### *Annex 1*

### SÚKL Questionnaire

**Study title** (exact title of the protocol in the original language):

### Shortened study title:

**Protocol number:**

**EudraCT number:**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| **Was the CT rejected by any ethics committee in the Czech Republic or abroad?***If YES, specify the reason:***Was the CT rejected by any EU or third-country regulatory authority? NA***If YES, specify the reason:***Was Scientific Advice issued for the CT?***If YES, please submit it.***Is the CT part of a PIP** (Paediatrics Investigational Plan)**?***If YES, specify the PIP number.***Is the CT being submitted as part of a VHP (**Voluntary Harmonisation Procedure**)?***If YES, provide the VHP number and declaration of conformity of the submitted documentation.***Is the CT a first-in-human trial?****Does the CT use any products containing addictive or psychotropic substances?***If YES, please specify which ones.***Does the CT use a radiopharmaceutical product?***If YES, submit the opinion of the State Office for Nuclear Safety (SÚJB).***Does the CT use a GMO (**genetically modified organism**) containing product?***If YES, provide the opinion on the Czech Ministry of the Environment.***Was the tested product previously used in a CT in the Czech Republic?***If YES, please provide the trial identification (EudraCT number, SÚKL file no.) + attach the documents referred to under Annex 3.***Was the non-authorised comparator product previously used in a CT in the Czech Republic?***If YES, please provide the trial identification (EudraCT number, SÚKL file no.) + attach the documents referred to under Annex 3.* |

|  |  |  |
| --- | --- | --- |
| **Date:** | **Name:** | **Signature:** |

Stamp