The Promise of Decentralised Trials: What does Industry need to Consider

Nick Sykes
Senior Director
Pfizer, UK

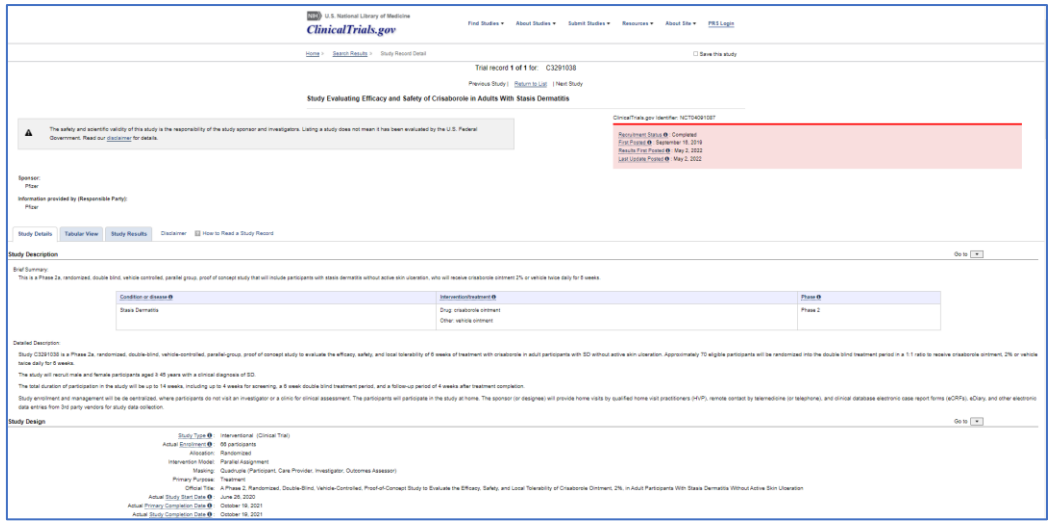
Today I will cover:

- Why is pharma interested in DCT
- Main issues to consider when deciding on a DCT
- What have we learned from the pandemic
- What is actually novel

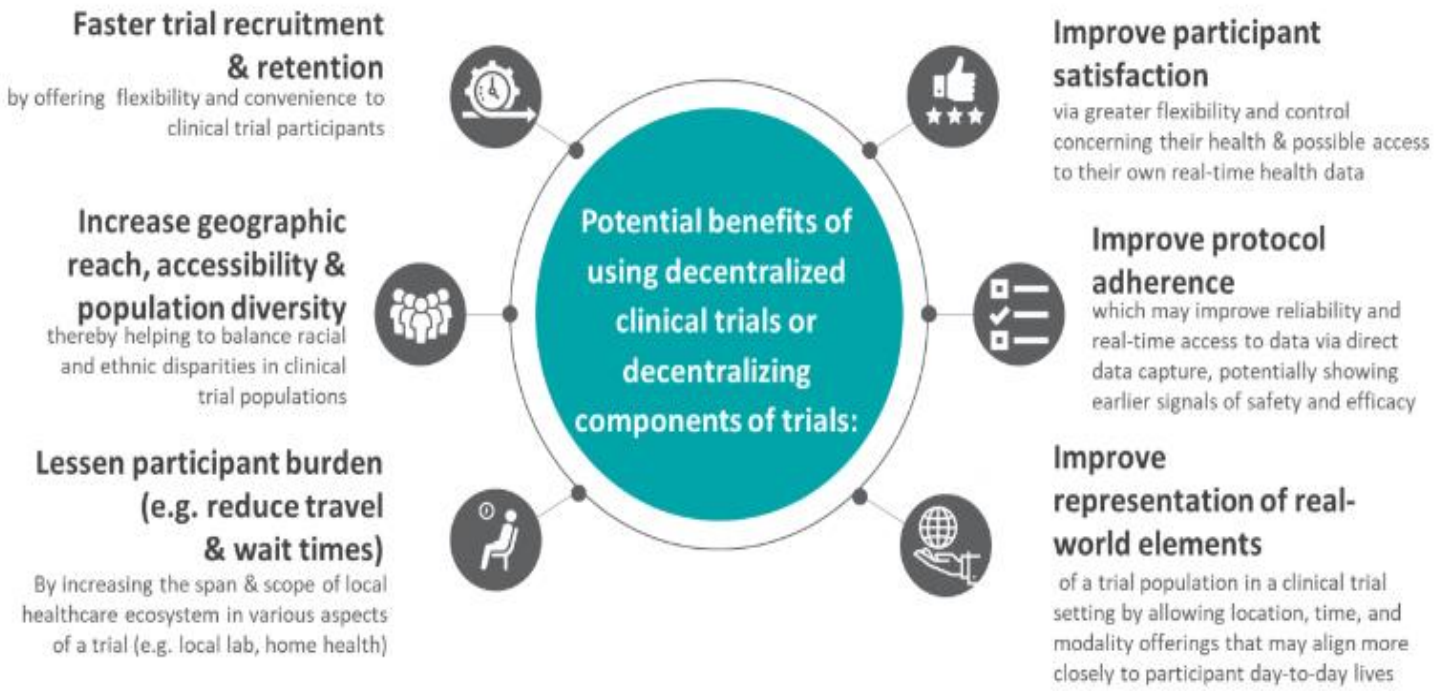
What is a Decentralised Trial?

