

Electronic Data Capture Systems and Data Management Best Practices

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Learning Objectives

JTF Clinical Research Competency Domains – 4 and 6

- Describe Good Clinical Practice guidance regarding data quality and audit trails
- Discuss the differences between Source Documents and Case Report Forms
- Apply ALCOAC-CEA principles to paper and electronic database design
- Incorporate Quality Assurance into your electronic database design

Nobel Prize-winning scientist Frances Arnold retracts paper



Frances Arnold

@francesarnold



It is painful to admit, but important to do so. I apologize to all. I was a bit busy when this was submitted, and did not do my job well.



Frances Arnold @francesarnold

For my first work-related tweet of 2020, I am totally bummed to announce that we have retracted last year's paper on enzymatic synthesis of beta-lactams. The work has not been reproducible. science.sciencemag.org/content/364/64...

1:02 PM · Jan 2, 2020



5.1K



965 people are Tweeting about this



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<https://www.bbc.com/news/world-us-canada-50989423>

Nobel Prize-winning scientist Frances Arnold retracts paper

"Efforts to reproduce the work showed that the enzymes do not catalyze the reactions with the activities and selectivities claimed. **Careful examination of the first author's lab notebook then revealed missing contemporaneous entries and raw data for key experiments.** The authors are therefore retracting the paper."



Good Clinical Practice (GCP)

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, **recording and reporting trials** that involve the participation of human subjects.

Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, **and that the clinical trial data are credible.**

Good Clinical Practice (GCP)

Audit: A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and **the data were recorded, analyzed and accurately reported** according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Audit Trail: Documentation that allows reconstruction of the course of events.

- ICH GCP E6

Good Clinical Practice (GCP) - Essential Documents

- **“If it isn’t documented, it didn’t happen”**. This highlights how important record keeping/data collection is in the field of clinical research and it applies to regulatory and clinical documentation.
- The documents/data should be maintained so that an independent person, with no knowledge of the study, can review the study documents and follow the life cycle of the study without input from the study team.

Source Documents



- All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.

- Section 1.51 ICH E6 GCP

Examples:

- Signed informed consent forms
- Hospital records and clinical notes
- Laboratory result reports



*Note: All source material must be signed and dated by the person who documented the information. This includes electronic signatures.

Case Report Forms (CRFs)

- A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. - Section 1.11 ICH E6 GCP

Examples:

- A CRF to record patient demographics
- A CRF to record laboratory results

Notes:

- CRFs can be paper or electronic (e.g. REDCap, RAVE)
- CRFs should only capture data that is specified in the approved protocol
- Every data point collected on a CRF requires complementary source data in order to be verified

The image shows a sample 'Personal Information Sheet' form. It is a light blue document with black text. The title 'Personal Information Sheet' is at the top. Below it are various fields for patient information, each followed by a line for writing. The fields include: SURNAME, FORM CLASS, FIRST NAME, BIRTHDAY, PREFERRED NAME, AGE, RESIDENTIAL ADDRESS, POSTAL ADDRESS (if different from above), HOME PHONE NUMBER, MOTHER'S NAME, EMAIL, WORK PHN, MOTHER'S MOBILE, FATHER'S NAME, EMAIL, WORK PHN, FATHER'S MOBILE, CAREGIVERS NAME/S (if different from Mother/Father), PHONE NUMBER, OPTION CHOICES, and SPORTING/CULTURAL INTERESTS.

Source

LabCorp
Laboratory Corporation of America

LabCorp San Diego
13112 Evening Creek Dr So Ste 200
San Diego, CA 92128 4108
Phone: 858-668-3700

333-086-0655-0 22247228
DONAIRE
NONITO
4897 THOMPSON DR.
SAN MATEO CA 94401
11/29/10 10:52 11/29/10 12/02/10 06:08ET

Request A Test, LTD.
VART Verified
8803 Brecksville Rd. Ste. 7-130
BRECKSVILLE OH 44141
PHOTO ID REQUIRED

CBC With Differential/Platelet; Comp. Metabolic Panel (14); IGF-1; Testosterone, Serum; LDL; Creatine Kinase, Total, Serum; Magnesium, Serum; Zinc, Plasma or Serum; Ferritin, Serum; Venipuncture

