Beyond Right of Access

CONNECTING MICHIGAN
for health and more

Deven McGraw Ciitizen

Deven McGraw is Lead, Data Stewardship and Data Sharing for the Ciitizen platform at Invitae. Previously she directed U.S. health privacy and security as Deputy Director, Health Information Privacy at the HHS Office for Civil Rights and Chief Privacy Officer (Acting) of the Office of the National Coordinator for Health IT.

Widely recognized for her expertise in health privacy, she directed the Health Privacy Project at the Center for Democracy & Technology for six years and led the privacy and security policy work for the HITECH Health IT Policy Committee. She also served as the Chief Operating Officer of the National Partnership for Women and Families. She advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP.

Deven graduated magna cum laude from Georgetown University Law Center and has a Masters of Public Health from Johns Hopkins University.

What is Ciitizen?

✓ **Patient-mediated** SaaS platform that allows users to collect and store their medical records. Ciitizen turns documents into **computable**, **digital**, and **relevant** datasets that can be shared at the patient's direction.
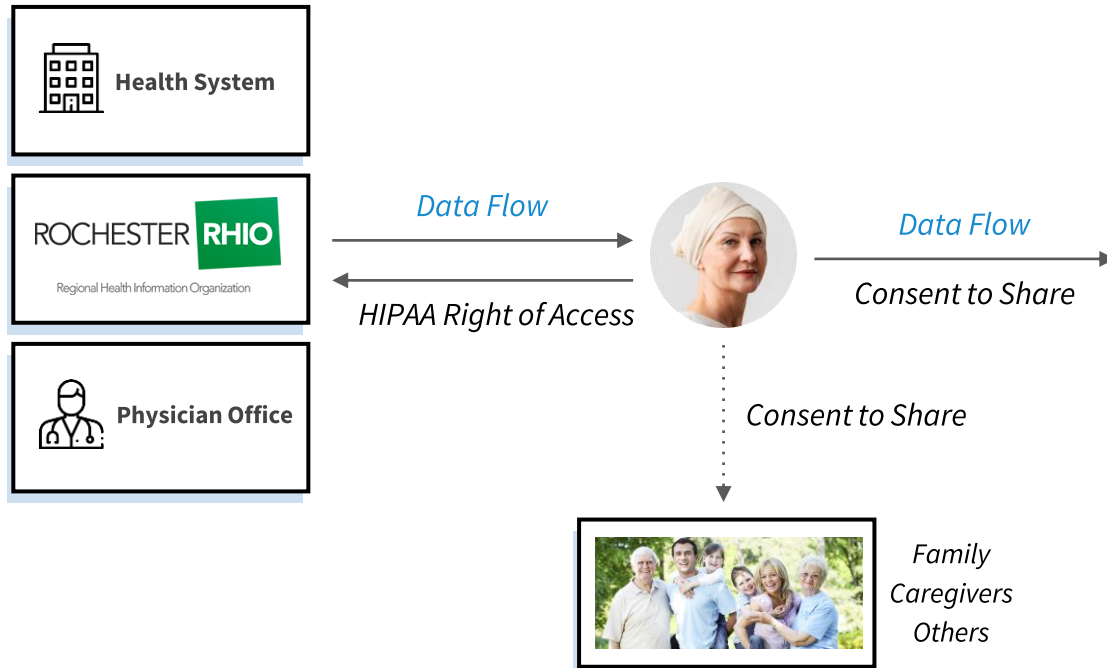
✓ Provides **data management** and **analytics** software to leading HIEs in the U.S.

Ciitizen-powered Healthcare

Empower patient to get ALL their data and then allow them to do what they want with it

Health System

ROCHESTER RHIO
Regional Health Information Organization

Physician Office

Data Flow

HIPAA Right of Access

Data Flow

Consent to Share

Consent to Share

Family
Caregivers
Others

BENEFITS

- Data is consented directly by the patient

- Data is comprehensive across clinical, imaging, genomic and PRO's

- Data is on-going as a Ciitizen profile is dynamic; "follow" the patient through their journey

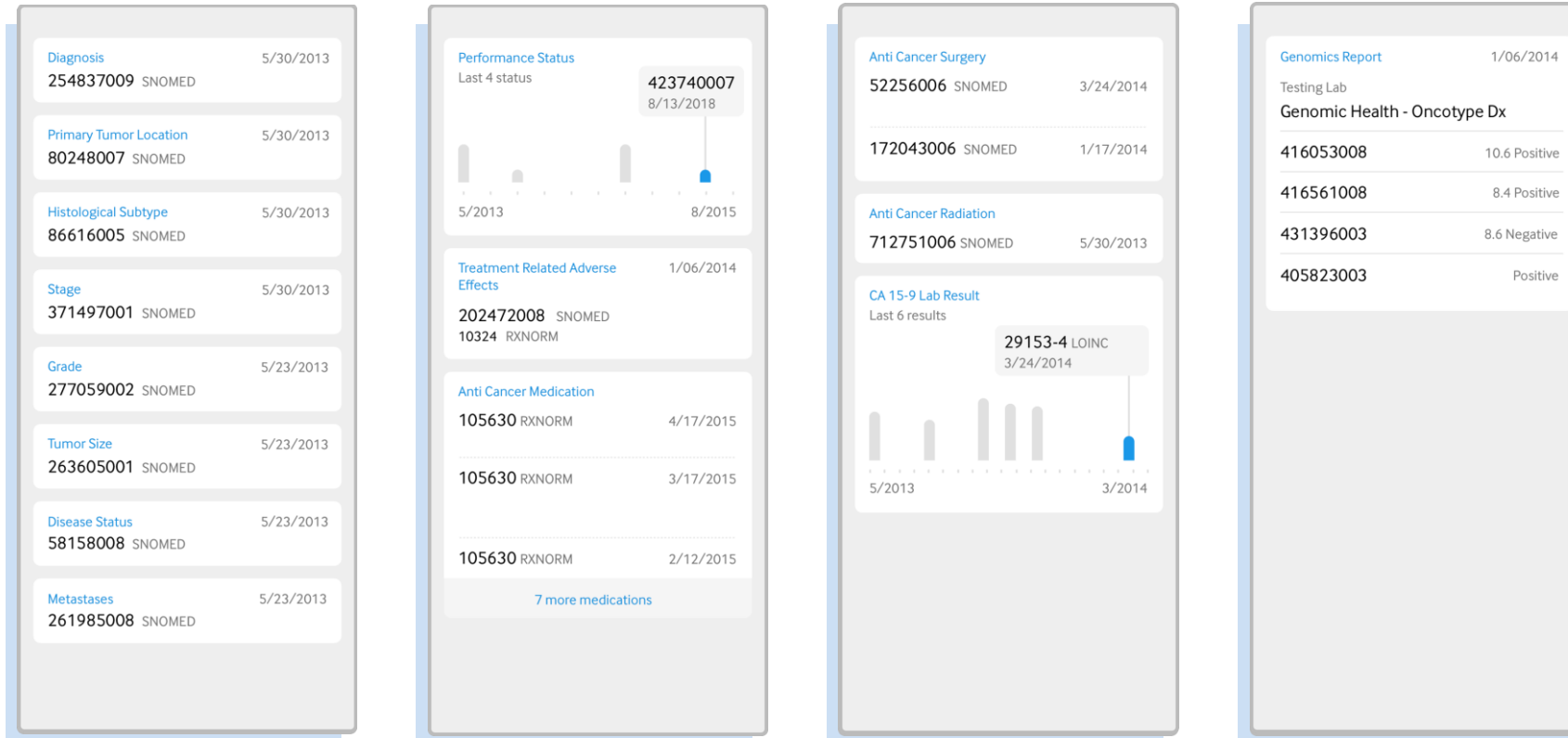- The Ciitizen Marketplace allows stakeholders to connect directly with patients

