

# Project: Cancer Data Interoperability

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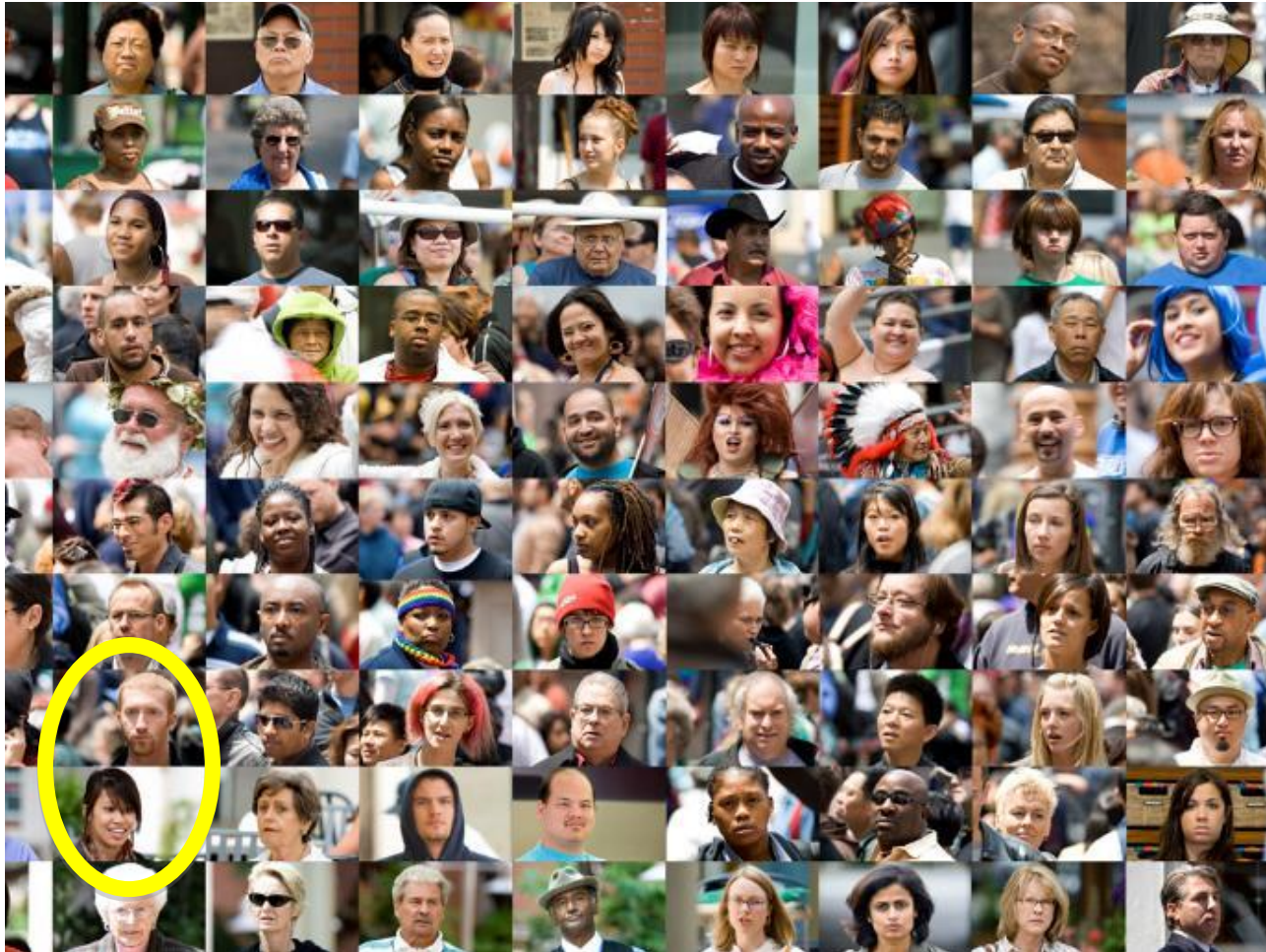
mCODE™



# Wanted: High-Quality Data for All Cancer Patients

Only 3% of adult cancer patients participate in clinical trials

1.7M New  
Cancer  
Patients  
each year  
in US



## Understudied populations

- Age 15-19 and > 65
- Underrepresented minorities
- Residents of rural communities
- Patients with co-morbid conditions
- Uninsured patients