TESTS RESULT FLAG UNITS REFERENCE INTERVAL LAB

CBC With Differential/Platelet

WBC 5.1 x10E3/uL 4.0 - 10.5 01

RBC 4.94 x10E6/uL 4.10 - 5.60 01

Hemoglobin 15.1 g/dL 12.5 - 17.0 01

Hematocrit 46.2 % 36.0 - 50.0 01

MCV 94 fL 80 - 98 01

MCH 30.6 pg 27.0 - 34.0 01

MCHC 32.7 g/dL 32.0 - 36.0 01

RDW 13.2 % 11.7 - 15.0 01

Platelets 201 x10E3/uL 140 - 415 01

Neutrophils 44 % 40 - 74 01

Lymphs 44 % 14 - 46 01

Monocytes 9 % 4 - 13 01

Eos 3 % 0 - 7 01

Basos 0 % 0 - 3 01

Neutrophils (Absolute) 2.2 x10E3/uL 1.8 - 7.8 01

Lymphs (Absolute) 2.3 x10E3/uL 0.7 - 4.5 01

Monocytes (Absolute) 0.5 x10E3/uL 0.1 - 1.0 01

Eos (Absolute) 0.1 x10E3/uL 0.0 - 0.4 01

Baso (Absolute) 0.0 x10E3/uL 0.0 - 0.2 01

Immature Granulocytes 0 % 0 - 1 01

Immature Grans (Abs) 0.0 x10E3/uL 0.0 - 0.1 01

Comp. Metabolic Panel (14)

Glucose, Serum 95 mg/dL 65 - 99 01

BUN 12 mg/dL 5 - 26 01

Creatinine, Serum 1.02 mg/dL 0.76 - 1.27 01

eGFR >59 mL/min/1.73 >59

eGFR AfricanAmerican >59 mL/min/1.73 >59

Note: Persistent reduction for 3 months or more in an eGFR <60 mL/min/1.73 m2 defines CKD. Patients with eGFR values >=60 mL/min/1.73 m2 may also have CKD if evidence of persistent proteinuria is present. Additional information may be found at www.kdopi.org.

DONAIRE, NONITO 22247228 333-086-0655-0 Seq # 5966

FINAL REPORT

Page 1 of 2

This document contains private and confidential health information protected by state and federal law. If you have received this document in error, please call 800-542-7708

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CRF



IRB Protocol #: 19-0001

Study PI: Dr. Smith

Research Blood Work Results

Subject ID: 001

Study Visit #: 1

Date and Time Collected: 11/29/10 @10:52

Date and Time Reported: 12/02/10 @06:08

Test	Result	Units	Clinical Significance? (Y/N)
WBC	5.1	IU	N
RBC	4.94	IU	N
Hemoglobin	15.1	g/dL	N
Hematocrit	46.2	%	N
Glucose, serum	95	mg/dL	N
BUN	12	mg/dL	N
Creatinine, serum	1.02	mg/dL	N

NOTES: Drawn from median cubital vein from right arm with 23-gauge butterfly needle using only one

attempt with no complications

* Document location of blood draw, size of the needle, number of attempts, and if there were any complications or trauma to the site. (ex: Right Antecubital, 23 gauge butterfly needle, 1 attempt, no complications.)

Study Personnel Signature: Alyssa Matthews

Completion Date: 12/3/10



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Can a study specific CRF be used as a source document?

Yes – CRFs may be used as source documents if they are the first place that the collected data was recorded.

For Example:

- An Incentive Spirometry Measurement taken in-person for research purposes only
- The results from this measurement are recorded directly onto a study specific CRF
- This is the original record of this data, and is considered a source document
- The CRF must be signed and dated by the member of key personnel responsible for this data and this form should be filed as a source document in the subject's file



Can something be used as both a source document and a CRF?

Yes – A CRF is a document designed to record protocol specific information, so if this is the original place this data is being recorded, then a study specific CRF can also be signed and dated and considered a source document.

For Example:

REDCap is a secure database used to record and maintain data and can be used as a CRF or a source document.

- Used as a Source Document – if this is where the data was initially recorded (in-person data recording or a subject survey sent out via REDCap)
- Used as a CRF – if the original recording of the data is elsewhere (a subject's lab results where the original results are in the medical record)*

*NOTE: If being used as a CRF, the complementary source documentation is required

Do I need hard copies of all of my source documents?

No. However, there must be a verifiable audit trail for all source documentation.

- If the source documentation is being kept electronically (the EMR or a share drive) then a Note to File must accompany any CRFs in the subject file to clearly outline the path to access the source documentation.

