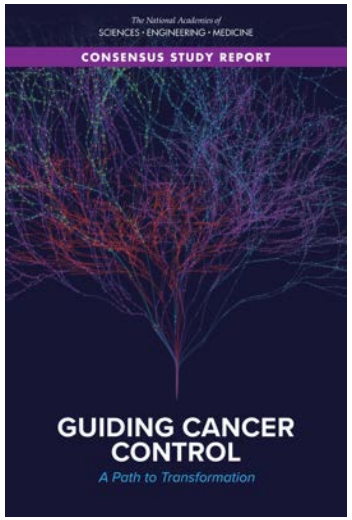
Opportunities to Develop an Evolvable Planning and Monitoring Dashboard

11/13/2019

Every patient's journey improves all future care

Standard Health Record



mCODE™

Synthea™

MITRE

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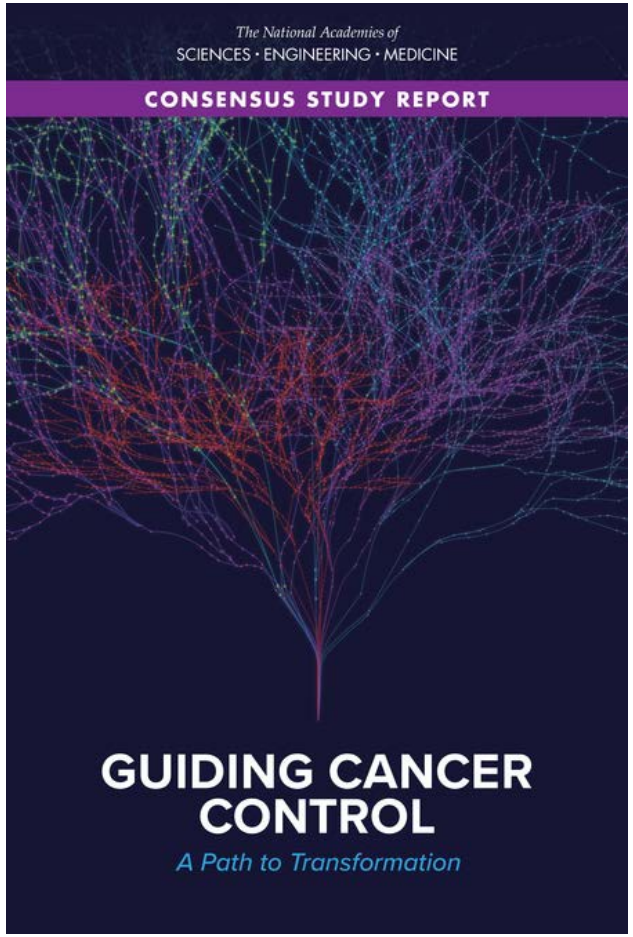
The National Academies of SCIENCES · ENGINEERING · MEDICINE

Guiding Cancer Control

A Path to Transformation

RECOMMENDATION C:

In support of the U.S. National Cancer Control Plan, the ***Department of Health and Human Services*** *and the federal partner agencies should fund and support an* ***independent organization*** *- or a consortium - with principal competencies in* ***systems engineering, industrial design, software development, and information and visual analytics*** *to prototype and develop a publicly available, interactive, and evolvable planning and monitoring tool [for the U.S. National Cancer Control Plan].*



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Building the Trusted Partnerships and Coalition

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Key Stakeholders for Engagement & Governance

Research

Patients

Health Systems

Regulators

Payers

Industry

Innovators

Registries

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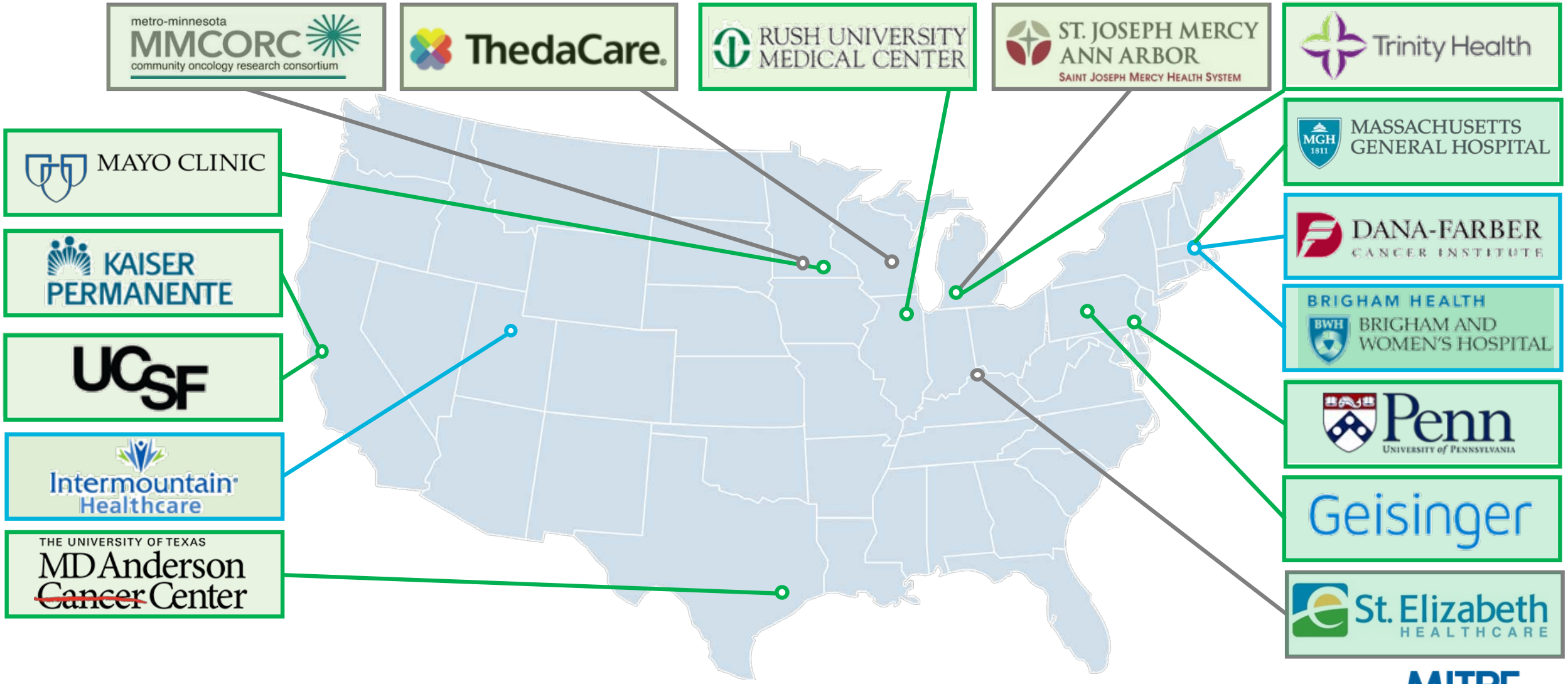
Notional Future - Building a Trusted Network of Health Systems



