Srini Kalluri, Founder, President & Chief Customer Officer
Carrie Nemke, Business Development Manager

CTMS Support of Billing Compliance Best Practices
Research Compliance Conference
Austin TX, June 2013

Agenda

• Background
• OnCore Billing Compliance
• EMR/OnCore Integration
  – Goals
  – Integration Options
• OnCore Billing Compliance Workflow Demonstration

Background

* Founded in 2000
* 60 employees @ Headquarters: Madison, WI, USA
* 22 employees @ India office, Bangalore
**Online Collaborative Research Environment**

- Clinical Research Management
- Integration
- OnCore
- Electronic Data Capture
- Billing Compliance
- Biospecimen Management
- Patient Registries

**2013 OnCore Research Organizations**

2013 OnCore Research Organizations

- 35 Cancer Centers (of NC and designates)
- 23 Multi-disciplinary (NCCN)

**Billing Compliance in OnCore**

1. Qualified Clinical Trial Determination Checklist
2. Protocol Event Schedule
3. Indicate Billing Designation & Rationale
4. Ability to filter and report on information
5. Attach documents to support decisions
6. Integration with EHR
Cross Functional Impact

- **Clinical Calendar (create/new)**
- **Protocol Billing Grid (view)**

- **Clinical Calendar (create/new)**
- **Subject Visit (add add'l procedures w/ billing designations)**

- **Protocol Calendar (create/view)**
- **Coverage Analysis (update billing designations, Q0/Q1 modifiers, and comments)**

- **QC Checklist (update)**
- **Protocol Billing Grid (able to group items/services)**
- **Coverage Analysis (update billing designations, Q0/Q1 modifiers, and comments)**

- **Research Coordinator**
- **Clinical Calendar (create/new)**
- **Subject Visit (add add'l procedures w/ billing designations)**

- **Research Financial Specialist**
- **Clinical Calendar w/ footnotes (view)**
- **Research Charge Master (view)**
- **Protocol Budget incl Q0/Q1 modifiers (update/view)**
- **Billing designations (view)**

- **Patient Billing Specialist**
- **Billing Slip for a subject visit augmented with relevant Coverage Analysis details (view)**
- **Coverage Analysis for a protocol with appropriate billing designations – possibly organized differently than for Coverage Analyst (view)**

Billing Compliance: New vs. Legacy Studies

- **New Studies**
  - Clinical Calendar
  - Initial Budget
  - Coverage Analysis
  - Final Budget

- **Legacy Studies**
  - Clinical Calendar & Final Budget
  - Coverage Analysis
  - Initial Budget / Final Budget

Shared Protocol Calendar

- Patient Billing
- Protocol Calendar
- Coverage Analysis
- Sponsor Invoicing/Payments
- Subject Visits
- Protocol Budget
**Epic-OnCore Integration Goals**

- Initial Effort: Define Priorities Across Teams
- Reduce Redundant Data Entry Efforts
  - Workflow in legacy system/process
  - Consolidating systems?
- Streamline Billing Compliance Efforts

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**OnCore / Epic Integration for Billing Compliance**

**RPE**
- “Flagging” a patient in the EMR as participating in a research study

**Protocol Billing Grid**
- Provides an EMR with relative time points of a research study calendar including codes, billing designations and modifiers for assigned charge events & items.
- Purpose is to support billing compliance.

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**RPE – Retrieve Process for Execution**

**Overview**
- Technical profile contained within the IHE – QRPH technical framework.
- Defines how research systems exchange data with EMRs.

**Implementation Considerations**
- Unique identifiers (recommend demographics interface)
  - Protocol identifier
  - Subject identifier
- Currently Epic EMR is the only EMR to use RPE with OnCore
RPE Operations

Protocol Billing Grid Integration

Overview
- Defined by CRPC, a supplement to the RPE profile.
- Provides EMR with relative time points of a research study calendar including codes, billing designations and modifiers for assigned charge events & items.
- Purpose is to support & streamline billing compliance.

