Hutch Integrated Data Repository and Archive (HIDRA)

Paul A. Fearn, MBA
Director, Biomedical Informatics
Fred Hutch Cancer Research Center

October 23, 2014
HIDRA

• Vision and Strategy
• Systems & Requirements
• Program Overview
• Argos user interface
• Next steps
Hutch Integrated Data Repository & Archive (HIDRA)

Strategic Drivers

Catalyzing our efforts to build strength in clinical molecular diagnostics and precision oncology
- FHCRC “Center News”, 4/1/13

Contribute to building a strong Fred Hutchinson / University of Washington Cancer Consortium [translational research] program
- Center Strategic Plan 2010-2015

Strengthening the Consortium's clinical research programs and infrastructure to permit more rapid development of diagnostics and therapeutics
- Senior Leadership, Cancer Consortium, RE: areas that require continuing resource commitment

Need an integrated database approach and a Consortium-wide informatics platform strategy
- CCSG Reviewers, 2008
Vision for HIDRA Data Integration Scope & Axes
Master Indexes of Consortium Patients, Specimens, Studies and Assays

HIDRA

Outcomes
Clinical Data
Subjects

Assays
Specimens

Studies

Molecular Profile / Biomarker
Sequence, SNP, Gene or Protein ID
PI and Study Staff
Consent / Restrictions
Sample Type
Sample Annotation

PI and Study Staff
Consent / Restrictions

HIDRA LabKey User Conference– 10/23/2014
HIDRA Goals
Rapid-Learning Informatics Platform for Competitive NCI CCC

• Enable us to learn from every patient who comes through the door, and integrate that knowledge back into the clinical care
  – Use of clinical data for research, activities preparatory to research, healthcare operations, QI/QA, and public health reporting purposes

• Integrate
  – Integrate data and systems across all disease groups
  – Link specimen, genomic and other assay data with clinical data
  – Integrate security/permissions with Consortium CTMS

• Automate or facilitate manual, repetitive work
  – Manual data abstraction, feeds and NLP from medical records
  – Outcomes data (e.g. CSS, long-term follow-up and patient reported)

• Strong competitive platform
  – Be ready for FISMA security or FDA regulatory reviews or audits
HIDRA

• Vision and Strategy
• **Systems & Requirements**
• Program Overview
• Argos user interface
• Next steps
Pre-HIDRA Informatics Ecosystem at Fred Hutch
Consortium Data Flows before HIDRA Core

UW

PUMA
Sunquest
EpicCare
MIND
Epic Cadence
ORCA
Epic ADT
Amalga
PowerPath
IDX

FHCRC
Cloverleaf
MINDMap

SCCA
Requisitions DB
LabVision
LabWare

Gateway

PATS

FYI
Consents

CODI

CBR
Hemebase

Caisis Breast
Caisis GU
Caisis ...

Data Abstractors

Seattle Children’s

CSS

hi7 (ADT. Labs)
file (appts)
consents

cdr-xml
enrollment
documents

sql (appts)

sql
NLP Requirements Analysis

We condensed over 14,000 existing and desired fields from 13 different disease groups into just under 4,000 individual elements

• 65% of data elements come from unstructured sources

  (this estimate was made assuming that patients are diagnosed and receive all of their treatment within the consortium)

• 15% of data elements could be patient reported

  (about 75% of these elements are currently coming from unstructured sources)

• 15% of data elements are computed from other elements
HIDRA

- Vision and Strategy
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- Program Overview
- Argos user interface
- Next steps
Legal and IRB framework

<table>
<thead>
<tr>
<th>Use</th>
<th>Terms*</th>
</tr>
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<tr>
<td>Healthcare Operations</td>
<td>Approved role or project</td>
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<tr>
<td>QI/QA</td>
<td>CQIP Approval</td>
</tr>
<tr>
<td>Research with Consent / Authorization</td>
<td>IRB Approval + minimal PHI constraints</td>
</tr>
<tr>
<td>Research with Waiver of Consent / Authorization</td>
<td>IRB Approval + minimal PHI constraints</td>
</tr>
<tr>
<td>Activities Preparatory to Research</td>
<td>IRB Approval + minimal PHI constraints</td>
</tr>
<tr>
<td>Approved** Partners or Uses (e.g. LabKey)</td>
<td></td>
</tr>
<tr>
<td>Public Health and Other Mandatory Reporting (e.g. CSS)</td>
<td></td>
</tr>
</tbody>
</table>

MOU/BAA: MOU/IRB

* Terms of use may vary by activity and level of PHI
** Approved in upstream BAAs

“Gate” regulating data flow
Past Work – Caisis @ MSKCC
1998 - present

What is Caisis?

Caisis is an open source, web-based cancer data management system that integrates research with patient care. The system promotes standards and collaborative research, and has been downloaded by thousands of institutions worldwide.

