Ensuring Integrated Diagnostics Facilitate Oncology Care

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Research Funding and Partnerships

- GE Healthcare
- Microsoft
- GenomOncology
- Conquer Cancer Foundation
- National Cancer Institute

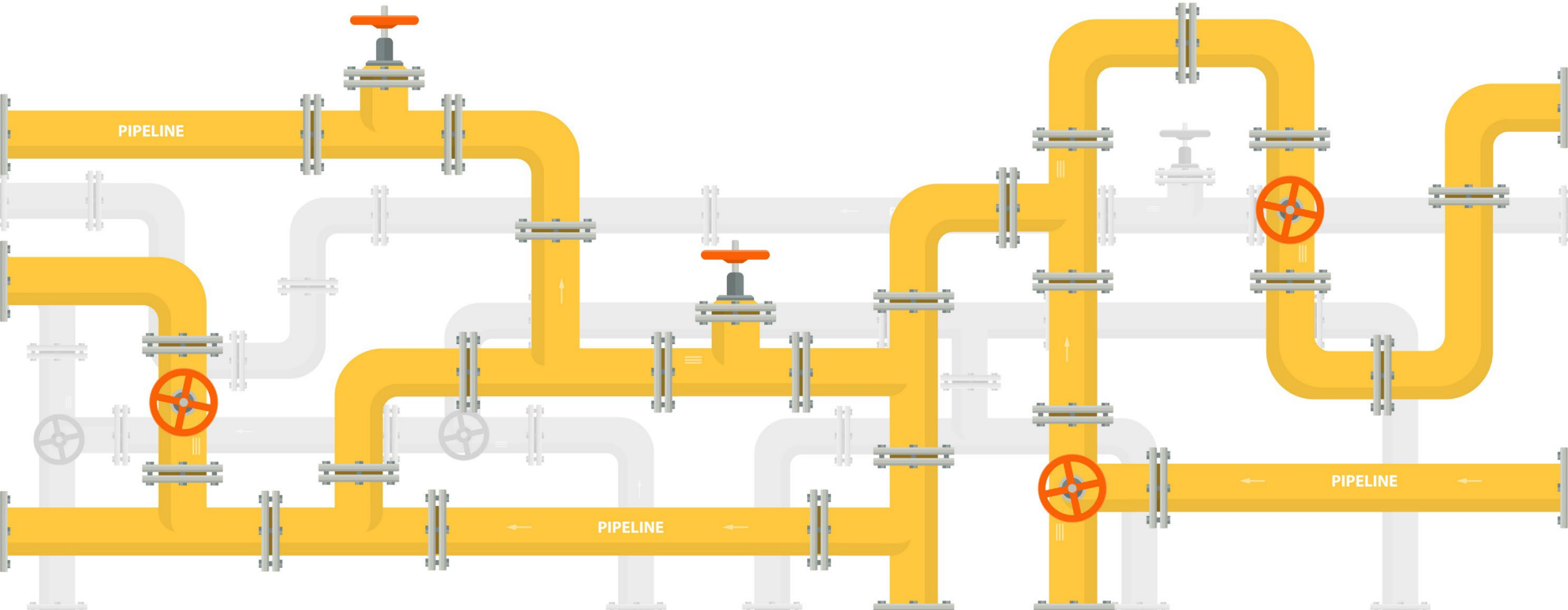
Advising

- AstraZeneca
- eHealth Technologies
- MD Outlook
- Biodesix

Ownership

- Infostratix, LLC

Integrated Diagnostics as a Pipeline



Overview

Topics

- Surgical Oncology
- Clinical Staging
- Genomic Reporting
- Recording Outcomes
- Clinical Trials

Questions

- Do we have a standard?
- Is the standard being adopted?
- Are clinical workflows aligned?