# Approach

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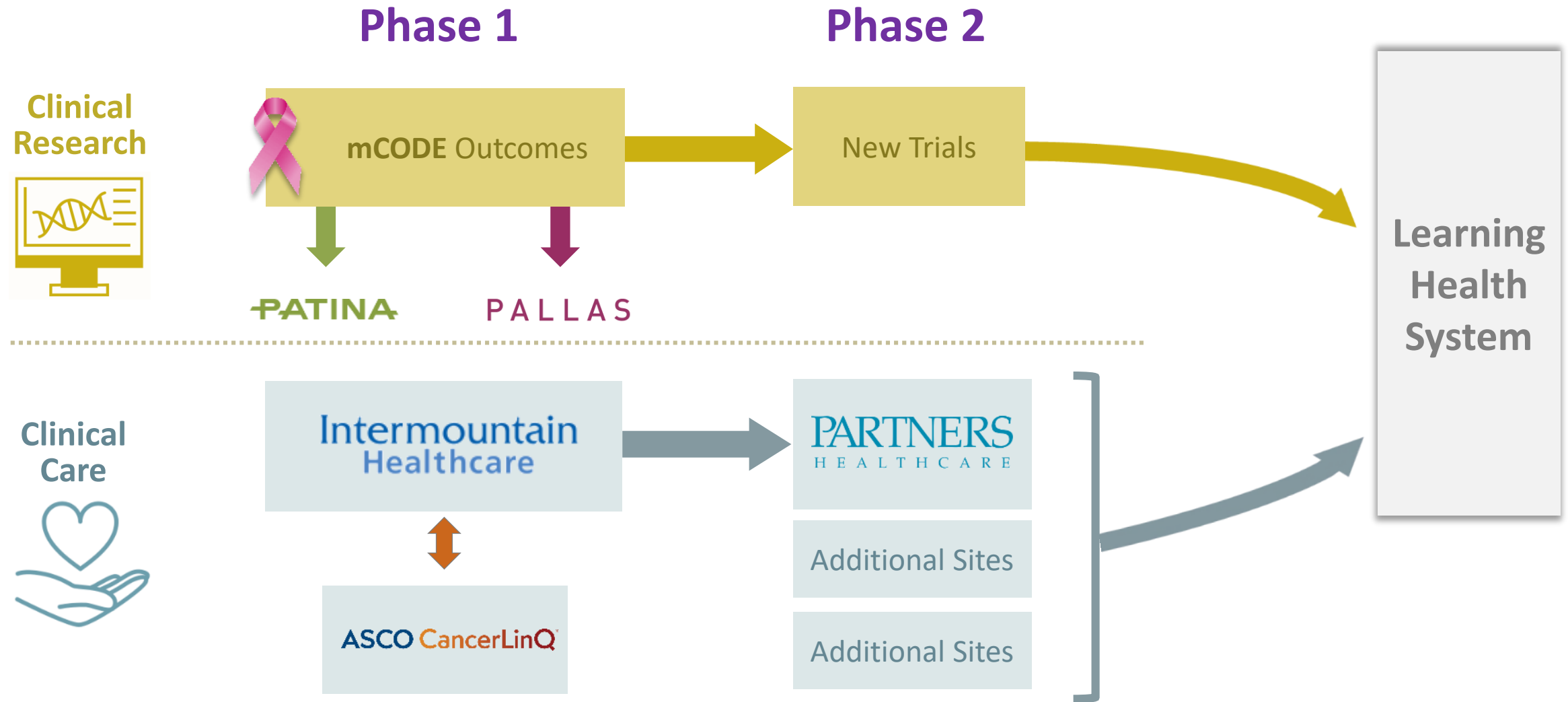
Build a vibrant **community** that **collaborates** on:

- **Use cases**
- **Data models and FHIR Implementation Guides**
- **Implementations**
- **Pilots**
- **Open**

# mCODE™ Initial Collaborators



# Research and Care Use Cases leading toward a Learning Health System for Cancer



# mCODE™

**mCODE**, or Minimal Common Oncology Data Elements, is a data standard that can be widely adopted. It holds promise to greatly increase **high-quality data** for all cancer types.

