Sub-contracting – the odd one out

Sub-contracting in clinical trials proves to have privileges in comparison to other projects. In Horizon 2020 projects, core activities cannot be sub-contracted. When it comes to peripheral activities, although it is possible to assign work to sub-contractors (while ensuring “best value for money”), it is still known to be frowned upon by the EC. The rationale behind this is rather simple – the official beneficiaries are responsible and liable to their own financial management vis-à-vis the EC via a contractual relationship (the Grant Agreement). But when it comes to sub-contractors the situation is different: The EC does not have a direct contractual relationship with them, hence limited ability to monitor their performance. Therefore, in most areas of Horizon 2020 it is highly recommended to avoid or reduce the work delegated to sub-contractors.

Sub-contracting in Clinical Trials is different

The nature of clinical trials forces, to some extent, the utilization of sub-contracting in such projects, in core activities as well as peripheral ones.

The reason for this is two-fold:

- **Patient recruitment flexibility** – It is not always possible to know where the actual patients will be recruited for the clinical trial. This is more prevalent in rare diseases or when having highly stringent inclusion/exclusion criteria. In such cases it can be pointless to assign specific medical centers as beneficiaries to the grant agreement, as we cannot know ahead to what extent each medical center will be successful in recruiting patients. Alternatively, and in line with the common practice of sponsored-funded clinical trials, the right thing to do is to pay the medical

centers on a ‘per-patient’ basis. In Horizon 2020 the only mechanism that allows such payment structure is sub-contracting.

- **CRO are usually for-profit organisations** – The Contract Research Organisations (CROs) provide various services (statistical, monitoring, etc.) to the pharma industry, carrying relatively high profit margins, and usually they do not have a direct interest in the research itself, in contrast to the sponsor and the clinical partners. The limitations associated with the financial management of Horizon 2020 beneficiaries (the ‘no-profit’ rule, the fixed allowed indirect costs, etc.), may drive CROs away from participating in such projects as direct beneficiaries. The only way to bypass these limitations and allow the CROs to provide their services under their terms is via sub-contracting.

The EC has realized that in order to attract excellent clinical trials to the programme, it has to comply with some of the industrial standards in this context. For this reason it has chosen to enable a privileged sub-contracting policy in clinical trials.

Implementing sub-contracting in clinical trials

If the clinical trial is the **main activity** (“core task”) of the project, then we are able to sub-contract only certain parts of the project, such as ethical approvals, GMP production, auditing, monitoring and to some extent patient recruitment. Note that in this case, where the clinical trial is the main activity of the project, we cannot sub-contract the entire clinical trial.

However, if the clinical trial is **not the main activity** (“core task”) of the project, and can be considered as secondary or minor part of the project, then it is possible to sub-contract it **entirely** (or partially, of course).

This enables us to have more flexibility when structuring the clinical trial in Horizon 2020.

Learn more about possible consortium structures for clinical trials in Horizon 2020.