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Engage Industry

Electronic Health Records

Epic
varian
MEDITECH
flatiron
Cerner
athenahealth

Vendors

Amazon Comprehend
M2GEN
Clarify
Google
PHILIPS Healthcare
NUANCE

Pharma

Pfizer
MERCK
NOVARTIS

Payers

aetna™
Cigna
BlueCross BlueShield
blue california

Registries / Networks

commonwell® HEALTH ALLIANCE
NATIONAL CANCER DATABASE
carequality

Research

citizen ii
COTA
Emerson Collective
BROAD INSTITUTE

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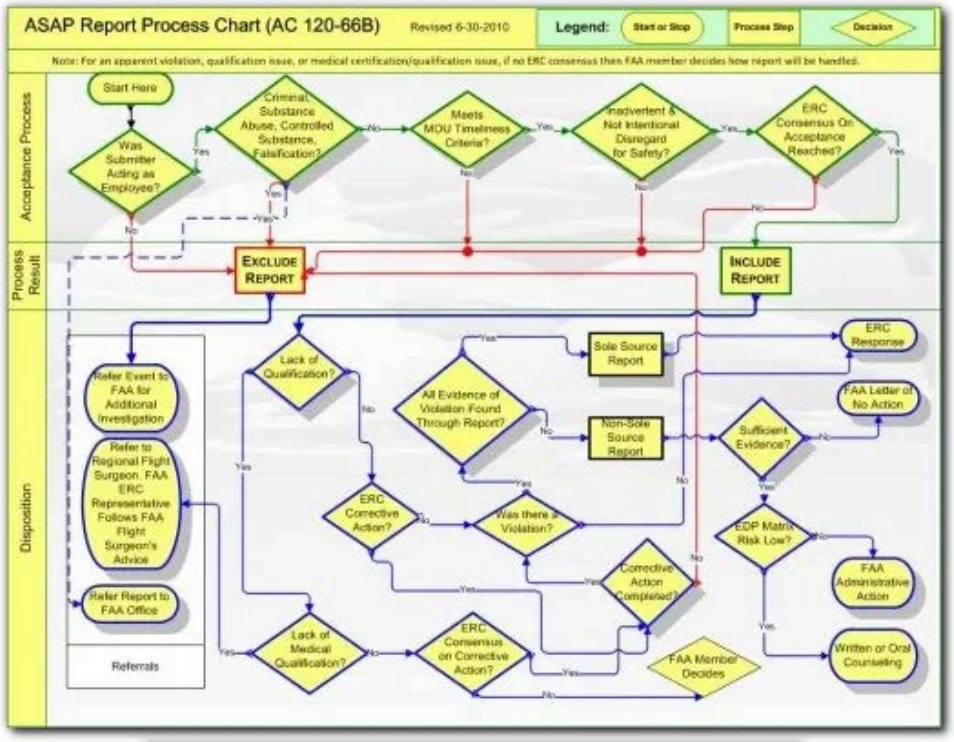
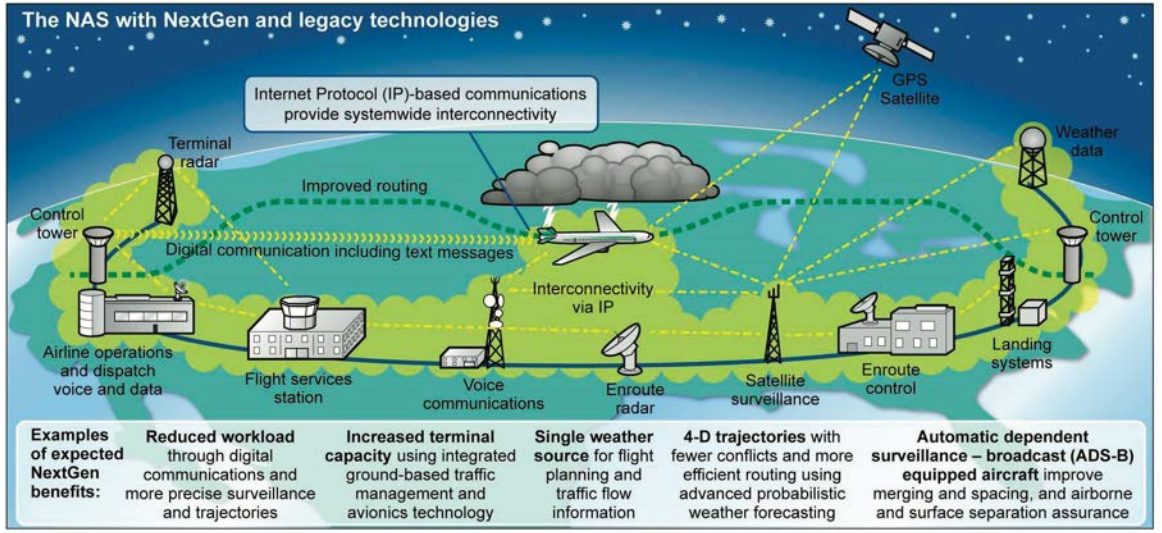
Building the Interactive Model





The ASIAS Model

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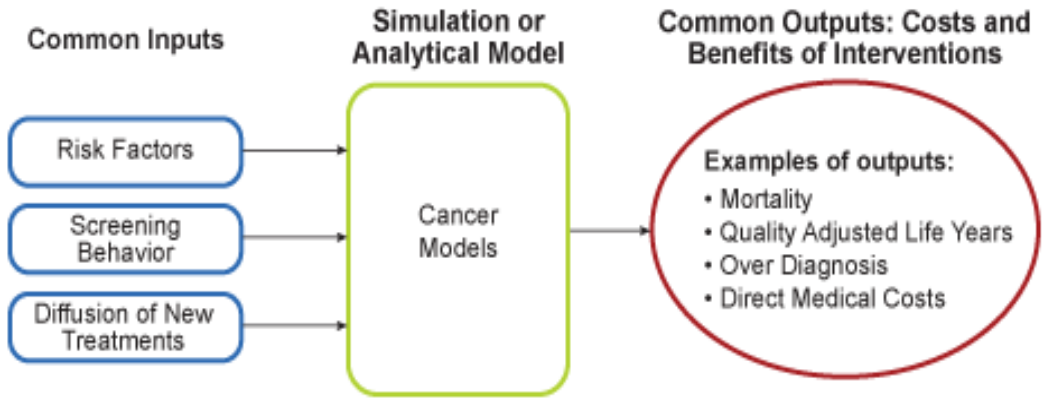
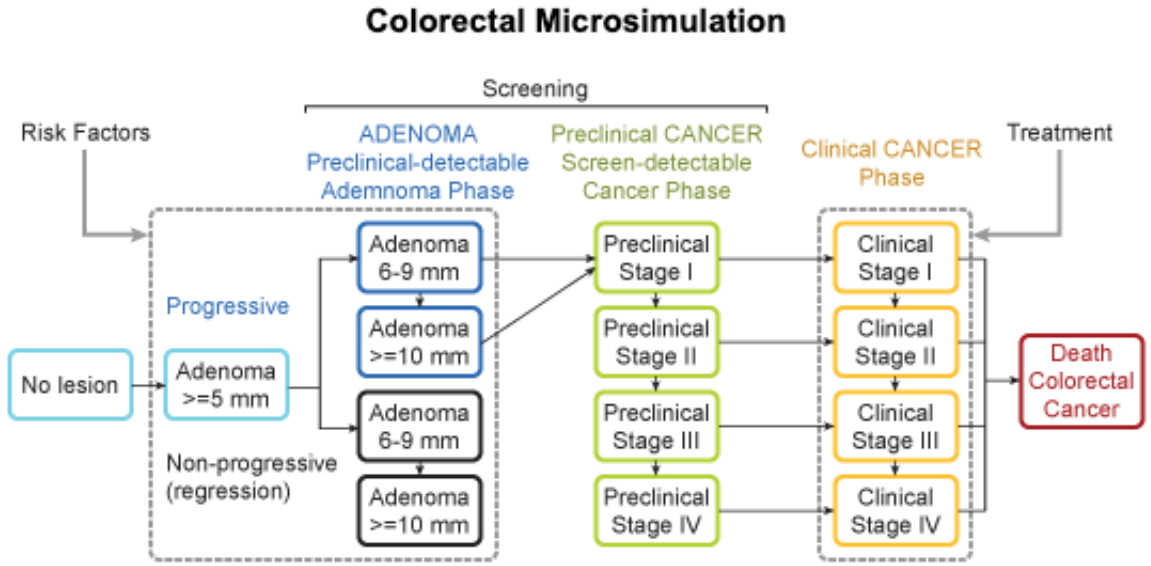
Building the Interactive Model





Example of a colorectal microsimulation, including a natural history model that can be altered by interventions.

The CISNET Model

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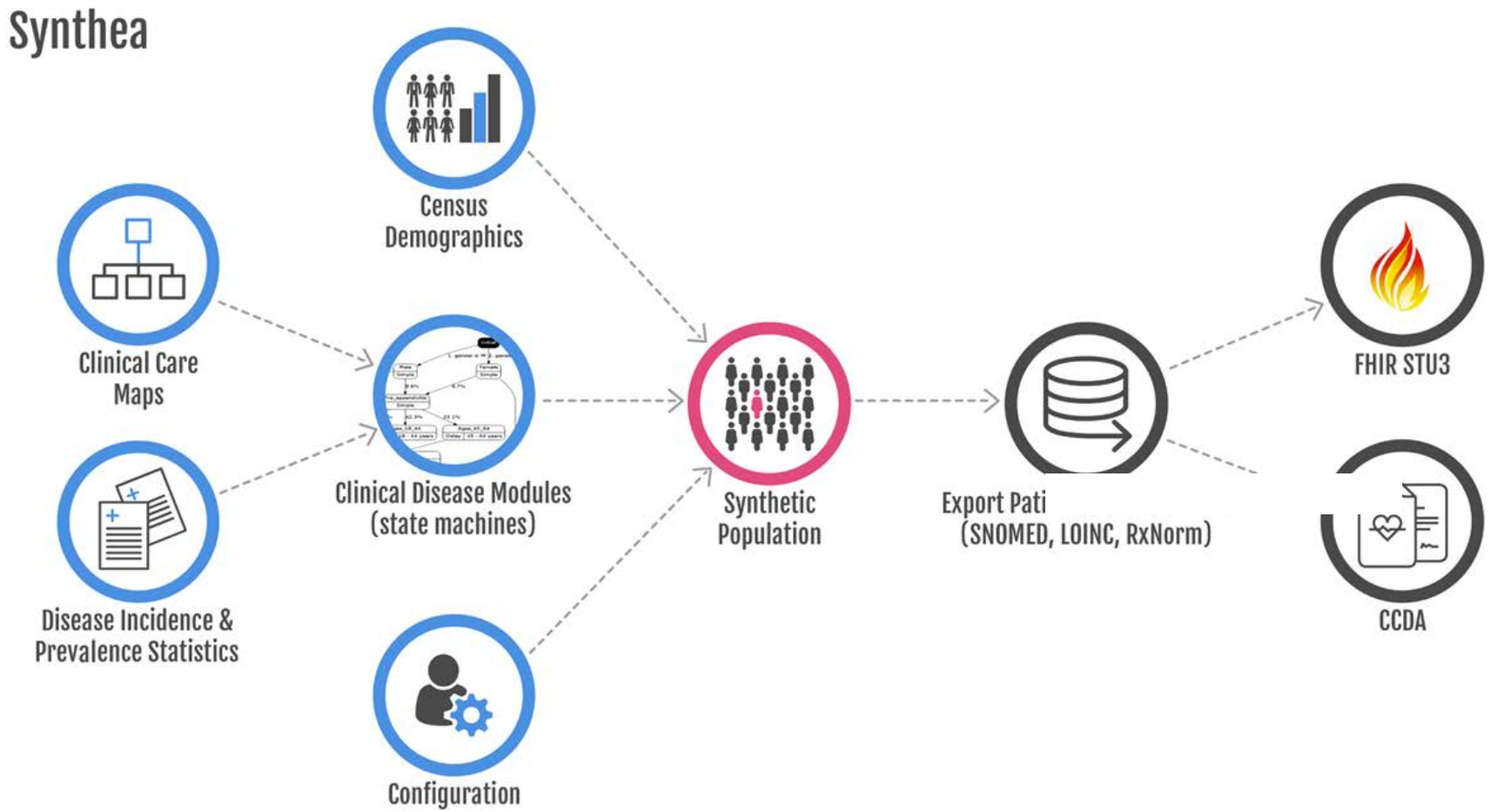
Synthea Architecture



