



Research Informatics at Duke

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Vice Dean for Research Informatics,
Duke Medicine

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2015



Topics

- Research Informatics at Duke, the Office of Research Informatics and our Programs
- Status update on Enterprise Data Management tools at Duke

Duke Medicine Facts and Figures



- 3 Integrated hospitals using a single instance of Epic 2012
 - Duke University Hospital 924 beds (live June 22nd 2013)
 - Duke Raleigh Hospital 186 beds (March 1st 2014)
 - Duke Regional Hospital 369 beds (March 1st 2014)
 - 16,318 employees
 - >7,000 simultaneous users of Epic (Epic's largest big bang go-live)
- Revenues \$2.54B, 1.2m outpatient visits
- 1,780 faculty and clinician scientists. 203 basic scientists (incl our first homegrown Nobel Laureate)

Clinical Research at Duke

- 2013 total research revenues - \$651m
- 2013 NIH funding \$284m - ranked 10th
- 2012 Industry funded research \$215m
- Duke Clinical Research Institute is the largest Academic CRO in the world with over 900 employees
- Duke is the Coordinating Center for PCORI, NIH Collaboratory Grants
- Our CTSA was renewed in 2013
- Duke School of Medicine Ranked 8th 2014.



Investigator Survey 2012 - Comments



“Maybe some or all of these things exist and I'm simply unaware of them. In any case, the way my lab currently deals with these needs is mom and pop - i.e., I try to do these things myself or we grapple around trying to find collaborators inside or outside of Duke who can help us.”

“Duke has so many great people and great resources that we are only capturing a small fraction of what our collective power could be. Imagine if groups of researchers, MDs and non-MDs, actually worked together like a focus group to solve a disease or a clinical problem, we could blow away what most pharmaceutical companies spend years trying to achieve.”

“Most of what I need is right here at Duke, the greater question is how do I access it and take advantage of it.”

Duke's Translational Research Vision



- **High-quality research** requires a nurturing academic environment with a pervasive culture of mentorship, continuous learning, and exchange of ideas.
- **Research and clinical practice**, linked by high-quality data, must power a **complementary cycle of continuous learning and improvement**
- Duke must catalyze a **measurable improvement in the health and healthcare of individuals and their communities**
- We must **link discovery science to a creative engine** that accelerates development of new technologies
- Research must be **continually evaluated for academic productivity, safety, efficiency, and cost.**
- We must create a **fabric of analyzable data of defensible provenance** and provide **tools that help researchers locate and use resources.**

Searching for a Set of New (More Specific) Goals for Informatics



- Significantly increase enrollment in research
- Significantly increase URM participation in research
- Improve the efficiency and cost effectiveness of research
- Reduce the institutional risk of research
- Maintain or improve SOM's academic ranking through a) increased share of NIH funding and b) increased funding success for faculty
- Introduce measures that improve research reproducibility
- Improve the availability and visibility of core shared research services
- Remove silos and barriers to collaboration
- Improve the quality and understanding of data in our source systems that support research
- Provide a robust infrastructure supporting research in terms of network, storage, statistical and informatics services.
- Provide an infrastructure that supports precision medicine

The Duke Office of Research Informatics

- DORI is an organization that spans The School of Medicine, the Clinical and Translational Science Award, DHTS and academic informatics to provide enterprise solutions for research
- “DORI is The Research informatics organization of the SOM and DHTS”
- Funded by all of the above. Currently 60FTE

DORI

DUKE OFFICE
OF RESEARCH
INFORMATICS

Mission of the Research IT and Informatics Organizational Structures



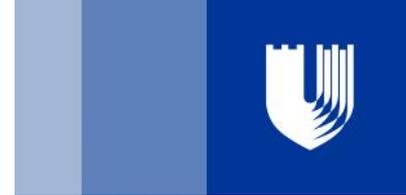
Mission of Duke Office of Research Informatics

“ To create and support the world’s leading research IT infrastructure, including a cohesive portfolio of useful and user-driven applications that realize the Integrated Research Home, as well as supporting the Learning Health and Personalized Health Visions of Duke Medicine”

Mission of Academic Research Informatics at Duke

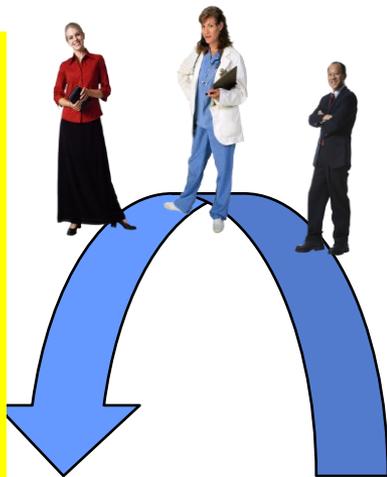
“To research, innovate, educate and publish the applications, methods and approaches that enhance the productivity of the research and clinical environments for subjects, faculty and staff, with the ultimate goal of improving health, and the experience of healthcare, for both patients and providers”

Research IT and Informatics: Organizational Vision

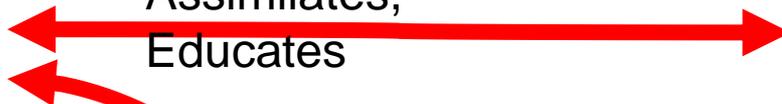


B&B/ DCHI

Build an academic informatics group to research the methods and systems that improve our research and clinical care environments



Disseminates,
Assimilates,
Educates



Champions, Innovates,
Publishes and provides
Mentorship.

