Society for Clinical Data Management
DATA DRIVEN

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

SCDM Live
India conference

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

DCT Opportunities and Challenges

Decentralized Clinical Trials (DCT)

The decentralization of clinical trial operations where innovative technology is used to communicate with study participants and collect data.

Decentralized clinical trials can either be fully remote or adopt a hybrid approach where some physical-site attendance is required.

The term "decentralization" infers that activities which previously took place at sites can now be done remotely, most often in people's homes but also at local pharmacies, labs, and other proximate options.

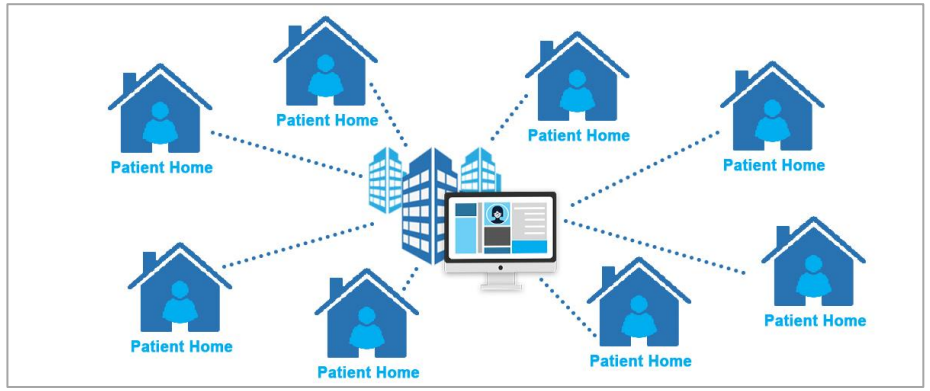
Technology sits at the heart of this paradigm shift, enabling a level of participant convenience that would otherwise be impossible.

It's about implementing Digital Health Technologies (DHT) and other novel solutions to enable sponsors and CROs to take a hybrid approach to clinical trial design, providing an alternative to a brick-and-mortar site, inflexible system

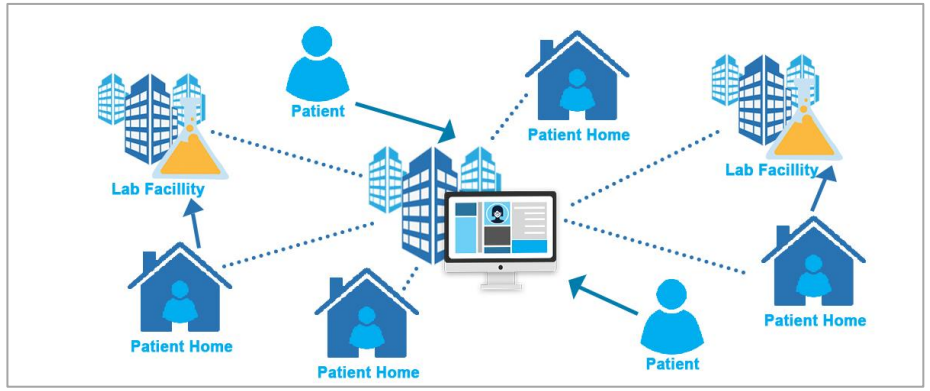
Evolution from "Can a trial be decentralized?" to

"How decentralized can a trial be"?

Fully Remote



Hybrid



Goals of Decentralized Clinical Trials

Improvement in Patient recruitment, selection and retention ensuring study continuity