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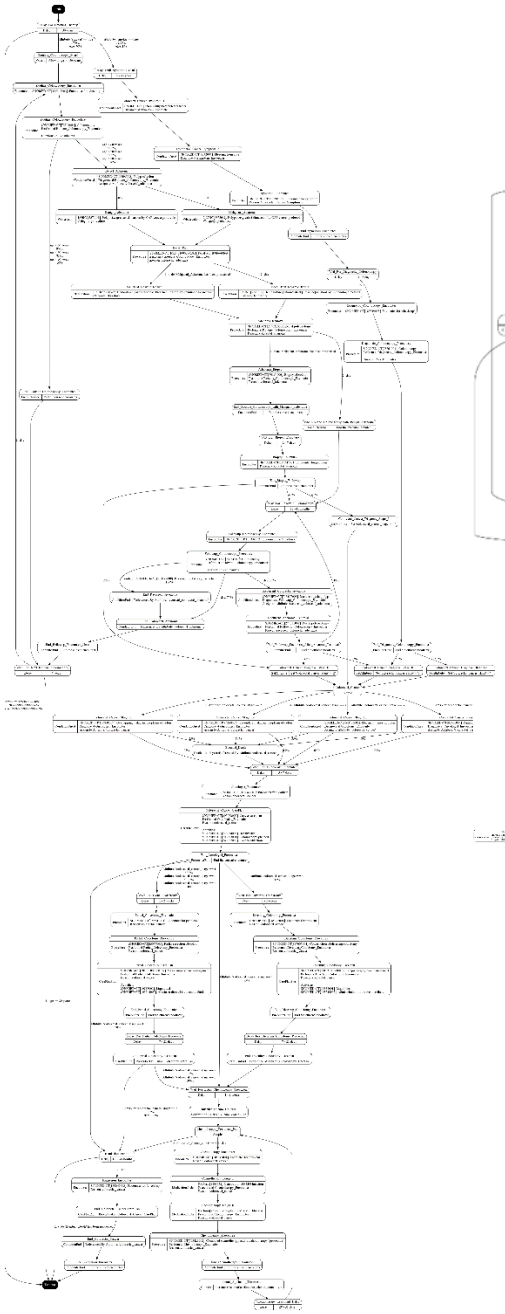

