OnCore Enterprise: A CTMS for the School of Medicine

S.M.A.R.T. Meeting
Tuesday, December 13, 2016

Don Mitchell, Director of Application Services, IRT
Yona Shulaker, Process Improvement Manager, Spectrum

Agenda

• What is OnCore?
• Benefits
• Current state and future vision
• Timeline
• Progress on expansion across SoM
• Questions?
What is OnCore?

OnCore is a CTMS – Clinical Trials Management System
• IT system to manage clinical research with an emphasis on clinical trial research
• Tracks studies and enrolled participants, study events, milestones, participant visits and interactions, enables reporting, generates financial transactions and information for billing needs

The OnCore Choice:
• A leading CTMS system
• Supports academic med. centers, health care systems nationally; in > 50% of NCI-designated cancer centers; >33% of CTSAs
• OnCore in use by Stanford Cancer Institute for ~11 years
• Robust, function-rich: evaluated to be best choice for our enterprise-wide CTMS

Benefits of OnCore

Metrics reporting
• From the protocol to department level. We can be smarter about how we do research ... “You can’t improve what you don’t measure!”

All clinical research studies in one system
• Database of all enrolled participants
• “At-a-glance” picture of what is happening in a study
• Easy access and reports immediately available, e.g., demographic breakdown enables easy reporting to IRB, NIH

Tools to inform effort requirements and understand workload
• Improved staff workload balancing, time and effort management
• More accurate start-up effort estimates, better study budgeting

Customizable dashboards
• Quick access to protocols, participants and reports

Future developments
• Automatic feeds: budget & billing, IRB, Epic, investigational pharmacy, sponsor invoicing
• Patient safety enhancement – flag patient record in Epic
• Participant calendars automatically generated, enabling participant visit tracking
• Standardized system for staff, for recording deviations, AE reporting, eligibility verification, pre-screening tracking, and participant calendar management – each with reports readily available
Current ➔ Fragmented information, many systems, little or no integration

Unconnected with any other systems:
- Misc. study management – Excel, etc.
- Misc. subject management – Excel, etc.

Current ➔ Fragmented information, many systems, little or no integration

Future ➔ Replace budget/billing worksheets process; build interfaces to streamline processes; gain consistency

Future ➔ Replace budget/billing worksheets process; build interfaces to streamline processes; gain consistency

Comprehensive data and management reports
**Parallel Efforts**: To realize benefits as soon as possible

**Expansion of current OnCore use**

*Now in progress, through Sept 2017*

- **Study and participant management**: track clinical research (all funding sources):  
  - By division, department, study, funder, PI  
  - **Reporting**: Readily available, enables easy reporting to IRB, NIH  
  - Accrual, actual v. target  
  - Demographic breakdown

- **Effort Tracking** (staff time spent on various study activities):  
  - Provides more accurate effort assessment that can be used in constructing future budgets  
  - Allows researchers to balance staff workload

- **Demographic feed from LPCH Epic (addition to current SHC feed)**:  
  - Automated feed to OnCore of race/gender/ethnicity from LPCH Epic for pediatric participants. Triggered upon admission, treatment, discharge.

**OnCore – Epic Financials**

- **Study Calendars & Automated Subject Calendars**:  
  - Allow Visit Tracking  
  - Flexibility to add extra and mark missed visits/procedures  
  - Visit tolerances

- **Coverage Analysis**  
  - Study Budget Development:  
    - Research/Billable to Patient or Insurance/No billing charges  
    - Research charges, study schedule of events, budget all in one system using the same data

- **Automated Feed to Epic for basic protocol information, patient flagging and linking to protocol**:  
  - Patient safety

- **Automated Billing Info to Epic**:  
  - Improve billing compliance & accuracy (SoC and Research)  
  - Reduce re-work and associated study staff effort

- **Sponsor Invoicing capabilities (impact/integration w/CRISP TBD)**:  
  - Automated invoice generation  
  - Invoiceable items  
  - Account for visit variations  
  - Payment tracking

---

**Current Progress v. Projected User Expansion (Non-cancer)**

<table>
<thead>
<tr>
<th>Department</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ONS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spectrum Child Health</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatrics</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesia</td>
<td></td>
<td>60</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiology</td>
<td></td>
<td></td>
<td>31</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td></td>
<td>1</td>
<td></td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurosurg</td>
<td></td>
<td>23</td>
<td>14</td>
<td>74</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatry</td>
<td></td>
<td>23</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OB/GYN</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermatology</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OrthoSurg</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT Surgery</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency Medicine</td>
<td>14</td>
<td>74</td>
<td>7</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>14</td>
<td>74</td>
<td>7</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urology</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Otolaryngology</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RadTech</td>
<td></td>
<td>14</td>
<td>74</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**As of 12/12/16**: > 100 trained staff  
**As of 12/13/16**: 75 studies registered in OnCore  
**With 790 participants registered to studies in OnCore**
Studies registered in OnCore — as of December 12, 2016 (Non-cancer)

Current:
- **75 studies registered**
- **56 of these are open-to-accrual**
- **43 PIs have studies registered**
- **790 participants registered**

Questions?