Examples:

- “Verification of eligibility criteria can be found in subject’s clinic visit note in their electronic medical record signed on 10/15/19 by Dr. Smith”.
- “All lab results recorded on individual subject CRFs have complementary source documents saved in participant-specific folders on the hospital share drive. Path: S:\Groups\Stark\00-001\Labs”

****All Notes to File must be signed and dated****

ALCOAC-CEA Principles

- Attributable – Who collected the data, performed a test, completed the documentation or edited the document and when.
- Legible – The documentation and all subsequent changes should be permanent and easy to read.
- Contemporaneous – Documentation should be completed and dated in real time.
- Original – Study documents should be the originals, or it should be noted where the originals are located.
- Accurate – Documentation should be comprehensive and truthfully reflect what was observed.
- Complete – Maintenance of complete and up-to-date study documents.
- Consistent – The data's sequence of events is in the expected sequence of operations and date and time stamped.
- Enduring – Paper and electronic data are appropriately recorded in lab notebooks, spreadsheets, databases etc.
- Available – Paper and electronic data are required to be readily available for review, audits, or inspections.



Correcting Study Documents Using ALCOAC-CEA

Error	Do's	Don'ts
<ul style="list-style-type: none">• Correction needed on the original source document or a case report form	<ul style="list-style-type: none">• Cross out wrong information with a single line, write in the correct information and initial and date the correction	<ul style="list-style-type: none">• Scribble over the mistake• Use white out• Write over the original data to correct it• Destroy the originals• Forget to initial and date!
<ul style="list-style-type: none">• Missing data located at a later date	<ul style="list-style-type: none">• Incorporate the data into the research record and initial and date with the current date	<ul style="list-style-type: none">• Ignore the missing data• Backdate or predate the information

Activity 1

Take a minute and try to find all of the ALCOAC-CEA Principle errors in this document.

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/2020	Jan, 1 st 2000	20

Height (in)	Weight (lbs)	BMI (kg/m ²)†
5ft. 4in.	124	22

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated? ☐ Yes ☒ No

Did the subject rest for 15 minutes? ☐ Yes ☒ No

Systolic BP	Diastolic BP

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/12	2:55 pm	7

Notes

no complications from blood draw
2 5mL tubes were drawn

Signature: Air P/d-Gy

Date: _____

Patient wants
reminder of next visit
a few days before



Bad ALCOAC-CEA

THE
University of Vermont
HEALTH NETWORK

IRB Protocol #: Citadel Study
Principal Investigator: _____

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/2020	Jan, 1 st 2000	20

Height (in)	Weight (lbs)	BMI (kg/m ²)†
5ft. 4 in.	124	22

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Systolic BP	Diastolic BP
Did the subject rest for 15 minutes?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/21	2:55 pm	7

Notes
no complications from blood draw
2 5mL tubes were drawn

Signature: Am P/d-Gy

Date: _____

Patient wants
reminder of next visit
a few days before

Good ALCOAC-CEA

THE
University of Vermont
HEALTH NETWORK

IRB Protocol #: STUDY01234
Principal Investigator: Dr. Samuel Torrey

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/21	01/01/20	21

Height (in)	Weight (lbs)	BMI (kg/m ²)†
64	125	21.3

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Systolic BP	Diastolic BP
Did the subject rest for 15 minutes?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	135	75

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/21	2:55 pm	7

Notes
no complications from blood draw
2 5mL tubes were drawn

Signature: Am P/d-Gy

Date: 01/01/21

Patient wants a reminder
of their next visit a
few days before the visit APC 1/1/21

Options for Data Collection

- Paper Forms
- Electronic Forms
 - Electronic Health Record (EHR) Epic
 - Electronic Data Capture (EDC) REDCap, RAVE
 - Clinical Trials Management System (CTMS) OnCore, Velos
- Combination of Paper and Electronic

Electronic Database Development - Where to Begin?

Start at the end!

- What specific data points are required to perform the statistical analysis?
- What specific data points are on the Case Report Forms (CRFs)?
- What is described in the protocol and other study documents?

Electronic Database Development – Team Work

All study team members involved in data collection, data entry, or data analysis must be actively involved in the

- Development
- Testing
- Training

Electronic Database Development - Preparation

Database development requires very detailed knowledge about each data point/field.

- What is being collected and in what format?
 - Weight: lbs or kg?
- When is it being collected? (Every 12 weeks +/- 7 days)
 - Base off of which starting date? Date of Consent, Date of Enrollment, Day 1 Rx?
- Who is collecting it?
 - Who needs access, who needs to be involved in the process?

