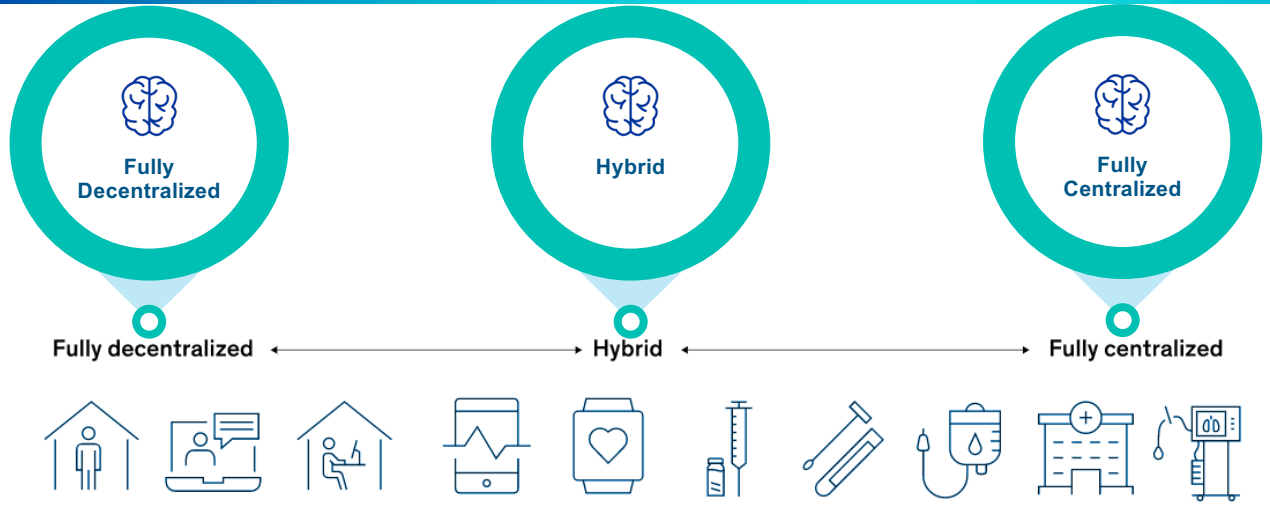
phuse·virtual

Single Day Event

Sujith Kurup, *IQVIA*

phuse.global

DECENTRALIZED CLINICAL TRIALS



All trial procedures are conducted virtually, enabled by digital technologies and supply delivery

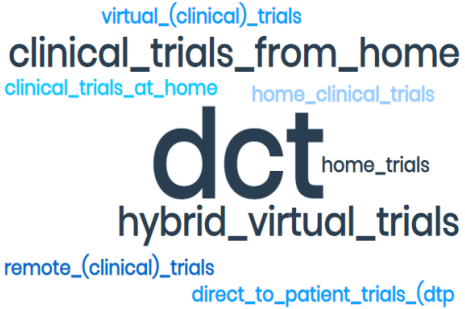
Less complex trial procedures that don't require in-person visits (eg, vital signs, electrocardiograms) are conducted via telehealthcare, remote data collection, or direct-to-patient supply

Less complex trial procedures that require in-person visits (eg, injections) are conducted via mobile clinicians or alternative sites (eg, mobile clinics, retail sites)

Complex trial procedures (eg, complex screening protocols, cell therapy, magnetic resonance imaging) are conducted via research sites (eg, academic medical centers) or local hospitals