DOCR

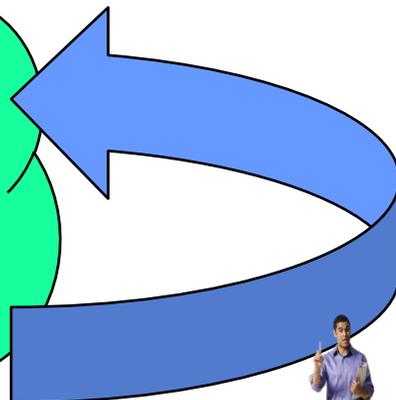
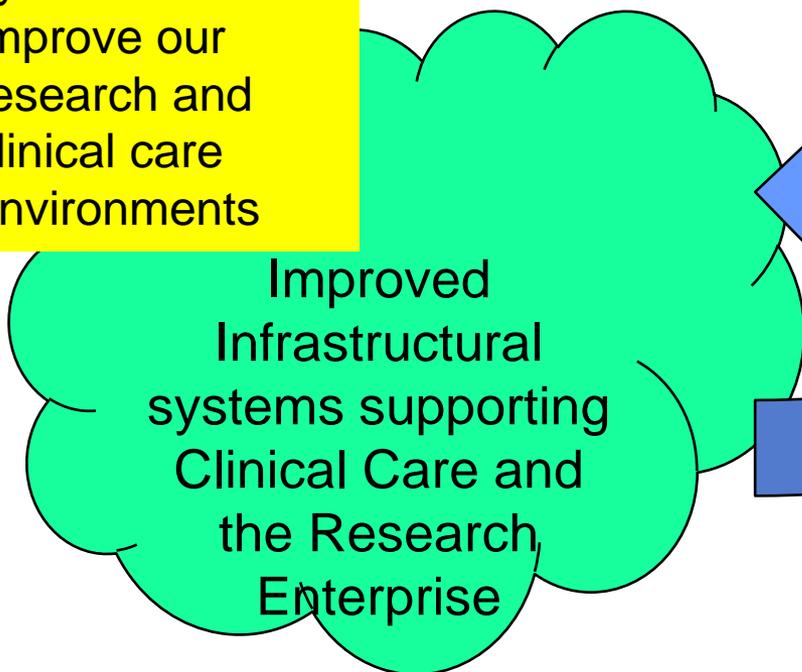
Provides services
to investigators

Materializes, Realizes,
Operationalizes and
Productizes



ORI

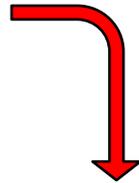
Build an effective
organization
group to build and
operate these
systems



Progress in Academic Research Informatics.



Department of
Biostatistics and
Bioinformatics
(B&B)



A new Division of Translational
Bioinformatics



Duke Center for Health
Informatics
(DCHI)

First 3 Faculty Hires –
Erich Huang, Meredith Nahm
Jessie Tenenbaum
Research interests: Applied
Genomics, Data Provenance,
Data Standards, Data Quality.
CTSA and SOM funding for more
faculty (up to 10).

First Educational Program:
Masters of Management and
Clinical Informatics transferred to
SOM under
B&B administration (MMCi)



- Translational Research Executive Committee (TREC)
 - SOM, Duke Health Technology Solutions and CTSA senior leadership
 - Governs Issues that involve both SOM and CTSA resources and funding
- Information Technology Integrated Operations Committee (ITIOC)
 - Duke Medicine senior leadership (SOM, DUHS)
 - Governs IT issues that cross-cut the clinical and research environments of Duke Medicine
- DTMI Executive Committee
 - CTSA Senior Leadership
 - Governs IT issues involving CTSA funding and resources.

