



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

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

Meet Your Presenters



- 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

Garun Yadav



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

Agatha Moses

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



Priyanka Pandhare

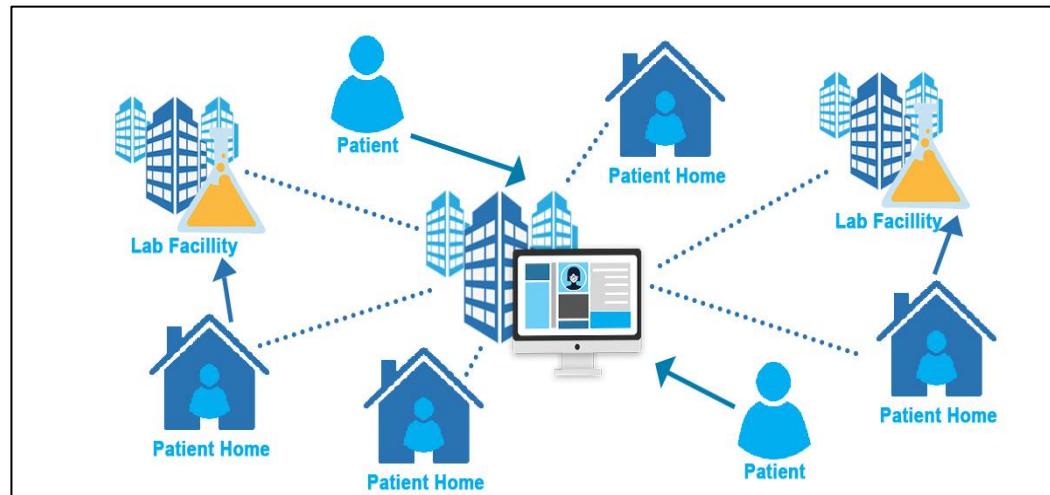
- General Manager, Accenture
- 13 years CDM Experience
- E2E DM, Start-up SME
- Oncology, Autoimmune, Vaccines
- M. Pharm, From Bengaluru