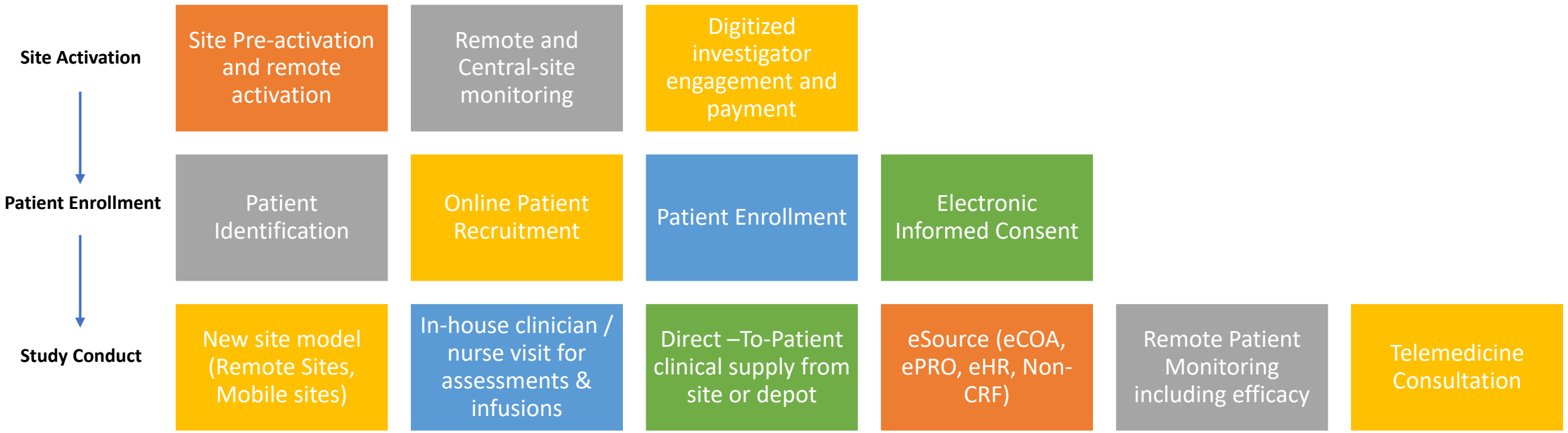
Patient Centric clinical trials – Improves Patient experience, Convenience and Engagement

Increase diversity and Inclusion representative cohorts – Improves Research quality, Scientific understanding of rare diseases

Flexible fewer in-person study visits, allows for passive data collection, and removes barriers to participation such as geographical factors, time, and travel.

Eliminates duplicate data entry, captures real-time and accurate data directly from the patient leading to lesser data cleaning, reduced operating cost and cycle time

