OHDSI evidence in action

Personalized Oncological Surgery
The right treatment to the right patient at the right time

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²Odysseus Data Services, Inc, USA.

Presented by professor Ismail Gögenur, DMSc
Director of the Center for Surgical Science (CSS)
Center for Surgical Science
leading an international network of excellence for personalized oncological research

- State of the art research and everyday clinical practice based on multidisciplinary collaboration.
- Innovative surgical methods with significant impact on patients’ quality of life and treatment cost.
- Incorporating in its organizational structure the main scientific domains of CAG-POS:
  - Surgery
  - Epidemiology
  - Translational Research
  - Big data and personalized surgery

- Participating and leading national, European and international studies about clinical research and development.

- At CSS we emphasize on **personalized medicine being part of medicine** and has to follow the same GCP as any other medical field and
- Contribute our expertise in **multidisciplinary collaboration** to ensure the synergy between the different domains involved in personalized oncological research and lead an international network of excellence.

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3. most common cancer

- Incidence x 2 in 2030
- Mortality x 2 in 2030
Phenotype is essential for prognosis

More than 1 out 3 patients dependant / frail
CRC incidence in younger age groups!

- Increasing incidence < 50 years - 15% of CRC
- 67% increase from age 40 to 49
- Colon cancer increased 56%
- Rectal cancer increased 94%

More aggressive tumors!

Evidence is biased!

- 24 cancer drugs approved from 2007-2010

Scher and Hurria JCO 2012
Complications are common after surgery

N = 587 CRC surgery (2015-17)

- LOS Colon = 2 days
- LOS Rectum = 4 days

> 96 % MIS

33% of the total hospital budget is used on complications!

- 10% Reоперated
- 13% Readmitted
- 14% LOS > 14 days
- 25% Complications

Bennedsen et al Col Dis 2018

Goveart et al EJSO 2015

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Overtreatment in CRC surgery

Overtreatment?

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Cancer recurrence a huge challenge

Preoperative
25-35% Stage IV

Surgery
65-75% R0

Recovery

Recurrence
25-35% Recurrence <5 years

Long-term survival
Major recent progress in the understanding and treatment of patients with colorectal cancer needs to be integrated in a PERSONALIZED surgical approach.
Immune system in CRC

Galon et al. Science, 2006

Mlecnik et al. Journal of Clinical Oncology, 2011

Infiltration of lymphocytes is related to prognosis!
Immunotherapy has a major potential
Prehabilitation

Standard treatment

Prehabilitation
Stratified approach through risk assessment

Postoperative complication risk

Recurrence risk

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Patients like me
High quality and granularity of information leading to improved perioperative patient care?

Inputs
- Social, behavioral
- Genomics and -omic layers
- Biosensors
- Immune system
- Gut microbiome
- Anatom
- Environmental
- Physical activity, sleep, nutrition
- Medication, alcohol, drugs
- Labs, plasma DNA, RNA
- Family history
- Communication, speech
- Cognition, state of mind
- All medical history
- World’s medical literature, continually updated

Output

Virtual health guidance

Eric J. Topol Nat Med 2019
Creating a platform where both PHENOTYPIC and OMIC data contribute to improve healthcare services.
Research infrastructure

Clinicians

Translational Scientists

Data Scientists
Choosing data sources for the CDM

- **Biochemistry**: 27 lab measurements targeting cancer and adverse drug reactions
- **Anesthesia**: Detailed information for colorectal cancer operations
- **Microbiology**: Blood analysis results 180 days after surgery
- **Pathology**: Hospital admissions, procedures, and treatments during admission
- **Medication**: Prescriptions and administrations

**Colorectal Cancer**
Detailed description of all pathology aspects

**OpusMed**
**DCCG**
**DAD**
**MiBa**
**CPR**
**LPR**
**SKS**
**OpusMed**
**BEFUS**
**BC**
**BTH**
...
OHDSI PoC Skills

A wide range of skills and knowledge lead to a tight collaboration

- **Technical**
  - OMOP CDM ETL
    - Python, SQL, Postgres
  - OHDSI ATLAS
    - Java, SQL, R

- **Medical**
  - Colorectal Cancer Surgery
  - Local medical processes and patient data

- **OHDSI Standards and Data Analytics**
  - OMOP CDM
  - OMOP Standardized Vocabs
  - THEMIS
  - R and Statistics
  - OHDSI Methods (IR, PLE and PLP)
A few known challenges:

- Unfamiliar clinical data with unknown quality and data… What is DCCG? DAD? LPR?