Electronic Database Development - Preparation

STUDY DESIGN AND SCHEDULE OF ASSESSMENTS

Assessment	Screening	Run-in	Baseline	Treatment				Follow-up		
Study Week	-2	-1	0	1	2	3	4	5	6	8
Informed Consent	x									
History	x									
Physical Exam.	x									x
<u>Effectiveness</u>										
primary variable	x	x	x	x	x	x	x	x	x	x
secondary variable	x	x	x	x		x			x	x
<u>Safety</u>										
Adverse events	x	x	x	x	x	x	x	x	x	x
Lab. tests	x		x	x			x		x	x
Body weight	x		x						x	x



Electronic Database Development - Preparation

But my study uses EHR (source) and RAVE (CRF), this doesn't apply to me.

Electronic Database Development – Quality Assurance

Maximize features that minimize errors

- Field validation
 - Calculation
 - Logic
 - Remote Data Capture
 - Automation
 - Alerts
- Scheduling
 - Double Entry
 - Queries
 - Audit Trail
 - Reports



Electronic Database Development – Data Field

Add New Field ✕

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...) ▼

Field Label ❏ Use the Rich Text Editor ?

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilized in logic, calcs, and exports)

☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use [\[S\] Smart Variables](#) [Piping](#) [Field embedding](#)

Validation? (optional) ----- None ----- ▼

– OR –

-- select ontology service -- ▼

Required?* ☒ No ☐ Yes
* Prompt if field is blank

Identifier? ☒ No ☐ Yes
Does the field contain identifying information (e.g., name, SSN, address)?


Custom Alignment Right / Vertical (RV) ▼
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field

Save **Cancel**



Electronic Database Development - Field Type

Field Type: ---- Select a Type of Field ---- 

- Select a Type of Field ----
- Text Box (Short Text, Number, Date/Time, ...)
- Notes Box (Paragraph Text)
- Calculated Field
- Multiple Choice - Drop-down List (Single Answer)
- Multiple Choice - Radio Buttons (Single Answer)
- Checkboxes (Multiple Answers)
- Yes - No
- True - False
- Signature (draw signature with mouse or finger)
- File Upload (for users to upload files)
- Slider / Visual Analog Scale
- Descriptive Text (with optional Image/Video/Audio/File Attachment)
- Begin New Section (with optional text)



Electronic Database Development - Field Validation

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...) ▼

Field Label

☐ Use the Rich Text Editor ?

Subject's Date of Birth

Variable Name (utilized in logic, calcs, and exports)

dob

☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use [+] Smart Variables [P] Piping [D] Field embedding

Validation? (optional)

Date (M-D-Y) ▼

Minimum: 01-01-1920

Maximum: 08-18-2002

-- select ontology service -- ▼



Electronic Database Development - Field Validation

Variable Name (utilized in logic, calcs, and exports)

ONLY letters, numbers, and underscores

☐ Enable auto naming of variable based upon its Field Label?

How to use [\[+\] Smart Variables](#) [Piping](#) [Field embedding](#)

Validation? (optional) ---- None ----

– or –

Required?* ☒ No ☐ Yes
* Prompt if field is blank

Identifier? ☒ No ☐ Yes
Does the field contain identifier?

Custom Alignment
Align the position of the field

Field Note (optional)
Small reminder text displayed

- None ----
- Date (D-M-Y)
- Date (M-D-Y)
- Date (Y-M-D)
- Datetime (D-M-Y H:M)
- Datetime (M-D-Y H:M)
- Datetime (Y-M-D H:M)
- Datetime w/ seconds (D-M-Y H:M:S)
- Datetime w/ seconds (M-D-Y H:M:S)
- Datetime w/ seconds (Y-M-D H:M:S)
- Email
- Integer
- MRN (10 digits)
- Number
- Number (1 decimal place)
- Number (2 decimal places)
- Phone (North America)



Electronic Database Development - Validation

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Calculated Field

Field Label

☐ Use the Rich Text Editor ?

