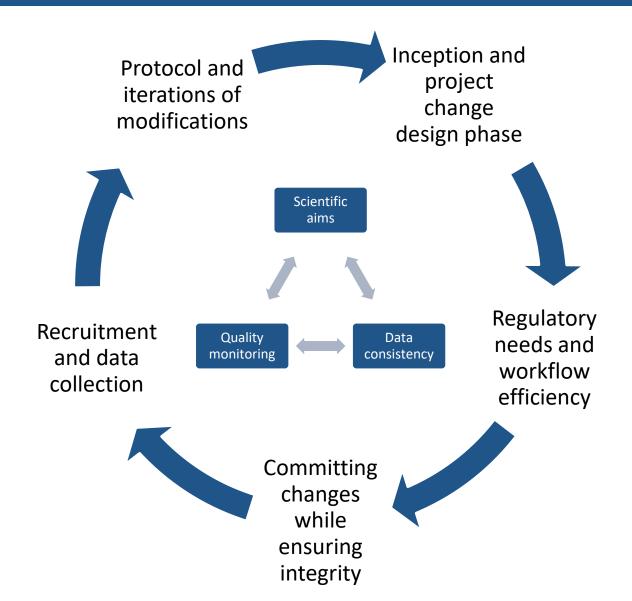




Research Electronic Data Capture

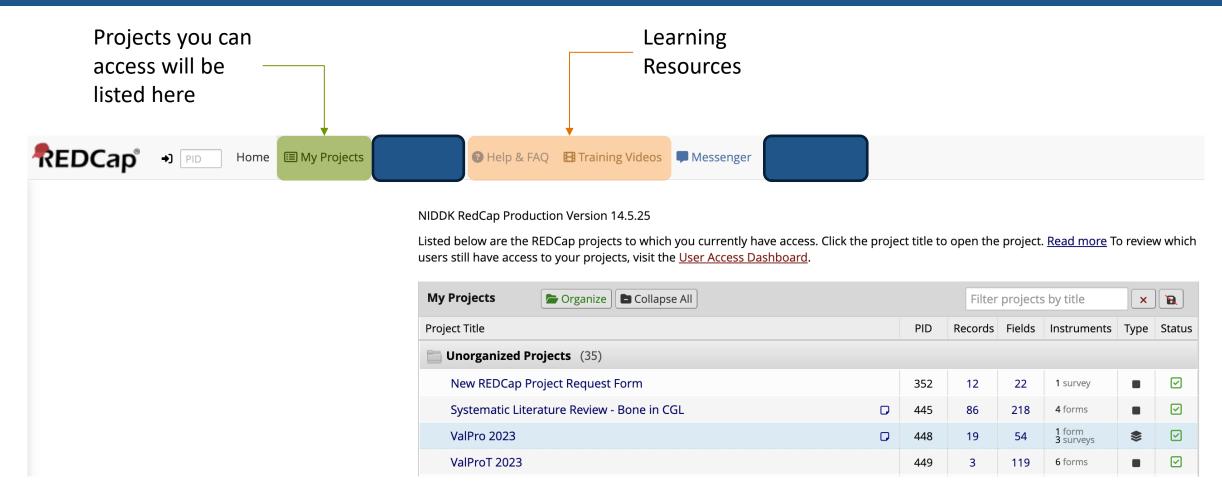


REDCap is an effective tool for building data quality, data collection efficiency, and regulatory compliance directly into research workflow.





REDCap – A first look







REDCap[®] testing project PID 518 REDCap △ Logged in as 76370212 | Log out **♦ Other Functionality ♦ Project Revision History ☑** Edit Project Settings ■ My Projects or Control Center Contact REDCap administrator Project status: & Development Completed steps 0 of 8 Let View project as user: -- select a user -- V → Enter PID to go to project Main project settings **Project Home and Design** Disable Use surveys in this project? ☑ VIDEO: How to create and manage a survey ♠ Project Home · ¥ Project Setup Disable Use longitudinal data collection with defined events? ☑ Designer · 💵 Dictionary · 🗏 Codebook For real data ject status: Development I'm done! **Project status Data Collection** Modify project title, purpose, etc. should say Get a public survey link or build a participant list for **№** Design your data collection instruments & enable your surveys "Production"!!! Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the III Record Status Dashboard Online Designer (online method) or by uploading a Data Dictionary (offline method). You may then enable your Content instruments to be used as surveys in the Online Designer. Quick links: <u>Download PDF of all instruments</u> OR Add / Edit Records Download the current Data Dictionary I'm done! Go to Online Designer or Data Dictionary Explore the REDCap Instrument Library Applications Have you checked the Check For Identifiers page to ensure all identifier fields have been tagged? Project Dashboards Alerts & Notifications Multi-Language Management **№** Define your events and designate instruments for them # Calendar Create events for re-using data collection instruments and/or set up scheduling. ■ Data Exports, Reports, and Stats Data Import Tool Project metadata Go to Define My Events | or Designate Instruments for My Events ≠ Data Comparison Tool Logging and 5 Email Logging Field Comment Log & Enable optional modules and customizations File Repository User Rights and A DAGs ☐ Customize & Manage Locking Optional Disable Auto-numbering for records ? Data Quality Enable Scheduling module (longitudinal only) 💽 I'm done! ■ API and ■ API Playground Randomization module REDCap Mobile App Designate an email field for communications (including survey invitations and alerts ?) Mosio SMS services for surveys and alerts **External Modules** Enable SendGrid Template email services for Alerts & Notifications 🔃 Help & Information Additional customizations Learning Pelp & FAO ■ Video Tutorials resources Set up project bookmarks (optional) Learn Advanced Design Features Suggest a New Feature You may create custom bookmarks to webpages that exist inside or outside of REDCap. These bookmarks will be seen as links on the left-hand project menu and can be accessed at any time by users who are given privileges to do so. Every project bookmark has custom settings that allow one to control its appearance and