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Human Readable

Treatment. Longitudinale. Portable.
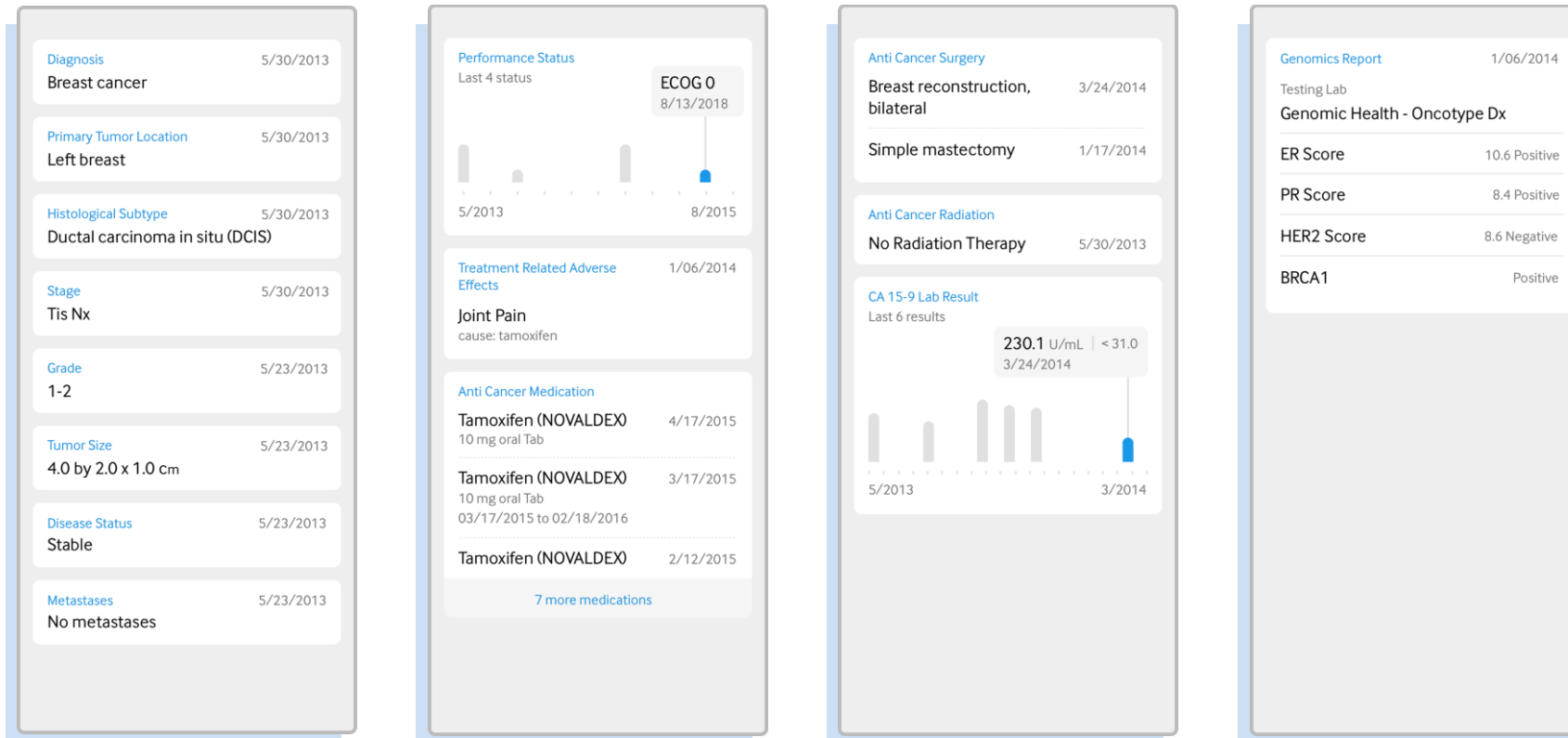
Machine Readable

Codified. Standardized. Computable.

Information Blocking

What is information Blocking

- A <u>practice</u> by a healthcare provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the **Secretary as a reasonable and necessary activity**, is likely to interfere with access, exchange, or use of electronic health information.

What are the exceptions?

- Section 4004 of the Cures Act authorizes the Secretary to identify reasonable and necessary activities that do not constitute information blocking.

- In consultation with stakeholders, we have identified eight exceptions for practices that are reasonable and necessary, provided certain conditions are met.

ℹ️ INFORMATION BLOCKING

Three categories of "Actors":

- Health Care Providers

- Health IT Developers of Certified Health IT

- Health Information Exchanges and/or Health Information Networks

Information Blocking

What is information Blocking

- Applies to any request for any purpose.

- Intent matters:

  ○ If conducted by a certified EHR vendor or an HIE, the entity "knows or *should know*" that the practice is likely to interfere…

  ○ If conducted by a health care provider, the provider knows that the practice is likely to interfere…

A. Exceptions for NOT Fulfilling Requests

01 **Preventing Harm:** Reasonably necessary practices to prevent harm to a patient or another person.

02 **Privacy:** Refusing to fulfill a request to protect a person's privacy.

03 **Security:** Interference with the access/exchange/use of EHI to protect the security of EHI.

04 **Infeasibility:** Does not fulfill a request to access/exchange/use EHI due to the infeasibility of the request.

05 **Health IT Performance:** Reasonable, necessary measures to assure health IT availability & performance

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B. Exceptions: Procedures FOR Fulfilling Requests

01
Content & Manner:
Limiting content, manner in which an actor fulfills requests.

02
Fees Exception:
Reasonable fees (including those that generate a reasonable profit),

BUT:

Cannot charge fees "based in any part on electronic access by an individual, their personal representative, or an entity designated by that individual to access the individual's EHI."

03
Licensing Exception:
Actors may license interoperability elements for EHI to be accessed/exchanged/used.

Priority Areas From Rules

Info blocking "will almost always be implicated" when a practice interferes with access/exchange/use of EHI for these purposes:

- <mark>Providing patients with access to their EHI and the ability to exchange and use it without special effort (also charging individuals a fee to electronically access their EHI)</mark>

- Ensuring healthcare professionals, caregivers, and other authorized persons have EHI for treatment and care coordination

- Ensuring payers get information they need to "assess clinical value" and promote transparency of cost and quality of care

- Ensuring providers can get information for quality improvement and population health management activities

- Supporting access/exchange/use for patient safety and public health purposes.