For over a decade, collaboration with multiple centers has allowed Caisis to develop and evolve in an environment of constant community input to shape the features, usability, and overall vision of creating large, clean, unbiased datasets that will improve care.
HIDRA Environment: Conceptual Diagram

**PHASE 2 HIDRA ENVIRONMENT:**
- Security
- Auditing
- Data
- LabKey UI
- Amalga V3 Compatibility

**Repositories:**
- Databases
  - UW CDR
  - SCH
  - CSS
  - Archive (Access, etc)

**Aligned Data From Multiple Sources**
(Caisis Data Structure)

**Gateway**

**Repository**

**Curated Cubes**
(i.e., reports, views into the data, etc)

**Applications**
- ARGOS

**Related Non-HIDRA Applications**
- CTMS
- Onco-scape
- Future App’s

FY15
FY16-17
A mammogram was obtained dated 01/28/12, which showed a mass in the right breast. On 02/10/12, she underwent an ultrasound-guided biopsy. The pathology showed an infiltrating ductal carcinoma Nottingham grade II. The tumor was ER positive, PR positive and HER-2/neu negative. On 02/22/12, she underwent a lumpectomy and sentinel lymph node biopsy. The pathology showed a 3.3 cm infiltrating ductal carcinoma grade I, one sentinel lymph node was negative. Therefore it was a T2, N0, M0 stage IIA breast cancer. Of note, at that time she was taking hormone replacement therapy and that was stopped. She underwent radiation treatment ending in May 2008. She then started on Arimidex, but unfortunately she did not tolerate the Arimidex and I changed her to Femara. She also did not tolerate the Femara and I changed it to tamoxifen. She did not tolerate the tamoxifen and therefore when I saw her on 11/23/12, she decided that she would take no further antiestrogen therapy. She met with me again on 02/22/13, and decided she wants to rechallenge herself with tamoxifen. When I saw her on 04/28/13, she was really doing quite well with tamoxifen. She tells me 2 weeks after that visit, she developed toxicity from the tamoxifen and therefore stopped it herself. She is not going take to any further tamoxifen.

Overall, she is feeling well. She has a good energy level and her ECOG performance status is 0. She denies any fevers, chills, or night sweats. No lymphadenopathy. No nausea or vomiting. No change in bowel or bladder habits.

CURRENT MEDICATIONS: Avapro 300 mg q.d., Pepcid q.d., Zyrtec p.r.n., and calcium q.d.
ALLERGIES: Sulfas, Betadine, and IV contrast.
HIDRA

- Vision and Strategy
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Select your Argos portal.

This sets your filter categories and more. You can change this any time by clicking the Argos logo.

By Disease Group

Brain
Since: Feb. 10, 2014

By Study

IRB 8234
Since: Feb. 10, 2014
Terms of Use

I AGREE to the terms of use for Coded/No PHI in Research Operations in the Brain group.

1. "Confidential Information" means Any data in HIDRA that is linked to or could be used to identify a patient or subject, including 1) electronic data feeds from UW Medicine, SCCA and Children's medical records (Exhibits B.1 and B.2 in HIDRA MOU); 2) other clinical data manually abstracted data from UW Medicine, SCCA and Children's medical records; 3) other clinical data from long-term follow-up that has been manually abstracted from medical records; 4) outcomes data from CSS; 5) data about associated specimens (e.g. from NW BioTrust); 6) data about associated studies (e.g. from CTMS); and 7) data about associated assays (e.g. molecular data associated with the Consortium patients and subjects in HIDRA).

2. I agree not to make use of, disseminate, disclose or in any way circulate any Confidential Information except as expressly permitted by this Confidentiality Pledge. Confidential Information may be published or otherwise disclosed in connection with the study entitled "Enrichment, Linkage and Secondary Use of Clinical, Biospecimen and Study Data from Hutch Integrated Data Repository and Archive (HIDRA)." (Institutional Review File #8234) provided, however, that no disclosure may be made which permits identification of any individual patient or the patient's physician unless permitted by applicable law and approved by an Institutional Review Board of FHCRC. Confidential Information may also be disclosed to other persons working on the Study who have signed a Confidentiality Pledge.

