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SNOMED CT Implementation Guide for Cancer Synoptic Reporting

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The accurate and consistent documentation of pathology assessments of malignant tumors (i.e., cancer) is essential for accurate cancer diagnosis and treatment information to support effective patient care. The use of a standardized terminology, such as SNOMED CT, is essential to improve the quality of this information. SNOMED CT is a comprehensive clinical terminology system used in the healthcare industry to standardize the description of clinical concepts.

The purpose of this SNOMED CT Implementation Guide for Cancer Synoptic Reporting is to provide a structured and comprehensive roadmap for the implementation of SNOMED CT in this field. The guide covers topics important for the implementation of clinical information systems facilitating high-quality, consistent and meaningful use of SNOMED CT in cancer synoptic reporting.

By adopting SNOMED CT, healthcare organizations can improve patient care, facilitate research, and promote collaboration between healthcare providers.

Targeted at both clinical users and technical implementers, this Implementation Guide will provide the necessary resources and guidance to ensure a successful SNOMED CT implementation in the field of cancer synoptic reporting.

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Executive Summary

The SNOMED CT Clinical Implementation Guide for Cancer Synoptic Reporting serves as a comprehensive resource designed to facilitate standardized and structured reporting in cancer care. The guide highlights the role of SNOMED CT in standardizing and enhancing cancer reporting practices. SNOMED CT, as a comprehensive clinical terminology, includes clinical concepts that can be used to represent cancer diagnosis, treatment, and outcomes. By adopting SNOMED CT in cancer synoptic reporting, healthcare organizations can improve the quality of information captured, facilitate data exchange, support research initiatives, and enhance collaboration among healthcare providers.

The guide is aimed at providing clinicians with an overview of the content of SNOMED CT that supports cancer synoptic reporting. In addition the guide provides detailed description for vendors and system developers wishing to implement the approach within systems.

The guide underscores the pivotal role of synoptic reporting in improving the quality of cancer care by ensuring that critical data elements are accurately documented and easily shared across different healthcare settings. Through the use of standardized terminology and structured templates, healthcare professionals can streamline the documentation process, reduce variability in reporting reporting practices, and promote adherence to evidence-based guidelines.

In the realm of oncology, the guide provides examples of how synoptic reporting can benefit specific scenarios such as hematologic malignancy evaluations, cervical cancer screenings, and neuro-oncology tumor resections. By capturing detailed information about tumor characteristics, diagnostic findings, treatment interventions, and post-operative care, synoptic reports play a crucial role in guiding clinical decision-making and optimizing patient outcomes.

The guide demonstrates how existing standards, such as SNOMED CT and HL7 FHIR Questionnaires, can be effectively utilized to create implementable and shareable representations of synoptic reporting forms. By leveraging SNOMED CT within structured templates and questionnaires, healthcare professionals can capture detailed and clinically relevant information in a consistent and interoperable format. This approach not only ensures the accuracy and completeness of data but also enables seamless sharing and analysis of information across different healthcare systems and settings.

The guide serves as a roadmap for healthcare organizations looking to implement SNOMED CT in cancer synoptic reporting, providing practical guidance on how to leverage existing standards to create standardized, structured, and clinically meaningful synoptic reports. By following the recommendations outlined in the guide, healthcare providers can streamline reporting processes, improve data quality, and ultimately enhance the delivery of care to patients with cancer.

1. Introduction

Audience

SNOMED CT is a comprehensive, multilingual clinical terminology that can be used to standardize and improve the quality of data related to cancer synoptic reporting. This Cancer Synoptic Reporting Clinical Implementation Guide is targeted at the various stakeholders involved with the implementation of SNOMED CT in this domain:

- **SNOMED International Members** who are seeking uniform, clear best practices for documenting **structured cancer pathology reports**, and understanding how SNOMED CT can be applied in this domain
- **Clinicians** who are interested in understanding how SNOMED CT can support the clinical needs for data collection and acquisition within the field of **cancer pathology reports** for patient care.
- **Information managers** who are looking to learn how SNOMED CT can be integrated into health information models within the domain of **cancer pathology and cancer care** to support the implementation of SNOMED CT and enhance data interoperability.
- **Software developers** who want to learn how to integrate SNOMED CT into software applications used in the domain of **structured cancer pathology reporting**.

Objective

The objective of this Cancer Synoptic Reporting Clinical Implementation Guide is to provide instruction and guidance regarding the SNOMED CT content produced by the Cancer Synoptic Reporting Project Group. The guide provides instruction on implementing SNOMED CT for use in cancer synoptic reporting. After review of this guide, the reader will have knowledge to implement SNOMED CT encoded cancer synoptic reports for use in the electronic health record, for electronic transmission and for use in analytics.

Scope

The scope of the Cancer Synoptic Reporting Project Group was specific to the creation of SNOMED CT necessary to unambiguously represent the data elements required for cancer reporting for all solid tumors, adult and pediatric, as published by the College of American Pathologists (CAP) and the International Collaboration on Cancer Reporting (ICCR). The ICCR is supported by the CAP, RCPath, and RCPA as well as other societies of pathology. As a result, data sets produced by the Royal College of Pathology (RCPath) and the Royal College of Pathology Australasia (RCPA) were also used as references for this work. Data sets produced by the ICCR are open source and are now the foundation for the data sets used throughout SNOMED International Member Nations in Europe and Australasia. The protocols produced by the CAP are used in the United States and Canada and are required for laboratory certification. It is estimated that there is a 95% overlap of content between the CAP and ICCR, thus making these two protocol providers reasonable foundations for this project.

As noted the content addressed in this guide is specific to structure pathology reporting of malignant neoplasms as specified by the CAP and ICCR. The content created is intended to represent the specific observations made and reported by the pathologist during the examination of excised tissue. It is NOT intended to define the clinical interpretation of the data. Indeed, it is expected that the pathologist and clinicians using the pathology report understand the clinical meaning of the data as contained within any particular report. For example, the criteria to differentiate between an adenocarcinoma and a mucinous carcinoma in the colon versus the breast is expected to be understood by the data creator (pathologist) and user (surgeon or clinician). It is not reflected in the SNOMED CT concept.

The Cancer Synoptic Reporting Project Group highly leveraged the work of the Observables Project Group and used the observable entity hierarchy for much of the new SNOMED CT content developed in this project. This decision was made for three specific reasons:

1. Synoptic reports are structured as a series of tumor features to be observed and the subsequent observation. The use of observable entities to describe the "thing" being observed or measured is consistent with the definition of the observable entity hierarchy.

2. The context for the synoptic data elements is reflected in specific observations to be made by the pathologist. The observations, or answers, to the feature of the neoplasm being observed are often repeated across protocols. (For example: Present, Absent, Adenocarcinoma, Carcinoma, etc). To unambiguously represent all content for all forms of solid tumor protocols would require a substantial number of new concept definitions in many SNOMED CT hierarchies that would exceed the number of Observable entity concepts needed to represent the same data elements.

3. Legacy content as inherited as part of the creation of SNOMED International and the merger of SNOMED RT and the READ codes, was found in both the observable entity and clinical finding hierarchies. SNOMED CT content in either hierarchy was exclusively primitive without concept definition. Substantial changes to the clinical finding hierarchy concept model would have been required in order to create necessary and sufficient concept definitions for these findings. Furthermore, new finding concepts for each tumor type would be necessary to meet the objective of this project as well as the observable entity hierarchy.

Content included in this project consists of:

1. All required data elements for adult and pediatric solid tumors as specified by the CAP and ICCR
2. Biomarker data elements for immunohistochemistry

Content to be further developed:

1. Biomarker data beyond immunohistochemistry, for example, fluorescent in situ hybridization
2. Reporting protocols used for Central Nervous System neoplasms and Hematolymphoid tumors
3. Cancer screening protocols

Content NOT included in this project:

1. Cancer disorder modeling
2. Data elements not explicitly enumerated in published structured pathology reporting protocols
3. Histology modeling quality improvement (separate but related project)
4. Genomics modeling
5. Tumor staging modeling

Background and Attribution

Pathology reports for cancer diagnosis and prognosis are increasingly structured in synoptic form, following guidelines from esteemed organizations such as the College of American Pathologists, the Royal College of Pathology, and others. These reports, guided by national and international protocols, ensure consistency and accuracy across various entities involved in cancer care.

These structured reports, often referred to as data sets, maintain high consistency among different publishing entities. It's imperative to represent the data elements within these reports in both human-readable and machine-readable formats. Computable data elements enable integration into electronic health records for clinical support and seamless transmission to cancer registries for public health purposes, enhancing clinical translational research.

However, prior to 2020, the availability and clarity of SNOMED CT content for cancer synoptic reporting were lacking. Studies by the US Centers for Disease Control and Prevention in 2005 and 2009 highlighted the inadequacy of SNOMED CT and LOINC in encoding cancer data unambiguously for reporting purposes.

Recognizing this deficiency, the Cancer Synoptic Reporting Project Group was established in 2020 with a specific aim: to develop comprehensive SNOMED CT concepts suitable for structured pathology reports. Their objective encompasses supporting clinical, public health, and research applications. Specifically, they aim to create SNOMED CT content necessary for structured reporting across all solid tumor protocols, including those tailored for pediatric cases, as published by leading pathology organizations.

This SNOMED CT Clinical Implementation guide and the underlying work have been developed by the Cancer Synoptic Reporting Project Group. This Clinical Project Group (CPG) is composed of experts in the field of **pathology** providing input from the community of practice on the development, maintenance, and use of SNOMED CT in this specific domain. The CPG members have been instrumental in the development of this guide, providing their expertise, knowledge, and experience to ensure that it is accurate, up-to-date, and relevant to the needs of its intended audience. Their dedication and hard work have made this guide possible and SNOMED International is

grateful for their contributions. This guide is a product of SNOMED International's ongoing commitment to improving healthcare through the use of high-quality, standardized clinical terminologies.

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Guide overview

This SNOMED CT Clinical Implementation Guide is designed to provide guidance for the use of SNOMED CT within the domain of allergies, hypersensitivity, and intolerance. The guide is organized into five main chapters:

- **Chapter 1:** Introduction - This chapter provides a background on the guide, including the objectives, scope, and target audience.
- **Chapter 2:** Clinical Use Cases - This chapter describes the key use cases that have motivated the creation of this guide and explains scenarios where implementation of SNOMED CT within this domain is needed.
- **Chapter 3:** Content in SNOMED CT - This chapter describes how SNOMED CT addresses the terminological needs within the domain of Cancer Synoptic Reporting.
- **Chapter 4:** Information Model and Terminology Binding - This chapter introduces the knowledge representation techniques used in this guide.
- **Chapter 5:** Technical Application - This chapter presents technical considerations related to the implementation of the cancer synoptic report forms as FHIR Questionnaires.

Review

This SNOMED CT Clinical Implementation Guide represents the culmination of work started by Scott Campbell and James Campbell in 2014 and continued by the the Cancer Synoptic Reporting Project Group in 2020.

We welcome feedback from readers on the Guide and encourage them to share their insights and experiences with us. Your comments and suggestions will help us improve the content of the Guide and ensure that it is relevant and useful to those who use it. We will review any feedback received and make updates to the Guide as needed.

We appreciate your interest in this Guide and thank you for your contributions to the improvement of healthcare through the use of high-quality, standardized clinical terminologies like SNOMED CT. Please raise any comments to this document by emailing info@snomed.org, and please mark your response "Cancer Synoptic Clinical Implementation Guide"

2. Use Cases

Cancer synoptic reporting plays a pivotal role in delivering not only clinical advantages but also an array of benefits that extend to areas such as interoperability, surveillance, quality assurance, and research. This structured and standardized approach to documenting cancer-related information brings forth a harmonized approach that fosters seamless data exchange, enhances monitoring capabilities, ensures high-quality care standards, and contributes to the advancement of medical research.

In the subsequent pages, a range of general and clinical use cases will be outlined, and two detailed use cases are presented to illustrate the use of cancer synoptic reports.