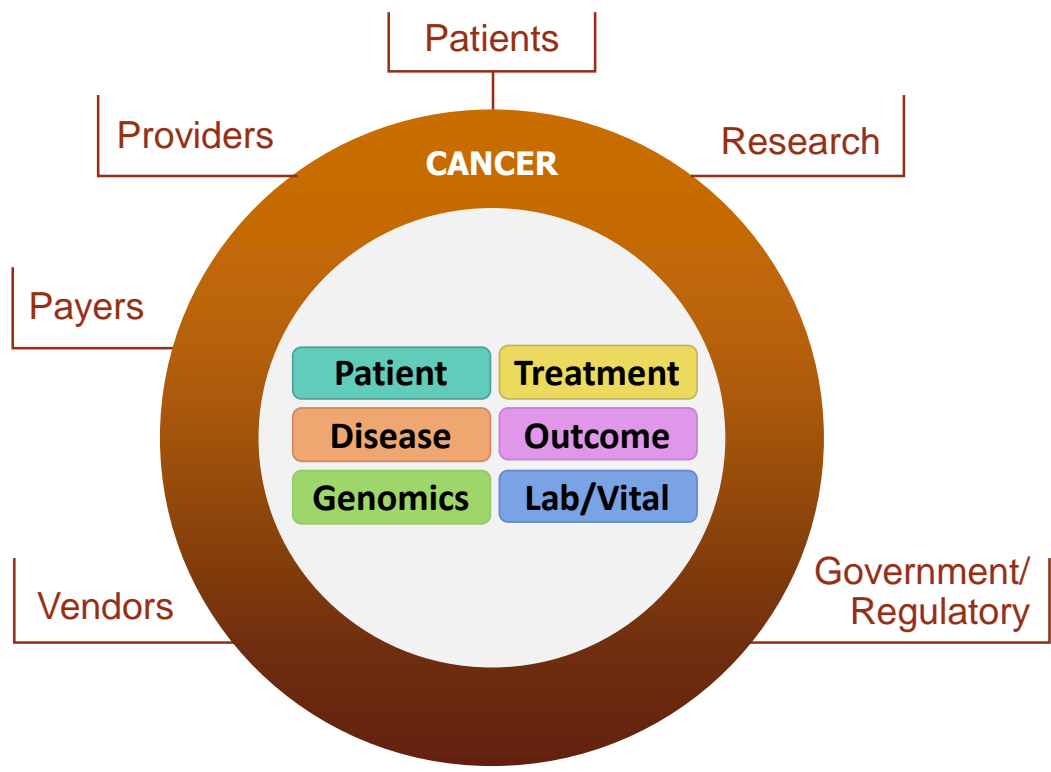
A **standard health record** for oncology