Subject's age when signed consent form

Calculation Equation [How do I format the equation?](#)

```
rounddown(datediff([general_forms_arm_1][dob],[general_forms_arm_1][initial_consent_date],"y", "mdy"), 0)
```

[Clear calculation](#)

Variable Name (utilized in logic, calcs, and exports)

age_entry

☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use: [Smart Variables](#) [Piping](#) [Field embedding](#)

Required?* ☒ No ☐ Yes

* Prompt if field is blank

Identifier? ☒ No ☐ Yes

Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)

Align the position of the field on the page

Field Note (optional)

Small reminder text displayed underneath field



Electronic Database Development - Field Calculation

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Calculated Field

Field Label

☐ Use the Rich Text Editor [?](#)

Subject's age when signed consent form

Calculation Equation [How do I format the equation?](#)

```
rounddown(datediff([general_forms_arm_1][dob],[general_forms_arm_1]  
[initial_consent_date],"y", "mdy"), 0)
```

[Clear calculation](#)

Variable Name (utilized in logic, calcs, and exports)

age_entry

☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#) [Field embedding](#)

Required?* ☒ No ☐ Yes

* Prompt if field is blank

Identifier? ☒ No ☐ Yes

Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)

Align the position of the field on the page

Field Note (optional)

Small reminder text displayed underneath field



Electronic Database Development - Piping

 Editing existing Record ID **002**

Event Name: **General Forms (Arm 1: Arm 1)**

Record ID

Name: John Lennon

DOB: 10-09-1940

Preferred Name: John

Pronouns: he/him/his, _____

Allergies: None known, _____



Electronic Database Development – Logic

Have you traveled outside your state of residence in the last 14 days for non-essential travel?

☒ Yes
☐ No

[Link to answers for travel questions and definitions of essential travel](#)

* must provide value

According to the Vermont Department of Health (VDH) website does the county you traveled from require quarantining at this time?

☐ Yes
☐ No

[Map of quarantine and non-quarantine counties throughout the Northeast](#)

* must provide value

Have you traveled outside your state of residence in the last 14 days for non-essential travel?

☐ Yes
☒ No

[Link to answers for travel questions and definitions of essential travel](#)

* must provide value

Please check the appropriate box (yes or no) to the following question: Have you had COVID-19 symptoms that cannot be attributed to a pre-existing condition?

Have you had a fever (100.4°F/38°C or higher) in the last 14 days?

☐ Yes
☐ No

* must provide value



Electronic Database Development – Remote Data Collection



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Resize font:
⊕ | ⊖

Electronic Consent - Research Study


Thank you for your interest in the Research Study.

If you have any questions about the study, please email [Insert study contact email](#) or call 802-XXX-XXXX before signing the consent form.

Thank you!

Page 1 of 9

If you would like to download a blank copy of the Informed Consent to review prior to signing electronically, please click on the PDF document below to download and save to your computer.

Attachment:  [Placeholder for IRB ICF.pdf](#) (0.06 MB)

Informed Consent Form



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Electronic Database Development - Automation

Automated Invitations

Choose an event below for which to set up or modify automated survey invitations.

 Modify

2 1/2 Year Follow Up

 Modify

3 Year Follow Up

 Modify

3 1/2 Year Follow Up

 Modify

4 Year Follow Up

 Modify

4 1/2 Year Follow Up

 Modify



5 Year Follow Up







Electronic Database Development - Alerts




Alerts & Notifications




The Alerts & Notifications feature allows you to construct alerts and send customized email notifications. These notifications may be sent to one or more recipients and can be triggered or scheduled when a form/survey is saved and/or based on conditional logic whenever data is saved or imported. When adding/editing an alert, you will need to 1) set how the alert gets triggered, 2) define when the notification should be sent (including how many times), and 3) specify the recipient, sender, message text, and other settings for the notification. For the message, you may utilize customized options such as rich text, the piping of field variables (including Smart Variables), and uploading multiple file attachments. [Learn more](#)

 My Alerts  Notification Log

 Add New Alert ☐ Show deactivated alerts

 Alert #1: Fundamentals in the Conduct of Clin...  Edit  Options ▾

 When the instrument "Fundamentals in the Conduct of Clinical Research Registration (Registration)" is saved and has any form status.
 Send immediately
 Send one time (only once per event in a record and also on every instance of a repeating instrument/event)

 Activity:  75 records were alerted ([view list](#))  Last sent: 01/04/2021 9:25am

























Email Preview ▾

From: Jennifer.Holmes@uvmhealth.org
To: annie.penfield-cyr@med.uvm.edu; jennifer.holmes...
Subject: NEW Fundamentals in the Conduct of Clinical...
([record_id], [first] [last],) just registered for [dates] Fu...



