

R + REDCap Example Data Cleaning Workflow

Jennifer Thompson, MPH

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Chapter 1

Introduction

Summary and Goals

This document demonstrates the ongoing process of data cleaning used by the Vanderbilt CIBS Center. Most of our data is stored in REDCap databases and is cleaned at multiple points throughout data collection, with the goal of the highest quality data possible in the least amount of time once enrollment is complete. Using a toy example, this tutorial will describe our general process and demonstrate the R code we use to accomplish this goal.

Key Points

- First and foremost, take full advantage of REDCap’s design features to *prevent* data entry errors. The following process is helpful for correcting data entry problems that will always occur, but the more you can *prevent*, the better.
- This process may seem like it takes a lot of time - and it does, especially at the beginning. But the end result is worth it: When done well, you will finish your study with the highest quality data possible, and will save time and pain by catching systematic problems early. It is especially important for long and/or multicenter studies, which have more opportunity for staff turnover and sites entering and leaving the study midway.
- Data cleaning should be performed *early* and *often* to be of the most value.
- The process and the R code will never be perfect or complete from the beginning - and that is okay! You should expect to update this process in an iterative manner throughout the course of the study.
- It is incredibly important for the clinical and statistical/database teams to **communicate** during the entire process. This will improve the R code, the process, and the data.
- For R code specifically:
 - Using REDCap’s API allows you to export data automatically every time your script is run, saving manual labor and decreasing room for error.
 - Take advantage of REDCap’s metadata (data dictionary)! It can help save you time and work, especially if the database is designed to take advantage of features like data validation.
 - For longitudinal studies, it is very helpful to start off by creating a “dummy” dataset, with one record per every patient + event that you expect to be present. This can be simple or complicated depending on the study design and population, but will be very useful in several ways (we’ll see an example).

Notes on the Tutorial

- All code for data export assumes that the user has rights to use the REDCap API for data export, and that a working API token is stored in the `.Renviron` file in the working directory, in the format

```
RCTOKEN=manylettersandnumbers
```

If you don't want to use the `.Renviron` file, you can replace `Sys.getenv("RCTOKEN")` with `"manylettersandnumbers"`. If you do this, do not share your code - it is very important to keep your API token secret.

- The code will use several helper functions, sourced from `dataclean_helpers.R` in the same working directory/Github repository. The code will also be copied in an appendix to this document so that the tutorial is self-contained.
- This script intentionally uses base R (with the exception of the `httr` package), to maximize adoption and minimize dependencies. Should you care to refactor with the tidyverse or other packages, alternate versions are welcome!
- The primary information and code needed for this process will be within this PDF; all code and files related to this tutorial can be found in this Github repository, which is public and can be cloned or downloaded as a zip file.

Motivating Example

This example uses a sample REDCap database for a three-month longitudinal study of adult patients taking a dietary supplement and measuring creatinine, HDL and LDL cholesterol, and weight over time. (Sample database is adapted with thanks from REDCap's project templates.) The study codebook is available [here](#).

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Chapter 2

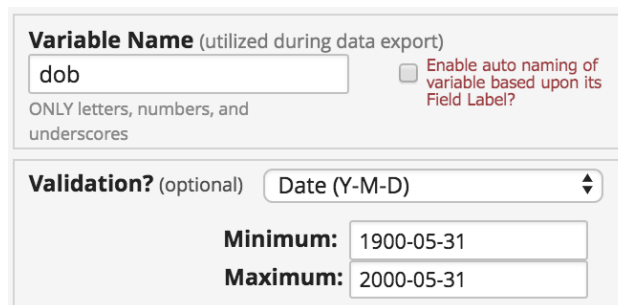
Process Overview

Study Startup

Our data cleaning process begins during the study startup period, with careful design of the REDCap database. We take full advantage of features like:

- Data validation rules: These tools can help you ensure that lab values are entered as numbers with no text, or that dates are entered in consistent formats. You can also add minimum and maximum values for numeric and date fields. REDCap has built-in validation for some special types of text, such as email addresses. For more information, please see REDCap’s Help & FAQ page.
- Branching logic: This logic tells a specific field when to appear during data entry. For example, we often use it to ask whether a patient has taken a specific medication; if yes, the branching logic will show a field that allows us to enter the dose of that medication. Branching logic helps enforce data collection protocols (“if this, then that should be entered”) and helps prevent data from being accidentally entered in the wrong fields.

During this time, the clinical coordinators and statistics/database team also work together to develop an initial list of very specific items that should be checked during the data cleaning process. Depending on the study design, this can be quite a lot of work! But the more thorough we are in this phase, the easier the process during the study, and the better the data at the end.



The screenshot shows the REDCap variable configuration interface. The 'Variable Name' field is set to 'dob' with a note 'ONLY letters, numbers, and underscores'. A checkbox for 'Enable auto naming of variable based upon its Field Label?' is unchecked. The 'Validation?' dropdown is set to 'Date (Y-M-D)'. Below this, the 'Minimum' date is set to '1900-05-31' and the 'Maximum' date is set to '2000-05-31'.

Figure 2.1: Example of date validation

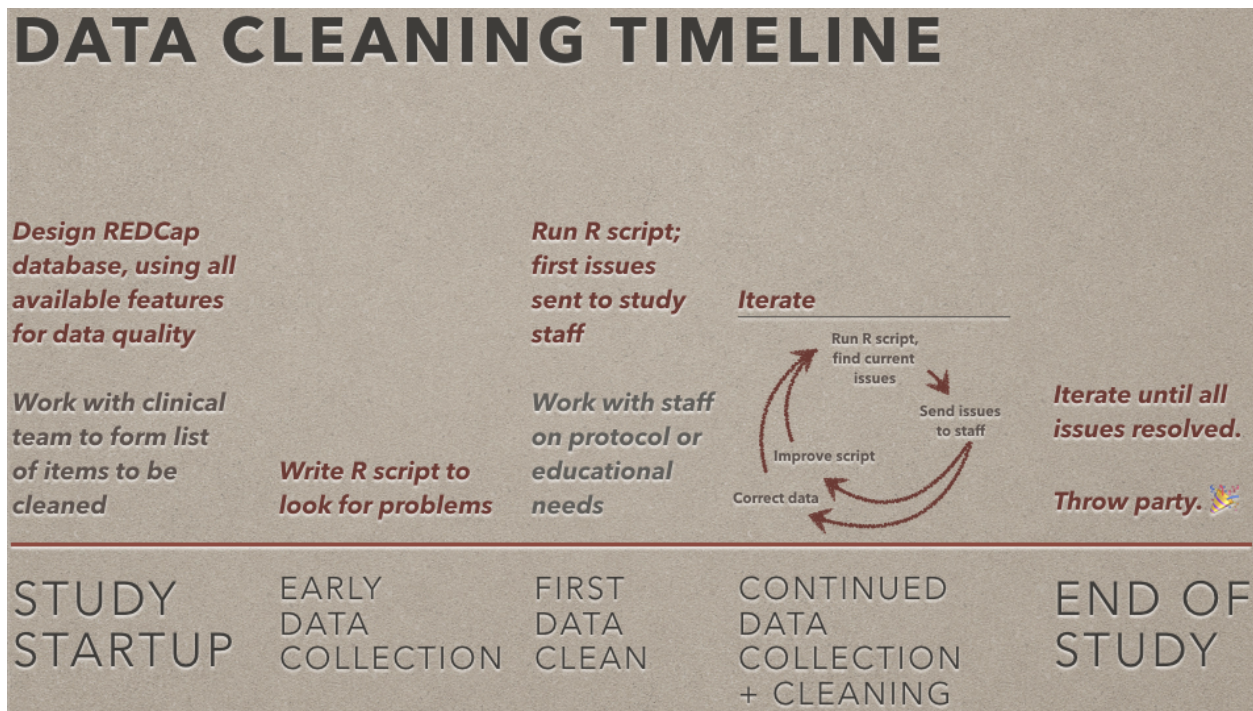


Figure 2.2: General Data Cleaning Timeline

Early Data Collection

Once study staff has begun entering data into the study database, the statistician/database team will write the first version of the R script for data cleaning. (It's very hard to write a script before data is available to test it!) This is the most time-consuming part of the process for the database team.

