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.