reporting, UAT, Operations
- M. Tech, From Chennai

- Group Lead, DM, Icon
- 12 Years CDM Experience
- E2E DM, CDM SME
- Oncology, Neuroscience
- M.SC CR, From Chennai



**Priyanka Pandhare**

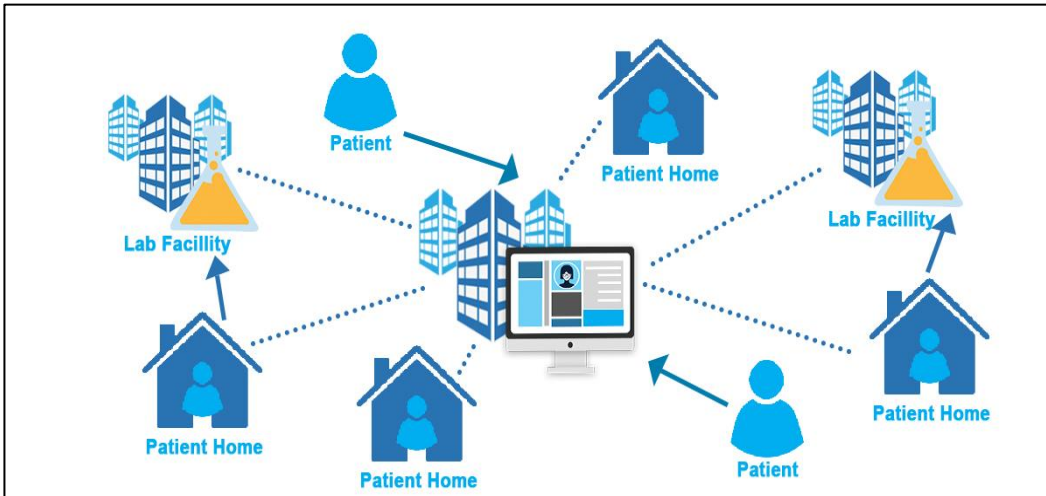
- General Manager, Accenture
- 13 years CDM Experience
- E2E DM, Start-up SME
- Oncology, Autoimmune, Vaccines
- M. Pharm, From Bengaluru



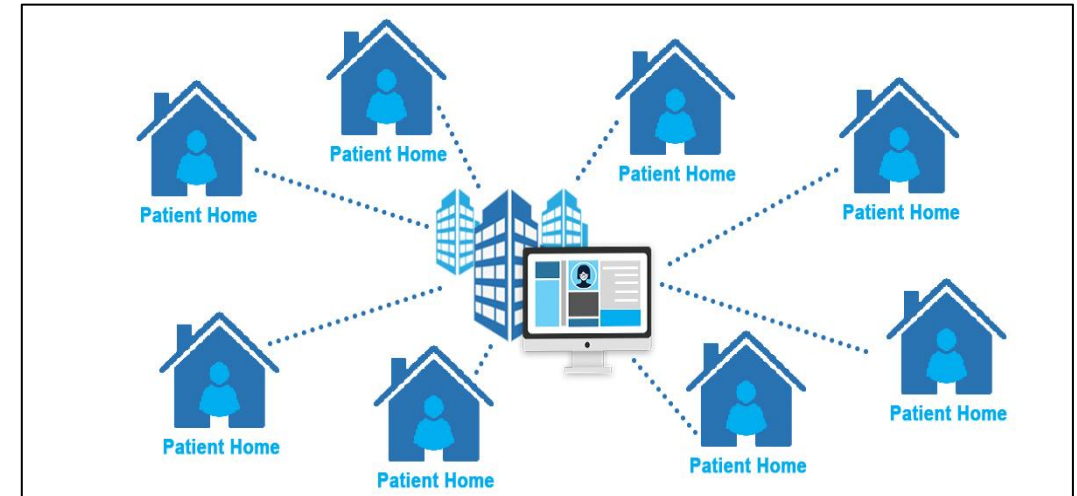
**Manikanthachar SN**

# Decentralized Clinical Trials (DCT)

**Decentralized Clinical Trials**, also known as Hybrid, Virtual, Remote or Direct to Patients (DtP) trials, are the ones where part of or all of the trial happens outside a traditional physical clinic or trial site