First Data Clean

After a reasonable period of data collection, the statistician/database manager will run the R script and create the first list of data entry issues to be corrected or addressed. This can be a scary time for study staff! There will likely be a few bugs to be worked out, both in the code and in the list of items to check. It may take a few tweaks before the team is ready to upload the issues to our documentation database and begin the process of correcting them. Correcting the data and documenting those steps are the most time-consuming part of the process for the clinical team.

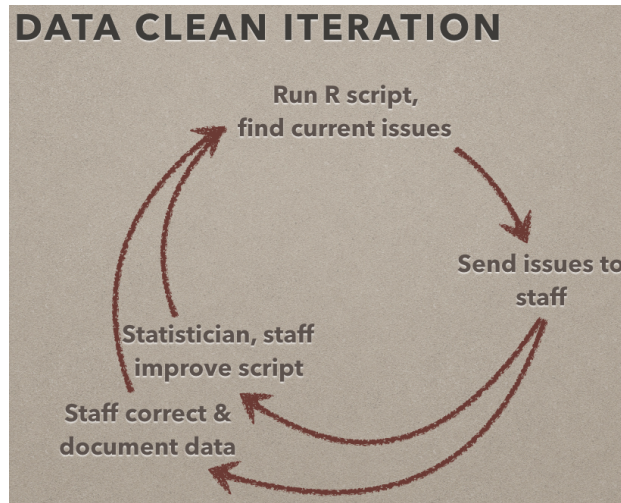


Figure 2.3: Data Cleaning Iteration

Continued Data Collection & Cleaning

As the study progresses, this process continues: the statistician runs the R script to find data issues; the study staff corrects or documents issues, and communicates potential coding issues or new additions back to the statistician, who then updates the script and repeats the process.

Some changes are coding mistakes or misunderstandings, but others may be the result of protocol changes, or ideas for new things to check from the project coordinators, based on interactions with study staff. This maintenance process takes some time on the part of both the statistician/database team, working to investigate and debug potential issues or add code for new checks. The following things are very helpful during this process:

- Agreement that the data clean is a top priority: This doesn't necessarily mean that it is everyone's most *urgent* priority, but it does mean that everyone agrees that this is important and should have designated time at an appropriate date.
- Detail-oriented team members: This is a meticulous process for everyone.
- Strong relationships and open communication between the clinical and statistics/database team.

End of Study

Once data collection is finished, we continue to iterate the data cleaning process until there are no more queries from the R script. At that point, you should feel free to throw a party.

The rest of this tutorial will focus on the steps of building the R script.

Chapter 3

Step 1: Use REDCap API to Export Raw Data

We use REDCap's API capabilities to export the data automatically every time the script is run, reducing the potential for error and saving time compared to manually exporting every time data is cleaned.

Requirements:

1. Working API token

You must have appropriate user rights for your database in order to request an API token. Once you have the correct user rights, log into the REDCap project. On the lefthand side under **Applications**, you will see a line for **API** and **API Playground**. Click here, then on the button titled **Generate API token**.

Once your token is generated, **never share it with anyone**. It gives you permission and ability to access research data, and should be kept protected at all times. If you share code with other people, one way to do this safely is to store your API token in a hidden `.Renviron` file in the appropriate working directory, like this:

```
RCTOKEN=manylettersandnumbers
```

You can then access the token using the function `Sys.getenv()`.

For more information on the REDCap API, please see **Project Setup -> Other Functionality** within an existing REDCap project. For general information on working with the API, the Github wiki of the `redcapAPI` package has a good overview. *(This example includes basic API usage and will not use the package, but if you are interested in using more of the API's functionality, it could be a good package to investigate.)*

2. R's `httr` package, built for working with APIs

More information on `httr` can be found in the documentation and vignettes, linked from CRAN. (Everything else in this tutorial is intentionally in base R to avoid dependencies.)

Approaches

There are (at least) two approaches to exporting REDCap data:

REDCap

Logged in as: [] | Log out

My Projects

Project Home or Project Setup

REDCap Messenger 1

Project status: Development

Data Collection

Edit Instruments

Record Status Dashboard

View data collection status of all records

Add / Edit Records

Create new records or edit/view existing ones

Applications

Calendar

Data Exports, Reports, and Stats

Data Import Tool

Data Comparison Tool

Logging

Field Comment Log

File Repository

User Rights and DAGs

Data Quality

API and API Playground

REDCap Mobile App

External Modules

Help & Information

Data Cleaning Example

API

The REDCap API is an interface that allows external applications to connect to REDCap remotely, and is used for programmatically retrieving or modifying data or settings within REDCap, such as performing automated data imports/exports from a specified REDCap project. For details on the capabilities of the REDCap API and how to use it, please see the [REDCap API documentation](#).

API Security: Best Practices

It is important to remember that when making requests to the REDCap API, you should always validate the REDCap server's SSL certificate to ensure the highest level of security during communication with the API. For details on what this means and how to do it, see the 'API Security: Best Practices' section in the [REDCap API documentation](#).

Obtain API token for "Data Cleaning Example"

Use the button below to generate an API token for this project. You will need a different token for each project you would like to access.

Generate API token

Event names for Data Cleaning Example

| Unique event name | Event Name | Arm |
|----------------------|----------------|-------|
| baseline_visit_arm_1 | Baseline Visit | Arm 1 |
| month_1_arm_1 | Month 1 | Arm 1 |
| month_2_arm_1 | Month 2 | Arm 1 |
| month_3_arm_1 | Month 3 | Arm 1 |

Figure 3.1: Getting an API token

1. Read in the entire database in a single `httr::POST` call, then create subsets in R as needed
2. Read in specific subsets in separate calls

Approach #1 is fine if your database is not longitudinal, complex, or very large, and/or if you are not yet comfortable working with the API. Approach #2 is valuable in more complicated situations.

For example, here, our database is longitudinal, and different data is collected at different time points (for example, date of birth is only collected at baseline). If we read in the entire database at once, we will have a lot of missing values (for example, date of birth will be missing at each monthly visit and study completion, unless we proactively subset the data).

I will show both approaches for reference, but I primarily use Approach 2. Either way, we want to create the following datasets:

- Baseline data
- Monthly data
- Study completion data

For both approaches, we need this setup:

```
## Load httr
library(httr)

## Source helper functions (script should be stored in this working directory)
## Function post_to_df(), which is useful in API code, is stored here, along
## with other helper functions we'll use later
source("dataclean_helpers.R")

## Set URL for REDCap instance (yours may be different)
rc_url <- "https://redcap.vanderbilt.edu/api/"
```

Approach 1: Example

This approach uses the simplest API call, but needs some R work after exporting the data.

```
## Use API + httr::POST to get all data at once
main_post <- httr::POST(
  url = rc_url,
  body = list(
    token = Sys.getenv("RCTOKEN"),
    ## API token gives you permission to get data
    content = "record",      ## export *records*
    format = "csv",          ## export as *CSV*
    rawOrLabel = "label",    ## export factor *labels* vs numeric codes
    exportCheckboxLabel = TRUE ## export ckbox *labels* vs Unchecked/Checked
  )
)

## main_post has class "response"; read it as a CSV to create a data.frame
main_df <- post_to_df(main_post)

## Create subsets with data collected at various time points
baseline_df <- subset(main_df, redcap_event_name == "Baseline Visit")
monthly_df <- subset(main_df, redcap_event_name %in% paste("Month", 1:3))
completion_df <- subset(main_df, redcap_event_name == "Study Completion")
```

Note that unless we spend the time to manually subset them, each of those three data.frames will have many columns with blank values. For example, `baseline_df` will have a column for `compliance`, even though `compliance` is only collected at monthly visits. This is not a major problem if your project is small, but can be a problem if you have a large project.