ACS AMERICAN COLLEGE OF SURGEONS

Commission on Cancer Operative Standards 2020

Synoptic Operative Reports: CoC Standards 5.3–5.6

Definition

Standardized sets of data elements organized as a structured checklist or template

Each data element's value is filled in using a pre-specified format

Benefits

Allow information to be easily collected, stored, and retrieved, resulting in:

↑ Accuracy
↑ Efficiency of entry
↑ Efficiency of data abstraction

↓ Variability
↓ Costs

... thereby increasing the **quality of cancer care**

Timeline

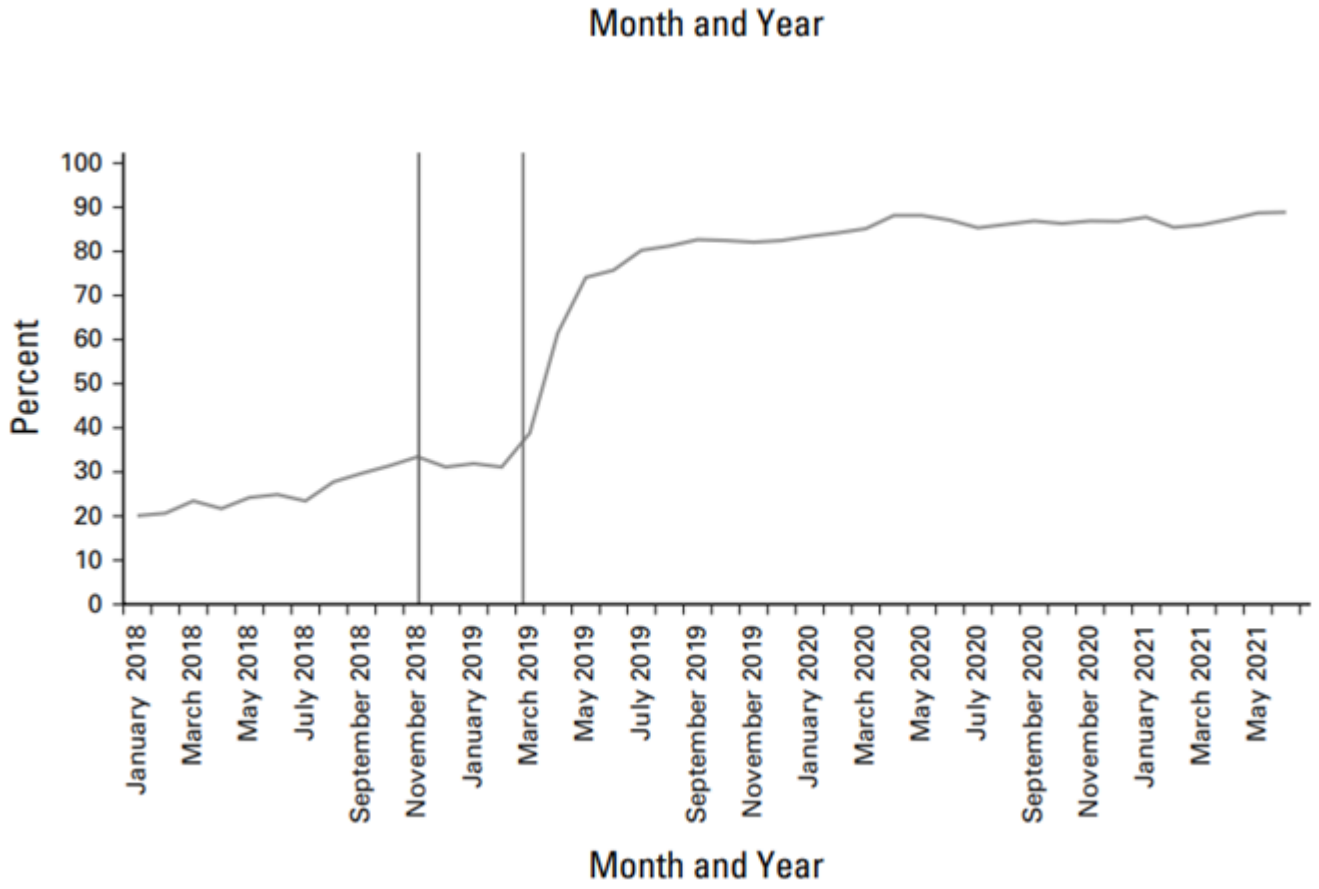
2022
Programs document final plan for implementation

