Feasibility of Large-Scale Observational Cancer Research using the OHDSI Network—Aim 2 Findings

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NCI Contract Aims

- **Aim 1.** Understand the sequence of treatments in cancer patients with diabetes, depression or high blood pressure
  - Presentation and webinar at NCI on 2/14/18

- **Aim 2.** Understand the feasibility of using existing data infrastructure to conduct cancer treatment and outcomes research.
Aim 1 example: Depression treatment pathways in cancer care

Truven CCAE
Columbia
IMS France
IMS Germany
Truven Medicaid
Truven Medicare
Optum Extended SES
Stanford
Aim 1 example: Type II DM treatment pathways in cancer care
Aim 1 example: Hypertension treatment pathways in cancer care
Aim 2: Phenotyping and Validation of Cancer Diagnoses

Any cancer, AML, CLL, pancreatic, and prostate cancer

How good is the data?
Cancer Demographics at Columbia University Medical Center (CUMC)

- 6.38 million unique patient records
- 5.33 million unique patients with at least 1 diagnosis/condition
- 667,328 unique patients diagnosed with cancer
- 38,670 unique patients in cancer registry (NAACCR Tumor Registry)
  - Includes patients with reportable cancers actively being treated at NYP/CUMC
  - Collected as part of hospital's ACOS accreditation
  - Manually abstracted by contracted 3rd party of cancer registrars
  - Requires significant time/manpower, can lag behind real time especially with data dictionary updates
Most prevalent diagnoses (SNOMED diagnosis):

- Prostate Cancer (Primary malignant neoplasm of prostate)
  - 33,094 unique pts

- Breast Cancer (Primary malignant neoplasm of female breast)
  - 31,281 unique pts

- Unknown (Primary malignant neoplasm of unspecified site)
  - 28,428 unique pts

- Lung cancer (Primary malignant neoplasm of respiratory tract)
  - 20,134 unique pts
Phenotyping and Validation of Cancer Diagnoses: Any Cancer

- All conditions ICD9CM, ICD10CM, SNOMED mapped to standardized SNOMED codes
  - SNOMED codes => condition_concept_id
    - 55342001-Neoplastic Disease => 438112
  - Excluding:
    - 20376005-Benign neoplastic disease => 435506
    - 254827004-Lipomatous tumor => 4112852
Phenotyping and Validation of Cancer Diagnoses: Any Cancer

- Manual chart review of 100 patients (randomly chosen)
  - 2 pt charts unable to be found
  - 94/98 (95.9%) pts verified to have cancer

- **PPV: 95.9%**

- Using chemotherapy agent doxorubicin to identify false negatives and calculate sensitivity
  - 2294 patients with drug exposure to doxorubicin (ancestor is doxorubicin ingredient)
  - 2270 patients with diagnosis of cancer and drug exposure to doxorubicin
  - Missing: 24/2294 (1%) patients exposed to doxorubicin who were not captured as having cancer based on these SNOMED codes

- **Sensitivity: 99%**
Phenotyping and Validation of Cancer Diagnoses: Any Cancer

- Using other chemotherapy drugs to verify sensitivity:
  - 1589/1599 (99.4%) patients who got cisplatin correctly identified as having cancer
  - 1986/2133 (93.1%) patients who got fluorouracil (5FU) correctly identified as having cancer
  - 2351/2366 (99.4%) who got carboplatin correctly identified as having cancer
  - 107/112 (95.5%) who got abiraterone correctly identified as having cancer
  - 2217/2222 (99.8%) who got docetaxel correctly identified as having cancer
Phenotyping and Validation of Cancer Diagnoses: Any Cancer

- PPV 95.9% from manual review
- Sensitivity 99% using doxorubicin exposure
- Specificity (calculated): 99.87%
Phenotyping and Validation of Cancer Diagnoses: Next Step

- Chose 4 specific cancers for in-depth review
- Represent a variety of malignancies
  - Solid tumor vs hematologic
  - Aggressive vs indolent
  - Adult vs Pediatric
- AML
- CLL
- Pancreatic Cancer
- Prostate cancer
Phenotyping and Validation of Cancer Diagnoses: AML

- SNOMED codes => OMOP condition concept_id's
  - SNOMED: 91861009; Acute myeloid leukemia, disease (disorder)
  - Condition concept_id: 140352

- CUMC stats:
  - 2619 unique patients with AML
  - 95,875 condition occurrences of AML
Phenotyping and Validation of Cancer Diagnoses: AML

- Validation: random selection of 100 patients for chart review; manually reviewed first 51
- 50/51 had cancer
- 36/51 confirmed as AML (large portion was ALL incorrectly coded)
- PPV: 70.6%
Phenotyping and Validation of Cancer Diagnoses: AML