Approach 2

This approach uses three separate `httr::POST` calls to create separate datasets that are exactly what we need.

REDCap's API Playground can be useful in figuring out which options to include in the `body` argument of `httr::POST`. (Do note that as of the time of this writing, the example R code from the Playground uses `RCurl`; `httr` is currently more commonly used and thus it is easier to find documentation and assistance for it.)

Differences from Approach 1 in the `body` of `httr::POST`:

1. We specify **forms**, using their raw names (eg, `baseline_data` instead of `Baseline Data`).
2. We specify **events**, again using their raw names (eg, `baseline_visit_arm_1` instead of `Baseline Visit`).
3. We always specify `study_id` as a **field** in addition to the other forms. REDCap does not always export the ID by default.

If you are exporting >1 form or event, separate them with commas. You can find raw event names by going to **Project Setup -> Define My Events** within your REDCap project, and raw form names by looking at the data dictionary. (They can also be exported as project metadata using the API; there is an example in `dataclean_helpers.R`.)

Note: The function `post_to_df()`, which creates a data.frame from the result of `httr::POST`, is created in `dataclean_helpers.R`.

Baseline and Demographic Data

This code chunk exports all the fields collected at the baseline visit (the Demographic and Baseline Visit forms), as well as study ID. It only exports the Baseline Visit event, because all other events would have NA values for these fields. Therefore, each study ID will have at most one record in this dataset.

```
## Data from baseline visit only: Demographics and Baseline Data forms
baseline_post <- httr::POST(
  url = rc_url,
  body = list(
    token = Sys.getenv("RCTOKEN"), ## API token gives you permission
    content = "record",            ## export *records*
    format = "csv",                ## export as *CSV*
    forms = "demographics,baseline_data", ## forms
    fields = c("study_id"),        ## additional fields
    events = "baseline_visit_arm_1", ## baseline visit event only
    rawOrLabel = "label",          ## export factor *labels* vs numeric codes
    exportCheckboxLabel = TRUE ## export ckbox *labels* vs Unchecked/Checked
  )
)

## baseline_post has class "response"; read it as a CSV to create a data.frame
baseline_df <- post_to_df(baseline_post)

## Double-check if you like! Commented out to save space
## baseline_df
```

The `rawOrLabel = "label"` and `exportCheckboxLabel = TRUE` elements in the `body` argument of `POST` are personal preference. I set these to export labels because I usually find that it is more clear - ie, it is easier to figure out what `sex == Male` is doing than `sex == 1`. However, depending on your database and your purposes, you may want to change these to use the raw numeric codes - for example, if you have fields with very long labels.

Monthly Visit Data

This code chunk exports all the fields collected at each monthly visit (the Monthly Visit form), as well as study ID. It exports all three monthly visit events; all other events will have NA values for these fields. Each study ID will have up to three records in this dataset.

```
## Data from all monthly visits
monthly_post <- httr::POST(
  url = rc_url,
  body = list(
    token = Sys.getenv("RCTOKEN"), ## API token gives you permission
    content = "record",            ## export *records*
    format = "csv",                ## export as *CSV*
    forms = "monthly_data",        ## forms
    fields = c("study_id"),        ## additional fields
    events = paste(sprintf("month_%s_arm_1", 1:3), collapse = ","),
      ## all 3 monthly visit events
    rawOrLabel = "label",          ## export factor *labels* vs numeric codes
    exportCheckboxLabel = TRUE ## export ckbox *labels* vs Unchecked/Checked
  )
)

monthly_df <- post_to_df(monthly_post)
```

```
## Double-check if you like! Commented out to save space
## monthly_df
```

Study Completion Data

This code chunk exports all the fields collected at study completion, as well as study ID. It exports only the study completion event; therefore, each study ID will have at most one record.

```
## Data from study completion visits
completion_post <- httr::POST(
  url = rc_url,
  body = list(
    token = Sys.getenv("RCTOKEN"),      ## API token gives you permission
    content = "record",                  ## export *records*
    format = "csv",                      ## export as *CSV*
    forms = "completion_data",           ## form
    fields = c("study_id"),              ## additional fields
    events = "study_completion_arm_1",   ## study completion event
    rawOrLabel = "label",                ## export factor *labels* vs numeric codes
    exportCheckboxLabel = TRUE           ## export ckbox *labels* vs Unchecked/Checked
  )
)
completion_df <- post_to_df(completion_post)

## Double-check if you like! Commented out to save space
## completion_df
```

For Demonstration Purposes

To allow you to run the rest of this tutorial, I've stored some toy data in the same format as our example REDCap databases in the `rawdata/` folder in this repository, along with a copy of the data dictionary. All are in the same format we would see if we used the API as described above.

```
datadict <- read.csv(
  "rawdata/datadict.csv", stringsAsFactors = FALSE, na.strings = ""
)
baseline_df <- read.csv(
  "rawdata/baseline_df.csv", stringsAsFactors = FALSE, na.strings = ""
)
monthly_df <- read.csv(
  "rawdata/monthly_df.csv", stringsAsFactors = FALSE, na.strings = ""
)
completion_df <- read.csv(
  "rawdata/completion_df.csv", stringsAsFactors = FALSE, na.strings = ""
)
```

Chapter 4

Step 2: Create a data.frame of All Issues

This sounds deceptively straightforward, but is the most involved part of this process. Our goal is to create a single data frame of all potential problems in our REDCap project as of the date we run the script, which can then be imported into our documentation database(s) (more on that later) so that the issues can be resolved.

Workflow

Typically, I work form by form: here, we'll clean the entire demographic form, then the entire baseline data collection form, then... This keeps the code in manageable chunks and makes it easier to both write initially and debug and maintain as the study progresses.

We often have groups of very similar potential problems: There are many fields that should be present no matter what, for example, and there are several fields which should be between specific limits. We can write custom functions to check these types of issues.

Remember: REDCap has many data validation capabilities built in - **use them!** If your database already checks fields like email for formatting, or gives live warning if you enter unlikely lab values, it will save you and the study staff time and headaches later. The same applies to using branching logic often and well. The added value for this data cleaning script comes from the more complex data checks that are possible here and not within REDCap itself. But the more of REDCap's powerful features you can use from the beginning, the better your data will be throughout the study (eg, for DSMB reports and interim analyses).

Data Management

Several of our error checks will involve comparing dates, or using fields from different time points. We'll do all this data management here.

```
## -- Helper functions; we're doing the same thing a lot -----
## Another reason to make sure all your dates have the same formatting!
date_ymd <- function(x){ as.Date(x, format = "%Y-%m-%d") }
diff_days <- function(x, y){ as.numeric(difftime(x, y, units = "days")) }

## Baseline data
baseline_df$dob <- date_ymd(baseline_df$dob)
baseline_df$date_enrolled <- date_ymd(baseline_df$date_enrolled)

## Dates out of characters
baseline_df$date_visit_b <- date_ymd(baseline_df$date_visit_b)
baseline_df$date_supplement_dispensed <-
  date_ymd(baseline_df$date_supplement_dispensed)

## Calculate days between baseline visit and other milestones
## Creating these variables will make our code later much more readable
baseline_df$days_visit_consent <- with(baseline_df, {
  diff_days(date_visit_b, date_enrolled) })
baseline_df$days_visit_supp <- with(baseline_df, {
  diff_days(date_supplement_dispensed, date_visit_b) })

## Monthly data
monthly_df$date_visit_m <- date_ymd(monthly_df$date_visit_m)

## Study completion data
completion_df$completed_date <- date_ymd(completion_df$completed_date)
completion_df$studywd_date <- date_ymd(completion_df$studywd_date)
completion_df$death_date <- date_ymd(completion_df$death_date)
```

Dummy Dataset

For many types of checks, it's helpful to have a dataset with every record that *should* be available for each patient. In our example study, patient 2 has a baseline record, but no monthly or study completion data. If we clean each form separately, it would be very hard to realize that this patient is missing that data.