Implementation Considerations
- RPE integration is required
- Epic 2012 version required
- Epic Beacon oncology module considerations
- OnCore financials implementation

Workflow Impact of Epic-OnCore Integration
- Workflow Definition Across Teams and Systems
- Streamlining workflows: Interface does not mean no effort in Epic
- Identify and define all workflows, not just those related to the interface (e.g., Scheduling)
Key Lessons Learned:
Critical Success Factors

• Shared Vision and Sense of Purpose across teams
• Strong leadership
• Efficient Decision Making Ability
• Communication – At Institution and With Forte/Epic

In Summary

• OnCore-Epic Integration:
  – Driven by goal of streamlining billing compliance
  – Current priority to improve use of integration with Beacon
• Successful Integration relies on:
  – Workflow Definition
  – Leadership, communication across teams and systems

ONCORE BILLING COMPLIANCE WORKFLOW DEMONSTRATION
Online Collaborative Research Environment

OnCore Clinical Research Workflow

Research Administration
- Protocols
  - Basic Protocol
  - Regulatory
  - Scientific Reviews
  - IRB Reviews
  - Protocol activation
- Subjects
  - Pre-Screening
  - Registration
  - Consenting
  - Eligibility
  - Subject Status
  - SAPs
  - Deviations
- Financials
  - Practice Management
  - Billing Compliance
  - Biospecimen Management
  - Patient Registries

OnCore Clinical Research Workflow

Study Setup
- Calendars
  - Procedures & Evaluations
  - Treatment & FU
  - Visit Tolerances
  - Foot Notes
- eCRF's
  - Forms Design
  - Assign forms to studies
- Study Data Management
  - Data Monitoring
  - Data Discrepancy Management
  - Research

Visit Tracking & Data Capture
- Automated subject calendars
- Visit & Procedure Tracking
- Additional Visits & Procedures
- SOC vs.
- Research
- eCRF completion
- Query resolution

Revenue Management
- Automated invoice
  - Items
  - Invoice generation
  - Receivables tracking
  - Unplanned visits & procedures
  - Exceptions

Study Data Management
- Data Monitoring
  - Data Discrepancy Management
  - Research

Study Setup
- Study Budgets
- Negotiated Rates
  - Payment Milestones

Discussion

Thank You
Lessons Learned: The Implementation of an Enterprise-wide Clinical Research Management System and Integrating an Electronic Health Record

June 4, 2013

Tesheia Johnson, MBA, MHS
Associate Director for Clinical Research, Yale School of Medicine
Chief Operating Officer, Yale Center for Clinical Investigation

We are new to this game!!!

Disclaimer
Yale purchased EPIC in June of 2010 and went live February 2013. Yale purchased OnCore clinical research management system in March of 2011. This session is intended to share common knowledge. This session is in no way intended to imply that we have figured it all out yet.

EPIC - Current Status

Epic Timeline
- Kickoff October 19, 2010
- Yale Medical Group first go-live October 19, 2011
- October 2012 — 300 YMG physicians live
- February 2013 — >800 YMG physicians live
- YMG on Epic Revenue
- Epic / OnCore integration

- YNHHS Hospitals
  - Greenwich April 2012
  - Yale New Haven – York Street Campus February 2013
  - Yale New Haven – Saint Raphael Campus June 2013
  - Bridgeport September 2013
- Rollout substantially complete EOY 2013
Yale clinical research profile

- Research without an identified clinical component: 49%
- Federally sponsored research: 6%
- Corporate Clinical Trial: 10%
- Career awards: 3%
- Other: 51%

Career awards
Federally sponsored research
Corporate Clinical Trial
Other

Industry sponsored research presents a growth opportunity at Yale

Source: Yale Grants and Contracts data – active research as of December 2012

Total submissions

Number of Submissions (Actions) Reviewed by the HIC & HSC FY 2010-2012

- FY 2010: 500
- FY 2011: 850
- FY 2012: 1,190

Number of Submissions (Actions) Reviewed by the HIC & HSC FY 2010-2012

Source: Coeus data – Presentation by Jan Hewitt March 23, 2013

New submissions

HIC New Submission Approvals FY2012 (n=1229)

- Full: 10%
- Expedited: 10%
- OHRP/FDA Regulated: 5%
- Other: 75%

Source: Coeus data – Presentation by Jan Hewitt March 23, 2013
Why did Yale go shopping?

- **Need a more robust solution**
  - Homegrown solution was too expensive
  - NIH (multi-center coordination/data coordinating center grants)
  - Industry research (better feasibility data)

- **Enterprise Reporting**
  - Senior leadership (YSM/YNHH), Chair, center director, and dept admin level reporting

- **Regulatory Compliance**
  - Data Safety and Monitoring plan compliance
  - Clinicaltrials.gov reporting
  - IND management

- **Financial management**
  - Better invoicing and fund management
  - Enhanced reporting

120 faculty and staff participated (YSM and YNHH)

Research Flow – Prior to Epic/OnCore
Where are we today? We have an interface!!!

http://medicine.yale.edu/ycci/oncore/newstudysetup/index.aspx

Where are we today? We have a process!!!

