

# ICCR Harmonisation Guidelines

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## Document history

Version	Description	Date
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Version 1.1	Updates included – tumour thickness and general rules for dataset development	March 2014
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Version 1.3	Inclusion of block identification key	December 2014
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## Abbreviations

ICCR	International Collaboration on Cancer Reporting
FIGO	International Federation of Gynaecology and Obstetrics
UICC	Union for International Cancer Control

## 1. PURPOSE

The purpose of this document is to ensure conformance to standard terminology across all of the International Collaboration on Cancer Reporting (ICCR) cancer datasets.

As part of the ICCR process, harmonisation of the cancer data element names as well as the responses is undertaken to ensure consistency across all datasets. Common cancer elements e.g., tumour site, margin status and response terms e.g., 'absent' versus 'not identified', are defined and recommended uses and groupings of responses are documented for application across all datasets. The *ICCR Harmonisation Guidelines* are not a comprehensive list of all possible terms but rather seek to describe common terms and may differ with specific use cases.

This document will be updated periodically as required in order to maintain its currency and to take advantage of improvements in process which will be achieved as the collaborative process progresses.

## 2. HARMONISATION OF DATA ELEMENTS

To promote harmonisation the use of the following terms is recommended where they are to be included in a dataset:

Term	Comment
<b>CLINICAL INFORMATION</b>	
Clinical information	Describes clinical information required by the pathologists and supported by evidence, often provided with the specimen.
Operative procedure	Describes the range of procedures which may be used with this specimen – e.g., radical prostatectomy for prostate specimens.
<b>MACROSCOPIC FINDINGS</b>	
Specimen orientation	This refers to the information received from the surgeon/clinician regarding orientation of the specimen by marking sutures, clips or other techniques.
Specimen(s) submitted	Record the body part, organ or tissue received in the laboratory i.e., the result of the operative procedure. All components of the anatomical specimen received must be listed at the required level of detail e.g., the relevant quadrant within a breast specimen; the specific segment of bowel e.g., ascending colon.
Specimen laterality	Used in conjunction with the specimen type or site e.g., breast/right.
Specimen integrity	Used to describe the quality of the specimen which may impact on the determination of an accurate diagnosis.
Specimen description	General description of the specimen which may include such features as shape, colour, etc.
Specimen weight	Quantitative measure of the weight of the specimen received in grams (g).
Specimen dimensions	Quantitative measure(s) of the specimen received in millimetres (mm).
Tumour site	This refers to the site of the tumour within the anatomical structure received e.g., cardia, fundus, antrum for gastric specimens.
Tumour focality	This refers to separate foci of the same tumour within a single organ e.g., thyroid. Specific use cases may apply in some cancers e.g., breast.
Number of tumours	Used in conjunction with 'tumour focality'. Specific use cases apply e.g., thyroid and kidney, this does not apply to multiple synchronous primary tumours, in which case a separate dataset is required.
Tumour dimensions	Quantitative measure(s) of the tumour in mm.

Term	Comment
Maximum tumour dimension	A measure in mm of the greatest length. Where there are multiple tumours it is implied that this is for the largest tumour.
Tumour perforation	Used to record that the tumour has/has not been received intact/fully encapsulated.
Block identification key	Used to record block for specialist review and the identification of the best material for ancillary studies and research.
<b>MICROSCOPIC FINDINGS</b>	
Histological tumour type	Histological tumour type is used when type is assessed by histology.
Histological subtype/variant	Histologic subtype/variant is usually used in conjunction with Histological tumour type where this type is assessed only by histology.
Histological tumour grade	Use histological tumour grade when assessed by histology only – i.e., counting mitoses, assessment of other morphological features e.g., pleomorphism, necrosis, gland formation/features of differentiation etc. Histologic grading includes grading according to specific grading systems e.g., Gleason, International Federation of Gynaecology and Obstetrics (FIGO) etc.
Microscopic description	This is used when a narrative description is required. Where information can be recorded in discrete fields this is preferable.
Mitotic count/Mitotic index	This is a calculation of the number of mitoses per mm <sup>2</sup> . The term mitotic rate is inaccurate as it is not a measure in units of time. Mitotic count and Mitotic index are functionally identical.
Necrosis	Used to record the presence or absence of necrosis.
Ulceration	Used to record the presence or absence of ulceration.
Depth of invasion	An indication of the greatest depth of invasion. This may be in mm or it may be described in terms of the infiltration of anatomical layers.
Tumour thickness	Direct measurement in mm, taken at right angles to the skin or mucosal surface, usually from that surface (unless otherwise specified, e.g., for Breslow thickness of melanoma) to the deepest part of the tumour.
Extra- ( <i>organ/nodal/capsular</i> ) extension	<p>Per the following examples:</p> <ol style="list-style-type: none"> <li>1) Extra-<i>organ</i> extension. Where the word ‘organ’ is replaced with a specific/named organ e.g., extra-thyroid extension. Refers to extension of the tumour external to the specified organ.</li> <li>2) Extra-<i>nodal</i> extension is used when the tumour extends beyond the lymph node.</li> <li>3) Extra-<i>capsular</i> extension is used when the tumour extends beyond the confines of an organ capsule e.g., ovary, thyroid, adrenal.</li> </ol> <p>Note: this excludes prostate specimens; no hyphen.</p>