Therefore, we create a “dummy” dataset with one record per patient per expected event, and merge this dataset with our other forms as needed. (Depending on the study design, this can be straightforward or difficult, but it is *always* helpful!)

```
## Create "dummy" datasets that have a record for every patient + time
## This helps us check things like "pt X is missing Monthly Visit 2"
## Knowing the study design is key!

## Lists of all unique IDs, events
## In our case, every patient should have a record for every month, unless they
## have died or withdrawn, along with baseline data & a study completion form.
## So we create a dummy dataset with all five events for each patient. Later,
## we'll also create an indicator variable for whether the patient has died or
## withdrawn at that point (and therefore should not have data entered).
```

```

all_ids <- sort(unique(c(
  baseline_df$study_id, monthly_df$study_id, completion_df$study_id
)))
all_events <- c("Baseline Visit", paste("Month", 1:3), "Study Completion")

dummy_df <- data.frame(
  study_id = rep(all_ids, each = length(all_events)),
  redcap_event_name = rep(all_events, length(all_ids))
)

## Merge on relevant dates for each event: enrollment, completion, death,
## withdrawal - we will use these to help clean things in each form
dates_everyone <- merge(
  subset(baseline_df, select = c(study_id, date_enrolled)),
  subset(completion_df, select = c(study_id, completed_date, death_date, studywd_date)),
  by = "study_id", all = TRUE
)

dummy_df <- merge(
  dummy_df,
  dates_everyone,
  by = "study_id", all.x = TRUE
)

dummy_df <- merge(
  dummy_df,
  subset(monthly_df, select = c(study_id, redcap_event_name, date_visit_m)),
  by = c("study_id", "redcap_event_name"), all.x = TRUE
)

## Merge subsets of dummy data onto individual datasets, to make sure every
## dataset has all the patients/records it's supposed to
## This step also adds dates from baseline and completion forms onto forms where
## they're needed (eg, adds date of study withdrawal onto monthly form, so we
## can tell whether they *should* have a monthly visit or not)
baseline_df <- merge(
  subset(
    dummy_df,
    redcap_event_name == "Baseline Visit",
    select = c(study_id, redcap_event_name)
  ),
  baseline_df,
  by = c("study_id", "redcap_event_name"), all.x = TRUE
)

monthly_df <- merge(
  subset(
    dummy_df,
    redcap_event_name %in% paste("Month", 1:3),
    select = -date_visit_m
  ),
  monthly_df,
  by = c("study_id", "redcap_event_name"), all.x = TRUE
)

```



```

completion_df <- merge(
  subset(
    dummy_df,
    redcap_event_name == "Study Completion",
    select = c(study_id, redcap_event_name, date_enrolled)
  ),
  completion_df,
  by = c("study_id", "redcap_event_name"), all.x = TRUE
)

## Add an indicator to the monthly form for whether the patient should have a
## form filled out this month. (They should *not* if they have died or withdrawn
## before [month] * 30 days.)
monthly_df$month_num <-
  with(monthly_df, as.numeric(substr(redcap_event_name, 7, 7)))
monthly_df$days_enrolled_actual <- with(monthly_df, {
  diff_days(date_visit_m, date_enrolled) })
monthly_df$date_visit_planned <- with(monthly_df, {
  date_enrolled + (month_num * 30) })
monthly_df$out_of_study <- with(monthly_df, {
  (!is.na(death_date) & death_date < date_visit_planned) |
  (!is.na(studywd_date) & studywd_date < date_visit_planned)
})

## Indicator: Does the patient have any monthly visit data this month?
## Use the data dictionary to save typing!
monthly_vars <- subset(datadict, form_name == "monthly_data")$field_name
## `consent_reminder` is just a reminder field, is not exported
monthly_vars <- setdiff(monthly_vars, "consent_reminder")

monthly_df$any_data <- rowSums(!is.na(monthly_df[, monthly_vars])) > 0

## Create a variable for *last* month's visit, to check hospitalization dates
## Note: There may be better ways to do this in base (maybe split/unsplit?).
## I would usually use dplyr:
## monthly_df %>%
##   group_by(study_id) %>%
##   mutate(last_visit = lag(date_visit_m))
monthly_df$last_visit <- as.Date(
  unlist(
    lapply(
      unique(monthly_df$study_id),
      FUN = function(i){
        df <- subset(monthly_df, study_id == i)
        c(NA, df$date_visit_m[1:(nrow(df) - 1)])
      })
  ),
  origin = "1970-1-1"
)

```

Demographics Form

The Demographics form is one of the two collected at the baseline visit. In Step 1, we exported it as part of `baseline_df`; this data.frame has one record per patient. If you take Approach 1 (export everything at once), make sure that you subset the data to only keep the **Baseline Visit** event.

1. Decide what to clean

The first step is to determine what issues need to be looked for. Some of these are straightforward: for example, every patient should have a date of birth. Some are more complex or not as obvious, however. **This is where communication and detail are key.** Typically, our project manager will spend a good deal of time creating a list of things that need to be checked, based on the study protocols and goals. It is enormously important for the clinical data team and the statistician/database manager to overcommunicate at this stage!

For our demographics form, we want to check the following:

- Study ID should always be an integer (no letters or special characters)
- These fields should always be present:
 - Date of consent
 - Consent form
 - All contact information
 - Phone
 - Mood
 - Statins
- Postal code should be properly formatted (*so should email, but REDCap will validate this field automatically - take advantage of REDCap's capabilities when designing your study!*)
- Date of birth should be between 18 and 110 years before consent
- If the patient is female, whether she has ever given birth should be entered
- If the patient has given birth, the number of births should be entered
- If no activity questions are marked, study staff should confirm this (it might be OK, but it is unusual and should be checked)
- If the patient is marked as being on statins, at least one specific statin should be checked; if the patient is marked as *not* being on statins, *no* statins should be checked
- Height and weight should both be present and within soft limits set in the database

2. Custom error checking (+ demo of the process)

Our next step is to create a `n x 2` data.frame where each row represents one potential problem; the first column is an error code; and the second column is the corresponding error message. For example, our error code might be `id_format`, and the corresponding error message might be **Study ID should be an integer with at most four digits.**

```
## -- Create error codes + corresponding messages for all issues *except* -----
## -- fields that are simply missing or should fall within specified limits ----

## Codes: Short, like variable names
## Messages: As clear as possible to the human reader
demog_codes <- data.frame(
  code = c(
    "id_format", "postcode_format", "dob_limits", "birth_yn", "birth_num",
    "no_activity", "which_statin", "no_statins"
  ),
```

```

msg = c(
  "Study ID should be an integer with at most four digits",
  "Postal code should be formatted properly",
  "Date of birth should be within 18 and 110 years prior to consent",
  "If patient is female, whether she has given birth should be marked",
  "If patient has given birth, number of births should be present",
  "This patient has no activities marked; please confirm or correct",
  "Patient is marked as taking statins, but no specific statins checked",
  "Patient is marked as not taking statins, but at least one statin is checked"
)
)

```

The second step is to create a matrix with `# rows = nrow(data frame we're checking)`, and `# columns = nrow(data frame of error codes)`. Every column is logical, indicating whether or not this problem exists at this row in the data.frame. For many issues, we'll do this manually.

```

## Preliminary setup: Create empty matrix to hold all potential issues
## Rows = # rows in baseline_df
## Columns = # potential issues
## Everything starts off FALSE
demog_issues <- matrix(FALSE, ncol = nrow(demog_codes), nrow = nrow(baseline_df))
colnames(demog_issues) <- demog_codes$code
rownames(demog_issues) <- with(baseline_df, {
  paste(study_id, redcap_event_name, sep = '; ') })