- Validation—Using Columbia’s cancer registry as gold standard for sensitivity
  - Identify whether pts in registry with AML are identified using our phenotype => obtain false negative rate
- 190 patients in registry with morphotype of 9861/3 (ICD-O 9861/3--Acute myeloid leukemia, NOS)
- 184 found in CUMC_pending using SNOMED code/phenotype above
- **Sensitivity: 96.8%**
- Based on prevalence of .001,
- **Specificity: 99.9%**
Phenotyping and Validation of Cancer Diagnoses: CLL

- SNOMED codes => OMOP condition concept_id’s
  - SNOMED: 92814006 ; Chronic lymphoid leukemia
  - Condition concept_id: 138379

- CUMC stats:
  - 3354 unique patients with CLL
  - 114,991 condition occurrences of CLL
Phenotyping and Validation of Cancer Diagnoses: CLL

- Validation: random selection of 90 patients for manual review
- 70/90 confirmed as CLL
- **PPV: 77.8%**

If addition of RxNorm codes in addition to SNOMED code to identify CLL patients:
- 397 unique patients identified using this method
  - Sampled 32 patients (~8% of identified patients in total), 30 of whom were confirmed in source data to have CLL
  - **PPV of 93.75%**
Phenotyping and Validation of Cancer Diagnoses: CLL

- Validation—Using cancer registry as gold standard for sensitivity
- 421 patients in registry with morphotype of 9823/3 (9823/3 Chronic lymphocytic leukemia/small lymphocytic lymphoma)
- 403 found in CUMC_pending using SNOMED code/phenotype from earlier
- Sensitivity: 95.7%
- Based on prevalence of .00135,
- Specificity: 99.9%
Phenotyping and Validation of Cancer Diagnoses: Pancreatic Cancer

- SNOMED codes => OMOP condition concept_id's
  - SNOMED: 126859007; Neoplasm of pancreas
  - Condition concept_id: 4129886

- Exclude:
  - Benign neoplasm of pancreas SNOMED 92264007 (concept_id: 4243445)
  - Benign tumor of exocrine pancreas SNOMED 271956003 (concept_id: 4156048)

- CUMC stats:
  - 10,241 unique patients with pancreatic cancer
  - 199,988 condition occurrences of pancreatic cancer
Phenotyping and Validation of Cancer Diagnoses: Pancreatic Cancer

- Validation: random selection of 100 patients for chart review; manually reviewed first 50
- 50/50 had cancer
- 44/50 confirmed as pancreatic cancer (5 incorrectly diagnosed; 1 unclear because dx was in 1993)
- PPV: 88%
Phenotyping and Validation of Cancer Diagnoses: Pancreatic Cancer

- 1206 patients in registry with morphotype of 8140/3 (Adenocarcinoma) and primary site of C25.* (Pancreas)
- 1194 found in CUMC_pending using SNOMED code/phenotype above

- Sensitivity: 99.0%
- Based on prevalence of .004,
  - Specificity: 99.9%
Phenotyping and Validation of Cancer Diagnoses: Prostate Cancer

- SNOMED codes => OMOP condition concept_id’s
  - SNOMED: 399068003 ; Malignant tumor of prostate
  - Condition concept_id: 4163261

- Exclude:
  - Secondary malignant neoplasm of prostate, SNOMED 94503003 (concept_id=4314337)
  - Non-hogkin’s lymphoma of prostate, SNOMED 449318001 (concept_id=40486666)

- CUMC stats:
  - 37,157 unique patients with prostate cancer
  - 455,562 condition occurrences
Phenotyping and Validation of Cancer Diagnoses: Prostate Cancer

- Validation: random selection of 100 patients for chart review; manually reviewed first 50
- 48/50 had cancer (1 unclear as it was never biopsied, just suspected)
- 47/50 confirmed as prostate cancer
- PPV: 94%
Phenotyping and Validation of Cancer Diagnoses: Prostate Cancer

- Validation—Using cancer registry as gold standard for sensitivity
- 3803 patients in registry with morphotype of 8140/3 adenocarcinoma and primary site =C61.9 (would have been 4807 with just C61.9 for prostate)
- 3786 found in CUMC_pending using SNOMED code/phenotype above
- **Sensitivity:** 99.6%
- Based on prevalence of .015,
- **Specificity:** 99.9%
## Phenotyping and Validation of Cancer Diagnoses: Summary

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<th>Sensitivity</th>
<th>Specificity</th>
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<td>Prostate</td>
<td>94.0%</td>
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<td>99.9%</td>
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</table>
Phenotyping and Validation of Cancer Diagnoses