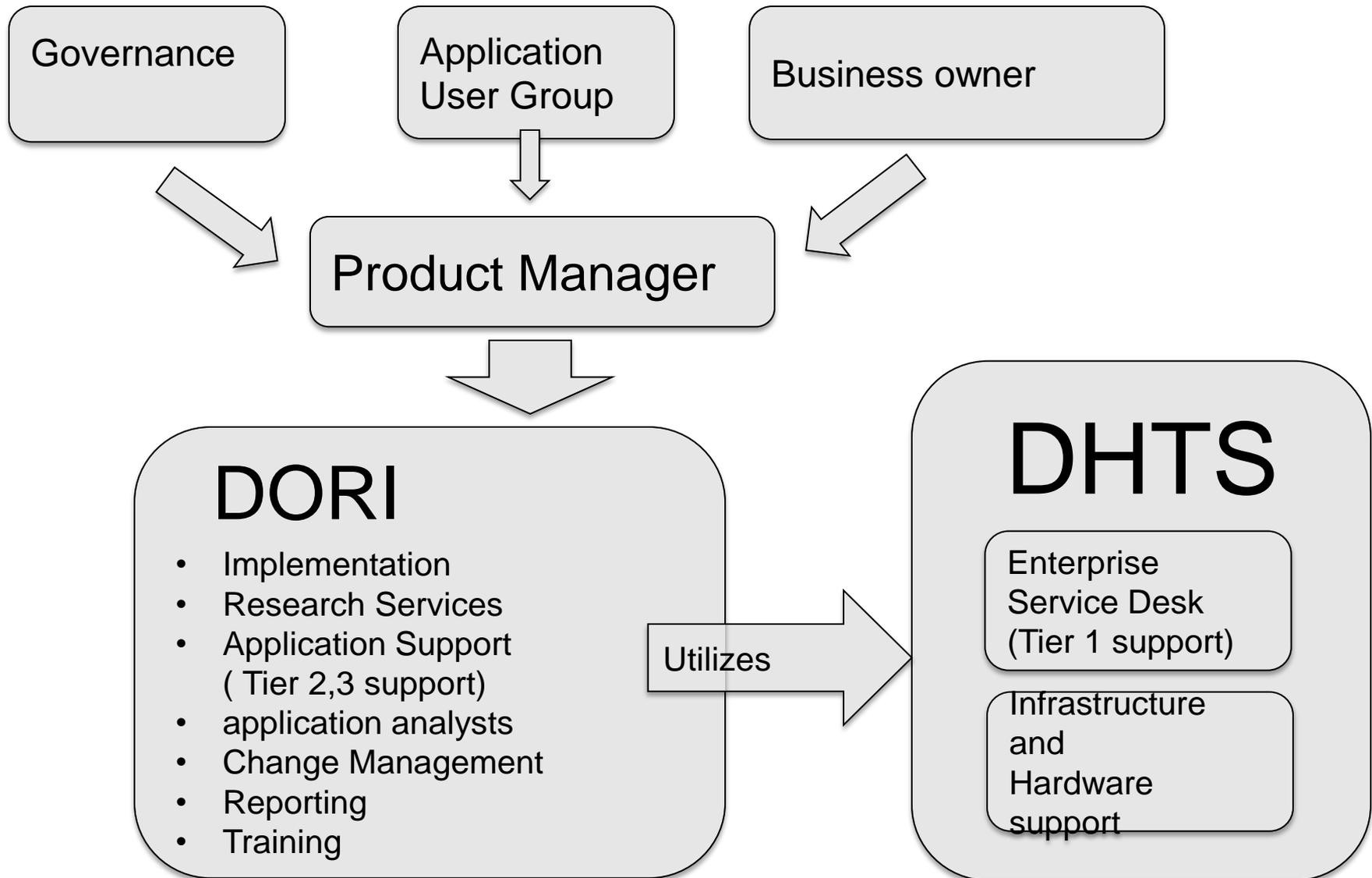
DORI Guiding Principles

- DORI should be customer focused and relevant in everything that we do
- DORI should be planned, accountable and able to deliver on its promises
- DORI should provide a pathway to IT innovation across Duke
- DORI will create delightful applications to foster brilliant research
- DORI will be technically cohesive, robust and secure, while fully aligned with the strategies and operations of DHTS, the SOM and our CTSA
- DORI will build on the talents and strengths of our people while maintaining good corporate citizenship and fiscal responsibility
- DORI will be a fun place to work

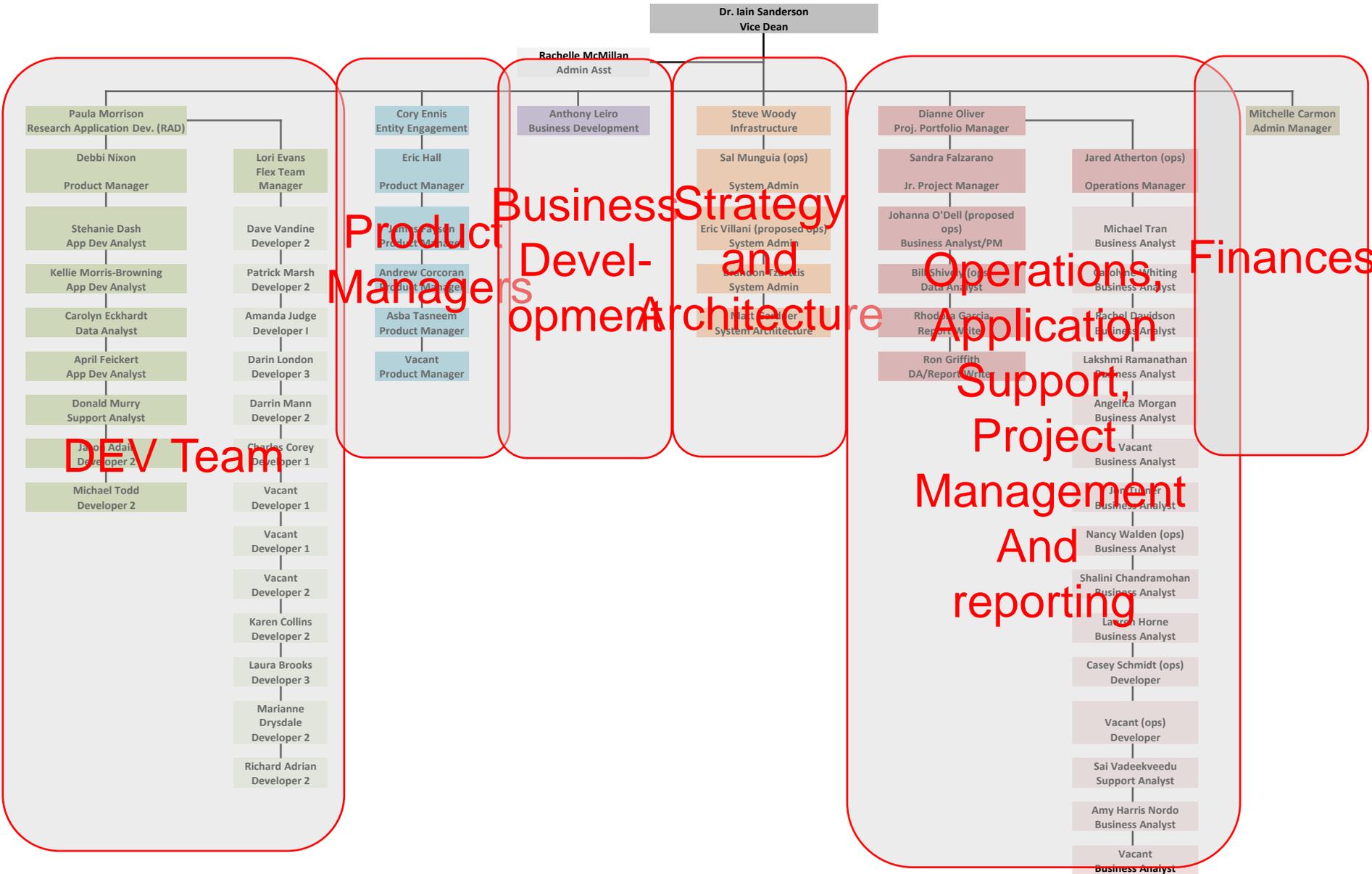
DORI

DUKE OFFICE
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INFORMATICS

Central Role of the Product Manager to Ensure User Centricity and Business Relevance



DORI – Org Structure 60 FTE



Our Collaborative Workspace



- Co-location of Duke Office of Research Informatics, Duke Office of Clinical Research (DOCR) and the Duke Center for Health Informatics in 24,000 sq ft of Hock Plaza on the main campus.