2023
Operative reports must meet technical & synoptic formatting requirements

2024
Site visits assess 2023 reports for 70% compliance

https://www.facs.org/media/avukq4nc/coc_standards_5_3_5_6_synoptic_operative_report_requirements.pdf

Challenges with (Clinical) Staging



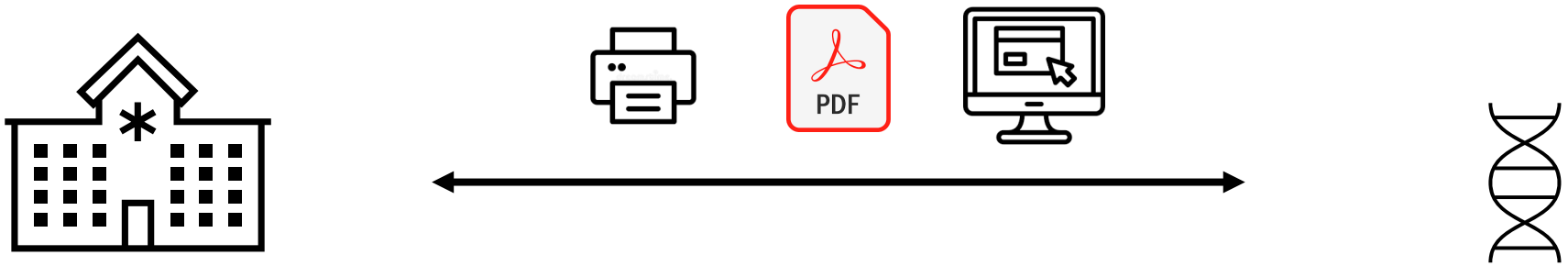
Patients with structured staging

20% ⟶ 90%

JCO® Clinical Cancer Informatics
An American Society of Clinical Oncology Journal

Emamekhoo, H. *et al.* Supporting Structured Data Capture for Patients With Cancer: An Initiative of the University of Wisconsin Carbone Cancer Center Survivorship Program to Improve Capture of Malignant Diagnosis and Cancer Staging Data. *JCO Clin Cancer Inform* **6**, e2200020 (2022).

