Verification List

Substantial Amendment

EudraCT number:	**CEIC number:**
Done by:	
Start Date:	**End Date:**
☐ **Valid**	☐ **Not Valid**
Task number	

- **Clinical trial with CEIC number and the expert .**

☐ XML if applicable (if not present, request to applicant)

☐ Cover Letter

- ☐ In paper
- ☐ In portuguese
- ☐ EudraCT number
- ☐ Protocol number
- ☐ Title of the clinical trial
- ☐ Index (identification of the documents kept in each folder of the CD-ROM)
- ☐ Adressed to CEIC
- ☐ Wet ink signature
- ☐ Reasons for amendment
- ☐ Description of the modified documents

☐ Application Form

- ☐ In paper
- ☐ Adressed to CEIC
- ☐ EudraCT number
- ☐ Title
- ☐ Sponsor ID
- ☐ Applicant's wet ink signature
- ☐ Specified changes

☐ Insurance

- ☐ Coverage (valid at the submission date)

☐ Documents modified with changes highlighted.

☐ **Subject information leaflet and informed consent form**

- ☐ Portuguese
- ☐ Highlighted changes
- ☐ Updated version

Note: If there are different versions produced for individual sites, these different versions, with the changes highlighted in the cover letter, should be submitted.

☐ **Protocol**

- ☐ Title
- ☐ Number
- ☐ Updated version
- ☐ Date
- ☐ Signatures:
  - ☐ Sponsor
  - ☐ All the investigators
- ☐ Signed declaration by the sponsor stating that all the investigators will be informed about the changes before its implementation.
- ☐ Highlighted changes

Note: On the protocol's item, either one of the options is enough to validate the process: signature (sponsor and all the investigators) or a signed declaration by the sponsor stating that all the investigators will be informed about the changes before its implementation.

☐ **Protocol synopsis**

- ☐ Portuguese
- ☐ Highlighted changes
- ☐ Updated version

☐ **Investigator's brochure**

- ☐ Name of the experimental drug matches with the one in the CTA
- ☐ Updated version
- ☐ Date
- ☐ Highlighted changes

☐ **Others**

If exist a submission of a new site or an investigator replacement, please continue.

☐ CV of the investigators

- ☐ Readable
- ☐ Matches with the CTA
- ☐ Signature
- ☐ Date
- ☐ Present for all new investigators

☐ Financial contract

- ☐ Confirm subcontractors (sponsor/ site)
- ☐ Draft Contract
- ☐ Final contract
- ☐ Present for all new sites
- ☐ Investigator payment for all sites involved

Note: Signing one of the options is enough to validate the process: contract draft or final contract.

☐ Facilities of the site (s)

- ☐ Declaration of the Department Head
  - ☐ Infrastructure description
  - ☐ Equipments description
  - ☐ Human resources description
  - ☐ Authorization for the realization of the clinical trial in the Department
  - ☐ Authorization for the investigational team composition
  - ☐ Signature
- ☐ Present for all sites

☐ Information about the contact person in the new site(s):

- ☐ ID
- ☐ Contact
- ☐ Present for all new sites

Appendix I – auxiliary documents/supplements

☐ List of the submitted documents and versions in *Word* format. (see note 1) ☐ EudraCT number ☐ Protocol number ☐ Title of the clinical trial
☐ Case Report Form (CRF)
☐ Patient quality of life questionnaires
☐ Scales to be used in the study ☐ Validation in the portuguese population ☐ Validation of the translation
☐ Other documentation to be provided to the participant (e. g. patient cards, informative sheets, etc.)
☐ Declaration of the responsible pharmacist ☐ Present for all sites
☐ Experimental drug circuit ☐ Present for all sites

NOTES:

1. This list will be updated and sent back to the sponsor with the final CEIC notification, including the indication of the final version of all documents submitted.
2. All documentation should be sent in electronic format (two copies) including those documents requested in paper format. The documents should be submitted preferably in *Word* or in a format that allows copy.