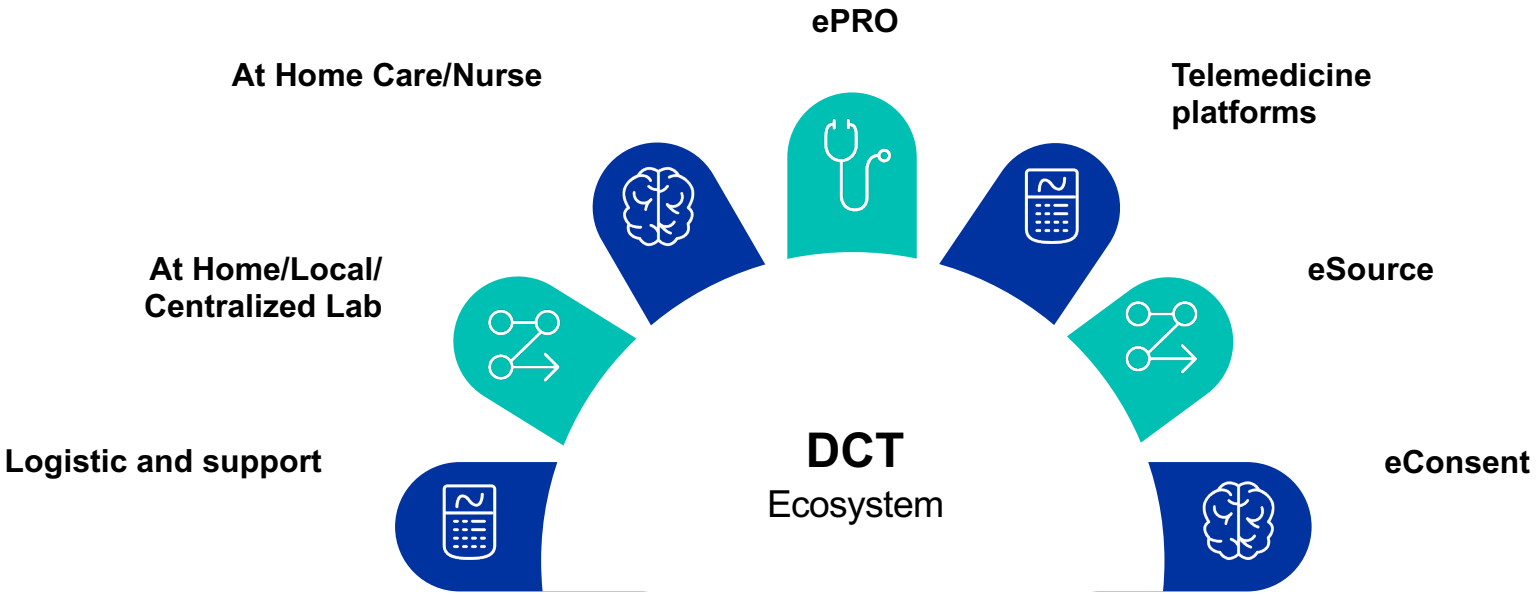
All trial procedures are conducted at a research site (eg, academic medical center)

*No place like home? Stepping up the decentralization of clinical trials www.mckinsey.com



Catalyzed by the COVID-19 pandemic, Decentralized Clinical Trials emerged as an opportunity to reimagine the traditional clinical trial model and transform how research studies are conducted, keeping the patient at the center of this dynamic paradigm.

DECENTRALIZED CLINICAL TRIALS ECOSYSTEM

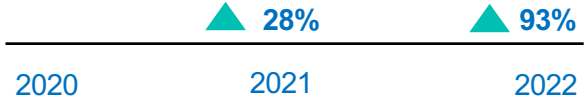


Decentralization Elements & Projections

48-95%
Sponsors

Using decentralized elements in at least one Phase III trial

Projections



Trials with decentralized components will represent a **28%** increase from 2021, and a dramatic **93%** boost from 2020.

