HEALTH INFORMATICS SEMINAR SERIES

Optum Digital Research Network & Optum De-identified Data Workspace (ODDW)
Optum’s Digital Research Network (DRN) is an integrated research offering developed to support design, start-up, and execution of clinical studies that are faster, utilize fewer resources, and are grounded in real-world clinical practice.

**Optum Medical and Rx Claims**

**70M Linked Claims/EHR**

**Other Data Sources**
- Medical and Rx Claims
- EHR data

**Optum De-identified Data Workspace (ODDW)**

**Natural language processing:**
- LVEF module
- Pulmonary function tests and results module
- Smoking Status module
- Oncology Biomarkers module
- Oncology Cancer Concept module
- Medication’s module

**Clinical Trial Center of Excellence**

**Accelerate patient identification:** Prospector allows HCO sites to identify patients who meet eligibility for a trial protocol within seconds

**Precision enrollment:** Precision patient finding enables sites to enroll the right patients by identifying those that most closely match study eligibility criteria

**Optum ODDW Data Science Center of Excellence**

**Optum's Digital Research Network**

**Cardiovascular Disease**

**Oncology**

**Lupus Disease**

**Other Data Sources**
- Medical and Rx Claims
- EHR data

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Optum Insurance Claims
- Sourced from a single payer
- Medical and Rx Claims
- Complete enrollment and eligibility control
- Prioritized if there are duplicates from other sources
- 21M+ linked EHR/Claims patients

Provider Claims
- Sourced from risk sharing provider agreements
- Eligibility controlled medical and Rx claims
- ~3.2M linked EHR/Claims patients

Partner Insurance Claims
- Sourced directly from payers as well as claims clearinghouses
- Medical and Rx claims
- Some eligibility control and enrollment information
- 40M+ linked EHR/Claims patients

Other Data Sources
- Medical and Rx Claims
- Some eligibility control and enrollment information
- 40M+ linked EHR/Claims patients

De-identified Data Workspace (ODDW)

Accelerate patient identification: Prospector allows HCO sites to identify patients who meet eligibility for a trial protocol within seconds
Our mission in clinical research

Re-invent clinical research by uniquely combining our data, technology, network, and expertise to accelerate and reduce the cost of developing new therapies and improve the patient and provider experience.
How does the DRN Help Healthcare Systems and Investigators?

- **Improve patient care**: Improve the patient experience by integrating care delivery and research.
- **Save time executing trials**: DRN accelerates precision patient finding and eliminates the need for data transcription.
- **Add profitable revenue**: Participate in incremental clinical trials.
- **Implement with no cost**: The DRN is committed to supporting your efforts in research.
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Prospector: relieves the burden of manual patient recruitment by accelerating trial planning and start-up processes.
- Assess and refine protocol criteria
- Receive customized query results
- Estimate patient counts and compile a precise study cohort

Loyola University Chicago will receive the following services and tools when joining the Optum Digital Research Network.

- Natural language processing
- Next-scheduled Visit
Site identification and precision patient finding

Connect sponsors to sites and identify eligible patients to investigators

- Determine study feasibility
- Identify specific sites with sufficient patients that match the inclusion/exclusion criteria
- Contract with sites for study conduct
- Identify eligible patients to sites

Prospector: DRN feasibility analysis & patient finding tool

Prospector enables your team to interact with your own EHR data and identify potential subjects for study feasibility assessments or for recruitment into an ongoing clinical trial.

The DRN searches EHR to find patients that match eligibility criteria. These records include:

- Diagnoses
- Procedures
- Medications
- Lab Results
- Vital Signs
- Observations
- 1450+ Biomarkers
- Provider Notes (NLP)

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Prospector™
Features and functionality
Key Features of Prospector for Providers

**Rapid Data Processing**
Prospector processes site data in seconds to identify patient counts for each criteria of a study protocol, saving you time when building complex studies.

**Intuitive Protocol Creation**
Quickly and easily create key study criteria using Prospector’s flexible classification of diagnoses, procedures, labs, medications, etc. and search-as-you-type features without knowledge of specific codes or programming.

**Support for Complex Study Criteria**
Create complex study criteria with date/event anchoring including relative dates, latest, earliest and number of encounters/occurrences.

**Patient Level Detail**
Gain granular insights by drilling down to the individual patient level for an interactive view of the entire patient’s medical history.

**Natural Language Processing Concepts**
Optum leverages its internal NLP capabilities to enrich Prospector with additional structured terms from unstructured data including measurements (LVEF, FEV1), biomarkers* and genomic tests*.

**Full-text Search and Analysis of Unstructured Notes**
Further augment your protocol design by performing full-text search in unstructured notes, then seamlessly include search results in your study. This capability also allows review of individual note documents.

All Prospector features are supported by a security model, which provides seamless role-based access to HIPAA compliant sets of data based on user’s privileges. This allows for studies within a site, HCO, or multiple HCOs.
Prospector™ Demo
Features and functionality
Enabling Optum data for use in pragmatic and explanatory clinical trials

Data sources
- Epic
- Cerner
- Allscripts
- Athena
- Next Gen
- Centricity
- eClinicalWorks
- Meditech
- McKesson
- + 10 other EMR vendors
- 837P (doctor)
- 837I (institutional)
- ADT feeds
- HIE feeds
- Custom files
- All commercial payers
- Medicare/Medicaid

Stage environment for bulk load
- Provenance
  - Find data and determine strategy for incorporation
  - Update/run ETL
- Normalization
  - Create common values set (e.g., weight converted from lbs. to kg.)
- Mapping
  - Data fields mapped to common domains (e.g., local gender M/F, 1/0)
- Validation
  - Normalized data validated against quality standards