```

Note that our matrix has specific rownames - this will be important later, especially for longitudinal forms. The rownames are formatted as `study_id; event_name`. Later, we'll separate these rownames into the ID and event fields to upload to the documentation database.

```

## -- Determine true/false for each potential issue -----
## Study ID, postal codes are checked using regular expressions; set rows which
## do *not* meet the regex to TRUE
## (For regexes, it's easier to do this by using the first-column notation here,
## because of how grep() works. For other custom checks, however, I find it more
## readable to say `df_issues[, "issue_name"] <- [condition]`.)
demog_issues[
  grep("^\\d{1,4}$", baseline_df$study_id, invert = TRUE), "id_format"
] <- TRUE
demog_issues[
  grep("^\\d{3}-\\d{4}$", baseline_df$postal_code, invert = TRUE),
  "postcode_format"
] <- TRUE

## Date of birth: Should be within 18 and 110 years of consent date
demog_issues[, "dob_limits"] <- with(baseline_df, {
  !is.na(date_enrolled) & !is.na(dob) &
  (diff_days(date_enrolled, dob) < (18 * 365.25) |
   diff_days(date_enrolled, dob) > (110 * 365.25))
})

## Birth questions
demog_issues[, "birth_yn"] <- with(baseline_df, {
  !is.na(gender) & gender == "Female" & is.na(given_birth) })
demog_issues[, "birth_num"] <- with(baseline_df, {
  !is.na(given_birth) & given_birth == "Yes" & is.na(num_children)

```

```

})

## Activity questions: If all are missing, ask site to confirm

## Versions if using API to export: options given download checkboxes as
## `day of the week` or NA
demog_issues[, "no_activity"] <- rowSums(
  !is.na(
    baseline_df[,grep("(gym|aerobics|eat|drink)\\_[0-6]$", names(baseline_df))]
  )
) == 0

## Statins
demog_issues[, "which_statin"] <- baseline_df$any_statins == "Yes" &
  rowSums(!is.na(baseline_df[, paste0("which_statins_", 1:9)])) == 0
demog_issues[, "no_statins"] <- baseline_df$any_statins == "No" &
  rowSums(!is.na(baseline_df[, paste0("which_statins_", 1:9)])) > 0

# ## Versions if using manually exported CSV "labels" format: exports checkboxes
# ## as `Checked` or `Unchecked`
# ## Activity
# demog_issues[, "no_activity"] <- rowSums(
#   baseline_df[,grep("(gym|aerobics|eat|drink)\\_[0-6]$", names(baseline_df))] == "Checked"
# ) == 0
#
# ## Statins
# demog_issues[, "which_statin"] <- baseline_df$any_statins == "Yes" &
#   rowSums(baseline_df[, paste0("which_statins_", 1:9)] == "Checked") == 0
# demog_issues[, "no_statins"] <- baseline_df$any_statins == "No" &
#   rowSums(baseline_df[, paste0("which_statins_", 1:9)] == "Checked") > 0

demog_issues

```

```

##           id_format postcode_format dob_limits birth_yn birth_num
## 1; Baseline Visit      FALSE          FALSE      FALSE  FALSE  FALSE
## 2; Baseline Visit      FALSE          FALSE      FALSE  FALSE  FALSE
## 3; Baseline Visit      FALSE          TRUE       FALSE  FALSE  TRUE
## 4A; Baseline Visit     TRUE           FALSE      TRUE   FALSE  FALSE
##           no_activity which_statin no_statins
## 1; Baseline Visit      FALSE          FALSE      FALSE
## 2; Baseline Visit      FALSE          FALSE      FALSE
## 3; Baseline Visit      FALSE          TRUE       FALSE
## 4A; Baseline Visit     TRUE           FALSE      TRUE

```

Success! The next step is to take our matrix, look for only the actual errors (TRUE values), and combine them into a data.frame with one row per actual error. To do this, we create a data.frame for every column in `demog_issues` with one row per TRUE value, then bind all those rows together.

Because we'll be doing this frequently, there is a helper function, `create_error_df()`, in `dataclean_helpers.R` to do it for us. The function takes as inputs our `error_codes` and `error_matrix`, and returns a data.frame with one row per actual problem.

```

demog_errors <- create_error_df(
  error_matrix = demog_issues, error_codes = demog_codes
)

```

```
demog_errors
```

```
##          id
## 1 4A; Baseline Visit
## 2 3; Baseline Visit
## 3 4A; Baseline Visit
## 4 3; Baseline Visit
## 5 4A; Baseline Visit
## 6 3; Baseline Visit
## 7 4A; Baseline Visit
##
##                                     msg
## 1          Study ID should be an integer with at most four digits
## 2          Postal code should be formatted properly
## 3          Date of birth should be within 18 and 110 years prior to consent
## 4          If patient has given birth, number of births should be present
## 5          This patient has no activities marked; please confirm or correct
## 6          Patient is marked as taking statins, but no specific statins checked
## 7 Patient is marked as not taking statins, but at least one statin is checked
```

4. Simple checks: Are these fields present?

One of the most common issues we check is simply whether every record has a certain field that should always be present. For example, in our Demographics form, every patient should have date of birth and gender, among other fields.

Because these checks are so common, I have a helper function, `check_missing()`, that lets us do it easily. It follows the same basic steps as we did for our custom checks, but every check is `is.na(df[, x])`, and every error message is “Missing [field label].” It takes as inputs our data.frame, a character string of variables to check, and the data dictionary, from which it gets variable labels to create the full error message.

(Variable labels can be very helpful in error messages! No matter how descriptive your field names are, your data entry team is used to seeing “Subject Global Assessment,” not “sga_b”. With little effort, you can make their lives much easier and also make the data cleaning process much faster. Here, the data dictionary is imported in `dataclean_helpers.R`, using a process similar to the one we used to download our raw data, and stored as the object `datadict`.)

```
demog_missing <- check_missing(
  df = baseline_df,
  variables = c(
    "date_enrolled", "patient_document", "family_name", "given_name",
    "street_address", "city_prefecture", "postal_code", "phone", "email",
    "dob", "gender", "mood", "any_statins", "height", "weight", "bmi"
  ),
  ddict = datadict
)
```

```
demog_missing
```

```
##          id                                     msg
## 1 3; Baseline Visit      Missing Date subject signed consent
## 2 2; Baseline Visit Missing Upload the patient's consent form
## 3 2; Baseline Visit      Missing Phone number
## 4 4A; Baseline Visit      Missing E-mail
## 5 2; Baseline Visit      Missing Specify the patient's mood.
```

```
## 6 3; Baseline Visit      Missing Weight (kilograms)
## 7 3; Baseline Visit      Missing BMI
```

4. Check for Values Outside Limits

We have several numeric fields that we want to make sure fall within reasonable limits (or if they do not, that the values are confirmed to be correct). For example, it would be very easy for someone to enter a height of 19 centimeters when they actually meant 190 centimeters. REDCap has built-in data validation rules, and you should take full advantage of them - this will make data entry errors much harder. However, it is still possible to enter incorrect values, especially if you forget to build these rules into the design of the database from the beginning. It will also give you more confidence in these outlying values at the time of analysis if these outliers are checked during the process, rather than waiting until the point of analysis, when study staff may no longer be available or you have to make quick decisions.

The `check_limits_numeric()` function in `dataclean_helpers.R` follows a very similar process to `check_missing()`. The difference is that you can specify minimum and maximum allowed values for each variable, using either the limits set in the REDCap data dictionary, or a custom data.frame.

Let's take a look at the way the relevant columns in the data dictionary are formatted:

```
subset(
  datadict,
  field_name %in% c("study_id", "dob", "height", "weight"),
  select = c(
    field_name, field_label, field_type,
    text_validation_type_or_show_slider_number,
    text_validation_min, text_validation_max
  )
)
```

```
##   field_name      field_label field_type
## 1  study_id      Study ID      text
## 11 dob          Date of birth  text
## 24 height       Height (cm)    text
## 25 weight       Weight (kilograms) text
##   text_validation_type_or_show_slider_number text_validation_min
## 1                                           <NA>                <NA>
## 11                                          date_ymd              1900-05-31
## 24                                          number                130
## 25                                          integer                35
##   text_validation_max
## 1                    <NA>
## 11                   5/31/00
## 24                   215
## 25                   200
```

All four of the fields we've chosen to display are `text` fields, but with different validation types. `study_id` is purely text; `dob` is text that must be formatted as a date; `height` and `weight` are numeric/integer text. `check_limits_numeric()` currently only works with numeric field types; if you have several dates/times in your database, you could certainly write a second version to work with dates.