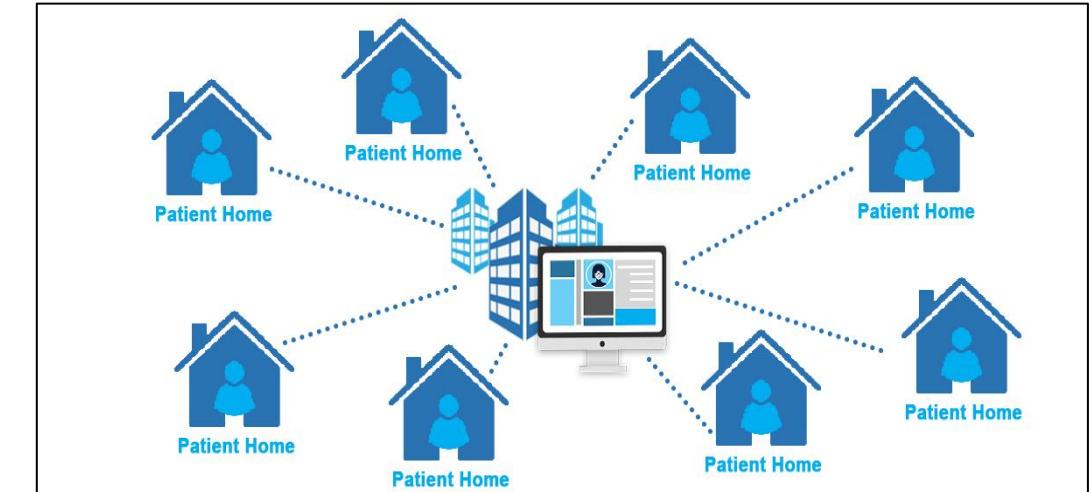
Manikanthachar SN

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

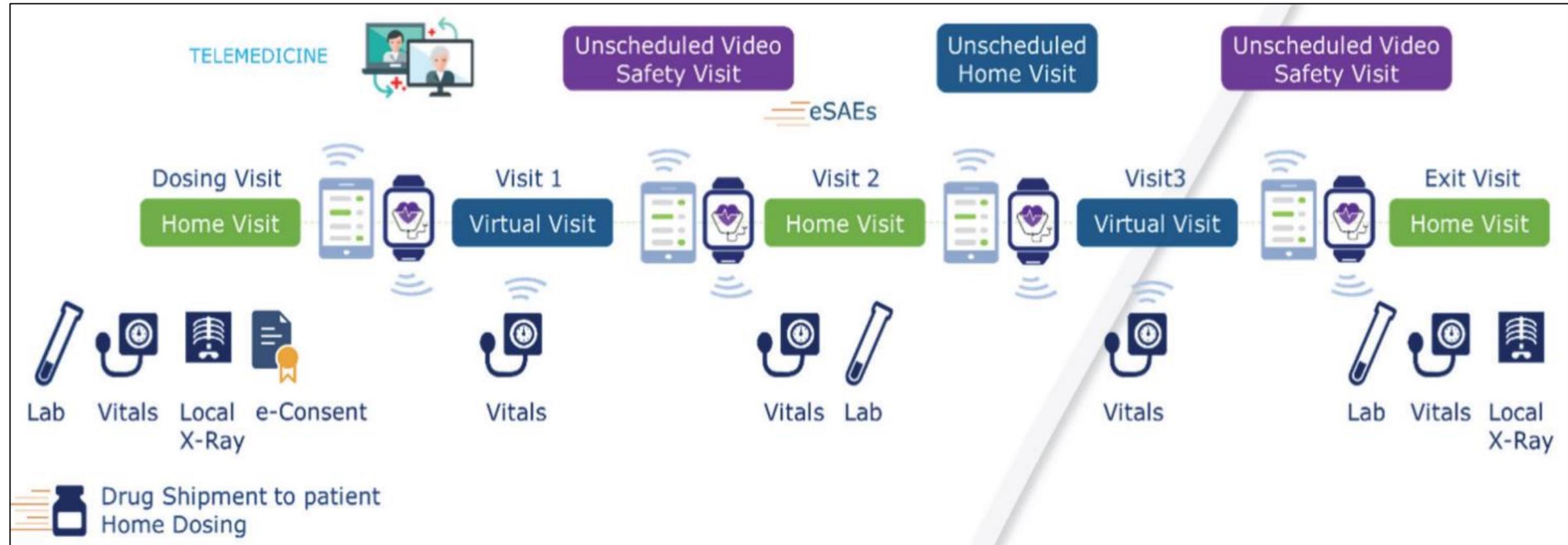


Hybrid Model

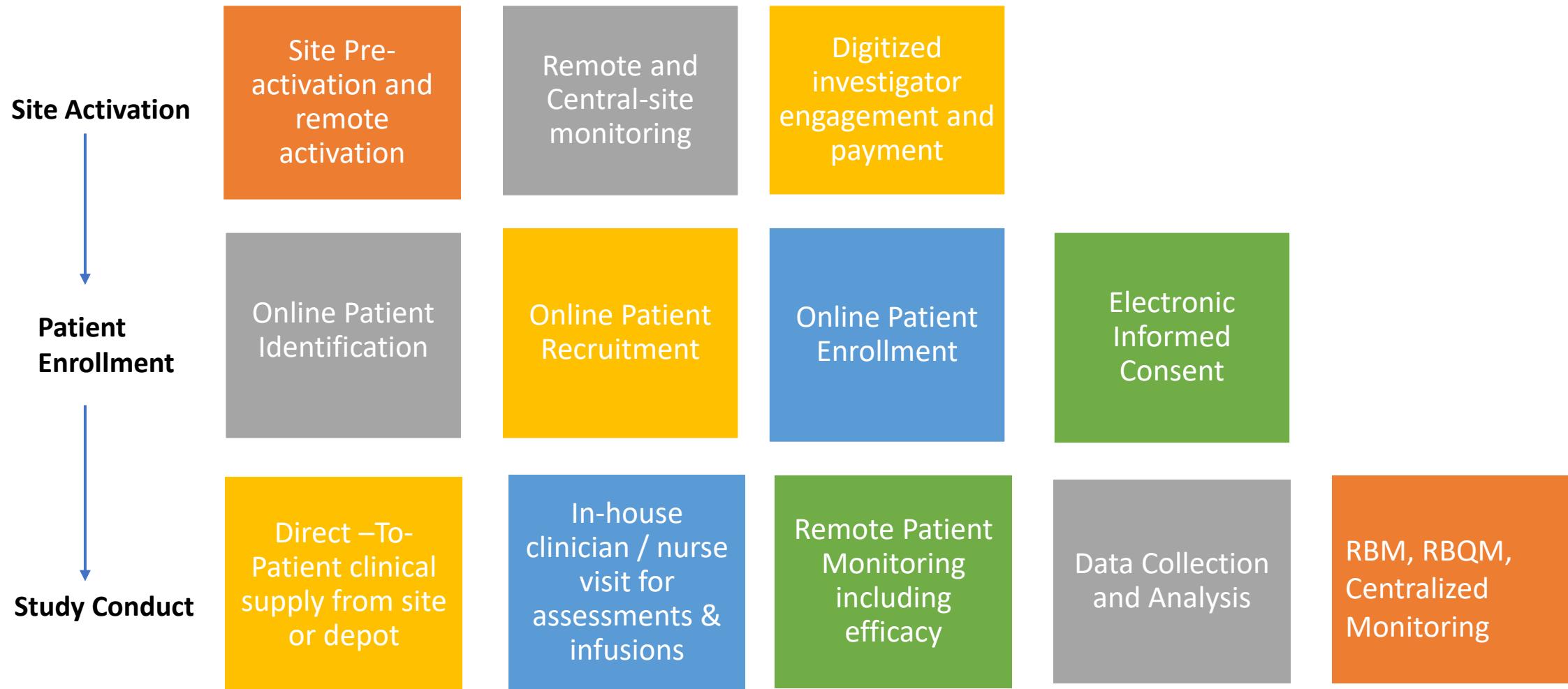


Fully Remote Model

Graphical Representation of DCT



Opportunities



Key Considerations for DCT

