Site and Patient Perspectives on Decentralized Trials
How Can They Inform Operational Strategy?

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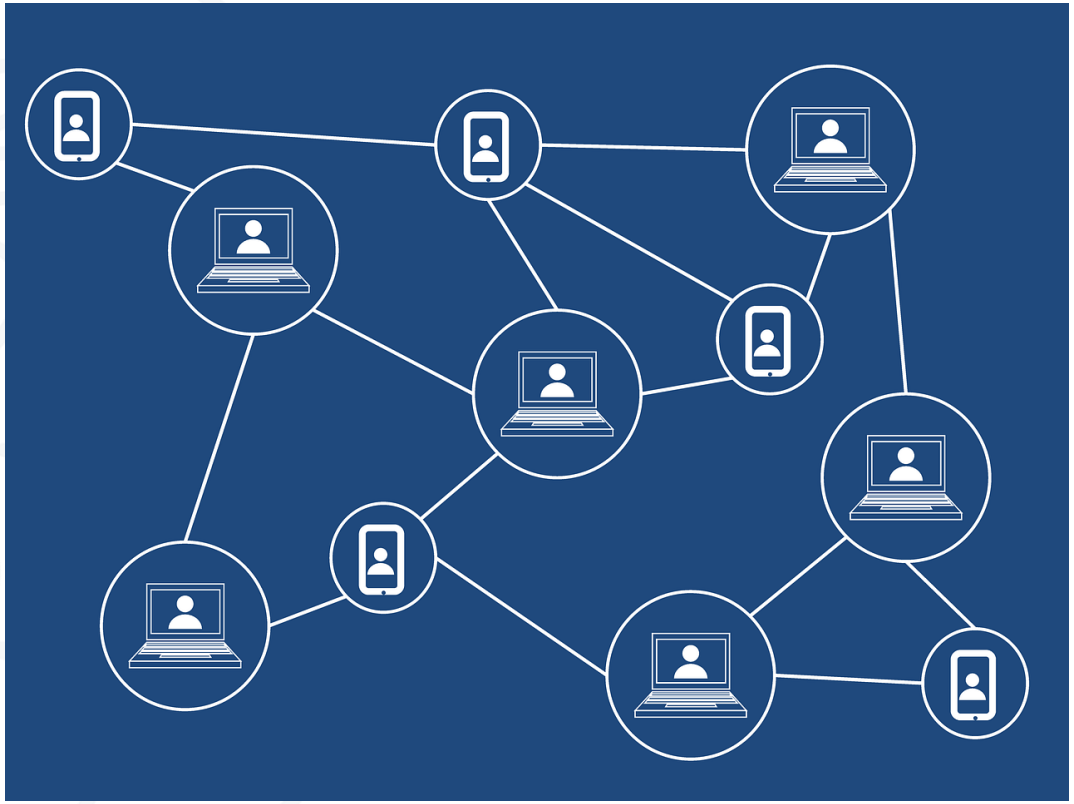
What is a decentralized trial?

What is a Decentralized Trial (DCT)?

- My definition: anything that can be added to a clinical trial that allows for some aspect of the research process to happen away from the traditional brick-and-mortar process – typically with the goal of removing barriers to entry for patients

- This is not an "all or nothing" approach – while fully virtual trials exist, in most cases we are talking about hybrid studies that have a blended traditional / decentralized approach

- If even one tactic is employed that is a "DCT tactic" I am considering the study a "hybrid" study



Current DCT Landscape

- 94% of research sites had adopted at least one decentralized methodology and 88% of sites had hosted hybrid trials (Source: WCG, 2021)
- Hybrid clinical trials have grown from 20% of all trials initiated in 2019 to 77% of trials in 2022 (Source: Innvocept Global Solutions, 2023)
- Several new “technology” or service-oriented vendors popping up every year to address decentralized trials, even while some legacy “DCT” vendors are struggling – why is this and has the bubble burst on DCT?