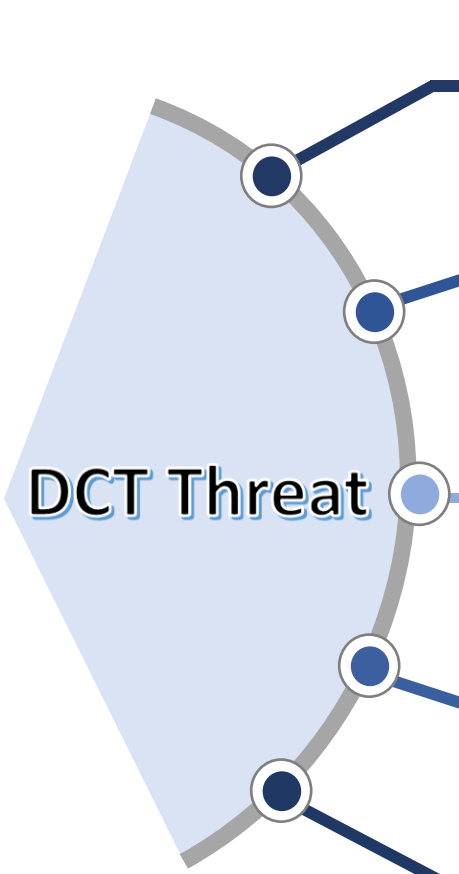
DCT Opportunities - Enablers



Key Considerations for DCT

- Size of patient population
- The indication (Less AE and mild indication, self-administered)
- The phase of the study
- The investigational product
- The maturity and capabilities of the sponsor and its trial infrastructure
- The trial population's access to and familiarity with health technology and the reliability of internet connections
- Depending on the protocol, data are received from ePRO, eCOA, eDiaries, wearables and/or sensors, Televisit and eConsent in addition to standard non-CRF data such as lab data. EDC should be capable to query and consolidate the information.
- Digital Health Technology (DHT) should be "**fit-for-purpose**" that is sufficient to support its use and interpretability in the clinical investigation.
  - The education and technical aptitude of trial population to use the tool
  - The design and operation of the DHT
  - Ability to ingest the DHT measurements into the data platform using public data exchange standard
  - The functioning of the DHT should ensure privacy and security to prevent unauthorized access to the DHT and the data it collects
  - Sponsors should ensure reliable data collection, the maintenance of the device, the data output of the device, and how the DHT measures the clinical event
  - Ability for DHT to leverage the patient's own smart devices
  - sponsors should evaluate physical features of the device for any potential to cause injury
  - Meet regulatory guidance

DCT Threat



Complexity

- Risk of Technology complexity. Increases the no. of technologies, data sources & stakeholders on a study
- Hybrid DCT requires careful planning leading to the set-up of multiple systems with complex data flows and integrations

Regulatory Rejections

- Regulatory might reject the qualification of Investigational Product if the novel clinical endpoint are not defined clearly (i.e., exactly what are they measuring)
- Not all DHTs are FDA-approved or cleared for a given purpose

Risk to Data Quality and Integrity

- May collect more data than needed. Sites review data in real-time and raise any potential query that may be overwhelming and difficult to manage.
- Inability audit data from DHT