- Danish registry uses Danish medical coding system (SKS), including for diagnosis, procedures, observations - needs custom mappings / vocabularies…

- Multiple data sources (DCCG, BigTempHealth) will be integrated and interlinked…

- 4 - 6 weeks to a completion of the POC

- Highest quality expected

<table>
<thead>
<tr>
<th>PoC study</th>
<th>Data-source name</th>
<th>Targeted data domain</th>
<th>Variables of interest (approximation)</th>
<th>Number of Records</th>
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<tr>
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<td>Danish National Patient Registry</td>
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</tbody>
</table>

A typical project of this type takes 3-4 calendar months w/ 4-5 FTE resources!!!
• ACHILLES database level characterization
• Vocabulary search
• Database level statistics (Achilles)
• Patient profile
• Cohort definitions
• Incidence Rate Analysis tool
• Population-level Estimation (PLE)
• Patient-level Prediction (PLP)
• TxPathways

CSS OHDSI Tool stack

- ATLAS / WebAPI
- ACHILLES

<table>
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<tr>
<th>Project</th>
<th>Data-exchange name</th>
<th>Targeted data domain</th>
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<td>The Danish NegTreatHealth population study</td>
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<td>200,000</td>
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</tbody>
</table>

Gregory Klebanov, CTO – VP, Odysseus Inc

gregory.klebanov@odysseusinc.com
OMOP CDM V5.3.1

CDM Version 5 Key Domains

- ATLAS 2.x only supports OMOP CDM 5.x
- OMOP CDM and vocabularies still have gaps in supporting rich oncology data
OHDSI ATLAS

- Supports complex cohorts building and analytical designs (Characterization, Prediction and Estimation) on OMOP CDM
- Execution of the analytics against local OMOP CDM data
- Installed at most of the OHDSI Network sites
- Enabled PLP/PLE execution from ATLAS with ARACHNE Execution Engine
- OHDSI Team work on making sure ATLAS 2.7.3 is a stable version
OHDSI Achilles (ATLAS Data Sources)

- Provides characterization, quality assessment and visualization of observational health databases.

- Used extensively during testing and for data validation
ATHENA

Allows search, navigation and distribution of the OMOP Standardized Vocabularies

• Used extensively during concept mapping process

Gregory Klebanov, CTO – VP, Odysseus Inc  gregory.klebanov@odysseusinc.com
2018 OHDSI PoC results

PoC completed in record times by mid-September, 2018

• OMOP CDM version 5.3 populated with Danish colorectal cancer data
• ~2,000 custom concepts created and mapped
• 13,500 total concepts mapped
• ATLAS 2.5.2 installed (upgraded to 2.7.3 in June 2019)
• Enabled ARACHNE Execution Engine to run PLE/PLP studies

Done!!!

Nope, it is just a beginning ....
Interesting Challenge #1

“Computed” Custom Concepts

To address research needs, we created a number of custom concepts that were computed.

“Neutrophil-to-Lymphocyte Ratio” = ratio of “Neurophils” and “Lympocytes”

Used for cohort creation as well as a covariate in PLP. Such concepts may be subject to further proposal for adding them into official vocabularies (like LOINC).

Opportunity (pros and cons):
Should it be an enhancement enhancement in ATLAS?
Or
should these be precomputed during the ETL CDM?
Interesting Challenge #2

Storing “Negative information” e.g. absence of off

“No diabetes mellitus”

Introduced a new approach storing all negative information in OBSERVATION table by mapping the source entities to ‘No evidence of’ (Maps to) and the entity itself (Maps to value, can be disorder, procedure, observation or any other domain).
Interesting Challenge #3

Storing rich Oncology data

Oncology data is complicated and sometimes obscure. The granularity of our datasets didn’t allow us to map it to the existing concepts without losing important aspects of disorders.

- neurofibrosarcoma, relapse
- malignant schwannoma, direct spread
- malignant schwannoma, uncertain whether primary or metastatic
- precursor B-lymphoblastic lymphoma / leukemia relapse [<1.1.04]
- T-cell chronic lymphocytic leukemia, relapsed
- Hodgkin lymphoma in incomplete remission

How to store cancer stages??

Opportunity:
- OMOP CDM Oncology Extension
- Richer oncology vocabularies
PoC Learnings

• Strict QA/QC and validation is a must

• Vocabulary mappings “done right” is critical. Agree on “mapping review and validation” process. And yes - there are sometimes errors and gaps in OHDSI Vocabularies too!

