



## MOHCCN Clinical Data Model Release Notes

### Version 3.1:

Release Date: September 5, 2024

#### **All tables**

- program\_id: added regex `^[A-Za-z0-9\-\.\_]{1,64}$` for permissible values

#### **Sample Registration**

- specimen\_tissue\_source - added new term 'Other'

#### **Donor**

- gender - added new terms 'Other', 'Prefer not to disclose', and 'Not available'
- sex\_at\_birth - added new term 'Not available'
- cause\_of\_death - changed term 'Unknown' to 'Not available'
- lost\_to\_followup\_reason - changed term 'Unknown' to 'Not available', removed 'Not applicable', added new term 'Discharged from follow-up'

#### **Specimen**

- specimen\_anatomic\_location - added new term 'Not available'
- tumour\_histological\_type - added new term 'Not available'
- reference\_pathology\_confirmed\_diagnosis - added new term 'Not available'
- reference\_pathology\_confirmed\_tumour\_presence - added new term 'Not available'
- tumour\_grading\_system - added new term 'Not available'
- tumour\_grade - added new term 'Not available'
- percent\_tumour\_cells\_range - added new term 'Not available'
- percent\_tumour\_cells\_measurement\_method - added new term 'Other' and 'Not available'
- specimen\_storage - changed term 'Unknown' to 'Not available' and added new term 'OCT embedded'
- specimen\_processing - changed term 'Unknown' to 'Not available'
- specimen\_laterality - change 'Unknown' to 'Not available'

#### **Primary Diagnosis**

- basis\_of\_diagnosis - changed term 'Unknown' to 'Not available'
- laterality - changed term 'Unknown' to 'Not available'
- clinical\_tumour\_staging\_system - added new term 'Not available'
- clinical\_stage\_group - added new term 'Not available'

- pathological\_tumour\_staging\_system - added new term 'Not available', changed term the field description
- pathological\_stage\_group - added new term 'Not available'

### **Treatment**

- treatment\_type - added new term 'Other', changed term 'Other targeting molecular therapy' to 'Targeted molecular therapy'
- is\_primary\_treatment - added new term 'Not available'
- treatment\_intent - added new term 'Not available'
- response\_to\_treatment\_criteria\_method - added new term 'Not available'
- response\_to\_treatment - added new term 'Not available'
- status\_of\_treatment - changed term 'Unknown' to 'Not available', removed 'Not applicable', added new term 'Treatment ongoing'

### **Systemic Therapy**

- drug\_dose\_units - added new term 'Not available'

### **Radiation**

- radiation\_therapy\_modality - added new term 'Not available'
- radiation\_therapy\_type - added new term 'Not available'
- anatomical\_site\_irradiated - added new term 'Not available'
- radiation\_boost - added new term 'Not available'

### **Surgery**

- surgery\_reference\_database - added new term 'CCI'
- tumour\_focality - changed term 'Unknown' to 'Not available'
- residual\_tumour\_classification - changed term 'Unknown' to 'Not available'
- margin\_types\_involved - changed term 'Unknown' to 'Not available'
- margin\_types\_not\_involved - changed term 'Unknown' to 'Not available'
- margin\_types\_not\_assessed - changed term 'Unknown' to 'Not available'
- lymphovascular\_invasion - changed term 'Unknown' to 'Not available'
- perineural\_invasion - changed term 'Unknown' to 'Not available'

### **Follow Up**

- disease\_status\_at\_followup - added new term 'Not available'
- relapse\_type - added new term 'Not available', changed term 'Progression (liquid tumours)' to 'Progression'
- date\_of\_relapse - updated the field description

### **Biomarker**

- er\_status - changed term 'Unknown' to 'Not available'
- pr\_status - changed term 'Unknown' to 'Not available'
- her2\_ihc\_status - changed term 'Unknown' to 'Not available'

- her2\_ish\_status - changed term 'Unknown' to 'Not available', updated the field description
- hpv\_ihc\_status - changed term 'Unknown' to 'Not available'
- hpv\_pcr\_status - changed term 'Unknown' to 'Not available'

### **Comorbidity**

- prior\_malignancy - changed term 'Unknown' to 'Not available'
- laterality\_of\_prior\_malignancy - changed term 'Unknown' to 'Not available'
- comorbidity\_treatment\_status - changed term 'Unknown' to 'Not available'

### **Exposure**

- tobacco\_smoking\_status - changed term 'Smoking history not documented' to 'Not available'
- tobacco\_type - changed term 'Unknown' to 'Not available'

## **Version 3.0:**

Release Date: May 13, 2024

### **Donor**

- Removed required field "primary\_site"

### **Specimen**

- Added optional field "submitter\_treatment\_id" to indicate the treatment ID of the surgery if the specimen was resected during the surgery
- Removed the conditional field "pathological\_tumour\_staging\_system"
- Removed the conditional field "pathological\_stage\_group"
- Removed the conditional field "pathological\_t\_category"
- Removed the conditional field "pathological\_n\_category"
- Removed the conditional field "pathological\_m\_category"