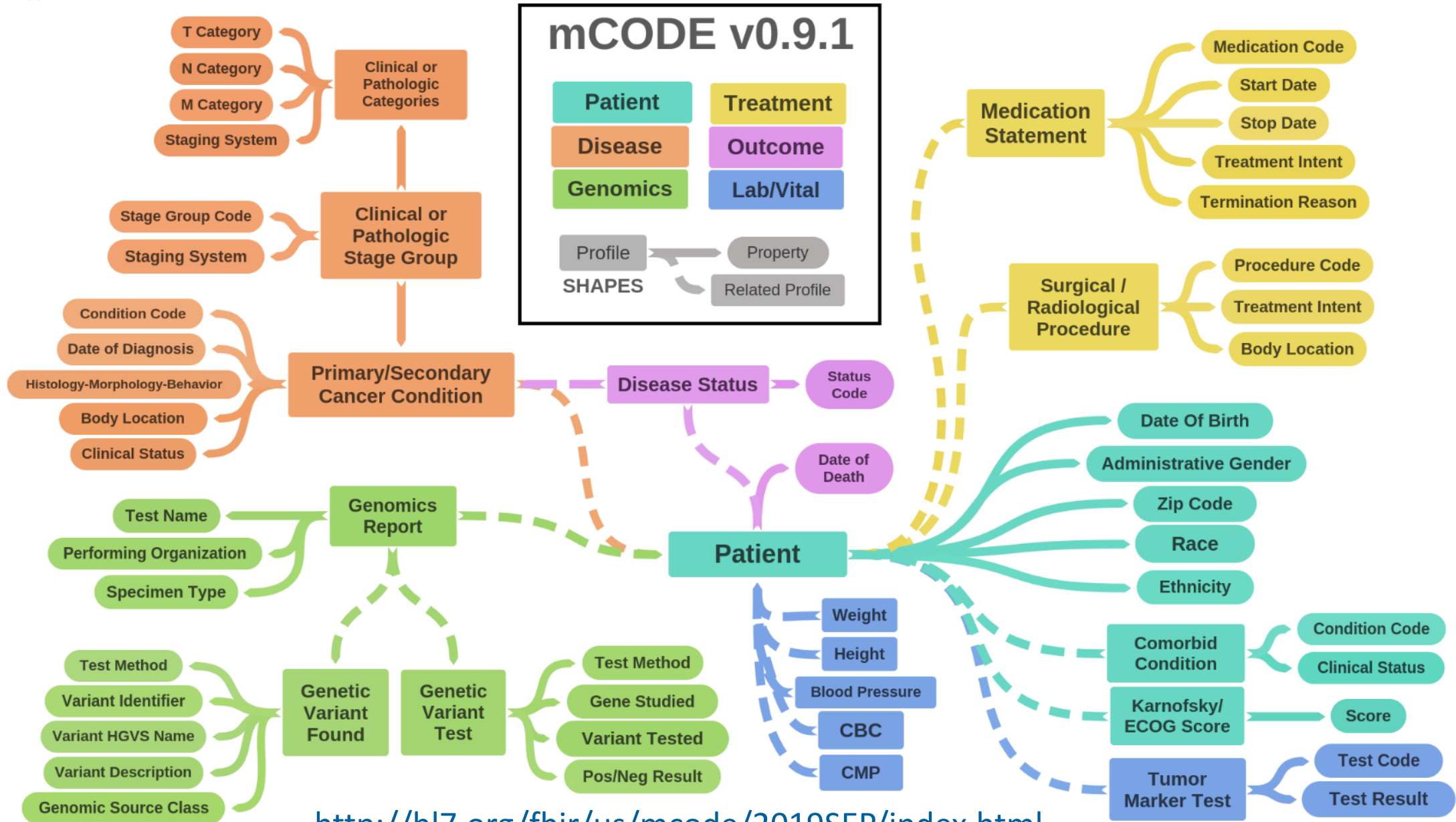
The **minimal set of data elements** applicable to all cancers, and collected for:

Standardized information exchange

Use-case driven and targeted use

Oncology data element domains: **patient, disease, treatment, outcomes, genomics, lab/vital**





<http://hl7.org/fhir/us/mcode/2019SEP/index.html>



# ICAREdata<sup>®</sup> Study Phase 1

Validate can prospectively collect high-quality data



Clinical Research

## Clinical Site Partners

DANA-FARBER  
CANCER INSTITUTE

ST. JOSEPH MERCY  
ANN ARBOR  
SAINT JOSEPH MERCY HEALTH SYSTEM

metro-minnesota  
MMCORC  
community oncology research consortium

 ThedaCare<sup>®</sup>

 St. Elizabeth  
HEALTHCARE

## Clinical Trials

PALLAS PATINA

## Approach

- Clinicians collected *Cancer Disease Status* as structured phrases in patient clinical note
- Evaluated correspondence between this RWD and clinical trial data

## Results

- 96% concordance with 95% probability
- Led to NCI funding for Phase 2





# ICAREdata<sup>®</sup> Study Phase 2

## EHR-based clinical trials endpoints collection



Clinical Research

### ICAREdata Approach

- Demonstrate that research-quality RWD can support clinical trial endpoints
- Incorporate ICAREdata and mCODE into clinical trial protocols
  - Alliance A071701 (Brain Mets) trial
  - Alliance A021703 SOLARIS (Vitamin D) Trial
- Use existing EHRs to collect key outcome data not structured today
  - Cancer disease status (*In mCODE v0.9.1*)
  - Cancer treatment plan change (*Possible mCODE extension*)
- Aggregate mCODE data across trial sites

