

DECENTRALISED TRIALS BEST PRACTICE EVALUATION

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2. IMPROVING PATIENT EXPERIENCE

DCT at their core should address the needs of patients, caregivers and therapeutic experts. Uplifting the experience and engagement with these key stakeholder groups should be demonstrable as a driving consideration for DCT best practices.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate	Guidance notes
The opportunity to reduce the number of physical assessments and/or physical site visits and reduce the burden of participation, whilst maintaining high rates of trial activity adherence	 Reduction of physical visits to the hospital can be a key driver here, but it should be kept in mind that some patients will prefer the hyper-care of a physical trial setting. Patient optionality is key to truly minimizing the burden of participation.
Evidence of positive feedback from key stakeholders.	 DCT practices are evaluated and receive positive approval from stakeholders including Patient/Caregiver Advocacy/Therapeutic experts. Teams should recognize that some patients may not consider a DCT an optimal trial experience (e.g. patients for whom the hyper-care of a clinical trial is desirable). Patient experience feedback and data should be collected early and often throughout the trial
That patients are empowered with greater access to information about the trial, the schedule of events and their role in the conduct of the trial	 Supporting patients not only improves their experience, it enhances their ability to drive the desired study data collection and compliance thus meeting the primary goals of the study. Technology should employ design principles to allow data collection (e.g. push notifications and reminders). Explain how technology has been leveraged to ensure patients will have greater access to ad-hoc, remote engagements with the site team
A seamless interaction with patient's ordinary care routine, wherever possible	Features are implemented in such a way that data collection is integrated within patient's daily routine (e.g. application reminders, triggers, etc.).
The capacity to increase the diversity of patients recruited	 Diversity of patient populations (including age, gender, ethnicity, race) is a prime potential benefit of DCTs. Steps should be taken to ensure trial design and recruitment strategy provides enhanced opportunities for diverse patient participation. IMPORTANT: Decentralization can also introduce a new
	type of bias, towards adherent/motivated/technologically literate patients. Steps should be taken to avoid this bias wherever possible