Genomic Reference Laboratories



Genomic Reference Laboratories

Genomics Reporting Implementation Guide

2.1.0-SNAPSHOT - trial-use

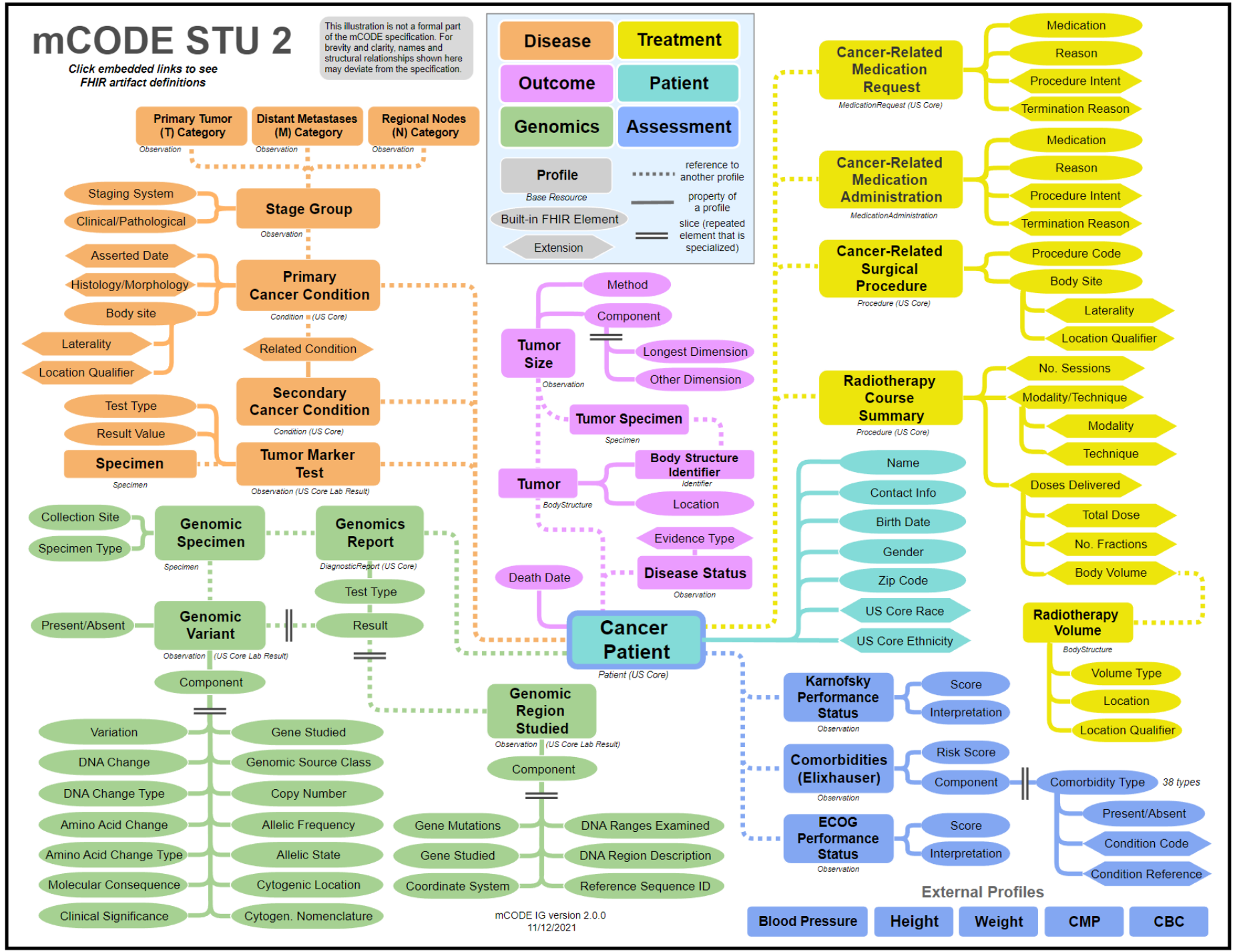
https://build.fhir.org/ig/HL7/genomics-reporting/