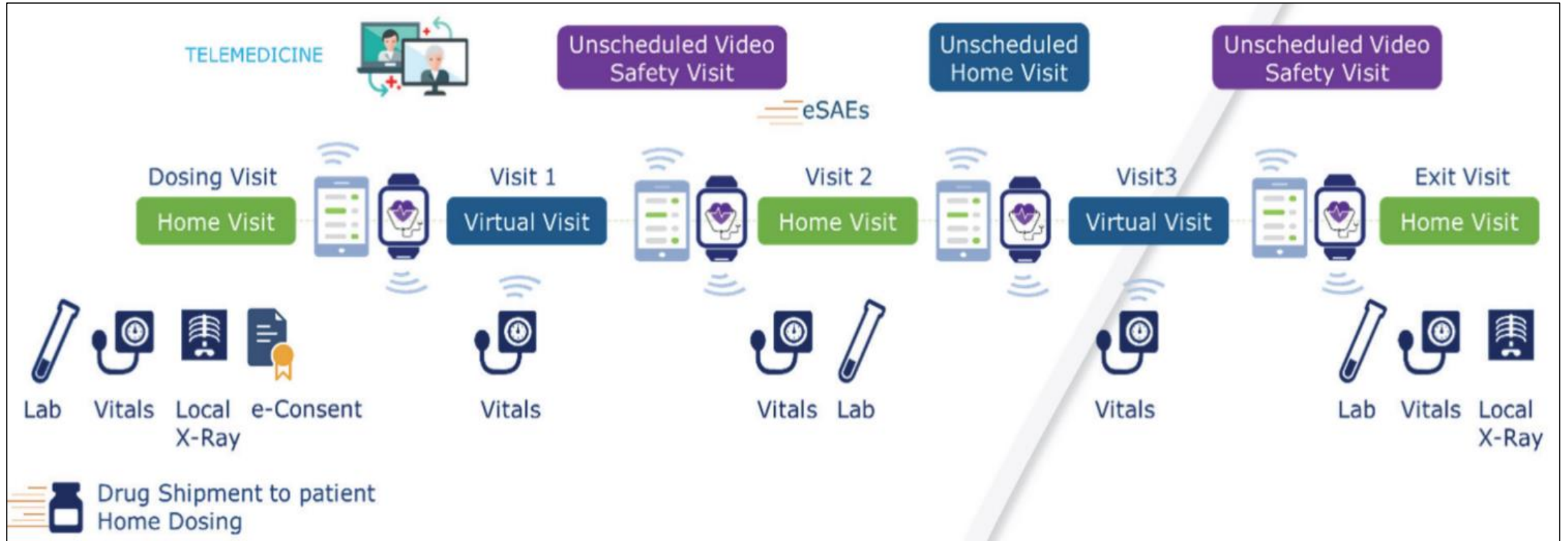


**Hybrid Model**



**Fully Remote Model**

# Graphical Representation of DCT



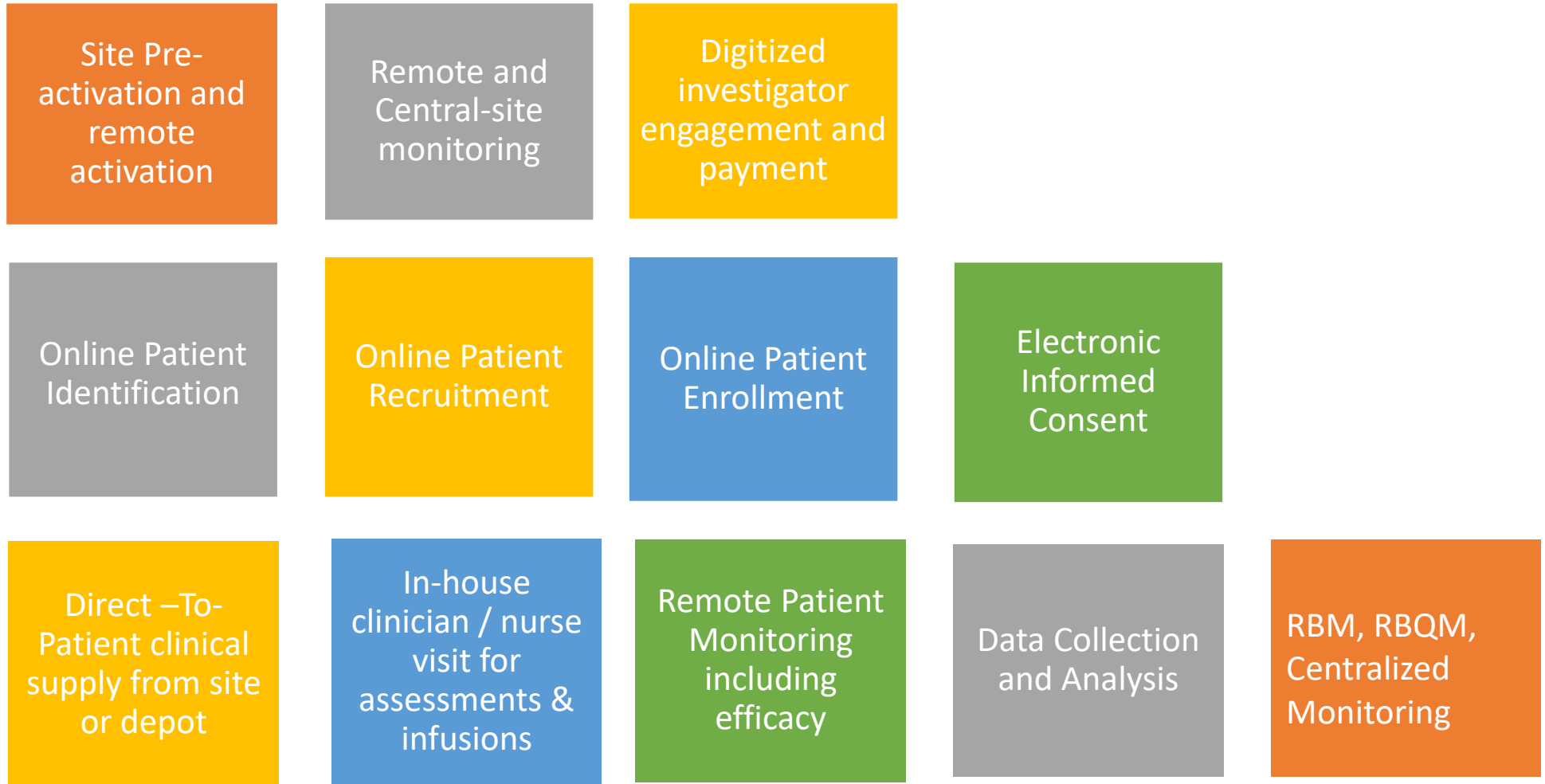
## Site Activation



## Patient Enrollment



## Study Conduct



# Key Considerations for DCT

DCT TRIAL PLANNING



## SIZE, PHASE and INDICATION

Patient population size, Study Phase and indication



## INFRASTRUCTURE

Maturity and capabilities of the sponsor and its trial infrastructure



## INVESTIGATIONAL PRODUCT

Storage and administration at patient home



## DATA SOURCES

Data from eConsent, ePRO, eDiaries, eCOA, wearables and/or sensors, Televisit and lab data



