Clinical Trials Management System
Kick-off Meeting

Samuel Volchenboum, MD, PhD
Director, Center for Research Informatics

Bethany Martell
Director, Office of Clinical Research

Brian Furner
Director, Application Development, CRI
Agenda

1. Welcome (Dr. Polonsky)
2. Scope and mandate (Mumtaz Darbar)
3. Introduction and overview (Sam Volchenboum)
4. Tech overview (Brian Furner)
5. Summary and questions (Sam / Beth)
Opening Remarks

Kenneth Polonsky, MD
Executive Vice President for Medical Affairs
Dean, Division of the Biological Sciences
Dean, Pritzker School of Medicine
Richard T. Crane Distinguished Service Professor of Medicine
Scope and Mandate

Mumtaz Darbar
Vice Dean, Administration and Finance
Vice President Clinical Practice Finance
Project leadership

Beth Martell
Executive Director
Office of Clinical Research

Brian Furner
Director, Application Development
Center for Research Informatics

Sam Volchenboum, MD, PhD
Associate Professor of Pediatrics
Director, Center for Research Informatics
The life of a clinical trial

This process can take 10 years and billions of dollars

- Study conception, design, writing
- IRB, contracts, budgeting
- Implementation
- Patient enrollment
- FDA submission
- Sponsor reporting
- Billing / Accounting
- Data collection

Because of a lack of standardization, every step requires manual data abstraction, transformation, and re-entry
Much of the clinical trials workflow is manual.
Introduction and Overview

Moving a trial through IRB/OCR, contracts, and budgeting is complex and has many manual steps.
The process of trial budgeting and billing has a complex and manual workflow.

The workflow has loosely connected manual steps.
Request for proposals

In 2015, an RFP was issued by the University to address administrative and financial aspects of clinical research that are not adequately managed in any other system or in a standardized manner.

After a competitive process, the CRI was chosen to build the CTMS.
CRI resources

Applications
- Enterprise software
- Sample tracking
- Patient registries
- Shared clinical data
- Custom websites
- REDCap support
- Multi-site trials
- PCORI integration

Data Warehouse
- Clinical data from 2008
- Retrospective studies
- Quality measures
- i2b2 cohort discovery
- Self-service data mart
- NLP over clinical notes
- Data aggregation
- System modeling

Systems
- 2 PB of Isilon storage
- Backup, 30-day retention
- Hosted servers (VMs)
- 4000-core HPC
- Custom solutions
- Galaxy server
- Commercial analytics
- Data visualization

Bioinformatics
- 8 PhD Bioinformaticians
- Machine learning experts
- Industry-grade pipelines
- Custom workflows
- Grant preparation
- Manuscript writing
- Multi-omic integration
- Training and education
Epic vs. CTMS functions

Epic: Patient Information
- Comprehensive management of the patient over time.
- Patient involvement in research
- Supports high-quality care
- Patient safety
- Clinical user efficiency and productivity
- Clinical billing-> Research billing

CTMS: Study Information
- Comprehensive administrative and financial study management
- Standard budget development
- Per Subject visit/earning tracking
- Standard reporting
- Subject related protocol compliance

Both need:
- Basic study information
- Patient-Study association/visits
- Billing/visit information
- Epic definitions
Scope of CTMS build

Includes
1. Central repository for all clinical trial/clinical research administrative and financial data
2. Standardized budget template/development to support billing protocol build in Epic
3. Support ancillary engagement and budget quotes
4. Support standard processes related to earnings tracking and FAS account close out
5. Interface with AURA-IRB (PI, title, staff)
6. Interface with Epic (Research record [RSH], patient, visits, charges)

Excludes
1. Replacement of Velos functions for Cancer Center needs
2. Electronic Data Capture (REDCap and Velos support EDC needs)
3. Replacement or duplication of AURA-IRB or Epic functions
Vision for clinical trials at UChicago

By building the CTMS to accept and output structured data, the entire clinical trials pipeline can be automated.
CTMS stakeholders

- **BSD**
  - Dean’s Office
  - Information Security Office (ISO)
  - Cancer Center and Cancer Clinical Trials Office (CCTO)
  - Center for Research Informatics (CRI)
  - Department of Medicine- Clinical Trials Financial Group (CTFG)
  - Department of Medicine- Clinical Research Support Office (CRSO)
  - Department of Pediatrics- Clinical Trials Office (Pediatrics CTO)
  - Human Imaging Resource Office (HIRO)
  - Human Tissue Resource Center (HTRC)
  - Institute for Translational Medicine (ITM)
  - Office of Clinical Research (OCR) / Institutional Review Board (IRB)
  - Office of the CRIO

- **University of Chicago Medicine**
  - Chicago Biomedicine Information Services (CBIS)
  - UCM Information Security Office (ISO)
  - Investigational Drug Service (IDS)

- **University**
  - UChicago Information Technology Services (ITS)
  - University Research Administration (URA)
### CTMS stakeholders

