4. OPERATIONAL AND TECHNICAL FEASIBILITY

DCT practices will often involve the use of new operational processes and technologies. This dimension is intended to ensure that operational and technical aspects have been considered fully, for ongoing support, resilience, security, integrity, scaling and reuse.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
A clear problem statement, addressing specific challenges or needs, developed during Programme Planning.	❑ Is the problem clearly defined? E.g. ○ Reduce Patient/Caregiver burden ○ Increase/Ensure Patient Safety ○ Increase Patient Retention/Reduce Drop-Out ○ Improve Data Quality/Integrity ○ Reduce/Eliminate manual entry/human error ❑ Identify all stakeholders who can help solve the problem (e.g., Vendor collaboration is key to risk/benefit analysis with coordination of all DCT capabilities/services)?
A thoroughly defined strategy, including solutions to specific challenges or needs, has been developed during Trial Planning.	❑ Include only what is required, and: ○ Mitigate risks of both operational and technical challenges when considering multiple solutions ○ Align with data privacy guidance and data security at the local country and site level (see dimension 5) ○ Ensure blinding/unblinding requirements will not be impacted by the solution(s) ❑ Keep the end in mind and takes a holistic approach to DCT solutions ❑ Ensure the solution is fit for use for the patient population and does not require patients to have their own devices and hardware in order to participate?
An implementation plan has been created and followed through Trial Set-up and Launch	❑ Document the Study Build Plan and Launch Plan ❑ Collaboratively modify the plans as needed ❑ Ensure all stakeholders are aligned with the plan
Controlled delivery throughout Trial Conduct phase with suitable tracking and measures	❑ Document Roles/Responsibilities. ❑ Document how to measure performance and/or compliance (Patient, Site, Vendor). ❑ Track issues and trends, improvements
Trial Close requirements have been considered to allow for continual improvement.	❑ Analyse operational data to assess evidence of impact and define future improvements. ❑ Analyse site and patient survey data to understand experience and ID future improvements. ❑ Site survey / feedback process is built into the trial deployment plan, including questions on implementation / integration with other systems, ease of use, time to train, troubleshooting / helpdesk experience and NPS score.