**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 2016*** | ***Overall Accrual until June 30, 2017*** | ***Financial***  ***Sponsor*** | ***Peer-***  ***Reviewed*** |
| ***Therapeutic Trials (Phase I-III)*** | | | | | | | | | | | | | |
| 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Therapeutic Trials (Phase IV)*** | | | | | | | | | | | | | |
| 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Other Therapeutic Trials*** | | | | | | | | | | | | | |
| 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Supportive Care Trials*** | | | | | | | | | | | | | |
| 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Screening / Diagnostic / Early Detection Trials*** | | | | | | | | | | | | | |
| 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Epidemiologic / Observational / Outcome Trials*** | | | | | | | | | | | | | |
| 11 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 12 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Prevention Trials*** | | | | | | | | | | | | | |
| 13 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 14 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Biomarker Trials*** | | | | | | | | | | | | | |
| 15 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 16 |  |  |  |  |  |  |  |  |  |  |  |  |  |

\*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).**
* **Clinical trials in which also non-cancer patients are enrolled, must be highlighted.**

*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.

**Therapeutic trials (Phase IV):** Please include here prospective Phase IV trials (requiring a vote of the responsible ethics committee) only.

**Other therapeutic trials:** Trials according the Medical Devices Act, 'Medizinproduktegesetz/MPG'.

**Supportive care trials:** Clinical trials intended to treat side effects or complications as well as to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral or other interventions.

**Screening / Diagnostic / Early Detection Trials**: Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease.

**Epidemiologic / Observational / Outcome Trials:** Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.

**Prevention Trials:** Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.

**Biomarker trials:** Prospective studies which aim at the correlation of markers (from patient samples, imaging) with the prognosis of disease or at the impact of markers for pathogenesis (retrospective investigation of pathological material is excluded).

Please highlight in yellow those trials which were performed in the Early Clinical Trials Unit (see also section E.2 of the application guidelines).

**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 4. 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, IV or combinations such as I/II. For other studies, indicate “N/A”.

**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 2016:** Number of patients newly enrolled in 2016 (in the applying center only). A patient is considered to be newly enrolled in 2016, if he/she has signed the informed consent in 2016 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 until June 30, 2017**: Number of patients enrolled since accrual start until June 30, 2017 (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".