New studies intake at Yale

http://medicine.yale.edu/ycci/oncore/newstudysetup/index.aspx

Where are we today? We have a process!!!

OnCore Calendar Release
Where are we today? We have a process!!!

OnCore Study Build

OnCore Study Build

How the interface works (in OnCore): Sending a study

Study reviewed for billable procedures.
This is captured in the annotations in the PC Console.

Study sent to Epic via the RPE Console.

How the interface works (in OnCore): Sending a study

Confirm the correct study has been selected.

Verify the study went across the interface successfully.
Our overall plan: Deploy a team of YCCI staff to assist with some of the behind the scenes work to allow department research staff to continue their normal research responsibilities.

YCCI support for ALL departments indefinitely:
• In OnCore, send new studies, billing grids, and subjects to EPIC
• Activate new studies and publish newly released calendars/budgets in EPIC
• Set and update all study timelines in EPIC

Departments (or YCCI until they are trained/ready) will manage the following updates:
• Registering new subjects in OnCore
• Updating subject Status information in OnCore
• Checking in visits in OnCore
What is next?
The possibilities - nationally?

OnCore sites with EPIC

CTSA sites with EPIC

What is next – My functionality wish list?

• OnCore to feed – EPIC recruitment BPA and MyChart
• Integration screening and registries functionality to support recruitment
• Integration EHR data and OnCore case report form
• MyChart as EDC for patient reported outcomes for quality of life and other research.

Dreaming bigger than a phase on the map now:
Regulatory and metric support
Lessons so far and roadmap for the future

• Decide what you want to be when you grow up and work hard
  – What kind of things should your systems enable?
  – Dreaming in phases is easier and has rewards along the way

• Compliance is important, but not the only thing
  – Zero risk = zero research
  – What do the faculty care about?

• You can’t do everything at once
  – What is first and why?
  – Message consistently and constantly
  – Get help when you need it
  – Allocate resources to your dream

Questions?

Consulting Vendors

• (2008) Deloitte Consulting assesses current state and crafts a recommendation for a long-term draft plan
• (2009 - 2010) Kurt Salmon Associates Consulting assists with contract negotiations and develops Total Cost of Ownership (TCO) and funding models for EHR
• (2010 - 2011) Kurt Salmon Associates Consulting assists with contract negotiations and develops TCO for CRMS
• (2010-2011) Attorneys specializing in information technology contracts are engaged to develop Yale contract with CRMS vendor
• (2011 - present) Huron Consulting assists with CRMS implementation
• (2012) Meade, Roach & Annulis LLP / Aegis Compliance & Ethics Center, LLP assists with calendar build for go live
Yale-driven additional contracted functionality

- Yale customized reports
  - Yale customized datasets (April and September 2012)

- Randomization functionality
  - Automated randomization with an interactive algorithm (April 2012)

- SAS data extracts
  - Generation of study visit required to import data into study specific data (April 2012)

- Disease-centric research tools
  - (e.g., psychiatry, etc.)
  - (Delay data: Prior to Psychiatry Implementation)

- Epic Integration
  - Working closely with Epic and other Epic/OnCore centers to improve study and subject information
  - Support clinical research and billing data exchange
  - Will allow advanced randomization functionality and single data entry in support of billing and other functions (Delivery date: In conjunction with Epic go live, November 2012 - Moved to Feb 2013 new Epic go live)

- Clinical data interfaces
  - Automated upload of data from various systems in OnCore
  - Will allow enhanced recruitment functionality and single data entry in support of billing and other functions (Delivery date: In conjunction with Phase II of Cancer Center implementation)

- Patient access
  - Patient access to enter data directly (e.g., quality of life questionnaires, rating scales, etc.)
  - Delivery date: Prior to Psychiatry Implementation

OnCore vs. Epic

- Study Centric
  - Contains subject calendar with SOC vs R designation

- Patient Centric
  - Electronic Medical Record
  - Patient Billing system
  - Schedules patient visits
  - Allows for continuity of information between research and primary care

- Sponsor Invoicing System
  - Additional Research functionality beyond billing compliance

- Disease-centric research tools
  - (e.g., psychiatry, etc.)
  - (Delay data: Prior to Psychiatry Implementation)
OnCore – High Level Functionality

Helps manage all regulatory, patient, and financial needs throughout the lifecycle of a clinical trial.

Unified Regulations Management

Allows ad-hoc development of patient registries which can be de-identified to allow for data sharing and analysis.

Clinical Research Management

Allows for data capture of collection, processing, storage and shipment information.

Bio-Specimen Management