



**Irish Pharmaceutical
Healthcare Association**

**Explanatory note V2 for the
8th Nov 2022
model Clinical Trial Agreement
for use in all interventional clinical trials in Ireland**

1. The model Clinical Trial Agreement (mCTA) is mandatory and effective from 11.11.22 for CTAs that have not yet been circulated between Sponsors and Hospitals. However, where CTA negotiations have commenced then the CTA that is the subject of the negotiations may continue to be used in the clinical trial.
2. Standard Contractual Clauses (SCC)¹ safeguard the transfer of data to countries of non-adequacy. Where these are required it is suggested that the clauses are included as an appendix to the mCTA or if the mCTA has been executed then to implement it as a separate Data Transfer Agreement. We have templated the SCCs (with model data transfer descriptions) for the purposes of an appendix or to sign as a standalone DTA for controller-to-controller transfer.
3. The mCTA is standardised and therefore changes to the standard text in the document are not permissible.
4. In the event that the clinical trial is being supported by a University Clinical Research Centre or Clinical Research Facility, a tripartite agreement should be put in place to set out the roles and responsibilities of each party. This tripartite agreement should be largely based on the HSE.IPHA mCTA to expedite contract review and approval.

BACKGROUND

- A. 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.
- B. 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.
- C. 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 CTA²) that is convention in a number of other EU countries.
- D. Until now, there have been various slightly different CTAs that our members have agreed with the hospitals and other institutions. However, there were endless versions of those CTAs, each of which underwent review, costing money 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.
- E. To that end IPHA and the HSE have created a standard (model) CTA for use between the Site and the Sponsor. The IPHA.HSE model CTA (mCTA) has been reviewed extensively to develop a fair and balanced standardised document. The key to the success of the new 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 both the hospitals and members. 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.

¹ Standard contractual clauses for data transfers between EU and non-EU countries (see <https://ec.europa.eu/info/law/law-topic/data-protection/publications/standard-contractual-clauses-controllers-and-processors>)

² This is a Bipartite contract intended to formalise the agreement between the Clinical Trial Site and the Sponsor, thus only the site signature and Sponsor signature is required for this document.