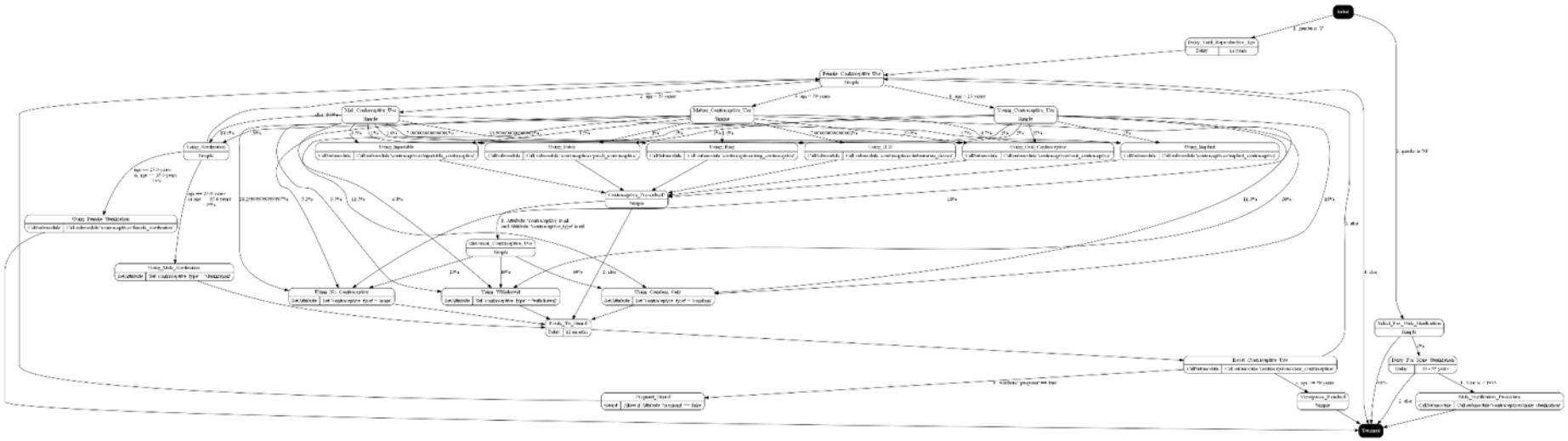

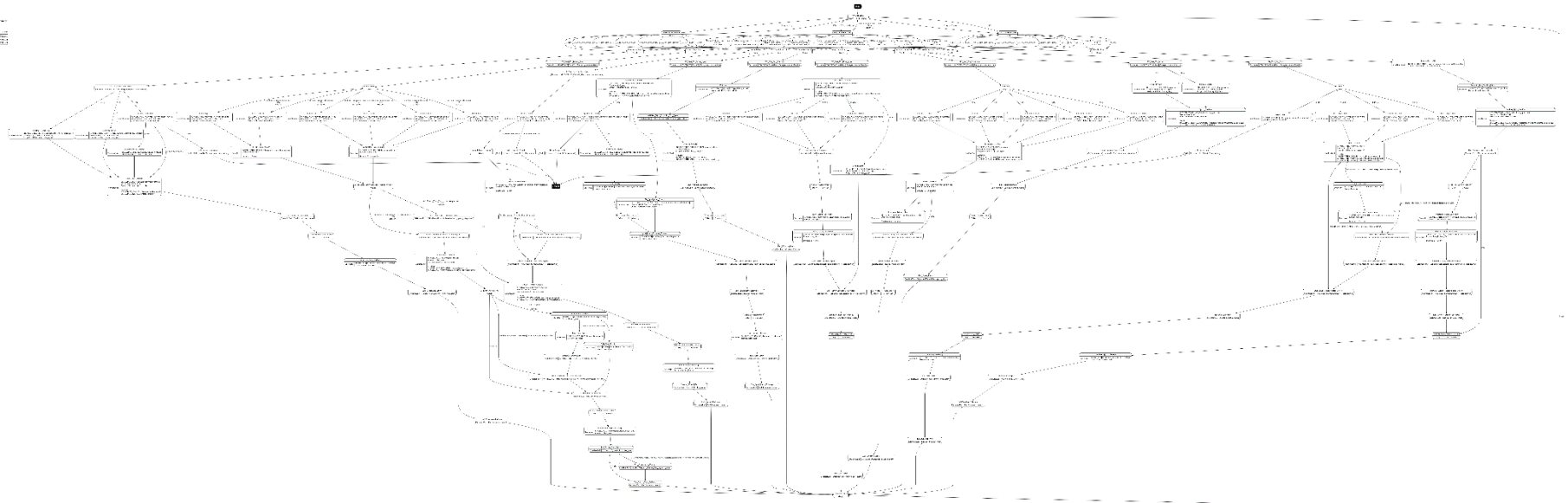

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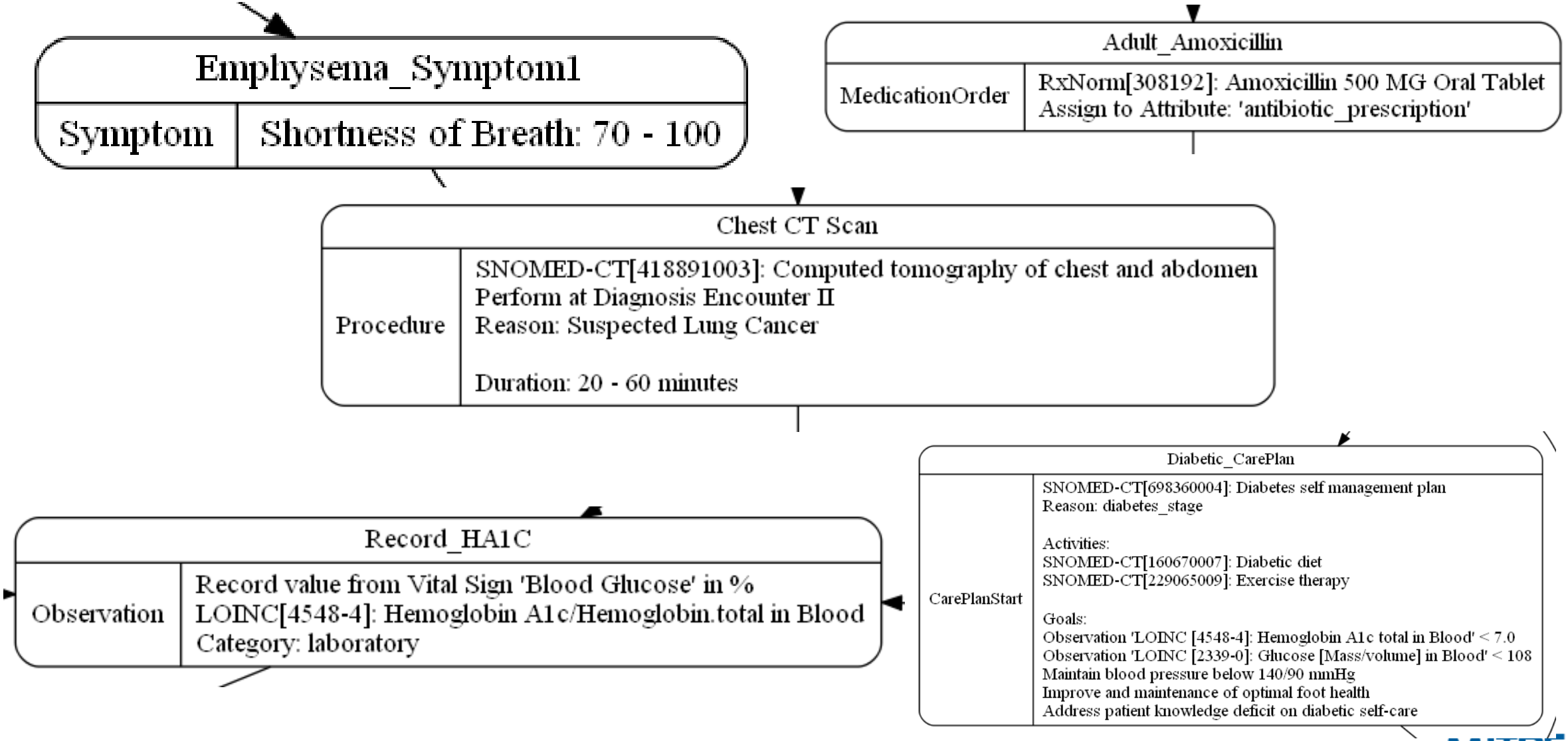
Clinical States drive the progression of disease and care



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SyntheticMass: Day 407 | Home | SyntheticMass Dashboard | About This Project | Feedback

Source of Data: Synthea | Geographic region: Cities and Towns | Data Value: Population | Zoom map to all

Bedford

× Close

County	Middlesex	
Population	2,106	
Population Density	154.2 (per mi²)	
Area	14 sq. mi.	Zoom
Demographics		
Female Population	50.6%	(151 of 351)
Male Population	49.4%	(201 of 351)
Diabetes Prevalence	6.2%	(313 of 351)
Opioid Addiction Prevalence	0.9%	(124 of 351)
Heart Disease Prevalence	4.9%	(20 of 351)

Name	Gender	DOB
Terry123, Bessie159	female	03.Jun.1918
Hudson573, Colleen618	female	19.Dec.1921
Herman43, Hettie503	female	25.Apr.1939
O'Reilly259, Aidan944	female	21.Dec.1944
Aufderhar874, Carlee265	female	26.Sep.1951
Skiles93, Julianne73	male	07.May.1952
Kuvalis486, Darwin648	male	18.Mar.1957
Gorczany106, Kali960	female	16.Feb.1958

Patient Record

× Close

Family name	Kuvalis486
Given name	Darwin648
Address	6057 Stoltenberg Throughway
City, State	Bedford, MA
Postal Code	01730

Download Patient Data (FHIR JSON) | Download Patient Data (CCDA XML)
Send Data via Direct Messsage

Height	187.09 cm	**DOB**	18.Mar.1957
Weight	128.39 kg	**Age**	60
Blood Type	n/a	**Gender**	male
Vision	n/a	**Race**	White
		Ethnicity	Nonhispanic
		Spoken language	n/a

Observations | Conditions | Medications | Allergies | Care Plans | More

Conditions	Date of Onset	Date Resolved
Prediabetes	03.Jan.1991	n/a
Diabetes	04.Nov.1993	n/a
Diabetic retinopathy associated with type II diabetes mellitus (disorder)	03.Dec.1999	n/a
Nonproliferative diabetic retinopathy due to type 2 diabetes mellitus (disorder)	03.Dec.1999	n/a

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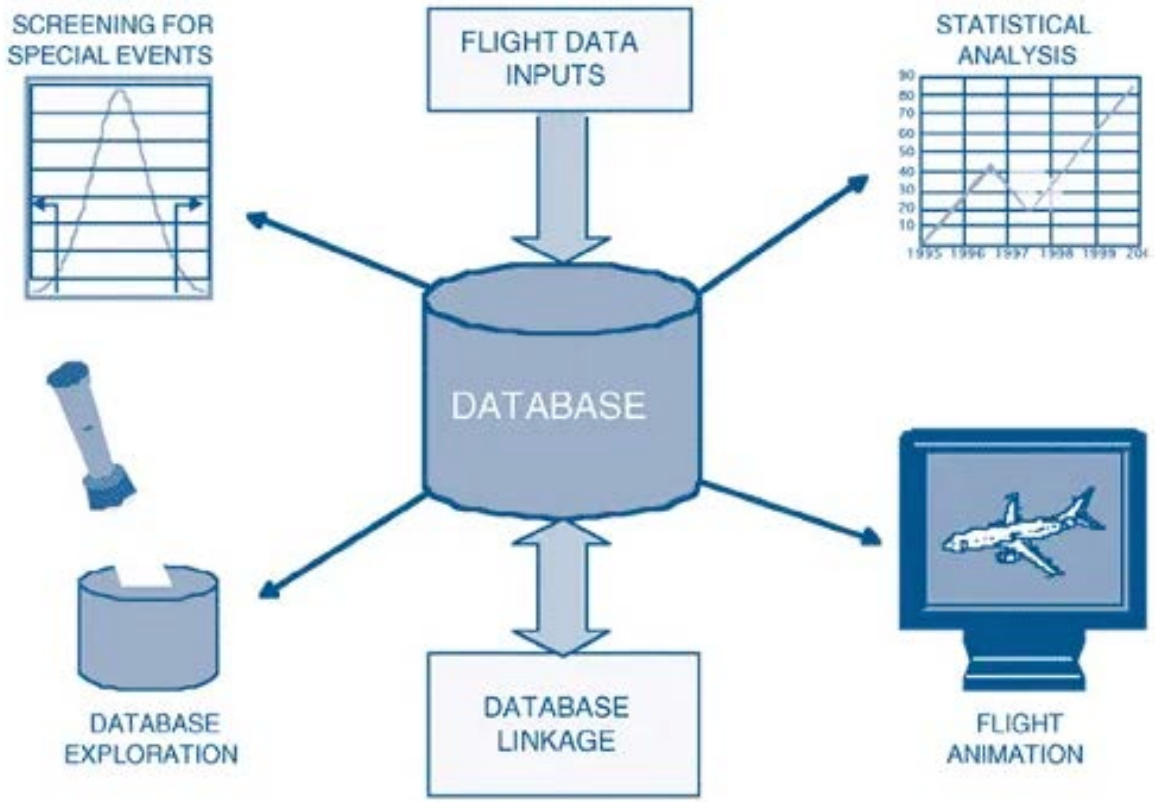
Connecting AND Making Sense of the Data



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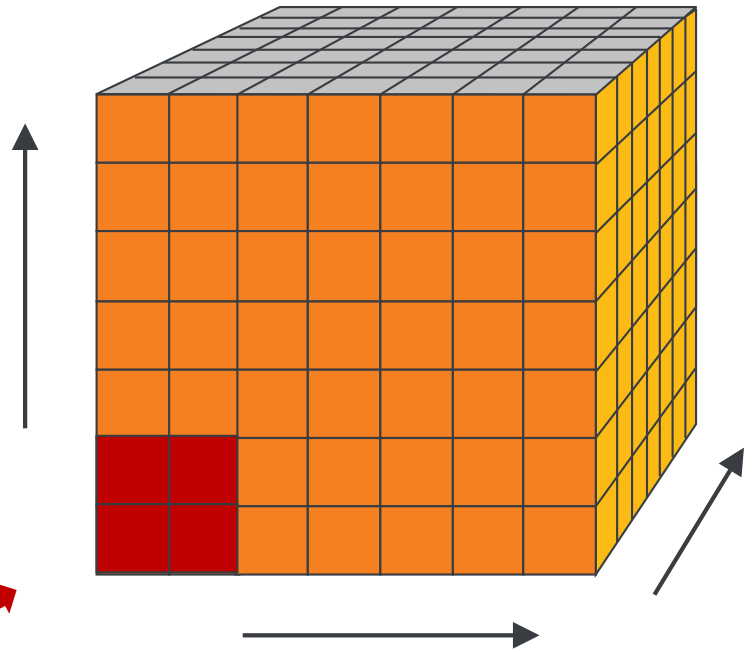
Scratching the Surface

FHIR API



Content
- structured clinical data
- clinical notes
- administrative
- genomics
- SDOH

Use case availability
- provider-provider, provider-payer, etc

Functions
- CRUD
- bulk data access, hooks, etc

Current EHR Certification requirement
- Content: CCDS
- Functions: Read
- Use case: Provider → Patient
- Technical: Functional requirement

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Engaging the Standards Community - Current FHIR Accelerators

