Questionnaire for the Submitted Clinical Trial of a Medicinal Product

1 Questions Related to the Protocol

1.1 Full title of the clinical trial in Czech, including acronym:

1.2 Protocol number:

1.3 EudraCT number:

1.4 Objective of the clinical trial (How will the clinical trial contribute to diagnostic and therapeutic practice, medical knowledge, or what benefit will it bring to the individual subject of the trial)**:**

1.5 The clinical trial is *(tick as appropriate):*

a) Conduct of a clinical trial of a medicinal product pursuant to Act No 378/2007 Sb., on pharmaceuticals and amending certain related acts, as amended, and relevant regulations of the European Parliament and Council (EU); (in this case circle the phase of the clinical trial): I – II – III – IV
b) Funded from own resources / by a professional organisation / company
c) Has a different nature (please specify):

1.6 Study design *(tick as appropriate):*

a) Randomisation
b) Blinding
c) Prospective / Retrospective
d) Comparator
e) Single-centre only: YES: NO:
f) Is this a multicentre trial with two or more sites in the Czech Republic: YES: NO:
g) Is this an international multicentre trial with one site in the Czech Republic: YES: NO:

1.7 Inclusion criteria:

1.8 Exclusion criteria:

1.9 Approvals:

a) State Institute for Drug Control (SÚKL): YES (date): NO:
b) Other site in the Czech Republic: YES (date, specify): NO:

2 Contact Details

2.1 Principal Investigator:

Full name, academic titles:

Institution, address:

Phone number:

Email:

Co-investigator:

2.2 Sponsor / Funder of the Clinical Trial:

Name:

Address:

Contact person:

Phone number:

Email:

Company / Tax ID No:

2.3 Applicant / CRO conducting the Clinical Trial:

Name:

Address:

Contact person:

Phone number:

Email:

Company / Tax ID No:

3 Questions Related to the Trial Subjects

3.1 Duration of the clinical trial for each participant:

3.2 Duration of the clinical trial for the investigation team:

3.3 Planned number of subjects:

a) At the site:
b) In the Czech Republic:
c) Total:

3.4 Characteristics of the trial subjects *(tick as appropriate)**:***

Men		Outpatients	
Women		Hospitalised patients	
Healthy volunteers		Patients unable to give informed consent	

3.5 What risks are expected for the trial subjects *(What ethical issues may arise? If ethical issues arise, how will the investigator address them?)*

3.6 How much time will be given to trial subjects to consider participation in the clinical trial after receiving the subject information sheet?

3.7 What type of informed consent (IC) will be obtained from the trial subjects or their legal representatives?

	YES	NO
Written IC		
Written IC of the subject's legal representatives		
Oral IC (if the subject is unable to write) in the presence of at least one witness In this case, please describe the exact enrolment procedure.		
Cannot be obtained in advance (emergency situations / unconsciousness) In this case, please provide a proposed description of the enrolment procedure.		

3.8 What information will be provided to the subject's attending (GP) physician?

3.9 How will expenses incurred by the trial subjects be covered?

3.10 Will other payments be provided to the trial subjects?

4 Questions Related to Medicinal Products

4.1 List all medicines that will be administered as part of the clinical trial:

4.2 Does the clinical trial require the application of a radioisotope?
YES (which one): NO:

4.3 Has authorisation for radioisotope application been issued (State Office for Nuclear Safety – SÚJB)?
YES: NO:

4.4 Does the clinical trial require the administration of antimicrobial agents?
YES (which ones): NO:

4.5 If antimicrobial agents are used in the clinical trial, has the applicant informed the antibiotic centre of the medical facility?
YES: NO:

4.6 Does the clinical trial require any medicines to be discontinued: (If yes, which ones and for how long)*:*

4.7 Is the use of a placebo planned in the control group*:*
YES: NO:

5 Questions Related to Visits and Examinations

5.1 Which of the following examination procedures are included in the clinical trial:

a) Clinical monitoring only (number)**:**

b) Functional tests (which ones, how many)**:**

c) Blood samples (blood volume, number of venipunctures, blood loss over time)**:**

d) X-ray or radioisotope examination (which ones, how many, radiation dose)**:**

e) CT or MRI examination (which ones, how many)**:**

f) Instrumental invasive methods (which ones, how many)**:**

g) Other examinations (please specify)**:**

h) Tissue samples:

i) Is pharmacokinetics part of the clinical trial:

j) Does the clinical trial require DNA testing (if yes, which)**:**

6 Questions Related to Insurance

Liability insurance arranged for the sponsor and the investigator, providing compensation in the event of death of the subject or damage to health resulting from the conduct of the clinical trial.

6.1 Is insurance arranged for the investigator:

6.2 Is insurance arranged for the sponsor:

6.3 Will the insurance policy contain exclusions from cover (if the relevant part of the insurance policy with exclusions is not attached, please specify which exclusions apply)**:**

6.4 Will the insurance policy include a deductible (if yes, please specify the amount. How will compensation to the subject be ensured if the compensation amount is lower than the deductible agreed in the sponsor's insurance policy)***:***

6.5 Maximum compensation amount agreed in the insurance policy for one trial subject:

Date

Name and signature of the person completing the questionnaire