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Ciitizen Cures Gateway
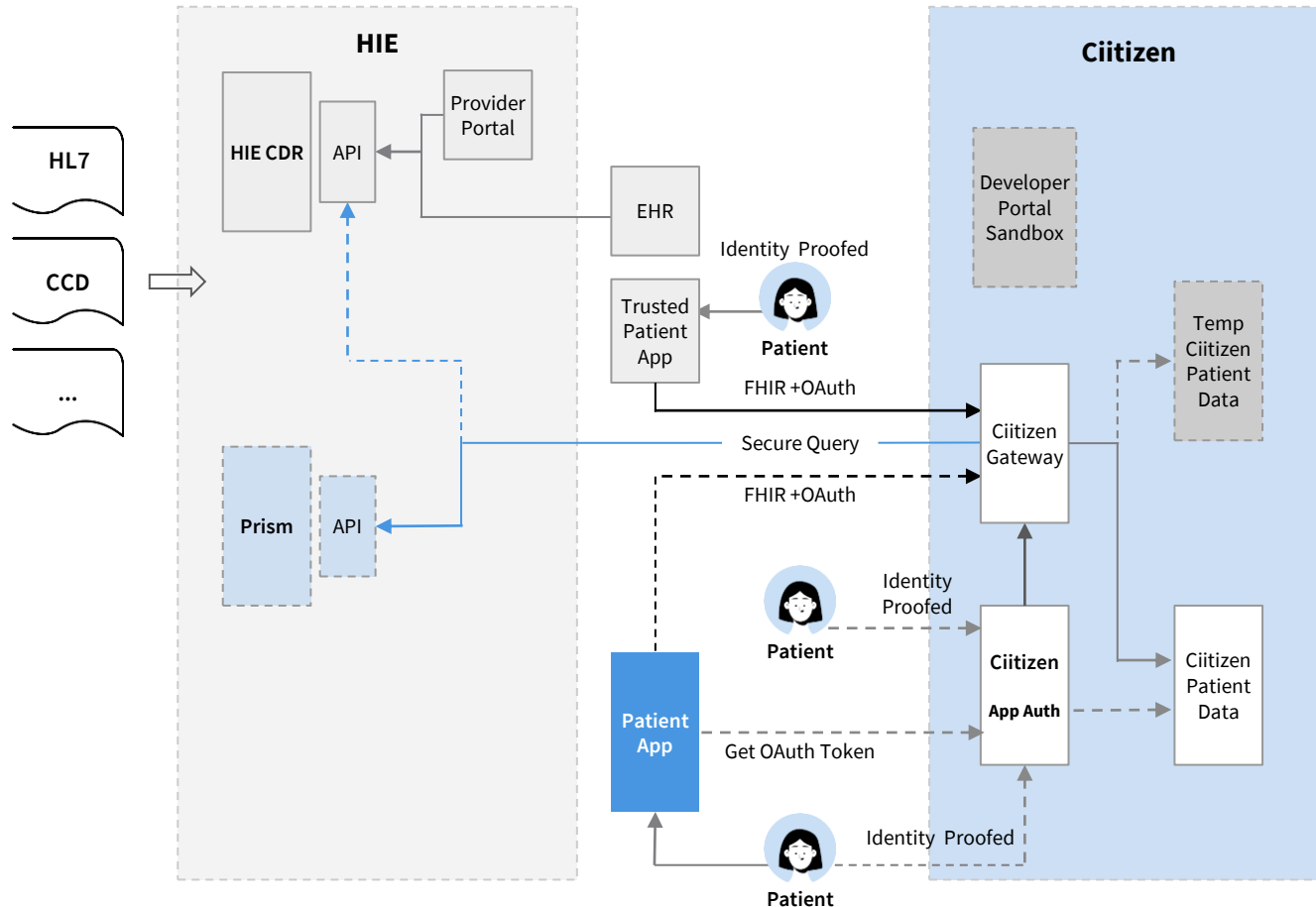
**Central Gateway:**

Ciitizen manages
- Patient identity proofing
- App onboarding
- App authorization

3rd party apps (trusted or untrusted)
- Queries Citizen for FHIR data
- Citizen gets data from HIE,(transforms to FHIR), and responds

Walkin Patients:
- Patient will be id proofed.
- Patients who become Citizen can
  - Get data from all connected data sources (FHIR or IHE or other)
  - Get ongoing data refresh
- Patient who do not become a Citizen will have to
  - EITHER provide a destination for sending the data (Email account) OR have temporary data in Citizen for limited time (e.g. 30 days) which they can download
  - need to be id proofed again when querying for new data
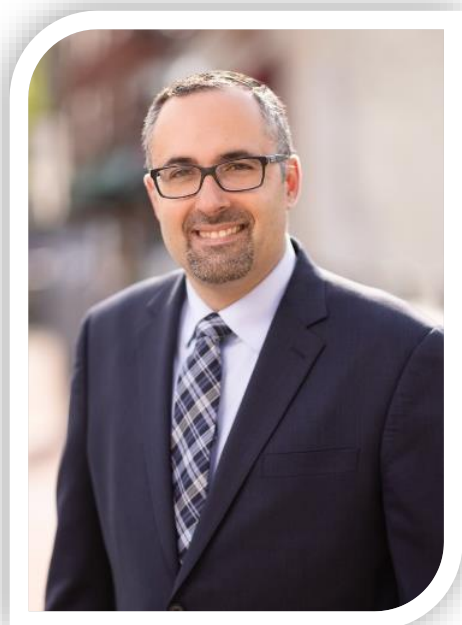
Paulo Pinho
Diameter Health

Dr. Paulo Pinho is currently the Vice President & Medical Director of Innovation for Diameter Health, a Farmington, Connecticut based company that normalizes, cleanses, deduplicates and enriches clinical data from across the care continuum (HIE's, EHR's, labs, ACO's, etc.) to create a unified source of longitudinal structured patient information for improved care and actionable analytics across different verticals. He provides clinical expertise and thought leadership on existing and emerging regulations, quality measures, healthcare data standards and technologies relevant to Diameter Health solutions.

Prior to his current role, he worked at Optimum Life Reinsurance where he served as the Chief Medical Director and was responsible for medical strategy as it pertains to trends and breakthroughs in care delivery, legislation and governance, changing demographics and mortality patterns. He was charged with exploring innovations that could allow healthcare to become more predictive, personalized and continuous for patients leading to morbidity and mortality outcomes improvement.

Previously he was Vice President and Lead Medical Director for Prudential International Insurance focusing on global innovation for Prudential's markets in Asia Pacific and Latin America.

Paulo has practiced Medicine for close to 20 years – he is dual board certified in Internal Medicine and Pediatrics and board eligible in Insurance Medicine. He spent over a decade practicing both Internal Medicine and Pediatrics at PASE Healthcare, a medical practice serving over 8,000 patients that he founded and ran as sole proprietor. He continues as a clinical assistant professor in the Department of Internal Medicine at Rutgers, New Jersey Medical School and remains clinically active an urgent care organization.
In his spare time, he enjoys travel, sports and rooting for his teenagers in their weekend sports activities. Paulo has completed over 60 half marathons, and between 2006 and 2018 he completed a half marathon in every US state.
Paulo is on the board of an organization in Leogane, Haiti that organizes healthcare and education in a village in Haiti. He has traveled to Haiti to volunteer and has remotely organized emergency care and public health through technologies like bedside remote ultrasound and telemedicine wound care.

CONNECTING MICHIGAN
for health and more

Semantic Interoperability is the Foundation of Access, Innovation and Contextual Clinical Interoperability

Presented To:

MiHIN - Connecting Michigan for Health and More

HIPAA Right of Access/CMS Patient Access

November 9, 2021

Diameter Health®

Patient Access mandate moves healthcare into modern age

"

Delivering interoperability actually gives patients the ability to manage their healthcare the same way they manage their finances, travel and every other component of their lives. This requires using modern computing standards and APIs that give patients access to their health information and give them the ability to use the tools they want to shop for and coordinate their own care on their smartphones.