• Sometimes there is no “black and white” in mapping a concept. ~11% were wrong, ~35% with less granularity

• OHDSI components must be harmonized and up to date – it’s about a full stack e.g. OMOP CDM, ATLAS, Method Packages, latest vocabularies, R libraries /R

• Disciplined delivery approach and ongoing communication
Hackathons

7 sources: 1) colorectal cancer, 2) anesthesia, 3) pathology, 4) microbiology, 5) causes of death, 6) biochemistry, 7) in-hospital medication

13,683 concepts (54,761 patients)

4 months (March – June 2019)

12 Medical doctors + 2 Data scientists in two teams:
  • A great team of 12 MDs sweeping through the mapping files
  • A task-force of 6 MD with more experience in medicine and OMOP, finetuning and approving the corrections

46% improvements in mapping quality identified:
  • 11% concepts mapped completely wrong
  • 35% concepts mapped with granularity loss

73% of the erroneous mappings corrected
  • 76% of the wrong mappings corrected
  • 72% of the granularity loss retrieved
## Hackathons

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<td>Anastomosis technique: hand-stitched</td>
<td>Internal fixation using staple</td>
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### Tag 1

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<td>Hånsyet anastomose, ikke stapler</td>
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### Tag 2

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### Solution

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<td>Replace</td>
<td>new tag</td>
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</tbody>
</table>

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## Hackathons

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<td>Type of anastomosis</td>
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<td>New Comment</td>
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SKS: DC809A

Malignant cachexia

D = diagnosis

Danish extension

Pure ICD10 code

SKS: DC809A

Malignant cachexia

ICD10: C80.9

Malignant neoplasm, primary site unspecified

ICD10 description for C80.9 includes
- Cancer NOS
- Carcinoma NOS
- Malignancy NOS
- Malignant cachexia NOS
- Multiple cancer NOS

SNOMED-CT: 4149322

Primary malignant neoplasm of unknown site

SNOMED-CT: 134765

Cachexia

ICD10 description for C80.9 includes
- Cancer NOS
- Carcinoma NOS
- Malignancy NOS
- Malignant cachexia NOS
- Multiple cancer NOS
Patient X
• Gender: Female
• Age: 64
• Colon tumour
• Stage 2
• Is having a primary malignant neoplasm of unknown site. Colon tumour may be considered secondary condition.

≠

Patient X
• Gender: Female
• Age: 64
• Colon tumour
• Stage 2
• Experiencing discomfort and weight loss because (cachexia) of cancer
A network for excellence aiming to establish a research platform for *personalized medicine in surgery* through a collaboration between scientist and stakeholders in the clinical pathway of the surgical oncological patient in order to *reduce morbidity and increase cancer survival*.
One-week workshop in Personalized Oncological Surgery

June 2019
Kusadasi, Turkey

27 medical professionals + 7 data scientists + 7 days

EDUCATION - INFRASTRUCTURE - RESEARCH

Study design & cohort definition using ATLAS
Standardized population level estimations & patient level predictions
Validation of the PM infrastructure of CAG-POS
Clinical questions & hypotheses validation in real-time
4 + 1 research papers

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Penelopes, Ulysses’ and Hommers

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- Anna Ostropolets, Columbia University
- Alexander Davydov, Odysseus
- Andreas Rosen, Center for Surgical Science
- Betul Okutan, Center for Surgical Science
- Camilla Grube, Center for Surgical Science
- Dunja Kokotovic, Center for Surgical Science
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- Fatima Buzquurz, Center for Surgical Science
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- Iannis Drakos, Center for Surgical Science
- Ilya Pyatin, Odysseus
- Ismail Gögenur, Center for Surgical Science
- Johanne Gormsen, Center for Surgical Science
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- Rune Trangbæk, Center for Surgical Science
- Sofie Møller, Center for Surgical Science
- Thea Degett, Center for Surgical Science
- Tina Fransgård, Center for Surgical Science
- Ali Shaker, Center for Surgical Science
- Jawad Ahmad Zahid, Center for Surgical Science

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Study 1

Exposure to inhalation anesthesia and risk of mortality for patients undergoing surgery for colorectal cancer

