HSE proposed approach to the review of DPIAs for Regulated Clinical Trials or Investigations with Medical Devices involving multiple CT host sites.

Acronyms:

CT: Clinical Trial
CF: Consent Form
DPO: Data Protection Officer
DPIA: Data Protection Impact Assessment
NREC: National Research Ethics Committee
REC: Research Ethics Committee
PIL: Participant Information Leaflet

RESEARCH & DEVELOPMENT
TAIGHDE & FORBAIRT

Regulated Clinical Trial where Sponsor is Data Controller and the host sites may or may not be data controller for the CT (i.e commercially or academic sponsored clinical trial) and a DPIA is required

Scenario 1

WHO	WHAT	HOW	WHY
CT Sponsor supported by Clinical Trial National Lead *	Sponsor DPIA Template or National DPIA Template **	Sponsor completes DPIA for the Clinical Trial*	The CT sponsor will always be the controller (regardless of the role of host sites) and therefore takes the lead.
Sponsor DPO	Completed DPIA	Sponsor DPO reviews and annotates the DPIA	Providing access via a cloud facility enables sharing of feedback and reduces duplication of effort.
CT Sponsor	Annotated DPIA, PIL and CFs	Submission to DPOs of CT participating sites via a cloud based platform (ie Teams)	DPOs from the participating sites are given the opportunity to review the CT DPIA before NREC review
DPOs of CT Participating sites	Annotated DPIA, PIL and CFs	Review and provide feedback **on the same document** WITHIN 2 WEEKS (10 WORKING DAYS) ***	
CT Sponsor	Feedback from DPOS of CT participating sites	Feedback is considered and amendments to Protocol, PIL or CF made before submission to NREC	This **approach will avoid the need for subsequent amendments** to DPIA and to the NREC application.
CT Sponsor	DPIA annotated by all DPOs + NREC applic.	Submission to NREC	

* Sponsor should make themselves aware of requirements of participating sites in order to include them in the first draft. The CT National Lead (person responsible for the overall trial in Ireland) should support the process
** Currently in development
***The CT National Lead is the designated person to liaise with the local DPOs to answer any questions