DCT TRIAL PLANNING



SIZE, PHASE and INDICATION

Patient population size, Study Phase and indication



DATA SOURCES

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



INFRASTRUCTURE

Maturity and capabilities of the sponsor and its trial infrastructure



TECHNOLOGY RELIABILITY

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



INVESTIGATIONAL PRODUCT

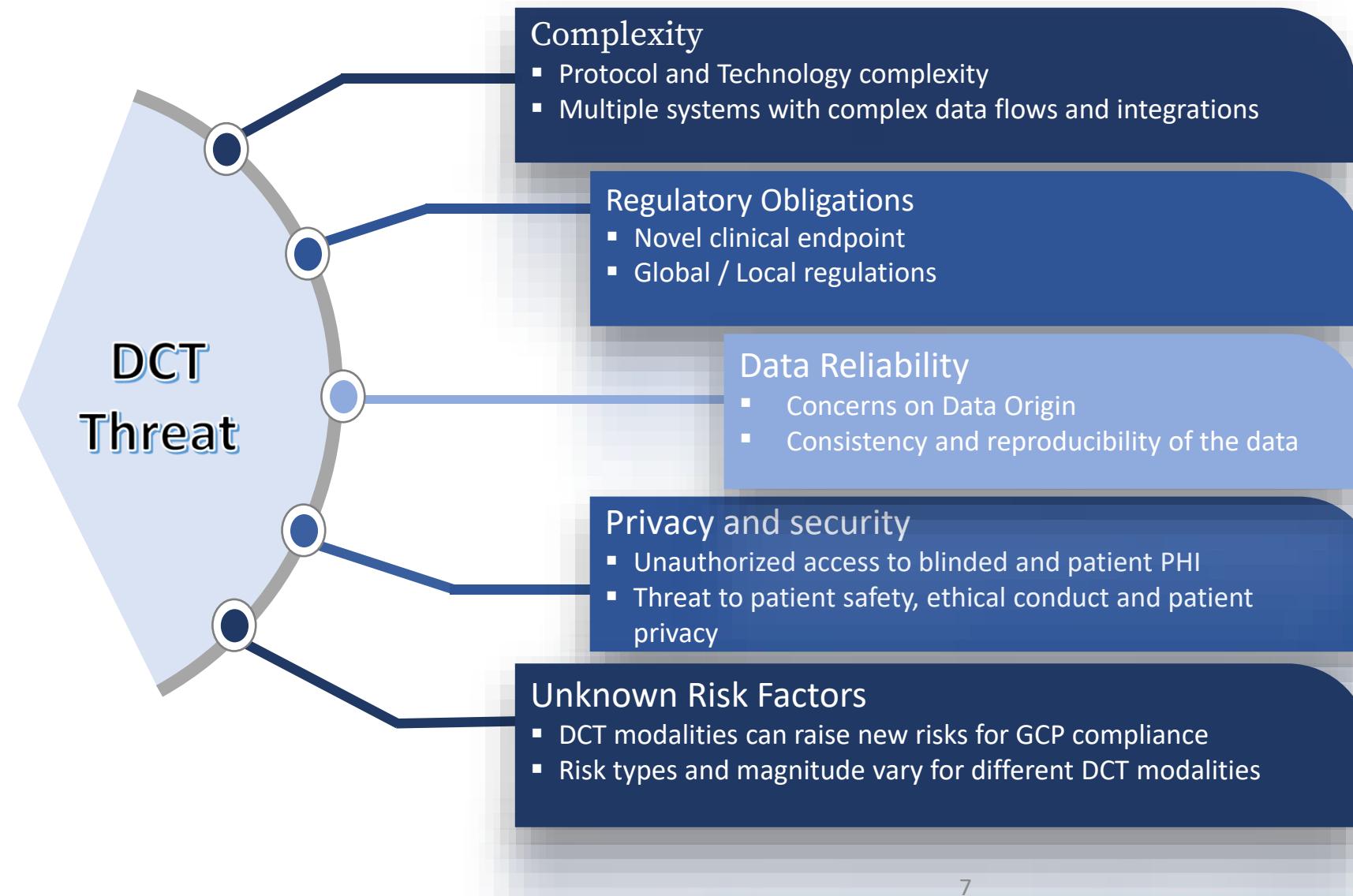
Storage and administration at patient home



DIGITAL HEALTH TECHNOLOGY

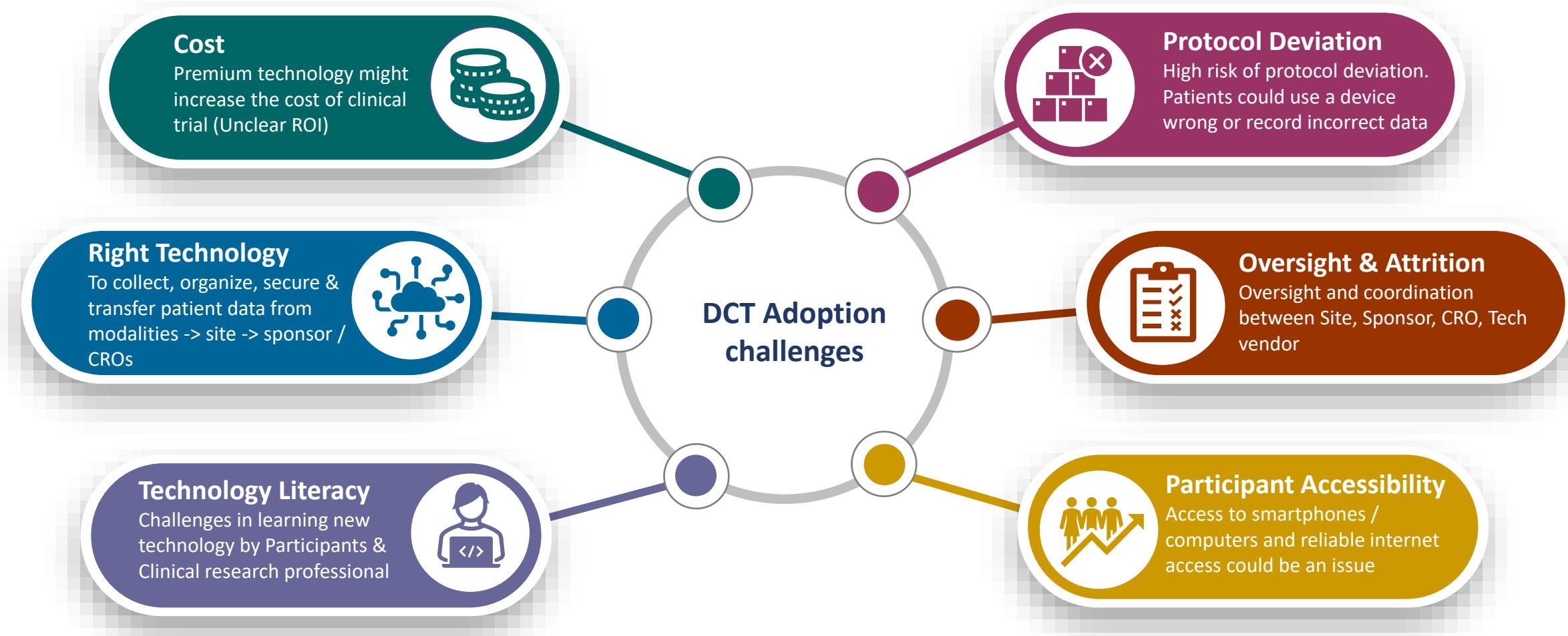
Sufficient to support its use and interpretability in the clinical investigation