Table 3. Implementation of DCT/Hybrid Technologies

	Use prior to COVID		Currently use		Plan to use		Do Not Plan to Use	
Technologies	***n***	**Percent**	***n***	**Percent**	***n***	**Percent**	***n***	**Percent**
ePRO	35	65%	36	67%	15	28%	3	6%
eDiaries	34	63%	33	61%	12	22%	3	6%
eCOA	33	61%	33	61%	15	28%	2	4%
Remote monitoring	23	43%	38	70%	11	20%	5	9%
Decentralized lab work (including local labs)	22	41%	23	43%	17	31%	4	7%
eConsent	22	41%	35	65%	20	37%	0	0%
Wearables / Sensor data collection	21	39%	26	48%	21	39%	0	0%
Home health	20	37%	33	61%	18	33%	0	0%
EMR / EHR data integration	14	26%	15	28%	22	41%	0	0%
Telemedicine	12	22%	31	57%	15	28%	4	7%
Direct-to-patient (home IP drug shipments)	11	20%	33	61%	21	39%	2	4%

Source: Tufts CSDD Study, 2022 (https://www.appliedclinicaltrialsonline.com/view/the-impact-of-decentralized-and-hybrid-trials-on-sponsor-and-cro-collaborations)

Key Stakeholders in the Process – Sites and Patients

- At Worldwide, we want to approach DCT differently – by working with and learning from the stakeholders we are trying to impact – sites and patients
  - How do sites really feel about decentralized trials?
  - Are patients really benefiting from the use of decentralized tactics?

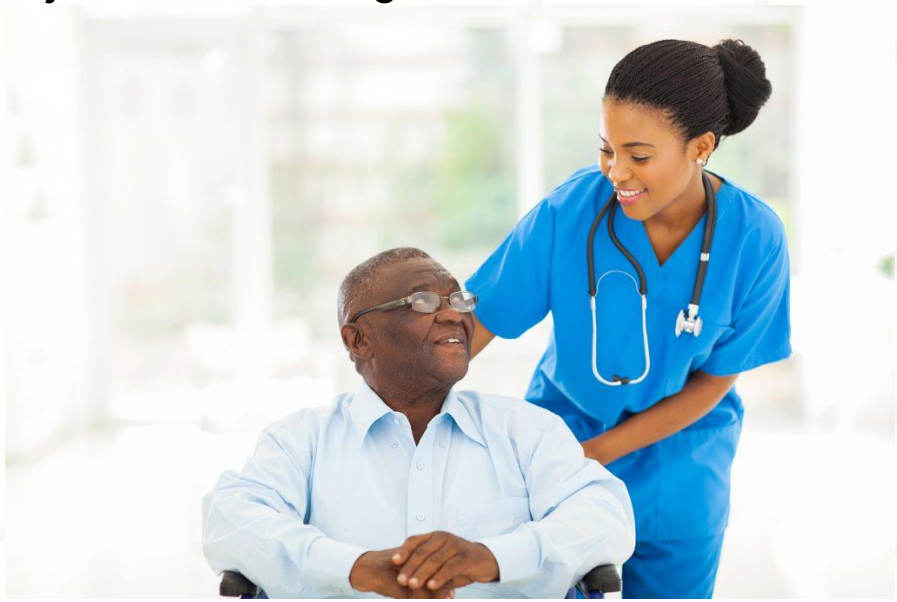
- Key Questions asked via qualitative surveys of a small group of sites:
  - Site profile (therapeutic area, location, site setup)
  - Percentage of current studies including decentralized components (eConsent, home health, telehealth, wearables, ePRO/eCOA, fully virtual all named)
  - Do you think clinical trials provide a better or worse site experience today as decentralized components increase in use? How about for patients?
  - For which types of studies do decentralized components work best and for which do they not work well?
  - If you could tell Sponsors and CROs one thing about designing clinical trials with decentralized components in mind, what would you tell them?