	Resources	Use Cases
HL7 FHIR ARGONAUT PROJECT	USCDI data elements	Provider-Provider Provider-Patient
carin Creating Access to Real-time Information Now through Consumer-Directed Exchange	Common Payer Data Set (Blue Button plus additional commercial payer data)	Payer-Patient
DA VINCI HL7 FHIR	Administrative and clinical data elements	Administrative and clinical data elements
gravity PROJECT	Social determinants of health	Food insecurity, housing instability and quality, and transportation access
CodeX™ Common Oncology Data Elements eXtensions	mCODE – minimal clinical oncology data elements	Cancer clinical research, payment models, registry reporting & clinical care

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mCODE™

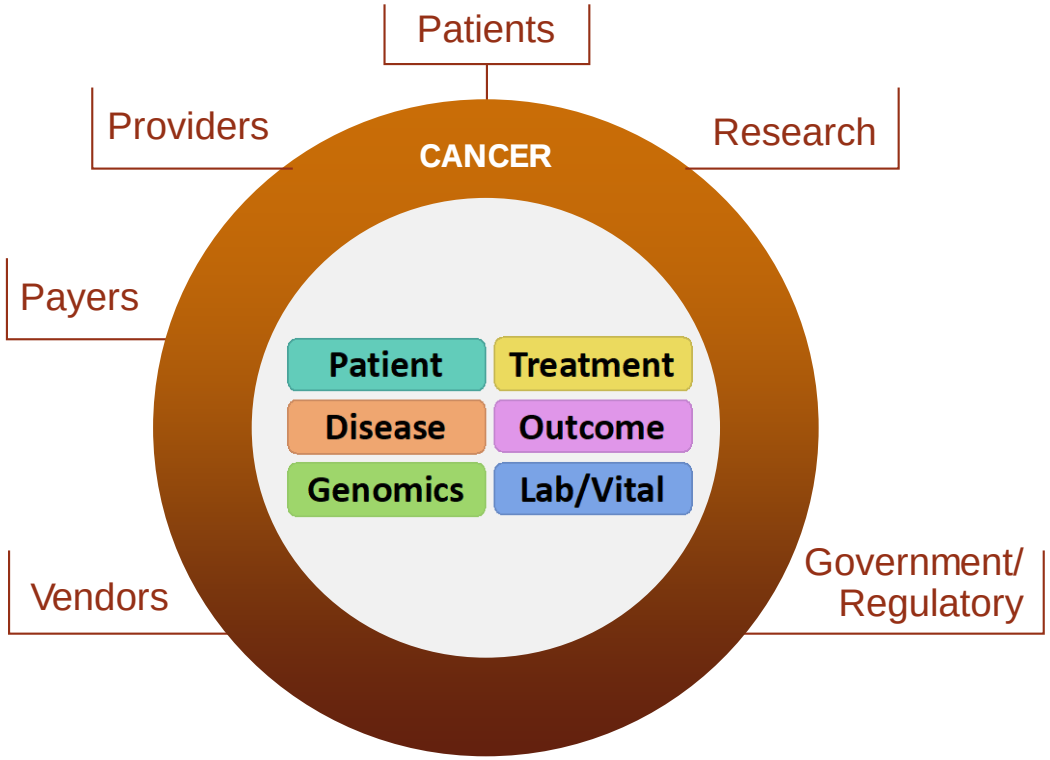
mCODE™, or Minimal Common Oncology Data Elements, is a data standard that can be widely adopted. It holds promise to greatly increase **high-quality data** for all cancer types.

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



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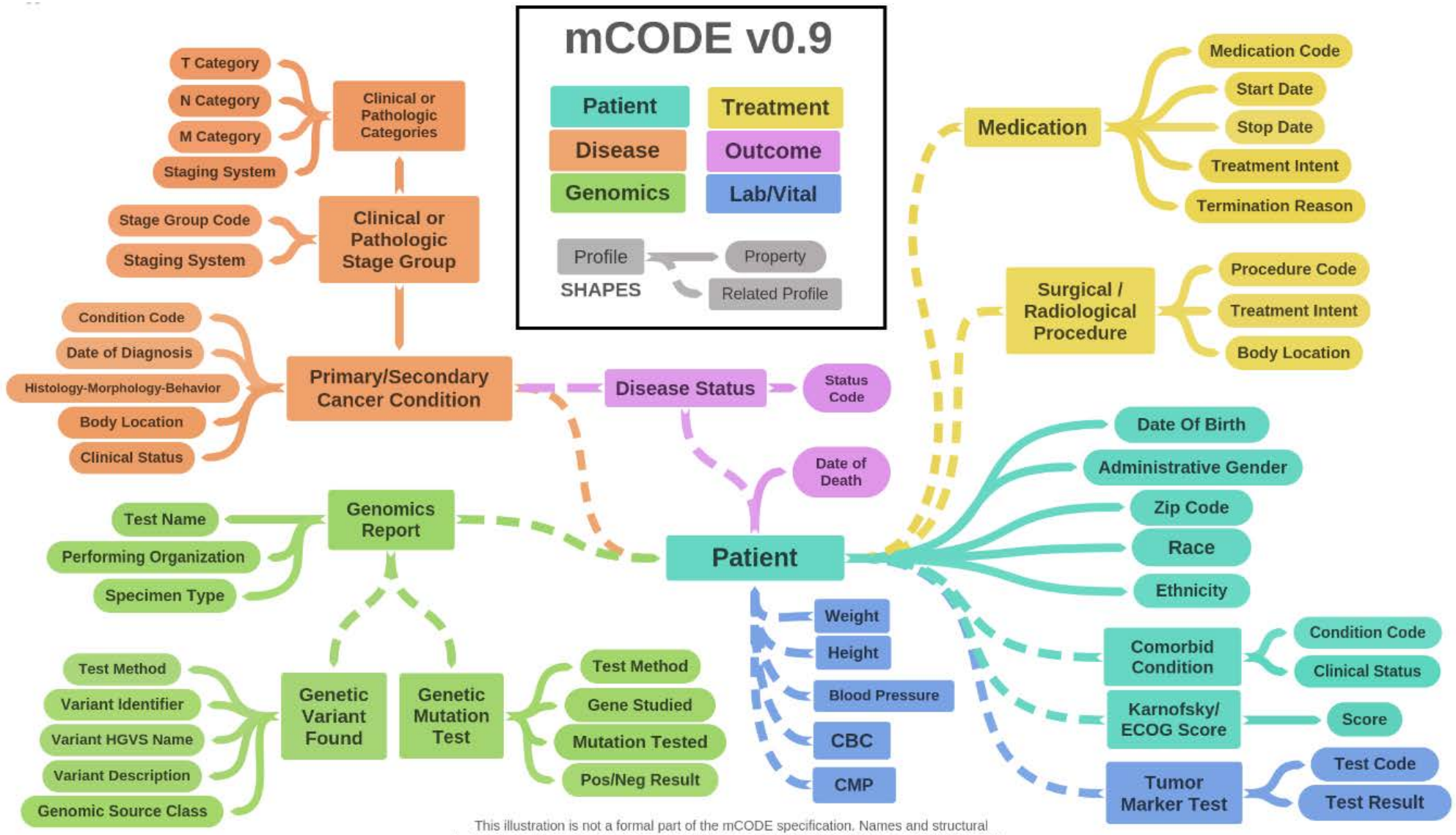
mCODE™ Logical Model



This illustration is not a formal part of the mCODE specification. Names and structural relationships shown here may not precisely correspond to the data dictionary and FHIR profiles.

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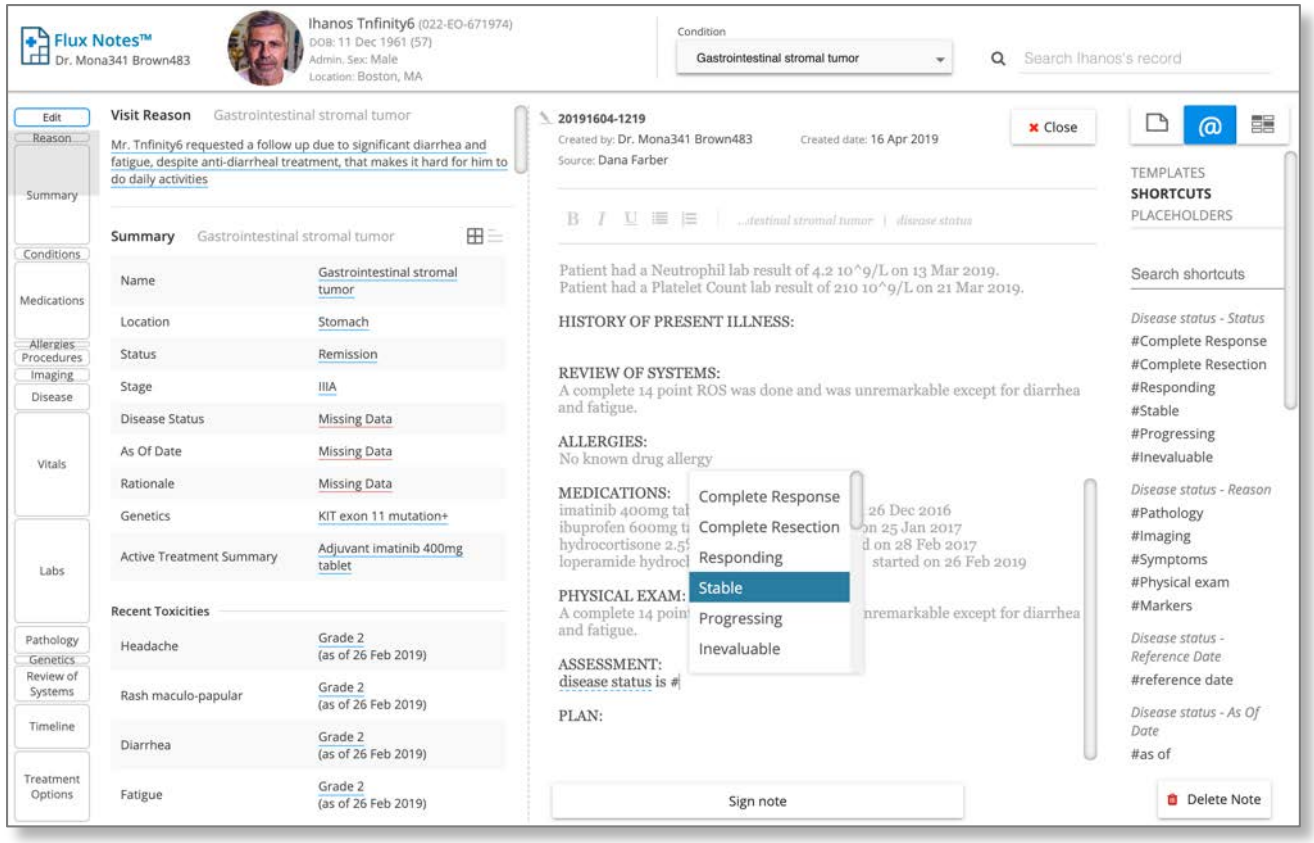
mCODE Collection