2.1 General Use Cases

Incorporating cancer synoptic reporting into clinical practices offers a range of benefits, including improved communication, enhanced research capabilities, and ultimately, better patient outcomes. Below find a summary of the general clinical use cases.

2.1.1 Diagnosis and Staging

Pathologists need to accurately diagnose and stage a patient's cancer.

Pathologists use the synoptic reporting system to document key diagnostic information, including tumor type, grade, size, margins, lymph node involvement, and metastasis. This structured data aids in determining the appropriate treatment plan.

2.1.2 Treatment Planning

Oncologists and multidisciplinary teams require comprehensive information for treatment planning.

Synoptic reports provide detailed information about the patient's cancer, helping oncologists choose the most effective treatment options. This includes critical information like cancer characteristics, markers, or spread, which helps choose available therapies like surgery, chemotherapy, radiation therapy, targeted therapies, and immunotherapy.

2.1.3 Surgical Procedures

Surgeons need precise information for performing cancer surgeries.

The reporting system captures critical details about surgical procedures, such as the extent of invasion, organ and lymph node involvement, and risk factors for complications. Surgeons can refer to these reports to ensure consistent and accurate surgical approaches.

2.1.4 Pathological Findings

Pathologists need to communicate important pathological findings to oncologists and other specialists.

Synoptic reporting includes standardized language to describe histological features, biomarker expressions, and genetic mutations. This enables clear communication of diagnostic and prognostic information to guide treatment decisions.

2.1.5 Clinical Research and Analysis

Researchers require standardized data for cancer studies and clinical trials.

Synoptic reports provide a structured dataset that can be easily aggregated and analyzed for research purposes. This promotes data-driven insights into treatment outcomes, survival rates, and disease trends.

2.1.6 Follow-up and Monitoring

Healthcare providers need to monitor patients' progress over time.

Synoptic reporting allows consistent documentation of follow-up information, such as treatment responses, recurrence, metastasis, and long-term outcomes. This facilitates ongoing patient care and enables early intervention if issues arise.

2.1.7 Quality Assurance and Accreditation

Healthcare institutions aim to maintain high standards and achieve accreditation.

Synoptic reporting helps institutions adhere to standardized reporting guidelines, ensuring the quality and accuracy of cancer-related documentation. This can support accreditation processes and improve overall patient care.

2.1.8 Data Exchange and Interoperability

Health information needs to be easily shared among different healthcare systems.

Synoptic reports follow standardized formats, making it easier to exchange data electronically between different healthcare providers, institutions, and electronic health record (EHR) systems.

2.1.9 Educational and Training Purposes

Medical education and training programs require illustrative case studies.

Synoptic reports serve as valuable educational resources for medical students, residents, and other healthcare professionals to learn about real-world cancer cases and treatment strategies.

2.1.10 Patient Empowerment

Patients seek comprehensive information about their cancer diagnosis and treatment.

Synoptic reports, presented in a patient-friendly format, can help patients understand their condition, treatment options, and prognosis, empowering them to make informed decisions about their care.

2.2 Clinical Application Examples

This page highlight how cancer synoptic reporting contributes to accurate diagnosis, appropriate staging, tailored treatment planning, and ongoing patient management across various types of cancer. Keep in mind, that this list isn't complete, but it offers common examples of specific clinical applications of cancer synoptic reporting.

2.2.1 Breast Cancer Lumpectomy

A patient with early-stage breast cancer undergoes a lumpectomy.

The synoptic report documents details, such as tumor size, margins, lymph node involvement, and any additional findings. This information helps oncologists determine if further treatments like radiation therapy or chemotherapy are necessary.

2.2.2 Colon Cancer Resection

A patient undergoes surgery to remove a tumor in the colon.

The synoptic report records the extent of the resection, involvement of adjacent structures, lymph node status, and whether the tumor breached the serosa. This aids in staging the cancer and planning subsequent treatments.

2.2.3 Prostate Cancer Biopsy

A patient undergoes a prostate biopsy due to elevated PSA levels.

The synoptic report captures the number of biopsy cores taken, the Gleason score (a measure of cancer aggressiveness), and the percentage of cancer involvement in each core. This information guides treatment decisions.

2.2.4 Lung Cancer Staging

A patient is diagnosed with non-small cell lung cancer.

The synoptic report documents tumor size, lymph node involvement, and any distant metastases. This information helps stage the cancer using the TNM (Tumor, Node, Metastasis) system, informing treatment options.

2.2.5 Ovarian Cancer Debulking Surgery

A patient with ovarian cancer undergoes surgery to remove as much tumor tissue as possible.

The synoptic report records the extent of debulking achieved, the presence of residual disease, and the involvement of nearby organs. This information guides decisions regarding subsequent chemotherapy.

2.2.6 Melanoma Excision

A patient has a suspicious melanoma lesion removed.

The synoptic report details the Breslow thickness (a measure of tumor depth), Clark level (depth of invasion), ulceration status, and mitotic rate. These factors contribute to determining prognosis and treatment strategies.

2.2.7 Gastric Cancer Surgery

A patient undergoes surgery for gastric cancer.

The synoptic report documents tumor location, depth of invasion, involvement of adjacent structures, and lymph node metastases. This information guides treatment decisions, including surgery and chemotherapy.

2.2.8 Hematologic Malignancy Bone Marrow Biopsy

A patient is evaluated for hematologic malignancy.

The synoptic report includes details about bone marrow cellularity, percentage of blasts, presence of chromosomal abnormalities, and any immunophenotypic findings. This aids in diagnosing and classifying the malignancy.

2.2.9 Cervical Cancer Screening

A patient undergoes a Pap smear for cervical cancer screening.

The synoptic report records the cytological findings, the presence of high-risk human papillomavirus (HPV), and any abnormal cellular changes. This information guides follow-up and management.

2.2.10 Neuro-oncology Tumor Resection

A patient with a brain tumor undergoes surgery for tumor resection.

The synoptic report documents tumor type, location, extent of resection, and involvement of critical structures. This information informs treatment decisions and post-operative care.

2.3 Clinical Scenarios

In the following section, we delve into two distinct use cases that vividly illustrate the multifaceted advantages of cancer synoptic reporting. These use cases not only underscore its pivotal role in guiding clinical decision-making but also highlight its invaluable contributions to research endeavors, quality assurance, and overall healthcare excellence.

Scenario 1: Colorectal Cancer Staging and Treatment Planning

Background:

A 58-year-old patient presents with symptoms indicative of colorectal cancer. Following diagnostic tests, it is confirmed that the patient has adenocarcinoma of the colon, and a treatment plan needs to be formulated.

Description:

- **Synoptic Reporting**: The oncology team utilizes a cancer synoptic reporting system to create a comprehensive report for the patient. The report captures crucial information about the tumor, including its size, location, histological type, grade, and lymph node involvement. The synoptic template prompts the clinicians to input standardized data, ensuring consistent and accurate documentation.
- **Staging Accuracy**: The structured synoptic report allows the oncologists to accurately stage the cancer using the TNM (Tumor, Node, Metastasis) system. The report includes details about the depth of tumor invasion, the number of affected lymph nodes, and the absence or presence of distant metastases. This precise staging information aids in determining the optimal treatment strategy.
- **Treatment Plan**: Based on the synoptic report, the oncology team can confidently recommend an appropriate treatment plan. In this case, the patient's cancer is determined to be at an early stage with no lymph node involvement. Therefore, the patient becomes a candidate for surgical resection. The synoptic report's standardized data helps the surgical team understand the extent of the surgery required and enables a focused approach.
- **Post-Operative Follow-up**: After surgery, the synoptic report continues to play a role. It documents the success of the resection, ensuring that clear margins were achieved. This information becomes a part of the patient's medical record, guiding future monitoring and potential interventions if necessary.

Outcome:

Through the use of cancer synoptic reporting, the patient's colorectal cancer is accurately staged, and a tailored treatment plan is initiated. The structured documentation contributes to informed decision-making, improves communication among healthcare professionals, and enhances the patient's overall care journey.

Scenario 2: Breast Cancer Pathological Assessment and Research

Background:

A 45-year-old patient undergoes a mastectomy due to an aggressive form of breast cancer. Pathologists are tasked with assessing the tumor's characteristics and providing accurate information for treatment planning and research purposes.

Description:

- **Synoptic Reporting**: Pathologists employ a synoptic reporting system to record detailed information about the tumor. The report covers factors such as tumor size, histological type, nuclear grade, lymphovascular invasion, hormone receptor status, and HER2/neu expression. This structured data ensures consistent reporting across cases.
- **Treatment Guidance**: The synoptic report's data is essential for guiding the patient's treatment plan. The receptor status information, including estrogen and progesterone receptors as well as HER2/neu expression, helps oncologists determine appropriate targeted therapies such as hormone therapy or HER2-targeted agents.
- **Research Contribution**: The structured synoptic data is not only confined to the individual patient's care. Aggregated and anonymized synoptic reports contribute to research initiatives. Researchers can analyze the data to identify trends, assess treatment outcomes, and develop insights into the effectiveness of different therapies across various subtypes of breast cancer.
- **Quality Assurance**: The synoptic report also serves as a tool for quality assurance within the pathology department. Standardized reporting ensures that key diagnostic information is consistently documented, reducing the risk of errors and improving overall reporting quality.

Outcome:

Through the utilization of cancer synoptic reporting, the pathologists provide accurate diagnostic information to guide the patient's treatment plan. Additionally, the structured data contributes to ongoing research efforts, enhancing the collective understanding of breast cancer subtypes and treatment outcomes.

These detailed use cases underscore the tangible benefits of cancer synoptic reporting in enhancing clinical decision-making, enabling research, and maintaining high standards of quality in cancer care.

3. SNOMED CT Content

The Cancer Synoptic Reporting Project Group followed a template-based, subject matter expert driven process to develop the content produced in this project. Content developed is based on the content represented in published reporting protocols using the Observable entity concept model. The overall approach and assumptions are described in the following pages.

3.1 Scope of Cancer Synoptic Reporting

Knowledge Representation Model

The underlying principle of the Cancer Synoptic Reporting Project Group is that the "question" (represented by a SNOMED CT observable entity) should include all the context needed to clearly understand the "answer" (or observation) that is recorded. The criteria for deciding these results depend on additional information and knowledge that can't be conveyed by SNOMED CT alone, such as clinical guidelines.

For example, the differentiation between an adenocarcinoma and a mucinous adenocarcinoma is based on the amount of mucin measured in the cells and the organ system involved. In breast tissue, the amount of mucin in the cells to be considered a mucinous adenocarcinoma is > 80% but in the colon is > 50%. The pathologist is responsible for this knowledge, not SNOMED CT. So, this type of explicit knowledge of the pathologist is outside of the scope of the SNOMED CT concepts, and will not be discussed further in this document.

Part	Type	SNOMED CT Scope	Description
Question	CODED_TEXT	<< |Observable entity (observable entity)|	The question
Observation (Answer)	CODED_TEXT	<< 123037004 |Body structure (body structure)| OR << 404684003 |Clinical finding (finding)|	The coded result of the observation
Decision criteria	*Implied - Context dependent*	N/A	The interpretation of the observation based on agreed guidelines/rules

The observable entity/observation pairs below each state that the histologic type of the neoplasm assessed is a mucinous adenocarcinoma in the breast and in the colon. It is the SNOMED CT observable entity that provides the context for the observation, specifically the organ system of concern. It does not directly state the amount of mucin in the cells as observed by the pathologist. The pathologist exercised domain-specific knowledge to reach such a conclusion.

Mucinous adenocarcinoma of the breast: 1660001000004100 |Histologic type of primary malignant neoplasm of breast (observable entity)| = 72495009 |Mucinous adenocarcinoma (morphologic abnormality)| reflects the pathologist's *interpretation* of the microscopically evaluated slides that the percent tumor cells containing mucin as a proportion of the total number of tumor cells is > 80%.