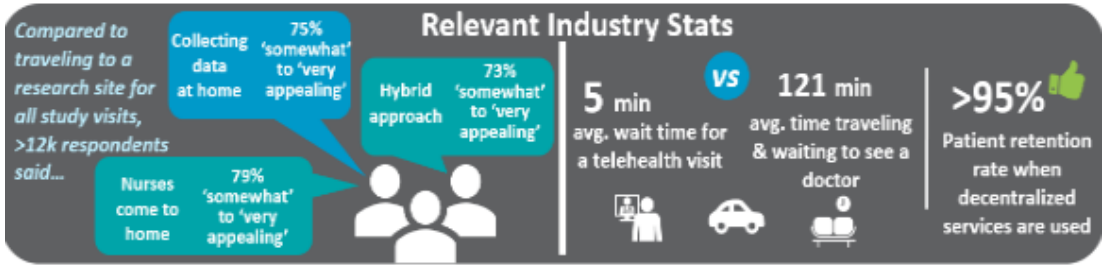
DECENTRALIZED CLINICAL TRIALS

TRADITIONAL CENTRALIZED CLINICAL TRIAL	PROTOCOL-DEFINED LOCATION FLEXIBILITY	PARTICIPANT-PREFERENCE LOCATION FLEXIBILITY	FULLY REMOTE
Studies conducted at designated brick-and-mortar sites and study procedures are generally performed by investigators and their delegated study personnel.	Studies that pre-define specific visits as allowing an in-home or remote study visit (whether via technology, visiting staff, or both).	Studies that allow the participant to choose whether a visit may be performed in the clinic or at-home (based upon convenience and personal preference).	Studies designed to run entirely from the home or other remote locations (without a conventional site, but perhaps one central, coordinating site/PI).



Why are we Interested in DCTs





Not sure that we're able to tie DCT to an improvement in diverse representation, it's still too early to tell

Some Key Issues to Address when Planning a DCT

- Plan Early - Consider DCT early in the clinical development plan
  - ensure to include the considerations for implementation of DCT modalities as early as possible
- Keep in mind participant perspectives and the participant journey to ensure study participants are receptive to the idea
- Legal and regulatory considerations are vital to include upfront
- Solution/Technology Considerations
- Identifying & Mitigating Risks
  - Outline how each component of the study is executed and how data is expected to be obtained, including all modalities/technologies to be utilized in the context of each visit and each study procedure
  - Help to assess protocol compliance risk elements

Clinical Operational Issues to Consider When Deciding on a DCT

- Patient population
- Assessing participant eligibility & patient verification
- Performing consent/reconsent
- IMP delivery & retrieval
- What education and training (participant, site, investigator, HCP) may be needed
- What validation and/or validation studies may be required (e.g. for digital health technologies being used)
- Assessments - clinician-led or self-administered (e.g. eDiary's, eCOA's, ePRO's, etc.)
- What study procedures require certain equipment (e.g. ECG, BP, MRI, etc) & where can they be performed
- Where to conduct lab tests and how to draw, ship, track specimens
- Potential source data and how will the study team ensure appropriate access
- How will safety reporting requirements be addressed

