

Solid tumours

Guide to the completion of the EBMT data collection form:

Solid_tumours_v2.1

28 March 2025

EBMT Registry

EBMT Clinical Research & Registry Department



**Co-funded by
the European Union**

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Introduction

Please make sure you have already checked the **Introduction to the EBMT Registry Completion Guidelines** document latest version available under *Manuals and Reference Documents* section on [EBMT website](#).

Solid Tumours

Solid Tumours are a group of malignancies presenting with masses internal or external to organs such as breast, ovarian or lung carcinoma. Although lymphomas may present with solid masses internally or externally, they are categorised under a different section because lymphomas are related to the lymphatic system and investigated under the lymphoma working party. The diagnosis form is meant for the indication of treatments.

Disease

Date of diagnosis

Report the date of the first pathological diagnosis of the disease. The diagnosis date is the date of when the sample was collected for examination, or (in its absence) the date indicated by a physician within the patient's medical record.

Classification

Select the classification that is appropriate for the solid tumour at the time of diagnosis and check the box next to it. If the diagnosis subtype is not listed, check the box **“Other”** and write the type of solid tumour in the text-box in English.

TNM classification

Clinical TNM classification was developed and is maintained by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC). It is used by most medical oncologists and pathologists to define the stage of the disease accurately. Most of the solid tumours have different TNM classification which are not transferable from tumour to tumour. Therefore, when completing the section on TNM, use the TNM classification specific for that diagnosis. (Please refer to "The Eighth Edition AJCC Staging Manual", published by Springer in 2017 ([Amin et al. 2017](#)) or "UICC TNM Classification of Malignant Tumours Eighth Edition", published by WILEY Blackwell in 2016 for TNM classification.)

Check the box for each solid tumour classification parameter:

Type

Specify the type according to TNM classification: if it is clinical or pathological.

Note: if both clinical and pathological TNM tests are done for the patient (usually this is the case for breast cancer), the pathological ones have to be preferred and reported.

Tumour

Indicate the tumour according to the size or number of tumours as per corresponding tumour TNM classification:

- TX - the assessment was not possible;
- T0;
- T1;
- T2;
- T3;
- T4;
- Not evaluated;
- Unknown.

Nodes

Indicate the nodes according to the spread or size of nodes involved as per corresponding tumour TNM classification:

- NX - the assessment was not possible
- N0
- N1
- N2
- N3
- Not evaluated
- Unknown

Metastases

According to the number of metastases as per corresponding tumour TNM classification indicate if it is:

- MX - the assessment was not possible;
- M0;
- M1;
- Not evaluated;
- Unknown.

Disease-specific staging

Once the values of TNM classification and any other factors that affect the stage have been determined, they are combined to assign an overall stage. Select the overall stage of the disease and check the box next to it. Most of the solid tumours in the field of medical oncology are staged 1 to 4. Also, histological grading is done 1 to 4. This has to be marked appropriately according to the stage of the disease. If the stage is “**unknown**” or “**not evaluated**” check the appropriate box.

Breast carcinoma risk factors and staging at diagnosis

Only complete this section if the diagnosis is breast carcinoma.

Receptor status

Breast carcinoma cells have several receptors which can characterise it. The most common receptors are oestrogen (estrogen) receptors (ER), which bind oestrogen, and progesterone receptors (PgR) which bind progesterone. Pathologists report receptor positivity as a percentage, for example, 70% ER+, 10% PgR+. This positivity is measured by immunohistochemical methods.

Based on the results of laboratory or pathology reports, specify:

- If oestrogen receptors (ER) were reported “**negative**”, “**positive**” (specify ER values in percentage) or were “**not evaluated**”.
- If progesterone receptors (PgR) were reported “**negative**”, “**positive**” (specify PgR values in percentage) or were “**not evaluated**”.
- If HER2/neu (c-erbB-2) (receptor tyrosine-protein kinase erbB-2) were reported “**negative**”, “**positive**” or were “**not evaluated**”.
 - If HER2 was tested positive, indicate whether it is defined by “**IHC 3+**” or “**IHC 1/2+ and FISH+**”.

Axillary lymph nodes at surgery

Indicate the number of lymph nodes obtained by a surgeon during axillary dissection that had tumour involvement before the slash, and the number of how many lymph nodes were examined after this axillary dissection after the slash (number of positive/number of examined). Otherwise mark this field as **Not evaluated**.

Sentinel Node

Mark as “**positive**” if cancer cells were found in the sentinel lymph node and “**negative**” if no cancer cells were found. If the sentinel node was not analysed, select the “**Not evaluated**” box.

Carcinoma type

Indicate if the carcinoma is “**ductal**” or “**lobular**”. Select “**Other**” if neither are applicable and specify breast carcinoma type in the text box in English (for example: mixed ductal–lobular carcinomas, or other histologies not lobular nor ductal).

Proliferation index (activity by Ki67 or MiB1 immunostaining)

Indicate the percentage of positive cells as a result of immunohistochemical staining for Ki-67 and MiB1, widely used methods for prognostic and predictive information in various cancers including breast carcinoma.

Inflammatory breast cancer

Indicate if the patient has inflammatory breast cancer type (answer **yes**) or not (answer **no**), otherwise mark it as **Unknown**. Inflammatory breast carcinoma is a clinical diagnosis not a histological one.

Germ cell tumour risk factors and staging at diagnosis

This section is to be filled only for germ cell tumour (incl. extra-gonadal and gonadal) diagnosis.

Histological classification

Select “**seminoma**” if 100% of the tumour is seminoma (pure seminoma), or select “**non-seminoma**” for all other germ cell tumour histological subclass (for example: choriocarcinoma, yolk sac tumour or others)

Note: mixed tumours to be considered as “**non-seminoma**” despite the presence of seminoma.

Site of origin

Indicate where in the body the germ cell tumour started, by choosing if it is “**gonadal**” or “**extra-gonadal**”. The majority of germ cell tumours arise from testicles. Rarely their origin is in the anterior mediastinum, or retroperitoneum or in other sites like pineal gland. If there is also a testis lesion at diagnosis it is not extragonadal.

Extra-gonadal origin

For extra-gonadal germ cell tumours, indicate if it was “**retroperitoneal**”, “**mediastinal**” or if it is originating from another organ.

If the germ cell tumour was neither retroperitoneal nor mediastinal, and “**other sites**” was selected, specify the other organ(s) in the text-box in English.

Bibliography

1. Eisenhauer EA, Therasse P, Bogaerts J, Schwartz LH, Sargent D, Ford R, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). *Eur J Cancer*. 2009 Jan;45(2):228–47.
2. International Prognostic Factors Study Group, Lorch A, Beyer J, Bascoul-Mollevi C, Kramar A, Einhorn LH, et al. Prognostic factors in patients with metastatic germ cell tumors who experienced treatment failure with cisplatin-based first-line chemotherapy. *J Clin Oncol*. 2010 Nov 20;28(33):4906–11.