### Potential Clinical Site Partners



MASSACHUSETTS  
GENERAL HOSPITAL



UNIVERSITY OF  
PENNSYLVANIA  
HEALTH SYSTEM



DANA-FARBER  
CANCER INSTITUTE



MAYO CLINIC

Geisinger

THE UNIVERSITY OF TEXAS  
MDAnderson  
Cancer Center

UCSF Health



Trinity Health



RUSH UNIVERSITY  
MEDICAL CENTER

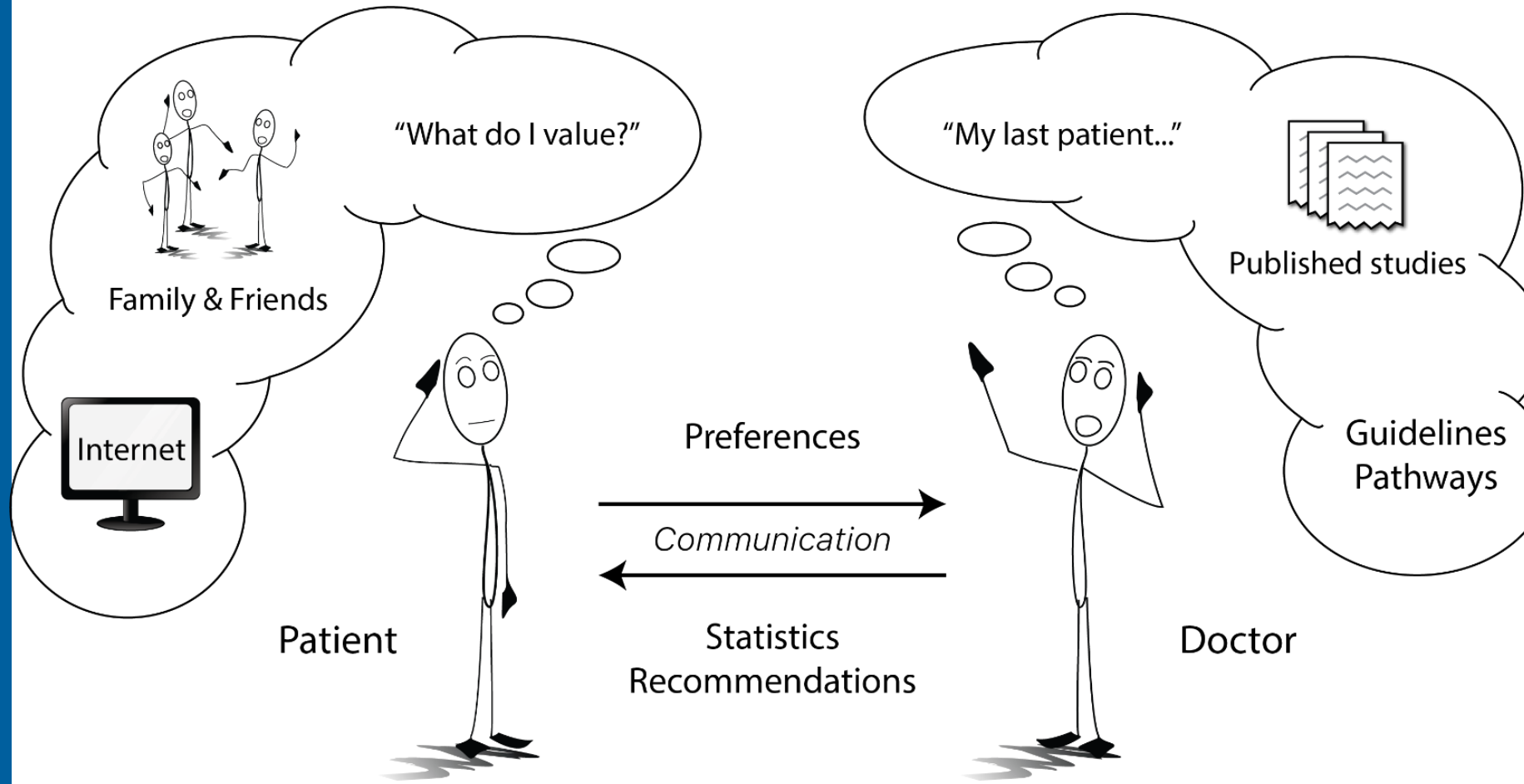
BRIGHAM HEALTH



BRIGHAM AND  
WOMEN'S HOSPITAL