Electronic Database Development - Scheduling

Arm name: **Arm 1**

	Event #	Days Offset	Offset Range Min / Max	Event Name
 	1	-1	-15/+0	General Forms
 	2	0	-14/+0	Day 1 - Visit
 	3	7	-3/+3	Day 8 - Phone Call
 	4	28	-3/+3	Day 29 - Visit
 	5	35	-3/+3	Day 36 - Phone Call
 	6	56	-3/+3	Day 57 - Visit
 	7	89	-5/+5	Day 90 - Visit
 	8	179	-10/+10	Day 180 - Visit
 	9	359	-15/+15	Day 360 - Visit
 	10	729	-30/+30	Day 730 - Visit
 	11	730	-0/+0	Unscheduled Visit
 	12	731	-0/+0	Miscellaneous Forms



Electronic Database Development - Scheduling

Arm name: **On Study**

Begin Editing

Save

Data Collection Instrument	Injury (1)	Registration (2)	Screening/enrollment (3)	Week 0 Day1 (4)	Week 1 (5)	Week 2 Day 1 Visit (6)	Week 10 (7)	Week 3 (8)	Week 4 (9)	Week 5 (10)	Week 6 Visit (11)
Injury	✓										
Screening/enrollment			✓								
Registration		✓									
Week 0 Day 1				✓							
Week 1 - Medication Compliance Phone Call					✓						
Week 2 Day 1						✓					
Week 3 - Medication Compliance Phone Call								✓			
Week 4									✓		
Week 5										✓	
Week 6 Visit											✓
Week 8											
Week 10							✓				
Week 12 Visit											
Week 24 Visit											
Week 52 Visit											



Electronic Database Development - Scheduling

◀ January ▼ 2021 ▼ ▶

🖨️ [Print Calendar](#)

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					+ New 1	+ New 2
+ New 3 ☆ 001 (General Forms)	+ New 4 ☆ 001 (Day 1 - Visit)	+ New 5	+ New 6	+ New 7	+ New 8	+ New 9
+ New 10	+ New 11 ☆ 001 (Day 8 - Phone...	+ New 12	+ New 13	+ New 14	+ New 15	+ New 16
+ New 17	+ New 18	+ New 19	+ New 20	+ New 21	+ New 22	+ New 23
+ New 24	+ New 25	+ New 26	+ New 27	+ New 28	+ New 29	+ New 30
+ New 31						



Electronic Database Development - Scheduling

View/Edit Calendar Event

Record ID: **001** [view schedule](#)

Event Name: **Day 1 - Visit** (Arm 1: Arm 1)

Status: ☆ **Due Date** [change status](#)

Date: **01/04/2021 (Monday)**

Time: HH:MM

Notes:

Data Entry Forms

- ☒ Eligibility Criteria
- ☒ Screening Period - Schedule of Activities
- ☒ Day 1 - Visit - Nursing Form
- ☒ Vitals Form
- ☒ Day 1 - Visit - Physical Exam
- ☒ Day 1 - Specimen Collection
- ☒ Vaccine Administration
- ☐ Missed Visit
- ☒ RAVE Data Entry Tracking Form
- ☐ Research Participant Covid19 Screening Tool



Electronic Database Development – Double Entry


≠ Data Comparison Tool

This page may be used for comparing two records currently in the project. Select a record from each of the lists below and hit the 'Compare' button. A comparison table will then be displayed showing the differences between the two records.


Record ID	
<div>--- Choose a record ---</div>	<div>--- Choose a record ---</div>
<div>Compare</div>	



Electronic Database Development – Queries

 **Data Resolution Workflow** ✕


This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.


Study ID: **1002**
Field: **last_name** ("Last Name")
Status:  Not Opened

Date/Time	User	Comments and Details
05/21/2013 10:36am	site_admin	<div><input type="radio"/> Verified data value</div> <div>— OR —</div> <div><input checked="" type="radio"/> Open query</div> <div>Assign query to a user (optional): <input type="text" value="taylorr4 (Rob Taylor)"/></div> <div>Comment: <input type="text"/></div>





Electronic Database Development – Built-in Notes to File



Field Comment Log 

This pop-up displays all the field comments for the record and field specified below. Users with access to data entry forms may leave one or more comments on any field on a data collection instrument, after which the balloon icon will stay lit up to signify that comments exist for that field for this record. All field comments for all records/fields can also be viewed, keyword searched, and filtered on the [Field Comment Log](#) page in this project. **NOTE: If you wish to prevent all users in this project from editing or deleting field comments below, see the Additional Customizations popup on the Project Setup page.**

Record ID: **Test 10**
Event: **Baseline Visit**
Field: **email** ("Subject's Email")