- What we learned

- Overall, feasible to accurately create phenotypes for subsets of cancer diagnoses and validate against chart and cancer registries
- Errors in coding can lead to lower PPV
  - AML miscoded as ALL or vice versa
  - Hematologic malignancies more likely to be miscoded
  - However, due to low prevalence, still high specificity and sensitivity
- Later dates/recent data are more reliable and accurate for coding
Aim 2: Phenotyping and Validation of Cancer Treatments

Chemotherapy, hormone therapy, immunotherapy, radiation therapy, and procedures

How good is the data?
Phenotyping and Validation of Cancer Treatments: Chemotherapy

- Utilized WHO-ATC list of antineoplastic agents (L01)
- WHO: ATC list of Antineoplastic agents
  - 163 RxNorm codes
  - 162 concept_id's found from these RxNorm codes in CUMC (missing inotuzumab ozogamicin, 1942950)

- 536,082 drug exposures to 162 RxNorm codes found in CUMC
- Significant proportion included celecoxib and tretinoin
  - Excluded celecoxib as antineoplastic benefit not an indication and still being proven
  - Can tailor future studies to include/exclude tretinoin to improve accuracy, depending on whether it is used for the cancer of interest
Phenotyping and Validation of Cancer Treatments: Chemotherapy

- Validation: random selection of 100 patients for chart review; manually reviewed first 50 (if available in inpatient EMR)
- 50/50 received the drug at the time specified (correct drug exposure)
- 41/50 received drug for cancer
- PPV: 100% for drug exposure; 82% as chemotherapy for cancer
Phenotyping and Validation of Cancer Treatments: Hormone therapy

- Utilized WHO-ATC list for Endocrine therapy (L02) under ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS (265)
- 27 RxNorm codes/drugs
- 27 concept_id's found in CUMC
- Limitations: includes estradiol in OCPs, medroxyprogesterone (depoprovera)
- Excluding estradiol and medoxyprogesterone:
  - 123012 drug exposures to hormone therapy
  - 20462 unique patients
Phenotyping and Validation of Cancer Treatments: Hormone therapy

- Validation: random selection of 100 patients for chart review; manually reviewed first 50 (in inpatient EMR)
- 49/50 received the drug specified
- 43/50 patients received the drug at the correct date/time listed in database
  - Most of discrepancies due to recording of med rec as exposure (will be fixed)
- 42/50 patients received the drug specified for cancer treatment
  - Megestrol was the primary medication identified not used for cancer
- PPV: 98% for receiving the drug documented; 84% for receiving the drug as cancer therapy
Phenotyping and Validation of Cancer Treatments: Immune therapy

- WHO-ATC list; L01 Antineoplastic Agents
  - L01X Other Antineoplastic Agents
    - L01XC Monoclonal Antibodies

- 23 concept_id’s found from these RxNorm codes in CUMC
- 36,285 drug exposures
- 4,531 patients
Phenotyping and Validation of Cancer Treatments: Immune therapy

- Validation: random selection of 100 patients for chart review; manually reviewed first 50 (in inpatient EMR)
- 50/50 received the drug specified
- 49/50 received drug at the time specified
  - Because IV medications/infusions and considered chemo, generally great documentation; only wrong time was for old chart
- 47/50 patients received the drug specified for cancer treatment
  - All exceptions due to Rituximab; only drug used for non-cancer treatments
- PPV: 100% for receiving the drug documented; 94% for receiving the drug as cancer therapy
Phenotyping and Validation of Cancer Treatments: Drug therapies

- What we learned
  - Most of observational EHR data/OMOP accurately identifies drug exposures
  - No currently curated list is perfect
    - Non-cancer related chemotherapy identified often for rheumatologic or other hematologic disorders: RA, sickle cell, polycythemia
    - Hormone therapy: Megace; Immunotherapy: rituximab
  - Adding more criteria to phenotypes further improves accuracy (add cancer as condition to reduce false positives)
  - Limitation: do not yet have access to outpatient EMR; may find more drugs used for non-chemotherapy purposes there
Phenotyping and Validation of Cancer Treatments: Radiation Therapy

- List of procedure codes (CPT4, ICD9Proc, HCPCS, Revenue codes) from NCI Cancer Research Network
- 266 codes total
- 190755 procedure exposures in CUMC_merged (all through CPT4 or ICD9Proc)
- 19,950 unique patients
Phenotyping and Validation of Cancer Treatments: Radiation Therapy

- Validation: random selection of 100 patients for chart review; manually reviewed first 50 (if in inpatient EMR)
- 49/50 patients had cancer (1 unknown; from 1989), despite no cancer condition codes
- 43/50 patients received RT ever; 2/50 clearly did not (wrongly coded); 5/50 patients unknown (lack of inpatient chart data)
- 11/18 with clear inpatient dates of administration received RT on the exact date specified by the procedure code
- PPV: 86% for receiving RT
Phenotyping and Validation of Cancer Treatments: Radiation Therapy