Programs to Support the Integrated Research Home (with 5 yr program funding and funding source)



Data Quality

- **Data Quality Program** – Data Governance, stewardship and meta-data management for the Data Warehouse. (CTSA funded and led \$2.3m)

Data Access

- **EDW for Research** – Enhanced use of the EDW for data delivery for research, mart generation, honest brokering, i2b2. (CTSA \$1.5m)
- **Research Management Data Mart** – A data mart for research administration in the EDW. (CTSA \$1.5m)
- **Analytics Workspace** – Virtualized analytics platform for management of PHI from the data warehouse. (DUHS \$2.9m)
- **Flexible Research Data System** – A high provenance data store with fingerprinting, meta-data tagging and provenance chain from data collection in the cores and labs to result generation and publication. (SOM reserve funding \$2.1m)

Our Research Informatics Programs (Continued 2)



Support for Site Based Research

- **Retrieve Form for Data Capture** – Surfacing a REDCap form in Epic and creating a service at scale. (CTSA direct- \$1.3m)
- **Investigator Portal MyResearchHome@Duke**– University wide portal for investigators. Our One-stop-shop. (CTSA direct \$2.1m)
- **Common Services Application** – Services, Pricing and Applications for Research Centers SPARC. Service catalog and Amazon shopping for proposal generation (CTSA direct \$2.1m)
- **Research Support Services**- an integrated service desk (one number to call), tier 2/3 support, field services, ORI, DOCR and research navigators via myResearchTeam@duke (DHTS, SOM and CTSA -\$?)

Our Research Informatics Programs (Continued 3)



Support for Site Based Research (Continued)

- **Maestro for Research.** Configuration of Epic to support research. Administrative workflow, split billing, ordersets, billing grids, BPA's, enrollment, MyChart. (DUHS \$1.8m)
- **Clinical Trials Management System** –Velos. (SOM \$1.6m)
- **Electronic IRB** – Huron Click (SOM \$2.3m)

CoreResearch@Duke

- **Biobanking** (SOM \$5.6m – IT only)
- **Cores Management** and Shared Resources storefront, booking and fulfillment (SOM \$1.8m – IT only)

University-wide, Research Administrative Programs (SOM \$6.7m)

- **Conflict of Interest, SPS** (Proposal workflow and generation, **grants.duke** (electronic submission to federal programs) and others.

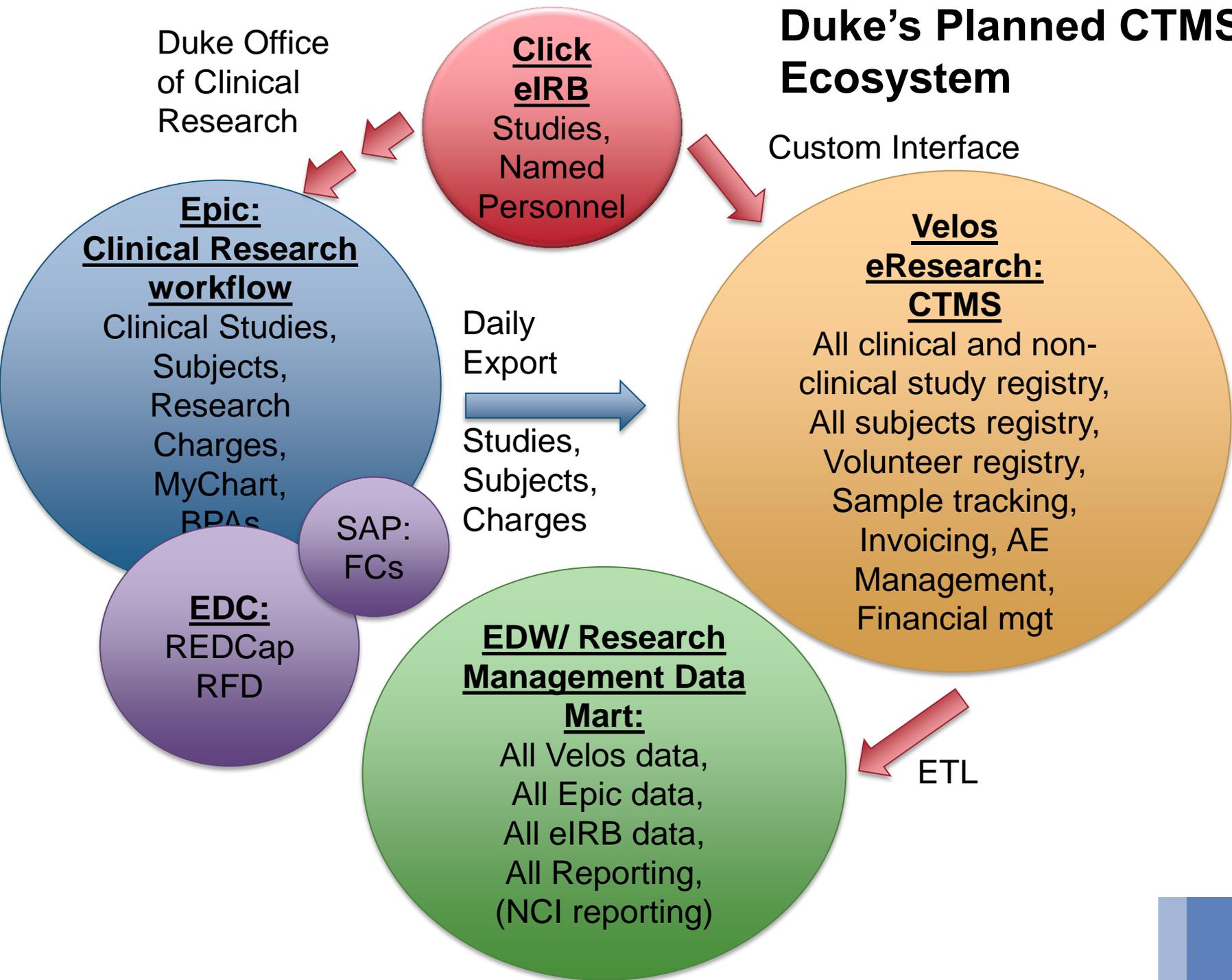
Our Research Informatics Programs (Continued 4)