# How Are Treatment Decisions Currently Made?





Clinical Care



Overview

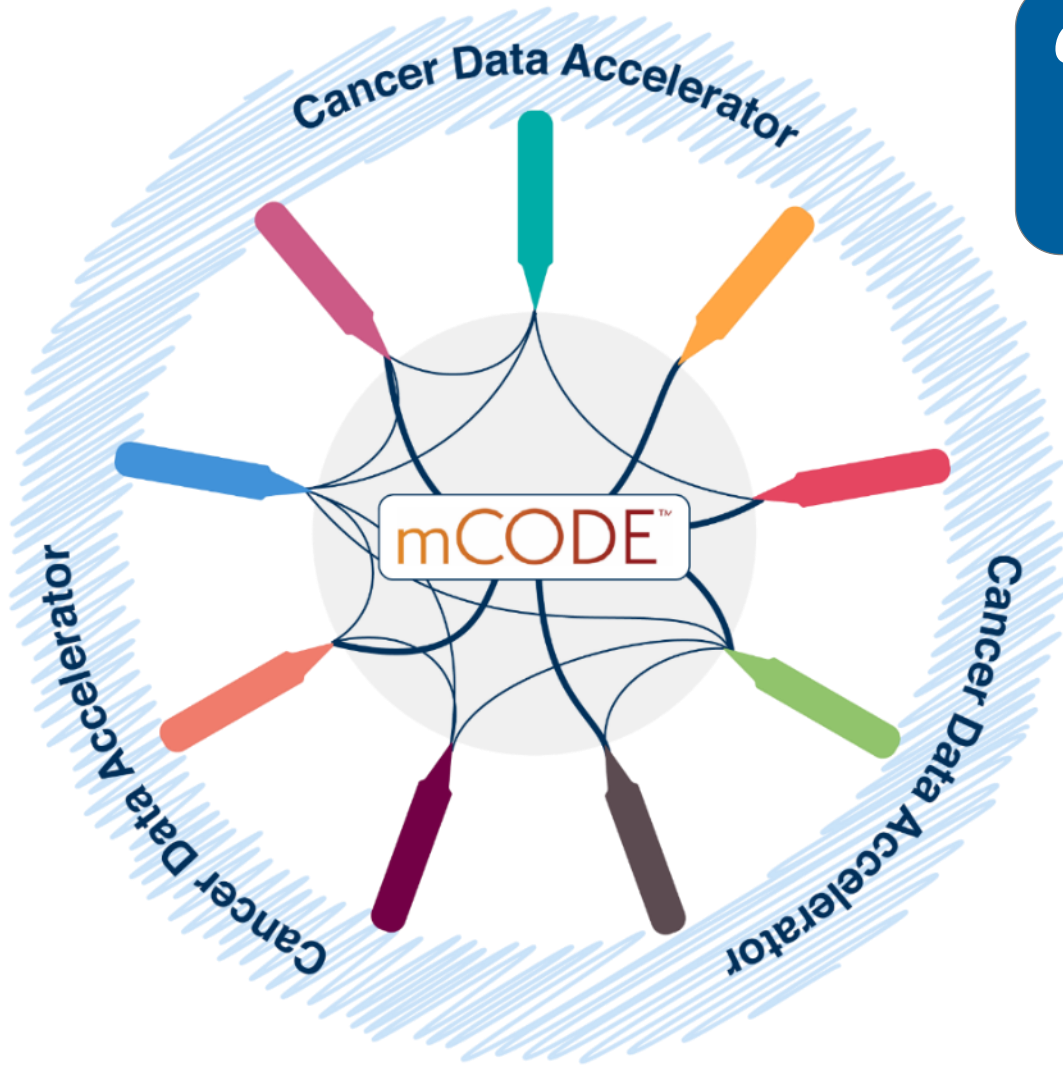
Name	Invasive ductal carcinoma of breast	Receptor Status ER	Positive
Date of Diagnosis	18 Dec 2018 (age 51)	Receptor Status PR	Negative
Laterality	Right	Receptor Status HER2	Positive
Tumor Histology	ductal carcinoma	Tumor Size	2.0 cm
Histological Grade	2 (moderately differentiated)		
Clinical Stage	IA		

