International Collaboration on Cancer Reporting

ICCR Harmonisation Guidelines

Version: 2.6

Document history

Version	Description	Date
Version 0.1	Initial draft	Aug 2012
Version 0.2	Refinement of initial draft	Sept 2012
Version 0.3	Review by ICCR	Oct 2012
Version 0.4	ICCR team updates included	Oct 2012
Version 0.5	Refinement of ICCR updates	Nov 2012
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Version 1.1	Updates included – tumour thickness and general rules for dataset development	March 2014
Version 1.2	Updates agreed	June 2014
Version 1.3	Inclusion of block identification key	December 2014
Version 1.4	Change to specimen type/site to specimen submitted, tumour multi-focality to tumour focality and confirmation of Block identification key.	January 2015
Version 2	Document ratified by DSC	February 2015
Version 2.1	Removal of block identification key	June 2016
Version 2.2	Minor edits and formatting	March 2019
Version 2.3	Suggested updates for yearly review	February 2020
Version 2.4	Changes approved by DSC	February 2020
Version 2.5	Suggested updates for yearly review	February 2021
Version 2.6	Changes approved by DSC	March 2021

1. 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
MACROSCOPIC FINDINGS	Heading – used to group elements from the macroscopic inspection of the specimen.
Operative procedure	Describes the range of procedures which may be used with this specimen – e.g., radical prostatectomy for prostate specimens
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 dimensions	Quantitative measure(s) of the specimen received in mm.
Specimen weight	Quantitative measure of the weight of the specimen received in grams (g).
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 site	This refers to the site of the tumour within the anatomical structure received e.g., cardia, fundus, antrum for gastric specimens.
Tumour dimensions	Quantitative measure(s) of the tumour in mm.
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.

Term	Comment
Tumour perforation	Used to record that the tumour has /has not been received intact/fully encapsulated.
Block identification key	Used to record the types of tissue included in each block for further reference.
MICROSCOPIC FINDINGS	Heading – used to group elements from the microscopic (morphological) inspection of slides.
Histological tumour type	Histological tumour type is used when type is assessed only 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, FIGO, FNCLCC 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^2. 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- *(organ/nodal/capsular)* extension	Per the following examples: 1) Extra-*organ* extension. Where the word 'organ' is replaced with a specific/named organ e.g., extra-thyroid spread. Refers to extension of the tumour external to the specified organ. 2) Extra-*nodal* extension is used for spread of tumour beyond the lymph node. 3) Extra-*capsular* extension is used when the tumour extends beyond the confines of an organ capsule e.g., ovary, thyroid, adrenal Note: this excludes prostate specimens. Note: no hyphen.

Term	Comment
Lymphovascular invasion	Indication of invasion into the lymphatics or vascular system.
Extent of invasion	Use to record the types of anatomical structures into which tumour has invaded.
(specific anatomical structure) invasion	This refers to invasion of a specific anatomical structure e.g., **myometrial** invasion. These should be specific to support TNM staging.
Coexistent pathology	Used to describe any other relevant non-neoplastic pathology. This is generally used with a list of the most common/relevant pathologies found.
Response to neoadjuvant therapy	Used to record the volume and state of tumour remaining following treatment.
Margin status	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.
(name of relevant margin) margin	Use when recording involved or not involved. Include the specific name of the margin e.g., **peripheral** margin, **deep** margin etc.
Distance of tumour to *(specific)* margin	Use with the name of a specific margin e.g., distance of tumour to **deep** 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 *(specific site)* nodes submitted	Include the specify type/group of nodes where possible e.g., Number of **sentinel** lymph nodes submitted.
Number of *(specific site)* nodes examined	Include the specify type of node such as sentinel/non-sentinel/specific node group e.g., Number of **sentinel** lymph nodes examined
Number of positive *(specific site)* nodes	Include the specify type of node such as sentinel/non-sentinel e.g., Number of positive **sentinel** lymph nodes
Size of largest nodal metastasis	A quantitative measure in millimetres (mm) of the largest dimension.
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.
ANCILLARY STUDIES	Heading – used to group a set of elements related to specific ancillary tests e.g., FISH, molecular genetics etc.
Immunohistochemistry	Subheading (under ancillary studies)
Molecular testing	Subheading (under ancillary studies)
Cytogenetic analysis	Subheading (under ancillary studies)

Term	Comment
Electron microscopy	Subheading (under ancillary studies)
Representative blocks for ancillary studies	This element is used to record those blocks best representing tumour and or normal tissue for further study.
SYNTHESIS AND OVERVIEW	Heading used to group 1) synthesised information – that is information which is the result of the integration and interpretation of information from two or more modalities to derive new information e.g., staging, type in which more than histologic means are used; 2) summary data (composite of previous information) and 3) the overarching case commentary (pathologists opinion)
Pathological staging	Heading – used to group a number of elements on staging e.g., Primary tumour, Regional lymph nodes, Distant metastases e. AJCC 8th edition is usually used but specific use cases apply. The specified staging system and version should be included in the name. Note: pathologists often do not receive information on distant metastasis and cannot determine this from the specimen received and therefore including an option of "not applicable" is advised.
Tumour type	Tumour type is used when determination of type uses non-histological criteria – e.g., FISH, Cytogenetics, molecular or flow studies.
Subtype/variant	Subtype/variant is usually used in conjunction with Tumour type where this type is not determined solely by histologic means.
Tumour grade	Use tumour grade when grade is determined by non-histological criteria

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 nnn(s) e.g., Tumour site(s)
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.

2. 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 sections reviewed.	USE for microscopic findings e.g., LVI, 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	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.
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.	
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	USE for recording the absence of anatomical structures in the

Recommended Terms	Meaning/implications of use	Recommended use
	the specimen e.g., lymph nodes, fallopian tubes etc	specimen.
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).

Recommended response groupings*

Group 1	Group 2	Group 3	Group 4	Group 5
Present	Involved	Present	Submitted	Not provided
Not identified	Not involved	Absent	Not submitted	
Indeterminate	Cannot be assessed	Cannot be assessed		
		Not applicable		
Use e.g., for microscopic findings: • LVI • Perineural invasion	Use for: • Margins • Assessment of specific anatomical structures e.g., extent of invasion • Lymph nodes	Use e.g., for macroscopic findings: • Multiple lesions/multifocal tumours • Involvement of adjacent structures • Ulceration • Haemorrhage • Necrosis • Associated pathologies	Use for recording the absence or presence of specific anatomical structures in the specimen e.g., • Lymph nodes • Adjacent structures e.g., fallopian tubes	Use for clinical information expected to be supplied by the requestor e.g., • pre-operative results • treatment

*not all responses will be used in all use cases.

3. 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.