DCT Threats

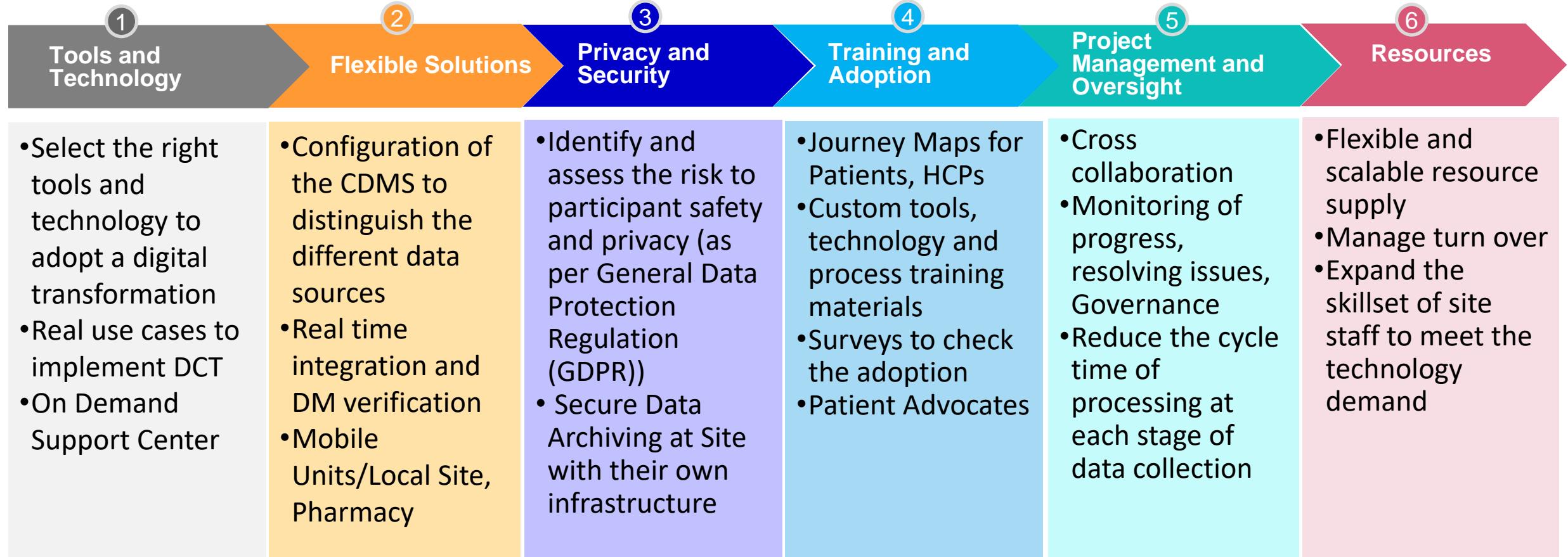


- Phase III protocols undergo an average of **3 substantial amendments**
- Phase III clinical trials generate an average of **3.6 million data points**, three times the data collected by late-stage trials 10 years ago
- Data Reliability contributes to **49%** of the DCT threat
- Direct-to-patient medication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