mCODE™  
Data elements

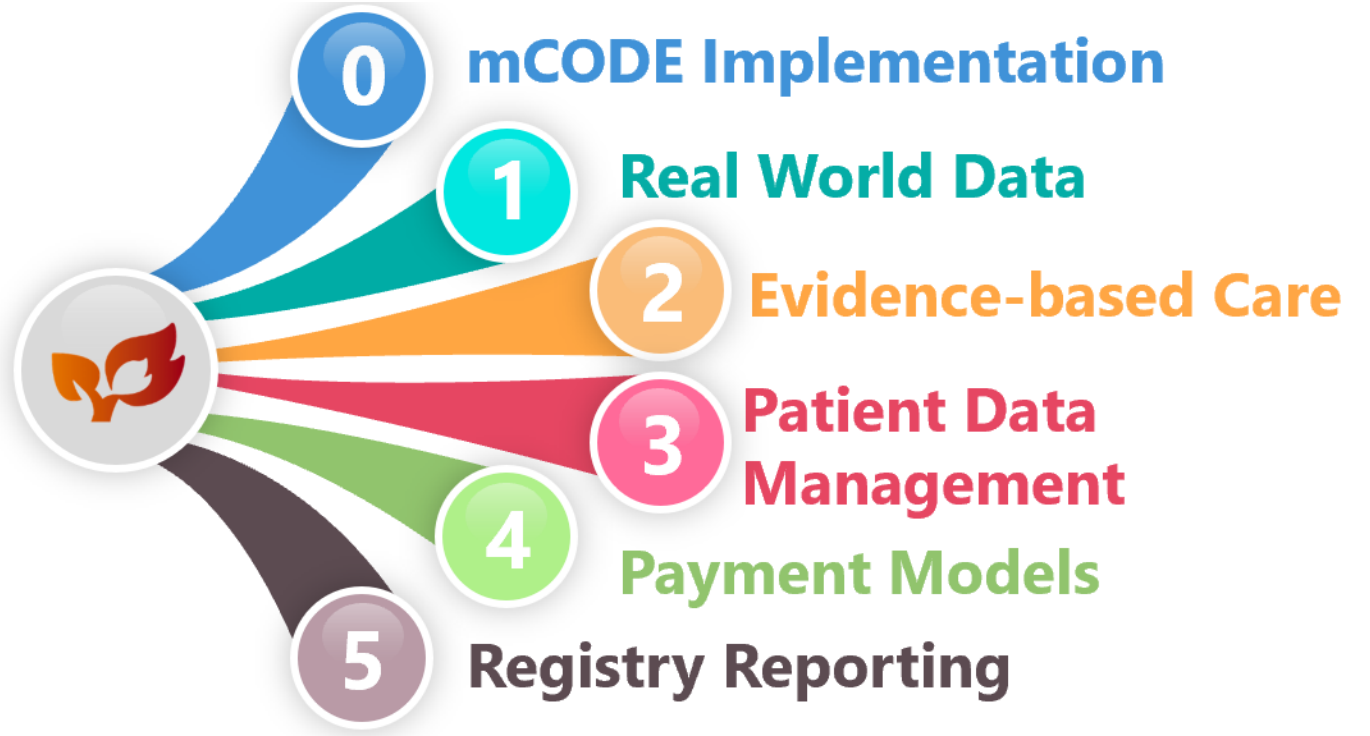
Matching to similar patients in CancerLinQ database

