Clinical Trials Management Application (CTMA)
University of Pittsburgh Medical Center
Questions to answer:

• What resources exist currently to manage clinical trials information?
  – The clinical trials management application (CTMA)

• What is the future of data management in clinical trials?
  – The BRIDG model of clinical trials research
Clinical Trials Lifecycle

- Research Development
- New Idea Generation
- Data Analysis
- Study Setup
- Study Approval
- Subject Screening & Enrollment
- Subject Management
- Financial & Billing
- Reporting & Administration

'Typical' Clinical Trial Life-cycle
CTMA Overview

- Integrated tool for managing administrative (e.g., IRB approvals) and clinical (e.g., tumor measurements) functions for the collection and analysis of data generated from a clinical trial

  A web-based delivered application, written in Java with an Oracle 9i database

- Developed in collaboration with University of Pittsburgh Cancer Institute (UPCI) over the past 5 years

- Provides standardized reporting via Crystal Enterprise Server

- Manages all or part of 250 active protocols representing in-house, Co-op, NCI and pharmaceutical-sponsored trials

- Contains clinical data for approximately 16,000 patients (including legacy systems)

- Hillman Support Center, On-line Bug/Enhancement System, Training Facility, Online Help/Training Videos
User Community Members

- UPMC Cancer Centers (UMPCCC) & University of Pittsburgh Cancer Institute (UPCI)
- Western Psychiatric Institute and Clinic (WPIC) / (Patient Scheduling)
- Critical Care Medicine (CCM)
- Prostate, Lung, Colorectal & Ovarian Cancer Screening Center (PLCO)
- General Clinical Research Center (GCRC) / (Patient Scheduling)
- Department of Pharmaceutical Sciences
- Lupus Center of Excellence
- Department of Biostatistics

- **Future Members**
  - Anesthesiology
  - Radiology
  - Transplantation
  - UPP
  - Department of Surgery
  - Magee Gynecological

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2005 Data Statistics (UPCI Studies)

**Active Studies (Open to Accrual)**
- Therapeutic: 1,045
- Non-Therapeutic: 919

**Subjects on Treatment**
- Therapeutic: 2,436
- Non-Therapeutic: 576

*Represents various study sources from Investigator initiated, NCI funded and pharmaceutical-sponsored studies*
Coordinators/Investigators construct treatment schemas in the Layout Editor by choosing pre-defined temporal periods from the toolbar, and defining the day occurrences within those periods...
The computer generates a treatment schedule template representing the temporal periods in a linear format...

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Pre</th>
<th>v1</th>
<th>v2</th>
<th>v3</th>
<th>v4</th>
<th>v5</th>
<th>v6</th>
<th>v7</th>
<th>v8</th>
<th>v9</th>
<th>F/U</th>
<th>F/U</th>
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<td>7</td>
<td>14</td>
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</table>

Temporal Periods
Treatment Schedules

Then, the user selects the treatment events or procedures they wish to apply to the schedule template...
## Treatment Schedules

- By checking the appropriate event/period pairing, intersection points are added to complete the grid.
- A completed treatment schedule.

![Treatment Schedule](image)

### Grid

<table>
<thead>
<tr>
<th>Cycle/Week/Visit</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
<th>V6</th>
<th>F/U</th>
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<tr>
<td>Pre</td>
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<tr>
<td>Cycle 1</td>
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<td>21</td>
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<td>Day</td>
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<td>BSA</td>
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<td>CXR</td>
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<td>✔</td>
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<tr>
<td>ECG/Urinalysis</td>
<td>✔</td>
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<td>MRI</td>
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</tbody>
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Treatment Schedules Integration

- Patient Treatment Calendar
- Complete Patient Treatment Activity
- Adverse Events
- Drug Administration
Patient Enrollment Registry

Clinical Data Collection Forms

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Patient Calendar

- All patient activities
- Schedule & completed treatment (based on the treatment schedule)
- An interactive tool
  - Add new treatment items
  - Recording other events such as contacts or correspondence
- Printing of hard-copy calendars for distribution to patients
Administration and Regulatory Event Monitoring/Correspondence

Regulatory Monitoring

Email Correspondence

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## Treatment Progress Chart

### Completed Treatment

### Treatments due within 7 days of current date

### Overdue treatments based on current date

### Normal scheduled treatment

### Treatment Chart for Patient Study: 11

<table>
<thead>
<tr>
<th>Cycle/Week/Visit</th>
<th>Pre</th>
<th>v1</th>
<th>v2</th>
<th>v3</th>
<th>v4</th>
<th>v5</th>
<th>v6</th>
<th>v7</th>
<th>v8</th>
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<td>Patient Accrual (Single)</td>
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<td>Vitals Signs</td>
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</tbody>
</table>

*Completed Treatment Completed All Selected Treatments View Treatment Details*
Cost Mapping in the Financial Module

Standard of Care (SOC)

Cost Mapping View
- Maps costs for all treatments
- Toggles between normal view and treatment map

Variable Costs = designated per individual treatment occurrences
Fixed Costs = Costs applied across a series [or all] of occurrences

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Data Analysis and Data Mining: Crystal Enterprise Reporting
Questions to answer:

• What resources exist currently to manage clinical trials information?
  – The clinical trials management application (CTMA)

• What is the future of data management in clinical trials?
  – The BRIDG model of clinical trials research
Computerized doesn’t mean interoperability
Semantic interoperability: “Protocol” and the Semiotic Triangle

Concept 1
“We need to sign off on the protocol by Friday”

Concept 2
“Protocol XYZ has enrolled 73 patients”

Concept 3
“Per the protocol, you must be at least 18 to be enrolled”

Source: John Speakman/Charlie Mead
What is BRIDG?

- A formal model of the shared semantics of regulated clinical trials research
- A communication bridge between
  - clinical trial domain experts and technical experts
  - different models of clinical trials information
- An open community of stakeholders interested in developing standards for exchanging information about clinical trials
  - HL7 Domain analysis model in Regulated Clinical Research (RCRIM) technical committee
  - caBIG analysis model for model-driven development
  - CDISC integrating model for current standards
- The semantic foundation for application and message development in HL7, caBIG, and CDISC
BRIDG projects and contributors

BRIDG model
- Protocol Authoring & Trial Design
- Protocol Registration
- Clinical Trials Operations
- Adverse Events
- Lab Specification
- eDCI

Related Projects:
- EudraCT
- SDTM (CDISC)
- CONSORT (cancerGRID)
- WHO
- JANUS (IBM)
- PDQ ClinicalTrials.gov
- Study calendar (caBIG)
- FastTrack
- SDTM (CDISC)
- CTOM (caBIG)
- ODM (CDISC)
- HL7 (M Walker)
- JANUS (IBM)
- SDTM (CDISC)
- Lab SIG (caBIG)
- CTLab std (CDISC)

Contributors:
- FDA (M. Walker)
- HL7 (M Walker)
- caAERS (caBIG)
- caBIG NCI
- Oracle
- CDISC ODM
- Oracle

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Achieving interoperability

BRIDG – Domain Analysis Model for Clinical Research

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Further Information

- www.CDISC.org
- ncicb.nci.nih.gov
- caBIG.nci.nih.gov
- www.BRIDGproject.org
- fridsma@cbmi.pitt.edu

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