CANCEL OK
## Overall Patient Statistics

<table>
<thead>
<tr>
<th>Diagnoses</th>
<th>This Month</th>
<th>This Year</th>
<th>Total</th>
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<tr>
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<td>0</td>
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<tr>
<td>Ependymal Tumors</td>
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<td>0</td>
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<td>Gliomas</td>
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<tr>
<td>Procedures</td>
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<td>8</td>
<td>487</td>
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<td>Radiation Therapy</td>
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<tr>
<td>Meningothelial Tumors</td>
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<td>Metastatic Tumors</td>
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<td>Nerve Sheath Tumors</td>
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<td>Other</td>
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<td>Sellar Tumors</td>
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</table>

## My Links

- Saved Filter: MyFilter
- Saved Filter: study
- Saved Filter: new filter!
- Saved Filter: DemoMonday
- Saved Filter: Alex spence filter
- Saved Filter: Donald Born Pathology records
## Filter Patients

### by Demographics
- 3 genders, 11 races, 1 ethnicity, 10 ages, 10 ages at diagnosis, 7 years of survival, 10 ages at first surgery

### by Diagnostics / Imaging
- 4 types, 4 diseases, 21 results

### by Encounters
- 29 kps, 116 physicians, 10 heights, 32 weights, 12 bsas, 44 bmis

### by Medical Therapy
- 80 agents, 23 years, 13 routes, 45 cycles

### by Medication
- 0 types, 0 medications

### by Pathology
- 75 histologies, 29 secondary histologies, 744 specimen types, 70 sites, 9 sides, 12 institutions, 39 pathologists, 5 diseases, 14 grades, 35 test results

### by Procedures
- 67 procedures, 51 operating room details/institutions, 128 case surgeons, 31 years, 80 sites, 5 institutions, 7 services

### by Radiation Therapy
- 15 types, 6 diseases, 28 years, 163 sites, 4 isotopes, 163 targets, 80 physicians, 47 institutions
Filter Patients by Radiation Therapy

Types

- Brachytherapy: 22 (31)
- Conformal: 2 (15)
- External Beam: 184 (184)
- External Beam, 3D Conformal: 84 (84)
- External Beam, IMRT: 48 (48)
- GammaKnife: 0 (2)
- High-Dose Rate Brachytherapy: 1 (1)
- IMRT/VMAT: 6 (6)
- Neutron Beam Radiation Therapy: 0 (1)
- Proton Beam: 1 (9)
- Radiation Therapy, Unspecified: 5 (103)
- Stereotactic Radiosurgery: 111 (196)
- TOMO-IMRT: 0 (1)
- VMAT: 1 (1)
- Whole Brain Radiation: 0 (3)
Filter Patients by Demographics

<table>
<thead>
<tr>
<th>Genders</th>
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<tr>
<td>NULL</td>
<td>13 (533)</td>
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<tr>
<td>Female</td>
<td>123 (537)</td>
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<tr>
<td>Male</td>
<td>0 (665)</td>
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136 of 1,735 Patients
428 of 2,788 Specimens
11 of 26 Studies

ACTIVE FILTERS [clear all]
In Saved Group (none)

New Filters
Patients with
Radiation Therapy (Types): External Beam, 3D Conformal, External Beam, IMRT, IMRT/VMAT
Demographics (Genders): Female, NULL

SAVE FILTER SAVE FILTER AS
Patient Accrual (End Date 2012-09-15)
**Column Chooser**

<table>
<thead>
<tr>
<th>Source</th>
<th>Variables</th>
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<tr>
<td>Demographics</td>
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<td>Diagnostics</td>
<td>MedTxDate (year)</td>
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<tr>
<td>Encounters</td>
<td>MedTxStopDate (year)</td>
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<tr>
<td>Lab Tests</td>
<td>Protocol #</td>
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<tr>
<td>Medical Therapy</td>
<td>Route</td>
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<tr>
<td>Medications</td>
<td>Schedule</td>
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**Definition: Route**

Route for medical therapy
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<th>Coded Id</th>
<th>Lab Test</th>
<th>LabDate (year)</th>
<th>Result</th>
<th>MedTxDate (year)</th>
<th>Agent(s)</th>
<th>Route</th>
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<td>Orally</td>
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<th>LabDate (year)</th>
<th>Result</th>
<th>MedTxDate (year)</th>
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<th>Route</th>
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</thead>
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Displaying 101 – 200 of 326
### Filter Studies by Study Characteristic

<table>
<thead>
<tr>
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<tr>
<td>Celldex Therapeutics, Inc</td>
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<tr>
<td>Eastern Cooperative Oncology Group</td>
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<td>Gynecological Oncology Group</td>
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<tr>
<td>Medarex, Inc.</td>
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<td>Myriad Pharmaceuticals, Inc</td>
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<tr>
<td>Novacea, Inc.</td>
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<td>Omnicare Clinical Research</td>
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<td>Parexel, International</td>
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<td>Pharmaceutical Products Development, Inc.</td>
<td>1</td>
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<td>PPD, Inc</td>
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<td>Radiation Therapy Oncology Group</td>
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<tr>
<td>Southwest Oncology Group</td>
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</table>
Oncoscape

• Research and Innovation framework for rapid prototyping of features
• Candidate features for migration to Argos on LabKey Server (e.g. patient timelines graph)
a menu-driven, web-based, platform for exploration & analysis of multi-dimensional clinical data
Oncoscape

(version 1.1.30, 16 sep 2014)

This website is undergoing frequent modifications. Use at your own risk.