Rune Petring Hasselager, MD¹, Andreas Weinberger Rosen, MD¹, Tina Fransgaard, MD, PhD¹, Mahdi Alamili, MD, PhD¹, Johanne Gormsen, BSc¹, Thea Helene Degett, MD, PhD¹, Nicolas Derian, PhD¹, Pavel Grafkin, MSc⁶, Peter Rijnbeek, PhD², Patrick Ryan, PhD³,⁴,⁵, Ismail Gögenur, MD, DMSc¹, Iannis Drakos, PhD¹

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⁵Janssen Pharmaceuticals, New Jersey, USA
⁶Odysseus Data Services Inc., Cambridge, Massachusetts, USA
Study 2

Prediction of 90-day mortality after colorectal cancer surgery through standardized perioperative data analysis

Rasmus Vogelsang MD¹, Rasmus Bojesen MD¹, Emma Hoelmich BMSc¹, Adile Orhan BMSc¹, Fatima Buzquurx BMSc¹, Luyi Cai BMSc¹, Camilla Grube BMSc¹, Jawad Zahid BMSc¹, Hans Raskov MD¹, Gregory Klebanov, MSC⁶, Iannis Drakos PhD¹, Nicolas Derian PhD¹, Patrick Ryan PhD³,⁴,⁵, Peter Rijnbeek PhD², Ismail Gögenur MD, DMSc¹

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⁵Janssen Pharmaceuticals, New Jersey, USA
⁶Odysseus Data Services Inc., Cambridge, Massachusetts, USA
Study 3

Data driven hypothesis generation using the OMOP Common Data Model

Andreas Rosen¹, Nicholas Derian, PhD¹, Anna Ostropolets, MSc⁶, Peter Rijnbeek, PhD², Patrick Ryan, PhD³,⁴,⁵, Ismail Gögenur, MD, DMSc¹, Iannis Drakos, PhD¹ & the Center for Surgical Science Consortium¹

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³Observational Health Data Sciences and Informatics (OHDSI), New York, New York, USA,
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⁵Janssen Pharmaceuticals, New Jersey, USA
⁶Odysseus Data Services Inc., Cambridge, Massachusetts, USA
Characterization of anemic and non-anemic colorectal cancer patients undergoing cancer surgery

Ali Abbas Shaker, MD\textsuperscript{1}, Rune Petring Hasselager, MD\textsuperscript{1}, Andreas Weinberger Rosen, MD\textsuperscript{1}, Tina Fransgaard, MD, PhD\textsuperscript{1}, Mahdi Alamili, MD, PhD\textsuperscript{1}, Johanne Gormsen, BSc\textsuperscript{1}, Thea Helene Degett, MD, PhD\textsuperscript{1}, Eldar Allakhverdiiev, MSc\textsuperscript{6}, Iannis Drakos, PhD\textsuperscript{1}, Peter Rijnbeek, PhD\textsuperscript{2}, Patrick Ryan, PhD\textsuperscript{3,4,5}, Ismail Gögenur, MD, DMSc\textsuperscript{1}, Nicolas Derian, PhD\textsuperscript{1}

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\textsuperscript{5}Janssen Pharmaceuticals, New Jersey, USA
\textsuperscript{6}Odysseus Data Services Inc., Cambridge, Massachusetts, USA
The patient pathway

- **Patient Data**
- **Patient Risk**
- **Model selection Result interface**
- **Decision aid Multidisciplinary team conference (MDT)**
- **Stratification**
  - PREHABILITATION
  - SURGICAL APPROACH
  - ONCOLOGICAL TREATMENT
  - OTHER
  - NO TREATMENT

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**Critical phases of the patient journey**

**PREOPERATIVE (OUTPATIENT) PHASE**
- MDT
- Stratified preoperative treatment

**SURGERY**
- Anastomosis Yes/No
- Extended resection
- Damage control surgery
- FLUORESCENCE-BASED INFO, VITALS ETC.

**POSTOPERATIVE DISCHARGE**
- ALL ACCUMULATED DATA & POSTOP EVENT DATA
- Prolonged stay
- Intensified follow-up
- Adjuvant oncological treatment

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The best OHDSI slide ever!
Loosing a bet on the OHDSI journey!

Professor Ismail Gögenur, CSS, Zealand, Denmark

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The many faces of mapping!
The pleasures on the OHDSI journey!
Personalized Oncological Surgery
The right treatment to the right patient
at the right time

Thank you for your attention!

Presented by Prof. Ismail Gögenur, DMSc
Director of the Center for Surgical Science (CSS)