REQUIREMENTS FOR THE STUDIES FOLLOW-UP TO BE SUBMITTED BY THE SPONSOR TO CEIM

For research projects, clinical trials and others, of which the CEIm is an evaluating committee, the promoter has the obligation to send the following documents, each within the period established by the national regulations:

1. Annual monitoring report.
2. SUSARs (Suspected of serious and unexpected adverse reactions)
3. Annual safety report (DSUR)
4. Ad Hoc Report on urgent safety measures / substantial modifications
5. Intermediate reports
6. Deviations (serious breaches of the protocol)

1. Is it necessary to send an annual follow-up report?

It is required. The annual report aims to facilitate the tasks of monitoring the trial. It must be submitted annually from the start date of the trial and until the end date of the trial in Spain. The data regarding the number of participants in the trial will be accumulative; and annual data will be presented regarding serious breaches, withdrawals and withdrawals and corrective measures taken. In the case of clinical trials with medicines and medical devices, a model is available on the AEMPs website: https://www.aemps.gob.es/investigacionClinica/medicamentos/anexos-instrucciones-AEMPS-realiza-EC.html

In the rest of studies, these reports will be made in a free format, according to the criteria of the promoter or his representatives.

It will be presented to the CEIm by email to the following address: sarahivaldez.imas12@h12o.es

2. Should CEIm be notified of serious and unexpected adverse reactions?

No. Suspicions of serious and unexpected adverse reactions should be reported to the AEMPS but not to the CEIm. In all cases, whether the adverse reaction has occurred in Spain or has occurred in another country, the notification should be made only through Eudravigilance_CTM.

From the Technical Office we leave it to the promoter's discretion whether or not to notify SUSARs, if notified, it will be filed in the corresponding study folder and in our database.

3. The DSUR will be sent to the CEIm through the ECM Portal as a report on the progress of the trial.

- When a DSUR refers to a drug referred as clinical research product (PEI), a single and simultaneous application may be sent for all the trials related to that product.
- When a clinical trial is linked to more than one product, the corresponding DSUR must be sent to each product in a separate application, as indicated in the previous paragraph.
- When a DSUR linked to several clinical trials refers to drugs that are not investigational products, a request should be sent for each trial.

4. How to present urgent safety measures including stoppages / temporary interruptions of a clinical trial

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It will be done through these two models:

- Ad hoc report or initial notification of urgent safety measures already adopted (when these measures do not involve a substantial change that affects any of the trial documents (protocol, investigator's brochure…) and when the measures adopted imply substantial changes but at the time of making the communication, the necessary documents to request the substantial modification are still not available.
- Substantial modification: refers to urgent security measures already adopted that imply a temporary stoppage of the trial or to notify an urgent stoppage of the trial.

5. Interim Reports

When in a clinical trial it is expected that there will be several results analysis carried out at different times (efficacy and safety), it is necessary that these results are communicated to the CEIm in a period of not less than one year after the completion of this analysis.

6. Serious breaches

The promoter must communicate the serious breaches to the CEIm without delay and within a maximum period of seven days from the date on which it became aware of the breach. The communication of serious breaches of the CEIm will be made by email to the following address: sarahivaldez.imas12@h12o.es

The promoter must notify CEIm of the following dates of the trial:

1. The start date of the trial in Spain.
2. The date of the first visit of the first subject included in Spain.
3. The end date of recruitment in Spain.
4. The end date of the trial in Spain
5. The global end date.
6. The sponsor must send a copy of the summary of results published in EudraCT no later than one year after the end date of the trial.

References:

1. Royal Decree 1090/2015, of December 4, which regulates clinical trials with medicines, the Ethics Committee for Research with medicinal products and the Spanish Registry of Clinical Studies. http://www.boe.es/diario_boe/txt.php?id=BOE-A-2015-14082
2. Documento de instrucciones de la Agencia Española de Medicamentos y Productos Sanitarios para la realización de ensayos clínicos en España. https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/Ins trucciones-realizacion-ensayos-clinicos.pdf