Challenges in DCT Adoption

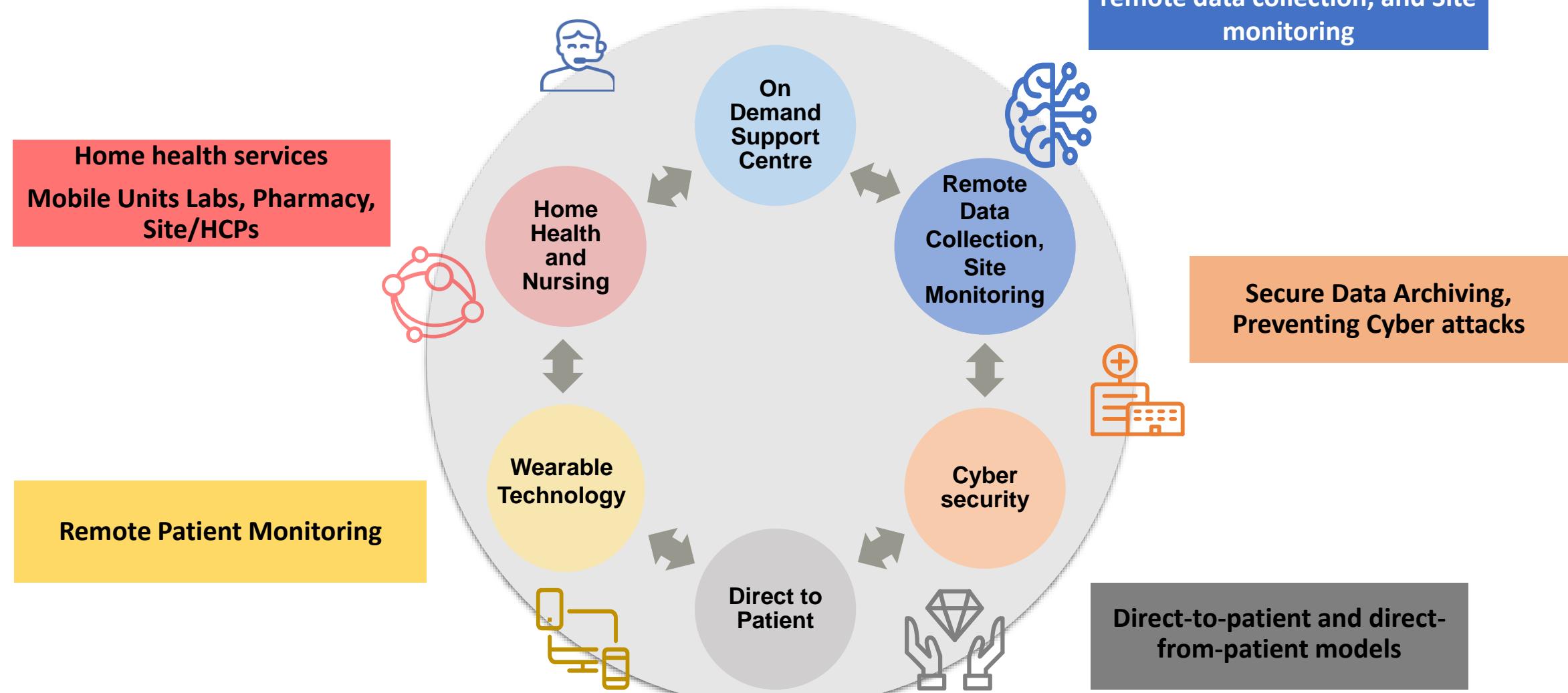


Mitigating the Challenges



Sponsor , CRO, Site, Regulators, Tech vendor, Third party vendors – Works as ONE TEAM

Industry Collaboration



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?

