

## I-SPY 2 & 3 TRIALs

Advances in Clinical Research & Data Capture

## I-SPY's Primary Aim: Accelerate Pace of Progress

Current drug development model is too slow, too expensive, and **not** sustainable

The I-SPY mission is to:

- Implement efficient trial designs with use of biomarkers and/or surrogate endpoints to drive knowledge turns
- Increase therapeutic agents tested with a standing trial and extensive network of clinical sites
- Integrate the processes of clinical care and research, both technologically and culturally with team approach



#### **I-SPY 2 TRIAL**

#### 22 Participating Trial Sites, Expanding to Canada Screening 40+ patients per month



## Clinical Trial Data Capture – Advances with TRANSCEND

- An integrated modular platform to support adaptive clinical trials like I-SPY 2 TRIAL
- Structured, coded eCRFs with source documents attached to CRF in Electronic Data Capture system
  - Enable real-time, remote source data verification within EDC
- Randomization as an automated web service
  - Using data that has been source data verified
- Combining evaluation of drugs and biomarkers together
  - Scientists need access to data early and in an integrated fashion (one stop shopping)
    - Clinical, Pathology, Imaging data along with biomarker data of various types (microarray, sequencing, etc.)

**I-SPY 2 TRIAL** 

## **TRANSCEND** Platform

### Data Flow



#### Key Features of TRANSCEND

- Scalability with Salesforce, cloud-based environment
- Modular, can securely integrate with other applications as well

## Clinical Care & Research: EHRs and EDCs

Typical process for clinical research today

- 'Abstract' from EHR records instead of paper
- Data quality is still very poor
- 'Forage' for information but now across the EHR because data 'location' and recording is not standardized









## Irony of EHRs, physician productivity, information 'finding'



 Data shows physician productivity is not improved by EHRs and may be negatively impacted due to documentation challenges

#### 'Note Bloat'

- Clinicians spend time 'constructing' large, verbose, narrative notes
- Providers spend time sifting through bloated notes of others to find key pieces of clinical data to care for the patient

#### Emerging Observations

- Survey of 9 family practice physicians at 1 academic medical center, Providers with 2+ years of experience with EHRs,
  - Average 46 mins of free time lost per clinic day per physician
- Means physicians charting not in clinic but at home, nights, weekends

(1) http://www.redwoodmednet.org/projects/events/20130725/rwmn\_20130725\_mcdonald\_v2.pdf
(2) McDonald, McDonald. Arch Intern Med. 2012. Feb 13;172(3):285-7

# EHR 'Data Quality'... it's not all you think it is

- EHR clinical notes are often subjected to 'cut & paste' by clinicians, causing risk:
  - Incorrect information/diagnoses propagated forward
  - Perpetuates out-of-date information, not clear if the author really is reflecting on the 'today events'
  - Leads to less independent thinking of the case (of concern in training clinics)
  - Auto-inserted data contributes to poor readability of the for no practical reason
  - Hammond study highest copying events physical examination!

#### 90% of EHR using physicians admitted to copying, 80% planned to continue

(1) Thornton, et al. Society of Critical Care Medicine. Feb 2013;41(2):382-388
(2) Hammond, et al. AMIA Proceedings. 2003. pages 269-273

## Project INSPIRE – Workflow Study

- Systems Engineers mapped clinical workflow at 4 University of California Breast Care Clinics, participating in Athena
  - UCSF, UCSD, UC Davis, UC Irvine
  - 2 are HIMSS Stage 7
  - 40 interviews, 12 unique roles/perspectives including California Cancer Registry
- Compilation of 348 pain points & observations
- Created high-level process map of clinical care of breast care patients



Role

## Breast Cancer Care – Process Map



- Who has ownership of what data element?
- What data elements should be captured?
- When should the data be capture?

## Most common pain point – finding information in EHR



Capturing key data in checklists rendered in EHR – data then reused in eSource



## Re-engineering how we capture data within EHR, integrate with better data



### **Project INSPIRE:**

'capturing and exchanging key clinical data for care coordination in high impact conditions'



COTSP = Chemotherapy Treatment Plan and Summary (Breast Cancer specific)

Decreasing the pain of information finding – Motivating a transformational culture change

Everyone has to search through notes to find the proper data, often it is conflicting

- Clinicians
  - Taking care of a returning patient
  - Ongoing care management
  - Generating survivorship care plans (ASCO standards)
- Billing, Abstractors
- Cancer Registrars
- Clinical Researchers & Trial Coordinators
- Quality improvement

We need to start putting in place the critical building blocs of a Quality Management System