We'll use these already-specified limits to check for extreme values in height and weight. Since we want to use the default values, using this function looks very similar to `check_missing()`:

```
demog_limits <- check_limits_numeric(
  df = baseline_df,
```

```

    variables = c("height", "weight"),
    ddict = datadict
  )

  demog_limits

```

```

##           id
## 1 2; Baseline Visit
##
## 1 Height (cm) is not between recommended limits of 130 and 215; please correct or confirm accuracy

```

Later we'll have an example where we specify custom limits.

5. Combine All Issues

That's all we want to check for the Demographics form, so we'll combine these data.frames into a single one for ease.

```

demog_final <- do.call(rbind, list(demog_missing, demog_limits, demog_errors))
demog_final$form <- "Demographics"

## demog_final

```

Baseline Visit Form

This process will be very similar to the Demographics form process above. We'll be making sure that:

- Date of visit is recorded, and is on or within a week of consent
- Creatinine present, within 0.3 - 9
- HDL cholesterol present, within 20-100
- LDL cholesterol present, within 30-300
- Weight present, within 35-200
- Two plasma, two serum variables answered
- Subject Global Assessment answered
- Date patient begins supplement answered, after date of baseline visit

Things aren't missing

We actually want to check that *everything* is present. We can save ourselves some typing by taking advantage of the data dictionary.

```

## Get all the variables in the Baseline Visit form
baseline_vars <- subset(datadict, form_name == "baseline_data")$field_name

## Now see if they're missing
baseline_missing <- check_missing(
  df = baseline_df,
  variables = baseline_vars
)

## baseline_missing

```

Things aren't extremely large or small

We have several lab values and patient characteristics measured at this visit. If we look at the data dictionary, all of these fields have limits entered (which is great!), but the limits for creatinine are very generous (someone with a creatinine of 20 mg/dL would be *very* sick). We'll create a data frame with our own limits (which in real life, we would do after talking with our clinical collaborators).

```
baseline_limit_vars <- paste0(c("creat", "hdl", "ldl", "drywt"), "_b")

baseline_limit_df <- data.frame(
  var = baseline_limit_vars,
  min_val = c(0.5, 20, 30, 35),
  max_val = c(10, 100, 300, 200)
)

baseline_limits <- check_limits_numeric(
  ## These arguments are similar to previous example
  df = baseline_df,
  variables = baseline_limit_vars,
  ddict = datadict,
  ## These arguments are how we supply our own limits:
  ## df_limits = data.frame; cname_min, cname_max = columns in df_limits with
  ## minimum, maximum limits
  df_limits = baseline_limit_df,
  cname_min = "min_val",
  cname_max = "max_val"
)

## baseline_limits
```

Custom checks

We just have a couple of other things to check, using custom code for each.

```
## -- Create error codes + corresponding messages for additional issues -----
baseline_codes <- data.frame(
  code = c("visit_consent", "visit_supp"),
  msg = c(
    "Baseline visit should occur within one week of consent",
    "Supplement start date should be on or within one week of baseline visit"
  )
)

## -- Issues matrix: in this case, two columns -----
## Rows = # rows in baseline_df
## Columns = # potential issues
## Everything starts off FALSE
baseline_issues <- matrix(
  FALSE, ncol = nrow(baseline_codes), nrow = nrow(baseline_df)
)

colnames(baseline_issues) <- baseline_codes$code
rownames(baseline_issues) <- with(baseline_df, {
  paste(study_id, redcap_event_name, sep = '; ') })
```



```
## -- Determine true/false for each potential issue -----
baseline_issues[, "visit_consent"] <- with(baseline_df, {
  !is.na(days_visit_consent) &
    (days_visit_consent < 0 | days_visit_consent > 6)
})
baseline_issues[, "visit_supp"] <- with(baseline_df, {
  !is.na(days_visit_supp) & (days_visit_supp < 0 | days_visit_supp > 6)
})

baseline_errors <- create_error_df(baseline_issues, baseline_codes)

## -- Combine all baseline errors into a final data.frame -----
baseline_final <- do.call(
  rbind, list(baseline_missing, baseline_limits, baseline_errors)
)
baseline_final$form <- "Baseline Data"
```

Monthly Visit

This form will go mostly the same as the two before, even though the form is collected at multiple time points. We'll check at every visit:

- At least some data exists for each month, unless patient has withdrawn or died
- Date of visit is recorded and is at within X months (+/- one week) of enrollment
- Creatinine present, within 0.3 - 9
- HDL cholesterol present, within 20-100
- LDL cholesterol present, within 30-300
- Weight present, within 35-200
- Number of treatments missed (out of 8) present
- % compliance present
- number of treatments should be between 0-8 and "match" % compliance
- Hospitalization (y/n) present
- If hospitalized, cause, dates, discharge summary questions present
- If hospitalized, dates should be between last and current visit
- Date of hospital discharge should be after date of admission

```
## -- Custom checks -----
## Create error codes + corresponding messages
monthly_codes <- data.frame(
  code = c(
    "incomplete_visit", "extra_visit", "visit_date", "trt_comp",
    "hosp_cause_miss", "hosp_adm_miss", "hosp_dis_miss", "hosp_sum_miss",
    "hosp_lastvisit", "hosp_adm_dis"
  ),
  msg = c(
    "Patient has not died or withdrawn, but has no data for this month",
    "Patient died or withdrew before scheduled monthly visit, but has data",
    "Date of monthly visit not within X months (+/- one week) after enrollment",
    "Number of treatments missed does not match % compliance",
    "Patient hospitalized since last visit, but missing cause of hospitalization",
    "Patient hospitalized since last visit, but missing admission date",
    "Patient hospitalized since last visit, but missing discharge date",
    "Patient hospitalized since last visit, but missing whether summary filed",
  )
)
```

```

    "Hospital admission date is prior to last visit",
    "Hospital discharge date is prior to admission date"
  )
)

monthly_issues <- matrix(
  FALSE, ncol = nrow(monthly_codes), nrow = nrow(monthly_df)
)

colnames(monthly_issues) <- monthly_codes$code
rownames(monthly_issues) <- with(monthly_df, {
  paste(study_id, redcap_event_name, sep = '; ') })

## Determine true/false for each potential issue
monthly_issues[, "incomplete_visit"] <- with(monthly_df, {
  !out_of_study & !any_data })
monthly_issues[, "extra_visit"] <- with(monthly_df, out_of_study & any_data)
monthly_issues[, "visit_date"] <- with(monthly_df, {
  !is.na(days_enrolled_actual) &
  (days_enrolled_actual < ((month_num * 30) - 7) |
   days_enrolled_actual > ((month_num * 30) + 7))
})
monthly_issues[, "trt_comp"] <- with(monthly_df, {
  !is.na(trt_missed) & !is.na(compliance) & (
    (compliance == "99-75 percent" & trt_missed > 2) |
    (compliance == "74-50 percent" & !(trt_missed %in% 3:4)) |
    (compliance == "49-25 percent" & !(trt_missed %in% 5:6)) |
    (compliance == "0-24 percent" & !(trt_missed %in% 7:8))
  )
})
monthly_issues[, "hosp_cause_miss"] <- with(monthly_df, {
  !is.na(hosp_yn) & hosp_yn == "Yes" & is.na(hosp_cause) })
monthly_issues[, "hosp_adm_miss"] <- with(monthly_df, {
  !is.na(hosp_yn) & hosp_yn == "Yes" & is.na(hosp_adm) })
monthly_issues[, "hosp_dis_miss"] <- with(monthly_df, {
  !is.na(hosp_yn) & hosp_yn == "Yes" & is.na(hosp_dis) })
monthly_issues[, "hosp_sum_miss"] <- with(monthly_df, {
  !is.na(hosp_yn) & hosp_yn == "Yes" & is.na(hosp_summary_binder) })
monthly_issues[, "hosp_lastvisit"] <- with(monthly_df, {
  !is.na(hosp_adm) & !is.na(last_visit) & hosp_adm < last_visit })
monthly_issues[, "hosp_adm_dis"] <- with(monthly_df, {
  !is.na(hosp_adm) & !is.na(hosp_dis) & hosp_dis < hosp_adm })

monthly_errors <- create_error_df(monthly_issues, monthly_codes)

## -- Missingness checks -----
monthly_vars <- c(
  paste0(c("creat", "hdl", "ldl", "drywt"), "_m"),
  "trt_missed", "compliance", "hosp_yn"
)
monthly_missing <- check_missing(
  df = subset(monthly_df, !out_of_study),
  ## takes out visits that shouldn't be there
  variables = monthly_vars
)

