REQUIREMENTS FOR THE REQUEST FOR EVALUATION OF RELEVANT MODIFICATION OF CLINICAL TRIAL AT THE DOCE OF OCTOBER HOSPITAL

In the trials in which we are an evaluating committee (CEIm), we comply with the requirements described in the Instructions Document of the Spanish Agency for Medicines and Health Products (AEMPS) for the conduct of clinical trials, available on the AEMPS website. . However, some clarifications are presented here regarding the documents to be presented. They can be presented on any day of the month, and will be evaluated at the next meeting established in the calendar, provided that the documentation is received at least 10 days before the meeting in which it is to be evaluated. The application must be submitted through the ECM Portal at the same time (first to the CEIm and immediately afterwards to the AEMPS).

Given that the same substantial modification can make reference to many changes of different importance within the authorized clinical trial, the most important thing in view of its evaluation is that these changes are shown in a summarized and simple manner.

Documents common to both parties:

1. The cover letter shall indicate whether the amendment relates only to part I, only to part II or to both parts.
2. Section F is not enough for the presentation of the amendment.
3. Summary and justification of the changes. No more than 1200 words and must be complemented with a Table of changes.

Applications that do not include the document "Summary and justification of the changes" that clearly explain the changes and the reasons for the modification and consequences thereof or lack modified documents with the trace of changes and justification thereof or failing of a table of changes will not be accepted as valid. When the information required in the "Summary and justification of the changes" is included in another document, this will be stated in the cover letter

Modifications that only affect Part I

These modifications must be notified to the CEIm and the AEMPs. This includes modifications to the Investigator's Manual (Investigator Brochure, IB) or Protocol that do not affect the Patient Information Sheet and Informed Consent . All modified documents with control and justification of the changes that have been explained in the document "Summary and justification of the changes". All documents must be versioned. What applies in each case:

1. New version of the IB with change control and clean version together with an IB Change Table.

2. New version of the Protocol with change control and clean together with a Table of changes of the Protocol

3. Protocol summary with change control and clean

Modifications that affect Part I and II

These modifications must be notified to the CEIm and the AEMPs. This includes relevant modifications in the IB / Protocol with changes in Patient Information Sheets. The documents in the previous section must be provided in addition to: All the Patient Information Sheets affected by the modification with tracked changes.

Modifications that only affect part II

These modifications should only be notified to the CEIm. Within these there are many possibilities; the most common ones are included here:

1. Change of IP
    a. Insurance policy updated
    b. CV of the new PI where there is training in good clinical practices and declaration of interests.
    c. Researchers Suitability Document signed by the Promoter (Annex III of the AEMPs)
2. Expansion of centers
    a. Insurance policy updated
    b. CV of the new IP where there is training in good clinical practices and declaration of interests.
    c. Researchers Suitability Document signed by the Promoter (Annex III of the AEMPs)
    d. Facilities Suitability Document (Annex IV of the AEMPs)
3. Changes in Patient Information Sheets: All documents affected by the modification with tracked changes and version.

Other documents: economic report, recruitment material, updated insurance policies, must be submitted in a version and indicated in the Letter of Presentation.

Involved

In the case of tests in which it is not evaluated, it will only be necessary to inform about those modifications that affect our center, that is, change of IP. In these cases it will be necessary to send to stecnicacei@h12o.es the documents indicated in the previous section in addition to the approval of the CEIm of the relevant modification.

* The opinion of the CEIm evaluator and the resolution of the AEMPs will be sent as soon as they are available for saving in the study file

IN BOTH CASES, whether or not we are CEIm:

The clinical trial contract will be processed and signed in parallel with the request for evaluation by the CEIm and the AEMPS, and for this they must contact the Contracts Management Area of the Foundation.

Contact: **ensayos.hdoc@salud.madrid.org**

Payment will be made for Clinical Trial processing. **Contact:** **facturacion.hdoc@salud.madrid.org**