Harnessing AI to Better Understand Health, Value and Well-Being
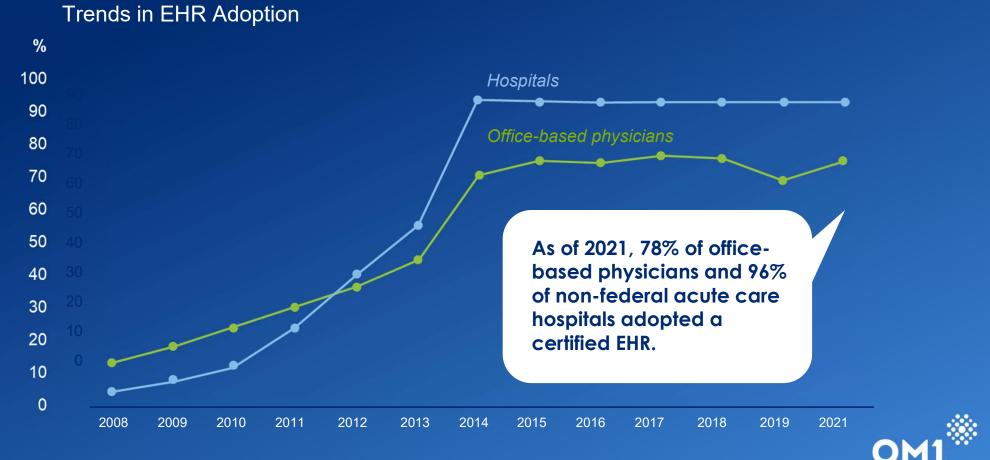
Richard Gliklich MD, CEO, OM1

November 19, 2024
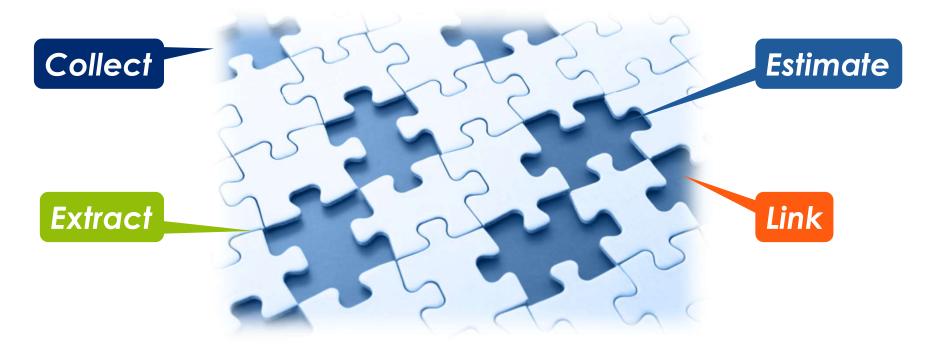
Missing data is the single greatest challenge to consistently using real-world data for understanding health, value and well-being

Variables thought to be critical from clinical trials (e.g. ICER reviews) are often not collected in standardized fields (i.e. hidden in notes or inaccessible documents) or sometimes not collected at all.

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What options are there to fill in Missing Data?

Collect

Estimate

Extract

Link

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What is Needed to Determine Outcomes?

What is Commonly Missing in RWD?

Collect

Link

Extract

Estimate

Framework data element categories

Characteristics ▼

Participant
- Demographics
- Genetics
- Family/participant history
- Functional/performance status
- Health behaviors
- Environmental exposures

Disease
- Diagnosis
- Risk factors
- Staging system
- Genetics of disease
- Tissue or infectious agent
- Biomarkers
- Comorbidity/symptoms
- Assessment/scales

Provider
- Training/experience
- Geography
- Practice setting:
  – Academic vs community

Treatment ▼

Type
- Surgical
- Medical
- Device
- Alternative

Intent
- Palliative vs curative

Outcomes ▼

Survival
- Overall mortality
- Disease-free survival

Disease response
- Recurrence
- Progression

Events of interest
- Adverse events
- Exacerbations

Patient/caregiver reported
- Physical functioning
- Health-related quality of life
- Other

Clinician reported
- Disease progression
- Other

Health system utilization
- Inpatient hospitalization
- Office visits
- ER visits
- Additional procedures
- Productivity/absenteeism
- Direct cost

Figure 2. Outcome measures framework model.