Contributing to the Integrated Research Home

- **Scholars@Duke** – VIVO for Duke. networking and profiling for researchers. CV and integration with myResearchHome@duke (SOM \$0.8m)
- **Miscellaneous Apps** – Enabling apps for the research environment
 - MentorMe (\$65k CTSA)
 - Project Registry (\$60k SOM)
 - CTSA registration app
 - REDCap
- Others
 - **Animal Management System** – Edstrom. IACUC and DLAR (SOM \$0.9m)

Duke's Planned CTMS Ecosystem

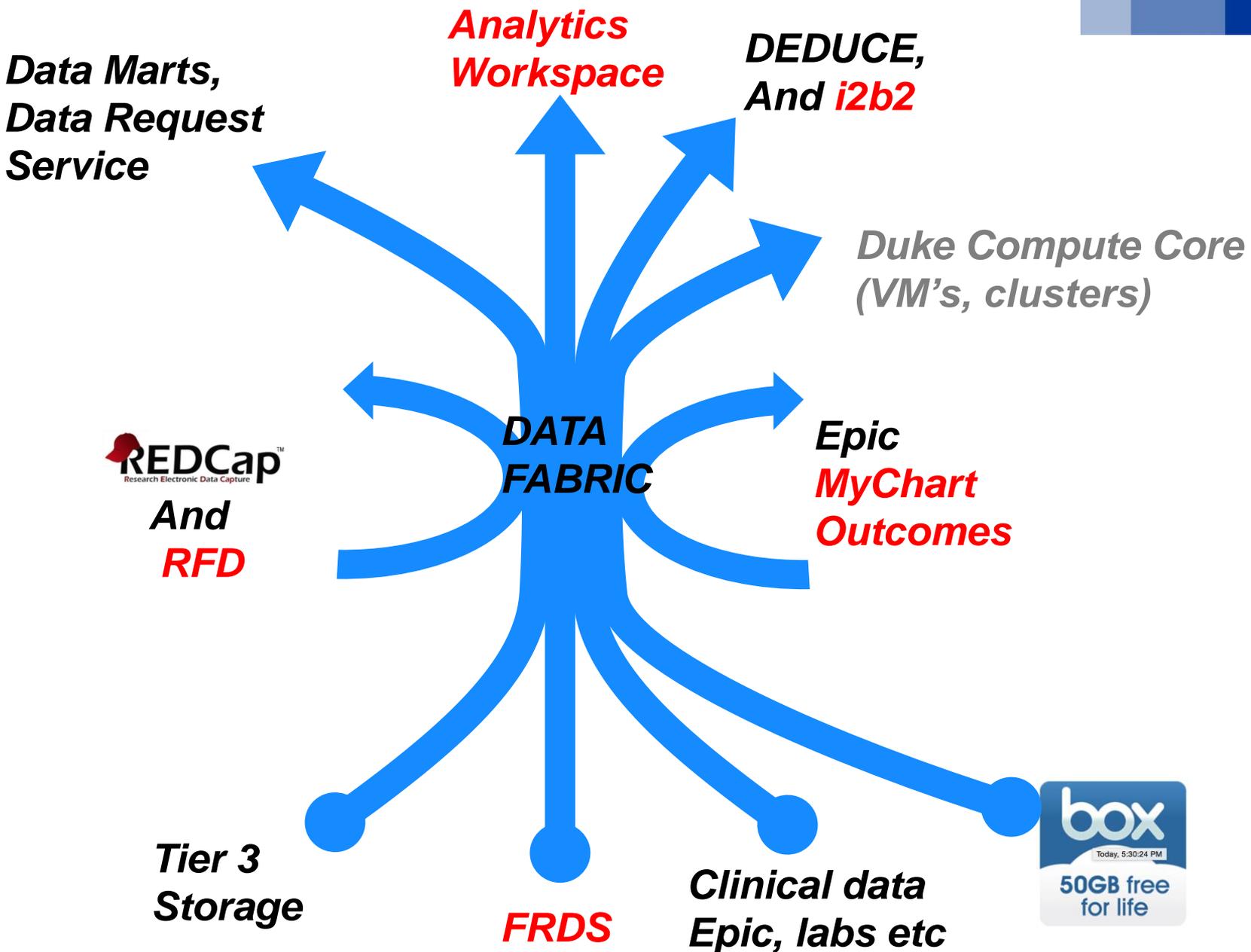




Wins and Opportunities of Significance

- **Epic configuration for Research** – National leadership
- **RFD and REDCap** – In collaboration with Hopkins and NYU.
- **Carolina's regional data sharing collaborative**
 - UNC, Duke, Wake and Health Sciences South Carolina with i2b2 and PopMedNet
- Our **Data Governance and Data Quality Program**
- Investigator portal - **MyResearchHome@Duke** - as a university-wide resource
- **Flexible Research Data Store/ Analytics Workspace**
- **CTSA/SOM integration.** Programmatic strategy. Service alignment with DOOCR and DHTS. 5 year funding.
- Duke's key role in the **Carolina's Collaborative and PCORI**