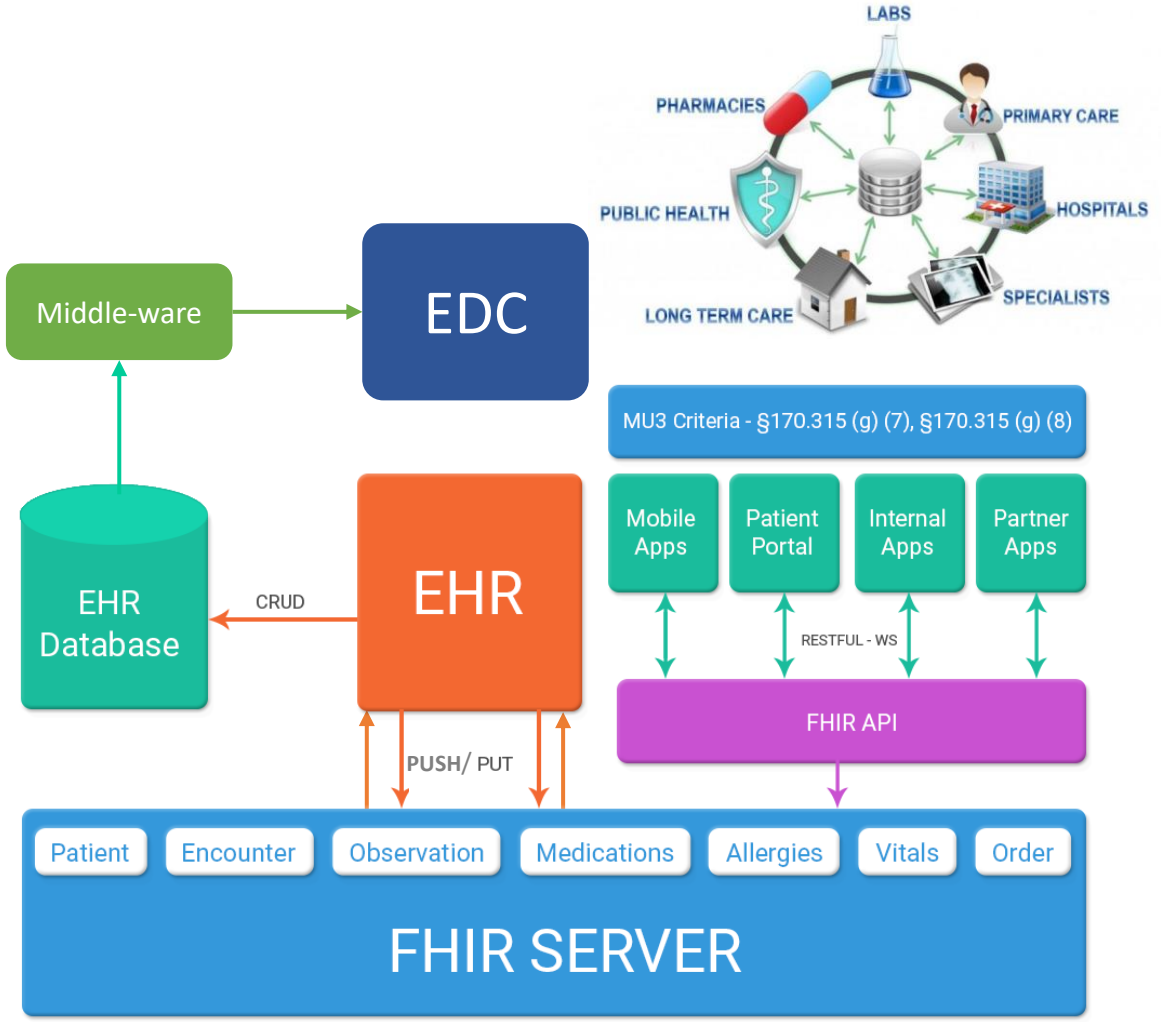
Privacy and security

- Unauthorized access to blinded and patient (Protected Health Information) PHI data collected through devices and other sources
- Threat to patient safety, ethical conduct and patient privacy

Training and Support

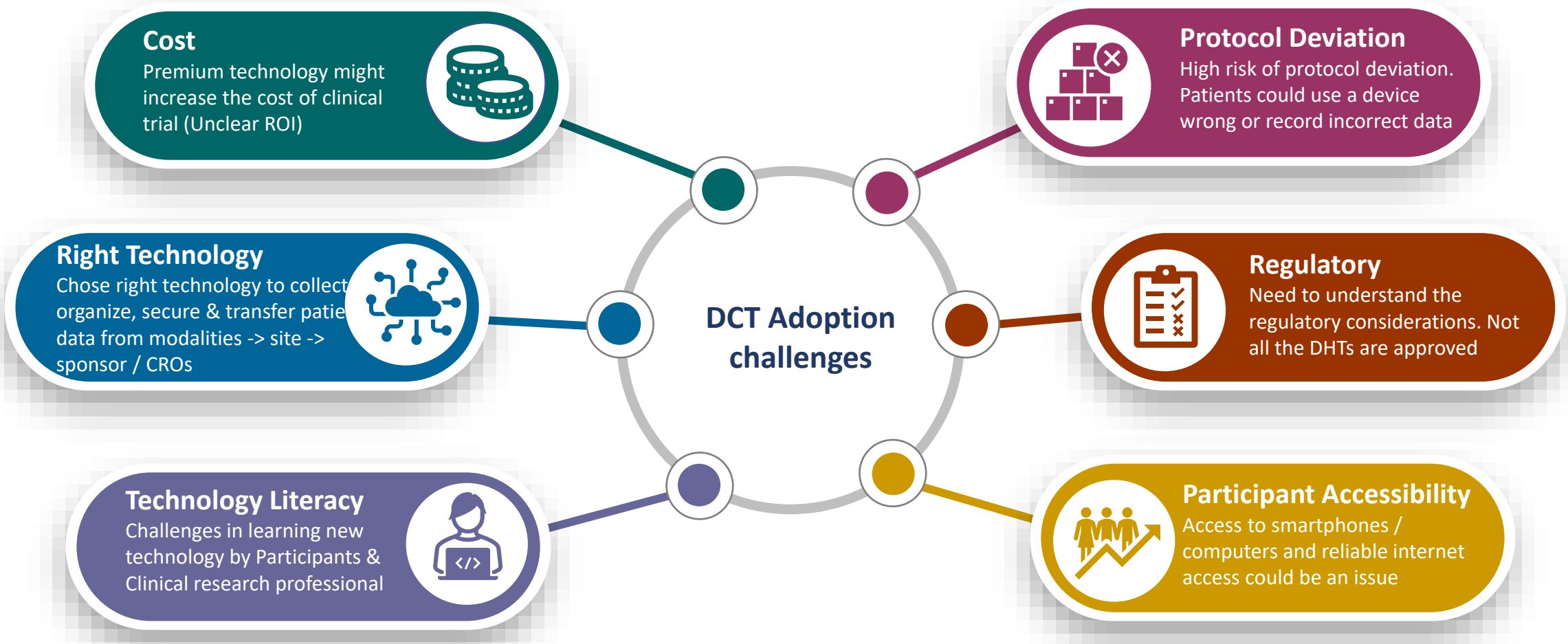
- Comfort levels of technology vary for patients and clinical research professionals
- Overhead on training and technical support

