Clinical Research Information System Team Presentation

• New Developments
• Existing Functionality
• Overview of Best Practices.

June 29, 2011
CRIS Developments

WHAT WE CALL IT…

CRIS aka Velos eResearch
CRIS New Developments

REDCap
Research Electronic Data Capture
CRIS New Developments

REDCap

Research Electronic Data Capture

REDCap SURVEY
Background

• The REDCap project was developed by Vanderbilt University and includes more than 200 active institutional partners

• This project supports two web-based applications REDCap and REDCap Survey that were designed exclusively to support data capture for research studies

• These applications allow users to build and manage online surveys and databases quickly and securely

The University of Kansas Medical Center - Department of Biostatistics went live with REDCap in February of 2011
• REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies.

• This online tool provides users with:
  • a fast and flexible database development environment
  • secure data hosting and backups
  • an intuitive interface for collecting data
  • printable web forms
  • multi-site access.

• All data may be easily exported to Microsoft Excel or a variety of statistical analysis packages.
• REDCap Survey is a secure, web-based application that is flexible enough to be used for a variety of types of research.

• This powerful online survey tool provides users with an intuitive interface and real-time validation rules, such as data type and range checks.

• You can create and design surveys in your web browser and engage potential respondents using a variety of notification methods.

• Participant responses may be easily exported to Microsoft Excel or a variety of statistical analysis packages.
Who can use REDCap?

Any User at KUMC with a Current Login

https://redcap.kumc.edu
**Creation Process**

1. **Step 1** Learn
2. **Step 2** Create
3. **Step 3** Preview
   - (Option) Revise
4. **Step 4** Launch

- Register your project with the Department of Biostatistics
- Create your REDCap project online
- Preview your project content and test functionality
- Revise your REDCap database as needed
- Launch your project into production to start collecting data
<table>
<thead>
<tr>
<th>Feature</th>
<th>REDCap</th>
<th>CRIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who can enter data</td>
<td>KUMC Login</td>
<td>KUMC Login</td>
</tr>
<tr>
<td>Multi-user</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Web-based</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Export data sets and custom subsets, e.g., for data analysis</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>SAS, Excel, R, SPSS, STATA</td>
<td>SAS, Excel, Word</td>
</tr>
<tr>
<td>File uploading</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Scheduling/Study Calendar</td>
<td>✓ (limited)</td>
<td>✓ (Full study calendar with many options for tracking patient visits)</td>
</tr>
<tr>
<td>Generate PDF version of Data Forms to Print</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Study Management (Enrollment, subgroups, data dictionary, user-access privileges)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Adverse Event Reporting</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Customize the CRF Design (Make the form pretty)</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
If you want the CRIS Team to design and build a database for you, CRIS is your best option.

If you want your clinical research experts on your staff to configure the forms, REDCap is your best option.
CRIS Existing Functionality

- CRFs Customization
  - Supporting Customization
- Patient Portal
  - Subject Accrual
  - Multiple Portals
- eFinance
  - Budgets
  - Milestones
CRF STANDARD (Case Report Form)
STANDARD CASE REPORT FORM

Form Name: HbA1c Values

HbA1c Values

Data Entry Date*

Record patients' HbA1c values/date:

Time 1:
Date:
HbA1c: %

Time 2:
Date:
HbA1c: %

Form Status* Work In Progress e-Signature*
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Date of Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field ID</td>
<td>or_dof_date_01</td>
</tr>
</tbody>
</table>

**FIELD VALIDATIONS**
- Mandatory
- Override Mandatory Validation

**For Text Box/Number Field**
- Field Length
- Number of Lines
- Maximum Characters/Numbers
- Default Response

**For Date Field**
- Date cannot be a future date
- Override Date validation
- Default date to current date

**For Number Field**
- Override Number Format Validation
- Specify the format and maximum numbers that can be entered e.g., ### or ##.# etc., where "#" signifies a number and "." signifies a decimal point
- Response Should Be: Select an Option

**e-Signature**
CRF WITH FORM SETTINGS
CRF WITH CUSTOMIZATION
CUSTOMIZATION USING JAVASCRIPT AND XSL
CRF WITH CUSTOMIZATION WITH NO CHANGES TO FORM
CRF WITH CUSTOMIZATION WITH CHANGES TO FORMS FIELD
CRF WITH CUSTOMIZATION WITH CHANGES TO FORM LABELS
SINGLE FORM

Form Name: Patient Information Form Lvl 3

Child for Whom Evaluation Is Needed

Date Entry: 06/29/2011

Full Name: 

Social Security No.: 
Date of Birth: 

School Name: 
School District: 

Child's Street Address: 
City: 

County: 
State: 
Zip: 

Home Phone: 
Work Phone: 
Cell Phone: 

Pager: 
E-mail: 

Name of Person Completing Form: 

Relationship to Child: Parent 
Adoptive 
Relative 
Guardian 
Foster 
Institution 
Other 

What questions or concerns are most important to you at this time?
1. 
2. 
3. 

In the space provided, please write a paragraph that best describes your child, including strengths and weaknesses.
Please use the links below to fill out all study measures. **Please make sure to click submit button before you close each study form.** When you are finished completing the Medical/Health Information form, a message will appear next to the link indicating that it has been completed.

For all other forms, this message **WILL NOT** appear because we are asking participants to complete the other forms at two different time points. **Please note which forms you have completed and which you have not;** do not worry if you accidentally open a form a second time because the system will remember your data each time you complete a form.

In some browsers (such as Internet Explorer), the links will change to a red color to indicate that you have already clicked on the link (but not necessarily that you are finished filling it out). In other browsers, the links will not change colors in other browsers.

Please contact one of the study coordinators if you have problems while completing the forms (Jason Van Allen, jvanallen@ku.edu, Brad Nelson, bnelson@kumc.edu, or Susana Patton, spatton2@kumc.edu). Thank you for participating!

**Your Forms:**
- Child Forms Part 1 (41 questions)
- Child Forms Part 2 (29 questions)
- Child Forms Part 3 (37 questions)
# MULTIPLE PORTALS

<table>
<thead>
<tr>
<th>Portal Name</th>
<th>Description</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCHD-2</td>
<td>-</td>
<td>Active H</td>
</tr>
<tr>
<td>CCHD-3</td>
<td>-</td>
<td>Active H</td>
</tr>
<tr>
<td>CCHD-4</td>
<td>-</td>
<td>Active H</td>
</tr>
</tbody>
</table>

![Player Images]

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![KU Medical Center Logo]
eFINANCE
eFINANCE
FEATURES

NOTIFICATIONS

PAYMENTS

INVOICING
CRIS Overview

BEST PRACTICES

• MULTIPLE CRFs
• AD HOC QUERIES
• MAXIMUM FIELDS
CRF

- Do not number the questions
- Do not use checkboxes
- Custom Coding is not something that is readily offered
- If Multiple timepoints must have separate forms for each timepoint

Ex. Timepoints = 5; create 5 separate forms
Ad-Hoc Queries

- Biostatisticians and CRIS Support team have the ability to create Ad Hoc Queries.
- Use “Shared With” option on reports for viewing restrictions.
- When copying an Ad Hoc Query, the Select Report Type section cannot be manipulated.
Maximum Fields

100 fields is the suggested maximum field for CRF’s

- More than 100 fields slows down the system
- To alleviate this issue break the CRF into multiple forms