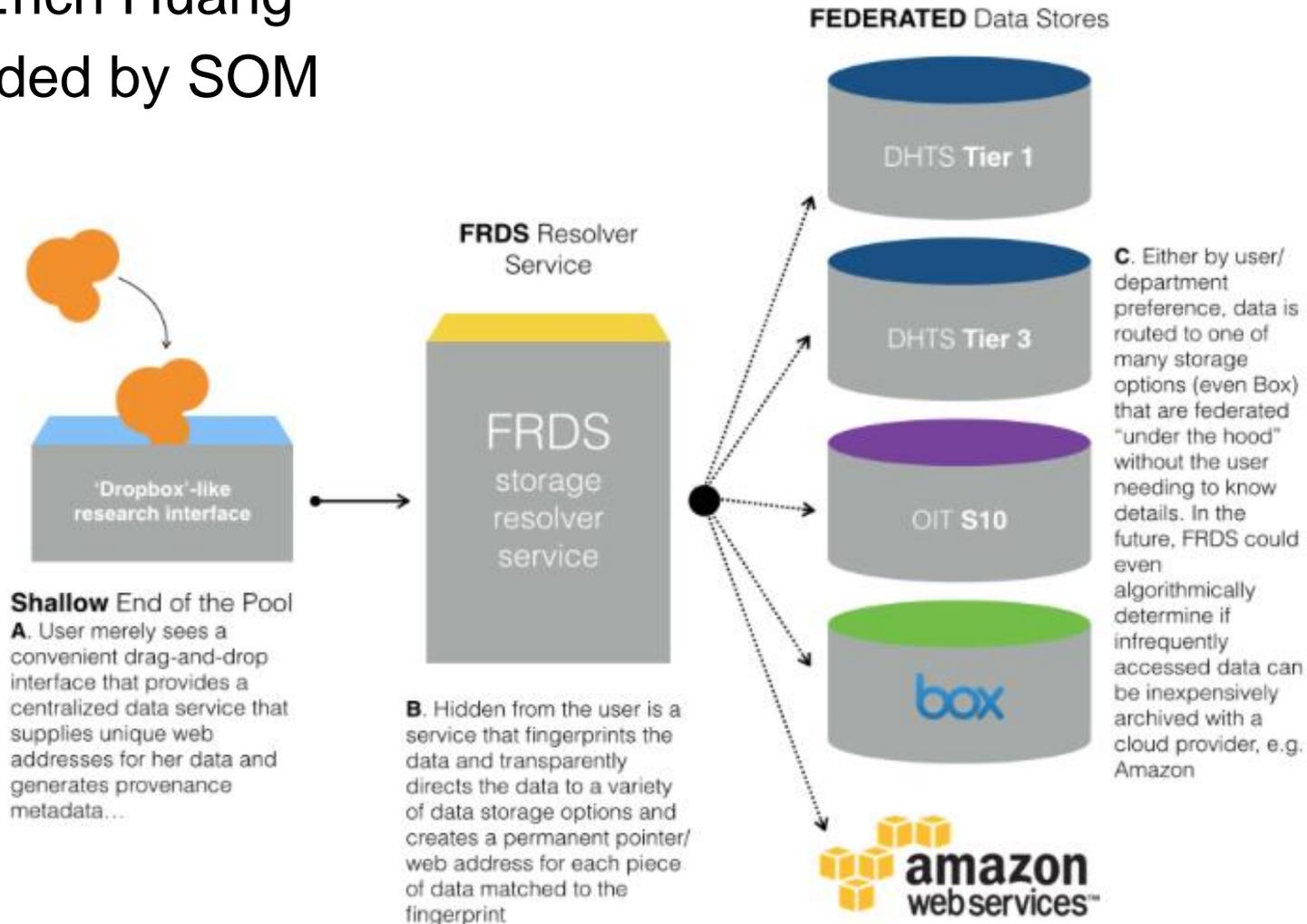
Enterprise Services to Support Data Management



Flexible Research Data Service



- Dr Erich Huang
- Funded by SOM



- Centralized Research Data Management
 - Forms generation, survey/questionnaire generation
 - Suitable for electronic Case report forms
- Very user friendly forms/survey design tool
- Web-based data capture forms
- Suitable for most Case Report Forms
- Used ubiquitously by Academic Medical Centers
 - Created by Paul Harris at Vanderbilt and released under a “Freeware” consortial license controlled by Vanderbilt.
- Central MySQL database stores data. CFR part 11 compliant
- Accessible metrics about projects/surveys through Portal
- Offered now at Duke by ORI/DOCR. Setup/ design and management
- Data Services by the Research Management Team under Denise Snyder.

The Virtual Analytic Workspace (Funded and coming)



- **Powerful and secure area** to analyze PHI from our clinical systems.
- **Tailored, virtualized analytics environment for each research data mart**
 - VM's tailored to research needs (size and rights)
 - VM's prebuilt with analytical applications (e.g., SAS, R, JMP, ArcGIS, etc.),
 - Users can only access the data mart associated with their research project.
 - By default, data can only be extracted via approved channels, such as the Honest Broker, significantly reducing likelihood of a breach of PHI.