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Emerging AI Tools and Use Cases

Extract from Text

Unstructured text undergoes AI-driven medical language processing with validation by clinical abstractors

Use Cases

- Missing data
- Automation

Estimate Endpoints

AI-driven endpoint estimations from structured and unstructured data are rigorously validated

Use Cases

- Missing data
- Insufficient endpoints

Digital Phenotyping/Subtyping

OM1 PhenOM digitally **phenotypes** patients by identifying and grouping unique signals in data with AI

Use Cases

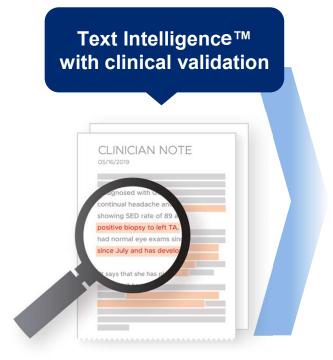- Patient Finding for uncoded diagnoses, under-diagnosed patients, under-treated patients
- Future prediction of events, outcomes (e.g. treatment response) and utilization

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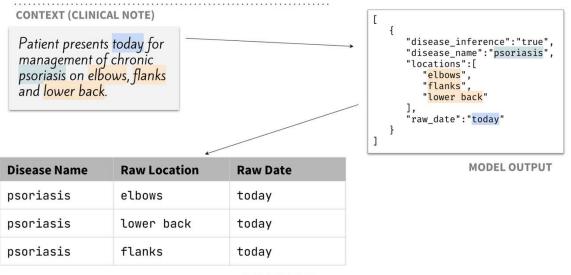
Extract: Medical Language Processing

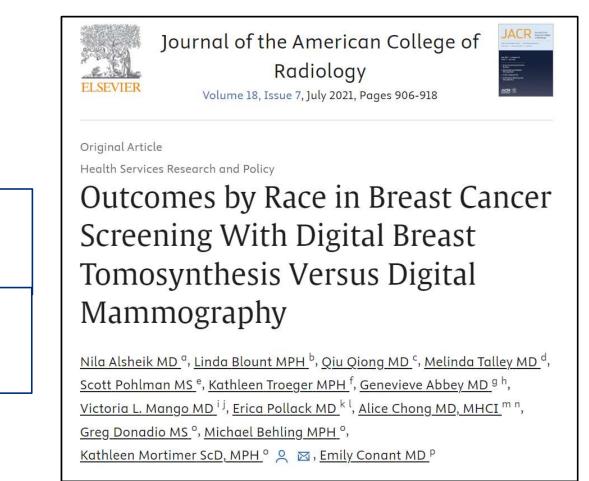**Text Intelligence™ with clinical validation**

CLINICIAN NOTE
05/16/2019

...agnosed with G...
continual headache an...
showing SED rate of 89 a...
positive biopsy to left TA.
had normal eye exams sin...
since July and has develo...
...t says that she has p...

Dermatology Location - Structured Output

CONTEXT (CLINICAL NOTE)

Patient presents today for management of chronic psoriasis on elbows, flanks and lower back.

```
[
    {
        "disease_inference":"true",
        "disease_name":"psoriasis",
        "locations":[
            "elbows",
            "flanks",
            "lower back"
        ],
        "raw_date":"today"
    }
]
```

MODEL OUTPUT

Disease Name	Raw Location	Raw Date
psoriasis	elbows	today
psoriasis	lower back	today
psoriasis	flanks	today

PARSED DATA

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1.1M Women Registry in Breast Cancer Screening

