Verification List

New Trial

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

☐ XML (if not present, request to applicant)

☐ Receipt of confirmation of the EUDRACT number

- ☐ Receipt from EMEA

☐ 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

☐ Application Form

- ☐ In paper
- ☐ Adressed to CEIC
- ☐ EudraCT number
- ☐ Title
- ☐ Sponsor ID
- ☐ Information about the experimental drug
- ☐ Information about the clinical trial
- ☐ List of investigators and sites
- ☐ Competent authority
- ☐ Applicant's wet ink signature

☐ Authorization letter that allows the applicant to represent the sponsor

- ☐ Applicable
- ☐ Includes the clinical trial that is being submitted
- ☐ Includes all intermediaries
- ☐ Signature

☐ List of competent authorities to which the application has been submitted and details of decisions, if available

☐ Decision from Ethics Committees to which the application has been submitted

- ☐ Portuguese

☐ Subject information leaflet and informed consent form

- ☐ Portuguese

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

☐ Information about the contact person

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

☐ Participants recruitment strategies (when applicable: variable depending amonq sites, announcements, etc.)

☐ 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

☐ CV of the coordinating investigator in Portugal

- ☐ Applicable (for multicentre trials)
- ☐ Readable
- ☐ Matches with the CTA
- ☐ Signature
- ☐ Date

☐ CV of each principal investigator

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

☐ Insurance

- ☐ ID of the clinical trial
- ☐ Insurance company
- ☐ Insured
- ☐ Policy number
- ☐ Type of insurance
- ☐ Coverage (valid at the submission date)
- ☐ Date
- ☐ Insurance company signature

☐ Participants reimbursement

☐ Financial contract

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

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

☐ Protocol and addendum updated version

- ☐ Title
- ☐ Number
- ☐ Version
- ☐ Date
- ☐ Signatures:
  - ☐ Sponsor
  - ☐ Principal investigator/coordinator

☐ Protocol synopsis

- ☐ Portuguese

☐ General description of all the active trials with the same experimental drug

☐ Scientific peer review of the trial, when available

☐ Ethical assessment of the principal/ coordinating investigator

- ☐ Evaluation
- ☐ Matches with the CTA
- ☐ Signature

☐ Investigator's brochure ☐ Name of the experimental drug matches with the one in the CTA ☐ Version ☐ Date ☐ Absence: see SmPC
☐ SmPC (for products with MA)

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. The documents should be submitted preferably in *Word* or in a format that allows copy.