**Sponsors**
- Kenneth Polonsky
- Susan Cohn
- Mumtaz Darbar

**Steering Committee**
- Cole Campese (ITS)
- Susan Cohn
- Mumtaz Darbar
- Bob Grossman (CRIO)
- David Liebovitz (CMIO)
- Mike Ludwig (URA)
- Bethany Martell (OCR)
- Vanessa Pico
- Eric Yablonka (CIO)

**Project Teams**

**CRI**
- Sam Volchenboum
- Brian Furner
- Alex Lapson
- Don Starkey
- Michael Baltasi

**OCR**
- Beth Martell
- Melissa Byrn
- Olga Vachtchenko
- Ryan Crist
CTMS stakeholders (cont.)

Subject Matter Experts

Budget Contract Managers
Ashley Hoambrecker
Anna Alecci
Jennifer Mitchell
Rob Clark

Regulatory Managers
Allison Buonomici
Melanie Nall
Becky Puplava

Hospital CBIS/EPIC
John Moses
Isaac Prasad
Shariq Ata
Christine Watts
David Holcomb

University: ITS and URA
Bill Stauffer
Suneetha Vaitheswaran
Laurel Dettman
Istvan Fekete

Oncology- Regulatory and Conduct
Lauren Wall
Amanda Spratt
Beth Manchen

OCR
Beth Martell
Melissa Byrn
Olga Vachtchenko
Ryan Crist
Shaun Carey
Lorrie Romer
Millie Maleckar
CTMS stakeholders (cont.)

Project technical staff

<table>
<thead>
<tr>
<th>University of Chicago</th>
<th>Bad Rabbit Consulting</th>
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<tr>
<td>Brian Furner (CRI)</td>
<td>Devon Holcombe</td>
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<td>Don Starkey (CRI)</td>
<td>Raph Martelles</td>
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<td>Olga Vachtchenko (OCR)</td>
<td>Andrea Wilson</td>
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<td>Ryan Crist (OCR)</td>
<td>Peggy Meyer</td>
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<td></td>
<td>Rebecca Wise</td>
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<td>Will Heger</td>
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<td>Shiva Kumar</td>
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<td>Tony Maxymillian</td>
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This system will only be successful as a partnership

1. Research community administrators
2. Research conduct staff

These are the users of this system, and they generate the data that go into it.

3. CBIS - Integration with Epic
4. ITS - Integration with AURA
# How we will engage partners

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<tr>
<th>Stakeholders</th>
<th>Information Security</th>
<th>System Integration</th>
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<tr>
<td>➔ Input from SMEs will be sought during user story planning</td>
<td>➔ Review of system architecture and implementation to ensure compliance with BSD and UC Medicine policies</td>
<td>➔ Working alongside key project leads at ITS and CBIS to get required integration work queued appropriately</td>
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<td>➔ As functionality gets rolled out in test environment, we will need users to perform testing</td>
<td>➔ Security scan and penetration testing to pro-actively mitigate risk</td>
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<tr>
<td>➔ All those interested in being test users, please contact us</td>
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CTMS development team

• **Center for Research Informatics**
  Sam Volchenboum, Director
  Brian Furner, Director of Applications

• **Office of Clinical Research**
  Beth Martell, Executive Director
  Melissa Byrn, Director, Research Operations & Conduct

• **Bad Rabbit Consulting** - development partner selected through RFP process led by CRI
CTMS development team

Center for Research Informatics

**Alex Lapson** - Senior Program Manager

- Alex joined the CRI in January 2017 to lead the development of our enterprise clinical trials management system.

**Don Starkey** - Lead Web Applications Developer

- Don joined the CRI in January 2017 to architect and develop our clinical trials management system.
Bad Rabbit Consulting

- Deep domain knowledge
- Solution delivery experts for research institutions for 10+ years
- Anticipated benefits of joint development
  - Retention of expertise in house post implementation
  - Ability to grow system internally with measured vendor involvement

Peggy Meyer - 7+ years research administration; CTMS / Grants Engineering Manager; Business Architect
CTMS development plan

Agile Development

- Work will proceed in iterative sprints
- Input from stakeholders critical during backlog creation and in user acceptance testing at the end of sprints
- Broad participation will be key to success
CTMS development timeline

Stage 1
- Requirements gathering and initial planning with ITS and CBIS

Development
- Iterations 2-15
- Study, Calendar, Visit Instance, Epic & AURA Integration

Reporting
- Iterations 16-19,
- Invoice, Billing Reconciliation,
- Final UAT,
- Transition to operations
- NOV 02, 2018

Development
- 1st Iteration
- Infrastructure development
- AUG 02, 2017

First Release
- Initiation phase release
- JUL 02, 2018
Where to get more information

http://cri.uchicago.edu/ctms

- Look for announcements in your email
- Please contact us directly with questions and suggestions
Closing remarks

This represents a tremendous opportunity for the BSD, hospital, and the University.

This CTMS build will address the administrative and financial requirements for clinical trials.

Future opportunities will leverage this work and provide many opportunities for expansion and innovation.
Questions?