~1.1M Patients

~64 facilities

Original Article

Health Services Research and Policy

Outcomes by Race in Breast Cancer Screening With Digital Breast Tomosynthesis Versus Digital Mammography

Nila Alsheik MD [a], Linda Blount MPH [b], Qiu Qiong MD [c], Melinda Talley MD [d], Scott Pohlman MS [e], Kathleen Troeger MPH [f], Genevieve Abbey MD [g h], Victoria L. Mango MD [i j], Erica Pollack MD [k l], Alice Chong MD, MHCI [m n], Greg Donadio MS [o], Michael Behling MPH [o], Kathleen Mortimer ScD, MPH [o] ✉, Emily Conant MD [p]

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AI Estimation

Estimating (and validating) a key outcome from a clinical encounter, when it has not been specifically reported

Results in an Increase in # patients and an **increase in # timepoints per patient** create a more complete longitudinal picture

SLEDAI

9x increase in patients
10x increase in timepoints

EDSS

10x increase in patients
15x increase in timepoints

CDAI

2x increase in patients
4x increase in timepoints

Implications for Research Using a Lupus Dataset: Disease Activity using eSLEDAI
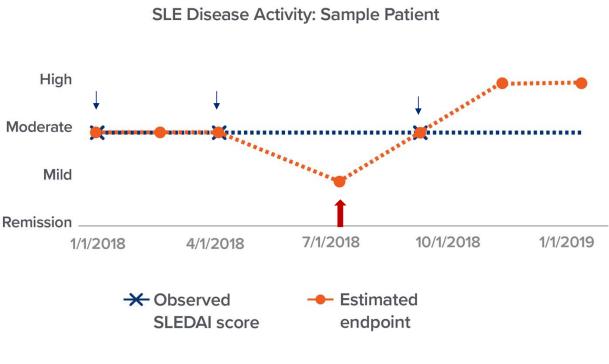
Estimated Measures and Endpoints

- 3 observed disease activity scores were available for 2018

- Estimation yielded 7 scores

- Validated estimated endpoints, in addition to those observed, paint a clearer picture of the patient's trajectory

SLE Disease Activity: Sample Patient

| | Observed SLEDAI score | Estimated endpoint |

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Estimation and Amplification of COAs and PROs

Examples across diverse conditions

Disease	Estimated Measure	Measure Amplification	Patient Amplification
Lupus	eSLEDAI	10x	9x
Rheumatoid Arthritis	eCDAI	2.2x	2x
Multiple Sclerosis	eEDSS	34x	15x
Major Depression	ePHQ-9	14x	4x
Schi...			
Hydr... Supp...			
Psor...			
AxSp...			
Heart Failure	eNYHA	1.7x	1.4x

Reductions in Depressive Symptoms After Brexpiprazole Augmentation Among Patients with Major Depressive Disorder Receiving Antidepressant Therapy in Real-World Settings

Severtson SG[1], Hadzi Boskovic D[2], Huang D[2], Talon B[3], Eisenberg D[3], Kapadia S[2], Ardic F[4], Awasthi S[2], Marci CD[1,5]

[1]OM1 Inc., Boston, MA, USA, [2]Otsuka America Pharmaceutical, Inc., Princeton, NJ, USA, [3]Lundbeck LLC, Deerfield, IL, USA, [4]H. Lundbeck A/S, Valby, Copenhagen, Denmark, [5]Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