"

Don Rucker, M.D.
National Coordinator for Health IT

Clinical Data Challenges

Semantically Non-normalized

50%
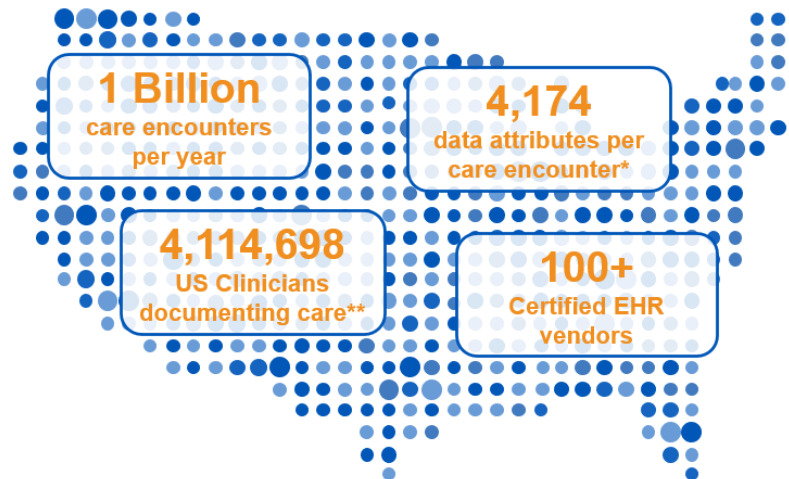of clinical data non-standard or incomplete and not usable at scale

70%
of lab results do not include appropriate vocabulary or units
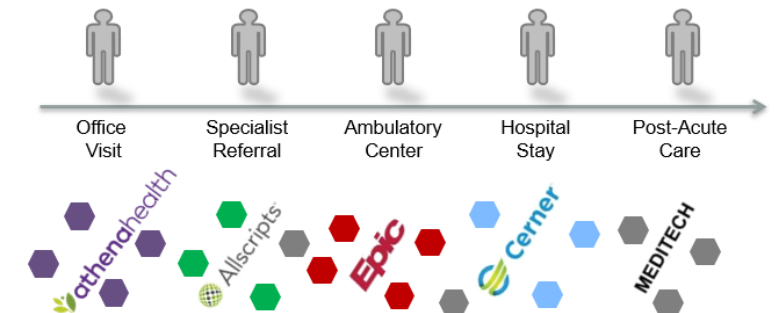
Up to 40%
of medications do not have appropriate coding

Voluminous & Growing

1 Billion
care encounters per year

4,174
data attributes per care encounter*

4,114,698
US Clinicians documenting care**

100+
Certified EHR vendors

Fragmented and Siloed

Complex patients see many providers annually with data spread across care settings

Office Visit | Specialist Referral | Ambulatory Center | Hospital Stay | Post-Acute Care

athenahealth   Allscripts   Epic   Cerner   MEDITECH

Patient Example – <mark>ALL history from patient</mark>

- **Chief Complaint** – Progressive Shortness of Breath, Cough and Fever
- **History of Present Illness** – Progressive shortness of breath beginning October 2018
    - October 16, 2018 – Urgent care visit
        - Diagnosis - sinus infection because of severe head and chest congestion
        - Treated with azithromycin (antibiotic) and benzonatate (cough medication)
    - October 29, 2018 – Emergency Department with worsening shortness of breath
        - Diagnosis - Chest Xray – pneumonia in both lungs
        - Treated with levofloxacin (antibiotic) and methylprednisolone dose pack (steroid)

- MB
- 70-year-old male
- Nuclear Engineer
- Emergency Room - November 29, 2018
- <mark>Had access to their medical records</mark>

Patient's 4-page summary of their clinical history

Urgent Care and ER

Pulmonary Issues:

- Initiating Event – Mid-October 2018
  - Severe head and chest congestion diagnosed as sinus infection. Z-Pack prescribed but ineffective.
- Hospitalized End-October 2018 due to difficulty breathing.
  - Chest X-ray indicated evidence of pneumonia in both lungs - *Summary Attached*
  - Treatment initiated for pneumonia – Antibiotics + Steroids.
  - Discharged from Hospital – continued home treatment with Antibiotics + Steroids.
    - It became noticeable that breathing difficult and fever occured once steroid medication was reduced or stopped.
  - Low blood oxygen saturation – below emergency "trigger" point (< 89%).

Primary Care

- Neurologic developments since October 2018 event
  - Pain and numbness in legs and arms
  - Moderate to severe numbness in left hand pinkie and left ring finger
  - Mild pain in right hand pinkie and right ring finger
  - Moderate to severe pain in right leg and foot.
  - Mild pain in left leg and foot
 - "foot drop" in right foot

GI Issues that emerged since October 2018

- Upper abdominal pain possible causes:
  - GERD
    - Ph testing indicates evidence of GERD
    - Hiatal hernia – indication of hernia (2.9 cm)
    - Omeprazole, 40 mg two times per day prescribed. No reduction in pain.
  - Esophageal dysmotility

Seen as pertinent medical history

Seen as non-pertinent medical history

Patient Example – 4-page document of history

- **Data in EHRs that was corroborated by patient's 4-pager**
  - **Past Medical History** – Coronary artery disease; Hypertension; Hyperlipidemia
  - **Medications**
    - Aspirin 81 mg daily
    - Atenolol 50 mg daily
    - Clopidogrel 75 mg daily
    - Simvastatin 20 mg daily
- **Key Data that was missing from EHRs, missing from 4-pager but "verbally" supplied by patient**
  - **Family History**
    - Father - arthritis and high blood pressure (died at 92)
    - Mother - pneumonia (died at 89)
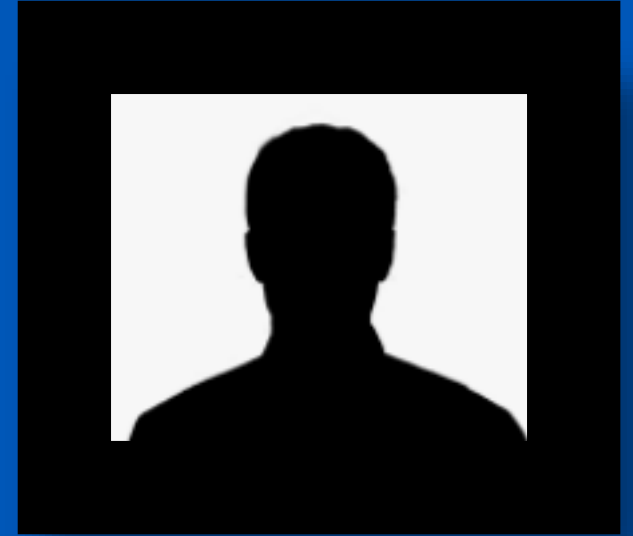
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Patient Example – Some "data" from encounters

Instructions from I_____a, MD

Acute bacterial sinusitis
Cough
Take Z Pack as directed
Rest
Stay hydrated
Can try saline nasal sprays 3-4 times a day
Can use a humidifier at home
Can try a teaspoon of honey once a day for the next 3-4 days
Can try tessalon perles 200 mg, 1 pill three times a day as needed for cough
Take advil or tylenol prn pain
Take advil with food
F/u if not better or if any other concerning signs or symptoms.

Today's Visit

You saw N_____, MD on Tuesday October 16, 2018.

Blood Pressure 141/65   BMI 23.79
Weight 170 lb 9.6 oz   Height 5' 11"
Temperature 99.2 °F   Pulse 59
Respiration 16   Oxygen Saturation 97%

Today's medication changes
START taking:
azithromycin (ZITHROMAX Z-PAK)
benzonatate (TESSALON)
Accurate as of 10/16/18 10:37 AM.
Review your updated medication list below.

PROCEDURE: CTA CHEST
ORD PROV:
EXAM DATE/TIME: 10/29/2018 2006
AUTH PROV:

HISTORY: Chest pain. Clinical suspicion for pulmonary embolus.

COMPARISON: There are no prior CTA studies available. Comparison made to today's chest x-ray.

Lungs: Interstitial type infiltration seen at the lung bases which extend to both lingula as well as the right middle lobe.

IMPRESSION:
1. No PE.
2. Bilateral lower lobe interstitial infiltration presumed to reflect pneumonia, follow-up exam recommended.