Mucinous adenocarcinoma of the colon: 1284862009 |Histologic type of primary malignant neoplasm of cecum and/or colon and/or rectum (observable entity)| = 72495009 |Mucinous adenocarcinoma (morphologic abnormality)| reflects the pathologist's *interpretation* of the microscopically evaluated slides that the percent tumor cells containing mucin as a proportion of the total number of tumor cells is > 50%.

Question	Observation (Answer)	Decision Criteria
1660001000004100 |Histologic type of primary malignant neoplasm of breast (observable entity)|	72495009 |Mucinous adenocarcinoma (morphologic abnormality)|	The microscopically evaluated slides with percent mucinous cells above 80%
1284862009 |Histologic type of primary malignant neoplasm of cecum and/or colon and/or rectum (observable entity)|	72495009 |Mucinous adenocarcinoma (morphologic abnormality)|	The microscopically evaluated slides with percent mucinous cells above 50%

Therefore, it is important to understand that the observable entity/observation pairs used throughout the cancer pathology synoptic reporting use cases reflect point in time observations as ultimately *assessed and interpreted* by the pathologist. Domain knowledge specific to the practice of pathology and oncology is *NOT* intended to be represented by the terminology, but rather, the terminology represents *what* the observation was and is *based* on specific domain expertise.

Neoplasm Characteristics to be Measured

As noted, the synoptic pathology report is comprised of a list of characteristics of the neoplasm that are required to be observed and reported by the pathologist. Each characteristic is modelled using the **363787002 |Observable entity (observable entity)|** hierarchy and concept model.

Major categories of neoplasm characteristics required in each report are listed below.

- Procedure used to collect the specimen(s)
- Tumor site
- Tumor dimensions
- Histologic type
- Histologic grade
- Anatomic location(s) involved by direct, contiguous extension of the neoplasm
    - *Tissue layers*
    - *Adjacent tissue structures*
    - *Lymph/vascular invasion*
    - *Perineural invasion*
- Presence of neoplasm at surgical margins
- Lymph node metastasis
    - *Number lymph nodes involved by metastasis*
    - *Number lymph nodes examined*
    - *Location of lymph nodes*
- Anatomic locations involved by metastatic, discontinuous spread of the neoplasm
- TNM staging (Tumor, Node, Metastasis)

Observations to be reported

The list of possible observations that can be made for each characteristic is comprised of a constrained list of acceptable observations (i.e., value sets). For example, a list of acceptable histologic types (morphologic abnormalities) is provided to the pathologist to select when reporting the histologic type of the neoplasm. Semantic types of these value sets are dependent upon the |Property| target value.

Semantic types in a response value set are all of the same semantic type with the exception of the use of |Qualifier value| concepts employed for pathologist observations such as 385432009 |Not applicable (qualifier value)| or 1156316003 |Cannot be determined (qualifier value)| .

For example, the concept, 911750741000004104 |Histologic type of primary malignant neoplasm of lung (observable entity)| , is modeled with 370130000 |Property (attribute)| = 6030001000004102 |Histologic type (property) (qualifier value)| . The range of possible observations must be << 1240414004 |Malignant neoplasm (morphologic abnormality)| .

In addition to the template constraints, the protocol publishers further constrain the acceptable value sets to include only those values that are possible for a particular malignant neoplasm. For example, the possible values for histologic types in the lung protocol would never contain values for Germ cell neoplasms (a condition only possible in reproductive organs).

3.2 Observable Entity/Observation Pairs versus Clinical Findings

Historical SNOMED CT content authored for use in cancer synoptic reporting can be found in the Observable entity and Clinical finding hierarchies.

Observable Entities vs Clinical Findings

The vast majority of these concepts are primitive and have effective dates of 2001-01-31, which is the beginning of SNOMED CT time. These concepts were deemed insufficient to unambiguously represent pathology observations and findings for use in cancer registries. An early design decision in the Cancer Synoptic Reporting Project Group project was to use the Observable entity hierarchy instead of the Clinical finding hierarchy. Regardless of approach, substantial concept modeling would be required in either hierarchy. Ultimately, the decision was made to provide a tangible, needed, and practical use case upon which to demonstrate the efficacy of the newly remodeled Observable entity concept model. Apart from the novelty of the approach, the question, or Observable entity, in each synoptic report must carry sufficient context to unambiguously interpret the observation or finding.

A practical consideration for this modelling approach pertained to the amount of new content that would be necessary to create to meet the needs of the cancer synoptic use case.

Content Development Approach

A significant number of concepts have been created as part of this effort, encompassing all hierarchies. In retrospect, the decision to utilize observable entities to encompass the complete clinical context for each observable entity/observation pair proved beneficial in managing the concept volume effectively.

The histologic type of *"malignant neoplasm of organ X"* is a good example of this.

Every organ system with a reporting protocol has an average of 10-20 morphologic abnormalities that could be recorded. Many of these morphologies may be observed in multiple organ systems. If clinical findings were used to represent the protocol data, a new concept would be necessary for every organ/morphology pair for example:

- *adenocarcinoma of organ X*
- *mucinous adenocarcinoma of organ X*
- *serrated carcinoma of organ X*

Using observable entities, however, required only a single concept to be created for each organ system The observable entity (e.g., Histologic type of malignant neoplasm of organ X) could be paired with any number of valid morphologies. Ultimately, the decision required less new content to be developed and maintained.

It should be noted that the observable entity/observation pairs in the Cancer Synoptic Reporting Project Group product do NOT follow the clinical finding MRCM specific that uses the defining attributes 363714003 |Interprets (attribute)| = << 363787002 |Observable entity (observable entity)| AND 363713009 |Has interpretation (attribute)| = << 260245000 |Finding value (qualifier value)| . The types of information solicited in the cancer pathology protocols extend beyond the content represented in the Qualifier value hierarchy and include values from the Procedure hierarchy, Body structure hierarchy, and concepts in the qualifier hierarchy NOT subsumed by << 260245000 |Finding value (qualifier value)| and discrete numerical values. Current MRCM rules for clinical findings do not include these concept areas in the range of possible concepts for |Has interpretation (attribute)| . Pathology synoptic data elements simply record a series of individual observations in a structured fashion.

> Please note that the Cancer Synoptic Reporting Project Group in conjunction with the Content Team, Editorial Committee, and Implementation Team is in discussion regarding existing clinical finding content originally developed for cancer pathology reporting.

3.3 Observable Entity Defining Attributes Employed in this Project

The Cancer Synoptic Reporting Project Group operated under the data modeling paradigm that the **|Observable entity (observable entity)|** concept provides the context to correctly and unambiguously interpret the observation. Therefore, understanding the observable entity concept model is fundamental to use of the cancer synoptic content. Authored content for observable entities of this project are found <<1145211006 |Proliferative mass observable (observable entity)|

The table below provides an overview of the defining attributes used to author cancer synoptic reporting concepts, including a description of the target values for these attributes.

Attribute	Description and Values
|Property|	This attribute is used to assert the property, or feature, being assessed by the pathologist. Target values for this attribute include: • << |Length property (qualifier value)| ; • << |Histologic feature (property) (qualifier value)| ; • < |Location property (qualifier value)| ; • |Presence (property) (qualifier value)| ; • |Anatomic location (property) (qualifier value)|
|Inheres in|	This attribute is used to assert the entity that carries the property being measured. In most cases, the target values are << |Neoplasm (morphologic abnormality)|
|Inherent location|	The inherent location attribute is used to describe the anatomical location of the entity that carries the property being assessed. In most cases, the inherent location indicates the anatomical location of the primary malignant neoplasm, that is the primary organ affected by the malignancy.
|Component|	This attribute is used to indicate an entity that is being assessed for presence such as necrosis within a neoplasm. It is also used to represent the numerator in a percent observation.
|Relative to|	This attributed is used for the denominator in a percent or number fraction observable.
|Direct site|	Direct site is specifically used to define the specimen in which the observation is being made.
|Technique|	Technique is used to define the method by which the observation is being made. This attribute is used to specific methods of tumor staging, histologic grading methods, direct vision (gross) evaluation, microscopy and immunohistochemistry methods.
|Time aspect|	The time aspect for all cancer pathology observable entities is |Single point in time (qualifier value)|
|Scale type|	This attribute is used to describe the evaluation scale used for the observation. • |Nominal value (qualifier value)| ▪ is used to describe observable entities assessing morphologies, body structures, and procedures. • |Ordinal value (qualifier value)| ▪ is used in histologic grade observations and observations indicating the presence, absence or degree of presence. • |Quantitative (qualifier value)| ▪ is used for numerical observations.
|Characterizes|	Characterizes is used to represent the underlying processes of the neoplasm. These include << |Malignant proliferation of neoplasm (qualifier value)| and |Regression of neoplasm (qualifier value)|

Attribute	Description and Values
|Process extends to|	This attribute is used to define the "end point" of the process indicated by the characterized attribute/value pair. In most concepts, this associated value of this attribute is << |Body structure (body structure)| to indicate where the neoplasm has grown or metastasized.

4. Information Models and Terminology Binding

This chapter delves into two crucial aspects of cancer synoptic reporting with SNOMED CT: information models and terminology bindings.

Information models serve as the framework for organizing cancer data elements, guaranteeing consistency and interoperability across various systems.

Terminology bindings forge the essential connection between these data elements and SNOMED CT concepts, ensuring uniform representation and exchange.

The chapter provides practical insights into designing the general cancer report structure, including sample forms to demonstrate cancer synoptic reporting protocols.

Additionally, detailed explanations of SNOMED CT bindings are provided, highlighting their significance in seamlessly implementing standardized cancer data capture and exchange mechanisms.

4.1 General Cancer Report Structure

The pathology cancer report follows a general structure. The synoptic report is a summation of the required diagnostic and prognostic data elements identified in each of the following steps:

1. **Case**. A case is defined as a review of all tissue excised from the patient during a single surgery. (Note: in many surgeries, multiple organs or portions of organs are excised. Each excised organ, or portion of an organ, is considered a "Part".)

2. **Gross Description**. Each tissue part excised is visually described by the pathologist as received from the surgeon/surgical suite. Information documented includes what organ, or portion of organ, the part consists of, the overall appearance, weight and size. The Gross Description is a non-microscopic assessment of the tissue to be microscopically examined.

3. **Microscopic examination**. This section of the pathology report is performed and recorded after each part is prepared for microscopic examination. Preparation includes dissecting portions of each part; fixing the tissue in formalin which stops tissue metabolism and degradation; embedding the tissue in paraffin wax; microtome (very, very thinly slicing portions) of the paraffin-embedded tissue; mounting microtome tissue onto glass slides; staining of mounted tissue using prescribed diagnostic staining techniques, primarily hematoxylin and eosin.

   Upon tissue preparation, tissue specimens are examined using light microscopy. The pathologist assesses each slide and determines the notable presence and absence of normal and diseased portions of the tissue. The report may consist of a textual review of each part or a summative enumeration of observations.