```

```

)

## -- Limit checks -----
monthly_limits_vars <-
  c(paste0(c("creat", "hdl", "ldl", "drywt"), "_m"), "trt_missed")

monthly_limit_df <- data.frame(
  var = monthly_limits_vars,
  min_val = c(0.3, 20, 30, 35, 0),
  max_val = c(9, 100, 300, 200, 8)
)

monthly_limits <- check_limits_numeric(
  df = subset(monthly_df, !out_of_study),
  variables = monthly_limits_vars,
  ddict = datadict,
  df_limits = monthly_limit_df, cname_min = "min_val", cname_max = "max_val"
)

## -- Combine all checks -----
monthly_final <- do.call(
  rbind, list(monthly_missing, monthly_limits, monthly_errors)
)
monthly_final$form <- "Monthly Data"

```

Study Completion Form

Each patient should have a study completion form filled out, at the end of the study or at death or withdrawal, if those events occur before the study's end. We'll check:

- Study completion (yes/no), date are recorded
- Whether patient withdrew or died are recorded
- If the patient withdrew, whether date and reason are recorded
- If the patient died, whether date and cause are recorded

```

## -- All checks -----
## Since there's only one variable that should be present for everyone, we'll
## just include it in the main section rather than doing a separate call for
## check_missing().

## Create error codes + corresponding messages
completion_codes <- data.frame(
  code = c(
    "miss_comp", "comp_date", "wd_date", "wd_reason", "died_date", "died_cause"
  ),
  msg = c(
    "Missing Has patient completed study?",
    "Patient completed study, but missing date",
    "Patient withdrew, but missing date",
    "Patient withdrew, but missing reason",
    "Patient died, but missing date",
    "Patient died, but missing cause"
  )
)

```

```

)

completion_issues <- matrix(
  FALSE, ncol = nrow(completion_codes), nrow = nrow(completion_df)
)

colnames(completion_issues) <- completion_codes$code
rownames(completion_issues) <- with(completion_df, {
  paste(study_id, redcap_event_name, sep = '; ') })

## Determine true/false for each potential issue
completion_issues[, "miss_comp"] <- is.na(completion_df$completed_study)
completion_issues[, "comp_date"] <- with(completion_df, {
  !is.na(completed_study) & completed_study == "Yes" & is.na(completed_date) })
completion_issues[, "wd_date"] <- with(completion_df, {
  !is.na(studywd_yn) & studywd_yn == "Yes" & is.na(studywd_date) })
completion_issues[, "wd_reason"] <- with(completion_df, {
  !is.na(studywd_yn) & studywd_yn == "Yes" & is.na(studywd_reason) })
completion_issues[, "died_date"] <- with(completion_df, {
  !is.na(death_yn) & death_yn == "Yes" & is.na(death_date) })
completion_issues[, "died_cause"] <- with(completion_df, {
  !is.na(death_yn) & death_yn == "Yes" & is.na(death_cause) })

completion_final <- create_error_df(completion_issues, completion_codes)
completion_final$form <- "Completion Data"

```

Combine Everything

That's it! Now we combine all our data issues into one data.frame and prepare it to upload to the documentation database.

```

all_issues <- do.call(
  rbind, list(demog_final, baseline_final, monthly_final, completion_final)
)

## Separate study_id, redcap_event_name from id column
id_event <- strsplit(as.character(all_issues$id), "; ")
all_issues$study_id <- unlist(lapply(id_event, FUN = function(x){ x[[1]] })))
all_issues$event <-
  unlist(lapply(id_event, FUN = function(x){ x[[2]] })))
all_issues <- all_issues[order(all_issues$study_id), ]

## Create a unique query number for all issues for each patient
all_issues$querynum <- unlist(
  lapply(
    unique(all_issues$study_id),
    FUN = function(i){ 1:sum(all_issues$study_id == i) }
  )
)

## Add today's date, create total query ID (study_id + date + querynum)
all_issues$date_query <- format(Sys.Date(), "%Y-%m-%d")
all_issues$queryid <-

```

```

with(all_issues, paste(study_id, date_query, querynum, sep = "_"))

## -- Final version to upload: Query ID, pt ID, date, form, event, issue -----
all_issues <- subset(
  all_issues,
  select = c(queryid, study_id, date_query, form, event, msg)
)

## Write out to CSV to more easily look at it - will store this in repo
write.csv(all_issues, "querydata/original_issues.csv", row.names = FALSE)

```

If this is the first time we've run the data clean, we can skip to step 4.

Chapter 5

Step 3: Remove Unfixable Queries

Sometimes, issues with the data are known but cannot be resolved. For example, if a patient was not weighed at a monthly visit, that value can never be entered. Repeating these queries forces study staff to re-investigate problems they have already documented, which is both irritating and a waste of time and effort.

Therefore, an important step in our process is the **documentation** of each issue. This both serves as a record of why the original data changed and enables us to **remove** issues which are unfixable or correct from future data cleans.

Documentation Project Structure

We document all issues and record their resolution in a separate REDCap project, which contains at minimum the following fields (example values in blue):

Values created by R script

Query ID is typically a combination of patient ID, the date of the data clean, and a number between 1 and the total number of queries found during that data clean.

| | |
|-------------------------|--|
| Query ID | Unique identifier for each issue |
| Study ID | <input type="text" value="001"/> |
| Date issue was queried: | <input type="text" value="2018-06-04"/> Today Y-M-D |
| Form or Issue Type | <input type="text" value="For example, 'Demographics'"/> |
| REDCap Event Name | <input type="text" value="For example, 'Baseline Visit'"/> |
| Data Issue | <input type="text" value="Missing Date of Birth"/> |

Expand

Figure 5.1: Example query in documentation database

| Site Response Section | |
|---|--|
| Date issue was reconciled by site staff: | <input type="text"/> <input type="button" value="Today"/> Y-M-D |
| Corrected? | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Value confirmed correct (for accuracy queries ONLY) |
| Electronic signature of person fixing the query | <input type="text"/> |

Figure 5.2: Study staff section in documentation database

| Coordinating Center Response Section for Issues Not Corrected | |
|---|--|
| Date | <input type="text"/> <input type="button" value="Today"/> Y-M-D |
| Issue closed? | <input type="radio"/> Yes (it is permanently unfixable) <input type="radio"/> Yes (programming has since been corrected) <input type="radio"/> No (Project Manager should contact the site to reconcile) |
| Additional Notes | <input type="text"/> |
| Electronic signature of CC person who reviewed this query | <input type="text"/> |
| Form Status | |
| Complete? | <input type="button" value="Incomplete"/> |

Figure 5.3: Study staff section in documentation database

Values filled out by study staff

“Accuracy queries” are those that ask staff to confirm extreme values - for example, “Height is less than recommended minimum of xxx cm; please correct or confirm.”

Values filled out by coordinating center/manager

“Permanently unfixable” queries are those that relate to data that can never be recovered; for example, weight is missing at a monthly assessment because the patient wasn’t weighed at all.

Some queries are due to errors in the script or miscommunications between the coordinating center and the statistician/database manager; as the study progresses, you will always find new, fun problems! Thus, we allow for this category of “not fixed.”