- MB
- 70-year-old male
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- Emergency Room - November 29, 2018
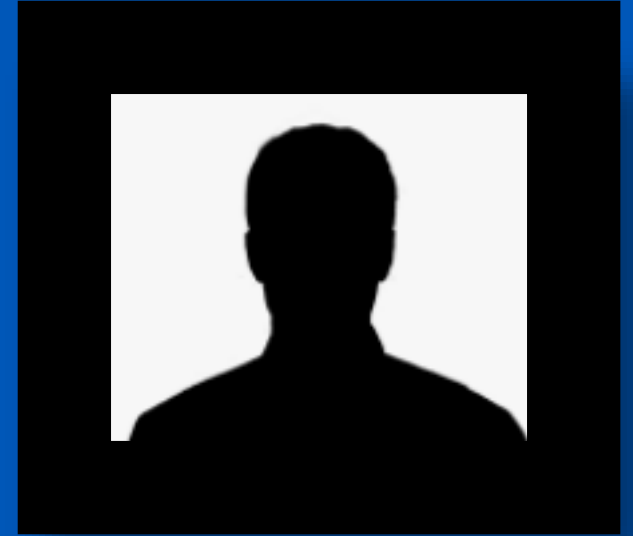- Had access to their medical records

The ER doc ordered tests, diagnosed and treated

PROCEDURE: CT CHEST WO CONTRAST
ORD PROV:
EXAM DATE/TIME: 11/29/2018 1503
AUTH PROV:

COMPARISON: CAT scan from Octob 2018

Lungs: Bilateral lower lobe infiltrat small subpleural infiltrates in the lingula of the left upper lobe and in the right middle lobe are increased and suspicious for pneumonia.

Pneumonia = Antibiotics

- MB
- 70-year-old male
- Nuclear Engineer
- Emergency Room - November 29, 2018
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But – wait . . . There's more!

- Nephew spoke to pulmonologist with key observations:

  - Family History data missing from EHRs, 4-page document and misunderstood by patient

    - Mother - idiopathic pulmonary fibrosis

    - Father - rheumatoid arthritis which began with pulmonary complications

  - Antibiotics seemed not to work

  - Steroids led to an improvement that regressed after the patient tapered

  - Key diagnoses of gastrointestinal and neurological conditions deprioritized

- The Nephew
- 47-year-old male
- Knows a thing or two about medical care
- Recruited by his mother to intervene

Patient Care | Fragmented

Nephew gather key data from previous history and fills in data gaps from history

MB's data journey

Patient Provided Data	Primary Care Data	Gastroenterology Data	Urgent Care Data	Emergency Room Data

WORKING DIAGNOSIS - *PNEUMONIA*

Nephew
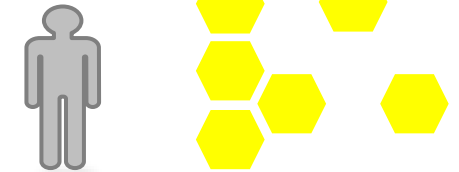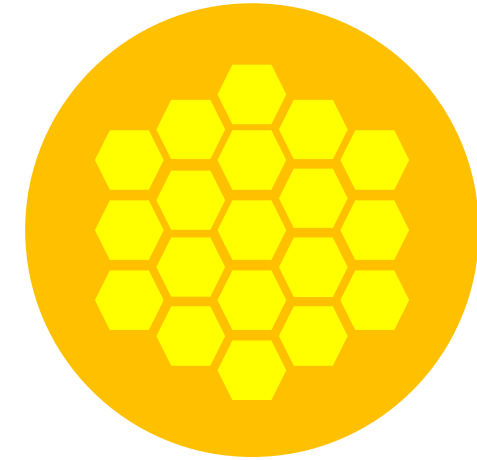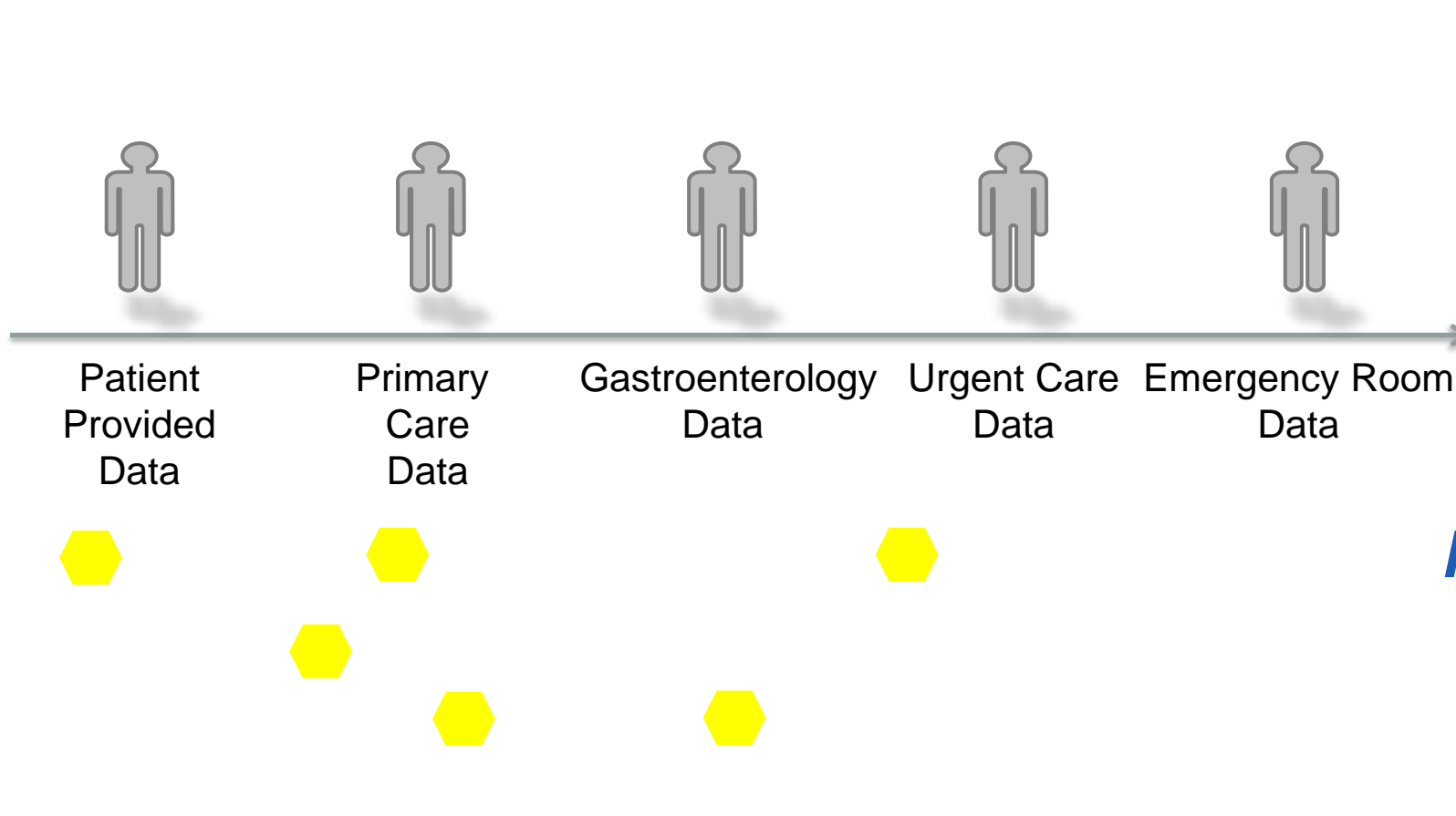
Diameter Health®

Diameter Health Solution | Where We Fit

Clinical Data Optimization

Clinical Data Acquisition

Clinical Data Inputs

- Allergies
- Encounters
- Immunizations
- Medications
- Diagnoses
- Procedures
- Labs & Vitals
- Demographics

DIAMETER HEALTH FUSION

Parse & Aggregate Data in Real-Time, At Scale

NORMALIZE — ENRICH — REORGANIZE — DEDUPLICATE — SUMMARIZE

Normalize clinical data to industry standards and improve quality.