The Analytics Workspace will **eliminate use of unsecured local databases to store PHI** and ensure a safe, secure, and scalable environment for research data.



We will **credential the entire EDW and Analytic Workspace through FISMA**

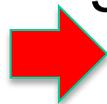


RFD – Retrieve Form For Data Capture

What is it?

Standards-based data capture at the point of care

- Standard originated from work with ex-Duke CIO, Landen Bain and Pharma.
- Landen worked with Epic to implement the RFD standard

 Allows data collection for research at the point of care in Epic

IHE Retrieve Form for Data Capture (RFD)

- Host externally standardized form in Hyperspace
- Submit information directly to form originator system
- Submit copy to archive
- Uses Continuity of Care (CCD) content standard



RFD forms mechanism in Epic at Duke



Hyperspace - Maxbuild Demo System - epic10574

Downy, Joseph
Male, -165 d.o., 08/22/2009

MRN: 294... Allergies: None Uninsured MRN: 29419 MyChart: Inactive

Research Studies

Status	Coordinators	Start Date	Updated
Enrolled			YASSIN, OMAR on 3/10/20...

Forms

Nextrials Demographics	Nextrials
Nextrials CDASH	Nextrials
Pfizer: Adverse Event Report	Outcome
Pompe Registry	Outcome

Click link to send CCD and request form

Form Originator System



Present pre-filled form to user

Research Form: Nextrials Demographics

nextrials

Demographics

Today's Date	<input checked="" type="checkbox"/> 3/10/2009
Race	<input checked="" type="checkbox"/> Asian
Initials	<input checked="" type="checkbox"/> oky
Sex	<input checked="" type="checkbox"/> Male
Date of Birth	<input checked="" type="checkbox"/> 6/24/1981
Consent Date	<input checked="" type="checkbox"/> 7/4/2008
Race Other	<input checked="" type="checkbox"/>
Consent Signed	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes

Submit

Target database

User completes non-CCD fields and submits

RFD and REDCap at Duke (coming soon)



- ORI has developed new middleware to connect the functionality of REDCap and RFD at Duke (CTSA funded)
- Design data Capture Forms in REDCap using standard data elements coordinated with those in Epic
- Surface the REDCap forms in Epic for particular studies and enrolled subjects at the point of care
 - Forms will prefill with required data elements, leaving others for study data collection
 - On submit, data returns to a REDCap, Centrally managed, CFR 11 compliant database.
 - Monitored, archived, logged and redactable for robust study management
- Available soon as a service through DOCR for all studies
- (pilot studies wanted – call Cory Ennis).



I2b2 – Informatics for integrating Biology at the Bedside

- NIH funded program from Harvard (Zak Kohane)
- Data mart, a “Hive” of interconnected applications, and a data management client
- Becoming a standard for intuitive research data management for AMC’s (Over 60 installations, including most CTSA organizations)
- That is changing
 - I2b2 opens up opportunities for cross institutional data sharing and collaboration.



i2b2 Client now live in Development at Duke

i2b2 Query & Analysis Tool Find Patients | Analysis Tools | Message Log | Help | Logout

Navigate Terms Find Terms

- Clinical Trials
- Ontology
 - Demographics
 - Diagnoses
 - Circulatory system
 - Conditions in the perinatal period
 - Congenital anomalies
 - Digestive system
 - Endocrine disorders
 - Other endocrine gland diseases
 - Diabetes mellitus
 - Diseases of thymus gland
 - Disorders of adrenal glands

Workplace

- SHARED
- hsscstest

Query Tool

Query Name: _____

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
			Disorders of adrenal glands	0-9 years old				
				10-17 years old				

one or more of these **AND** one or more of these **AND** drop a term on here

Run Query **New Query** 2 Groups **New Group**

Previous Queries

- AdrenalDiscordersInChildren@17:00:48 [1-31-2011] [hsscstest]
- AdultGt2Diabe-Obesi@21:22:29 [1-28-2011] [hsscstest]
- Adult-Diabe-Obesi@21:02:01 [1-28-2011] [hsscstest]
- Adult-NonInsulinDiabete@20:29:44 [1-28-2011] [hsscstest]
- Adrenogenital d@18:03:21 [1-28-2011] [hsscstest]
- 0-9 vea-Diabete@17:17:02 [1-28-2011] [hsscstest]

Query Status

Finished Query: "AdrenalDiscordersInChildren@17:00:48"
 Patient Set - 326 Patients - 326 patients **FINISHED [17.5 secs]**
 Patient Count - 326 patients **FINISHED [17.5 secs]**

