

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



CRIS New Developments



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

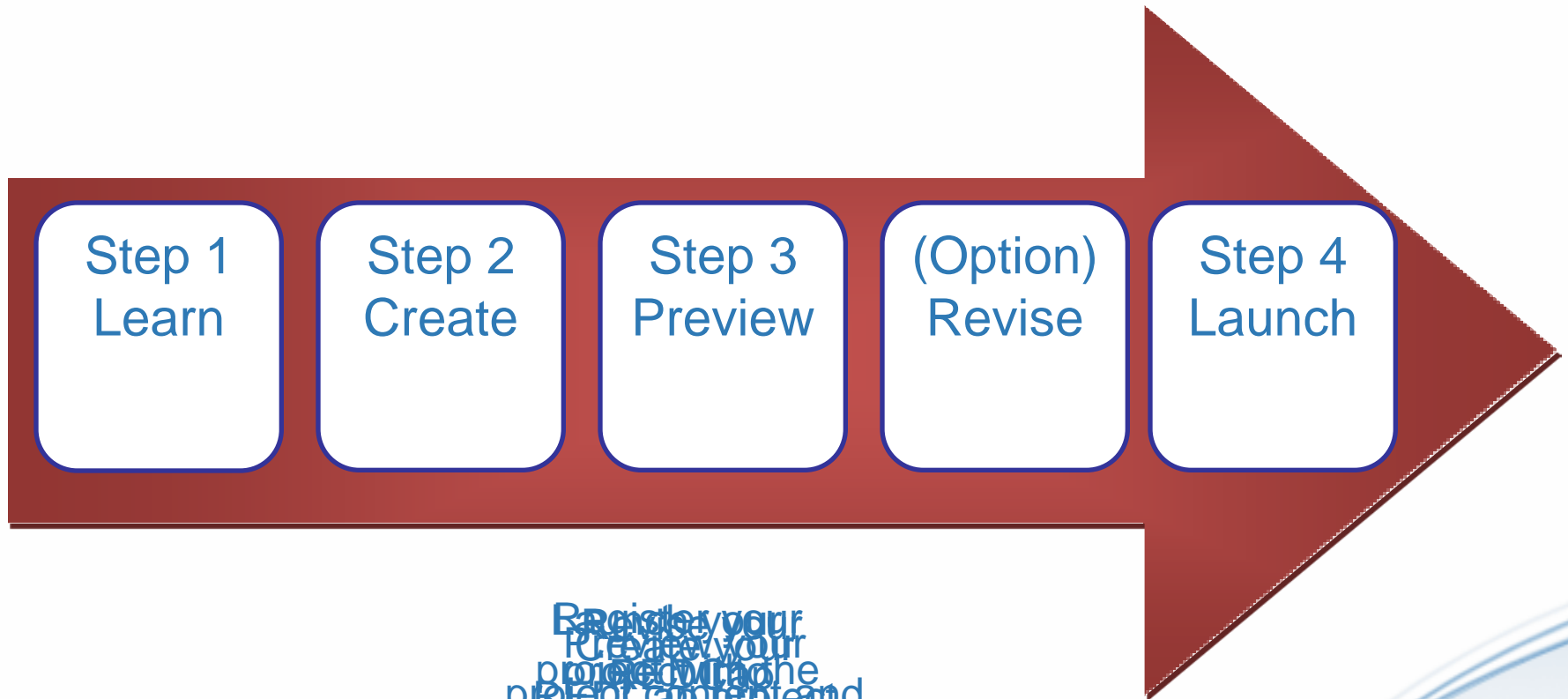
- REDCap Survey is a secure, web-based application that is flexible enough to be used for a variety of types of research.
- This powerful online survey tool provides users with an intuitive interface and real-time validation rules, such as data type and range checks
- You can create and design surveys 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>

REDCap Creation Process



Register your
KU data
project with the
project can help and
production start
test functionality
collecting project
data