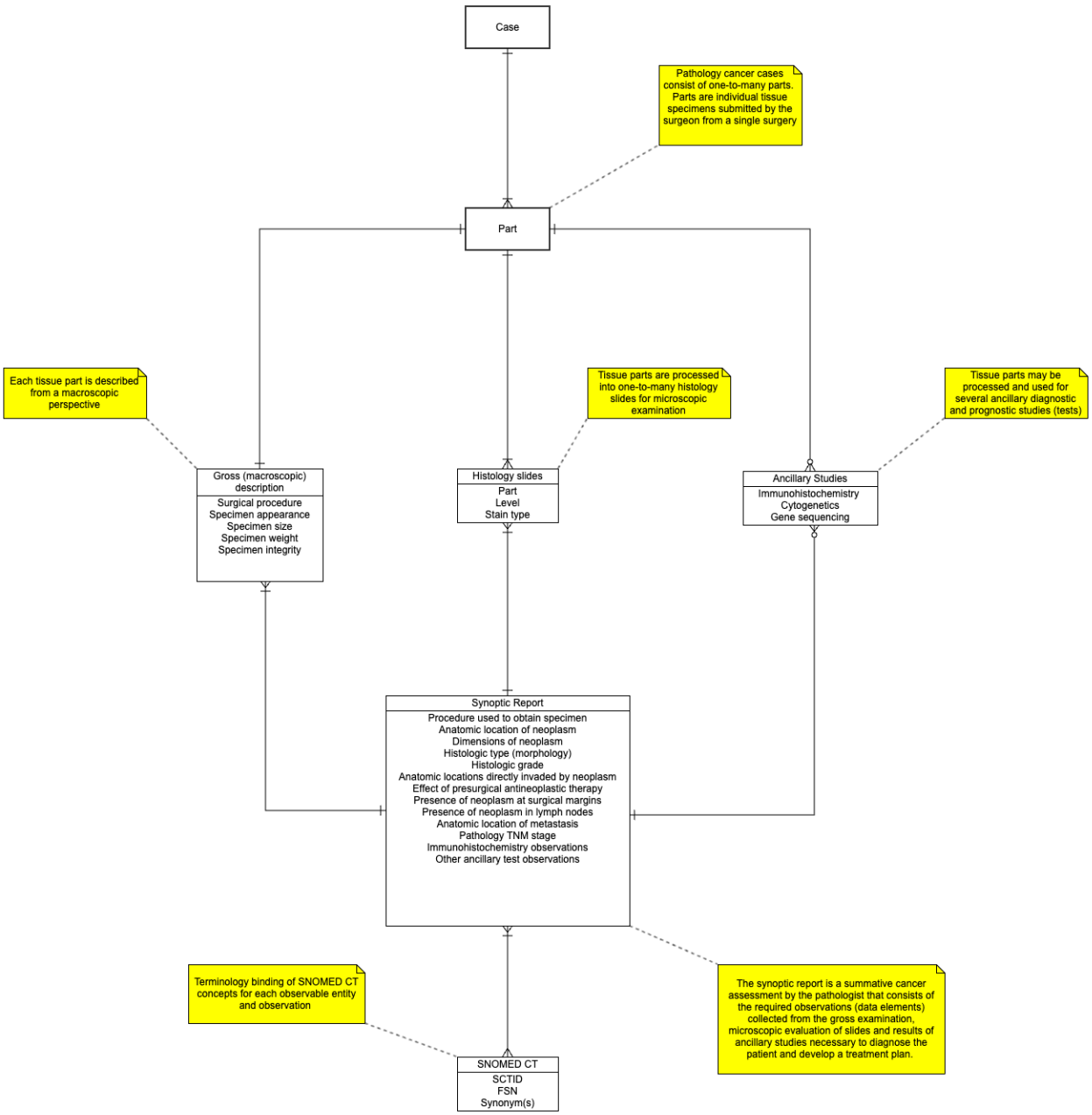
4. **Additional studies**. In this section, additional diagnostic and/or prognostic information is described. This may include review of immunohistochemically stained tissue, cytogenetic examinations, or gene sequencing results.

5. **The synoptic report.** One or more tissue parts examined are considered diagnostic and representative of the case in toto. If the case results in a diagnosis of cancer, a synoptic protocol is completed for the case. Usual practice is to associate the protocol to a single part as submitted that is considered representative of the entire case and supplement the protocol summation with notable components from other parts. For example, a colon resection will consist of portions of colon and lymph nodes. Each portion of colon and the lymph nodes are treated as different parts. Thus, a colon cancer diagnosis will be rendered and associated with a colon part, and the presence of lymphatic involvement will be based on lymph node parts but included in the overall cancer report associated with the colon part.

   Reporting protocols are specific to the primary organ system (anatomic location) of the malignant neoplasm. The specific aspects of the neoplasm to be assessed and the acceptable observations are

enumerated within each protocol. Types of necessary observations follow common concept modeling, but terminology binding is unique to each protocol. Terminology bindings for College of American Pathologists (CAP) and International Collaboration on Cancer Reporting (ICCR)-based reporting protocols are available from each organization.

The diagram below shows the pathology cancer report high-level information model in UML format



4.2 Cancer Synoptic Reporting Protocol Sample Forms

Cancer reporting protocols are published by national and international societies of pathology. The US and Canada employ the College of American Pathologists versions. Many nations in Europe and Australasia use the International Collaboration of Cancer Reporting (ICCR) published protocols as the foundation of national cancer reporting data sets. The ICCR is a collaboration of several national and regional societies of pathology including the CAP, the Royal Colleges of Pathology (UK and Australasia), and the European Society of Pathology.

Below are links and examples for the College of American Pathology (CAP) and the International Collaboration for Cancer Reporting (ICCR)

- **CAP** reporting protocols can be freely accessed and viewed at https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates.
- **ICCR** protocols can be freely accessed and viewed at: https://www.iccr-cancer.org/datasets/published-datasets/

4.3 SNOMED CT Bindings

Terminology binding of cancer pathology reporting protocols is specific to each particular malignant neoplasm type as defined by the publishing entity, such as the College of American Pathologists or the International Collaboration on Cancer Reporting.

Association of SNOMED CT concept with published data elements entails understanding the protocol content, the terminology definitions and any conditional logic based on "nesting" of questions, that is necessary observable entity/observation data to record.

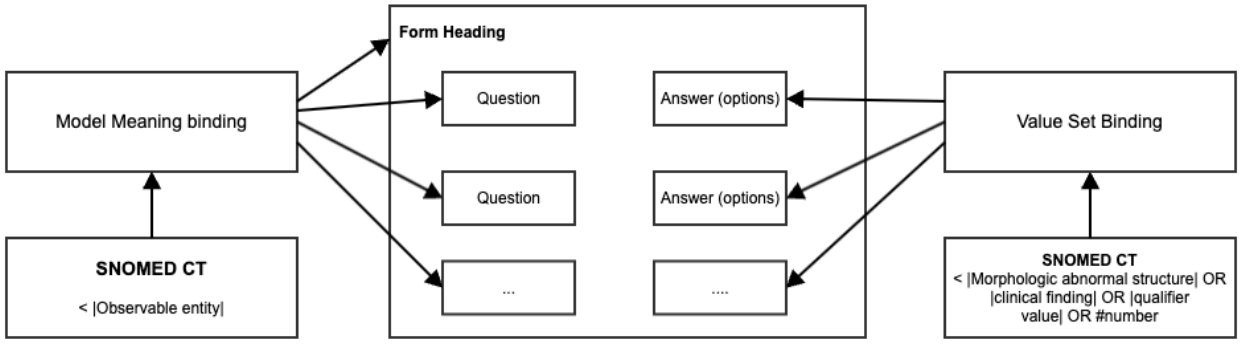
Optimally, the publishing bodies of the reporting protocols will incorporate and distribute SNOMED CT - Data element bindings as part of their documentation or software functionality. Given their domain expertise and the stakeholders they represent, these organization are well positioned to be qualified stewards of content and domain-specific distribution of encoded reporting protocols.

The basics of content binding are described in the following pages.

4.3.1 Terminology Binding Principles

Overall Principles

Performing SNOMED CT terminology binding for cancer synoptic reports involves the structured association of SNOMED CT concepts to precisely represent the meaning conveyed by the individual questions and each possible answer to these questions. This process aims to link observable entities to describe questions or attributes and morphologic abnormalities as answers, providing a standardized framework for recording detailed pathological observations.
The diagram below illustrates the overall approaches to binding SNOMED CT to the questions and answers of cancer synoptic reports and distinguishes the binding principles for model meaning bindings from the principles for value set binding.



Model Meaning Binding

Model meaning binding is focused on connecting the meaning or semantics of SNOMED CT concepts to the data model used within a particular system or healthcare application. It involves aligning the clinical concepts from SNOMED CT with the structural elements of a specific data model or information representation framework. This ensures that the SNOMED CT concepts are integrated effectively and consistently within the context of the application's data structure, allowing for accurate data capture, storage, and exchange.

Model meaning binding is crucial for the seamless integration of SNOMED CT concepts into specific healthcare system structures, allowing for accurate comparison of models representing similar types of questions or attributes. It aligns SNOMED CT's meaning with system elements, enabling:

1. **Interoperability:** Facilitating accurate data exchange between different systems.
2. **Standardization:** Promoting consistent interpretation and use of clinical terminologies.
3. **Accuracy:** Allowing precise capture and interpretation of clinical information.
4. **Efficiency:** Streamlining SNOMED CT implementation for smoother healthcare processes.

By enabling the comparison of models representing the same type of questions, model meaning binding ensures harmonization and alignment between SNOMED CT concepts and the data model used, enhancing data consistency and healthcare quality across systems.

Observable entities are utilized to represent the "question" within the context of clinical observations in a structured manner. In the field of cancer synoptic reporting, these observable entities act as descriptors or inquiries about specific aspects or attributes related to a patient's condition or findings. For instance, an observable entity might describe the histologic type of a malignant neoplasm of a particular organ system.

Observable entities serve as the broader category or question, asking about a particular aspect of the pathology or clinical findings, while the morphologic abnormalities act as the detailed answers, providing specific information or characteristics observed within that category. For instance, the observable entity "Histologic type of malignant neoplasm of organ X" could be paired with various morphologic abnormalities to describe the specific type or characteristics of the tumor observed within that organ system. This approach enables a more structured and standardized way of recording and representing clinical observations and findings in the context of cancer pathology or synoptic reporting.

Value Set Binding

Value set binding refers to the process of associating or linking specific codes or concepts from SNOMED CT to a predefined list or set of codes. These sets are often tailored to fulfill a particular purpose within a system or application. Value sets define subsets of SNOMED CT concepts that are pertinent to a specific use case or scenario. For instance, a value set might be created to represent all concepts related to allergies or a specific clinical procedure.

SNOMED CT morphological abnormalities serve as valuable representations for a variety of essential data items in a cancer synoptic report. Additionally, concepts from the clinical findings hierarchy and the qualifier value hierarchy

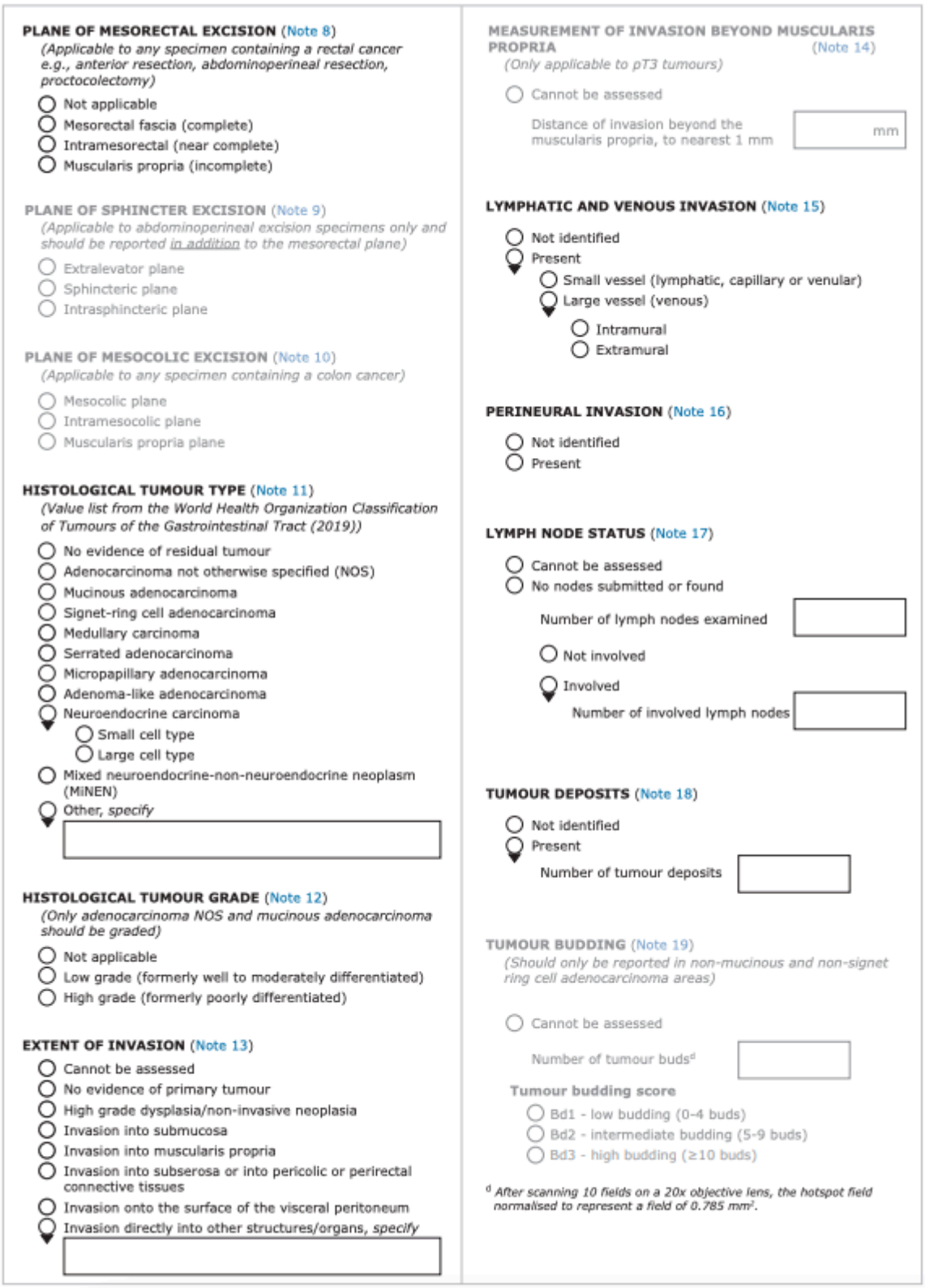
within SNOMED CT are employed to address specific answer options within the reports. Details and examples of bindings are found in 4.3.2 Terminology Binding Examples.

