



Additional notes on EDCTP grant agreements

Sponsor/Contractor relationship and responsibilities

EDCTP requires from its grantees the application of the ICH Guidelines for Good Clinical Practice (GCP). These guidelines provide that the sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written Standard Operating Procedures (SOPs) to ensure that trials are conducted and data are generated, recorded, and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s) (see article 5.1.1). This means that a sponsor needs to have an independent position towards the “Contractor” (as defined in the EDCTP Grant Agreements), without any (chance for a) conflict of interest. To satisfy this requirement in case the “Contractor” is the same legal entity as the sponsor, EDCTP follows the policy that two different departments within this legal entity execute the sponsor’s and the Contractor’s role.

Moreover, the ICH GCP provides that the financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution (read: the Contractor; see article 4.9.6), and that the sponsor is responsible for selecting the investigator(s) institution(s) (see article 5.6.1). However, in practice it is EDCTP that selects a number of investigators institutions under each of its programmes on clinical trials and contributes financially to the projects proposed by these investigators’ institutions. To make clear that nevertheless EDCTP has no intention to interfere with the rules of the ICH GCP, EDCTP negotiates only with these investigators’ institutions, and not with the sponsor. As for the sponsor, EDCTP limits itself to asking a written declaration that the institution concerned indeed will fulfill its sponsor’s role. Where the sponsor’s organisation is the Contractor’s organisation, EDCTP requires that a similar declaration is also provided to define the relationship and roles performed as sponsor and Contractor. This declaration has to be signed not only by the authority of the legal entity, but also by the authority of the department of the legal entity that executes the role of sponsor.

Insurance arrangements

Article 5.8.1 of the ICH GCP provides: “If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence”. This means that where the applicable regulatory requirements do not include such a requirement, the sponsor may lay (a considerable part of) the burden of those claims on the shoulders of the investigator/institution. As is well known, the highest risks of clinical trials cannot be covered by insurance. Even where the sponsor has concluded insurances for those claims, the investigator/institution will be liable for the claims surmounting the maximum insurance amount. Therefore the investigator/institution should check the applicable regulatory requirements, and if these ones do not mention any requirements on this subject, they should arrange with the sponsor that those claims come fully for the responsibility of the sponsor.

Intellectual Property Rights

Normally the sponsor claims the ownership of the trial data. Moreover the sponsor is, according to ICH GCP, responsible for supplying the investigators/institutions (the “Contractor”) with the investigational product(s) (see article 5.14.1 of ICH GCP). That means that the sponsor often concludes a (confidential) deal with the producer of the investigational product about the exploitation of the investigational product



and the trial data. The Contractor has to be aware of this fact. He needs to ask the sponsor about the contracts concluded on this subject by the sponsor with third parties, under which particularly the producer of the investigational product(s). Moreover the Contractor has to arrange with the sponsor before starting the trial that the intellectual property rights on the data and investigational product(s) do not prevent the use of these data and product(s) for the objectives of EDCTP in particular, as formulated under the article of the Grant Agreement with the Contractor that arranges the Intellectual Property.

Knowledge Management

The project to be executed (by you) will be financed by EDCTP in the first place to obtain the results as described in the approved proposal. However, the project may in addition generate improved practices, such as a superior laboratory technique, a more effective enquiry list, an investigational product with positive unexpected results. We encourage you to correctly manage any new findings resulting from the project and eventually translate the results to make these available for the general public.

Environmental responsibilities

The European Union requires sufficient action from anyone directly or indirectly receiving EU funds to prevent contamination of the environment. Because EDCTP is a EU funded organisation all our grantees must undertake sufficient steps to conserve the environment. During and after the conduct of the Project and report to EDCTP on how this has been achieved.