CAGR: 6.95% ▲ during the forecast period 2022-2032

38%
Pharma and CRO

Expected virtual trials to be a major component of their portfolios

48%
Pharma and CRO

Run a trial with most activities conducted in participants' homes

Pre-Pandemic

100%
Pharma and CRO

Expected virtual trials to be a major component of their portfolios

89%
Pharma and CRO

Run a trial with most activities conducted in participants' homes

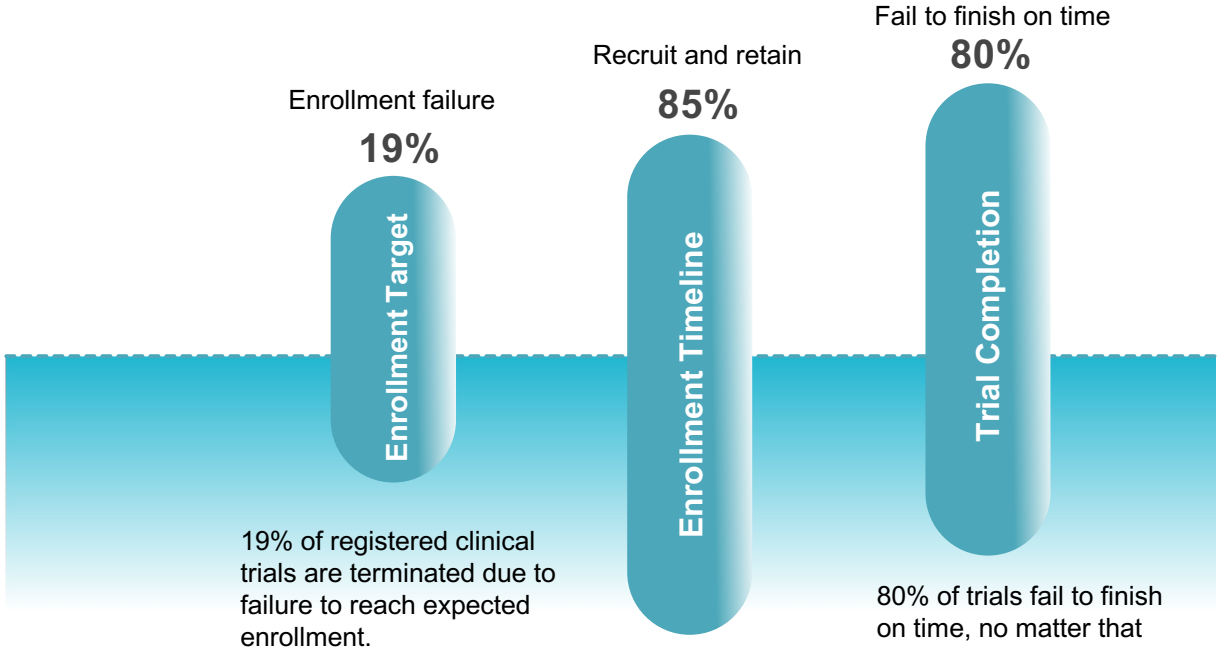
Post-Pandemic

www.mckinsey.com | www.clinicaltrialsarena.com/

RESTRICTED

Beyond Centralized Approaches

53.5%
of the clinical trials have been suspended, owing to the pandemic,



19% of registered clinical trials are terminated due to failure to reach expected enrollment.

85% of clinical trials fail to recruit and retain enough patients in order to meet their enrollment timeline;

80% of trials fail to finish on time, no matter that one-third of a study budget often goes into patient recruitment and retention

* (Frost & Sullivan PB21-52 August 2020)

Decentralized Trials – Solves Problems but Creates New Ones?

Patient/Participants at the center of the trial

- Send data from their homes instead of driving to the research site
- Serve participants who live hours away from research sites
- Minimal disruption of daily life

- Access to internet
- Digital literacy level of Patient
- In person support from research site staff
- Patient-physician interaction

- Participant Recruitment and Inclusivity: Global participants – Race and Ethnicity
- Better speed and patient retention
- Equipped and enhanced readiness for unprecedented situations – pandemic/war

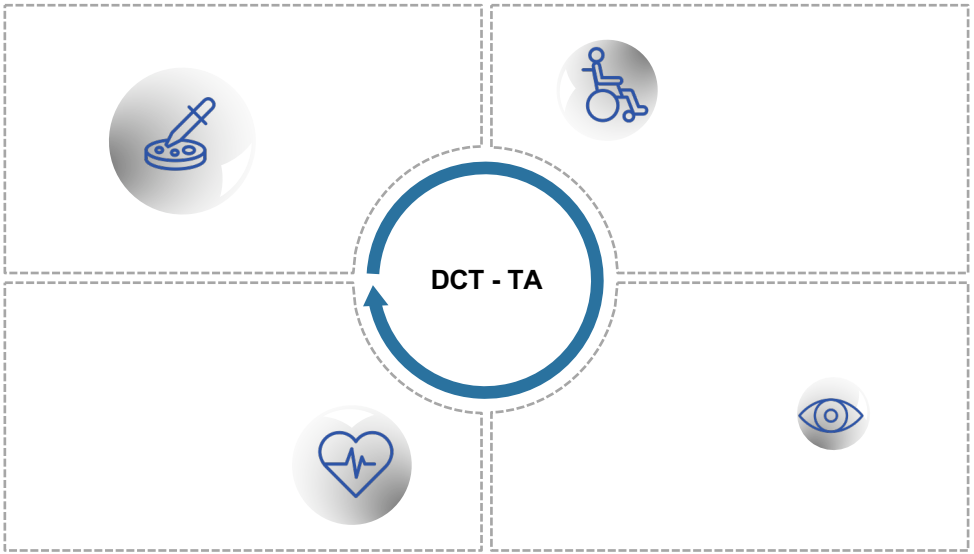
- Reduced site involvement
- Virtual engagement of patient, (learning curve)
- Challenges of patient–investigator experience
- Workloads to provide logistical and technical support

Decentralized Trials – Solves Problems but Creates New Ones?

One Size Does Not Fit All – TA Based Considerations

Oncology: Once believed to be challenging, COVID-19 pandemic didn't stop many oncology trials from adopting DCT

Cardiovascular: Depending on the type of intervention, DCT elements are used; including full DCT



CNS: Assumed ease of adoption - scales (verbal and visual) and interview types of assessments vs. standardization challenges.

