

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

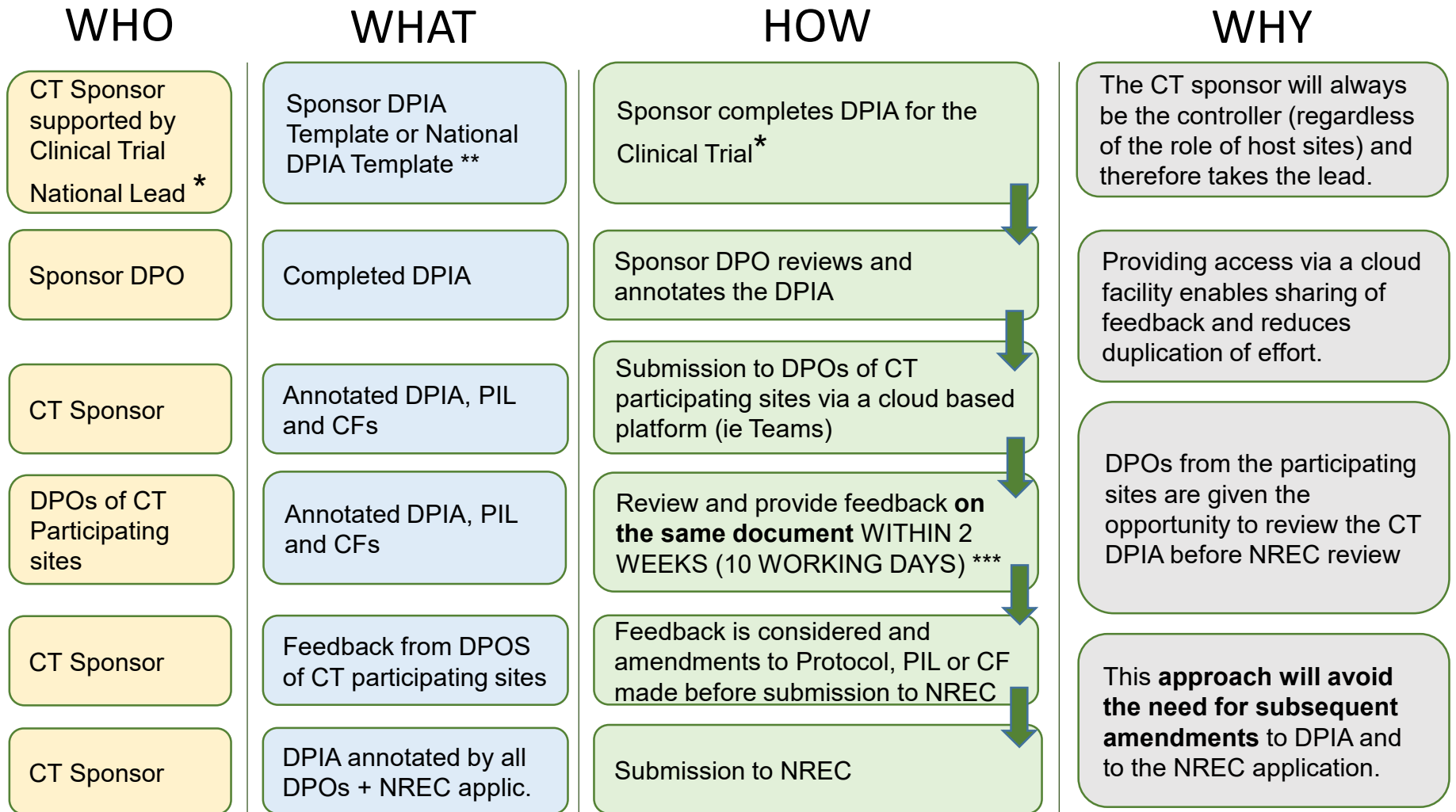
DPO: Data Protection Officer

DPIA: Data Protection Impact Assessment

NREC: National Research Ethics Committee

REC: Research Ethics Committee

PIL: Participant Information Leaflet



* 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

