Clinical Research Management System
**Online Collaborative Research Environment (OnCore)**
Forte Research Systems

Christian Stephens  
Office of Research Informatics Project Manager

Erica Reece  
Forte Product Specialist

Mike Neuenfeldt  
Forte Project Manager

Carrie Nemke  
Forte VP Business Development

**Why an Enterprise CTMS?**

Which consent form is current?  
How do we compare to other institutions?

What is our study start up timeline?  
Which studies are low accruing?

Why does it take us so long to open an industry study?  
Where is the information for the DSMC?

**WHAT IS OUR RESEARCH PORTFOLIO?**

Do I need to hire more staff?  
How many subjects has my department accrued this year?

What are they spending their time on?  
How many industry studies are we conducting?

How many studies are open to accrual?  
What is our study start up timeline?

What subject visits are scheduled next week?
Goals of OnCore Enterprise CTMS

**Enterprise Reporting**
- Research Portfolio
- Patient Safety
- Insight into operations

**Research Operations Management**
- Regulatory Compliance
- Improve communication & efficiencies
- Manage protocol lifecycle

**Financial Management**
- Billing Compliance
- Accurate & consistent budgets
- Track sponsor invoicing

Enterprise CTMS Benefits

**Research Staff**
- Improved communication across team and sites
- Automation support (subject calendars & re-consenting sponsor invoicing)
- EMR & lab integration to eliminate duplicate data entry

**Regulatory**
- Standardized collecting and reporting of clinical research data
- Consistent tracking of safety data and staff credentials
- Email alerts and reminders

**Leadership**
- Visibility to clinical research portfolio at different levels within the enterprise
- Effectively manage staff workload
- Streamline budget negotiations
- Billing compliance

**Public**
- Provides a searchable view of accurate and up-to-date open study information
- Patient safety
How Did We Get Here

Epic for Research (Maestro Care) implemented

Contract Review begins

Vendor demos

Pre-Implementation begins

2006

Velos eResearch implemented

Planning for eResearch upgrade begins

Decision to find a new vendor

Forte Chosen

Pre-Implementation ends (2 months)

Duke Project Work Begins

ONCORE RESEARCH ORGANIZATIONS

51 Cancer Centers (39 NCI-designated)
32 Academic Medical Centers (20 CTSA)
12 Health Care Systems & Hospitals
IMPLEMENTATION TEAMS

Duke University Core Project Team

• Project Manager
  – Christian Stephens
• Project Sponsors
  – Mark Stacy
  – Iain Sanderson
  – Billy Newton
• Project Champions
  – Lisa Varani
  – Denise Snyder
  – Cory Ennis
• Product Manager
  – Terry Ainsworth
• OnCore Coordinators
  – Lauren Horne
  – Susan Natoli
• OnCore Trainers
  – Virlesa Reed
  – Kristy Astin
• Business Analyst
  – Jeyalakshmi Ramanathan

• Finance
  – Catee Mullen
  – Cindy Maynard
  – Tracy Kerby
• Calendars/Start Up
  – Angie Padget
• DCI/Oncology
  – Lori Pickens
  – Ellen McCarthy Steinour
  – Patrick Barrera
• MC Analyst
  – Dalia Mack
  – Ira Togo
  – Earl Schwark
• Reporting/Data Analyst
  – Rhodora Garcia
  – Ron Griffith
  – Matt Schultz
  – Bill Shively
• PRMO
  – Julie McCauley
  – Ryan McGuire

DUKE UNIVERSITY IMPLEMENTATION PLANS

• OnCore functionality:
  – Protocol/subject management
  – Calendars, coverage analysis
  – Financials
• Interfaces:
  – ADT (demographics), RPE (subject status), CRPC, (calendar)
  – Custom SAP Interface
  – eIRB API
• Data migration:
  – 14,000 study protocols to migrate
  – All open studies in the IRB, all closed since January 1, 2013
  – Industry, Investigator Initiated, Grant, Federal
• Go-live Scope: Enterprise (SOM, SON, Campus Biomedical)
• Estimated protocols for initial go-live: 1500
• Proposed timeline: Go-Live February 2018
## ONCORE EVENT OUTCOMES

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<td><strong>Project Kickoff</strong>&lt;br&gt;Refine scope and timeline&lt;br&gt;Define communication plan&lt;br&gt;Review project progress</td>
<td><strong>Community Kickoff</strong>&lt;br&gt;Understanding of OnCore usefulness by Research Community&lt;br&gt;Communicate scope and timeline&lt;br&gt;Generate excitement</td>
<td><strong>Immersion</strong>&lt;br&gt;Initial OnCore high level workflows&lt;br&gt;Initial application configuration&lt;br&gt;Identify OnCore Champions</td>
<td><strong>Application Setup</strong>&lt;br&gt;Configuration strategy decisions&lt;br&gt;Application configuration&lt;br&gt;Initial environment</td>
<td><strong>OnCore Champion Training</strong>&lt;br&gt;Finalize high level workflows&lt;br&gt;Finalize application configuration&lt;br&gt;Documentation of detailed policies and processes</td>
<td><strong>End User Training</strong>&lt;br&gt;End Users demonstrate competence when using OnCore and prepared for Go-Live&lt;br&gt;Finalize preparations for Go-Live</td>
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### How can I be involved in this exciting process?

- Read the DOCR Clinical Research Update newsletter
- Go to the WIKI and see what’s going on at the OnCore page (select WATCH)
- Use the training opportunities to learn the application
- Ensure the information on your research studies are accurate
- Volunteer for a work group in an area that you know a lot about
Proposed Work Groups needing your participation

- Budgeting
- Calendar Building
- Cancer
- Central Office
- Community Engagement
- Contracts (includes ORC)
- Credentialing
- Grants (includes ORA)
- Invoicing
- Participant Management
- Protocol Management
- Publish to the Web
- Reporting
- Research Pricing
- Scientific Review
- Task Lists
- Training
- User Roles
- Volunteer Registry

Questions during the Demo?

Please send any questions about OnCore or the project to

cms136@duke.edu
Forte Attendees

- Mike Neuenfeldt
  - Project Manager
- Ann Kreeger
  - Program Manager
- Erica Reece
  - Product Specialist
- Carrie Nemke
  - VP Business Development
- Denali Stahlke
  - Business Development Manager
- John Starr
  - CFO
EVOLUTION OF SPECIALIZED SOFTWARE

Evolving with the research community and regulations to manage reporting compliance and operations across the entire enterprise.
OnCore Demo

ONCORE CLINICAL RESEARCH WORKFLOW

Research Administration
- PROTOCOLS
  - Protocol Attributes
  - Committee Reviews
  - Protocol Activations

SUBJECT MANAGEMENT
- Pre-screening
- Subject Status
- SAEs and Deviations

SUBJECT VISIT TRACKING
- Automated Subject Calendar Visit Management
- Reset Future Dates
- Printable View

Financials
- SETUP FINANCIALS
  - Billing Designation
  - Create Budget
  - Milestone Setup

VISIT VARIATIONS
- Additional Visits
- Addl/Missed Procedures

REVENUE MANAGEMENT
- Invoice Generation
- Receipt Tracking
- Alerts