**Appendix No. 11 - Number of pediatric cancer patients newly enrolled in prospective clinical cancer trials (in 2019)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **1** | **2** | **3a** | | | | |  |  | **3b** | **3c** | **3d** | **3e** | **3f** | **3g** |
| **Disease site** | Number of all cancer patients treated in the center in 2019 | Number of cancer patients newly diagnosed in 2019 | Number of patients newly enrolled in trials in 2019 | | | | | %  Columns  Total 3a/1 | %  Columns  Total  3a/2 | IITs: PI\*\* in Cancer Center | %  Columns 3b/Total 3a | IITs: PI\*\*\*\*  else-where | %  columns 3d/Total 3a | Industry Initiated Trials | %  columns 3f/Total 3a |
| Phase I | Phase I/II | Phase II | Phase III | **Total 3a**  (Sum 3a) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymphoid leukemias |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Acute myeloid leukemias |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hodgkin lymphomas |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non-Hodgkin lymphomas (except Burkitt lymphoma) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Astrocytomas |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intracranial and intraspinal embryonal tumors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Neuroblastoma and ganglioneuroblastoma |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Retinoblastoma |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Nephroblastoma and other nonepithelial renal tumors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Osteosarcomas |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Rhabdomyosarcomas |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Germ cell tumors, trophoblastic tumors, and neoplasms of gonads |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Others\*/\*\*\* |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\*Disease sites which are not listed above, can be indicated under 'Others', but must not be counted among 'Total (A)'.

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

\*\*\* Multiple entities: patients who were recruited in 'multiple entity trials', where a differentiation into specific entities is not possible, can be included here.

**Column 1:** Number of all cancer patients treated in the cancer center in 2019. Please transfer the numbers from appendix 3, column 1.

**Column 2:** Number of cancer patients newly diagnosed in 2019.

**Column 3a:** Number of patients that were newly enrolled in clinical (Phase I-III) trials in 2019.

Percentage of cancer patients newly enrolled in clinical trials (3a) in 2019 referring to all cancer patients treated in the center (Total 3a / 1).

Percentage of cancer patients newly enrolled in clinical trials (3a) in 2019 referring to the newly diagnosed cancer patients (Total 3a / 2)

**Column 3b:** Number of patients who were newly enrolled in clinical investigator initiated trials (IIT; only Phase I-III), where the Principal Investigator (PI = 'Leiter Klinische Prüfung') is member of the center.

**Column 3c:** Percentage of cancer patients newly enrolled in clinical IIT with the PI being member of the center (column 3b / Total 3a).

**Column 3d:** Number of patients who were newly enrolled in clinical IIT (only Phase I-III), where the PI is not member of the center.

**Column 3e:** Percentage of cancer patients newly enrolled in clinical IIT with the PI not being member of the center (column 3d / Total 3a).

**Column 3f:** Number of patients who were newly enrolled in clinical trials (only Phase I-III) initiated by the industry.

**Column 3g:** Percentage of cancer patients newly enrolled in clinical trials initiated by the industry (column 3f / Total 3a).

**Criteria for a patient to be counted:** 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.

**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 note that 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).**

Further explanation: To be counted as a prospective trial/study, the relevant data regarding the study end point has to be collected prospectively. A vote of the responsible ethics committee for the specific planned investigations must exist. The vote has to be issued after the formulation of the study protocol / patient information but before recruitment of patients or collection of data or biomaterial. If the analysis of biomaterial is part of the trial or is performed in the context of the trial, the study can be counted as prospective. Therefore, patients/studies cannot be counted when another independent analysis of biomarkers from the already collected biomaterial is performed.

\*Further details regarding the classification of childhood cancer are provided in enclosure 3.