As outlined in 3.1 Concept Areas Modeled, morphologic abnormalities are used to represent the actual observed abnormalities or characteristics identified during clinical examinations or pathological studies. In the context of cancer pathology, various morphologic abnormalities encompass different characteristics of tumor cells or tissues, such as adenocarcinoma, mucinous adenocarcinoma, or serrated carcinoma, each representing distinct pathological findings or characteristics observed within a specific organ system.

4.3.2 Terminology Binding Examples

Colorectal Cancer Resection Reporting Protocol

Below is a section of the International Collaboration on Cancer Reporting (ICCR) Colorectal Cancer Resection reporting protocol. This page exemplifies some of the bindings for this data set, namely the data elements for 'histological tumor type' and 'lymph node status'. Similar binding exists for each question/answer set within the protocol. View an excerpt from the ICCR Colorectal Cancer Histopathology Reporting Protocol:



PLANE OF MESORECTAL EXCISION (Note 8)
(Applicable to any specimen containing a rectal cancer e.g., anterior resection, abdominoperineal resection, proctocolectomy)

- ○ Not applicable
- ○ Mesorectal fascia (complete)
- ○ Intramesorectal (near complete)
- ○ Muscularis propria (incomplete)

PLANE OF SPHINCTER EXCISION (Note 9)
(Applicable to abdominoperineal excision specimens only and should be reported in addition to the mesorectal plane)

- ○ Extralevator plane
- ○ Sphincteric plane
- ○ Intrasphincteric plane

PLANE OF MESOCOLIC EXCISION (Note 10)
(Applicable to any specimen containing a colon cancer)

- ○ Mesocolic plane
- ○ Intramesocolic plane
- ○ Muscularis propria plane

HISTOLOGICAL TUMOUR TYPE (Note 11)
(Value list from the World Health Organization Classification of Tumours of the Gastrointestinal Tract (2019))

- ○ No evidence of residual tumour
- ○ Adenocarcinoma not otherwise specified (NOS)
- ○ Mucinous adenocarcinoma
- ○ Signet-ring cell adenocarcinoma
- ○ Medullary carcinoma
- ○ Serrated adenocarcinoma
- ○ Micropapillary adenocarcinoma
- ○ Adenoma-like adenocarcinoma
- ○ Neuroendocrine carcinoma
  - ○ Small cell type
  - ○ Large cell type
- ○ Mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN)
- ○ Other, *specify*

HISTOLOGICAL TUMOUR GRADE (Note 12)
(Only adenocarcinoma NOS and mucinous adenocarcinoma should be graded)

- ○ Not applicable
- ○ Low grade (formerly well to moderately differentiated)
- ○ High grade (formerly poorly differentiated)

EXTENT OF INVASION (Note 13)

- ○ Cannot be assessed
- ○ No evidence of primary tumour
- ○ High grade dysplasia/non-invasive neoplasia
- ○ Invasion into submucosa
- ○ Invasion into muscularis propria
- ○ Invasion into subserosa or into pericolic or perirectal connective tissues
- ○ Invasion onto the surface of the visceral peritoneum
- ○ Invasion directly into other structures/organs, *specify*

MEASUREMENT OF INVASION BEYOND MUSCULARIS PROPRIA (Note 14)
(Only applicable to pT3 tumours)

- ○ Cannot be assessed

Distance of invasion beyond the muscularis propria, to nearest 1 mm ____ mm

LYMPHATIC AND VENOUS INVASION (Note 15)

- ○ Not identified
- ○ Present
  - ○ Small vessel (lymphatic, capillary or venular)
  - ○ Large vessel (venous)
    - ○ Intramural
    - ○ Extramural

PERINEURAL INVASION (Note 16)

- ○ Not identified
- ○ Present

LYMPH NODE STATUS (Note 17)

- ○ Cannot be assessed
- ○ No nodes submitted or found

Number of lymph nodes examined ____

- ○ Not involved
- ○ Involved

Number of involved lymph nodes ____

TUMOUR DEPOSITS (Note 18)

- ○ Not identified
- ○ Present

Number of tumour deposits ____

TUMOUR BUDDING (Note 19)
(Should only be reported in non-mucinous and non-signet ring cell adenocarcinoma areas)

- ○ Cannot be assessed

Number of tumour buds[d] ____

Tumour budding score

- ○ Bd1 - low budding (0-4 buds)
- ○ Bd2 - intermediate budding (5-9 buds)
- ○ Bd3 - high budding (≥10 buds)

[d] *After scanning 10 fields on a 20x objective lens, the hotspot field normalised to represent a field of 0.785 mm².*

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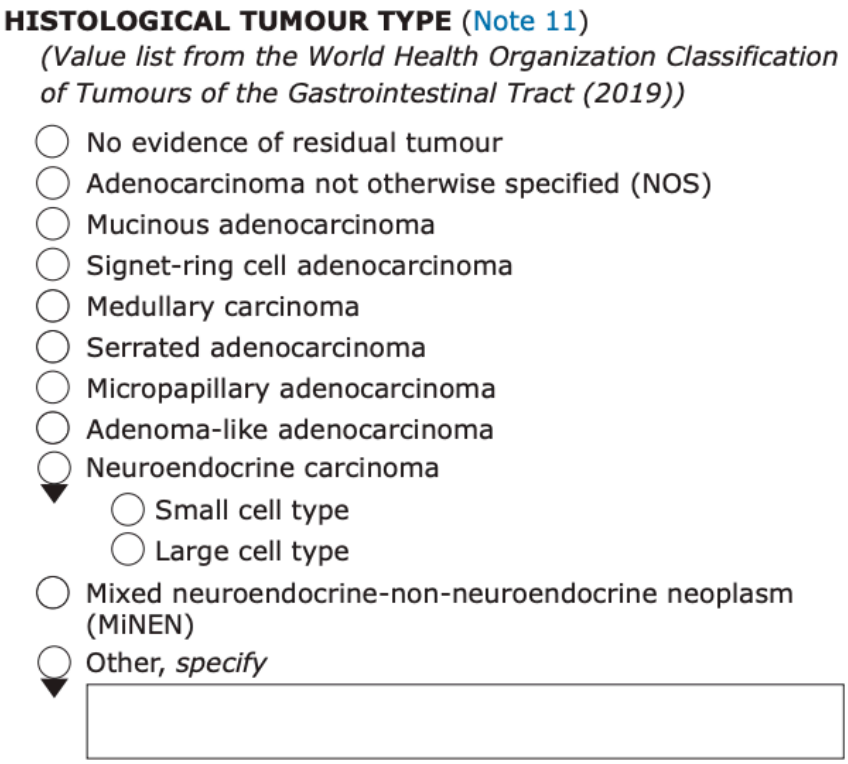
Binding of Histological Tumor Type

The diagram below shows the question and options for the 'histological tumor type' data element. The Observable entity to be measured/assessed is "Histological tumour type", which is represented by the SNOMED CT concept 1284862009 |Histologic type of primary malignant neoplasm of cecum and/or colon and/or rectum (observable entity)| and represents the "question" being answered. The possible "answers" or observations are listed in the table below with associated SNOMED CT concept bindings for each histology option.

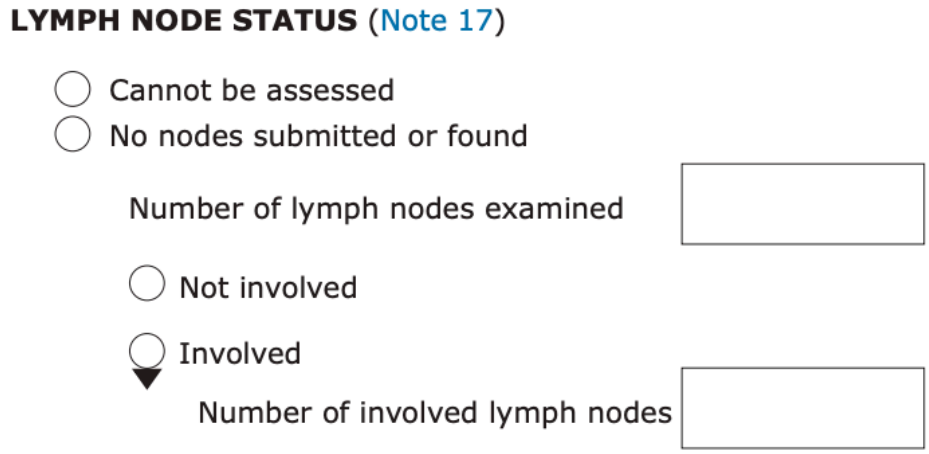


Data Item	Type	Cardinality	Display	Binding
HISTOLOGICAL TUMOR TYPE	Question	1..1	Histological tumor type	1284862009 |Histologic type of primary malignant neoplasm of cecum and/or colon and/or rectum (observable entity)|
	Response options (Group)	0..1	No evidence of residual tumour	.
			Adenocarcinoma not otherwise specified (NOS)	1187332001 |Adenocarcinoma (morphologic abnormality)|
			Mucinous adenocacinoma	72495009 |Mucinous adenocarcinoma (morphologic abnormality)|
			Signet-ring cell adenocarcinoma	87737001 |Signet ring cell carcinoma (morphologic abnormality)|
			Medullary carcinoma	32913002 |Medullary carcinoma (morphologic abnormality)|
			Serrated adenocarcinoma	450948005 |Serrated adenocarcinoma (morphologic abnormality)|

Data Item	Type	Cardinality	Display	Binding
			Micropapillary adenocarcinoma	450895005 |Micropapillary carcinoma (morphologic abnormality)|
			adenoma-like adenocarcinoma	28558000 |Villous adenocarcinoma (morphologic abnormality)|
			Neuroendocrine carcinoma, small cell type	719105002 |Small cell neuroendocrine carcinoma (morphologic abnormality)|
			Neuroendocrine carcinoma, large cell type	128628002 |Large cell neuroendocrine carcinoma (morphologic abnormality)|
			Mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN)	785766008 |Mixed neuroendocrine-non neuroendocrine neoplasm (morphologic abnormality)|
			Other, specify	

Binding of Lymph Node Status

The diagram below shows the question and options for the 'lymph node status' data element. The Observable entity to be measured/assessed is "Lymph node status", which is represented by the SNOMED CT concept 1268302004 |Presence of metastatic neoplasm in lymph node in excised tissue specimen (observable entity)| and represents the "question" being answered. The possible "answers" or observations are listed in the table below with associated SNOMED CT concept bindings for each option.



