**Appendix No. 13 – Specific Clinical Trials – Investigator Initiated Trials (IITs only)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***No*** | ***Disease site*** | ***Acronym/***  ***short title/***  ***EUDRACT no.*** | ***Phase*** | ***PI\****  ***at the center*** | ***PI \****  ***extra-mural*** | ***Multi -centered*** | ***Accrual***  ***Start*** | ***Accrual***  ***End*** | ***Targeted***  ***Accrual*** | ***Accrual in 2019*** | ***Overall Accrual in 2019*** | ***Financial***  ***Sponsor*** | ***Peer-***  ***Reviewed*** |
| ***Therapeutic Trials (Phase I)*** | | | | | | | | | | | | | |
| 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Therapeutic Trials (Phase I/II)*** | | | | | | | | | | | | | |
| 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Therapeutic Trials (Phase II)*** | | | | | | | | | | | | | |
| 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Therapeutic Trials (Phase III)*** | | | | | | | | | | | | | |
| 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |

\*In multinational trials the PI in charge for Germany ('LKP Deutschland') is to be regarded as the responsible PI.

**Please note:**

* **List only Investigator Initiated Trials (IITs).**
* **Only prospective studies with a scientific research question (defined study end point) - which require a vote of the responsible ethics committee - are accepted (e.g. marketing trials may not be counted).**

*Types of Trials:*

**Therapeutic trials (Phase I-III):** OnlyPhase I-trials, Phase I/II-trials and Phase II- and III-trials with therapeutic intent using drugs, radiation, surgery, or other biological agents are accepted.

Please highlight in yellow those trials which were performed in the Early Clinical Trials Unit.

**Disease site:** Identify the anatomic cancer site(s) on which the trial or study is focused. Please refer to the column 'disease site' as indicated in Appendix 3. If a trial or other clinical study is applicable to a number of potential anatomic sites, enter the term 'multiple' in this column.

**Acronym/short title/Eudract no.:** Provide Acronym/short title and EUDRACT no. (if applicable) for clear, concise identification of the trial.

**Phase:** Provide the study phase. Acceptable phases are I, II, III or combinations such as I/II.

**PI at the center:** Please indicate with an 'X' if the principal investigator (PI = 'Leiter Klinische Prüfung/LKP') is an employee of the applying institution.

**PI extramural:** Please indicate with an 'X' if the principal investigator (PI) is not an employee of the applying institution, e.g. the applying institution is attending to an extramural trial.

**Multi-Centered:** Indicate whether the trial/study is conducted at more than one medical center or clinic.

**Please note:** For 'PI at the center', 'PI extramural' and 'Multicentered' more than one choice is possible.

**Accrual Start:** Providethe date that this protocol or study was opened to accrual (dd.mm.yyyy) at the applying center.

**Accrual End**: Providethe date that the accrual for this protocol or study is expected to be closed (dd.mm.yyyy) at the applying center.

**Targeted Accrual:** Total number of patients or participants needed for the entire study at the applying center as stated in the trial protocol (no target range).

**Accrual in 2019:** Number of patients newly enrolled in 2019 (in the applying center only). A patient is considered to be newly enrolled in 2019, if he/she has signed the informed consent in 2019 and has actively participated in the trial. He/She may appear only once per trial protocol. A patient may appear more than once if he/she was on more than one trial protocol. Screening failures are not countable in therapeutic trials.

**Overall Accrual in 2019**: Number of patients enrolled since accrual start until December 31, 2019 (in the applying center only).

**Financial Sponsor**: Indicate who financially supports this trial/study by a grant.

**Peer-Reviewed:** Ifthe trial is supported by a grant: indicate whether the grant application has been peer-reviewed (Yes/No), otherwise, indicate "N/A".