Completing Data

Collect

Link

Extract

Estimate
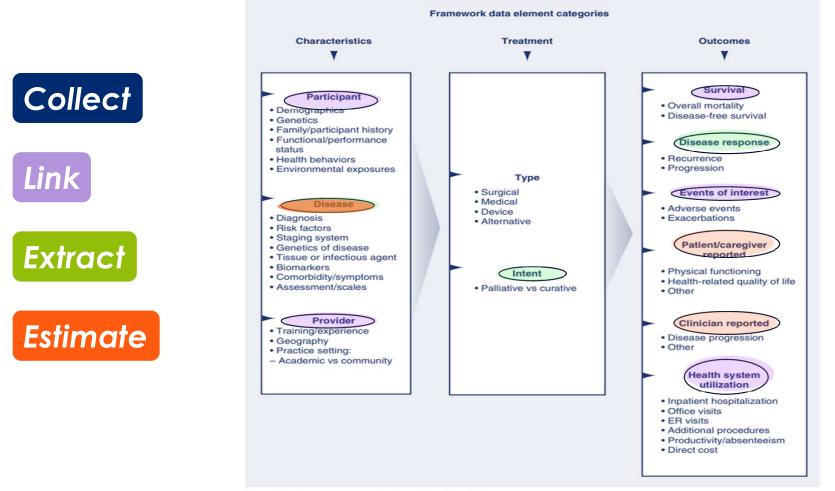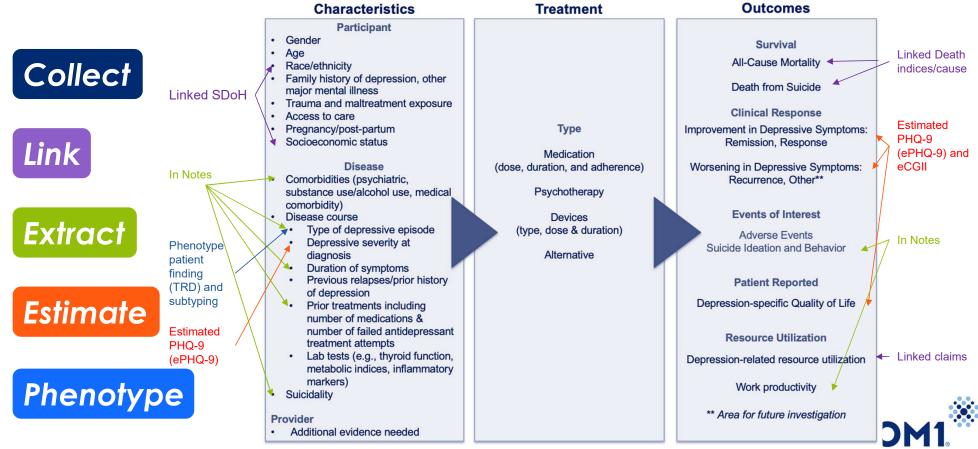
Figure 2. Outcome measures framework model.

Example: Major Depressive Disorder

Collect

Link

Extract

Estimate

Phenotype

Characteristics

Participant
- Gender
- Age
- Race/ethnicity
- Family history of depression, other major mental illness
- Trauma and maltreatment exposure
- Access to care
- Pregnancy/post-partum
- Socioeconomic status

Disease
- Comorbidities (psychiatric, substance use/alcohol use, medical comorbidity)
- Disease course
  - Type of depressive episode
  - Depressive severity at diagnosis
  - Duration of symptoms
  - Previous relapses/prior history of depression
  - Prior treatments including number of medications & number of failed antidepressant treatment attempts
  - Lab tests (e.g., thyroid function, metabolic indices, inflammatory markers)
- Suicidality

Provider
- Additional evidence needed

Treatment

Type

Medication
(dose, duration, and adherence)

Psychotherapy

Devices
(type, dose & duration)

Alternative

Outcomes

Survival
All-Cause Mortality

Death from Suicide

Clinical Response
Improvement in Depressive Symptoms: Remission, Response

Worsening in Depressive Symptoms: Recurrence, Other**

Events of Interest
Adverse Events
Suicide Ideation and Behavior

Patient Reported
Depression-specific Quality of Life

Resource Utilization
Depression-related resource utilization

Work productivity

** *Area for future investigation*

Linked SDoH

In Notes

Phenotype patient finding (TRD) and subtyping

Estimated PHQ-9 (ePHQ-9)

