Count of cases in the certification system

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1. General rules for counting cases in the certification system

- **Primary cases**
  = Patients with initial diagnosis treated at the centre
  - Incl. primary M1 at the time of initial diagnosis.
  - Counting time = highest diagnostic level according to "Tumour_Diagnosis Confirmation "[1] → first histological confirmation; organ-specific specifications listed in Chapter 2.
  - In principle, each patient can only be counted as a primary case once (other organ-specific specifications are possible, see table).
  - Presentation for a second opinion or consultation only does not count as a primary case.
- **Centre cases**
  = primary cases + patients with (locoregional) recurrence + patients with secondary distant metastasis
- Special feature haematological neoplasms: **Patient case** = patients with initial diagnosis as well as patients with recurrence/ Progres ~~distant metastasis~~ who are presented at the centre or tumour board for the first time and receive essential parts of the therapy there (systemic therapy, stem cell transplantation, active surveillance/watchful waiting).
  - Counting time is the time of the first presentation at the Centre.
  - Patients may only be counted once for the Centre, regardless of the calendar year (also in the case of a later diagnosis of another haematological neoplasm).
  - Presentation for a second opinion or consultation only does not count as a patient case.
- Within a certification system, ICD-based diagnosis groups exist that are relevant for counting cases:
  Definition: **Group** = Entity within a certification system
  Ex. KHT: Oral cavity, pharynx/larynx, nasal cavities/paranasal sinuses, salivary glands = 4 groups.
  Ex. DZ: colon, rectum = 2 groups
  Ex. PZ: Prostate = 1 group
- If an invasive carcinoma is diagnosed after a previous primary case of a pre-invasive lesion (for paired organs: on the same side) → no new primary case.

[1] **Tumour Diagnosis confirmation (according to Oncological Basic Data Set):** https://www.basisdatensatz.de/datensatz.php)
1 = Clinical: Diagnosis was made before death, but without the following measures (code numbers 2-7).
2 = clinical diagnostic: All investigative techniques, including X-ray, endoscopy, imaging, ultrasound, exploratory procedures (such as laparotomy) and autopsy, but excluding tissue examination.
4 = Specific tumour markers: Additional biochemical and/or immunological markers specific to a particular tumour site.
5 = cytology: examination of cells from a primary or secondary site, including those from aspirates obtained by endoscopy or by puncture; also includes microscopic examination of peripheral blood and bone marrow aspirates.
6 = histological examination of a metastasis: histological examination of tissue from a metastasis, including examination of specimens from an autopsy.
7 = histological examination of a primary tumour: histological examination of the tissue from a primary tumour, however obtained; including all incision techniques and bone marrow biopsies; also includes examination of samples of the primary tumour from an autopsy.

- Definition **metachronous** = Diagnosis date ≥ 93 days after diagnosis date of primary disease ~~therapy (= surgery and/or adjuvant therapy) of the first primary case must have been completed~~ [1].
- In the case of metachronous tumours or when counting primary cases in a certification system with several groups, the following applies: The counting is independent of the calendar year.

2. Organ-specific guidelines for counting primary cases or patient cases (HAEZ)

Organ/ Certification system	Group	Organ-specific guidelines
Breast	**1 Group:** C50.-, D05.1, D05.7, D05.9	• 1 primary case per breast
Gyn	**5 Groups:** Ovary/BOT (C56, D39.1) Endometrium (C54, C55), Cervix (C53), Vulva/Vagina (C51, C52), Other (C48, C57)	• Synchronous occurrence of tumours from different groups: 1 primary case. • Metachronous occurrence of tumours from max. 5 groups: max. 5 primary cases
Colorectal	**2 Groups:** C18, C20 (Colon, Rectum)	Synchronous occurrence of tumours from both groups: 1 primary case • Metachronous occurrence of tumours from both groups: 2 primary cases = 1 primary case colon and 1 primary case rectum • Metachronous occurrence of tumours in the colon in different localisations with different ICD codes: 2 primary cases = 1 primary case colon and 1 primary case rectum. • Counting day: - surgical primary case– Date tumour removal/operation - endoscopic PC – Date endoscopic ablation - palliative PC – Date of histological basis of diagnosis - WW PC – Date of histological basis of diagnosis
Stomach	**1 Group, if module Esophagus (MS) is not included:** C16 (incl. 16.0[1]) **2 groups if MS can also be counted:** C16 (incl. 16.0[1]) + C15.2, C15.5 and 16.0[2]	• Synchronous occurrence of tumours from both groups: 1 primary case • Metachronous occurrence of tumours from both groups: 2 primary cases = 1 primary case C16 and 1 primary case C15 • [1] Tumours whose centre is > 2 cm from the oesophagogastric junction are classified as gastric carcinoma,

		even if the oesophagogastric junction is included.