Specs and ETL

Central data repository
- Centralized database
- Common normalized data structure for all clients
- Core concept mapping
- Natural language processing (NLP)
- Aggregation
  - Patient ID merging
  - Provider ID merging
  - Algorithms

Ongoing quality checks

CDR

Data Curation
- Mature process developed over 10 years

Physicians and Patients
- Identifiable (with permission and participation in the DRN)

ALCOA+
- Attributable, Legible, Contemporaneous, Original, Accurate
- +Complete, Consistent, Enduring and Available

Rapid
- Moving to 24-hour data transfer standard

Portable
- Able to transfer data files to in-house repositories

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Implement with ease
Simplified network start-up reduces site implementation burden
Natural language processing (NLP) concepts
Extract structured data from notes
NLP concepts
Filter results by different values
Biomarkers

Released (04-Oct-2021)

• Estrogen receptor (ER)
• Prostate Specific Antigen (PSA)
• Erb-b2 receptor tyrosine kinase 2 (ERBB2 or HER2/neu)
• Progesterone receptor (PR)
• Estrogen receptor/progesterone receptor (ER/PR)
• BRCA1/BRCA2 DNA repair associated (BRCA1/BRCA2)
• Immunoglobulin G (IgG)
• Marker of proliferation Ki-67 (MKI67 or Ki-67)

90+ additional biomarker releases planned…
Full-text Search and Analysis of Unstructured Notes
Search notes in Prospector for uncoded criteria
Full-text Search and Analysis of Unstructured Notes

View individual notes
HIPAA Compliance
Performing study feasibility and identifying patients for study enrollment

Optum enters into an agreement with the Healthcare Organizations (HCO) that includes a Business Associate Agreement, under which Optum may:

- Bring potential studies to the HCO for review and, if the HCO contracts for study participation:
  - Run algorithms using HCO’s EHR data to find potentially eligible patients
  - Disclose patients to the HCO’s research organization
  - Continue to assist the HCO in identifying patients during the study enrollment period

HIPAA Section 45 CFR 165.512(i)(1)(ii) notes that in “Reviews preparatory to research. The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and
(C) The protected health information for which use or access is sought is necessary for the research purposes.

https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html
Prospector™
Features and functionality
Digital Research Network | Prospector

Sample use cases: Quality assurance

1. Review and identify patients with specific disease/diagnoses who aren’t taking the recommended medication or are not adequately controlled or meet recommended guidelines (LDL, SBP, DBP, HbA1c etc.)

2. Determine STAR ratings for specific patient populations.

3. Find patients receiving a drug of interest and understand whether the administration of the treatment was medically necessary.

4. Find patients who have not received their recommended vaccines or procedures (Pneumovax, Shingrix, mammogram, colonoscopy or ColoGuard, bone density, etc.).
Quality Assurance Example 1

Patients with Type 2 Diabetes and cardiovascular risk factors that could benefit from an SGLT2 inhibitor

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Patient Count within DRN Network (as of 01-Aug-2021)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult patients, non-deceased</td>
<td>17,042,319</td>
</tr>
<tr>
<td>Type 2 Diabetes (from 2 encounters on 2 dates in their history)</td>
<td>733,860</td>
</tr>
<tr>
<td>Metformin prescription in previous 18 months</td>
<td>215,021</td>
</tr>
<tr>
<td>Established ASCVD or CVD diagnoses (from 2 encounters on 2 dates in their history)</td>
<td>70,641</td>
</tr>
<tr>
<td><strong>NOT</strong> on SGLT2 inhibitor (alone or in combination)</td>
<td><strong>58,267</strong> (82% of those that should be taking the medication are not)</td>
</tr>
</tbody>
</table>
Quality Assurance Example 2

**STAR Rating: Patients prescribed an antipsychotic that must receive regular screening for metabolic disorders**

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Adult patients, non-deceased</td>
<td>17,042,319</td>
</tr>
<tr>
<td>Prescription for antipsychotic medication in the previous 12 months</td>
<td>88,744</td>
</tr>
<tr>
<td>Record of screening for metabolic disorders in the previous 12 months (e.g. had body mass index, blood pressure, blood sugar, and cholesterol level screenings)</td>
<td>77,935 (89%, higher percentage is better)</td>
</tr>
</tbody>
</table>
Quality Assurance Example 3

Patients with a diagnosis of opioid use or abuse that have not received therapy (counseling or medication)

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Adult patients, non-deceased</td>
<td>17,042,319</td>
</tr>
<tr>
<td>Diagnosis of Opioid use or abuse (from 2 encounters on 2 dates in their history)</td>
<td>25,648</td>
</tr>
<tr>
<td><strong>No record</strong> of receiving drug use/abuse counseling or treatment, including medications to treat opioid withdrawal.</td>
<td><strong>16,441</strong> (64% of patients with opioid use or abuse diagnosis are not receiving treatment)**</td>
</tr>
</tbody>
</table>
### Quality Assurance Example 4

#### Patients aged > 50 that have not had a colonoscopy/Cologuard

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Patient Count within DRN Network (as of 01-Aug-2021)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age &gt; 50 years old, non-deceased</td>
<td>8,651,027</td>
</tr>
<tr>
<td><strong>No record</strong> of colonoscopy or colorectal screening</td>
<td>7,667,481 (89% of those eligible have not had a colonoscopy or colorectal screening)</td>
</tr>
</tbody>
</table>

#### Patients aged > 65 that have not received a pneumococcal vaccination

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Patient Count within DRN Network (as of 01-Aug-2021)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age &gt; 65 years old, non-deceased</td>
<td>4,372,736</td>
</tr>
<tr>
<td><strong>No record</strong> of pneumococcal vaccine</td>
<td>3,775,969 (86% of those eligible have not received their pneumococcal vaccination)</td>
</tr>
</tbody>
</table>
Thank you!