NOTIFICATIONS THAT SHOULD NOT BE SENT TO THE CEIm

The following notifications should not be sent to the CEIm and will not be accepted:

- **Non-relevant amendments** for clinical trials.
- **Changing a centre monitor or responsible party at the study sponsor or CRO** if it does not imply a change of the contact person with our CEIm.
- **Technical sheet or prospectus updates.**
- **Researcher Handbook Updates:** Non-relevant changes. An annex to the next DSUR may be sent.
- **Security reports for periods shorter than a year** (quarterly/semester, etc.)
- **List of SUSARs** (quarterly/biannually/yearly): Must be included in the Development safety update report or DSUR.
- **SUSARs** from other countries and from those in Spain when the result is not death.
- **SAE Reporting form for medical devices** not related to the medical device under study and those that occur in other countries.
- **Changes in protocols** due to review by external data review committees.
- **International amendments not applicable to Spain** even as a notification.
- **Product Quality Notifications if they have not involved a safety modification or problem** affecting study patients.
- **Notifications addressed to researchers** such as DILs, note to files for the researcher's file, clarifying letters for the protocol or memos.
- **Material for the patient that does not correspond to part II of the trial** (such as patient card, questionnaires, etc.).
- **Test materials that do not correspond to part I or II of the trial** (for example CRD, investigator triptychs, etc.).
- **Modifications to the economic report that are not relevant for the CEIm** (the CEIm only considers assessment to be necessary for modifications involving changes in compensation to participants and researchers presented in the initial economic report).
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- **PIL-IC translations into other languages:** These need not be sent to the CEIm. The sponsor shall be responsible for the reliable translation of this information into other languages. If the CEIm requires it, the sponsor will be asked for this.