Data Item	Type	Cardinality	Display	Binding
LYMPH NODE STATUS	Question	1..1	Lymph node status	1268302004 |Presence of metastatic neoplasm in lymph node in excised tissue specimen (observable entity)|
	Response options (Group)	0..1	Cannot be assessed	1156316003 |Cannot be determined (qualifier value)|
		0..1	No nodes submitted or found	385432009 |Not applicable (qualifier value)|
		0..1	Not involved	47492008 |Not seen (qualifier value)|

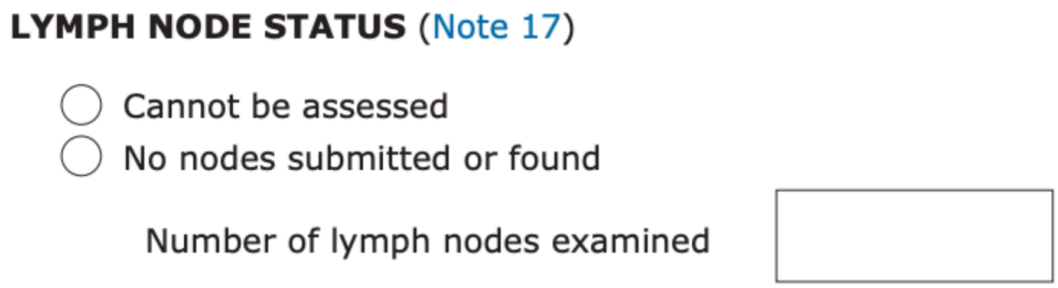
Data Item	Type	Cardinality	Display	Binding
		0..1	Involved	52101004 |Present (qualifier value)|
	Question	1..1	Number of lymph nodes examined	444025001 |Number of lymph nodes examined by microscopy in excised specimen (observable entity)|
	Response value	1..1	N/A	
	Question	1..1	Number of involved lymph nodes examined	443527007 |Number of lymph nodes containing metastatic neoplasm in excised specimen (observable entity)|
	Response value	1..1	N/A	

4.3.3 Conditional Logic and Nested Observable Concept Binding

A key feature often needed in Synoptic Cancer reports and other structured data entry forms is the ability to activate or deactivate certain fields based on selections made in different fields.

This condition occurs when user interface designers create data input forms to improve data entry efficiency. Specifically, entry form logic often solicits a response for a high-level observation, such as the presence of neoplasm invasion to any lymph or blood vessel. A negative observation negates the need for further elaboration. However, a positive answer may require the pathologist to indicate if the invasion is present in small lymph and/or blood vessels or larger blood vessels. Since the context of the observation, that is, "present" or "absent" is carried by the observable entity, the SNOMED CT concept for the observable entity/observation pair is different. Management of this scenario can also be managed using logical conditions. These conditions can be managed in forms logic or other rubrics.

For example:



In this form, we can see that if the lymph node status cannot be assessed, then the entering number of nodes is not required; otherwise, it should be a required field.

This type of logical connection between elements in the information model goes beyond what can be achieved with basic terminology bindings alone, necessitating an extra layer of representation. Upcoming chapters will explore how standards like HL7 FHIR offer structures specifically designed for this purpose.

5. Technical Application

In this chapter, the considerations related to the technical application of cancer synoptic reporting forms with SNOMED CT are presented. It explores the emerging use of FHIR for standardized model representation, comparing creating new FHIR resources to using FHIR Questionnaires. Benefits and limitations of each approach are outlined, with a focus on the practicality and advantages of FHIR Questionnaires in most scenarios.

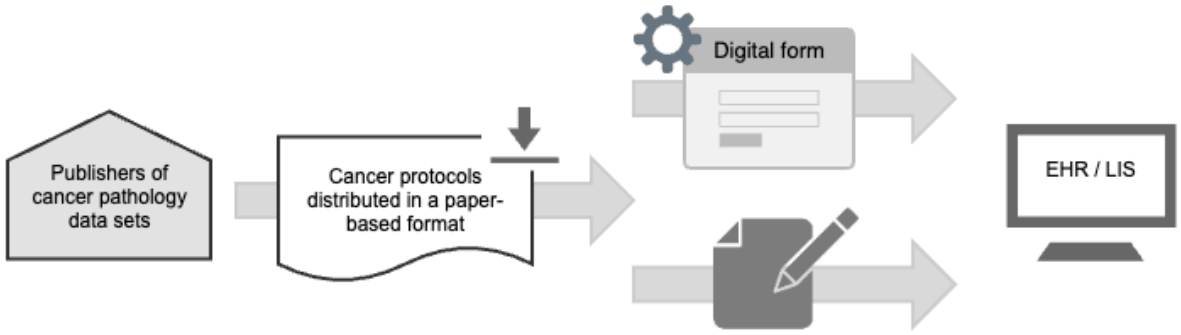
5.1 Implementation Approaches

Three approaches for cancer synoptic data recording are described in this section: paper-based forms, distributed electronic forms, and a centralized reporting platform. Each of these approaches has benefits and drawbacks which are described below. In addition, the emerging Fast Healthcare Interoperability Resources (FHIR) model is an elegant hybrid of central registry reporting and electronic health system integration. Although FHIR implementations for cancer synoptic reporting are in pilot phases only, the approach is also described.

Paper-based Approach

Structured, synoptic cancer reporting can be realized using a paper-based system. Multiple organizations release paper-based forms for cancer synoptic reporting.

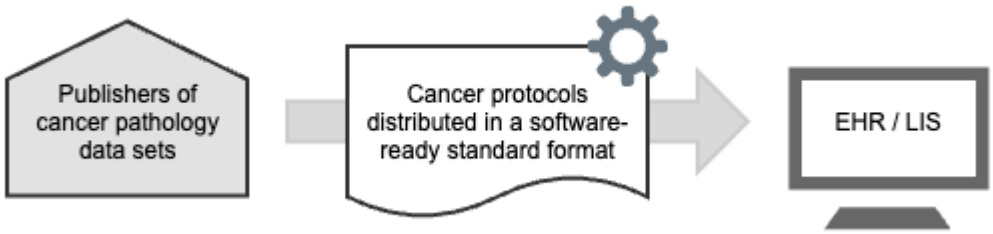
Pathologists can manually record their observations using these *pro forma* templates. This approach does provide structure and enhances the completeness of data records. However, it does not directly render cancer pathology data into computable form. That can only happen with a transcription or abstraction of the paper form into an electronic system that is encoded using SNOMED CT.



The limitations of this approach are readily apparent. Yet, in an environment where electronic health record systems are not readily available, this approach to pathology cancer reporting can be effective for completeness of reports for immediate use by clinical care teams, and these forms can be used by public health authorities to populate central cancer registries for surveillance and disease management efforts.

Distributed Approach: Electronic Health Record and Laboratory Information System Integration

This approach requires that publishers of cancer pathology data sets render their protocols (pro forma templates) into a format that can be ingested and used by EHR and LIS software platforms. The EHR/LIS vendor software then use these electronic representations to create an electronic version of the paper form for the user to complete as part of their usual reporting workflow.



Benefits of this approach:

- Structured, encoded cancer pathology reporting fully integrated into usual pathology documentation/ reporting workflows
- Centralized management and distribution of curated content
- Ability to customize workflow within institutional EHR/LIS
- Data can be incorporated into the EHR/LIS data structure for clinical decision support, analytics and electronic reporting to public health registries

Limitations of this approach:

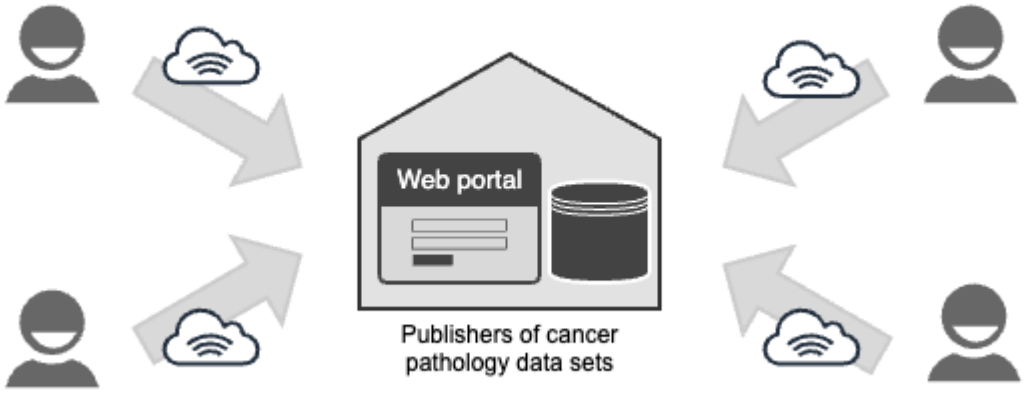
- Relies on a standard interoperability framework
- Approach relies on software vendors to implement content in accordance with publisher intent
- Approach relies on software vendors to incorporate encoded pathology cancer data into EHR/LIS data models
- Variation in implementation quality and capability

Example

In the United States, the College of American Pathologists (CAP) developed a process to render their published reporting protocols into a XML documents that electronic health records (EHR) and Laboratory Information System (LIS) vendors. This approach was unique to the US and Canada for many years. It is now expanding into other parts of the world through middleware vendors that customize cancer pathology datasets for incorporation into EHR/LIS workflows. It is the longest standing electronic method of capturing cancer pathology reports in computable fashion at the time of report generation.

Centralized Approach: Central Web Portal

In this approach, pathologists interact with a centralized application rendering the specific reporting form. Upon completion of the form, the data is fully encoded and stored within the central cancer registry. A pdf or other electronic form of the report is sent back to that pathologist for incorporation into the patient medical record.



Benefits of this approach:

- Central management of cancer pathology reporting data sets
- Immediate incorporation into registry
- Sophisticated user interface logic easily incorporated into the user interface to optimize workflow efficiency to ensure only the required data elements are presented for pathologist recording.
- Possible to integrate workflow with EHR/LIS as done by PALGA

Limitations of this approach:

- Requires "leaving" EHR/LIS to complete report. Can be additional work for the pathologist
- Documentation/ entry of data is required in both the EHR and the central web portal
- External report may be returned only as a pdf or other, non-computable form
- Computable data not available for local clinical decision support or analysis

Example

This approach is used in the Netherlands by PALGA and emulated in other nations uses a centralized web portal for cancer pathology reporting. Here, pathologists navigate to a web portal managed by national cancer registries.

5.2 Standardized Model Representation using FHIR

HL7's Fast Healthcare Interoperability Resources (FHIR) has emerged as an industry standard for representing and exchanging electronic health data. When dealing with synoptic cancer reports, there are different ways to represent the information using FHIR resources. Two of the options include creating a new FHIR resource or using the FHIR Questionnaire resource. The decision between creating a new FHIR resource or using the FHIR Questionnaire largely depends on the specific needs of the project, the desired level of granularity, and the available resources for development and maintenance. A thorough analysis considering both the short-term implementation and long-term maintenance aspects will help guide the best approach.

New FHIR Resource for Synoptic Cancer Report

Pros

1. **Tailored Representation**: Creating a bespoke resource allows for a more tailored and granular representation of the specific data elements in synoptic cancer reports.

2. **Improved Semantics**: Custom semantics can be built into the new resource, ensuring that the meaning of the data is captured more precisely.
3. **Standardized Structure**: With a custom resource, all implementers would follow the same structured format, promoting consistency across systems.
4. **Optimized Queries**: Custom indices can be built into the resource, potentially optimizing query performance.

Cons

1. **Development Time**: Creating a new resource requires more time and effort, from design to validation to publication.
2. **Adoption Barrier**: Introducing a new resource might create an adoption barrier, as systems need to be updated to recognize and process this new entity.
3. **Maintenance**: There's a need to maintain and update the new resource in line with FHIR's evolution and updates in clinical knowledge.
4. **Interoperability Challenges**: While FHIR aims to promote interoperability, introducing new resources can sometimes add complexity to integrations, as other systems might not immediately support the new resource.

