DECENTRALISED TRIALS
BEST PRACTICE EVALUATION

Version 1
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The DTRA Best Practice Rubric

The DTRA Best Practices Evaluation Rubric provides a consistent framework by which DCT (Decentralised Clinical Trials) practices may be evaluated, in order to determine whether they may be considered a 'best practice'. Best practices will be organized across the trial lifecycle:

Programme Planning | Trial Planning | Trial Set-up| Trial Conduct| Trial Close Analysis

Best practices are not intended to be explicit instructions for use. Instead, practices will aid DCT stakeholders as they interpret and apply to their circumstances. The rubric dimensions are interrelated and need to be considered holistically.

To be considered a **"best practice"** all expectations of the rubric should be met.

BEST PRACTICE RUBRIC

1. EVIDENCE OF SUCCESS

Best practices should have measurable and demonstrable success. This dimension is intended to consider whether there is a track record of successful outcomes from the use of the practice, that can be examined. KPIs and tangible outcomes are at the heart of evaluating best practices for DCT.

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.

3. SITE IMPACT

Sites will have a continuing importance for DCT. The impact on sites should be considered with any new practice, including the practical implications of adoption and change from todays working practices to increasing DCT.

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.

5. REGULATORY & ETHICAL COMPLIANCE

Best practices should appropriately consider global & local regulations and guidance. In doing so they should also adhere to appropriate privacy, consent and sharing guidelines, protect those stakeholders providing sensitive or personal data with safeguards to ensure ethical safety and compliance for patients and care givers.

1. EVIDENCE OF SUCCESS

Best practices should have measurable and demonstrable success. This dimension is intended to consider whether there is a track record of successful outcomes from the use of the practice, that can be examined. An unambiguous demonstration of KPIs and tangible outcomes is at the heart of evaluating best practices for DCT.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
The appropriate 'level' of detail in alignment with DTRA expectations	Reference DTRA Best Practices evaluation form. A template 'best practice' has been documented, including the: ❑ Best practice in the form of a checklist questionnaire ❑ Additional context regarding the best practice (e.g. why should it be considered a best practice, what is the value to Sponsor / site / patients) ❑ Relevant case study in which the proposed best practice was used
Availability of case studies whereby the practice has been successfully demonstrated	How was success measured? ❑ Consider both qualitative and / or quantitative values that were captured from successful implementation of the proposed practice ❑ Consider size, relevance and future reuse of the selected case studies
Relevance to sponsors who are developing new treatments, digital therapeutics and devices	❑ Consider whether the scope of practices will be relevant to new drug development, rather than generics, etc.. ❑ Future recommendations may expand to include best practices for other organizations (e.g. sites, patients).
A breadth of applicability that is relevant to drug development across all study phases	❑ If proposed practices are overly specific to an individual phase, the relevance to the DTRA community will be diminished.

2. IMPROVING PATIENT EXPERIENCE

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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

3. SITE IMPACT

Sites will have a continuing importance for DCT. The impact on sites should be considered with any new practice, including the practical implications of adoption and change from today's working practices to increasing DCT.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
A net reduction in burden for both patients and sites	❑ Burden may increase in some areas and decrease in others. Capture the details of this change. ❑ Easy to use systems, single platforms and access across systems where possible. ❑ Reduce data entry redundances while supporting a single point of source documentation. ❑ Reduce CRO Site Management time, CRA time on site, time to issue resolution. ❑ increase risk-based monitoring without sacrificing patient safety or data integrity. ❑ Trigger corrective action to data queries, non-compliance, and issue identification early and resolve/re-train site quickly. ❑ Reduced sponsor contacts across studies and disciplines.
Strong site compliance with minimal training and support	❑ Technology should be simple to use, intuitive and require minimal training ❑ If training is necessary, then it should be available "on-demand" through the life of the study ❑ Technical support from Helpdesks and protocol support from CRAs in local language
High engagement and adoption levels across sites.	❑ Sites are not defaulting back to traditional methods ❑ Measure and demonstrate improved uptake of new processes with visibility of the patient flow ❑ Operational performance by Sites includes, but is not limited to, compliance with protocol, regulations, patient safety, data quality and data integrity ❑ Demonstrate the benefits of improved engagement (e.g. recruitment and retention) including site engagement and feedback around operational and feasibility
Improved site staff experience and understanding of the benefits	❑ Positive experience working on DCTs vs traditional clinical trials, demonstrated through feedback from stakeholders.
Clarity of the fiduciary responsibility to Sites for clinical trial work using DCT	❑ Site Budgets should account for additional resources required for sites to support DCT. ❑ Considerations may need to be made for referrals to/from PI where Primary Care Doctor refers a patient and/or where PI refers a patient to a virtual site if used. ❑ Payment considerations for example with regard to increase remote SIV, site management call or remote IMV/COV payments due to more SC time on calls.

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.

5. REGULATORY & ETHICAL COMPLIANCE

Best practices should appropriately consider global & local regulations and guidance. In doing so they should also adhere to appropriate privacy, consent and sharing guidelines, protect those stakeholders providing sensitive or personal data with safeguards to ensure ethical safety and compliance for patients and care givers.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
Local health authority vetting and acceptance compliance in the region where it will be utilized	Regulatory Resources: ❑ Global Regulatory Authority Websites by Region
Compliance with relevant Health Authority and International guidance and regulatory requirements	Aligns with all ICH guidelines with main focus on efficacy: ❑ ICH E6-Guideline For Good Clinical Practice ❑ ICH E8-General Considerations For Clinical Trials
Consideration and alignment with any applicable privacy laws	For example, check, verify and prove that the practice does not contravene security rules ❑ (e.g., HIPAA) ❑ Aligns with GDPR guidelines ❑ Aligns with relevant study protocols and subject safety
That it does not lead to additional burden to key stakeholders	Consider specific users ❑ any effect on efficiency or usefulness to the wider audience including but not limited to site staff, patient/subject, sponsor/CRO, ethics committees, vendors, etc.? ❑ Determine level of burden and whether it will lead to safety concerns, ❑ Consider inefficiencies preventing any of the listed group's ability to complete deliverables.