Linked Death indices/cause

Estimated PHQ-9 (ePHQ-9) and eCGII
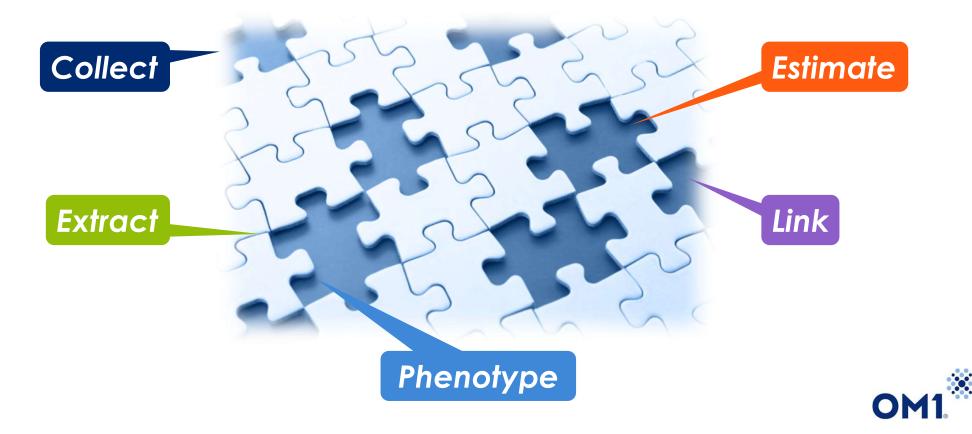
In Notes

Linked claims

From: Gliklich RE, Leavy MB, Cosgrove L et al. Harmonized Outcome Measures for Use in Depression Patient Registries and Clinical Practice. Ann Intern Med. 2020 Jun 16;172(12):803-809.
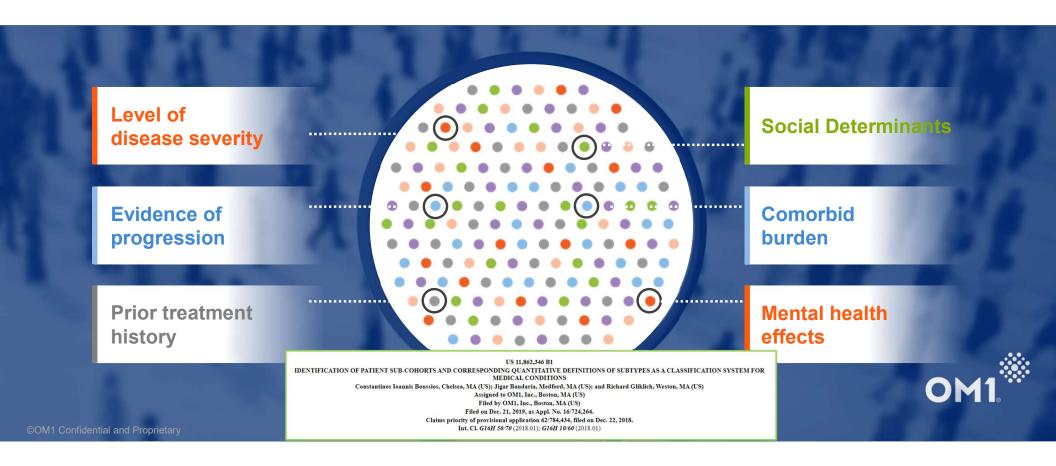
Enriched Conditions

Rheumatology & Immunology

- Axial Spondyloarthritis
- Giant Cell Arteritis
- Juvenile Idiopathic Arthritis
- Psoriatic Arthritis
- Rheumatoid Arthritis
- Systemic Lupus Erythematosus

Extracted & estimated outcomes including CDAI, BASDAI, SLEDAI

RAPID-3, MDHAQ Functional, Pain, Fatigue, Joint Counts

Gastroenterology

- Crohn's Disease
- Ulcerative Colitis

Extracted & estimated outcom including CDAI, M Score and components

Disease flares and remission, sympto

Cardiometabolic

- Heart Failure
- Metabolic Dysfunction- Associated Steatohepatitis (MASH)