eSource Implementation Threats



- Existence of varied standards (HL7® Health Level Seven) FHIR® (Fast Healthcare Interoperability Resources 1), HL7 healthcare standards, Version 2 and Clinical Document Architecture (CDA®) for data exchange and interoperability
- Not all the sites in the study support eSource capabilities / EHR HIPPA compliant technology
- Derive Universal Unique ID (UUID) to extract and load data to EDC system
- All data collected via eSource cannot be mapped to EDC
  - Site to enter the data that are not mapped
  - Inadequate reusability of mapped data
- Update / deletion and audit logs of data loaded
- Robust event management for data load errors
- Monitor the usage of eSource through data analytics
- Long Lead time from eSource site activation to data load into EDC

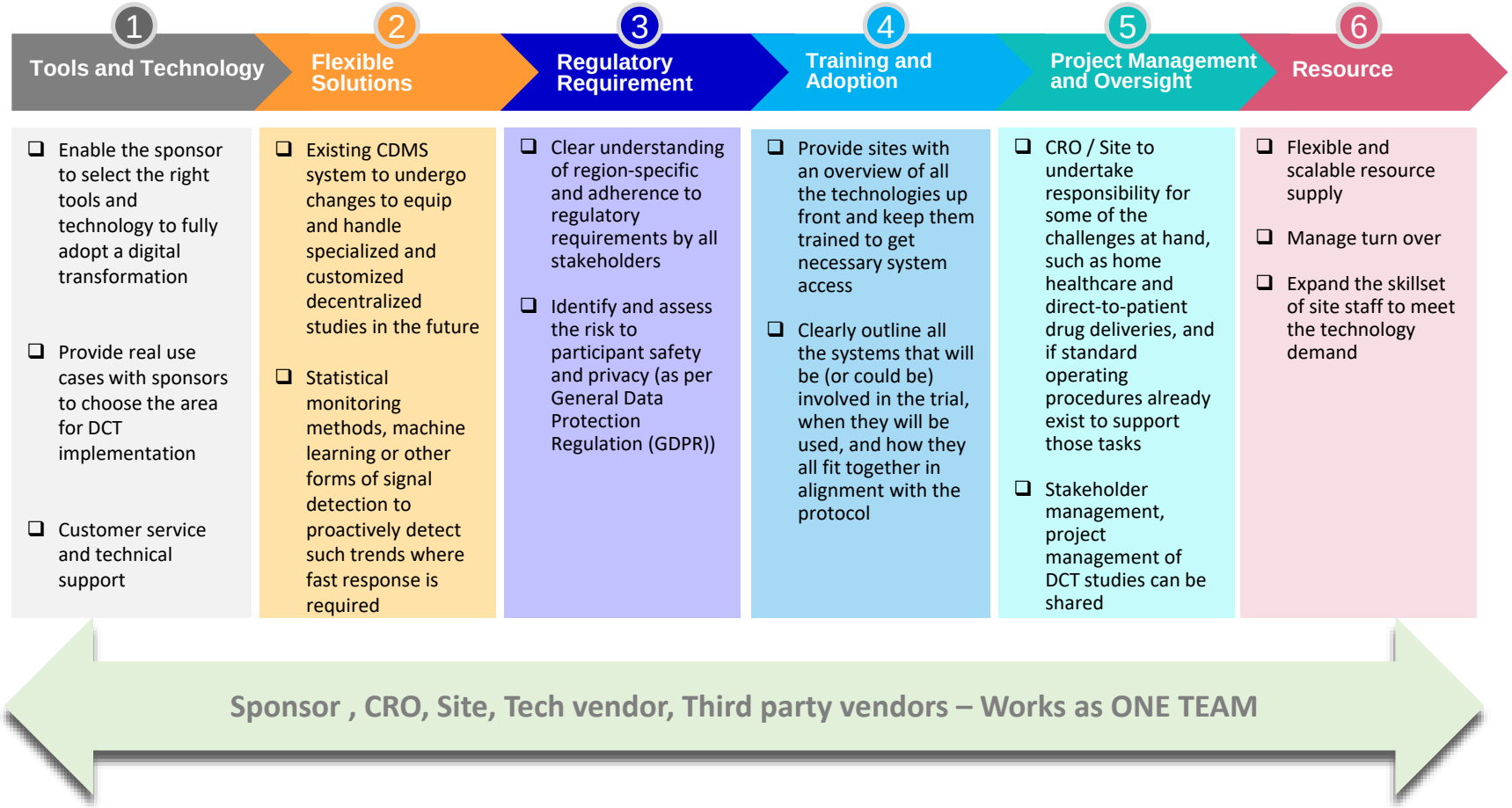
Challenges in DCT Adoption



Collaboration Capabilities in DCT

- Partner with a CRO / sites that have In-house DCT capabilities
- Sponsors looking for education on what DCTs encompass in practice
- Collaborate with sponsors to determine the level of virtualization and decentralization that is appropriate
- Both sponsor and CRO / technology vendors should be familiar with the regulatory landscape in which the technology is deployed
- Understanding the potential problems being inadvertently created for sites
  - An average of 17.5 hours in training per study per site
  - Clinical research coordinators (CRCs) use eight or more systems for each study assigned
  - Site staffs are responsible for implementing the technology
- Service providers / CRO to undertake oversight responsibility of some of the decentralized clinical research activities
- Support in administrative task

Collaboration capabilities to mitigate the challenges



Reference Links