Enrich with appropriate metadata for downstream use.

Reorganize clinical document data to appropriate sections.

Deduplicate repetitive data elements across and within data sources.

Summarize data into longitudinal patient records.

Clinical Data Application

Downstream Use

- Analytics Applications
- Research Databases
- Provider Workflow Solutions
- Provider & Patient Portals that are longitudinal and comprehensive-critical to "Access"

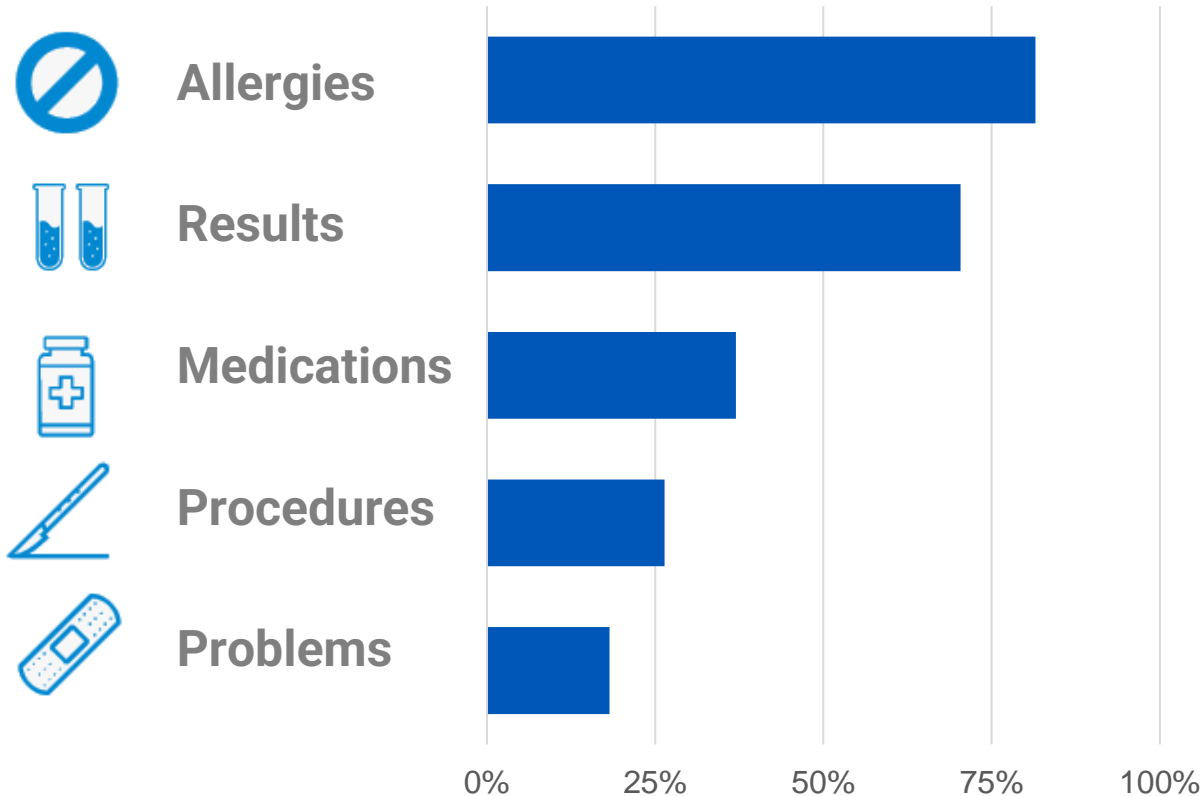# Challenge | The Wild West of Coding

%A1C   Hgb A1c MFr Bld   %A1C   Glycohemoglobin (A1c)   Hemoglobin A1c   hemoglobin A1C, blood, as
%A1c   Hgb A1c Quantitative   %A1c   Glycohemoglobin (GHb),Total Hemoglobin A1C   total hemoglobin
%A1c   (HbA1c)   %A1c   Glycohemoglobin A1c   HEMOGLOBIN A1C   Hemoglobin A1C, POC
%A1cwb Hgb Glycated A1C   %A1cwb   Glycohemoglobin A1C   HEMOGLOBIN A1c   Hemoglobin A1c/Hemoglobin.t
%A1cwb   HGB_A1C   %A1cwb   Glycohemoglobin A1C   HEMOGLOBIN A1C -   Hemoglobin A1c/Hemoglobin.t
.Hemoglobin A1c   Hgb_A1c_   .Hemoglobin A   ...in A1c - 001481   in Blood
        Hgb_A1c_MFr_Bld   Hemoglobin A1c/W Reflex
Hgb_A1c_with_eAG_Estimat   _Hemoglobin_   ...obin A1c - LA   Glycomark
A1c   ion   A1c   ...LOBIN A1C %   HEMOGLOBIN GLYCLATED (HGB
                                     A1c   ...lobin A1c %   HEMOGLOBIN GLYCLATED (HGB
A1C   HgbA1C   Blood hemoglobin   Hemoglobin Glyclated (HGB
Blood hemoglobin A1c/total   hemoglobin r   ...bin A1c (AMC)   HEMOGLOBIN GLYCLATED (HGB
    hemoglobin ratio   Blood_hemoglobin_A1c   ...n A1c (F/C/CTX)   (AFINION)
Blood_hemoglobin_A1c_total_   globin_rat   ...bin A1c (Fma)   Hemoglobin_A1c
    hemoglobin_ratio   Blood_hemoglobin_A1c   ...A1c (Fma/CMC,CX)   HEMOGLOBIN_A1C
Blood_hemoglobin_A1c_total_   globin_rat   HEMOGLOBIN_A1C
    hemoglobin_ratio   CMP14_LP_Hb_A1c_eAG   Hb_A1c_POC_DCA_Vantage Hemoglobin A1c (Glyco HGB) Hemoglobin_A1c
CMP14_LP_Hb_A1c_eAG   DA1C   HBA1C   HEMOGLOBIN A1C @   Hemoglobin_A1c_Hemoglobin.t
DA1C   EST AVE GLU   HbA1c   Hemoglobin A1c @   _in_Blood
                                    Estimated Average Glucose   HbA1c (Bld) [Mass fraction] Hemoglobin A1c Percent Hemoglobin_A1c_percentag
Estimated Average Glucose   Estimated Avg Glucose   Hba1c: Hemoglobin A1c percentage Hemoglobin_Hgb_A1c
Estimated Avg Glucose   Glycated Hemoglobin   HemoglobinA1c
Glycated Hemoglobin

100+ different ways
A1c is being collected
and reported

Opportunity | Semantic Interoperability

%A1C   Hgb A1c MFr Bld
%A1c   Hgb A1c Quantitative (HbA1c)
%A1c
%A1c   Hgb Glycated A1C
%A1cwb   HGB_A1C
%A1cwb   Hgb_A1c_
.Hemoglobin A1c   Hgb_A1c_MFr_Bld
Hgb_A1c_with_eAG_Estimation
A1c
A1C   HgbA1C
Blood hemoglobin A1c/total hemoglobin ratio
Blood_hemoglobin_A1c_total_hemoglobin_ratio
Blood_hemoglobin_A1c_total_hemoglobin_ratio
CMP14_LP_Hb_A1c_eAG
DA1C

