Guidance document - Template Clinical Trial Agreement 2025

Introduction

This document provides some guidance to the template clinical trial agreement for industry initiated and sponsored clinical trials with medicinal products as revised in 2025.

Since 2013 (revised in 2016 and 2025) there has been a template agreement in the Netherlands for clinical trials, which is initiated and sponsored by the pharmaceutical industry. The template facilitates conducting clinical trials in the Netherlands. It makes it easier to start clinical research more quickly, and therefore new medicinal products and treatment methods may become available to patients sooner. The template agreement includes all rights and obligations of the parties involved in research in hospitals funded by pharmaceutical companies in compliance with the guidelines, rules and regulations applicable in the Netherlands.

The template clinical trial agreement has been created in joint cooperation between the Nationale Federatie van Universitair Medische Centra (NFU), the vereniging Samenwerkende Topklinische opleidingsZiekenhuizen (STZ), Vereniging Innovatieve Geneesmiddelen (previously Nefarma), Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis (NKI/AvL), Prinses Máxima Centrum voor Kinderoncologie (Máxima), the Associatie van Contract Research Organisaties in Nederland (ACRON). This multi-stakeholder cooperation is initiated by the Dutch Clinical Research Foundaton (DCRF).

The template can **only** be modified as agreed upon between the Parties for example for accommodating the correct party structure, study-specific requirements, financial arrangements or any other terms and conditions which are relevant for the purpose of the collaboration. During the negotiations, any modifications should be marked and explained. The final modifications will be included in a annex of modification.

This guidance document is not meant a part of the template for the clinical trial agreement. Should there be any inconsistency between template clinical trial agreement and this guidance document, the template clinical trial agreement shall prevail.

Version

There a two versions of the template and is related to the different roles the Sponsor can assign to the CRO. The most common roles of Sponsor and its CRO are include in version A. In version B others roles are included as options. Based on the agreement between Sponsor and CRO the appropriate version will be used.

Main revision 2025

A new clause 8 regarding the data protection as been included. This new clauses incorporates the obligations of the General Data Protection Regulation (GDPR). Therefore,

the previous clause 8 on data protection and confidential information has been split in clauses 8 and 9 while the subsequent clauses have been renumbered.

Also, clause 10 on intellectual property, clause 11 on publicity and clause 12 on publication and authorship have been revised in more detail.

In addition, all other clauses have been checked and revised to resolve issues in daily practice as raised by the stakeholders involved.

Clause 8 – Data Protection

Controller, joint-controller, processor

Under the GDPR the actual processing activities are decisive in the GDPR-role (i.e., controller, joint-controller or processor) of a natural or legal person. The controller is the entity which alone or jointly with others determines the purposes and means of the processing of personal data. A processor is the entity which processes personal data on behalf of the controller. This needs to be assessed for specific processing activities. An entity cannot be considered to be a controller in the context of operations that precede or are subsequent in the overall chain of processing for which that entity does not determine either the purposes or the means.

As a consequence, it cannot be determined in the template clinical trial agreement what GDPR-role each entity has in any possible processing activity in the context of the agreement. Therefore, the template does not include a standard clause on who is controller, joint-controller, or processor in regard to the full Agreement, but specifies in Annex 9 the specific details relating to the personal data subject to processing activities under the agreement.

However, if one of the Parties in advance would be deemed processor, the parties will enter into a Data Processing Agreement according to article 28 GDPR.

Also ensure that the wording with respect to the roles of Parties in the PIF-ICF is aligned with the roles **to the extent outlined** in the Agreement.

Provision 8.20

As transfer of Personal Data outside the European Economic Area (EEA) may occur, clause 8.20 points out that such transfer must occur in accordance with the requirements of Chapter V GDPR. This means that the Parties must first verify if there is i) an adequacy decision pursuant to Article 45(3), or ii) derogation under Article 49 GDPR applicable. **In absence of** any other valid protection mechanism as listed under Chapter V of the GDPR **and** Institution needs to transfer the Personal Data outside the EEA as a data exporter, Sponsor ensures that there is an appropriate safeguard pursuant to Article 46 GDPR, **such as** Standard Contractual Clauses (SCC). In case Sponsor is located within the EEA and exports

Personal Data outside the EEA, it is Sponsor's responsibility to comply with Chapter V GDPR and confirm such compliance towards Institution upon request.
An SCC is usually included as an annex to an agreement (there is no separate agreement).

