



### 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: <ul style="list-style-type: none"> <li><input type="checkbox"/> Best practice in the form of a checklist questionnaire</li> <li><input type="checkbox"/> Additional context regarding the best practice (e.g. why should it be considered a best practice, what is the value to Sponsor / site / patients)</li> <li><input type="checkbox"/> Relevant case study in which the proposed best practice was used</li> </ul>
Availability of case studies whereby the practice has been successfully demonstrated	How was success measured? <ul style="list-style-type: none"> <li><input type="checkbox"/> Consider both qualitative and / or quantitative values that were captured from successful implementation of the proposed practice</li> <li><input type="checkbox"/> Consider size, relevance and future reuse of the selected case studies</li> </ul>
Relevance to sponsors who are developing new treatments, digital therapeutics and devices	<ul style="list-style-type: none"> <li><input type="checkbox"/> Consider whether the scope of practices will be relevant to new drug development, rather than generics, etc..</li> <li><input type="checkbox"/> Future recommendations may expand to include best practices for other organizations (e.g. sites, patients).</li> </ul>
A breadth of applicability that is relevant to drug development across all study phases	<ul style="list-style-type: none"> <li><input type="checkbox"/> If proposed practices are overly specific to an individual phase, the relevance to the DTRA community will be diminished.</li> </ul>