	Date/Time	User	Comments
 	01/05/2021 8:48am	jholmes	Jennifer is a University employee but uses her uvmhealth.org email account
	01/05/2021 8:48am	jholmes	<input type="text"/>



Electronic Database Development – Audit Trail

11/23/2020 1:42pm	a_penfield-cyr	Manage/Design Deactivate alert	Alert #1
11/23/2020 1:42pm	a_penfield-cyr	Created Record Test2 (Baseline Visit)	first_dem = 'Annie', last_dem = 'PC', email = 'annie.penfield-cyr@med.uvm.edu', phone = '8028028022', demographics_complete = '2', record_id = 'Test2'
11/23/2020 1:39pm	jholmes	Manage/Design	Send survey invitation to participants (via email)
11/23/2020 1:39pm	jholmes	Created Record test (Baseline Visit)	email = 'qowands@me.com', demographics_complete = '0', record_id = 'test'
10/19/2020 9:06am	jholmes	Manage/Design	Add/edit branching logic
10/19/2020 9:06am	jholmes	Manage/Design	Create project field
10/19/2020 9:03am	jholmes	Manage/Design	Reorder project fields
10/19/2020 9:03am	jholmes	Manage/Design	Create project field
10/14/2020 12:35pm	jholmes	Deleted Record 001	record_id = '001'
10/14/2020 12:34pm	jholmes	Updated Record 001 (Baseline Visit)	electronic_consent_complete = '0'
10/14/2020 12:34pm	jholmes	Created Record 001 (Baseline Visit)	first_dem = 'Jennifer', last_dem = 'Holmes',



Electronic Database Development – Reports


My Reports & Exports					
		Report name	View/Export Options	Management Options	Report ID [?] (auto-generated)
	A	All data (all records and fields)	View Report Export Data Stats & Charts		
	B	Selected instruments and/or events (all records)	Make custom selections		
1		People in Database	View Report Export Data Stats & Charts	Edit Copy Delete	8422
2		January 2021 Fundamentals Registration	View Report Export Data Stats & Charts	Edit Copy Delete	9275
3		November 2020 Fundamentals Registration	View Report Export Data Stats & Charts	Edit Copy Delete	8952




Electronic Database Development – File Repository

File Repository


This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

 User Files

 Data Export Files

 Upload New File

To upload a new file to the repository, in the fields below specify the file on your computer and provide a name/label for the file. Then click the "Upload File" button.

 Adding new file

Document

Name/Label

Browse...

No file selected.



Expand

Upload File


-- Cancel --




Electronic Database Development – Permissions

 Editing existing user "jholmes" 


You may set the rights for the user below by checking the boxes next to the application tools to which you wish to grant them access. You may also grant them or deny them access to individual data collection instruments, if so desired. To save your selections, click the "Save Changes" button at the bottom of the page.


 Editing existing user "jholmes"


Basic Rights

 Expiration Date (M/D/Y)
(if applicable)


Highest level privileges:


 Project Design and Setup ☒


 User Rights ☒

 Data Access Groups ☒

Privileges for data exports (including PDFs and API exports), reports, and stats:

 Data Exports ☐ No Access
* De-identified means that all free-form text fields will be removed, as well as any date/time fields and Identifier fields.☐ De-identified*☐ Remove all tagged Identifier fields☒ Full Data Set

 Add/Edit/Organize Reports ☒
Also allows user to view ALL reports (but not necessarily all data in the reports)

 Stats & Charts ☒

Data Entry Rights

*NOTE: The data entry rights *only* pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.*

	No Access	Read Only	View & Edit	Edit survey responses
Fundamentals in the Conduct of Clinical Research Registration (survey)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>
February 2020 Attendance - Fundamentals in the Conduct of Clinical Research	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	
OLD Exam - Fundamentals Training (survey)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>
Final Exam - Fundamentals Training (survey)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>
May 2020 Attendance -				

Save Changes

Cancel

Remove user

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Electronic Database Development – Part 11 Compliance

21 CFR Part 11 compliant?

The first is the IT level, which includes providing regular systems upgrades and daily backups as well as secure logins that are provided and monitored by the institution's administrators.

The second is the project level, which means it is the responsibility of the investigator to ensure training and compliance while using the EDC. This includes establishing appropriate standard operating procedures; to protect the collection and maintenance of data, ensuring the proper delegation of study specific roles and responsibilities to members of the study team, and instituting policies and procedures for the necessary training and oversight required throughout the study's operation.