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S HOSPITAL

Target aligning clinician incentives and reducing burden to improve the capture of structured clinical treatment data.

- Ongoing Pilot at Brigham Health with integration into the Partners Epic System
- Embrace the narrative clinical note
  - Eliminate double documentation
  - Semi-structured phrases for discrete data
  - Dynamic with auto-complete, targeted NLP, immediate feedback and assistance



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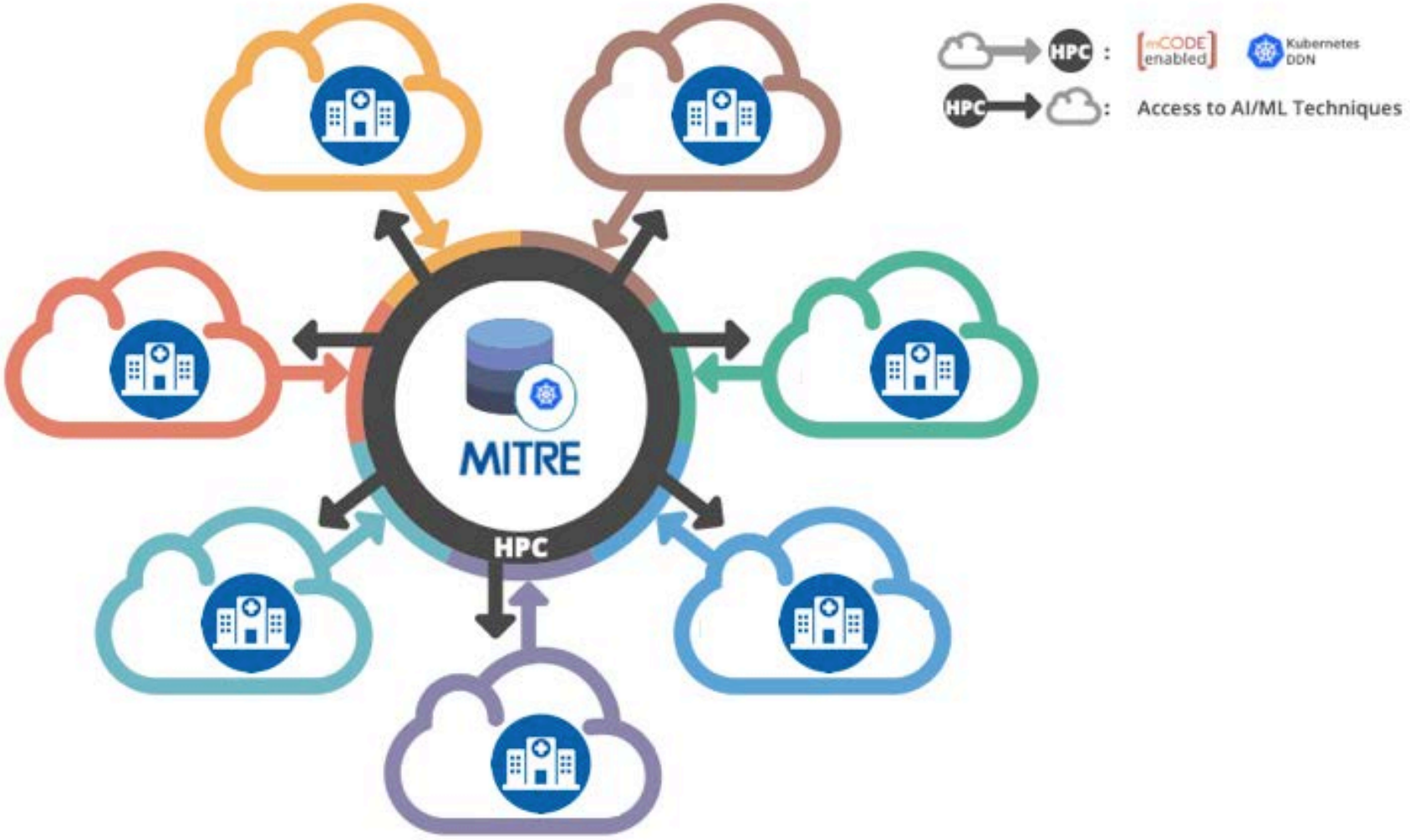
Notional Future: an interconnected, interoperable world…



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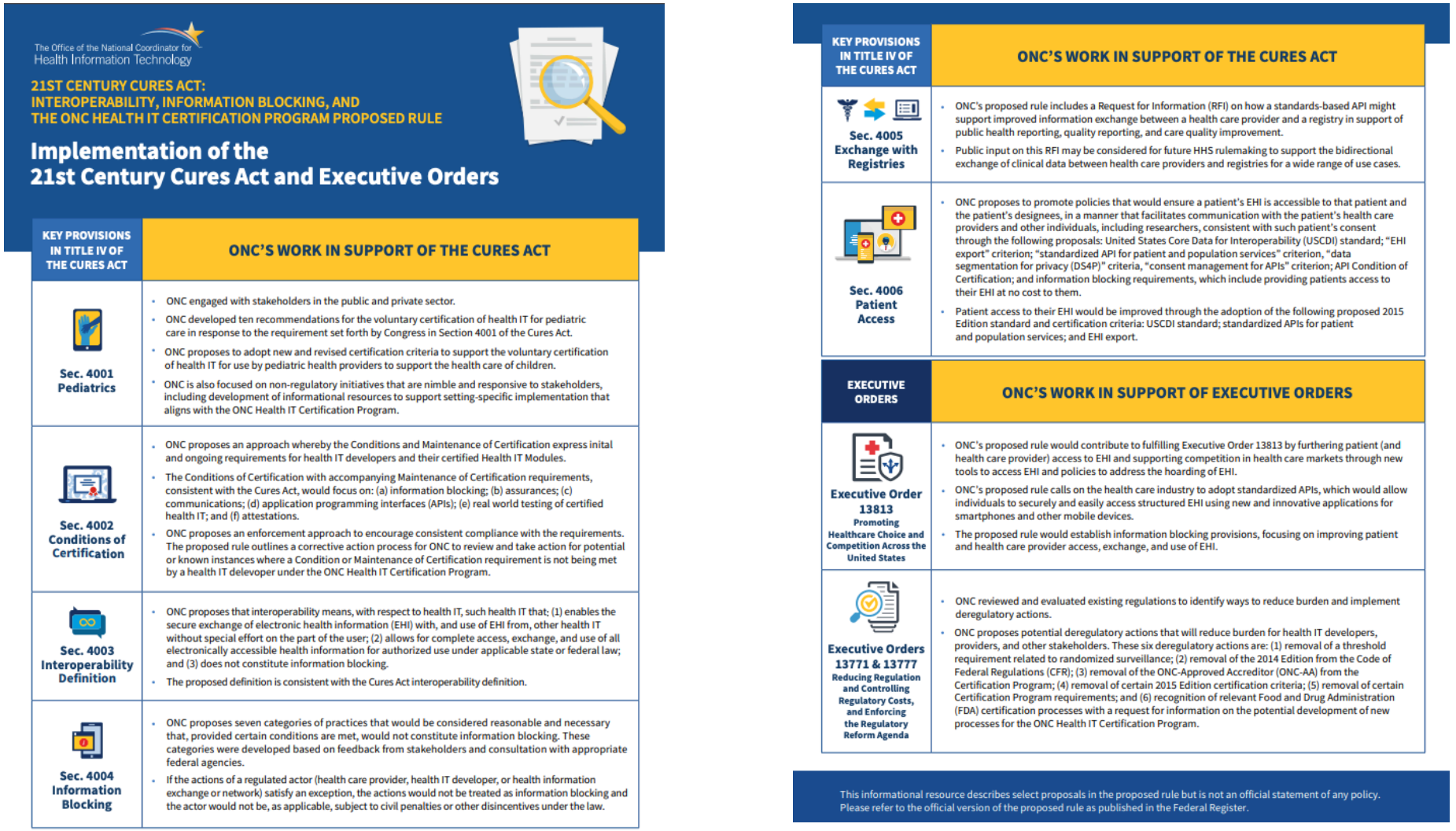
Future of FHIR & Interoperability