		• [2] Tumours involving the oesophagogastric junction and whose centre lies within the prox. 2 cm of the oesophagogastric junction (proportion Siewert type I/ Siewert type II) are counted as oesophageal carcinomas. • Counting time: Date of histological/cytological basis of diagnosis
Oesophagus	**1 Group:** C15, C16.0[2], D00.1	• Tumours that involve the esophagogastric transition and whose centre lies within the prox. 2 cm of the oesophagogastric transition (proportion Siewert type I/ Siewert type II) are counted as oesophageal carcinomas. • Counting time: Date of histological or imaging basis of diagnosis
Liver	**1 Group:** C22.0	• Counting time: Date of histological or imaging basis of diagnosis
Pancreas	**1 Group:** C25	• Counting time: Date of histological/cytological confirmation from primary tumour or metastasis with simultaneous presence of pancreatic tumour in cross-sectional imaging.
Lungs	**1 Group:** C34	• Synchronous: 1 primary case with synchronous treatment of the bronchial carcinomas (independent of the side or lobe localisation). • Metachronous: 2 primary cases in metachronous treatment of bronchial carcinomas if they occur on different sides (occurrence in different lobes of the same side is not counted as a second primary case)

Skin	**3 Groups:** Melanoma, Epitheliale Tm, Cutaneous Lymphome /Rare Tm	• Epithelial Tm and Cutaneous Lymphoma/ Rare T: 2 primary cases = 1 primary case Epithelial Tm and 1 primary case cutaneous lymphoma/rare tumours • Malignant melanoma: Each calendar year, 1x new primary case of a different primary case of a different localisation of MM can be counted.
Prostate	**1 Group:** C61	• Patients who first underwent AS or WW and then a subsequent interventional therapy in a subsequent calendar year = 2 primary cases • Patients who first received AS or WW and then interventional therapy in the same calendar year = 1 (interventional) primary case. • Counting time: Time of (first) presentation at the centre (usually presentation to the tumour board).
Urinaly Bladder	**1 Group:** C67, D09.0, D41.4	• No organ-specific guideline
Kidney	**1 Group:** C64	• 1 Primärfall pro Niere
Head and neck Tumours	**4 Groups:** Oral cavity, pharynx/larynx, nasal cavities/paranasal sinuses, salivary glands	• Synchronous occurrence of tumours of different groups: 1 primary case • Metachronous occurrence of tumours from max. 4 groups: max. 4 primary cases.
Neuro-oncology	**1 Group**	• Counting time: Date of histological diagnosis confirmation; exception: clinical confirmation of diagnosis with TK-Decision
Sarcoma	**3 Groups:** WGT, GIST, Bone (C40-41, C45-49)	• Synchronous occurrence of tumours from different groups: max. 3 primary cases • Occurrence of several tumours of different groups in a calendar year: max. 3 centre cases. • Further information: Data sheet Explanations Sarcoma
Paediatric oncology	**12 Groups :** I to XII	• Centre cases = first tumours, second tumours, first tumours with recurrence • First tumour: First cancer diagnosis independent of the tumour entity; in the case of synchronous diagnosis of two tumour entities, the leading tumour entity is to be defined as the first tumour

		(further tumours are then second tumours). Multiple answers are not possible. • Second tumour: All other tumours diagnosed for the first time in another (tumour) main group; If a second tumour is diagnosed within 1 main group, then this is not a second tumour, but a recurrence, irrespective of the localisation. Multiple answers possible. • Primary case: All initial diagnoses of first and second tumours; Multiple answers possible. • Counting time: Date of histological/cytological basis of diagnosis • "Secondary distant metastasis" is missing as a term in the KIO certification system because different tumour groups are combined here. A recurrence of a tumour within a main group - regardless of whether in the primary localisation or in another localisation as a metastasis - counts as a recurrence.
Haematolog. Neoplasia	**1 Group**	• Patient case: 1 patient can only be counted 1x for a centre, regardless of the type of initial and subsequent disease (recurrence, sec. distant metastasis), regardless of the ICD codes used and regardless of the calendar year. • Counting time: Time of (first) presentation at the centre.

3. General rules for counting recurrences and secondary metastases

a) Patients with locoregional recurrence

- Counting time is the date of diagnosis of the locoregional recurrence. The date of the highest diagnostic certainty according to the IARC-IACR/Oncology Basic Dataset is documented (see above, as for primary cases). If no corresponding date is available, the date of the first presentation of the patient with recurrence at the centre counts.
- Interdisciplinary therapy plan must be available
- Complete recording of the recurrence in the tumour documentation system (if possible with documentation of primary case)
- Patients are counted regardless of whether they were previously treated at the Centre (e.g. as a primary case or previous relapse) or not.
- Recurrence is counted for 1 centre

  (In principle, multiple counting is possible because the patient can be counted as a primary case and therefore also in the follow-up of the primary disease in another centre. However, since no

epidemiological mapping is to be achieved, the potential problem of double counting appears negligible).