Site Feedback – Key Trends

- eConsent is not used often (<10% of studies across sites surveyed) but would be helpful for ease of documentation. One site commented that they still want patients to consent on site even if eConsent is used
- System bloat is real – it came as no surprise that many sites remarked that lack of system integrations ends up creating more work when it came to anything enabling remote data collection (eConsent, ePRO/eCOA, home health called out specifically by different sites)
- Sites remarked that "DCT" is better for non-interventional studies and not for oncology studies. One site noted that DCT is typically a good idea for infectious disease, rare disease, or metabolic diseases
- While some oncology-focused responses were against DCT completely, others noted that a hybrid approach could be good for patients (non-treatment visits)
- Home health was called out by a couple of sites as an area that Sponsors and CROs do not implement well. Specific limitations called out included communication barriers with nurses and site bandwidth to correctly handle data transferred from nurses (lack of integration)
- Multiple sites noted that giving patients options vs. the traditional on-site approach is key to reaching underserved populations, especially in certain geographic areas
- Some sites expressed concerns that the "burden" of DCT solutions is being shifted to sites and that Sponsors and CROs are not offering sites the resources and budget to support these tactics

Patient Case Study 1 – Epidermolysis Bullosa Patient

- This patient had been a part of two clinical research studies with varying degrees of DCT involvement:
  - Study #1 – Oral medication over 7 months. Included 2 on-site visits and then daily diaries (ePRO). They had full access to the PI and had weekly calls. The IP was mailed to the patient for the study duration.
  - Study #2 – Topical gel over 6 weeks. Required 2 days on-site and then 1 day at the end of the study; also had weekly phone calls. This study used paper diaries and patients were provided a digital camera to take pictures. Scales in the paper diary were "very subjective" with ratings of 1-10.



Key Insights:

- The patient strongly preferred the experience of Study #1 even though it was significantly longer due to ease of the electronic diaries (although the patient also remarked that the diaries were not mobile optimized)
- The patient felt that they did not get proper training with how to properly use the digital camera or how to properly report changes in Study #2 which may have diminished quality of study results
- The patient remarked that they would be more eager to participate in another study if it was more like Study #1 with a better remote / electronic set-up. They also remarked that they think it is important for Sponsors to walk through the patient and site experiences when designing a study to avoid some of the challenges encountered in Study #2.

Patient Case Study 2 – Lennox-Gastaut Syndrome Patient (Pediatric)

We were recently participating in a talk with a parent of an LGS patient discussing how to improve endpoints and monitoring of seizures in studies of these patients

- The audience was primarily made up of pharma and site representatives (mostly academic institutions)
- One participant suggested that a video camera could be put in the patient's bedroom to monitor possible events
- The parent got very upset – stated that many parents of children with LGS co-sleep with their kids and that the invasion of privacy would not work for this population

What can we learn from these varied experiences?

DCT is not “One Size Fits All”

As Sponsors and CROs, we need to strive to create an ecosystem that makes it easier for patients to access trials without burdening our sites – how can we do this?

1. Reduce the fat – not every study needs “DCT” and not every hybrid study needs every tactic. Think of “DCT” as a category of tools in your toolbox alongside other site- and patient-focused tactics
2. Discuss solutions with sites – use those site relationships to understand what systems sites use and how your proposed technologies or strategies could integrate
3. Listen to patients and engage with communities – understand when patients will welcome decentralized tactics and when they will not. If you don’t know the community perhaps you should not be blanketing tactics that may not make sense and could drive patients away

The Worldwide Site and Patient Support Toolbox

DECENTRALIZED AND HYBRID TRIAL ELEMENTS – WORLDWIDE'S TOOLBOX

Remote Site Evaluation

Remote Site Activation

Metasites

eCOA

Virtual Investigator Training

Online Recruitment

Online Screening

Telephone Screening

On-site Screening

eConsent

Remote Coordinators

ePRO

Wearables

Connected Devices

Televisits

Local Clinics

Home Nursing

Digital Media Support

Remote Data Abstraction

Remote/Central Monitoring

Direct-to-Patient Trial Supplies

eSource Data

On-site Assessments

Patient Concierge

Local Labs

Mobile Phlebotomy

Imaging Centers

Patient Community Liaisons

Worldwide Clinical Trials

Questions?