PINK SHEET
CITELINE REGULATORY

29 Aug 2024 | **News**

Ireland Steps Up Efforts To Boost Clinical Trial Performance By Standardizing CTAs

by Ian Schofield

Standard templates for clinical trial agreements are expected to help do away with the costs and delays arising from the use of different versions in Ireland.

Ireland's Health Service Executive says that a new four-way model template for clinical trial agreements (CTAs) is being prepared as part of a drive to improve the country's performance in the clinical trials arena.

"Work has commenced on the creation of a model CTA for quadripartite engagements involving a commercial sponsor, contract research organization (CRO), academic partner and hospital(s) and we hope to be in a position to release this template shortly," the HSE said.

The new template, which is being developed in collaboration with the pharma industry body, the Irish Pharmaceutical Healthcare Association (IPHA), will add to the existing bipartite and tripartite templates.

The tripartite model CTA took effect on 20 May this year, and is mandatory for trials involving a commercial sponsor, a CRO and one or more hospitals where contract negotiations begin after that date. However, if negotiations began before 20 May, "the CTA that is already the subject of the negotiations may continue to be used for that specific clinical trial," the HSE noted.

Key Takeaways

- Ireland needs to boost its performance in the area of clinical trials after a report showed it was attracting fewer trials than some comparable European countries.

PINK SHEET
CITELINE REGULATORY

The bipartite CTA, involving the commercial sponsor and a hospital, took effect on 23 August (with the same caveat about negotiations already underway).

According to a *report* published by IPHA in May, Ireland is attracting fewer clinical trials than some European countries with similar populations and economic performances, including Finland and Denmark.

- The existence of several different versions of clinical trial agreements has led to higher costs and delays to trial initiation.
- Using a set of standard CTAs is expected to contribute to the efficient setting up of new trials.

Of 2,411 interventional clinical trials carried out in the three countries across the 10 years from 2014 to 2023, "19% were conducted in Ireland (460) compared to 27% in Finland (661) and 54% in Denmark (1,290)," the report said.

IPHA sees standardized CTAs for trials involving CROs as one way of improving the situation – something that is already common practice in a number of other EU countries.

"Until now, there have been various slightly different versions of those CRO CTAs, each of which underwent review, costing hospitals money and delaying clinical trial start-up," the association said when the tripartite CTA took effect.

IPHA works with the HSE in creating the model CTAs, "with both organizations ensuring that the templates are fit for purpose," Rebecca Cramp, Director of Code & Regulatory Affairs at IPHA, told the *Pink Sheet*. "Having a standard template saves legal costs, saves time and thus ensures that administrative delays do not prevent our patients having access to sometimes lifesaving clinical trials."

Moves to speed up the initiation of certain trials are under way in the UK, where during the summer the Health Research Authority put out for consultation a draft contract template that is being developed to help commercial and non-commercial organizations set up investigator-initiated CTAs more easily. (Also see "*Model Contract To Expedite UK Clinical Trial Negotiations Between Non-Commercial Sponsors & Companies*" - Pink Sheet, 8 Apr, 2024.)