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?

<table>
<thead>
<tr>
<th>Traditional Centralized Clinical Trial</th>
<th>Protocol-Defined Location Flexibility</th>
<th>Participant-Preference Location Flexibility</th>
<th>Fully Remote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies conducted at designated brick-and-mortar sites and study procedures are generally performed by investigators and their delegated study personnel.</td>
<td>Studies that pre-define specific visits as allowing an in-home or remote study visit (whether via technology, visiting staff, or both).</td>
<td>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).</td>
<td>Studies designed to run entirely from the home or other remote locations (without a conventional site, but perhaps one central, coordinating site/PI).</td>
</tr>
</tbody>
</table>
Why are we Interested in DCTs

- Faster trial recruitment & retention by offering flexibility and convenience to clinical trial participants.
- Increase geographic reach, accessibility & population diversity thereby helping to balance racial and ethnic disparities in clinical trial populations.
- Lessen participant burden (e.g. reduce travel & wait times) by increasing the span & scope of local healthcare ecosystem in various aspects of a trial (e.g. local lab, home health).
- Improve participant satisfaction via greater flexibility and control concerning their health & possible access to their own real-time health data.
- Improve protocol adherence which may improve reliability and real-time access to data via direct data capture, potentially showing earlier signals of safety and efficacy.
- Improve representation of real-world elements of a trial population in a clinical trial setting by allowing location, time, and modality offerings that may align more closely to participant day-to-day lives.

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

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.

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
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