- The prerequisite for counting as a recurrence is a previous R0 situation. (Exception haematological neoplasms: renewed disease detection after previously achieving complete remission).
- Locoregional recurrence = tumour and/or regional lymph nodes (as distinct from distant metastases (M1; any necessary organ-specific documentation of the LK as M1 must be observed, TNM 8th edition).

b) Patients with secondary distant metastases (M1) =

Distant metastases in the course

- Distant metastases in the course - counting time is the date of diagnosis of the distant metastasis. The date of the highest diagnostic certainty according to the IARC-IACR/Oncology Basic Data Set1 (as for primary cases) is documented. If no corresponding date is available, the date of the first presentation of the patient with secondary distant metastases at the centre counts.
- Interdisciplinary therapy plan must be available
- Complete recording of the secondary distant metastasis in the tumour documentation system (if possible with documentation of primary case/locoregional recurrences).
- Patients are counted regardless of whether or not they were previously treated at the centre (e.g. as a primary case, as a previous recurrence or as another previous distant metastasis)
- Counting of distant metastases for 1 centre

(this means that, in principle, multiple counting is possible because the patient can be counted as a primary case and, accordingly, also in the follow-up of the primary disease in another centre.

c) Examples

Organ-specific peculiarities (see table or data sheet explanation of sarcomas) are to be considered separately.

I. Primary case and recurrence <u>in the same indicator year</u> → 2 centre cases

If the initial diagnosis and the diagnosis of the relapse occurred in the same year, the patient can be counted twice.

E.g.: March 2020 initial diagnosis = patient is counted as Pf; Nov. 2020 diagnosis of recurrence = patient is counted as recurrence; patient is counted twice in 2020.

II. Primary case and sec. distant metastasis <u>in the same indicator year</u> → 2 centre cases

If the initial diagnosis and the diagnosis of the secondary distant metastasis occurred in the same year, the patient can be counted twice.

Ex: March 2020 initial diagnosis = patient is counted as PC; Nov. 2020 diagnosis of secondary distant metastasis = patient is counted as secondary distant metastasis; Patient is counted 2x in 2020

III. Recurrence and relapse <u>in the same indicator year</u> → 1 centre case

Pat. is counted 1x/year (independent of the number of recurrences in 1 year).

Ex: March 2020 recurrence; September 2020 recurrence = patient is counted once.

IV. Recurrence and distant metastasis in the same or different indicator year/s → 2 centre cases

If a secondary distant metastasis and metachronous recurrence occur in the same or in different key year(s) and a metachronous recurrence occur, the patient can be counted twice.

Ex: March 2020 distant metastasis = patient is counted as distant metastasis; Nov. 2020 diagnosis of recurrence = patient is counted as recurrence; patient is counted twice in 2020.

Ex: March 2020 distant metastasis and synchronous diagnosis of recurrence = patient is counted 1 x according to the distant metastasis.

V. Distant metastasis and distant metastasis (incl. recurrence after compl. remission) in the same indicator year → 1 centre case

Pat. is counted 1x/year with new localisation of the distant metastasis (independent of the number and localisations of further new distant metastases in 1 key figure year).

Ex: March 2020 lung metastases; September 2020 bone metastases = patient is counted once.

Ex: March 2020 lung metastases; September 2020 progress of existing lung metastases = Pat. is counted 1x

Ex: March 2020 lung metastases; June 2020 metastases no longer detectable after therapy; September 2020 foci of lung metastases again = patient is counted 1x

VI. Distant metastasis with progression in different indicator years → 1 centre case (in the year of the first manifestation of the distant metastasis)

A progression of an already existing distant metastasis is not recounted.

Ex: March 2019 lung metastases; February 2020 new foci of lung metastases = pat. is counted 1x in 2019, pat. is not counted in 2020.

VII. Distant metastasis with complete remission and recurrence in the same location in different indicator years → 2 centre cases (1x in the year of initial manifestation of distant metastasis and 1x in the year of recurrence)

Recurrence of a known distant metastasis after intermediate complete remission is counted again.
Ex: March 2019 lung metastases; March 2020 metastases no longer detectable after therapy; September 2020 new foci of lung metastases (independent of side localisation) = Patient is counted 1x 2019 and 1x 2020

VIII. Distant metastasis and distant metastasis of other localisation in different key years (independent of remission of the first distant metastasis) → 2 centre cases (1x in the year of the first distant metastasis and 1x in the year of the second distant metastasis)

Occurrence of a new distant metastasis of a different location in another calendar year. Independent of a successful/unsuccessful remission of the initial metastasis.

Ex: March 2020 lung metastases and March 2021 liver metastases = patient is counted 1x 2020 and 1x 2021.

~~[1] https://www.xml-oncobox.de/DownloadData/Dokumente/Darm/eb_darm_K1.1.1_spez%20xmloncobox-A1%20(201102).xlsx Appendix - Case Assignment~~

[1] Stegmaier C, Hentschel S, Hofstädter F, et al. (Hrsg). Manual der Krebsregistrierung. Zuckschwerdt Verlag, Germering (2019). https://www.basisdatensatz.de/download/165_Manual%20Krebsregistrierung_web.pdf