- **What we learned**
  - Overall, can effectively identify patients receiving RT using procedure codes
  - Dates may not be exact, sometimes date of note does not reflect date of procedure
  - Dates better aligned, improved documentation in recent years
  - RT frequently outpatient only
  - Current code sets can be modified to improve/adjust PPV, sensitivity, specificity (i.e., removing planning codes from NCI)
Phenotyping and Validation of Cancer Treatments: Registry

- As with diagnoses, used local NAACCR tumor registry as gold standard to determine sensitivity
- Registry treatments coded based on SEER*Rx categorization of medications
- Our phenotypes categorized treatments based on codes from WHO-ATC (for medications) and NCI Cancer Research Network (for RT)
- Often dramatic differences in code list
  - NAACCR registry and SEER*Rx include clinical trial/experimental drugs
    - For future studies, may be feasible to use NLP to extract from clinician notes if available
  - SEER*Rx always the larger code set
  - But only drug name, no mappings to any standardized vocabularies
  - For example, immunotherapy-27 codes in WHO-ATC; 2490 drugs in SEER*Rx
Phenotyping and Validation of Cancer Treatments: Registry

- **Chemotherapy**
- 162 RxNorm codes/drugs in our phenotype based on WHO-ATC
- 5066 drugs in SEER*Rx drug list
- Using RxDateChemo field in NAACCR Registry, determined if patient ever received chemotherapy
- 8476/12392 patients from registry also found based on WHO-ATC codes and current phenotype
  - Sensitivity: 68.4%
Phenotyping and Validation of Cancer Treatments: Registry

- **Hormone therapy**
- 27 RxNorm codes/drugs in our phenotype based on WHO-ATC
- 1460 drugs in SEER*Rx drug list
- Using RxDateHormone field in NAACCR Registry, determined if patient ever received hormone therapy
- 2863/5846 patients from registry also found based on WHO-ATC codes and current phenotype
  - Sensitivity: 49.0%
Phenotyping and Validation of Cancer Treatments: Registry

- **Immunotherapy**
- 23 RxNorm codes/drugs in our phenotype based on WHO-ATC
- 2429 drugs in SEER*Rx drug list for ‘Biologic therapy (BRM, immunotherapy)
- Using RxDateBRM field in NAACCR Registry, determined if patient ever received biologic therapy (not specific for immunotherapy)
- 232/1466 patients from registry also found based on WHO-ATC codes and current phenotype
  - Sensitivity: 15.8%
- Then redefined phenotype to use broader set of WHO-ATC does
- 735/1466 patients from registry found using new phenotype
  - Sensitivity: 50.1%
Phenotyping and Validation of Cancer Treatments: Registry

- **Radiation therapy**
  - Using RxDateRadiation field in NAACCR Registry, determined if patient ever received radiation therapy
  - 5081/7539 patients from registry also found based on current phenotype of procedure/revenue codes
    - Sensitivity: 67.4%
Phenotyping and Validation of Cancer Treatments: Registry

<table>
<thead>
<tr>
<th>Treatment</th>
<th>PPV (from chart review)</th>
<th>Sensitivity (from registry)</th>
<th>Prevalence</th>
<th>Specificity</th>
</tr>
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<tr>
<td>Chemotherapy</td>
<td>100%</td>
<td>68.4%</td>
<td>0.23%</td>
<td>99.9%</td>
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<tr>
<td>Hormone therapy</td>
<td>98%</td>
<td>49.0%</td>
<td>0.11%</td>
<td>99.9%</td>
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<tr>
<td>Immuno-therapy</td>
<td>100%</td>
<td>15.8%/50.1%*</td>
<td>0.03%</td>
<td>99.9%</td>
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<tr>
<td>Radiation therapy</td>
<td>86%</td>
<td>67.4%</td>
<td>0.14%</td>
<td>99.9%</td>
</tr>
</tbody>
</table>

*Based on different phenotypes from narrow and broader code sets, respectively, from WHO-ATC
Phenotyping and Validation of Cancer Treatments: Registry

- What we learned

- Feasible to create phenotypes for various types of treatments for cancer but may require more modification and testing than diagnoses

- Sensitivity may vary widely depending on phenotype and code set used as ‘gold standard’
  - Low when only capturing a small subset of the coded treatments in gold standard (large discrepancy in number of codes between phenotype and registry)
  - Some drug and procedure codes may miss clinical trial/experimental drugs and treatments