Ophthalmologic trial:

Complicated equipment that is only in use at a few facilities.

DCTs are NOT universally applicable to all the therapeutic areas

Decentralized Trials – Solves Problems but Creates New Ones?

Trial Data

Diverse sources: Wearables or sensors, ePRO, eCOA, Electronic patient diaries

More data can make trials more reliable: Gaining access to a larger population via a larger geographical footprint

Provide data which is closer to a real-world/real time setting

A higher data burden for sites

May lead to confusion and wasted time

Redundant data collection opens opportunities for transcription errors

Concerns for data privacy: track of data transactions through a tamper-proof chain of custody of all medical devices/Software

Compliance

Worry of compliance when using decentralized trial technology

Need of technology that follows local and federal regulations

Compliance with CFR Part 11, HIPAA, and GDPR

Higher risk of protocol deviations

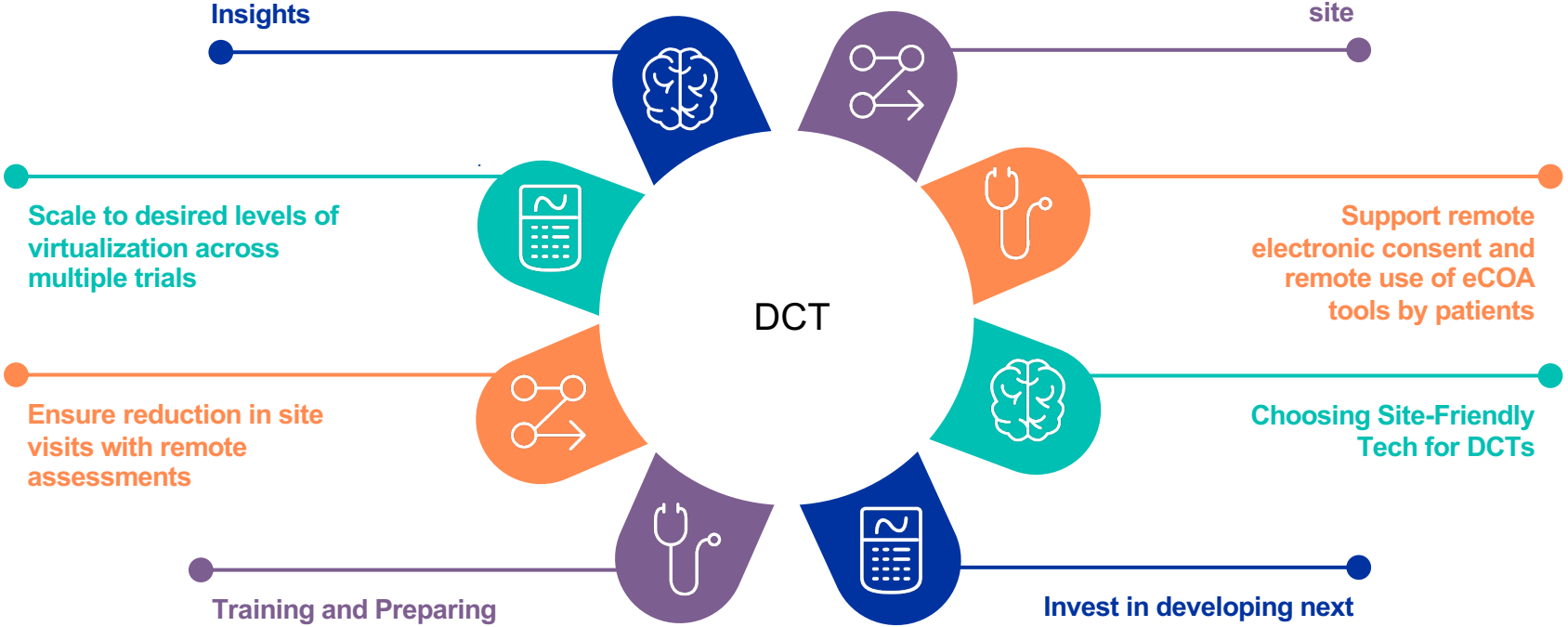
Regulators

Alignment trials with regulatory guidance, which evolves rapidly and may differ significantly from country to country

Cross-border data standards, as well as localization and retention rules

FDA/European Medicines Agency's new regulations to encourage flexible clinical trials

Way forward to successful DCTs




NK YOU
RE

The Global Healthcare Data Science Community

Contact Channels

UK +44 1843 609600
office@phuse.global
phuse.global

Social Media

@phusetwitta
/phusebook
/phusetube
/company/phuse