Estimated Average Glucose
Estimated Avg Glucose
Glycated Hemoglobin

%A1C
%A1c
%A1c
%A1cwb
%A1cwb
.Hemoglobin A1c
_Hemoglobin_A1c
A1c
A1C
Blood hemoglobin A1c hemoglobin rati
Blood_hemoglobin_A1c_to globin_ratio
Blood_hemoglobin_A1c_to globin_ratio
CMP14_LP_Hb_A1c_e
DA1C
EST AVE GLU
Estimated Average Glucose
Estimated Avg Glucose
Glycated Hemoglobin

Glycohemoglobin (A1c)
Glycohemoglobin (GHb),Total
Glycohemoglobin A1c
Glycohemoglobin A1C

Hb_A1c_POC_DCA_Vantage
HBA1C
HbA1c
HbA1c (Bld) [Mass fraction]
Hba1c:

Hemoglobin A1c
Hemoglobin A1C
HEMOGLOBIN A1C
HEMOGLOBIN A1c
HEMOGLOBIN A1C -
globin A1c - 001481
moglobin A1c - LA
HEMOGLOBIN A1C %
Hemoglobin A1c %
moglobin A1c (AMC)
globin A1c (F/C/CTX)
moglobin A1c (Fma)
obin A1c (Fma/CMC,CX)
Hemoglobin A1c (Glyco HGB)
HEMOGLOBIN A1C @
Hemoglobin A1c @
Hemoglobin A1c Percent
Hemoglobin A1c percentage

hemoglobin A1C, blood, as total hemoglobin
Hemoglobin A1C, POC
Hemoglobin A1c/Hemoglobin.t
Hemoglobin A1c/Hemoglobin.t in Blood
Hemoglobin A1c/W Reflex Glycomark
HEMOGLOBIN GLYCLATED (HGB
HEMOGLOBIN GLYCLATED (HGB
Hemoglobin Glyclated (HGB
HEMOGLOBIN GLYCLATED (HGB (AFINION)
Hemoglobin_A1c
HEMOGLOBIN_A1C
HEMOGLOBIN_A1C
Hemoglobin_A1c
Hemoglobin_A1c_Hemoglobin.t _in_Blood
Hemoglobin_A1c_percentag
Hemoglobin_Hgb_A1c
HemoglobinA1c

We auto-map it all to:
Code: 4548-4 (LOINC)
HbA1c

Diameter Health

Challenge | Current State of Clinical Data

Allergies

Results

Medications

Procedures

Problems

0%   25%   50%   75%   100%

How can we improve healthcare when

- 80% of allergies aren't coded appropriately (30% no code at all)

- 70% of lab results don't use right vocabulary or units (45% = no LOINC)

- Nearly 40% of medications don't have right coding for[1]

1. D'Amore et al. Using Clinical Data Standards to Measure Quality: A New Approach. *Applied Clinical Informatics.* 2018

Accelerating the Usability of Clinical Data at Scale

Source Example

Inbound Uncoded & Incomplete Lab Test:

```
<code code="" codeSystem="" codeSystemName="">
    <originalText>Systolic blood pressure</originalText>
</code>

<value xsi:type="PQ" unit="" value="110"
```

Recode to Standard LOINC Code:

```
"recode": {
    "code": "8480-6",
    "codeSystem": "2.16.840.1.113883.6.1",
    "codeSystemName": "LOINC",
    "displayName": "Systolic blood pressure",
    "lookup": "free text",
    "translation": [],
    "type": true
},
    "revalue": {
        "type": true,
        "unit": "mm[Hg]",
        "value": "110"
    },
```

Scale Across Clinical Domains

Assume the magnitude of data created from 300 million patients in country
x
3 clinical documents per patient/year

Health care data is big data:
SNOMED CT:
357,000 healthcare concepts (957,000 discrete descriptions).
1.37 million semantic relationships
AND
Between 2016-2020 the volume of health data increased by 878%

Downstream Impact

Technology Modernization lends itself to real time data in the hands of patients that is:

1. HIGH QUALITY and LONGITUDINAL
2. Able to show ASSOCIATIONS and RELATIONSHIPS
3. INTERPRETABLE and ACTIONABLE
4. ACCELERATED time to more ACCURATE patient insights

Codes, Code Systems, and Value Sets Supplemental Material (cms.gov)
Organizations See 878% Health Data Growth Rate Since 2016 (hitinfrastructure.com)

FHIR Converter | Improves quality and access to data

Converted In Real Time

No downtime for existing system, data available in FHIR immediately

	CCD Inbound Data	FHIR Observation Resource
Code	UNK	48642-3
Display Name	eGFR	GFR/1.73 sq M.predicted among non-blacks MDRD (S/P/Bld) [Vol rate/Area]
Value	50	50
Unit	Blank	mL/min/{1.73_m2}
Easily Queried?	No	Yes
Comment	No inbound Code or unit of measure	LOINC Code applied to data based on lookup. Once LOINC code applied can then apply the standard UCUM Measurement based on value and LOINC.

FHIR | Interoperability on a solid foundation of data quality

Key Features

Built on Fusion to address gaps and inconsistencies in source data, deliver greater quality, quantity of usable data

- Built-in CCD Converter taps into legacy data

- 20+ US Core and CARIN FHIR APIs that support broad range of use cases – this number is growing

- Patient Access Solution for compliance with CMS mandate

Patient Care | Fragmented

Complex patients see many providers annually with data spread across care settings

**Disparate, dirty and non-normalized clinical data creates gaps in care**

Office Visit • Specialist Referral • Ambulatory Center • Hospital Stay • Post-Acute Care