Note: Oncoscape works best with Chrome Version 37 or higher and a high resolution screen.

Features To Come...

- Saved Selections
- Interactive Kaplan Meier Plots
- Expression subtyping tool
- Expression correlation to TCGA samples using MDS
- Tool to find TCGA samples with similar mutational profiles
- Expression clustering and heatmaps
- Gene set enrichment analysis for user-selected groups
- Differential expression analysis for user-selected groups
- Hallmarks of Cancer

About Oncoscape

Oncoscape is developed at the Fred Hutchinson Cancer Research Center under the auspices of the Solid Tumor Translational Research Initiative. Oncoscape is a web-based, menu-driven analysis and visualization platform for large-scale, heterogeneous clinical and molecular patient timeline data as exemplified by the Fred Hutch HIDRA database.

Oncoscape was conceived, and is managed, by a Steering Committee comprising: Eric Holland, Desert Horse-Grant, Paul Fearn, Paul Shannon, Lisa McFerrin, and Hamid Bolouri.

Paul Shannon (lead) and Lisa McFerrin are the primary developers of Oncoscape, with additional code contributions by Cliff Rostomily and Hamid Bolouri.
**Mesenchymal**: 15/97 (15%)

**Proneural**: 5/54 (9%)

**G-CIMP**: 12/21 (57%)

**Classical**: 11/83 (13%)

**Neural**: 5/49 (10%)
Regulation of HGF expression by ΔEGFR-mediated c-Met activation in glioblastoma cells.

The hepatocyte growth factor receptor (c-Met) and a constitutively active mutant of the epidermal growth factor receptor (ΔEGFR/EGFRIII) are frequently overexpressed in glioblastoma (GBM) and promote tumorigenesis. The mechanisms underlying elevated hepatocyte growth factor (HGF) production in GBM are not understood. We found higher, coordinated mRNA expression levels of HGF and c-Met in monoclonal (M6) GBMs, a subtype associated with poor treatment response and shorter overall survival. In an HGF/c-Met-dependent GBM cell line, HGF expression declined upon silencing of c-Met using RNAi or by inhibiting its activity with SU11274. Silencing c-Met decreased anchorage-independent colony formation and increased the survival of mice bearing intracranial GBM xenografts. Consistent with these findings, c-Met activation by ΔEGFR also elevated HGF expression, and the inhibition of ΔEGFR with AG1478 reduced HGF levels. Interestingly, c-Met expression was required for ΔEGFR-mediated HGF production, anchorage-independent growth, and in vivo tumorigenicity, suggesting that these pathways are coupled. Using an unbiased, gene expression-based screen, we show that silencing c-Met and/or ΔEGFR downregulates several additional GBM markers, including HGF, and may represent a novel therapeutic target.
CHI3L1: A glycoprotein involved in inflammation & tissue remodeling marks low survival in 2 datasets.

Oncoscape using TCGA ‘unified’ microarray data (840 subtype classifier genes)

Oncoscape using MSKCC Nanostring data (137 genes)
<table>
<thead>
<tr>
<th>Gene symbol</th>
<th>Gene name</th>
<th>(Cox PH score)</th>
<th>Low risk Median</th>
<th>Mean</th>
<th>SD*</th>
<th>High risk Median</th>
<th>Mean</th>
<th>SD*</th>
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<td>3.409</td>
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<td>2.624</td>
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</tbody>
</table>

**Table 2.** Genes differentially expressed between MSKCC and TCGA long-term survivors versus TCGA patients with survival less than 1 year

<table>
<thead>
<tr>
<th>Gene Symbol</th>
<th>P value</th>
<th>Percent Change</th>
<th>Increase or Decrease in LTS vs. patients with survival &lt;1 year</th>
<th>Description</th>
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<tr>
<td>EFEMP2</td>
<td>0.000091</td>
<td>31.31</td>
<td>Decrease</td>
<td>EGF containing fibulin-like extracellular matrix protein 2</td>
</tr>
<tr>
<td>CHI3L1</td>
<td>0.004373</td>
<td>44.95</td>
<td>Decrease</td>
<td>chitinase 3-like 1 (cartilage glycoprotein-39)</td>
</tr>
</tbody>
</table>

*also significant in REMBRANDT data set.

*Neuro-Oncology 16(9), 1186–1195, 2014*
HIDRA

- Vision and Strategy
- Systems & Requirements
- Program Overview
- Argos user interface
- Next steps
HIDRA 2015

- Multiple disease portals
- NLP pipeline implementation
- Integrate data visualization features from Oncoscape
- Technical and operational rollout of use of PHI and data export
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