	REDCap	CRIS
Who can enter data	KUMC Login	KUMC Login
Multi-user	✓	✓
Web-based	✓	✓
Export data sets and custom subsets, e.g., for data analysis	✓ SAS, Excel, R, SPSS, STATA	✓ SAS, Excel, Word
File uploading	✓	✓
Scheduling/Study Calendar	✓ (limited)	✓ (Full study calendar with many options for tracking patient visits)
Generate PDF version of Data Forms to Print	✓	✓
Study Management (Enrollment, subgroups, data dictionary, user-access privileges)	✓	✓
Adverse Event Reporting		✓
Customize the CRF Design (Make the form pretty)		✓



REDCap vs. CRIS

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

CRIS Existing Functionality

- **CRFs Customization**
 - Supporting Customization
- **Patient Portal**
 - Subject Accrual
 - Multiple Portals
- **eFinance**
 - Budgets
 - Milestones


CRF STANDARD (Case Report Form)



Form Name: HbA1c Values


STANDARD CASE REPORT FORM

HbA1c Values

Data Entry Date* 


Record patients' HbA1c values/date:

Time 1:


Date: 

Hba1c: %

Time 2:

Date: 

Hba1c: %

Form Status* 

e-Signature *

FIELD TYPE: EDIT BOX

Section*	Child for Whom Evaluation Is Needed
Sequence*	1
Field Name *	Date of Entry: 44
Field ID *	er_def_date_01
Edit Box Type	<input type="radio"/> Text <input type="radio"/> Number <input checked="" type="radio"/> Date
Field Characteristics	<input checked="" type="radio"/> Visible <input type="radio"/> Hide <input type="radio"/> Disable <input type="radio"/> Read Only
Label Display Width	13 % <input type="checkbox"/> Expand Label <input type="checkbox"/> Hide Label <input type="checkbox"/> Bold <input type="checkbox"/> Italics
Field Description	
Search Keyword(s) ?	
Field Help (On Mouse Over)	
Align (Field Display Name)	<input type="radio"/> Left <input type="radio"/> Right <input type="radio"/> Center <input type="radio"/> Top <input checked="" type="checkbox"/> Same line as previous field

FIELD VALIDATIONS

Mandatory Override Mandatory Validation

For Text Box/Number Field

Field Length	<input type="text"/>
Number of Lines	<input type="text"/>
Maximum Characters/Numbers	<input type="text"/>
Default Response	<input type="text"/>

For Date Field

<input type="checkbox"/>	Date cannot be a future date
<input type="checkbox"/>	Override Date validation
<input type="checkbox"/>	Default date to current date

For Number Field

<input type="text"/>	Override Number Format Validation	<input type="checkbox"/>	
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	<input type="text"/>	Select an Option
	Select an Option	<input type="text"/>	
Override Number Range Validation	<input type="checkbox"/>		

e-Signature *

Submit

FORM FIELDS

CRF WITH FORM SETTINGS



FORM SETTINGS

Define Field Action

SKIP LOGIC

Select Source Field* pat_insur [pat_insur]

Select Action Condition* Equal To

Select Responses * [Patient does not have in

Select Target Fields * [Insurance Company].[F

Select Action* Disable

e-Signature *

Do not enter any 'Responses' for 'Is Null' and 'Is not null' conditions

RESTRICTIONS

Shared With

- Private
- All Account Users
- All Users In a Group
- All Users in Study Team
- All Users in an Organization

Define Field Calculation

SIMPLE CALCULATIONS

Select Source Fields*

Select Calculation Type* Select an Option

Select Target Fields *

e-Signature *

Form Settings >> Form Notification

Message Type Pop-up Message when user submits form Notification Email sent to specified users