I'm done!

behavior.

Go to Add or edit bookmarks





Maintaining Data Quality

Data Dictionary:

Defines content and allows versioning

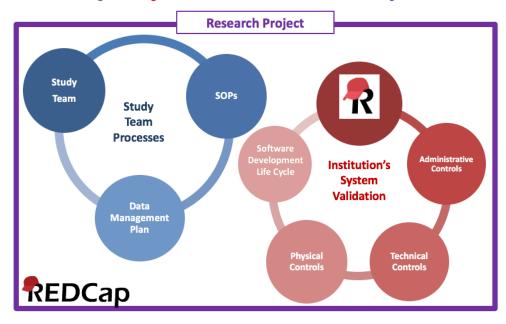
SOPs and Training

- REDCap trainings and troubleshooting support
- Recorded resources and documentation
- Study-specific SOPs and trainings

Data Quality Rules + Data Resolution Workflow

- Recurring quality checks
- Real-time execution
- Regular pre-auditing of collected data

Study + System = Part 11 Compliance







Project setup foundations

 Choosing the right structure:

Data Collection Instrument (7) Surveys Consent Tracking Demographics Longitudinal Diet Habit Survey \checkmark **V** Adverse Events ✓/ **Events Reporting** Cross-sectional Visit Log Study Disposition Randomization Notes & Enable optional modules and customizations Recurring data Repeating instruments and events ? Modify Optional ❷ Auto-numbering for records ? Disable collection Scheduling module (longitudinal only) ? Disable I'm done! Disable Jargon note: Forms are called "Instruments" in

Main project settings

started

I'm done!

Disable Use surveys in this project? ?

Modify project title, purpose, etc.

☑ Use longitudinal data collection with defined events? ?

● Use the MyCap participant-facing mobile app? ☐ Learn more about MyCap

Screening Baseline Follow-up 1 Follow-up 2 Follow-up 3 End of Study

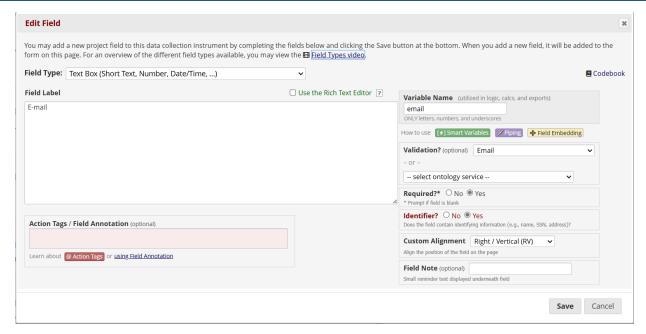
El VIDEO: How to create and manage a survey

REDCap terminology.



Regulatory Miscellaneous

Consistent Data Collection





eCRFs:

