### *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.* | | |

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

Stamp