Term	Comment
Lymphovascular invasion	Indication of invasion into the lymphatics or vascular system.
Extent of invasion ( <i>specific anatomical structure</i> ) invasion	Use to record the types of anatomical structures into which tumour has invaded. This refers to invasion of a specific anatomical structure e.g., <b>myometrial</b> invasion. These should be specific to support TNM staging.
Response to previous therapy	Used to record the volume and state of tumour remaining following treatment.
Margin status ( <i>name of relevant margin</i> ) margin	Margin status may be used to record the overarching findings e.g., involved/not involved or it may be used as a heading grouping other specific margin related features together. Use when recording involved or not involved. Include the specific name of the margin e.g., <b>peripheral</b> margin, <b>deep</b> margin etc.
Distance of tumour to ( <i>specific</i> ) margin	Use with the name of a specific margin e.g., distance of tumour to <b>deep</b> margin, measured in mm.
Lymph node status	Lymph node status is used as a heading grouping other specific lymph node related features together.
Number of ( <i>specific site</i> ) nodes submitted	Include the specify type/group of nodes where possible e.g., Number of <b>sentinel</b> lymph nodes submitted.
Number of ( <i>specific site</i> ) nodes examined	Include the specify type of node such as sentinel/non-sentinel/specific node group e.g., Number of <b>sentinel</b> lymph nodes examined.
Number of involved ( <i>specific site</i> ) nodes	Include the specify type of node such as sentinel/non-sentinel e.g., Number of positive <b>sentinel</b> lymph nodes
Size of largest nodal metastasis	A quantitative measure in mm of the largest dimension.
Coexistent pathology/Other pathology/Other findings	Used to describe any other relevant non-neoplastic pathology. This is generally used with a list of the most common/relevant pathologies found.
Histologically confirmed distant metastases	This element is used to record the presence of distant metastases found in the tissue available to the pathologist for evaluation. The final determination of distant metastasis or pM stage is determined by the clinician on review of all radiological, clinical and pathological information.
<b>ANCILLARY STUDIES</b>	Heading – used to group a set of elements related to specific ancillary tests e.g., FISH, molecular genetics etc.
Immunohistochemistry	Used to record the immunohistochemistry result
Molecular testing	Used to record the molecular testing result
Cytogenetic analysis	Used to record the cytogenetic result
Electron microscopy	Used to record the electron microscopy result
( <i>Name of relevant gene</i> ) alteration/rearrangement/fusion	Used to record the presence or absence of any molecular alteration, rearrangement or fusion.

Term	Comment
Representative blocks for ancillary studies	This element is used to record those blocks best representing tumour and or normal tissue for further study.
<b>SYNTHESIS AND OVERVIEW</b>	
Pathological staging	Heading – used to group a number of elements for staging e.g., Primary tumour, Regional lymph nodes e.g., Union for International Cancer Control (UICC) X <sup>th</sup> edition is usually used but specific cases apply. The specified staging system and version should be included in the name.

**Notes:**

1. Not all terms listed above will be used in all cancer specific datasets. Those most appropriate from the list above should be used where applicable. Additional cancer specific parameters and terms e.g., Breslow thickness may be used in addition to the terms above.
2. Plural should be listed as xxx(s) e.g., Specimen(s) submitted.
3. In general element names must not include a potential response e.g., lymphovascular invasion present, or presence of ulceration. These should be stated as lymphovascular invasion or ulceration etc.
4. The term Margin is not appropriate when used for punch biopsy and shave specimen. Use the term ‘tissue edges’ instead in these instances.