### **Primary Diagnosis**

- Added required field "primary\_site"
- Added the conditional field "pathological\_tumour\_staging\_system"
- Added the conditional field "pathological\_stage\_group"
- Added the conditional field "pathological\_t\_category"
- Added the conditional field "pathological\_n\_category"
- Added the conditional field "pathological\_m\_category"
- Removed the required field "lymph\_nodes\_examined\_status"
- Removed the conditional field "lymph\_nodes\_examined\_method"
- Removed the conditional field "number\_lymph\_nodes\_positive"
- Added new term "AJCC cancer staging system" to fields "clinical\_tumour\_staging\_system" and "pathological\_tumour\_staging\_system"
- Removed terms "AJCC 8th edition", "AJCC 7th edition", and "AJCC 6th edition" from fields "clinical\_tumour\_staging\_system" and "pathological\_tumour\_staging\_system"
- Added new terms "T1c1" and "T1c2" to fields: "clinical\_t\_category" and "pathological\_t\_category"

### **Treatment**

- Changed required field "response\_to\_treatment\_criteria\_method" to optional
- Changed required field "response\_to\_treatment" to optional
- Fixed the typos of permissible values in field "response\_to\_treatment"
- Removed optional field "line\_of\_treatment"
- Removed required field "treatment\_setting"
- Removed optional field "days\_per\_cycle"
- Removed optional field "number\_of\_cycles"

## **Systemic Therapy**

- Merged Chemotherapy, Hormone Therapy and Immunotherapy into new Systemic Therapy table
- Added the following fields to Systemic Therapy table
  - program\_id
  - submitter\_donor\_id
  - submitter\_treatment\_id
  - systemic\_therapy\_type
  - start\_date
  - end\_date
  - drug\_reference\_database
  - drug\_name
  - drug\_reference\_identifier
  - drug\_dose\_units
  - days\_per\_cycle
  - number\_of\_cycles
  - prescribed\_cumulative\_drug\_dose
  - actual\_cumulative\_drug\_dose

## **Chemotherapy**

- Removed the whole table

## **Immunotherapy**

- Removed the whole table

## **Hormone Therapy**

- Removed the whole table

## **Surgery**

- Removed the optional field "submitter\_specimen\_id"
- Added required field "surgery\_reference\_database"
- Added required field "surgery\_reference\_identifier"

## **Follow Up**

- Remove the optional field "recurrence\_tumour\_staging\_system"
- Remove the optional field "recurrence\_stage\_group"
- Remove the optional field "recurrence\_t\_category"
- Remove the optional field "recurrence\_n\_category"
- Remove the optional field "recurrence\_m\_category"

## **Version 2.1:**

Release Date: September 29, 2023

### **Clarifications to Data Field**

#### **Donor:**

- Added to the required field "date\_resolution" to indicate whether month or day resolution is used for all date fields for a given donor.
- It is the responsibility of the data curator at a particular site to convert the local data files into the CanDIG ingest format. An Extract-Transform-Load (ETL) python library is provided to facilitate mapping input files to the MOHCCN clinical data standard and converting into a json input format. Once CanDIG has implemented this model change, part of the ETL process will be converting dates to either month or day intervals. The ETL also includes a validation step that checks for model compliance, including intervals rather than dates.
- In this workflow, the conversion from dates to intervals happens when the data is still in the hands of the data curator, prior to ingest. The file that gets ingested into CanDIG must contain only intervals, and trying to upload a data file containing dates will generate a validation error and prevent ingest.

### **New Terms for Existing Fields**

#### **Primary Diagnosis:**

- Added new term "B cell selection" to "lymph\_nodes\_examined\_method" field.

#### **Chemotherapy:**

- Added new term "mg" to "chemotherapy\_drug\_dose\_units" field.

#### **Immunotherapy:**

- Added new term "mg" to "immunotherapy\_drug\_dose\_units" field.

#### **Hormone Therapy:**

- Added new term "mg" to "hormone\_drug\_dose\_units" field.

#### **Sample Registration:**

- Added new terms "Whole cell - protein", "Whole cell - DNA", "Whole cell - RNA" and "Whole cell (B-cell depleted)" to the "sample\_type" field.

## **Version 2.0:**

Release Date: February 17, 2023

### **All tables:**

- Changed fields related to dates to collect date instead of just year and month (ie. changed from "YYYY-MM" to "YYYY-MM-DD"). Collecting just the year and month prevents specificity in mapping clinical events. For example, if treatment and specimen collection occur in the same month, unable to determine if specimen was collected before or after treatment. Possible solutions include ingesting submitted data with dates so calculations can be done more precisely, and masking/hiding the date on the front-end.

### **Sample Registration:**

- "specimen\_tissue\_source" terminology refined and redundant terms removed. Added references to standard terminology.
- "gender" and "sex\_at\_birth" fields moved to the Donor table. If these fields are unknown, programs will need to apply for a clinical exception.