The Office of the National Coordinator for Health Information Technology

21ST CENTURY CURES ACT: INTEROPERABILITY, INFORMATION BLOCKING, AND THE ONC HEALTH IT CERTIFICATION PROGRAM PROPOSED RULE

Implementation of the 21st Century Cures Act and Executive Orders

KEY PROVISIONS IN TITLE IV OF THE CURES ACT	ONC'S WORK IN SUPPORT OF THE CURES ACT
Sec. 4001 Pediatrics	• ONC engaged with stakeholders in the public and private sector. • ONC developed ten recommendations for the voluntary certification of health IT for pediatric care in response to the requirement set forth by Congress in Section 4001 of the Cures Act. • ONC proposes to adopt new and revised certification criteria to support the voluntary certification of health IT for use by pediatric health providers to support the health care of children. • ONC is also focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.
Sec. 4002 Conditions of Certification	• ONC proposes an approach whereby the Conditions and Maintenance of Certification express inital and ongoing requirements for health IT developers and their certified Health IT Modules. • The Conditions of Certification with accompanying Maintenance of Certification requirements, consistent with the Cures Act, would focus on: (a) information blocking; (b) assurances; (c) communications; (d) application programming interfaces (APIs); (e) real world testing of certified health IT; and (f) attestations. • ONC proposes an enforcement approach to encourage consistent compliance with the requirements. The proposed rule outlines a corrective action process for ONC to review and take action for potential or known instances where a Condition or Maintenance of Certification requirement is not being met by a health IT delevoper under the ONC Health IT Certification Program.
Sec. 4003 Interoperability Definition	• ONC proposes that interoperability means, with respect to health IT, such health IT that: (1) enables the secure exchange of electronic health information (EHI) with, and use of EHI from, other health IT without special effort on the part of the user; (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and (3) does not constitute information blocking. • The proposed definition is consistent with the Cures Act interoperability definition.
Sec. 4004 Information Blocking	• ONC proposes seven categories of practices that would be considered reasonable and necessary that, provided certain conditions are met, would not constitute information blocking. These categories were developed based on feedback from stakeholders and consultation with appropriate federal agencies. • If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy an exception, the actions would not be treated as information blocking and the actor would not be, as applicable, subject to civil penalties or other disincentives under the law.

KEY PROVISIONS IN TITLE IV OF THE CURES ACT	ONC'S WORK IN SUPPORT OF THE CURES ACT
Sec. 4005 Exchange with Registries	• ONC's proposed rule includes a Request for Information (RFI) on how a standards-based API might support improved information exchange between a health care provider and a registry in support of public health reporting, quality reporting, and care quality improvement. • Public input on this RFI may be considered for future HHS rulemaking to support the bidirectional exchange of clinical data between health care providers and registries for a wide range of use cases.
Sec. 4006 Patient Access	• ONC proposes to promote policies that would ensure a patient's EHI is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent through the following proposals: United States Core Data for Interoperability (USCDI) standard; "EHI export" criterion; "standardized API for patient and population services" criterion, "data segmentation for privacy (DS4P)" criteria, "consent management for APIs" criterion; API Condition of Certification; and information blocking requirements, which include providing patients access to their EHI at no cost to them. • Patient access to their EHI would be improved through the adoption of the following proposed 2015 Edition standard and certification criteria: USCDI standard; standardized APIs for patient and population services; and EHI export.

EXECUTIVE ORDERS	ONC'S WORK IN SUPPORT OF EXECUTIVE ORDERS
Executive Order 13813 Promoting Healthcare Choice and Competition Across the United States	• ONC's proposed rule would contribute to fulfilling Executive Order 13813 by furthering patient (and health care provider) access to EHI and supporting competition in health care markets through new tools to access EHI and policies to address the hoarding of EHI. • ONC's proposed rule calls on the health care industry to adopt standardized APIs, which would allow individuals to securely and easily access structured EHI using new and innovative applications for smartphones and other mobile devices. • The proposed rule would establish information blocking provisions, focusing on improving patient and health care provider access, exchange, and use of EHI.
Executive Orders 13771 & 13777 Reducing Regulation and Controlling Regulatory Costs, and Enforcing the Regulatory Reform Agenda	• ONC reviewed and evaluated existing regulations to identify ways to reduce burden and implement deregulatory actions. • ONC proposes potential deregulatory actions that will reduce burden for health IT developers, providers, and other stakeholders. These six deregulatory actions are: (1) removal of a threshold requirement related to randomized surveillance; (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR); (3) removal of the ONC-Approved Accreditor (ONC-AA) from the Certification Program; (4) removal of certain 2015 Edition certification criteria; (5) removal of certain Certification Program requirements; and (6) recognition of relevant Food and Drug Administration (FDA) certification processes with a request for information on the potential development of new processes for the ONC Health IT Certification Program.

This informational resource describes select proposals in the proposed rule but is not an official statement of any policy. Please refer to the official version of the proposed rule as published in the Federal Register.

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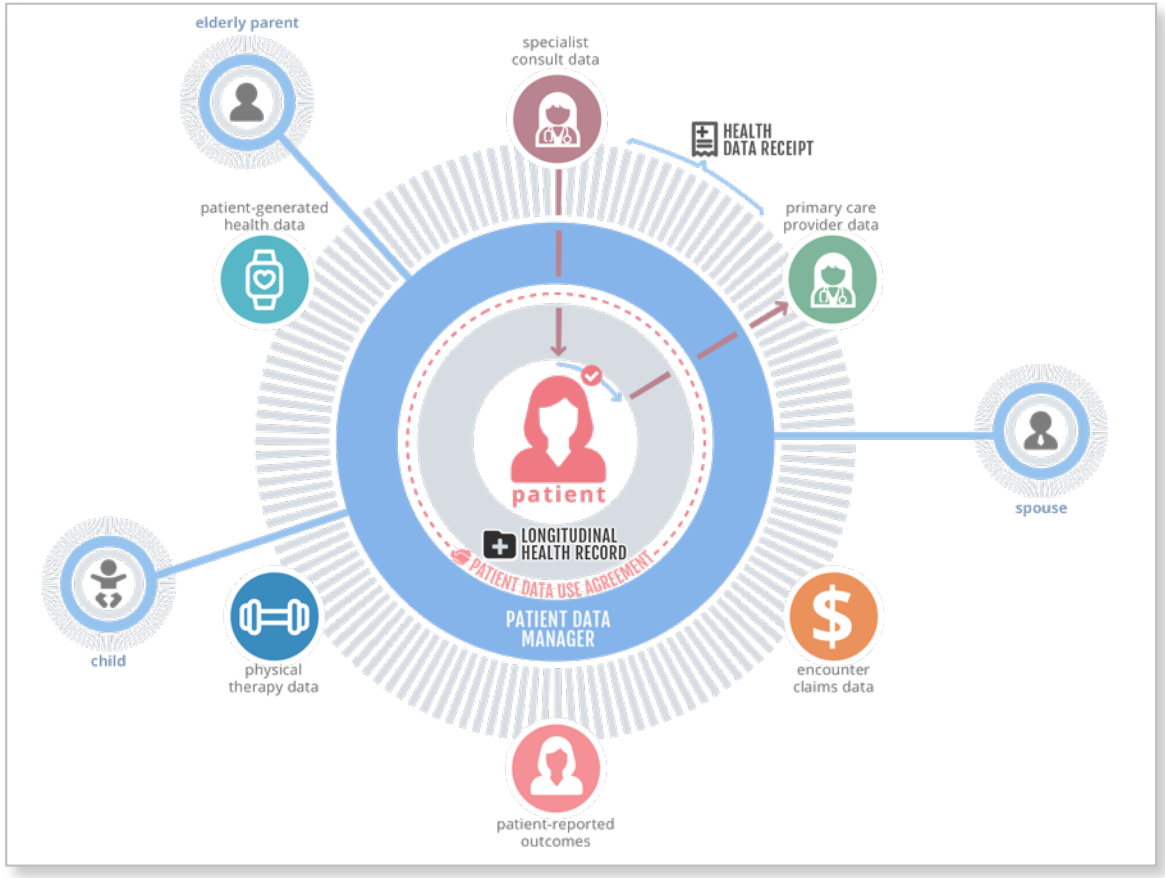
Patient Data Management

- **Putting the patient at the center of our healthcare system is a fundamental paradigm shift**
  - Patient ownership and right to access
  - Longitudinal health record
  - Patient centered research and care
  - Value-added services and APIs



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Real World Data in Clinical Trials

- **Grow a broader community around the RWD digital clinical endpoints**
  - Major academic medical centers
  - Pharmaceuticals
  - Government
- **Establish a network of mCODE research sites and a data collection infrastructure**
- **Demonstrate a real-world data strategy for clinical trials based on mCODE and Extensions**

