National requirements for the clinical trial application in the The Clinical Trials Information System (part II documents)

Until adoption of a national regulation, the national competent authority in Latvia-State Agency of Medicines (SAM) and ethics committee allow the use of EUDRALEX 10 public forms with a clear identificator of the trial. Specific national requirements are outlined in the table below:

Procedure of the recruitment	Description of the recruitment measures and all the relevant materials must be submitted, including the materials intended for health care specialists. The materials intended for trial participants and health care specialists must be submitted in the state language.
Informed consent form (ICF) for the trial subjects	The following general requirements must be fulfilled regarding ICFs: ✓ The form and content must be compliant with the requirements and the spirit of Regulation No. 536/2014, legal acts in Latvia and GCP guidelines ICF must be in accordance with the patient population and specific protocol characteristics: ✓ The document must be as short as possible and reader-friendly, avoiding repeats and redundancy ✓ The document must include contact information for the trial site, data controller, SAM, Ethics Committee and Data State Inspectorate Formal requirements: ✓ Inclusion of the date version and number of the study protocol as well as specific clinical trial identificators: – the clinical trial number assigned by the sponsor and the CTIS trial number

	✓ Choice of the language used in ICFs must be based on GCP requirements with a respect to the comprehensibility of informed consent by the trial subject
Investigator suitability	Requirements for the verification of the principal investigator's qualifications (CV): ✓ Inclusion of the investigator's (doctor's) speciality, place of employment and position ✓ GCP certificate training date, version and edition Please note - only qualifications of the principal investigator are to be submitted
Site suitability	A description of the clinical trial site in line with the Eudralex 10 template *Site suitability form* shall be accepted, if the following requirements are met: ✓ The document is signed by an official of the healthcare institution with signatory powers or another employee with appropriate authorisation.
Financial and other agreements	Planned patient compensations must be disclosed. Eudralex 10 form *Compensation for trial participants* may be used. In addition following documents must be submitted: ✓ Draft agreement with the investigator/site ✓ Draft trial budget for each investigator/site
Personal data protection	No specific requirements- data must be collected and processed in accordance with the General Data Protection Regulation (EU) 2016/679 (GDPR) and a statement of compliance must be provided Eudralex 10 template *Statement of compliance with Regulation (EU) 2016/679 (GDPR)* can be used. Also note the requirements for contact information in informed consent documents.
Compliance of biological samples	Eudralex 10 template *Compliance with applicable rules for biological samples* may be used.

Please note - the requirements of Regulation 536/2014, Annex I, Section L-R must be followed concomitantly.