- OnCore Information Sessions are being scheduled for January and February.
Appendix: How to get started in OnCore

✓ As groups or divisions are on-boarded we work with you to schedule the appropriate training and identify who will be taking the roles in the OnCore workflow ("Research Manager", and "Clinical Research Coordinator/Nurse")

✓ Hands-on training for research staff, only one 2.5 hour session needed, see Spectrum website OnCore - Resources

✓ Your OnCore login is activated after training is completed, and you can start using OnCore straight away

✓ Ongoing support:
  • extensive online help – tip sheets, at-a-glance quick guides
  • help-desk by phone or email

Cancer studies: OnCore training is conducted by the CCTO. Contact ccto-oncore@stanford.edu

Appendix: OnCore Enterprise for Stanford

➢ This short video explains why using OnCore is important for Stanford, and how it will help researchers with day-to-day study management:

➢ Article on the school-wide roll-out
Appendix: Contacts & Resources

- **Spectrum OnCore support (non-cancer studies)**
  
  Website: [https://spectrum.stanford.edu/oncore-resources](https://spectrum.stanford.edu/oncore-resources)

  Help Desk: 650-721-3508 | email the OnCore support team: 
  - Bertha deLanda, *OnCore Training Specialist*, (training and help desk) bdelanda@stanford.edu
  - Jen Honciano, *OnCore Application Specialist*, (tech. support and help desk) jhoncian@stanford.edu
  - Yona Shulaker, *Process improvement Manager*, (OnCore project manager) shulaker@stanford.edu

  - OnCore users will have access to additional training as new functionality is made available.

- **Cancer studies**: OnCore training for cancer studies is conducted by the CCTO:
  - Contact ccto-oncore@stanford.edu to schedule
  - Agnes Nika (agnesn@stanford.edu)

Appendix: OnCore Enterprise

**Full Suite of Modules with this Software**

**Using at Stanford currently:**
- Clinical research study management
- Participant management
- Research Reports (# studies, accruals, etc.)
- Staff Effort tracking

**Rolling out for non-cancer studies**
- Electronic Case Report Forms (eCRF)
- Scientific Review Committee management
- Biospecimen management

**In use for cancer studies**

Not using these yet:
- Sponsor invoicing
- Study budget management
- Patient registries
- Interface with other systems, e.g., Epic (currently get demographics feed (only) from SHC Epic)
Support in SoM for OnCore

- **Bringing OnCore Enterprise to implementation**: Collaborative effort between Spectrum and the Dept. of Medicine/Stanford Center for Clinical research (SCCR), working with Stanford Cancer Institute/ Cancer Clinical trials Office (CCTO)

- **Spectrum OnCore Team in place**: 
  - User Support & Training Specialist
  - Application Specialist
  - Project Manager
  - Implementation & Support Specialist (being hired)

- **SoM - Information Resources & Technology (IRT)**: Licensing, data center support and system maintenance for OnCore Enterprise

- **SoM Departments are asked for**:
  - Leadership support for divisions and investigators; positive encouragement for investigators to register and track clinical research in OnCore with the recognition that ultimately this will be the only vehicle for industry-sponsored trial billing, automated patient flagging in Epic, etc.
  - Identification of OnCore “specialist” or “liaison” familiar with study portfolio, who can recognize which studies should be registered and tracked in OnCore, answer routine questions, be conduit to central resources

- **Faculty and Researcher Teams**: Support for staff training time; Participate in training sessions; Use OnCore

**OnCore at Stanford - A brief history**

- **OnCore implemented by Stanford Cancer Institute**
  - Feb-Mar 2005: OnCore selected as enterprise-wide CTMS
  - May 2015: OnCore Enterprise, cancer & non-cancer studies
  - June: Project kick-off meetings with vendor & Stanford team
  - July-Oct: Test & training system set up; focus groups held
  - Nov: Pilot groups identified; pilot users selected and trained

- **Continued roll out throughout SoM**
  - Jan 2016: OnCore Enterprise live!
    - Pilot users begin to register (non-cancer) studies
  - Feb-Apr 2016: More pilot groups' users trained and using OnCore Enterprise to track studies
  - May-Nov 2016: SoM-wide roll-out begins by department, division

- **Recognize need for a CTMS**
  - Late 2014: OnCore is used for 9 years for cancer studies