one nucleus insights

Clinical Trials: Minimising Liability and Maximising Intellectual Property

On 14 April 2016 One Nucleus and Penningtons Manches organised a breakfast discussion on the topic of Clinical Trials: Minimising Liability and Maximising Intellectual Property.

The breakfast had good representation from the drug development value chain including an academic, a drug discovery company, a CRO, an insurance specialist and a regulatory specialist which led to interesting discussions and wide coverage of the topic.

The slides are available **here** for more details and please find below a summary of the main points addressed.

The Clinical Trials Framework and Key Issues

A contractual agreement in the context of clinical trials is generally between a sponsor and the other stakeholders i.e: trial site and investigator or could be through a contract research organisation (CRO) who will be the one contracting with them. The trial design is the sponsor's responsibility and principal investigator(s) are responsible for following procedures and protocols.

The benefits of using a CRO are usually that they already have contracts in place with sites and contacts with key opinion leaders which can be helpful especially in the case of multi-jurisdictional trials.

Whichever model is chosen it is important to have all the contracts between the different parties in place at the beginning and to ensure they are consistent especially regarding liability.

In the UK, in order to ensure consistency, the NHS, ABPI and BIA issued a Model Clinical Trials Agreement (MCTA) designed to be used 'off the shelf' for NHS trials. They are currently being reviewed to be updated especially relating to data transparency (bribery, healthcare professionals payments etc).

Some key points to take into consideration when setting-up clinical trial agreements are:

- Intellectual Property Rights: The UK position is that they belong to the person who created the IP or their employer. But it could be different if different jurisdictions are involved or compromise could be agreed e.g. with joint invention. NB: certain countries give the inventor first rights to the invention, so specific drafting is needed to comply with local legislation

- Data: the data is owned by sponsors but sponsors and CROs have an obligation to publish clinical trial summary results. Data publication could still be slightly inconsistent as it is not in the industry culture (the wrongful publication of confidential clinical trial data used to be a criminal offence in the UK). But it is improving and there is even a push in favour of pushing for the publication of failed trials.

The Case for Combination Trials

It is now more and more common to see combination trial agreements where two sponsors (two companies or a company and a 'not for profit') try a combination therapy. They aim to investigate an increased therapeutic efficacy compared to a monotherapy approach. Usually one sponsor funds and runs the trial and the other provides an investigational medical product at no cost. Know-how, IP rights (other than those which solely relate to each sponsor's drug) and data developed are likely to be jointly owned unless negotiated otherwise.

Liability

The EU Clinical trials Directive requires all clinical trials to have made provision for insurance or an indemnity to cover the liability of the Investigator and the Sponsor in relation to the trial.

Everyone has a potential for liability: the sponsor - for information provided to the CRO; the site/investigator - for medical acts during the subject's stay at the site; and even subject for lack of disclosure but this last point isn't directly covered in the regulation.
What is required is to provide a mechanism in the contracts to address every parties' liability if anything goes wrong.

It could be difficult for a trial subject to prove the damage caused by a study under general law, so guidelines (**see ABPI guidelines**) are followed by the industry. They recommend a 'no fault' compensation basis and apply some restrictions depending on trials phases.

Suppliers into clinical trials (i.e. the sponsor's sub-contractors), tend to use 'off the shelf' liability clauses in contracts with few variations. The tendency is for such suppliers to limit their liability to the sum of money involved in that particular sub-contract. A failure of one supplier, however, could require the full re-run of the trial so the impact on the Sponsor for the failure of a sub-contract supplier could be many times the value of that particular contract. So the recommendation is to consider all consequences of a failure and, instead of limiting liability to the value of any one contract, it should be linked to facts and the description of potential consequences.

The question of insurance flows from the Directive, which requires provision for insurance or an indemnity. On the strict reading of those words, there is no insurance obligation, but in practice, a trial would only exceptionally be allowed to proceed without insurance. It is important to check the standard policy wording the insurer may provide as they may exclude the very liability you want to insure (e.g. 'an exclusion that the policy would not cover patients with terminal conditions' would invalidate the whole policy for a phase III cancer drug). So it is very important to check policy terms, especially as they tend to come at the end of the contract negotiation process.

EU Clinical Trials Regulation

Currently under a directive, clinical trials in the EEA will be covered under a regulation probably not in force before 2018. The regulation will have direct effect in all member states, with the intention of bringing greater harmony to clinical trials throughout the EU. However, some matters are still left to individual state discretion, so do still expect variation.

The new law will have consequences in the centralisation of information, data transparency and application processes.

We mention this new Regulation because of the implications it will have in clinical trials framework contracts that may be begun before the Regulation, but complete after it is in force, but the topic could be a discussion in its own right in due course.

More information can be found in the presentation **here** and please watch out for this as a future topic of discussion at a One Nucleus event

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