	Overall survival rates	Side Effects				
		1 yr	2 yr	5 yr	all	most common
include only: <a href="#">add/remove</a>						
surgery & radiation therapy (11)	95% 90% 77%				24%	lymphedema (14%) skin irritation (5%)
combine with: <a href="#">select treatments</a>						
hormonal therapy & chemotherapy (70)	97% ▲2% 95% ▲5% 90% ▲13%				51%	nausea & vomit... (25%) hair loss (21%)
chemotherapy (6)	96% ▲1% 94% ▲4% 87% ▲10%				46%	nausea & vomit... (20%) neutropenia (12%)
hormonal therapy (76)	96% ▲1% 89% ▼1% 80% ▲3%				39%	hot flash (33%) nausea (5%)

Comparable outcomes and side effects from matched patients



*CodeX Domains of Interest to Prospective Members*  
Use cases within domains will be shaped by CodeX members



# CodeX announced at HL7/Atlanta (Sep 17)

Currently talking with prospective Founding Members



CodeX Website: <http://www.hl7.org/CodeX>

CodeX Confluence Page: <https://confluence.hl7.org/display/COD/CodeX+Home>

# 1<sup>st</sup> Cancer Data Summit

Oct 2-3 McLean, VA

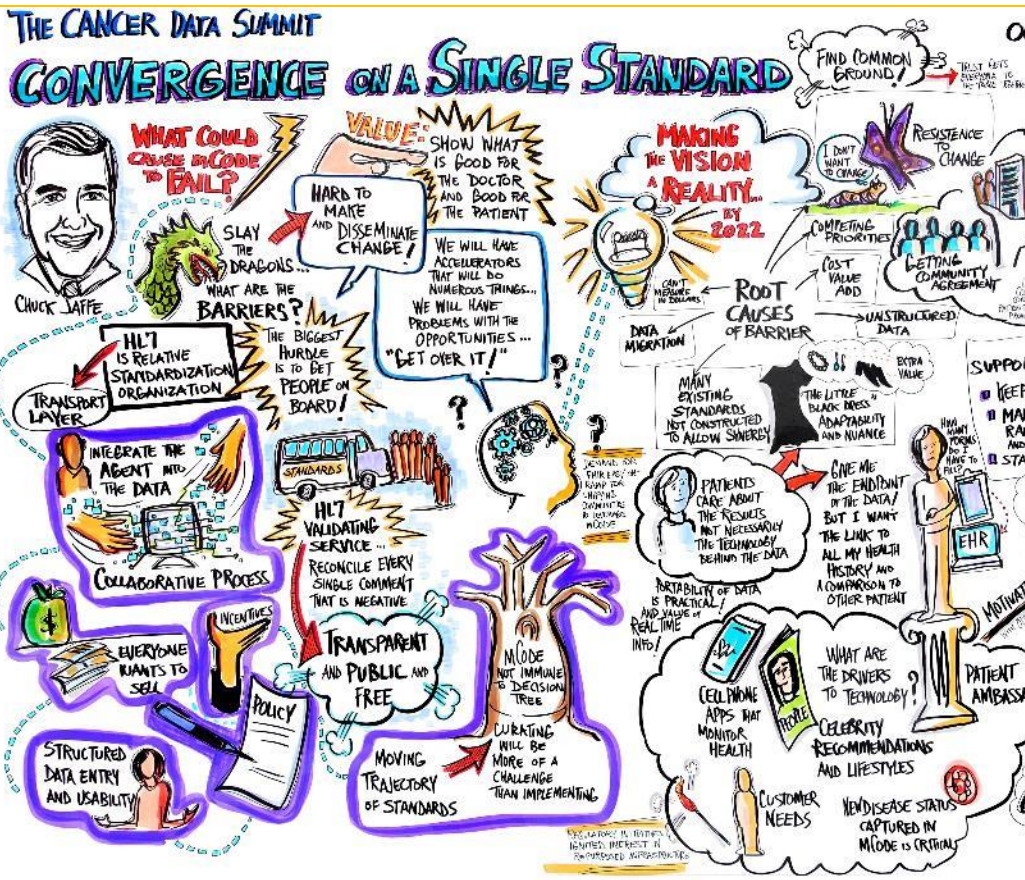


# 1st Cancer Data Summit

Oct 2-3 McLean, VA

15 | OCT 3 2019

# CANCER DATA SUMMIT CHANGING CLINICAL CULTURE



Public report coming within a month



# Discussion Questions

mCODE™

 Codex™  
Common Oncology Data Elements eXtensions