### **Donor:**

- New optional field "lost\_to\_followup\_after\_clinical\_event\_identifier" to indicate when the donor was lost to follow up. Previously this field was in the Follow Up table, so only donors lost to follow up after a Follow Up event could be indicated.
- New optional field "date\_alive\_after\_lost\_to\_followup" added to allow data submitters to indicate the use case where a donor was lost to follow up, but discovered to be alive later on without any information about their cancer disease status.
- Added references to ICD-O code for each term in "primary\_site"

### **Specimen:**

- Added new staging system to "pathological\_tumour\_staging\_system" field
- Added new stage groups in the "pathological\_stage\_group" field belonging to new staging systems added.
- Updated description for "specimen\_storage" to indicate that it is referring to long term storage.
- Added new optional field "specimen\_processing"
- Added new optional field "specimen\_laterality"
- Added new tumour grading systems in the "tumour\_grading\_system" field.
- Added new tumour grades in the "tumour\_grade" field belonging to new tumour grading systems added.

### **Primary Diagnosis:**

- Added a new optional field for "laterality".

- Added new staging systems to the "clinical\_tumour\_staging\_system" field.
- Added new stage groups in the "clinical\_stage\_group" field belonging to new staging systems added.

### **Treatment:**

- Removed the term "Ablation" from "treatment\_type" terminology, and moved it to the "surgery\_type" field.
- Removed the term "Endoscopic therapy" from "treatment\_type" terminology.
- Added a new optional field "line\_of\_treatment" to indicate line of treatment if it is not the primary treatment.
- Added new terms to "treatment\_setting" field.
- Added new terms to "treatment\_intent" field.
- Added "Blazer score" to "response\_to\_treatment\_criteria\_method" terminology
- Added response criteria belonging to Blazer score in "response\_to\_treatment" terminology.
- Added new optional field "status\_of\_treatment"

### **Chemotherapy:**

- Added a new required field "drug\_reference\_database" to indicate which drug database the drug name exists in.
- Renamed "drug\_rxnormcui" to "drug\_reference\_identifier" to allow submission of drug reference identifiers from other drug databases (not just restricted to RxNorm).
- Renamed "chemotherapy\_drug\_dosage\_units" to "chemotherapy\_drug\_dose\_units" (replaced the word "dosage" with "dose")
- Renamed "cumulative\_prescribed\_drug\_dosage" to "prescribed\_cumulative\_drug\_dose" for consistency with ARGO data model.
- Renamed "cumulative\_actual\_drug\_dosage" to "actual\_cumulative\_drug\_dose" for consistency with ARGO data model.
- Added "IU/kg" to the "chemotherapy\_drug\_dose\_units" field.

### **Hormone Therapy:**

- Added a new required field "drug\_reference\_database" to indicate which drug database the drug name exists in.
- Renamed "drug\_rxnormcui" to "drug\_reference\_identifier" to allow submission of drug reference identifiers from other drug databases (not just restricted to RxNorm).
- Renamed "hormone\_drug\_dosage\_units" to "hormone\_drug\_dose\_units" (replaced the word "dosage" with "dose")
- Renamed "cumulative\_prescribed\_drug\_dosage" to "prescribed\_cumulative\_drug\_dose" for consistency with ARGO data model.



- Renamed "cumulative\_actual\_drug\_dosage" to "actual\_cumulative\_drug\_dose" for consistency with ARGO data model.
- Added "IU/kg" to the "hormone\_drug\_dose\_units" field.

### **Radiation:**

- Added the term "Radiopharmaceutical" to "radiation\_therapy\_modality"
- Updated terminology for "anatomical\_site\_irradiated" (derived from Cancer Care Ontario).

### **Immunotherapy:**

- Added a new required field "drug\_reference\_database" to indicate which drug database the drug name exists in.
- Added a new required field "drug\_reference\_identifier" to allow submission of drug reference identifiers from other drug databases (not just restricted to RxNorm).
- Added a new required field "immunotherapy\_drug\_dosage\_units".
- Added a new required field "prescribed\_cumulative\_drug\_dose"
- Added a new required field "actual\_cumulative\_drug\_dose"
- Added a new required field "immunotherapy\_drug\_dose\_units" field.

### **Surgery:**

- New terms added to the "surgery\_type" field.

### **Follow Up:**

- Updated "Progression NOS" to "Progression not otherwise specified"
- Update requirements for "anatomic\_site\_progression\_or\_recurrence".
- Added a new staging systems to the "recurrence\_tumour\_staging\_system" field.
- Added new stage groups in the "recurrence\_stage\_group" field belonging to new staging systems added.

### **Biomarker:**

- Added new optional fields for ER, HER and PR status ("er\_status", "er\_percent\_positive", "her2\_ish\_status", "her2\_ihc\_status", "pr\_status", "pr\_percent\_positive")
- Added new optional fields for HPV status ("hvp\_ihc\_status", "hvp\_pcr\_status", "hvp\_strain")

### **Exposure:**

- New optional "Exposure" table added with optional fields related to tobacco exposure ("tobacco\_smoking\_status", "tobacco\_type", "pack\_years\_smoked")