Otolaryngology

- Asthma
- Chronic Rhinosinusitis

CRS subtypes, FEV1/FeNo results

Mental Health & Neurology

- Alzheimer's Disease
- Bipolar 1 Disorder
- Major Depressive Disorder
- Multiple Sclerosis
- ...on's Disease
- ...hrenia

...d & estimated ...s including ...uicidal Ideation, CGI-I, EDSS

Clinical subtypes, GAD7, MOOD DQ, MS relapses, evidence of TRD

Dermatology

- Alopecia Areata
- Atopic Dermatitis
- Hidradenitis Suppurativa
- Prurigo Nodularis
- Psoriasis
- Vitiligo

Extracted & estimated outcomes including %BSA, PGA, PASI, Hurley Stage

Disease location, subtype, flares and remission, itch severity

Extraction & Estimation as a service/API

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What options are there to fill in Missing Data?

Collect

Estimate

Extract

Link

Phenotype

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PhenOM®

A unified digital representation of patients' 'phenotypic profile space' – a single, multipurpose assay

Level of disease severity

Evidence of progression

Prior treatment history

Social Determinants

Comorbid burden

Mental health effects

US 11,862,346 B1
IDENTIFICATION OF PATIENT SUB-COHORTS AND CORRESPONDING QUANTITATIVE DEFINITIONS OF SUBTYPES AS A CLASSIFICATION SYSTEM FOR MEDICAL CONDITIONS
Constantinos Ioannis Boussios, Chelsea, MA (US); Jigar Bandaria, Medford, MA (US); and Richard Gliklich, Weston, MA (US)
Assigned to OM1, Inc., Boston, MA (US)
Filed by OM1, Inc., Boston, MA (US)
Filed on Dec. 21, 2019, as Appl. No. 16/724,264.
Claims priority of provisional application 62/784,434, filed on Dec. 22, 2018.
Int. Cl. *G16H 50/70* (2018.01); *G16H 10/60* (2018.01)

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PhenOM Case Studies

Phenotypes and Subtypes: We've successfully used PhenOM across therapeutic areas and treatments.

Identifying undiagnosed patients with rare genetic disease

- Focused on both 'classic' and 'non-classic' disease presentations
- Patients highlighted are at ~200x greater risk
- Currently in clinical deployment

Subtyping to spotlight rapid progression in MASH

- Identified characteristics preceding first MASH diagnosis indicating more rapid progressive disease
- Also focused on high HCRU, and long-term complications

Isolating treatment response phenotypes in vascular disease

- Complex disease without clear treatment guidelines or clinical consistency
- Created a phenotypic 'matrix' for relative benefit likelihood from different treatments

Highlighting uncoded conditions like treatment-resistant depression

- Used phenotyping to proxy for patients psychiatrists 'know when they see'
- Identified patients missed by other TRD definitions – and missed for more advanced treatment
- Currently testing clinical deployment

Reducing time to diagnosis in Hidradenitis Suppurativa

- Extracted patterning in HS patients' histories before they reached correct diagnoses
- Using HS phenotypes to improve HCP education and awareness (ongoing collaboration with AAD)

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Regulators Are Leaning In

> The use of AI, including to facilitate data collection… are really transforming the way drugs are developed and used.
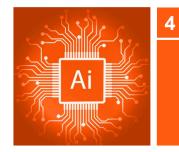
M. Khair ElZarrad, Ph.D., M.P.H, Director, Office of Medical Policy, **CDER | FDA, 2024**

Takeaways

1 Missing data is the achilles heel for real-world data programs

2 Linked data augments the patient journey

3 COA and PROs are often key and may need to be collected unless....

4 AI-powered Extraction, Estimation and Phenotyping fill in the gaps and opens new avenues

5 Regulatory guidance has enlightened the path

AI-powered prediction of future events, outcomes and resources will further change the paradigm

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