- Sensitivity can be improved by modifying the created phenotype
  - i.e. broadening immunotherapy codes to better match registry improved sensitivity more than 4-fold

- Specificity remains high due to low prevalence
Aim 2: Characterizing Treatments over Time

One example of clinical characterization study

- Diagnoses
- Treatments
- Characterization
- The Future

What can we do with the data?
Prostatectomy codes:
- SNOMED 90470006 (concept_id=42357388)
- MedDRA 10061916 (concept_id=37521400)
- CPT: 2109825 (transurethral electrosurgical resection), 2110031 (perineal, partial resection), 2110032 (perineal, radical),
- 2110033 (perineal, radical, with lymph node biopsy), 2110034 (perineal, radical, with bilateral pelvic lymphadenectomy)
- 2110036 (retropubic, partial resection), 2110037 (retropubic, radical), 2110038 (retropubic, radical, with lymph node biopsy)
- 2110039 (retropubic, radical, with bilateral pelvic lymphadenectomy)
- ICD-10-CM PCS: 2805820 (excision), 2899589 (resection)
# Treatments over Time - Prostate Cancer

- **Prostatectomy**

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Treatments over Time-Prostate Cancer

- Radiation Therapy codes
  - where (vocabulary_id like 'CPT4' and procedure_source_value in ('0073T','0082T','0083T','0182T','0190T','0197T','19296','19297','19298','20555','20660','31463','32553','40109','49411','49412','52250','58589','58680','58785','58876','59220','57155','57156','58346','61720','61735','61770','61781','61782','61783','61793','61795','61796','61797','61798','61799','61800','63620','63621','73670','76950','76965','77014','77261','77262','77263','77285','77290','77295','77299','77300','77301','77305','77306','77310','77315','77321','77326','77327','77328','77329','77331','77332','77353','77354','77356','77357','77360','77361','77362','77363','77364','77365','77366','77367','77368','77369','77370','77371','77372','77373','77374','77375','77376','77377','77378','77379','77380','77381','77385','77386','77387','77389','77400','77401','77402','77403','77404','77405','77406','77407','77408','77409','77410','77411','77412','77413','77414','77415','77416','77417','77418','77419','77420','77421','77422','77423','77424','77425','77427','77430','77431','77432','77433','77434','77435','77469','77470','77499','77520','77522','77523','77525','77528','77529','77532','77533','77535','77536','77537','77538','77540','77541','77542','77543','77544','77545','77546','77547','77548','77549','77550','77551','77552','77553','77554','77555','77556','77557','77558','77559','77560','77561','77562','77563','77564','77565','77566','77567','77568','77569','77570','77571','77572','77573','77574','77575','77576','77577','77578','77579','77580','77581','77582','77583','77584','77585','77586','77587','77588','77589','77590','77591','77592','77593','77594','77595','77596','77597','77598','77599','79005','79030','79035','79100','79101','79200','79300','79400','79403','79420','79440','79444','79900','79999')) / **** CPT4 codes ****/
  - or (vocabulary_id like 'HCPCS' and procedure_source_value in ('A4650','A4655','A9699','C1715','C1716','C1717','C1718','C1719','C1720','C1728','C2616','C2633','C2634','C2635','C2636','C2637','C2638','C2639','C2640','C2641','C2642','C2643','C2698','C2699','C9726','C9728','G0173','G0174','G0242','G0245','G0251','G0338','G0339','G0340','G6003','G6004','G6005','G6006','G6007','G6008','G6009','G6010','G6011','G6012','G6013','G6014','G6015','G6016','Q3001','S2270','S8049','C1325','C1348','C1350','C1700','C1701','C1702','C1703','C1704','C1705','C1706','C1707','C1708','C1709','C1710','C1711','C1712','C1790','C1791','C1792','C1793','C1794','C1795','C1796','C1797','C1798','C1799','C1800','C1801','C1802','C1803','C1804','C1805','C1806','C2632','C9714','C9715','G0178','G0256','G0273','G0338','G0339','G0340','G0458','C2644','C2645')) / **** HCPCS codes (CUMC doesn't use) ****/
  - or (vocabulary_id like 'Revenue' and procedure_source_value in ('0333','0344')) / **** Revenue codes (CUMC doesn't use) ****/
Treatments over Time-Prostate Cancer

Radiation Therapy

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Treatments over Time-Prostate Cancer

