**Appendix No. 12 - Number of cancer patients newly enrolled in prospective clinical cancer trials (in 201X)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1 | 2 | 3a |  | 3b | 3c | 3d | 3e | 3f | 3g | 4 |  |
| Disease site (without pediatric tumors) according to the list of tumor localizations used in the analysis of the Robert Koch Institute ('Krebs in Deutschland; 2013), modified on the basis ofthe National Cancer Certification Program 2015 | ICD-10 Code | Number of all cancer patients treated in the cancer center in 201X | Number of cancer patients newly diagnosed in 201X | Number of patients newly enrolled in trials in 201X | **%**ColumnsTotal 3a/1 | **%**ColumnsTotal3a/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 | Number of patients newly enrolled in trials in 201X | %ColumnsTotal 4/1 | %ColumnsTotal 4/2 |
| Thera­peutic (Phase I-III) | Thera­peutic (Phase IV) | Thera­peutic (Other) | Supportive Care | **Total 3a**(Sum 3a) | Screening/ Diagnostic/ Early Detection | Epidemio­logic/ Obser­vational/ Outcome | Prevention | Biomarker | **TOTAL 4**(Sum 4) |  |
| **A.** |
| *Head and Neck***Stoma/Pharynx** |  |
| C00-14 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Larynx**  | C32 |
| *Upper GI Tract***Esophagus**  |  |
| C15 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Stomach**  | C16 |
| **Intestine** | C18-21 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| *Liver/Gall Bladder* |  |
| **Liver** | C22 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Gall Bladder** | C23-24 |
| **Pancreas**  | C25 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Lung**  | C33-34 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Malignant Melanoma**  | C43 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Bone, Articular Cartilage, Connective and Soft Tissue** | C40-41, C45-49 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| *Breast/DCIS* |  |
| **Ductal Carcinoma in Situ (DCIS)** | D05 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Breast** | C50 |
| **Vulva** | C51 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Cervix** | C53 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Uterus** | C54-55 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Ovary**  | C56 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Prostate**  | C61 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Testes**  | C62 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Kidney**  | C64 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Urinary Bladder** | C67 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Central Nervous System** | C70-72**\*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Thyroid** | C73 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| *Total Solid Tumors* |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Morbus Hodgkin** | C81 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Non-Hodgkin Lymphomas** | C82-85 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Plasmocytoma** | C90 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Leukemias** | C91-95 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Other Hematological Malignancies** | C86-88, C96 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| *Total hematolymphoid* |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **TOTAL (A)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |
| **B.** |
| **Others\*\*(Examples)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Other Malignant Neoplasms of the Skin | C44 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pediatric Tumors (Patients < 18 y.)**\*\*\*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Multiple Entities**\*\*\*\*\*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **TOTAL (A + B)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\*Further CNS tumors which are requested within the 'National Cancer Certification Program' ('Erhebungsbogen Neuroonkologische Tumoren', Chapter 1.2.1; ICD-10: C75.1-3, D32, D33.3, D35.2-4; primary CNS lymphomas) can be listed under 'Others'.

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

\*\*\*Pediatric tumors may only be listed here and must not be counted under '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 201X. Please transfer the numbers from appendix 4, column 1.

**Column 2:** Number of cancer patients newly diagnosed in 201X. Please transfer the number from appendix 4, column 2.

**Column 3a:** Number of patients that were newly enrolled in clinical (Phase I-III, IV, other therapeutic and supportive care) trials in 201X.

 Percentage of cancer patients newly enrolled in clinical trials (3a) in 201X referring to all cancer patients treated in the center (Total 3a / 1).

 Percentage of cancer patients newly enrolled in clinical trials (3a) in 201X 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, IV, other therapeutic and supportive care trials are accepted), where the Principal Investigator (PI = 'Leiter Klinische Prüfung') is member of the cancer center.

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

**Column 3d:** Number of patients who were newly enrolled in clinical IIT (only Phase I-III, IV, other therapeutic and supportive care trials are accepted), where the PI is not member of the cancer center.

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

**Column 3f:** Number of patients who were newly enrolled in clinical trials (only Phase I-III, IV, other therapeutic and supportive care trials are accepted) initiated by the industry.

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

**Column 4:** Number of patients that were newly enrolled in clinical (Screening, Diagnostic, Early Detection, Epidemiologic, Observational, Outcome, Prevention, Biomarker) trials in 201X.

 Percentage of cancer patients newly enrolled in clinical trials (4) in 201X referring to all cancer patients treated in the center (Total 4 / 1).

 Percentage of cancer patients newly enrolled in clinical trials (4) in 201X referring to the newly diagnosed cancer patients (Total 4 / 2)

Cells highlighted in grey: use for Table 1 under D1; cells highlighted in yellow: use for Table 2 under D1

**Criteria for a patient to be counted:** A patient is considered to be newly enrolled in 201X, if he/she has signed the informed consent in 201X 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.

**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 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, at least a part of the information/data 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.