FHIR Questionnaire for Synoptic Cancer Report

Pros

1. **Pre-existing Structure**: Leveraging the FHIR Questionnaire means using an already defined and recognized resource, potentially speeding up development.
2. **Flexibility**: Questionnaires are inherently flexible and can be adapted to capture various kinds of data, including that of synoptic cancer reports.
3. **Wide Adoption**: Since the Questionnaire resource is already a part of the FHIR specification, many systems will already support it, potentially easing integration efforts.
4. **Evolves with FHIR**: As FHIR evolves, so will the Questionnaire resource. Using it means benefiting from ongoing enhancements and updates.

Cons

1. **Generalized Semantics**: As a generic tool, Questionnaires might not capture the specific semantics of synoptic cancer reports as precisely as a dedicated resource.
2. **Potential Complexity**: Capturing complex clinical data in a questionnaire format can become unwieldy or confusing.
3. **Less Optimized**: Queries might be less efficient when searching for specific data elements in a generic Questionnaire compared to a custom resource.

The next sections will outline both methods. However, it's important to note that in most cases, the advantages of using FHIR Questionnaires outweigh the reasons for developing new FHIR Resources. The upcoming implementation examples will, therefore, be provided as FHIR Questionnaires.

5.2.1 FHIR Resources

There is no specific FHIR Resource applicable for Synoptic Cancer Reporting, and the diversity of information required in different types of cancer makes it very difficult to use a single FHIR resource; this leads to the need for a specific FHIR resource for every kind of cancer.

Creating a new FHIR resource is a collaborative and iterative process. It requires significant engagement with the healthcare community to ensure that the resource is both technically sound and clinically relevant. The ultimate aim is to facilitate interoperability and improve patient care by representing health data in a standardized and meaningful way.

These are the typical steps involved in the creation of a new FHIR Resource:

1. **Identification of Need**:
    a. Consult with oncologists, pathologists, and IT professionals. Review current FHIR resources to ensure there's no overlap with existing structures concerning synoptic cancer reporting.
2. **Initial Research**:
    a. Gather templates and standards currently used in synoptic reporting. Identify unique data elements necessary for the report.
3. **Drafting the Proposal**:
    a. Define the data elements, structure, and relationships of the new resource. Document the purpose and use cases of the proposed resource.
4. **Community Engagement**:
    a. Share the draft proposal with relevant FHIR workgroups to gather feedback. Refine the proposal based on the insights and suggestions from the community.
5. **Development & Prototyping**:
    a. Utilize FHIR development tools to model and prototype the new resource. Ensure that it aligns with existing FHIR guidelines and conventions.
6. **Documentation**:
    a. Provide detailed information about the resource, including its purpose, structure, and examples, to assist future implementers.
7. **Formal Review**:
    a. Submit the resource for review by official FHIR governance bodies. Address any suggestions or concerns raised by HL7 committees.
8. **Trial & Feedback**:
    a. Implement the new resource in real-world healthcare settings. Gather feedback from these implementations and refine the resource accordingly.
9. **Standardization Process**:
    a. Push for the inclusion of the resource in future FHIR standards. Engage with the FHIR community and stakeholders to promote its adoption.
10. **Maintenance**:
    a. Regularly review and update the resource, considering new clinical insights or technological advancements.
11. **Promotion & Training**:
    a. Develop training materials or sessions for the new resource. Engage with health IT and clinical communities to increase awareness and understanding.

The decision to use FHIR resources for this Use Case will provide great specificity and level of detail in the captured data and great uniformity between implementations. However, the process of creating resource specifications from scratch is slow, taking many months to develop each resource. The stability of the resources, only updating in new FHIR versions and not independently, also complicates the need for continuous improvement or adaptations to new requirements.

> **Implementation advice**
>
> Taking into account all these factors, for the majority of applications, it is generally better to use FHIR Questionnaires, which are explained in the following section, rather than creating new FHIR Resources.

5.2.2 FHIR Questionnaires

Creating a FHIR Questionnaire for synoptic cancer reporting provides a simple and expedited way of representing custom information models with the flexibility of a dynamic specification that can adapt quickly to any required change. Each cancer type will use a new questionnaire definition in this approach, with some sections in common and some sections with specific content. Open-source tooling is available for authoring questionnaire definitions, and the questionnaires can be easily rendered in a clinical application for supporting data capture.

The information entered in a FHIR questionnaire can be shared as a FHIR Questionnaires Response or transformed into a bundle of specific FHIR resources like Observations Resources and others.

Creating a new questionnaire requires several methodical steps. Here's a step-by-step guide to help you accomplish that:

1. **Define the Scope**:
   - Understand the specific type of cancer and the information that needs to be captured in the synoptic report.
   - Determine the purpose of the Questionnaire: Is it for diagnostic purposes, treatment monitoring, research, etc.?
2. **Gather Information**:
   - Gather all the relevant clinical guidelines, standard synoptic templates, and any other resources that can guide the creation of the Questionnaire.
   - Consider input from oncologists, pathologists, and other stakeholders.
3. **Design the Questionnaire**:
   - Start by identifying the main sections or groups of the Questionnaire. For instance, patient information, tumor characteristics, treatment history, etc.
   - For each section, define the questions, possible answers, and any constraints.
   - Use the appropriate FHIR data types for each question. For instance, use `date` for dates, `string` f or free text, `choice` for multiple-choice questions, etc.
4. **Use FHIR Tools**:
   - Utilize tools like the HL7 FHIR Questionnaire Designer or any other FHIR-compatible tool to help design, visualize, and test your Questionnaire.
   - These tools can help ensure the Questionnaire is constructed correctly according to FHIR standards.
5. **Incorporate Conditional Logic**:
   - If certain questions should only appear based on the answers to previous questions, incorporate this conditional logic. For instance, if a specific treatment is selected, additional questions related to that treatment may be necessary.
6. **Iterative Testing**:
   - Test the Questionnaire in a FHIR-compatible system.
   - Collect feedback from potential users, like pathologists or oncologists.
   - Make necessary revisions based on feedback and testing results.
7. **Integrate with EHR Systems**:
   - Ensure that the Questionnaire can be integrated into Electronic Health Record (EHR) systems or any other health IT system where it will be used.
   - Consider aspects like how the data will be extracted, how it will be presented to clinicians, and how it will be stored.
8. **Training & Education**:
   - Once the Questionnaire is ready, provide training to potential users.
   - Create educational materials, guidelines, and best practices for completing the Questionnaire.
9. **Continuous Review & Updates**:
   - As medical knowledge evolves and new guidelines emerge, the Questionnaire should be reviewed and updated accordingly.
   - Set up regular intervals (e.g., annually) to review and make necessary modifications.
10. **Interoperability & Sharing**:
    - Consider sharing the designed Questionnaire with the broader medical and FHIR community. This can aid in standardization and promote interoperability.
11. **Documentation**:
    - Ensure you document the design choices, versions, and updates of the Questionnaire. This documentation is crucial for maintaining and updating the Questionnaire in the future.
12. **Compliance & Ethics**:
    - Ensure that the Questionnaire meets legal, ethical, and regulatory standards, especially when dealing with sensitive health data.

Remember, the aim of creating a FHIR Questionnaire for synoptic cancer reporting is to capture standardized, structured, and clinically relevant information that can be easily shared, analyzed, and utilized for patient care. It's crucial to keep end-users in mind throughout the process and prioritize clarity and ease of use.

5.2.3 Examples

In the realm of oncology, the standardized capture of diagnostic, treatment, and outcome data is paramount. FHIR (Fast Healthcare Interoperability Resources) provides a compelling solution through its Questionnaire resource, tailor-made to document information in a structured and interoperable manner. Recognizing the critical role of synoptic reporting in cancer care—a method that ensures consistent and comprehensive documentation—we've compiled a set of FHIR Questionnaire examples specifically geared towards cancer synoptic reporting.

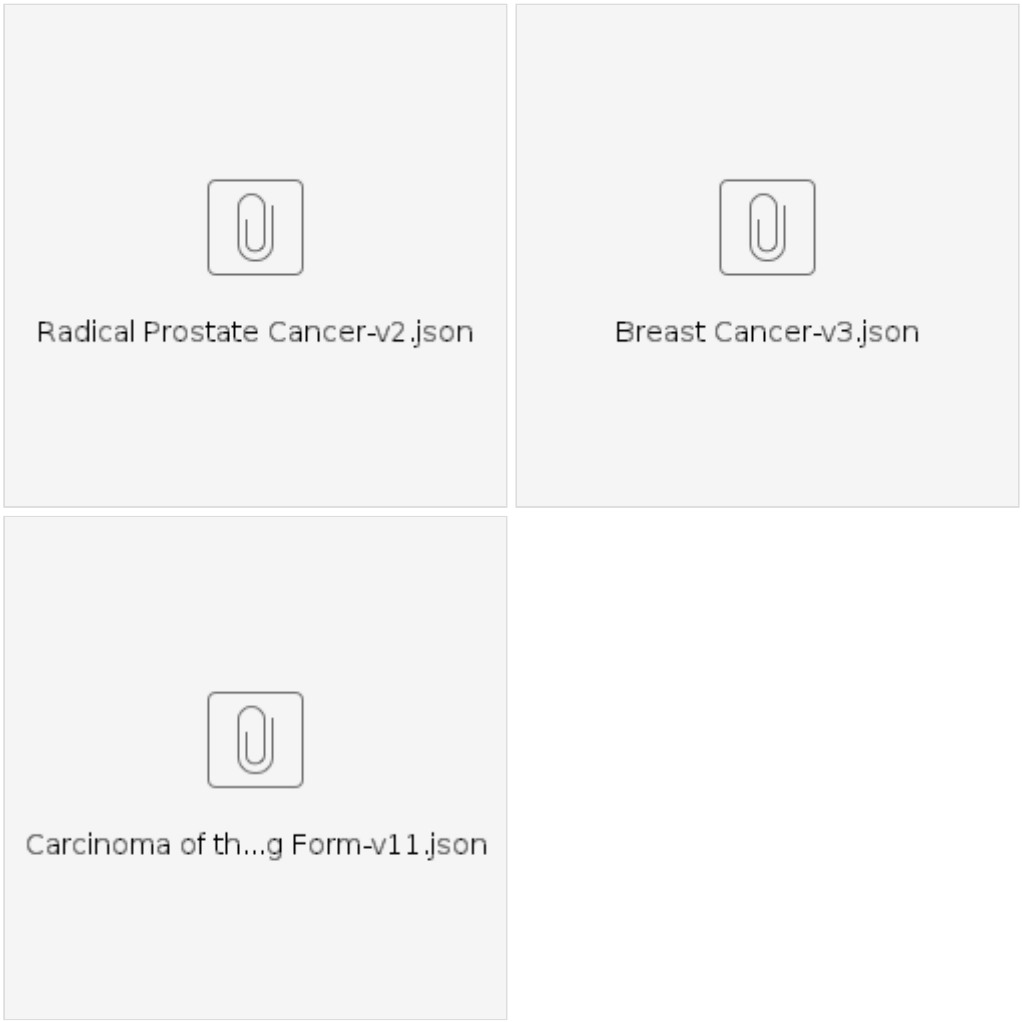
These examples demonstrate how the FHIR framework can be adeptly employed to encapsulate vital oncological data, ranging from tumor characteristics to treatment modalities. For oncologists, pathologists, and health IT professionals aiming to enhance the quality and consistency of cancer reporting, these examples serve as both a guide and a starting point for technical implementation.

Disclaimer

The FHIR Questionnaire examples provided for cancer synoptic reporting are for illustrative and educational purposes only. They have not been validated for clinical use and should not be adopted or relied upon in actual clinical settings. Before using any tools or templates in a clinical environment, thorough validation, and consultation with healthcare IT professionals, clinicians, and relevant regulatory bodies is essential. Always prioritize patient safety and data integrity. Use these examples at your own risk; the creators or distributors bear no responsibility for any adverse outcomes resulting from their use in clinical scenarios.