Receiving Structured Genomic Results by HL7

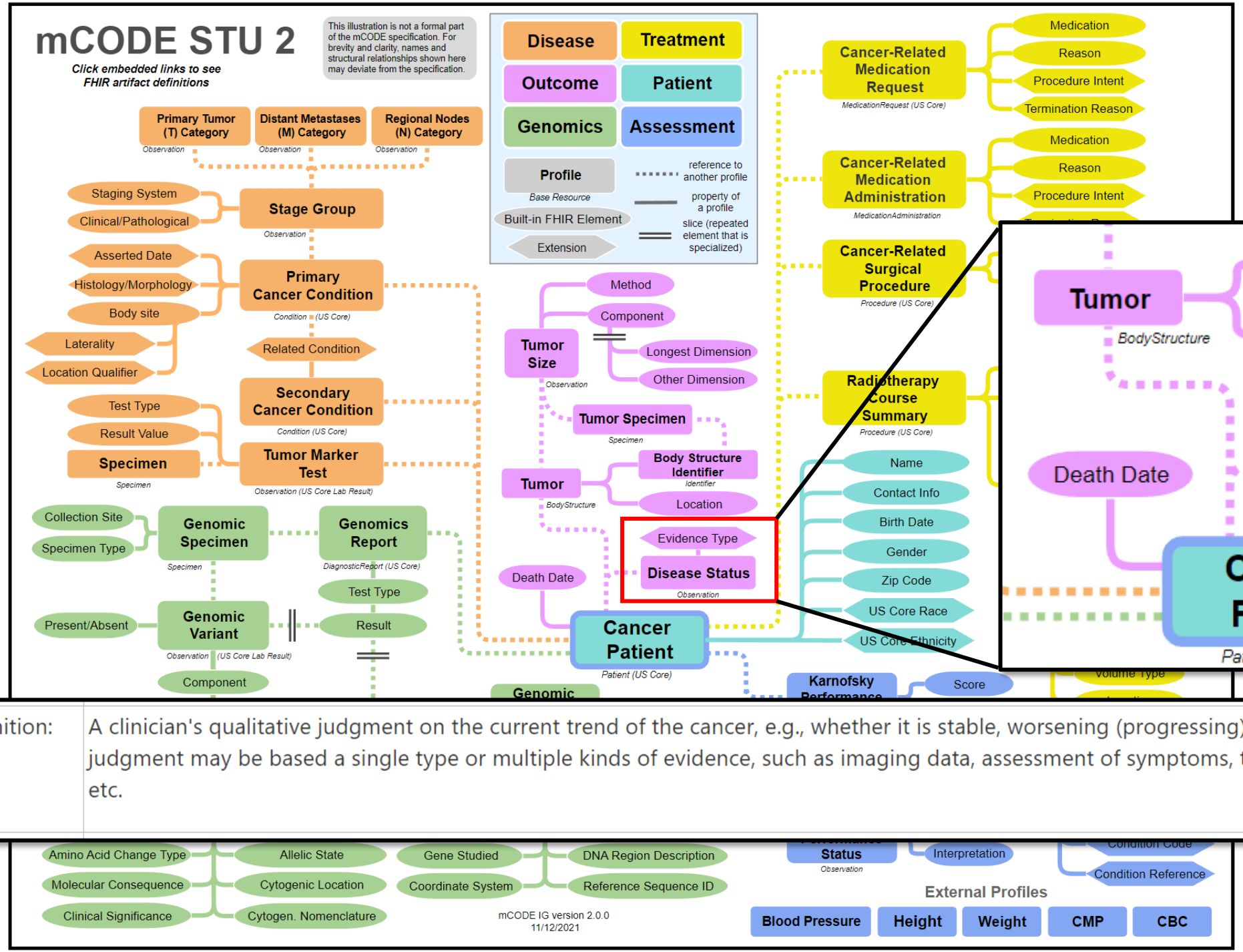
Source: Epic Systems Corp, 2/27/2023

Opportunities

- Disease Status
- Clinical Trials
  - Protocol interoperability
  - Inclusion Criteria



http://hl7.org/fhir/us/mcode/



Definition:	A clinician's qualitative judgment on the current trend of the cancer, e.g., whether it is stable, worsening (progressing), or improving (responding). The judgment may be based a single type or multiple kinds of evidence, such as imaging data, assessment of symptoms, tumor markers, laboratory data, etc.

http://hl7.org/fhir/us/mcode/

Clinical Trials: Matching

NIH U.S. National Library of Medicine

ClinicalTrials.gov API

Documentation

Use the following links to learn about the ClinicalTrials.gov API.

Link	Description
API URLs	List of info URLs for accessing information about the API and query URLs with parameters.
Query URL Responses	Description of information returned by query URLs.
Search Expressions and Syntax	Types and syntax of search expressions used in query URLs.
Search Operators	List of operators with examples and descriptions of search expressions used in query URLs.
Data Element-to-API Field Crosswalks	List of ClinicalTrials.gov data elements and their corresponding API fields.
Study Structure and Fields	Organization of API fields within a ClinicalTrials.gov study record and other information.
Search Areas	List and description of ways to specify the portions of a study record to search, ranging from multiple API fields (e.g., BasicSearch, ConditionsSearch) to a single field (e.g., Acronym).
Download Content for All Study Records	URLs for downloading all content for all study records available on ClinicalTrials.gov as a single zip file.