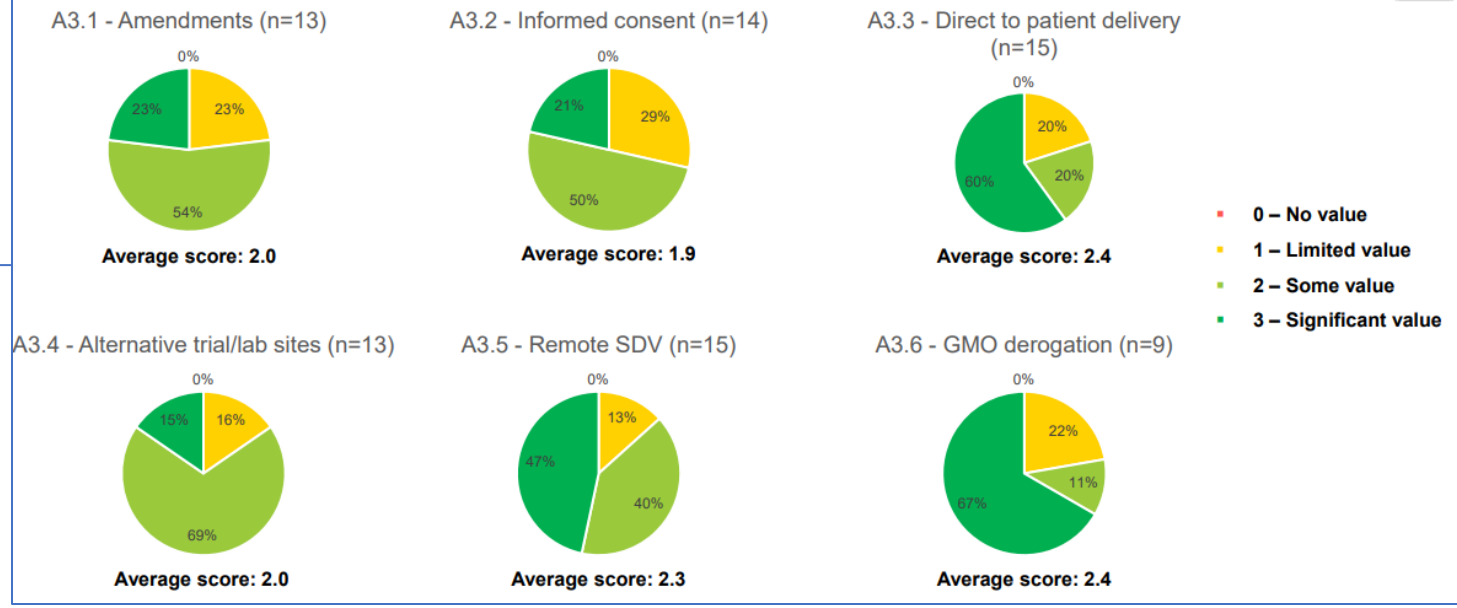
What did we Learn from the Covid Pandemic: Results of EFPIA Survey on Covid CT Flexibilities

Clinical Research Flexibilities – Key Findings for **Overall Operations**

Valued impact

- **Risk-based approaches** that facilitate prioritisation and free up resources in clinical settings, such as **direct to patient delivery** (A3.3) demonstrate the value for all stakeholders in future
  - Flexibilities in terms of **alternative trial and lab sites are valued in health emergencies**, when patient mobility and trial sites change; but at a cost of introducing variability and additional administration.
- **Virtual working and digital methods, such as remote source data verification** (A3.5) and to a lesser extent **electronic informed consent** (A3.2), hold great potential for future use, with progress in standardization and alignment within EU and globally.
- The **GMO derogation** (A3.6) for clinical trials are highly valued as a means to advance the EU research environment and ensure EU patient access to innovative new treatments in development. This must be **sustained post-pandemic.**

Overview of **clinical research** guidances and flexibilities – value for future use



Although Covid has increased the awareness of DCT and demonstrated the feasibility of many of its modalities, it hasn't completely 'flipped the switch' regarding regulators' acceptance

Source: [Therapeutic Innovation & Regulatory Science (2022) 56:366–377]

What is Still Needed for Greater Acceptance of DCTs?

The benefits of DCTs are broadly endorsed and the need for global adoption is recognised, however:

- Still in a learning mode so take ‘baby steps’, seek advice early, and describe reasons for using DCT modalities
  - Share experiences (good and bad) and learnings
  - Today, in a better position to have the discussion as we have real data to help us
    - 2 years ago we were talking concepts
- GCP compliance still needed but not well defined for DCT
  - ICH E6 R3 should help
- Ambiguities and variability on the regulatory pathways & evidence needed for validation of DHTs and digital endpoints
- Complexity is driven by many factors where not everything is under the responsibility of the regulators
- Not all countries are in the same place of understanding, experience, and acceptance
  - Different interpretations of laws by different countries

So, What is Actually Novel?

- DCT modalities (wearables, DHT, telemedicine, rSDV/R, etc) used for a number of years
  - Novelty is how they are being used together
- Novel Challenges:
  - Blurring of lines that divide the roles and responsibilities of sponsors and trial investigators
  - Overburdening of trial/hospital sites with new tasks or procedures to support remote processes
  - Concerns around data privacy and data integrity

Thank You - Let's keep the conversation going…

nick.sykes@pfizer.com