https://www.slideshare.net/HowardRosen129/the-future-of-mhealth-jay-srini-march-2011
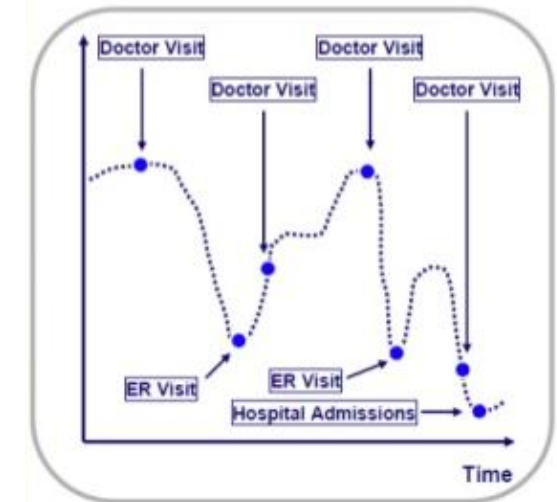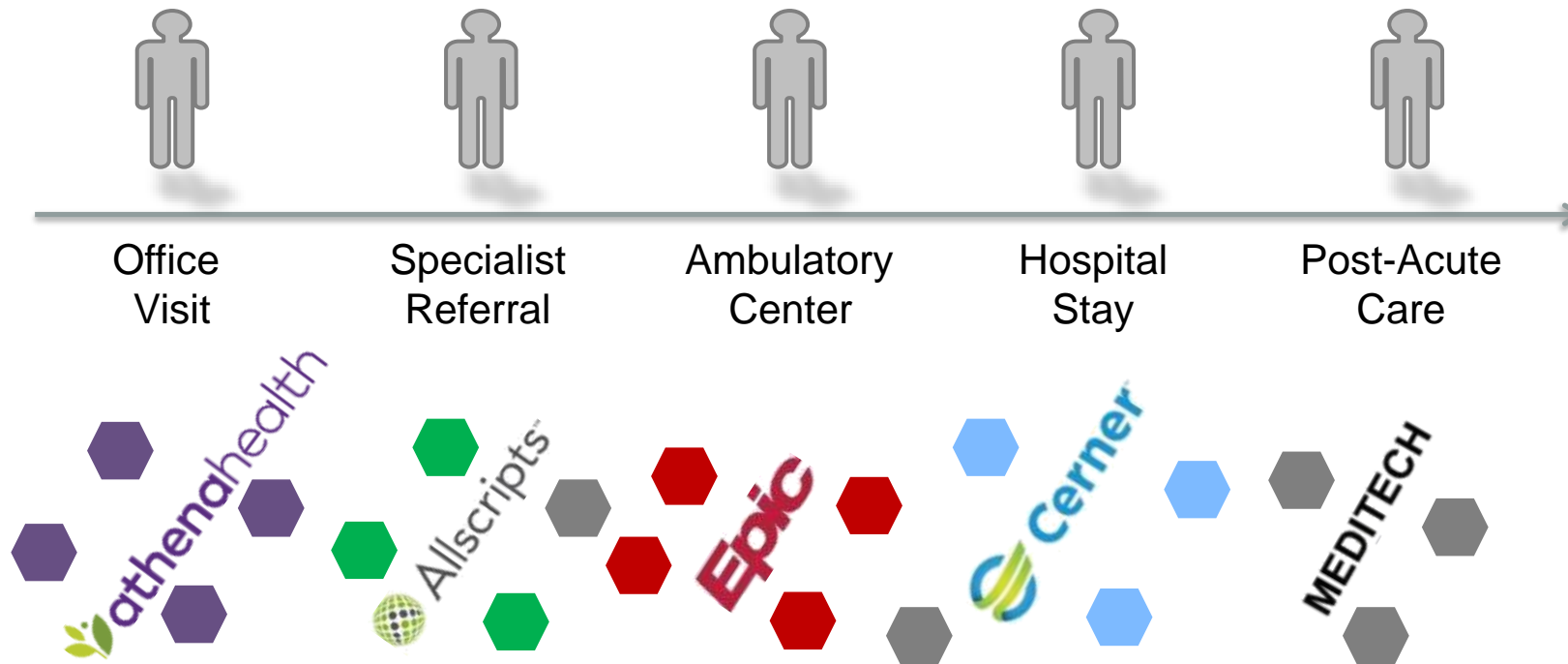
Patient Care | Defragmented

Unified and normalized clinical data, ready for improved patient experience and outcomes

Complex patients see many providers annually with data spread across care settings

Office Visit | Specialist Referral | Ambulatory Center | Hospital Stay | Post-Acute Care
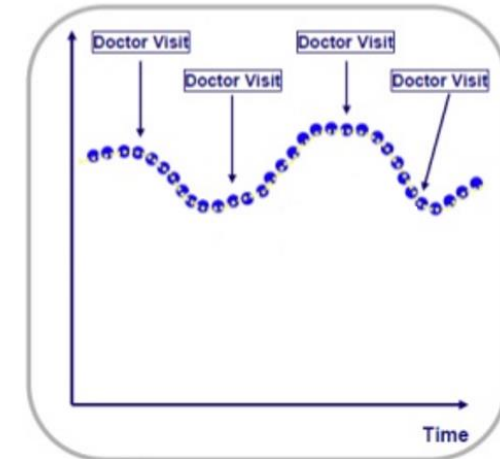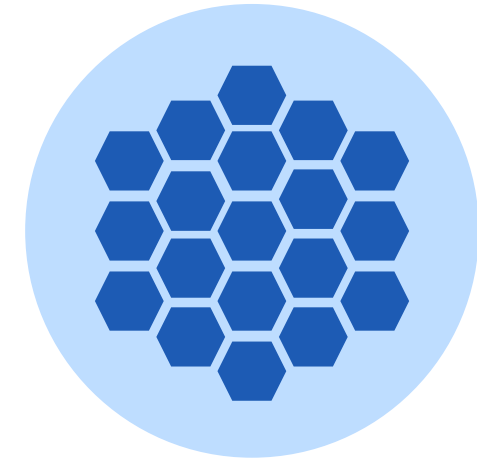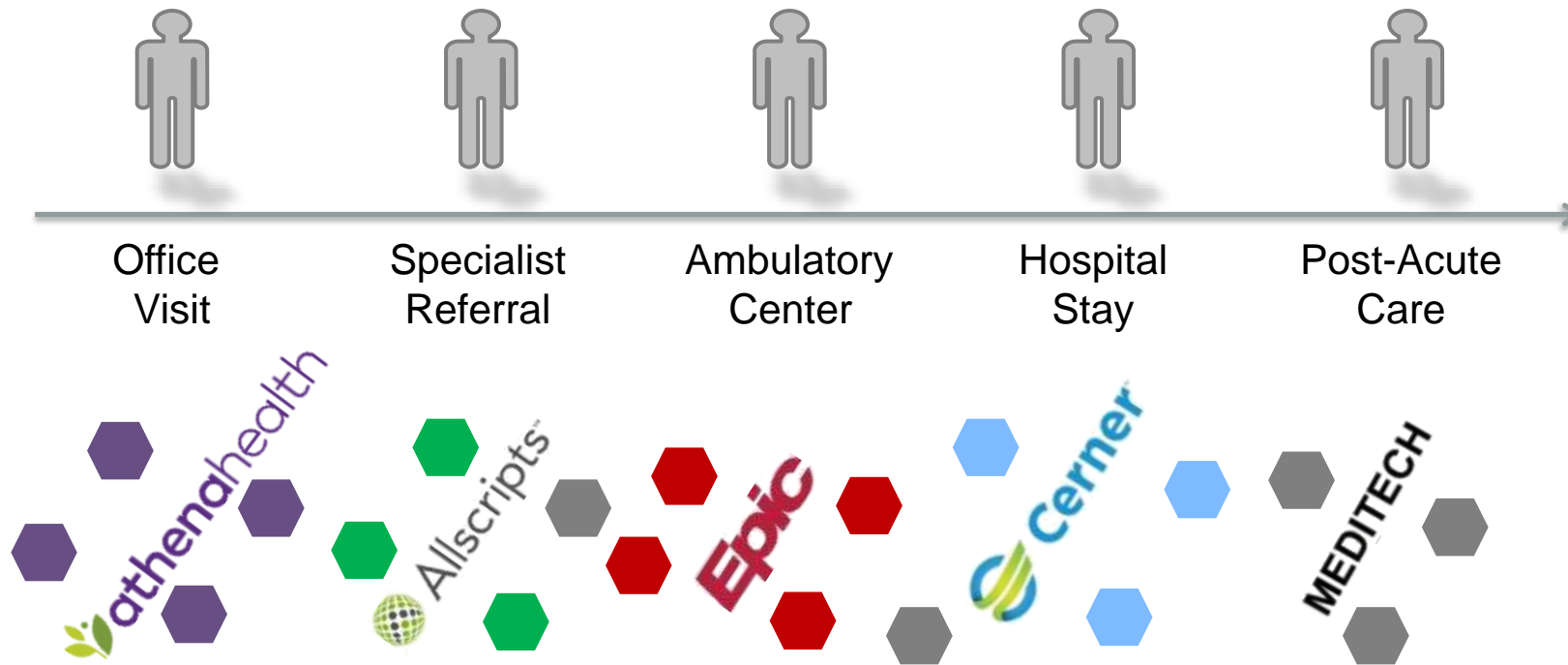
The End

MB's nephew

- Paulo Pinho, MD
- 47-year-old male
- Board Certified in Internal Medicine and Pediatrics

Diameter Health