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| Text  Description automatically generated | Explanatory note for the  20.05.24  Tripartite CRO model Clinical Trial Agreement  for use in all interventional clinical trials in Ireland |

1. The tripartite model Clinical Trial Agreement (CTA) is mandatory and effective from 20.05.24 for tripartite engagements involving a Commercial Sponsor, Contract Research Organisation (CRO) and Hospital(s). However, where negotiations commenced before 20.05.24, the CTA that is already the subject of the negotiations may continue to be used for that specific clinical trial.
2. There are now two approved HSE and IPHA agreed Clinical Trial Agreement Templates: 1) a bipartite one where the clinical trial involves a Commercial Sponsor and a Hospital(s) and 2) the aforementioned tripartite one where the clinical trial involves a Commercial Sponsor, CRO and a Hospital(s). Both CTAs are available at <https://hseresearch.ie/clinical-trials-2/#HSE-approved-Clinical-Trial-Agreement-Templates>
3. The CRO-mCTA is standardised and therefore changes to the standard text in the document are not permissible.

**BACKGROUND**

1. The originator pharmaceutical industry wishes to improve Ireland’s clinical trial footprint. Including patients in clinical trials is critical in developing new innovative treatments and ultimately in improving the nation’s health.
2. There is clear published evidence that by including patients in clinical trials their health will improve substantially. Further, we are of the view that Ireland can play a leading role in the provision of clinical trials in Europe. There is no doubt that Ireland’s decision to join the European Clinical Research Infrastructure Network has the potential to widen our access to clinical research networks in Europe.
3. There are practical steps we can take here at home to speed up and improve our performance in relation to clinical trials. These include the use of a standardised site contract for clinical trials (the CTA) that is convention in a number of other EU countries.
4. Until now, there have been various slightly different CTAs that our members have agreed with the hospitals and other institutions. However, there were numerous versions of those CTAs, each of which underwent review, incurring significant costs and seriously delaying the trial start. Provision of a single standard CTA for Ireland will reduce delays in hospitals, reduce costs for hospitals and companies, increase efficiencies, enable more trials to set up on time in Ireland and thus, importantly and ultimately, improve patient outcomes.
5. To that end HSE and IPHA have agreed a standard (model) CRO CTA for use between the Site, the CRO and the Sponsor. The HSE and IPHA CRO model CTA (CRO-mCTA) has been reviewed extensively  by a subgroup of CROs, IPHA member companies, the HSE and other stakeholders dedicated to developing a fair and balanced standardised document. The key to the success of the new CRO-mCTA is that it is standard and it is the standardisation itself that will speed up the process by reducing the number of rounds of discussion and review for this contract. This will in turn reduce the administrative and financial burden for the hospitals, CROs and companies. However, critically it will reduce the time taken to start up clinical trials in Ireland thus improving clinical trial competitiveness and most importantly improving individual patient health.