1. https://www.obviohealth.com/decentralized-clinical-trials#:~:text=Decentralized%20Clinical%20Trials%20Definition&text=According%20to%20the%20FDA%2C%20decentralized,study%20participants%20and%20collect%20data.%22
2. https://www.pfizer.com/news/articles/covid_19_as_a_catalyst_for_modernizing_clinical_trials
3. http://transceleratebiopharmainc.com/wp-content/uploads/2020/07/TransCelerate_Beyond-COVID19_Modernizing-Clinical-Trial-Conduct_July-2020.pdf
4. https://florencehc.com/learn/blog-posts/decentralized-clinical-trials-what-the-future-holds
5. https://mdgroup.com/blog/why-decentralisation-is-the-future-of-clinical-trials/#:~:text=The%20Main%20Benefits%20Of%20Decentralised,hours%20from%20a%20research%20site
6. https://clinicaltrials.gov/ct2/show/record/NCT04091087?view=record
7. https://www.pfizer.com/sites/default/files/plsr-studies/C3291038%20Plain%20Language%20Study%20Results%20Summary%20%28PLSRS%29%20Phase%202-4.pdf
8. https://florencehc.com/learn/blog-posts/9-challenges-and-risks-for-launching-decentralized-trials
9. https://www.appliedclinicaltrialsonline.com/view/overcoming-the-7-biggest-challenges-in-launching-decentralized-trials
10. https://www.linkedin.com/pulse/fdas-guidance-decentralized-trials-digital-technology-alexander/?trk=pulse-article_more-articles_related-content-card
11. https://www.pharmalive.com/the-risks-and-rewards-of-decentralized-clinical-trials/
12. https://www.iconplc.com/news-events/thought-leadership/pfizer-covid-vaccine-trial-proved-remote-monitoring-other-innovations-work/
13. https://www.pfizer.com/news/articles/covid_19_as_a_catalyst_for_modernizing_clinical_trials
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16. https://mobisoftinfotech.com/resources/blog/top-10-ehr-implementation-challenges-and-how-to-overcome-them/
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18. https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf
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Thank You!