## TECHNOLOGY RELIABILITY

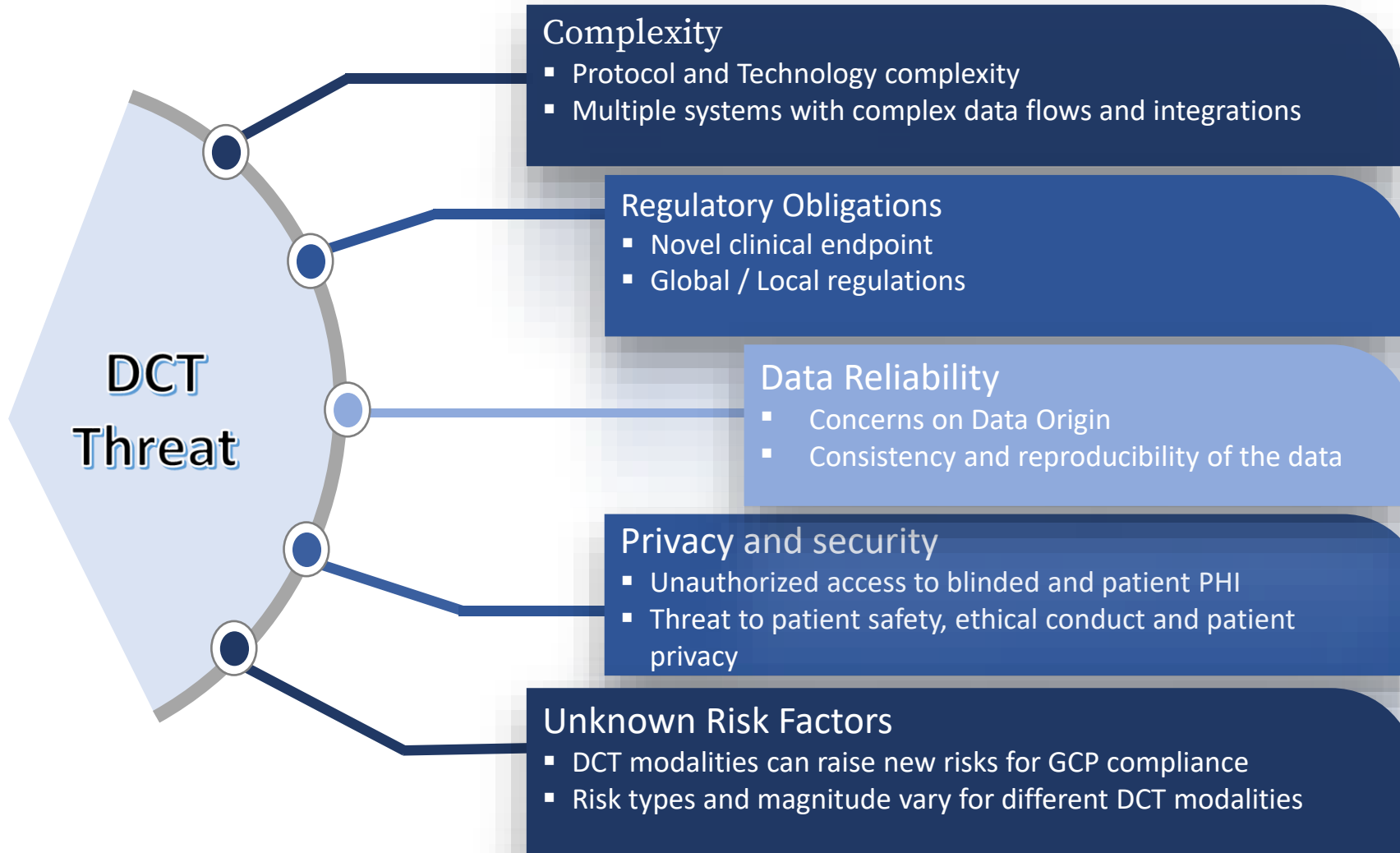
The trial population's access and familiarity with health technology and the reliability of internet connections