Electronic Database Development - Tips

- Standardization is key (use as little free text as possible)
- Use features to minimize errors (build in QA)
- TEST TEST TEST and then TEST some more!
- Develop a manual/SOPs (update when database is updated)
- Training (new study team members or when database is updated)
- Process in case system is down
 - PDFs of form/instruments (system to download copies when database is updated)
 - Build in flexibility with IRB for these occasions

ALCOAC-CEA Principles

- Attributable – Who collected the data, performed a test, completed the documentation or edited the document and when.
- Legible – The documentation and all subsequent changes should be permanent and easy to read.
- Contemporaneous – Documentation should be completed and dated in real time.
- Original – Study documents should be the originals, or it should be noted where the originals are located.
- Accurate – Documentation should be comprehensive and truthfully reflect what was observed.
- Complete – Maintenance of complete and up-to-date study documents.
- Consistent – The data's sequence of events is in the expected sequence of operations and date and time stamped.
- Enduring – Paper and electronic data are appropriately recorded in lab notebooks, spreadsheets, databases etc.
- Available – Paper and electronic data are required to be readily available for review, audits, or inspections.



Activity 2

Determine how the EDC features discussed in our presentation could be used to improve the quality of the data being collected electronically compared to this paper form

Atributable Legible Contemporaneous

Original Accurate Complete

Consistent Enduring Available



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Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/2020	Jan, 1 st 2000	20

Height (in)	Weight (lbs)	BMI (kg/m ²)†
5ft. 4 in.	124	22

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated? ☐ Yes ☒ No

Did the subject rest for 15 minutes? ☐ Yes ☒ No

Systolic BP	Diastolic BP

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/12	2:55 pm	7

Notes

no complications from blood draw
2 5mL tubes were drawn

Signature: A. P. D. - G.

Date: _____

Patient wants
reminder of next visit
a few days before

Activity 2

How EDC's Improve Data Collection

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/2020	Jan, 1 st 2000	20

Height (in)	Weight (lbs)	BMI (kg/m ²)†
5ft. 4 in.	124	22

Systolic BP*	Diastolic BP*
141	80

† If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Systolic BP	Diastolic BP
Did the subject rest for 15 minutes?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/12	2:55 pm	7

Notes: no complications from blood draw
2 5mL tubes were drawn

Signature: [Signature]

Date: _____

Patient wants
reminder of next visit
a few days before

Activity 2 – Examples of how an EDC can improve data entry

1. Headers can be piped in so they are auto-generated at the top of each form
2. Date fields can be validated so they are all consistent in their entry
3. You can create field notes that state what units should be used for each field and use field validation so that if someone tries to type “ft” into an integer field, it will error.
4. Calculated fields can be set up so that there is no question if they were done correctly.
5. The systolic and diastolic blood pressure fields could have a flag attached to it so that if the systolic pressure is above 140 or the diastolic is above 90 then it will notify the study team that they need to retake this measurement. Branching logic could also be used here so that the second question won’t appear if the first question is answered with a “No”.
6. Again, these date and time fields can use field validation to answer them in a consistent way and with the date field there is even a “Today” button which allows researchers to just hit the button to fill in today’s date instead of having to type it in. There is a similar button for time fields which allows you to click “Now” and it will fill in the current time if you’re doing data entry in real time.
7. EDCs automatically log who was entering data and when on the back end of the system, so this is taken care of by the logging function of an EDC. However, if you did need or want a signature on your electronic form, there is a signature field that allows users to sign with their mouse or finger.
8. And then finally for the note at the bottom, you can create a notes field for free text if you find it would be helpful to have a place to document things that come up over the course of your subject’s visit. But also with this particular note here, if your study team decided that reaching out to remind patients of their next visit a few days in advance was a best practice and you wanted to do this for all of your participants, the EDC can be set up to send email reminders to your participants a few days before their next visit based on their study calendar dates.



Research Professionals Network

“Our overarching goal is to enhance the quality of clinical research by supporting the professional development of clinical research faculty and staff.”

Site Specific REDCap Information

BU Med Campus/BMC:

To get started with REDCap you should: 1) Submit end user agreement: <https://redcap.bumc.bu.edu/surveys/?s=RYKEW4N4RX>; 2) Review training videos & FAQ: <https://redcap.bumc.bu.edu/index.php?action=training>; 3) Request a REDCap consult: rchelp@bu.edu

UF: <https://www.ctsi.ufl.edu/research/study-design-and-analysis/redcap/>

UVM: <https://www.uvm.edu/biostatistics/redcap>

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