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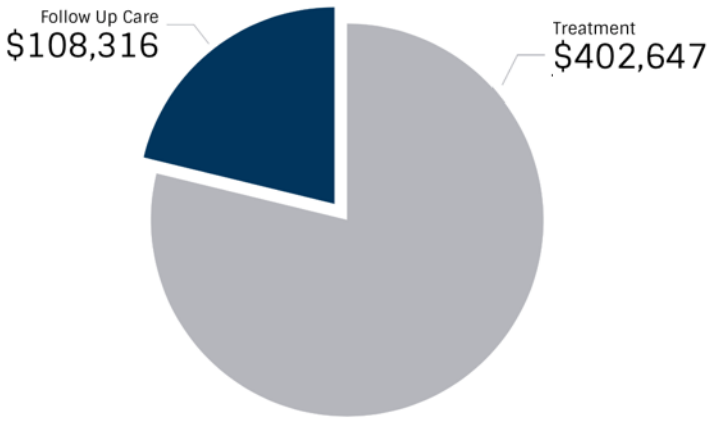
Payment Models – Evidence Based Reimbursement

- **Radiation Oncology Alternative Payment Model**
  - Mandatory CMS payment model recently released
  - Engage with health systems, vendors, and payers through a regulatory avenue
  - Large proportion of model reimbursement will be focused on collecting a core set of data (i.e., mCODE)

- **Chimeric Antigen Receptor T-Cell Therapy**
  - Breakthrough, personalized cure for cancer
  - Challenges include high cost, uncertain benefit
  - CMS and other payers are exploring coverage with evidence development requiring data in alignment with mCODE



$510,563 total expected cost of CAR-T

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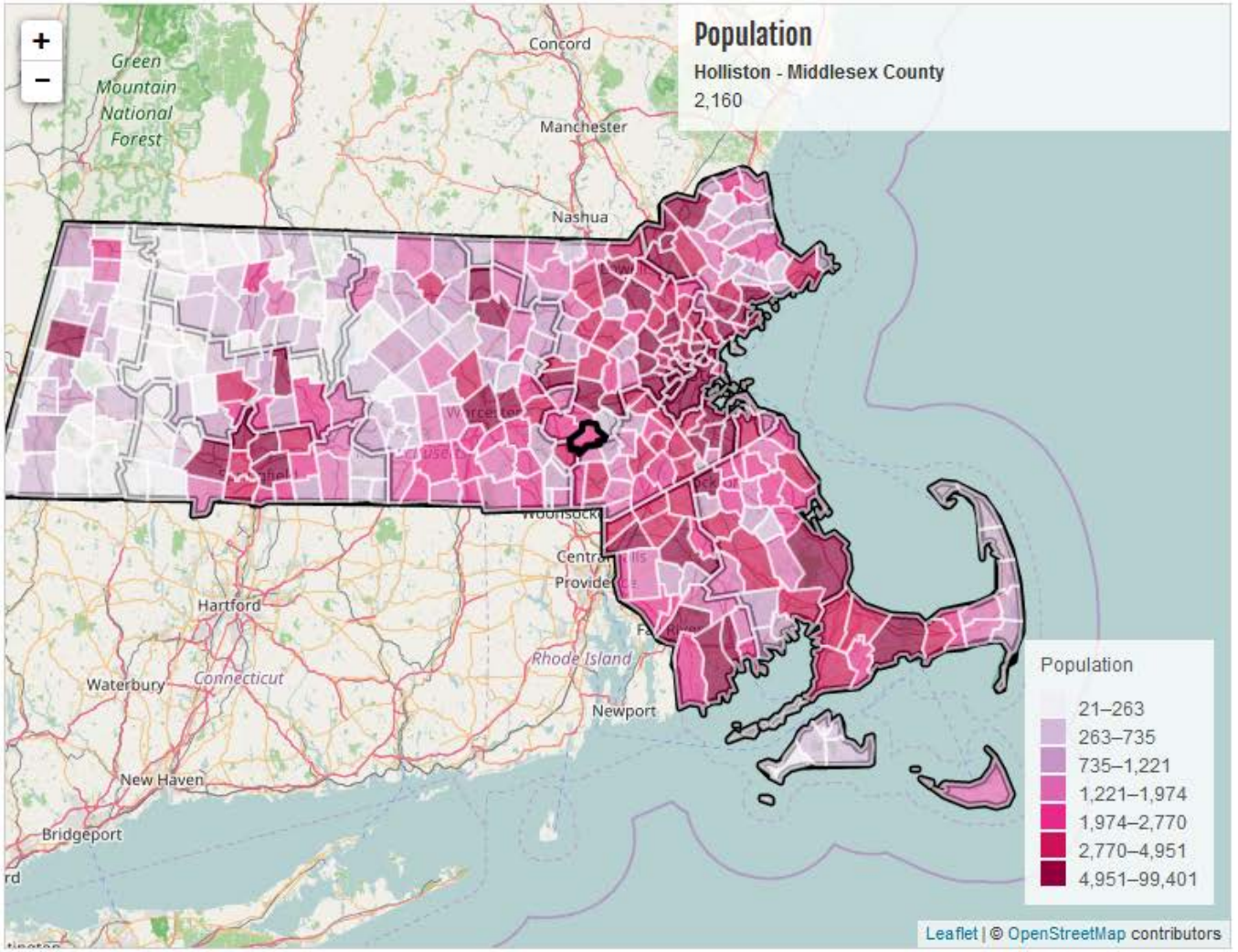
SyntheticMass: Day 407 | Home | SyntheticMass Dashboard | About This Project | Feedback

Source of Data: Synthea **Geographic region:** Cities and Towns **Data Value:** Population Zoom map to all

Population

Number of Residents

Region Type	Cities and Towns
Data Set	Synthetic data generated from Synthea
Total Population	1,009,150
Mean	2,875
Max	Boston Cities and Towns: 99,401
Min	Gosnold Cities and Towns: 21



Sort by Population | Sort by name

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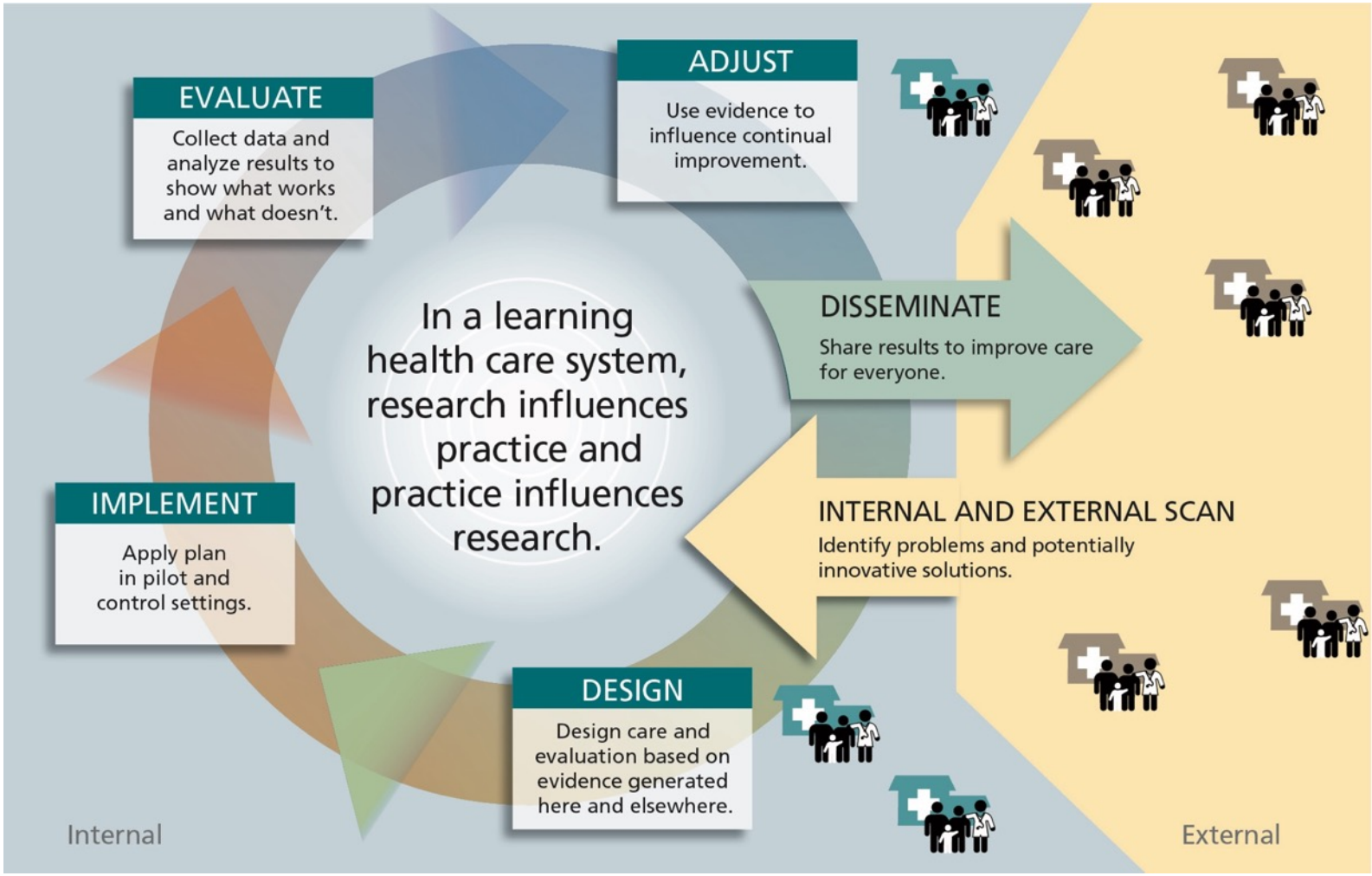
Oncology
Standard Health Record

"Every patient's journey improves all future care"



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