- **Hormone Therapy codes**
  - **Adrogen Deprivation Therapies**
  - **LHRH agonists**
    - Goserelin, 1366310
    - Histrelin, 1366773
    - Leuprolide, 1351541
    - Triptorelin, 1343039
  - **LHRH agonists (as above) plus first generation antiandrogen**
    - LHRH agonist plus nilutamide, 1315286
    - LHRH agonist plus Flutamide, 1356461
    - LHRH agonist plus bicalutamide, 1344381
  - **LHRH agonist (as above) plus second generation antiandrogen**
    - LHRH agonist plus enzalutamide, 42900250
  - **LHRH antagonist**
    - Degarelix, 19058410–PROS11–PROS14
    - first and second generation antiandrogens (see above)
    - ketoconazole, 985708
    - ketoconazole plus hydrocortisone, 975125
    - PROS12–PROS14
      - abiraterone (40239056)
Treatments over Time—Prostate Cancer

- Hormone Therapy

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Treatments over Time-Prostate Cancer

- Chemotherapy codes
  - Cisplatin, 1397599
  - Carboplatin, 1344905
  - Docetaxel, 1315942
  - Etoposide, 1350504

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Number of Drug Exposures
Treatments over Time-CLL

- **Chemotherapy codes**
  - Chlorambucil, 1390051 chemotherapy
  - Ibrutinib, 44507848 tyrosine kinase inhibitor
  - Bendamustine, 19015523 chemotherapy
  - Fludarabine, 1395557 chemotherapy
  - Cyclophosphamide, 1310317 chemotherapy
  - Pentostatin, 19031224 chemotherapy
  - Idelalisib, 45776944 kinase inhibitor
  - Venetoclax, 35604205 chemotherapy
  - (SEER categorized kinase inhibitors as chemo)
### Treatments over Time-CLL

#### Chemotherapy

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Number of Drug Exposures over time.
Treatment over Time-CLL

- Immune therapy
  - Obinutuzumab, 44507676 immune therapy/antibody
  - Ofatumumab, 40167582 immune therapy/antibody
  - Rituximab, 1314273 immune therapy/antibody

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Treatment over Time-CLL

- Procedures
  - Stem Cell Transplantation, concept_id: 4120445

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Feasibility of Additional Clinical Questions/Topics

- Treatment Burden: How many different clinical care providers/specialties do patients see in the first year after cancer diagnosis? How many visits?
  - Visits, procedures are all feasible to characterize now
  - Provider data not currently part of our merged (inpatient + outpatient database) but will be available on next reload; currently outpatient database only
  - In querying other sites, provider data is available in most databases; feasible to run network study

![Outpatient visits/inpatient days over 1st year-All cancers](image)
Feasibility of Additional Clinical Questions/Topics

- Treatment Burden: How many different clinical care providers/specialties do patients see in the first year after cancer diagnosis? How many visits?

- Specialty data not consistently available but National Provider Identification (NPI) number often is
- Created Python tool to identify and extract provider information from National Plan and Provider Enumeration System (NPPES) registry
- Validated tool by comparing extracted taxonomy codes and specialty with specialty data from local credentialing system
- 3752/3838 (97.7%) physicians had existing and valid NPI number identifiable in NPPES from which corresponding taxonomy data was successfully extracted
- 3659/3752 (97.5%) concordance between taxonomy data extracted by tool and specialty ‘gold standard’ from credentialing system
Feasibility of Additional Clinical Questions/Topics

- Location data
  - For example: Where do Medicaid patients living in highly rural areas (e.g. counties with RUCC category codes of 7,8,9) receive their diagnostic services (e.g. imaging and laboratory facilities) and treatment (e.g. community oncology or academic oncology practices) and how far are these facilities from the patients.
  
  - Currently do not have location information but can easily input; patient location is part of local source data.

  - Inconsistent and vary widely across other OHDSI sites and databases
    - Some have zip code, some have region, some only classify urban vs rural.
OHDSI Oncology Working Group

What are we working toward for the future?
Thank You!
Questions?
OHDSI Oncology Working Group Challenges

- **Source data challenges**
  - In cancer registries, data are cleaned and abstracted, but limited in time and feature coverage. In Electronic Medical Records, oncology data are arguably the least structured type of data.

- **Modeling and terminology challenges**
  - In order to represent and reconcile these data in OMOP CDM, significant model, vocabulary, and convention extensions are required.

- **Analytical derivation of the key disease features challenge**
  - To identify treatment episodes and response to treatment, cancer recurrences and progression of disease, we need to build derivation methods and tools.
Identification and follow-up of patients with a certain disease phenotype
Identification of treatment regimen and response to treatment
Identification of recurrences and progression of disease
Prediction of recurrences, length of remissions, end of life events
Mapping of ICD-O to SNOMED to represent cancer diagnosis

- Extended OMOP vocabulary to support cancer diagnosis representation at the most granular level.
  - Extended SNOMED anatomy and morphology terminology to ensure direct mapping from ICD-O topography and histology respectively.
  - Extended pre-coordinated concepts representing intersection of anatomy and morphology to cover all SEER reported combinations of ICD-O histology and topography.