- Required fields
- Validations
- Branching Logic

Branching Logic may be employed when fields/questions need to be hidden under certain conditions. If branching logic is defined, the field will only be visible if the conditions provided are true (i.e. show the field only if...). You may specify those conditions in the text box below for the Advanced Branching Logic Syntax or by choosing the Drag-N-Drop Logic Builder method, which allows you to build your logic in a much easier fashion by simply dragging over the options you want. You may switch back and forth between each method if you wish, but please be aware that since the advanced logic allows for greater complexity, it may not be able to be switched over to the Drag-N-Drop method if it becomes too complex. Choose method below for the following field: ae notify - *****NOTIFY PI IMMEDIATELY***** D... Advanced Branching Logic Syntax How to use → Branching Logic [+] Smart Variables √x Special Function [ae_grade] = '3' or [ae_grade] = '4' or [ae_grade] = '5' - OR -Drag-N-Drop Logic Builder Displaying field choices for the following data collection instrument: Ocd Ae Form Show the field ONLY if... O ALL below are true Field choices from other fields ANY below are true (drag a choice below to box on right) ae_grade = Grade 3, Severe or medically ae experience = Yes (1) significant but not immediat... (3) 💥 ae_experience = No (0) ae grade = Grade 4, Life-threatening ae_desc = (define criteria) consequences; urgent interventi... (4) 💥 ae term = (define criteria) ae grade = Grade 5, Death (5) * ae_date_onset = (define criteria) ae_date_team_aware = (define criteria) ae_grade = Grade 1, Mild; asymptomatic or mild symptoms; clinical or... (1) ae grade = Grade 2, Moderate; minimal, local Clear logic

> Add/Edit Branching Logic

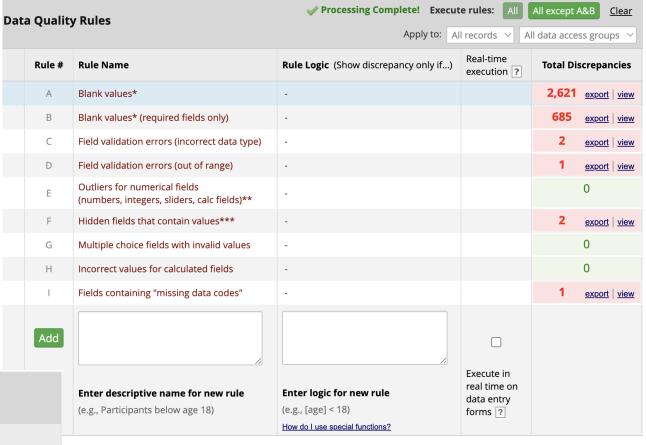
Building data quality checks at point of entry to enforce collection of specific data types and formats

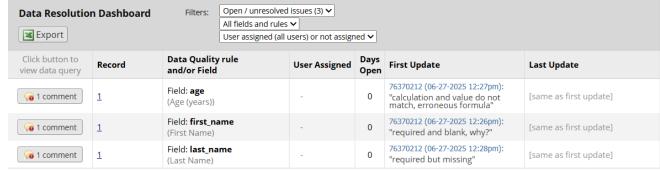




Data Quality Rules

Regular data quality monitoring is made easy, quick, and customizable by REDCap with interactive resolution steps





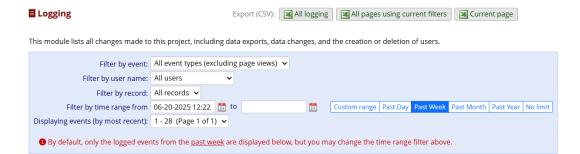




Access Controls and Traceability

Project permissions:

- Robust permissions structures (blinding, renumeration, specialized roles, scientific bias reduction)
- Data Access Groups (multi-site studies)
- Audit trails:
 - Logs
 - Data History
 - Comments/Data Resolution Workflow (21 CFR Part 11)
 - e-Signature (21 CFR Part 11)



Time / Date	Username	Action	List of Data Changes OR Fields Exported
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule I (Fields containing "missing data c odes")
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule H (Incorrect values for calculated fields)
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule G (Multiple choice fields with invalid values)
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule F (Hidden fields that contain values ***)
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule E (Outliers for numerical fields(nu mbers, integers, sliders, calc fi
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule D (Field validation errors (out of range))
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule C (Field validation errors (incorrect data type))
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule B (Blank values* (required fields on ly))
06-27-2025 12:17pm	76370212	Manage/Design	Execute data quality rule: Rule A (Blank values*)
06-27-2025 12:17pm	76370212	Manage/Design	Edit project field
06-27-2025 12:16pm	76370212	Create record 1	dob = '2005-06-27', age = '20', gender = '1', demographics_complete = '2', record id = '1'

E-signed by thejas2 (Sai Theja) on 07/18/2025 2:49pm

a Instrument locked by thejas2 (Sai Theja) on 07/18/2025 2:49pm

The instrument 'Survey' has been locked for record '1'. If you have instrument-level locking/unlocking privileges, you may unlock this instrument at the bottom of the page.





Data Collection Practices

Do's

Enter data as close to actual collection as possible

Limit complexity

Use field types and validations where possible

Plan thoroughly and collaboratively

Don'ts

Create a single form for literally EVERYTHING

Change coding/labels of variables to mean something different

Create ambiguous variable names and labels

Collect REAL data in DEVELOPMENT