## DIGITAL HEALTH TECHNOLOGY

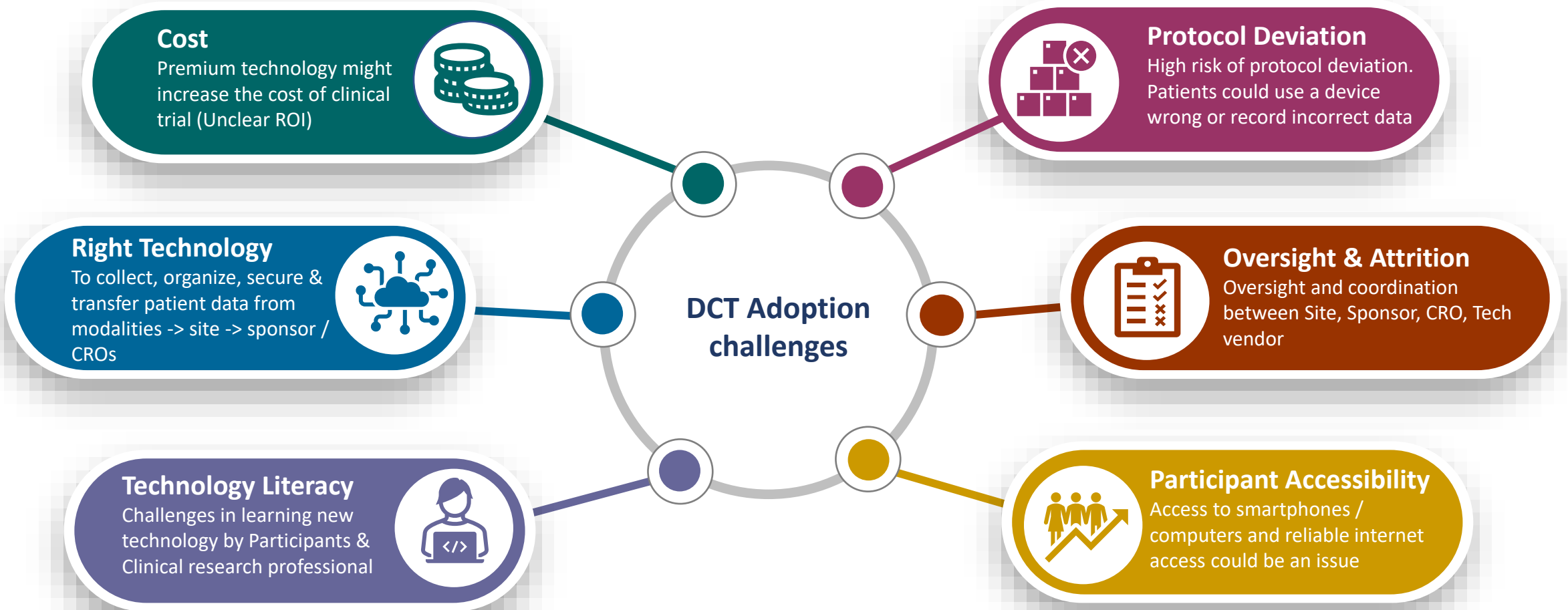
Sufficient to support its use and interpretability in the clinical investigation