Users to receive notification are

Message Text *

e-Signature *

NOTIFICATIONS

CRF WITH CUSTOMIZATION





CUSTOMIZATION USING JAVASCRIPT AND XSL

- Manage Account
- Select Datasource
- DB Maintenance
- Report Designer
- Data Migration
- CDUS
- Manage Forms
- Form from File**
- Form Transfer
- Customize Form
- caDSR Integration
- Manage Calendars
- Manage Budgets
- Logout

Manage Forms

- Form from File
- Form Transfer
- Customize Form
- caDSR Integration**

```
..
  <td width="0%" align="left"><label id="fldkumctest_109722_129869_id"
for="fldkumctest_109722_129869">&#xA0;</label> &#xA0;&#xA0;&#xA0;</td>
  <td>
    <span id="fldkumctest_109722_129869_span">
      <input id="fldkumctest_109722_129869" name="fldkumctest_109722_129869"
fldddatatype="T" type="text" maxlength="256" size="20" onChange="performAction
(document.er_fillform1,document.er_fillform1.fldkumctest_109722_129869)">
      <xsl:attribute name="value">
        <xsl:value-of select="fldkumctest_109722_129869"/>
      </xsl:attribute>
    </input>
  </span>
</td>
..
```

CRF WITH CUSTOMIZATION WITH NO CHANGES TO FORM

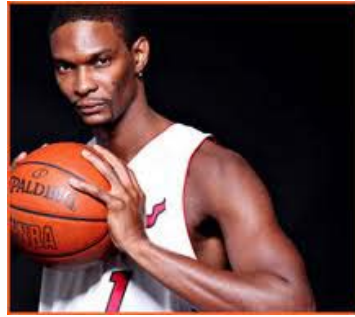


CRF WITH CUSTOMIZATION WITH CHANGES TO FORMS FIELD



CRF WITH CUSTOMIZATION WITH CHANGES TO FORM LABELS






PATIENT PORTAL



SINGLE FORM

Form Name: Patient Information Form Lvl 3

Child for Whom Evaluation Is Needed

Data Entry Date* 

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?

-
-
-

In the space provided, please write a paragraph that best describes your child, including strengths and weakness.



MULTIPLE FORMS

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 \(37 questions\)](#)



Powered By



MULTIPLE PORTALS

Portal Name	Description	Status
CCHD-2	-	Active H
CCHD-3	-	Active H
CCHD-4	-	Active H



eFINANCE



eFINANCE

Details | Budget | Appendix | Access Rights

Budget Name *

Version Number

Comments
(Limit 4000 characters)

Created By * [Select User](#)

Budget Currency *

Budget Template *

Budget Status

Budget is Organization non-specific

Budget is specific to Organization:

Associate Budget to the following Study:

e-Signature *

FEATURES

Milestones | Notifications | Invoicing | Appendix | Payments

Study Number:00000002 Study Title: [View Title](#)

Search By

Milestone Type: Status: Payment Type:

Calendar: Visit: Event:

Exclude Inactive Items

Saved Milestones: [Activate](#) [Delete](#) [Revert to Work in Progress](#) [View/Delete Achievements](#)

Rule	Calendar	Visit	Event	Status	Amount (in \$)	Type	Select
------	----------	-------	-------	--------	----------------	------	--------

Patient Status Milestones [ADD NEW](#)

20 'Enrolled' patients				Active	No Associated Amount	Receivable	<input type="checkbox"/>
--	--	--	--	--------	----------------------	------------	--------------------------

- Visit Milestones [ADD NEW](#)
- Event Milestones [ADD NEW](#)
- Study Status Milestones [ADD NEW](#)
- Additional Milestones [ADD NEW](#)

NOTIFICATIONS

Milestones >> Edit Milestones

Description: *

Amount (in \$): .

Payment Type:

Payment For:

Milestone Status:

e-Signature *

PAYMENTS

Type *

Description:

Payment Date *

Amount (in \$) * .

Comments:

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 can not 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

A decorative, classical-style column with a capital, rendered in a golden-brown color, is positioned on the left side of the image.

KU THE UNIVERSITY OF
KANSAS
Medical Center