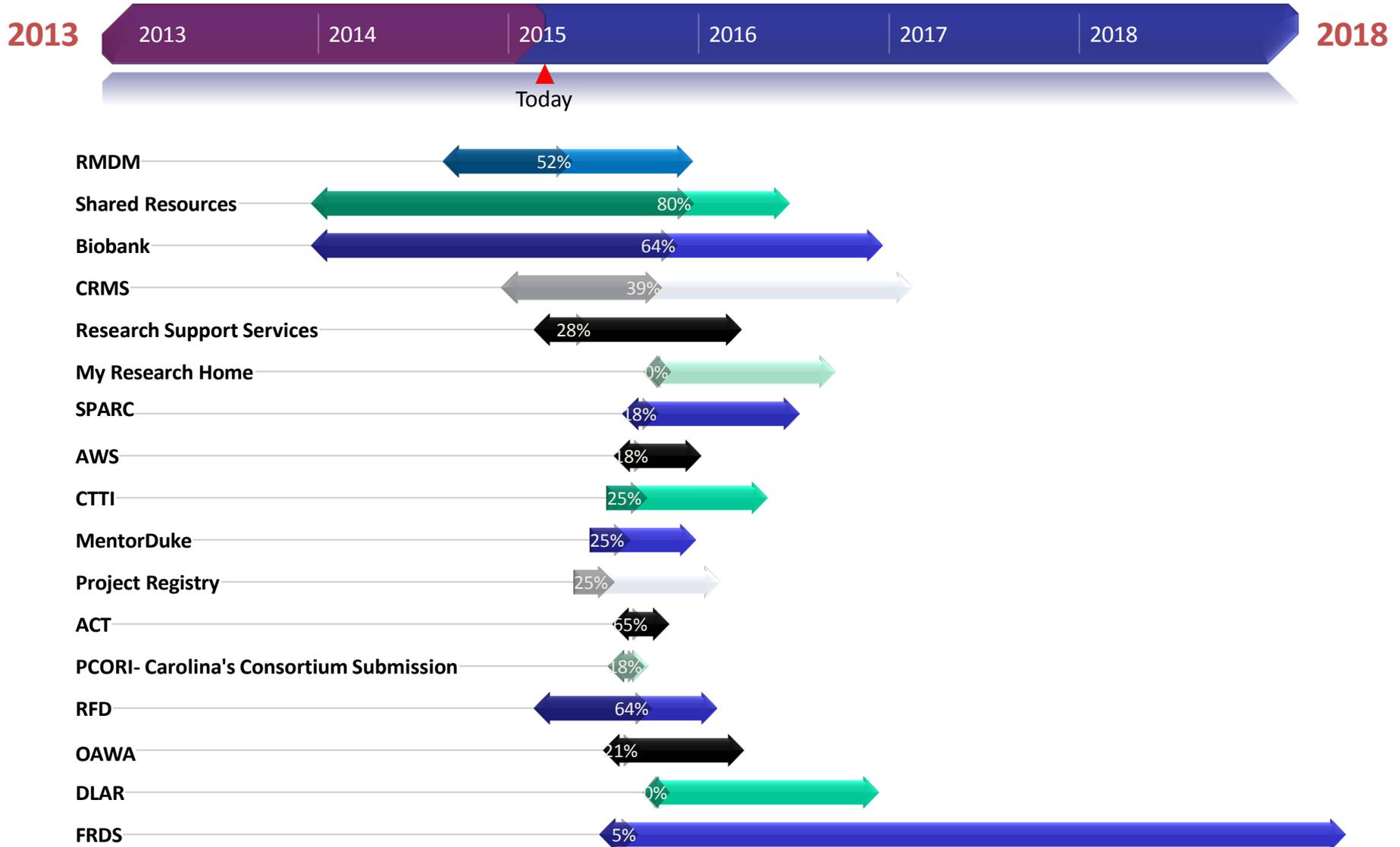
<https://hsscproxy1.clemson.edu/i2b2web/#>

Clinical Research Data Networks



- Duke is a partner in the Carolina's Collaborative
 - 3 CTSA organizations (Duke, UNC, MUSC), Wake Forest, and Health Sciences South Carolina
 - Representing active longitudinal clinical EMR data (2 encounters in the past year) on 3.1m patients across the Carolina's
 - I2b2/ SHRINE network currently active
 - Has received NIH funding as part of the Accrual for Clinical Trials (ACT) subaward.
 - Awaiting approval for 3 year funding from The Duke Endowment
- The Carolina's Collaborative has formed a partnership with the Vanderbilt's Mid-South Alliance for the current round of PCORI funding (\$6.25m) due April 7th
 - Will use the PCORnet common data model and PopMedNet technology to recruit from EMR data from over 6.2m patients.

ORI Project Portfolio



More information @

<http://ori.duke.edu/wiki>



Office of Research Informatics Dashboard



Opportunities

Opportunity	Status
Adult Immunization Initiative	PROPOSAL SUBMITTED
Research Planning Infrastructure to Develop Therapeutic Target-ID Strategies Based on Favorable Genetic Variants of Human Longevity or Health Span NIH - U24	PROPOSAL SUBMITTED
Cost Effective Storage Solution for the School of Medicine	PROPOSAL SUBMITTED
Accrual for Clinical trials i2b2/SHRINE	APPROVED
QI Research Project Registry	AWARDED
MentorDuke App	AWARDED
CTTI Products and Products Database	AWARDED
Foundant Software Support	AWARDED
CHDM Pipeline Management Program	AWARDED
Thyroid Cancer Registry	ON HOLD

Prev 1 2 3 Next

Projects

Project	Status
MyResearchHome@Duke Registration	COMPLETE
AWS-Lite	COMPLETE
Flexible Research Data Service (FRDS, new name pending)	APPROVED
Research Management Data Mart	IN PROGRESS
Shared Resources	IN PROGRESS
Biobank Project	IN PROGRESS
Smart Animal Management (SAM)	IN PROGRESS
CTSA ACT (Accrual to Clinical Trials) i2b2/SHRINE	IN PROGRESS
SPARC	IN PROGRESS
RFD (Retrieve Form for Data Capture)	IN PROGRESS

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Products

Product	Status
COI Admin	ACTIVE DEVELOPMENT
COI Form	ACTIVE DEVELOPMENT
eIRB	ACTIVE DEVELOPMENT
eResearch	OPERATIONAL
FCOI	OPERATIONAL
Grants.duke	ACTIVE DEVELOPMENT
MyResearchHome@Duke Registration	ACTIVE DEVELOPMENT
ORI Data Mart for LabVantage	OPERATIONAL
RAD Interfaces	OPERATIONAL
RCC Training Tracker	OPERATIONAL

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