### 3. HARMONISATION OF RESPONSES

The following response terms are recommended:

Recommended Terms	Meaning/implications of use	Recommended use
Not identified	A response which implies that the parameter was not observed within the material reviewed.	USE for microscopic findings e.g., lymphovascular invasion perineural invasion.
Absent	A response which implies a very high level of confidence in the result – should only be used where the assessment is comprehensive.	USE for macroscopic findings e.g., ulceration, haemorrhage, necrosis, associated pathologies. Should not be used where review is across routine slides only and the outcome is based on those alone which means there is a possibility it may exist in sections not examined.
Not involved	A response which implies comprehensive assessment of a specific anatomical structure.	USE for margin status or evaluation of involvement of adjacent structures; assessment of lymph nodes.
Cannot be assessed	A response which implies that the specimen was not able to be assessed e.g., due to sufficient quality or quantity.	USE for surgical margins.
Not provided	A response which records that the information was not supplied e.g., by the requestor.	USE for clinical information expected but not supplied by the requestor e.g., pre-operative results.
Not applicable	A response which implies that the specimen supplied does not support assessment of this parameter.	Use as indicated.
Indeterminate (Cannot be determined)	A response which implies that a clear result could not be reached but does not specify whether this is because it cannot be assessed or that the outcome is uncertain.	USE in cases where the level of granularity required by including both ‘uncertain’ and ‘cannot be assessed’ as options is onerous or not required by the circumstances.  The term should be used sparingly.  In some cases, ‘cannot be determined’ may alternatively be used.
Uncertain	While the specimen is of sufficient quality and quantity a clear result could not be reached.	
Present	A response used to record that an attribute has been found.	

Recommended Terms	Meaning/implications of use	Recommended use
Involved	A response which implies comprehensive assessment of a specific anatomical structure.	USE for margin status or evaluation of involvement of adjacent structures; assessment of lymph nodes.
Submitted	A response used to record the presence of anatomical structures in the specimen e.g., lymph nodes, fallopian tubes etc.	USE for recording anatomical structures in the specimen.
Not submitted	A response used to record the absence of anatomical structures in the specimen e.g., lymph nodes, fallopian tubes etc.	USE for recording the absence of anatomical structures in the specimen.
Not specified	A response used to record when it is not specified on the request form.	USE for recording where a response is not specified on the request form.
Positive	A response used to record that an attribute has been found.	USE for the assessment of cytology. Should not be used for the identification of histological findings – use Present or Involved (margins).
Negative	A response which implies a very high level of confidence in the result.	USE for the assessment of cytology. Should not be used for the identification of histological findings – use Not identified or Not involved (margins).
Normal	A response where the presence of a marker used in molecular testing is normal (retained).	USE for molecular testing under ancillary studies.
Abnormal	A response where the presence of a marker used in molecular testing is abnormal (lost).	USE for molecular testing under ancillary studies.

### Recommended response groupings\*

Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
Present	Involved	Present	Submitted	Not provided	Normal
Not identified	Not involved	Absent	Not submitted	Provided	Abnormal
Indeterminate (Cannot be determined)	Cannot be assessed	Cannot be assessed			
		Not applicable			
Use for microscopic findings: <ul style="list-style-type: none"> <li>• Lymphovascular invasion</li> <li>• Perineural invasion</li> <li>• Extra- <i>organ/nodal/capsular</i> extension</li> </ul>	Use for: <ul style="list-style-type: none"> <li>• Margins</li> <li>• Assessment of specific anatomical structures e.g., extent of invasion</li> <li>• Lymph nodes</li> </ul>	Use for macroscopic findings: <ul style="list-style-type: none"> <li>• Multiple lesions/multifocal tumours</li> <li>• Involvement of adjacent structures</li> <li>• Ulceration</li> <li>• Haemorrhage</li> <li>• Necrosis</li> <li>• Associated pathologies</li> </ul>	Use for recording the absence or presence of specific anatomical structures in the specimen e.g., <ul style="list-style-type: none"> <li>• Lymph nodes</li> <li>• Adjacent structures e.g., fallopian tubes</li> </ul>	Use for clinical information expected to be supplied by the requestor e.g., <ul style="list-style-type: none"> <li>• Pre-operative results</li> <li>• Treatment</li> </ul>	Use for molecular testing

\*Not all responses will be used in all cases.

#### 4. GENERAL RULES FOR DATASET DEVELOPMENT

##### **Including both macroscopic and microscopic elements of the same type e.g., Tumour size**

1. In developing a dataset where a measurement is taken macroscopically and then confirmed microscopically, the advice to authors is to include the measurement only once in the dataset and add a commentary indicating that this measurement reflects the final confirmed measurement.
2. Where both macroscopic and microscopic measurements are taken, the two measurements may be included in the report at the discretion of the reporting pathologist but must be clearly identified.
3. In the event that authors agree that it is necessary to include both a macroscopic and microscopic element such as the macroscopic and microscopic extent of invasion in the case of renal carcinoma for example, the word macroscopic and microscopic should prefix the appropriate element e.g., '*macroscopic* extent of invasion' and '*microscopic* extent of invasion' for clarity.