Furthermore, in 2021 SCC modules were revised by the EC, which allows for more flexibility within the standard contracts: among other things by means of a so-called 'docking clause'. Where the old SCCs were agreements between 2 parties, it is now possible on the basis of this docking clause for a new party (with the consent of both parties) to join the new SCCs.

For more information on this topic:
https://www.autoriteitpersoonsgegevens.nl/en/themes/international/transfer-within-and-outside-the-eea/personal-data-transfers-outside-the-eea

Provisions 8.24 and 8.25

The processing of Personal Data of Research Staff needs to be based on a legal basis in article 6 of the GDPR. The legal basis may be consent or any of the other legal bases. Various processing activities may be based on other legal bases than consent, such as compliance with a legal obligation (art. 6 (1)(c) GDPR), or the legitimate interests pursued by the controller (art. 6 (1)(f) GDPR).

It should be noted that 'consent' may not be the preferred legal basis. It is not practical to obtain consent and consent may be withdrawn at any time. Moreover, it is undesirable to request for consent if the processing can be based on another legal basis as well.

If, and as far as, consent constitutes the legal basis for processing Personal Data of the Research Staff, the clinical trial agreement determines as a clear principle that it is the responsibility of the Sponsor to obtain the consent of the Research Staff participating in the Clinical Trial. Sponsors are strongly encouraged to use the Clinical Trial delegation log to collect the consent.

While acknowledging the responsibility of the Sponsor to obtain consent from the Research Staff, both the Sponsor and the representatives of the Institution are encouraged to take a practical approach and to provide mutual assistance to facilitate the consent process. For example, a Sponsor's request to the Institution to assist in obtaining a signed form from someone who is on annual leave would be reasonable. A failure to obtain consent in a timely manner can result in delays to the start of a clinical trial.

Regardless of the legal bases the Research Staff as data subjects under the GDPR need to be informed – in accordance with article 13 and 14 GDPR – about the processing of their personal data. The Research Staff may be informed by providing a notice.

Clause 10 - Intellectual property

Four core principles underlie the template clinical trial agreement intellectual property (IP) clauses. First, each party retains ownership of any pre-existing IP or Know How owned by it or licensed to it.

Second, any IP or Know How generated at the Institution that directly relates to the Clinical Trial, Confidential Information of the Sponsor the Protocol (excluding any clinical procedure or related improvements), and/or the Investigational Medicinal Product (as far as directly/related to the Clinical Trial and/or Protocol), is the property of the Sponsor.

Third, clinical procedures and related improvements are the property of the Institution.

Four, the Institution also has the right to use Know How gained during the trial in its normal clinical work, provided it does not result in disclosure of the Sponsor's Confidential Information.

Example 1: If an investigator, supplied with information in the investigator brochure about the characteristics of a new drug, identified a possible role for the drug in a different disease, or a potentially more effective combination with a second drug, the rights to that IP would vest with the Sponsor.

Example 2: If a Protocol specified that a certain type of CT scan should be taken, and while analysing the scan, an employee at the Trial Site developed a new method of analysing CT scans, the rights to that IP would vest with the Institution.

Example 3: A Sponsor supplies a CRF for use by an investigator for the Clinical Trial. In the course of carrying out the Sponsor's Clinical Trial, the investigator develops, for her own convenience and without being requested to or paid to by the Sponsor, a novel database on which to manage the trial subject data. The rights to that IP would vest with the Institution.

The terms of the template clinical trial agreement do not give the Sponsor rights to all IP generated by employees at the Institution either in the course of the Clinical Trial or in the field of the Clinical Trial.