# DCT Threats



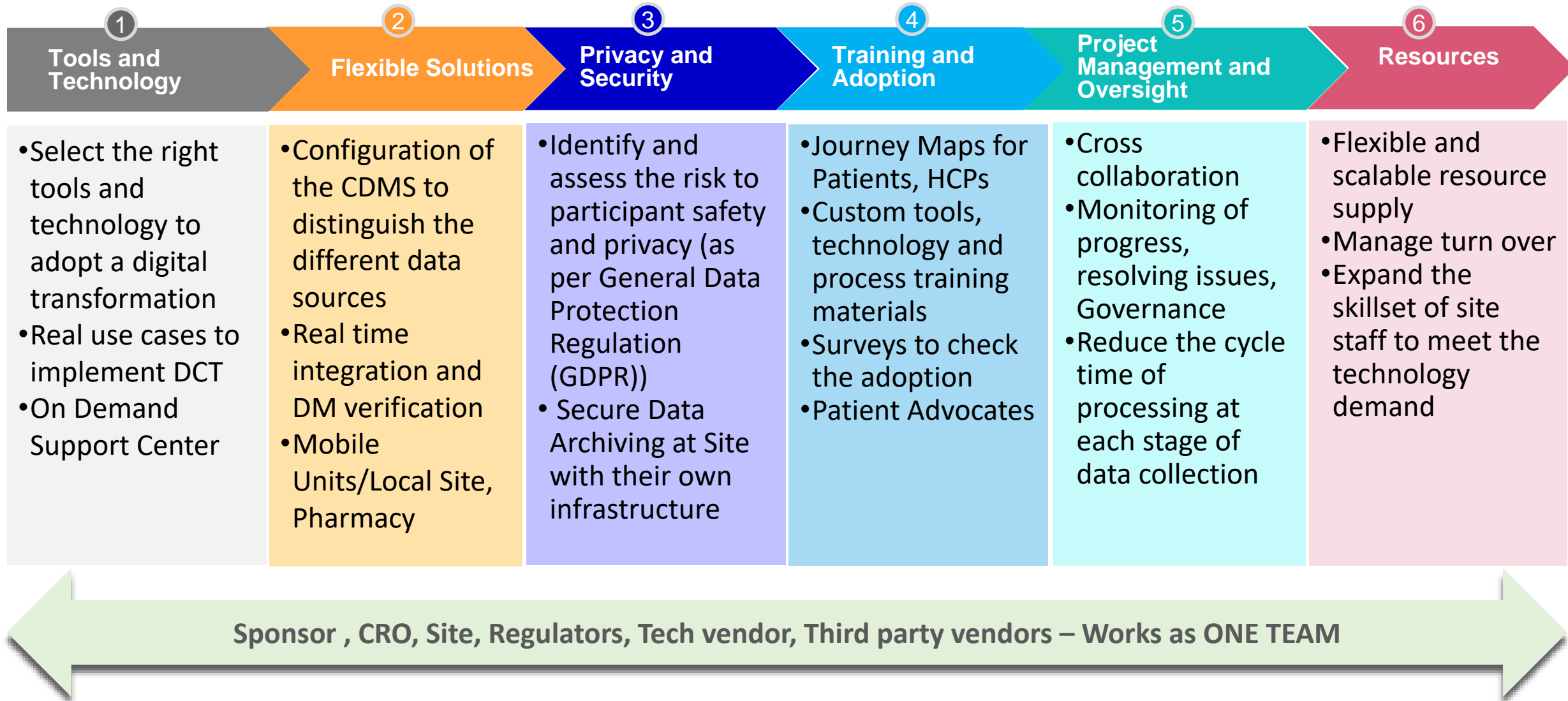
- Phase III protocols undergo an average of **3 substantial amendments**
- Phase III clinical trials generate an average of **3.6 million data points**, three times the data collected by late-stage trials 10 years ago
- Data Reliability contributes to **49%** of the DCT threat
- Direct-to-patient medication comes with risk, **increased four-fold** from 5% to 20%