- Testing of new mappings is in progress at Columbia

Representation of cancer diagnostic features in OMOP

- Extended OMOP CDM to represent cancer occurrences and diagnostic features, like stage, grade, and others.
OHDSI Oncology Working Group

- OMOP vocabulary expanded to include mapping of ICD-O diagnoses to SNOMED
  - Extended SNOMED anatomy and morphology terminology
  - Direct mapping from ICD-O topography and histology to SNOMED
  - Covers all SEER reported combinations of ICD-O histology and topography

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<th>OMOP Morphology Concept ID</th>
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<td>Breast structure</td>
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</table>
OMOP vocabulary expanded to include mapping of ICD-O diagnoses to SNOMED
- Extended SNOMED anatomy and morphology terminology
- Direct mapping from ICD-O topography and histology to SNOMED
- Covers all SEER reported combinations of ICD-O histology and topography
OHDSI Oncology Working Group

- Representation of cancer diagnostic features in OMOP
  - Extended OMOP CDM to represent cancer occurrences and diagnostic features, like stage, grade, and others

- Goal is to represent cancer registries in OMOP CDM
  - Allow for as much coverage as is currently in registries at local, regional or national level
  - Important benefits of also having EHR data to provide greater breadth and longitudinal information about patients
  - Represent whole patient rather than cancer-centric view only
OMOP CDM Extension for Cancer Diagnosis

- **event_occurrence_id** is a reference to an event the modifier modifies, in this case `condition_occurrence_id` or `condition_era_id`.
- **event_concept_id** is a table an event is stored in, in this case ‘CONDITION_OCCURRENCE’ or ‘CONDITION_ERA’.
- **condition_era_recurrence_flag** (Y/N) indicates if an era record represents cancer first occurrence or recurrence.
- **condition_era_type_concept_id** identifies method of era derivation.
- **diagnostic_method_id** indicates how cancer diagnosis/diagnostic feature was diagnosed (e.g. pathology, symptomatically, record abstraction, etc.)
OHDSI Oncology Working Group - Next Steps/Future Work

- Treatment regimens: ongoing work additions to vocabulary and development of algorithms to derive treatment regimens
  - Feasible to execute studies on treatment regimen now if phenotype is developed and validated for each research study
  - i.e. for R-CHOP (drug exposure for Doxorubicin, Rituximab, Prednisone, Cyclophosphamide, Vincristine within 2 days)

- Pathology reports included in notes as text
  - Can utilize NLP to extract desired features
  - In addition to representing diagnostic data from registry

- Continue ongoing work re: validation of ICD-O vocabulary, building of NAACR/registry elements into OMOP, reconciliation of cancer diagnoses derived from Cancer Registry and EHR
Pathology Report-NLP example
Other Ongoing OHDSI/Federal Projects

- FDA (Food and Drug Administration) BEST (Biologics Effectiveness and Safety) Award for biologics with CBER -- Sentinel Initiative Center for Biologics Evaluation and Research
  - BEST Initiative: Blood and Blood Product Safety Surveillance
- Dr. Hripcsak’s R01 from NLM: Discovering and applying knowledge in clinical databases, LM006910--includes OHDSI supplement for vocabulary evaluation
- All of Us Research Program uses OMOP data model. Implemented by its Data and Research Center, Columbia is subcontractor (grant U2COD023196); From NHGRI.
- The eMERGE Consortium, funded by NHGRI, uses OMOP and provided a supplement to each of its 10 sites to implement OHDSI. (Grant U01HG008680)
Summary

- OHDSI/OMOP CDM can effectively identify patients with cancer as well as patients with specific diagnoses of cancer using SNOMED.

- Identify receipt of drug therapies with very high accuracy using basic RxNorm phenotypes.

- Procedures and timing, while already accurate, can be further enhanced by additions to the phenotype or curated code lists.

- Observational data represents opportunity to obtain more complete and longitudinal view of patients with cancer (vs cancer-centric view of registries).
Observational Health Data Sciences and Informatics (OHDSI.org)

Mission: To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care

- >200 collaborators from 25 different countries
- Experts in informatics, statistics, epidemiology, clinical sciences
- Active participation from academia, government, industry, providers
- Over a billion records on >400 million patients in 80 databases
• Open science is about sharing the journey to evidence generation
• Open-source software can be part of the journey, but it’s not a final destination
• Open processes can enhance the journey through improved reproducibility of research and expanded adoption of scientific best practices
How OHDSI works:
Data stay local, total open science