Criteria

Inclusion Criteria:

•Previously registered to A151216 (NCT02194738)

•Central and/or local testing of EGFR with no EGFR exon 19 deletion or EGFR L858 R mutation (applicable to non-squamous patients only)

•Central and/or local testing of ALK with no ALK rearrangement (failed testing is considered negative) (applicable to non-squamous patients only)

•Central and/or local testing of PD-L1 immunohistochemistry (IHC) using one of the following assays: DAKO 22C3, DAKO 28-8, EIL3N or SP263

- Note: Local testing results of EGFR and ALK by a local Clinical Laboratory Improvement Act (CLIA) certified laboratory is acceptable. The report must indicate the result as well as the CLIA number of the laboratory that performed the assay. Local result of PD-L1 by DAKO 22C3, Dako 28-8, EIL3N or SP263 are acceptable for enrollment on A081801. Patients with local results for EGFR, ALK and PD-L1 still need to be registered to A151216 and follow all the submissions requirements but do NOT need to wait for the results to proceed to A081801 registration

•Completely resected stage IIA, IIB IIIA or IIIB (T3-4N2) non-small cell lung cancer (NSCLC) (squamous or non-squamous) with negative margins (complete R0 resection). Patients will be staged according to the 8th edition of the American Joint Committee on Cancer (AJCC) Staging Manual, 2017

- Note: Patients with pathologic N2 disease, completely resected, are eligible. However, patients known to have N2 disease prior to surgery are not eligible; guidelines do not recommend up-front surgery for this population

•Complete recovery from surgery. Registration to A081801 must be 30-77 days following surgery

•No prior neoadjuvant or adjuvant therapy for current lung cancer diagnosis

•No prior allogeneic tissue/solid organ transplant

•No current pneumonitis or history of (non-infectious) pneumonitis that required steroids

•Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial

•Age >= 18 years

•Eastern Cooperative Oncology Group (ECOG) performance status (PS): 0-1

•No active auto-immune disease that has required systemic treatment within the last 2 years (e.g., disease-modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid release therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment

•Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects. Therefore, for women of childbearing potential only, a negative pregnancy test done =< 7 days prior to registration is required

•No patients with a "currently active" second malignancy that is progressing or has required active treatment within the last 3 years. Participants with non-melanoma skin cancers or carcinoma in situ (e.g., breast carcinoma or cervical cancer in situ) that have undergone potentially curative therapy are eligible

•No hypersensitivity (>= grade 3) to pembrolizumab and/or any of its excipients

•No live vaccine within 30 days prior to registration. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster (chicken pox), yellow fever, rabies, Bacillus Calmette-Guerin (BCG), and typhoid vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however, intranasal influenza vaccines (e.g., FluMist) are live attenuated vaccines and are not allowed

•No known history of hepatitis B (defined as hepatitis B surface antigen [HBsAg] reactive) or known hepatitis C virus (defined as HCV ribonucleic acid [RNA] [qualitative] is detected) infection

•Absolute neutrophil count (ANC) >= 1,500/mm^3

•Platelet count >= 100,000/mm^3

•Hemoglobin >= 8 gm/dl

•Calculated (Calc.) creatinine clearance >= 45 mL/min

•Total bilirubin =< 1.5 x upper limit of normal (ULN)

•Aspartate aminotransferase (AST) / alanine aminotransferase (ALT) =< 2.5 x upper limit of normal (ULN)

Exclusion Criteria:

•Patients must NOT have uncontrolled intercurrent illness including, but not limited to, serious ongoing or active infection, symptomatic congestive heart failure, uncontrolled cardiac arrhythmia, unstable angina pectoris, that would limit compliance with study requirements

https://clinicaltrials.gov/api/gui

Clinical Trials: Protocol Interoperability

Clinical Trials Rapid Activation Consortium (CTRAC)

> “ can a small consortium of clinical trials sites develop methods to standardize workflows, drug formularies, drug administration procedures, and laboratory requirements leading to the creation of the components for a standardized, electronic, clinical- trials build system?

NCI: 3P30CA016672-44S4

Summary

- Remarkable progress toward interoperability
- Continue to have gaps in areas around clinical trials
- We need to work to identify gaps in data standards
- Systems cannot be implemented without workflow considerations

Questions