Introduction to OnCore
OnCore Project Overview

Project Description:
• The OnCore Enterprise project is a clinical trials management system that will provide a overall management tool for clinical trials and study-related information

Goals
• Provide a central system to track protocol activity from startup to closeout
• Provide integration to support electronic ordering of clinical services in Cerner
• Enhance regulatory and billing compliance
• Improve communication and efficiencies across teams
• Provide a tool to assist with study budgeting, research charge capture and invoicing

Expected Benefits
• Streamline the management and workflows of clinical trials by providing a means for consistently capturing and tracking protocol, administrative, and financial data
• Increase the capability to provide meaningful reports and data regarding the financial status of studies; improved ability to invoice sponsors, to track and invoice milestones more efficiently
• An interface to Impact allows for the transmission of study and patient data to PowerTrials. Provides improvement to patient safety through banner bar notification and attachment of research summaries.
Current View of Research Systems

- CERNER
- EHR
- PowerTrials
- HealthQuest/IDX
- Billing
- Institutional Account
- SiteMinder
- OnCore
- EMMI
- Patient ID
- Study Services
- Charges
- Clinical Study Accounting
- ORACLE
- IRAP
- IRB/OSP
- HSIS
- Campus IT
OnCore  Scope and Functionality

- **Scope**
  - Clinical Trials with Health System clinical services
  - Integration with Cerner and billing systems via PowerTrials

- **Clinical Research Management functionality**
  - Protocols
  - Subject Management
  - Budgets
  - Calendars
  - Coverage Analysis
  - Trial execution
Implementation Timeline

- Phased Approach - 17-month overall timeline
- Benefits:
  - Some end-users will be able to switch from using SiteMinder to OnCore sooner
  - Provides additional time for sequenced data entry for additional departments
  - Better option for achieving 80% of Clinical Billable Trials in OnCore by April 2018
- Wave 1 go-live: December 2017 and January 2018
- Wave 2 go-live: April 2018
- Wave 3 go-live: September 2018
- Timeline considerations
  - Calendar build/validation – manual building of existing DOM study calendars
  - End-user Training
  - Data Migration – migration of data from Siteminder
  - Workflow process development and documentation
  - Staffing – availability and timing of new project resources
Four Main Facets of OnCore
# PC (Protocol) Console

## Protocol Details

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<thead>
<tr>
<th>Protocol No.</th>
<th>Library</th>
<th>NCT Number</th>
<th>Department</th>
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<th>Short Title</th>
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<td>Training Protocol for Shelby Hall</td>
<td>Protocol for Shelby</td>
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<th>Age</th>
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<td>Involves Therapy</td>
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<td>RC Total Accrual Goal (Upper): 70</td>
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<td>Study Completion Date:</td>
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### CRA/SUBJECT CONSOLE

**Protocol No.: DEMO**
**Protocol Target Accrual: 170**
**RC Total Accrual Goal (Upper): 70**
**Short Title: WaveCrest vs. Watchman Transcatheter LA Closure to REDuce AF-Mediated STroke 2 (WAVECREST2)**

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<th>First Name</th>
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Subject Console

Subject MRN: 00851808

**Subject Demographics**

- **Last Name:** TWENTYDUDLEY
- **First Name:** TEST
- **Race:** Native Hawaiian or Other Pacific Islander, White
- **Gender:** F
- **SSN:** 010125263
- **Address:** 1312 Sumar Road
- **City:** BIRMINGHAM
- **State:** Alabama
- **ZIP:** 35213
- **Country:** Jefferson
- **Phone No.:** 205-566-6161

**Referring Physician:** Dr. Balkovetz

**Subject Comments**

No Information entered
FINANCIALS CONSOLE

Budget Related
- Rate Base
- Default Sponsor: Boston Scientific Corporation

Sponsor Settings
- Boston Scientific Corporation
- Rate Base: 10.0%
- Withholding: Y
- Protocol Related: Y
- Subject Milestones: Y
- Pass Thru Items: Y

Settings for Application of Indirect Charges
- Import From Charge Master: Y
- Protocol: N
- Subject: N
- Milestones: Y
- Cumulative: N

Apply Indirect charges during budgeting only: N

No. of Cycles for Budget Calculations: (Required if Specification is Open Ended)
- V1 (10/11/2017)
- View Budget Display Options: Y

Invoice Related
- Screening Failures Invoice Ratio: 1:3
- Initial Invoicable Screening Failures: 10
- Maximum Screening Failures
- No. of SAEs After Which Sponsor Will Be Invoiced: 0
- No. of OISRs After Which Sponsor Will Be Invoiced

Invoicable Milestone Prerequisite: Occurred

Invoicing Reminder
- Notification Frequency in Months: 1
- Number of Notifications after study closure: 2
- Notification Start Date: 11/01/2017
- Notification Comments

https://train.oncore.hs.uab.edu/smrs/SMRSControlServlet?hdn_function=PROTOCOL_BUDGET
## CALENDARS

### Treatment Visits

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<th>Procedure</th>
<th>Topple Full Screen</th>
<th>Forms</th>
<th>Treatment</th>
<th>Follow Up</th>
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<td></td>
<td></td>
<td>1@10Days</td>
<td>3@10Days</td>
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<td>2@10Days</td>
<td>Office Follow-Up</td>
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<td>Treatment</td>
<td>Discharge</td>
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### Informed Consent

- X

### Physical Exam

- X

### CBC

- X

### Probes

- X

### Serum Creatinine

- X

### PT/INR

- X

### Serum Pregnancy Test

- X

### CHA2DS2-VASc Score

- X

### HAS-BLED Score

- X

### TEE

- X

### Quality of Life questionnaire (QoL)

- X

### Neurology exam

- X

### Brain Imaging (MRI, contrasted CT)

- X

### mRS/NIH Stroke Scale

- X

### AE Monitoring

- X

### Randomization

- X
OnCore Billing Compliance

Protocol Calendar

- Patient Billing
- Sponsor Invoicing/Payments
- Subject Visits
- Protocol Budget
- Coverage Analysis