FHIR Questionnaires

These FHIR Questionnaires can be downloaded as JSON files and viewed and edited using any compatible editor. We recommend using the NLM Form Builder (https://lhcformbuilder.nlm.nih.gov/).



Also, SNOMED International provides a utility to store questionnaires in a standard FHIR server and to validate the SNOMED Terminology Bindings to manage updates of SNOMED versions:

https://ihtsdo.github.io/sct-implementation-demonstrator/#/questionnaires

5.2.4 Usage Considerations for FHIR Questionnaires

Sharing FHIR Questionnaires

FHIR Questionnaires can be shared between implementations, as their design does not depend on other FHIR resources or external information models. In this way, it is possible to create a repository of FHIR Questionnaires that anyone can access. In the case of Cancer Synoptic Reporting, one group can take the responsibility of transforming the paper-based forms into FHIR Questionnaires and making them available for the community of users.

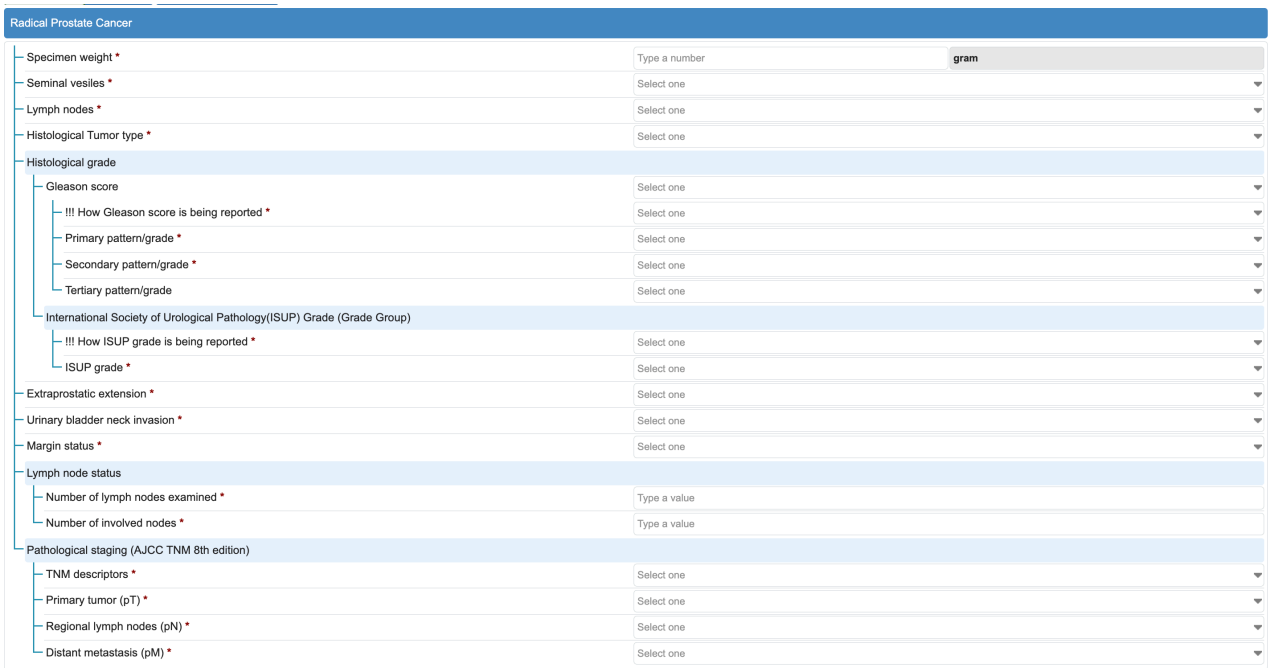
As an example, the SNOMED International Synoptic Cancer Reporting Clinical Reference Group maintains a GitHub repository with FHIR Questionnaires in: https://github.com/IHTSDO/cancer-synopting-protocol-fhir-questionnaires

This repository records all versions of the questionnaires, with the ability to identify changes and download them for local implementations. Using the collaborative tools in the GitHub repository, it is possible to fork the repository to introduce local customizations, report and discuss bugs and problems in the "Issues" section, and propose questionnaire improvements or changes using the pull request feature.

Rendering Questionnaires in a Clinical Application

It is possible to dynamically create data entry user interfaces based on questionnaire definitions, introducing rich and flexible data capture in clinical applications. Some ready-made open-source libraries can simplify incorporating these functions in clinical software.

This is an example of a Prostate Cancer Form rendered using an open-source library:



SMART on FHIR Integrations

The SMART on FHIR specifications allows the safe incorporation of a questionnaire rendering "plugin" into commercial clinical software. These plugins are executed locally on the client servers and don't share information with external parties.

The National Library of Medicine of the US has published an example SMART Application that can be adapted to render any questionnaire using this standard: https://github.com/lhncbc-fhir/lforms-fhir-app

How do the questionnaires coexist with the rest of the clinical data?

A clinical application records diagnoses, observations, and procedures. When capturing the same information using a FHIR Questionnaire, we can create a model duplication with the risk of inconsistencies or complicating data retrieval or analytics later. FHIR Standards proposed by the Structured Data Entry group can help minimize these risks and facilitate the integration of the questionnaires with the rest of the information model.

Automatic Population

The use of automatic population helps to reduce the pain of having to fill in the same information 'yet again' by allowing a form to automatically fill in answers already known to the EHR or other data source. The user can then verify that the information is still correct (and revise if necessary) rather than needing to fill out the information all over again (and possibly accidentally omitting or incorrectly entering some data).

Data Extraction

Data extraction procedures allow data captured in a QuestionnaireResponse to be extracted and used to create or update other FHIR resources - enabling the data to be more easily searched, compared, and used by other FHIR systems.

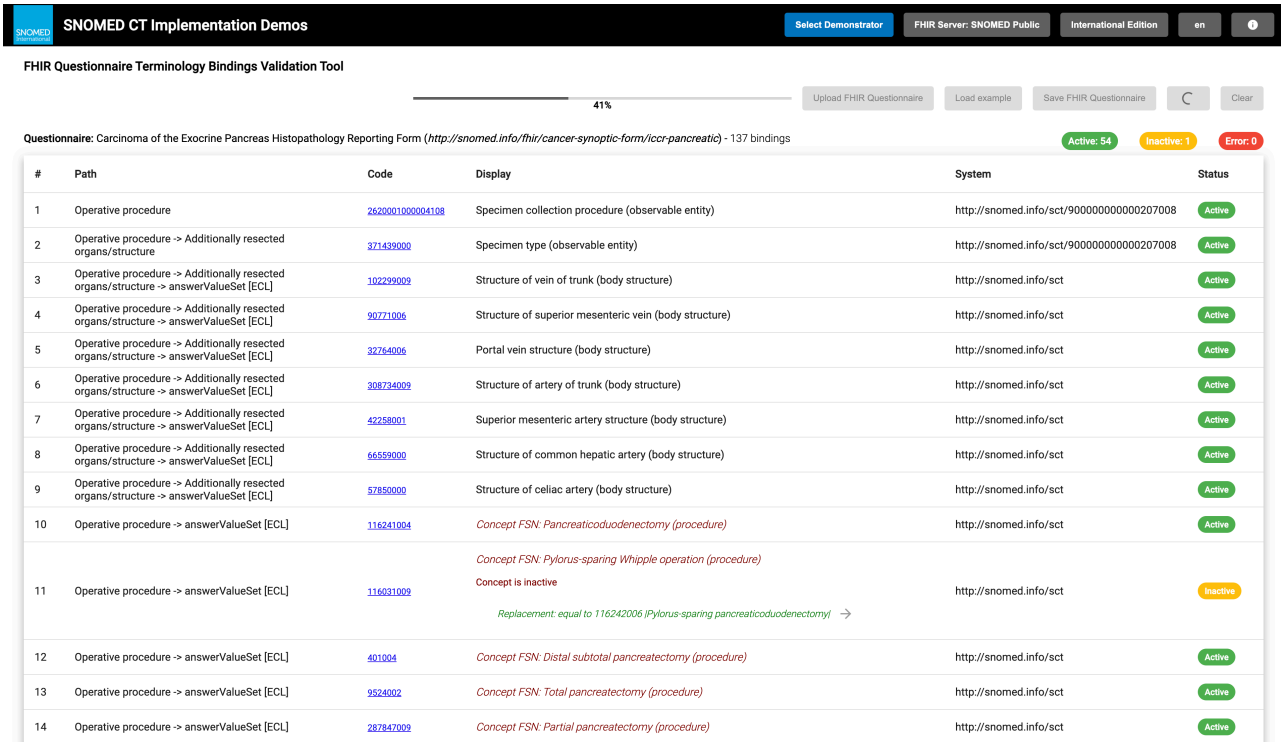
Read more about the Structure Data Capture guides on their website.

Maintaining terminology bindings in FHIR Questionnaires

FHIR Questionnaires contain direct references to SNOMED CT concepts as the codes for questions or responses and references as part of ECL expressions. With each new release of SNOMED CT, it is necessary to validate all referenced content to detect inactivations and make any necessary replacements.

SNOMED International makes a tool available for terminology bindings validations, where a FHIR Questionnaire can be uploaded and the inactive codes can be replaced using the historical associations published on each release.

https://ihtsdo.github.io/sct-implementation-demonstrator/#/questionnaires



#	Path	Code	Display	System	Status
1	Operative procedure	2620001000004108	Specimen collection procedure (observable entity)	http://snomed.info/sct/900000000000207008	Active
2	Operative procedure -> Additionally resected organs/structure	371439000	Specimen type (observable entity)	http://snomed.info/sct/900000000000207008	Active
3	Operative procedure -> Additionally resected organs/structure -> answerValueSet [ECL]	102299009	Structure of vein of trunk (body structure)	http://snomed.info/sct	Active
4	Operative procedure -> Additionally resected organs/structure -> answerValueSet [ECL]	90771006	Structure of superior mesenteric vein (body structure)	http://snomed.info/sct	Active
5	Operative procedure -> Additionally resected organs/structure -> answerValueSet [ECL]	32764006	Portal vein structure (body structure)	http://snomed.info/sct	Active
6	Operative procedure -> Additionally resected organs/structure -> answerValueSet [ECL]	308734009	Structure of artery of trunk (body structure)	http://snomed.info/sct	Active
7	Operative procedure -> Additionally resected organs/structure -> answerValueSet [ECL]	42258001	Superior mesenteric artery structure (body structure)	http://snomed.info/sct	Active
8	Operative procedure -> Additionally resected organs/structure -> answerValueSet [ECL]	66559000	Structure of common hepatic artery (body structure)	http://snomed.info/sct	Active
9	Operative procedure -> Additionally resected organs/structure -> answerValueSet [ECL]	57850000	Structure of celiac artery (body structure)	http://snomed.info/sct	Active
10	Operative procedure -> answerValueSet [ECL]	116241004	*Concept FSN: Pancreaticoduodenectomy (procedure)*	http://snomed.info/sct	Active
11	Operative procedure -> answerValueSet [ECL]	116031009	*Concept FSN: Pylorus-sparing Whipple operation (procedure)* Concept is inactive *Replacement: equal to 116242006 |Pylorus-sparing pancreaticoduodenectomy|* →	http://snomed.info/sct	Inactive
12	Operative procedure -> answerValueSet [ECL]	401004	*Concept FSN: Distal subtotal pancreatectomy (procedure)*	http://snomed.info/sct	Active
13	Operative procedure -> answerValueSet [ECL]	9524002	*Concept FSN: Total pancreatectomy (procedure)*	http://snomed.info/sct	Active
14	Operative procedure -> answerValueSet [ECL]	287847009	*Concept FSN: Partial pancreatectomy (procedure)*	http://snomed.info/sct	Active

Appendices

How to learn more ?

SNOMED CT

https://www.snomed.org/education

ICCR

https://www.iccr-cancer.org