- Source data warehouse, with identifiable patient-level data
  ETL
- Standardized, de-identified patient-level database (OMOP CDM v5)
  ETL
- Standardized large-scale analytics
- Analysis results
- OHDSI Data Partners
- OHDSI Coordinating Center
  - Data network support
  - Analytics development and testing
  - Research and education
- OHDSI.org
OHDSI OMOP CDM: Deep information model with extensive vocabularies (80)
ATLAS to build, visualize, and analyze cohorts

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<td>X with age Between 18 and 55</td>
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<td>X with a gender of: FEMALE</td>
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<td>with observation at least 180 days prior and 365 days after index</td>
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For people matching the Primary Criteria, include:

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ATLAS to build, visualize, and analyze cohorts
Improving reproducibility through large scale research

Literature is severely biased and 85% positive with p-value hacking

OHDSI 11% of exposure-outcome pairs have calibrated p < 0.05

Schuemie, Phil Trans A 2018
Treatment pathway event flow

- >365 day of prior observation
- ≤0 exposures 365d before index
- INDEX: First exposure
- ≥1 exposure 121d-240d after index
- ≥1 exposure 241d-360d after index
- ≥1 exposure 361d-480d after index
- ≥1 exposure 481d-600d after index
- ≥1 exposure 601d-720d after index
- ≥1 exposure 721d-840d after index
- ≥1 exposure 841d-960d after index
- ≥1 exposure 961d-1080d after index

>1095 days of observation post-exposure

≥1 condition occurrence of disease of interest between all time prior to index and all time after index

≤0 condition occurrence of any excluded diseases between all time prior to index and all time after index
**FDA BEST-NLP Example**

---

**Correct Patient Identity:** Verified patient MR#, last and first name and verbal spelling of name.

**Correct Blood Component:** Donor# on blood bag to donor# on cross match and transfusion form/tag (see co-signature).

**Blood Warmer Used:** N/A

**Transfusion Start:**

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**Temperature Source:** Core Temp: PA Catheter  Core Temp: PA Catheter  Core Temp: PA Catheter

**Monitor:** BLOODT  BLOODT  BLOODT

**Heart Rate:** 90 90 90

**Rhythm:** Paced  Paced  Paced

**Respiratory Rate:** 0 0 0

**Respiratory Rate, Patient (bpm):** 23 16 14

**SpO2 (Pulse Ox):** 100 100

**Arterial Systolic:** 141 117 127

**Arterial Diastolic:** 60 54 61

**Arterial Mean:** 87 75 83

**Blood Glucose Monitor mg/dL ref range 74-118 mg/dL:** 145

**Activity:** Bed rest

**Positioning:** HOB 30 degrees; Turned/positioned; Left side

**RASS Sedation Scale (ICU only):** -1 Drowsy

---

**Transfusion End:**

| Date/Time       | 12-Dec-1985 10:45 |

**Post-Transfusion Assessment:**

**Transfusion Reaction (if yes, complete next section):** No

---

**Extracted Structured Data**

---

**FILE: transfusion_notes/TNW_5.txt**

- **transfusionStart:** 1905-12-12 09:45:00
- **transfusionEnd:** 1905-12-12 10:45:00
- **elapsedMinutes:** 60
- **reaction:** no
- **bloodProductOrdered:** packed red blood cells
- **dateTime:** 1905-12-12 09:45:00
- **timeDeltaMinutes:** 0
- **dryWeightKg:** 83.8
- **heightCm:** 179.3
- **temp:** 37.9
- **heartRate:** 90.0
- **respRateMachine:** 0.0
- **respRatePatient:** 23.0
- **arterialSystolic:** 141.0
- **arterialDiastolic:** 60.0
- **arterialMean:** 87.0
- **cvp:** 15.0
- **spO2:** 100.0
- **dateTime:** 1905-12-12 10:00:00
- **timeDeltaMinutes:** 15
- **dryWeightKg:** 83.8
- **heightCm:** 179.3
- **temp:** 37.9
- **heartRate:** 90.0
- **respRateMachine:** 0.0
- **respRatePatient:** 16.0
- **arterialSystolic:** 117.0
- **arterialDiastolic:** 54.0
- **arterialMean:** 75.0
- **cvp:** 15.0
- **spO2:** 100.0
- **dateTime:** 1905-12-12 10:45:00
- **timeDeltaMinutes:** 60
- **dryWeightKg:** 83.8
- **heightCm:** 179.3
- **temp:** 36.0
- **heartRate:** 90.0
- **respRateMachine:** 0.0
- **respRatePatient:** 14.0
- **arterialSystolic:** 127.0
- **arterialDiastolic:** 63.0
- **arterialMean:** 83.0

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Source Transfusion Nursing Note