# Challenges in DCT Adoption





# Mitigating the Challenges

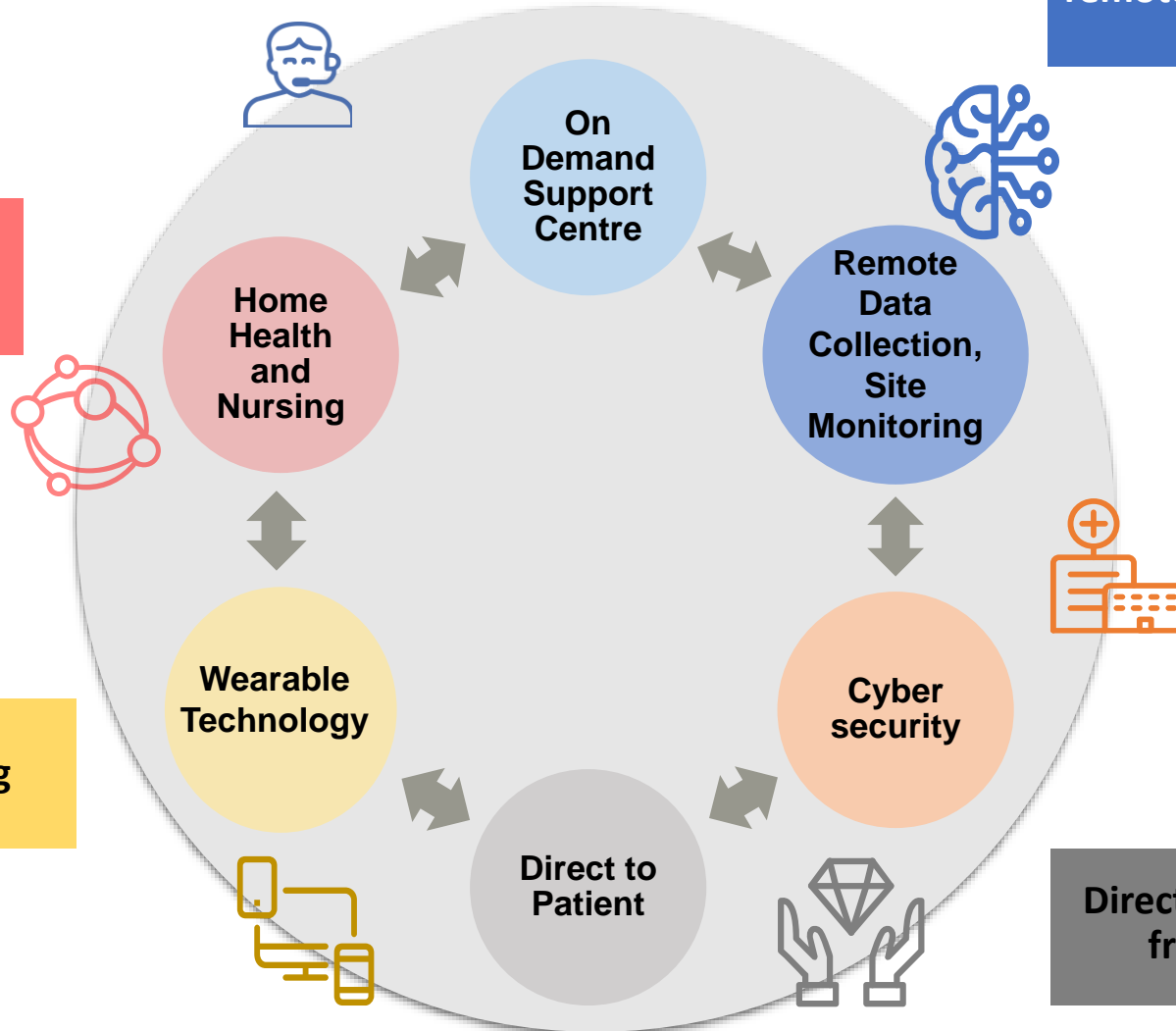


# Industry Collaboration

For Site staff, Patients for  
Technical and Care support

Technology companies enabling  
remote data collection, and Site  
monitoring

Home health services  
Mobile Units Labs, Pharmacy,  
Site/HCPs



Secure Data Archiving,  
Preventing Cyber attacks

Remote Patient Monitoring

Direct-to-patient and direct-  
from-patient models

*DCT is transforming the philosophy for the conduct of clinical trials by offering opportunities with use of Digitalization and giving Patient Centric approach*

*Robust processes, guidance documents with advanced statistical monitoring, analytic tool, AI and ML to identify patterns and anomalies is the way ahead*

*Collaboration is redefining The Future Of Healthcare. Specially for Decentralized Clinical Trials*

THANK YOU



# Questions?

