MOHCCN Clinical Data Model version 4.0 Release Notes

Release Version: 4.0
Release Date: TBD

Release Summary:

Updates	Total Fields/Terms	Details
Total new fields added	5 fields	1 required: - Surgery.margins_status 4 optional: - Donor.lost_to_followup - Donor.date_of_death_is_estimated - Treatment.treatment_setting - Biomarker.ca19-9
Total fields moved	3 fields	Moved from Sample Registration to Specimen: - specimen_type - specimen_tissue_source - tumour_normal_designation
Total fields removed	5 fields	5 optional: - Donor.lost_to_followup_after_clinical_event_identifier - Donor.date_alive_after_lost_to_followup - Surgery.margin_types_involved - Surgery.margin_types_not_involved - Surgery.margin_types_not_assessed
Total new schemas added	2 schemas	Program: 15 fields (8 required, 7 optional) Radiopharmaceutical Therapy: 14 fields (10 required, 4 optional)

Fields with terminology updates	8 fields	New terms added to controlled terminology for: - specimen_type - clinical_stage_group - pathological_stage_group - basis_of_diagnosis - anatomical_site_irradiated - radiation_therapy_modality - treatment_intent - treatment_type Removed terms from controlled terminology for: - specimen_type - basis_of_diagnosis
Fields with Null values added	69 fields	
New terminology added	17 new terms	
Retired terminology terms	2 terms retired	
Fields with data type changes	3 fields	Biomarker fields: - psa_level - cea - ca125
Fields with requirement changes	2 fields	Surgery fields: - surgery_site - surgery_location Treatment fields: - is_primary_treatment - treatment_start_date - treatment_end_date - treatment_intent - treatment_setting - response_to_treatment_criteria_method - response_to_treatment

		- status_of_treatment Systemic Therapy - end_date

Detailed Release Notes:

Donor schema

- Added new optional fields:
  - lost_to_followup
  - date_of_death_is_estimated

- Removed optional fields:
  - lost_to_followup_after_clinical_event_identifier
  - date_alive_after_lost_to_followup

Sample Registration and Specimen schemas:

- Fields moved from Sample Registration schema to Specimen schema:
  - specimen_type
  - specimen_tissue_source
  - tumour_normal_designation

Specimen schema:

Updates to “specimen_type” field controlled terminology:

- Added new terms:
  - "Locally recurrent tumour (non-metastatic)"
  - "Recurrent tumour, NOS"
  - "Metastatic tumour of uncertain primary"
- Removed term:
  - "Recurrent tumour"

Primary Diagnosis schema:

Updates to “clinical_stage_group” and “pathological_stage_group” fields’ controlled terminology:

- Added new terms (substage terms related to the FIGO staging system):
  - “IC1”
  - “IC2”
  - “IC3”

Updates to “basis_of_diagnosis” field controlled terminology:

- Added new terms (to reflect ENCR's recommendations for basis of diagnosis):
  - Cytogenetic and/or molecular testing
  - Histology at autopsy
  - Histology of a metastasis
  - Histology of the primary tumor
  - Histology
- Removed term from controlled terminology:
  - Histology of a primary tumor

Treatment schema:

- Updates to “treatment_intent” field controlled terminology:
  - Added new terms:
    - Combined diagnostic and therapeutic intent (SNOMED: 1279505009)
    - Life-sustaining intent (SNOMED: 1290527003)

- Updates to “treatment_type” field controlled terminology:
  - Added new terms:
    - "Unknown whether patient received treatment"
    - “Patient referred for treatment at other center, details unknown"
    - “Radiopharmaceutical Therapy”

- Added a new optional field with controlled terminology (this field was removed in an earlier version, but has been re-added in this version):
  - “treatment_setting:
    - Adjuvant
    - Neoadjuvant

        - Not available

Surgery schema:

- Added a new required field with controlled terminology:
    - “margins_status”:
        - Margins clear
        - Margin(s) involved
        - Not applicable
        - Not available
        - Unknown

- Removed optional fields:
    - margin_types_involved
    - margin_types_not_involved
    - margin_types_not_assessed

- Updated Requirement property for "surgery_site" and "surgery_location" fields:
    - Updated these fields from being "Required/Conditional" to only "Required".

Radiation Therapy schema:

- Updates to “anatomical_site_irradiated” field controlled terminology:
    - Replaced existing controlled terminology with new controlled terminology that pairs anatomical location with laterality.

- Updates to “radiation_therapy_modality” field controlled terminology:
    - Added a new term:
        - “Teleradiotherapy using photons"

Biomarker schema:

- Updated Type property of “psa_level”, “cea” and “ca125” fields:
    - Updated “Integer” to “Number::

- Added a new optional field:

- "ca19-9"

New schemas added:

- Program schema:
  - Aimed at collecting program metadata to support future ingestion and interoperability with Pan Canadian Genome Library
- Radiopharmaceutical Therapy:
  - Supports submission of radiopharmaceuticals.

Fields with Null values added:

- **Donor (9):** gender, sex_at_birth, is_deceased, date_of_birth, date_of_death, date_of_death_is_estimated, date_resolution, cause_of_death, lost_to_followup
- **Specimen (11):** specimen_collection_date, specimen_type, specimen_tissue_source, tumour_normal_designation, specimen_anatomic_location, tumour_histological_type, reference_pathology_confirmed_diagnosis, reference_pathology_confirmed_tumour_presence, tumour_grading_system, tumour_grade, percent_tumour_cells_range, percent_tumour_cells_measurement_method
- **Primary Diagnosis (14):** date_of_diagnosis, cancer_type_code, primary_site, basis_of_diagnosis, clinical_tumour_staging_system, pathological_tumour_staging_system, clinical_t_category, pathological_t_category, clinical_n_category, pathological_n_category, clinical_m_category, pathological_m_category, clinical_stage_group, pathological_stage_group
- **Treatment (9):** treatment_type, is_primary_treatment, treatment_start_date, treatment_end_date, treatment_intent, treatment_setting, response_to_treatment_criteria_method, response_to_treatment, status_of_treatment
- **Systemic Therapy (7):** systemic_therapy_type, start_date, end_date, drug_reference_database, drug_reference_identifier, drug_name, drug_dose_units
- **Radiation (5):** radiation_therapy_modality, radiation_therapy_type, radiation_therapy_fractions, radiation_therapy_dosage, anatomical_site_irradiated

- **Surgery (6):** surgery_reference_database, surgery_reference_identifier, surgery_type, surgery_site, surgery_location, margins_status
- **Follow Up (6):** date_of_followup, disease_status_at_followup, relapse_type, date_of_relapse, method_of_progression_status, anatomic_site_progression_or_recurrence
- **Biomarker (1):** test_date
- **Comorbidity (1):** comorbidity_type_code