Depending on the study, it might also be helpful to have additional fields in the documentation, such as a reason the query was not corrected or whether a Note to File was recorded.

The example documentation codebook for this project can be found [here](#).

| Coordinating Center Response Section for Issues Not Corrected | |
|---|---|
| Date | <input type="text" value="2018-05-12"/> <input type="button" value="Today"/> Y-M-D |
| Issue closed? | <input checked="" type="radio"/> Yes (it is permanently unfixable) <input type="radio"/> Yes (programming has since been corrected) <input type="radio"/> No (Project Manager should contact the site to reconcile) |
| Additional Notes | <input type="text" value="Re-communicated study protocol with site."/> |
| Electronic signature of CC person who reviewed this query | <input type="text" value="Winnie the Pooh"/> |

Figure 5.4: Documenting an unfixable missing value

| Site Response Section | |
|---|---|
| Date issue was reconciled by site staff: | <input type="text" value="2018-05-12"/> <input type="button" value="Today"/> Y-M-D |
| Corrected? | <input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Value confirmed correct (for accuracy queries ONLY) |
| Electronic signature of person fixing the query | <input type="text" value="Florence Nightingale"/> |

Figure 5.5: Correcting an outlying value

For the purposes of this tutorial, we're going to assume that this is *not* the first time we've run this script - ie, that there are already a few issues documented and fixed in the original database. These include:

- Entering a study withdrawal date for patient 2. *This should clear up some queries, but not baseline ones.*
- Entering an consent date for patient 3. *This should **introduce** a new query, because the patient's DOB is in 2018 and thus age will be <18 years.*
- Noting that we forgot to weigh patient 3 at baseline; thus that value is unfixable (query 3_2018-05-12_2). *We don't want this to be uploaded again.*
- Correcting a highly implausible creatinine value at baseline for patient 4A (query 4A_2018-05-12_7; changed from 95 to 9.5). *This will show up in the next clean, but as a "please confirm that this is accurate" query, because the creatinine value is still above the suggested maximum.*
- Confirming an outlying creatinine value at Month 1 for patient 4A (query 4A_2018-05-12_11; value of 9.1 was confirmed correct). *This shouldn't show up in the next clean.*

Everything else should show up again because it hasn't been fixed. This means that if study staff have not corrected and documented a query before the data clean is run again, the same issue will show up multiple times. In rare cases this could be a helpful motivator, but in general, it is very important for the

| Site Response Section | |
|---|---|
| Date issue was reconciled by site staff: | <input type="text" value="2018-05-12"/> <input type="button" value="Today"/> Y-M-D |
| Corrected? | <input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Value confirmed correct (for accuracy queries ONLY) |
| Electronic signature of person fixing the query | <input type="text" value="Florence Nightingale"/> |

Figure 5.6: Confirming an outlying but correct value

statistics/data team to communicate clearly with clinical/data entry teams about appropriate timelines for rerunning the script, to avoid unnecessary double-entry.

Pause: Download “Fixed” Data

To continue with the tutorial, we need to replace our three datasets with versions that include the corrections I detailed above. These files are stored in the `fixeddata/` directory.

```
rm("baseline_df", "monthly_df", "completion_df")

baseline_df <- read.csv(
  "fixeddata/baseline_df.csv", stringsAsFactors = FALSE, na.strings = ""
)
monthly_df <- read.csv(
  "fixeddata/monthly_df.csv", stringsAsFactors = FALSE, na.strings = ""
)
completion_df <- read.csv(
  "fixeddata/completion_df.csv", stringsAsFactors = FALSE, na.strings = ""
)
```

The script `dataclean_partial.R` in this repository essentially runs our data cleaning code thus far on these three updated datasets, resulting in the file `querydata/updated_issues.csv`. If we compare it to `querydata/original_issues.csv`, we see that:

- Many of the queries for patient 2 are gone, since this patient now is known to have withdrawn from the study soon after enrollment; however, we still need several baseline data points to be entered.
- There is no new query for patient 3’s consent date, but there is now a query for his/her age, which we can now calculate.
- There is still a query for patient 3’s baseline weight, even though it has been marked “unfixable.”
- There is no longer a query for patient 4A’s baseline creatinine value. (If this were a monthly creatinine, it would have been queried again, because we used custom minimum and maximum values in the monthly checks. However, at baseline, we used the limits specified in the REDCap database, which include a maximum of 20 - well above the new value of 9.5.)
- There is still a query for patient 4A’s Month 1 creatinine, even though it has been marked accurate.

We want to remove the third and fifth queries above so that they aren’t repeated. To do that, we’ll export the documentation database so that we can check it against our new query list.

Exporting Documentation Data

We download the data in our documentation database in the same way as the raw data. Note that since it is a separate REDCap project, you will need a separate API token. Mine is saved in my `.Renviron` file as the object `DOCTOKEN`.

```
## Documentation of queries already checked
doc_post <- httr::POST(
  url = rc_url,
  body = list(
    token = Sys.getenv("DOCTOKEN"),
    content = "record",
    format = "csv",
    rawOrLabel = "label",
    exportCheckboxLabel = TRUE
  )
)
```

```

)
)
doc_df <- post_to_df(doc_post)

## Double-check if you like! Commented out to save space
## doc_df

```

So that you can continue the tutorial, I've saved the result of the above in the file `querydata/doc_df.csv`; read it in using:

```

## -- Read in CSV version to continue tutorial -----
doc_df <- read.csv(
  "querydata/doc_df.csv", stringsAsFactors = FALSE, na.strings = ""
)

```

We now need to merge our current issues (stored in `all_issues`) with our previously documented issues and remove the potential errors which are either unfixable or actually correct. To be removed from future data cleans, queries must be marked as accurate in the field `corrected`, or must be confirmed by the coordinating center as being unfixable in the field `cc_conclusion`. We'll create an indicator variable for whether each query meets either condition.

```

doc_df$remove <- with(doc_df, {
  (!is.na(corrected) &
    corrected == "Value confirmed correct (for accuracy queries ONLY)") |
  (!is.na(cc_conclusion) &
    cc_conclusion == "Yes (it is permanently unfixable)")
})

subset(doc_df, remove)

```

```

##          queryid study_id date_query          form          event
## 35      3_2018-05-12_2          3 2018-05-12 Demographics Baseline Visit
## 54 4A_2018-05-12_11          4A 2018-05-12 Monthly Data          Month 1
##
## 35
## 54 Creatinine (mg/dL) is not between recommended limits of 0.3 and 9; please correct or confirm accuracy
##      site_date                                corrected
## 35 2018-05-12                                No
## 54 2018-05-12 Value confirmed correct (for accuracy queries ONLY)
##                                corrected_rsn ntf_added
## 35 Weight was not obtained at baseline visit.          Yes
## 54                                NA          NA
##      site_signature      cc_date                                cc_conclusion
## 35 Florence Nightingale 2018-05-12 Yes (it is permanently unfixable)
## 54 Florence Nightingale          NA                                NA
##                                cc_note      cc_signature
## 35 Re-communicated study protocol with site. Winnie the Pooh
## 54                                NA          NA
##      data_clean_complete remove
## 35          Complete      TRUE
## 54          Complete      TRUE

```

So far so good. Now we need to add that indicator variable onto our new set of data issues, then remove those two.

```

remaining_issues <- merge(
  all_issues, subset(doc_df, select = c(study_id, form, event, msg, remove)),
  by = c("study_id", "form", "event", "msg"),
  all.x = TRUE, all.y = FALSE
)

## write.csv(remaining_issues, "querydata/remaining_issues.csv", row.names = FALSE)

```

In `remaining_issues`, we have some queries with a value for `remove` of `FALSE` - these queries are *repeated* from our last clean because they have not been corrected. We have some with a value of `NA`; these are *new* queries (for example, now that patient 3 has a consent date entered, some new queries are showing up related to it). Finally, we have two queries with `remove = TRUE` - these are the two queries listed above. Let's remove them and we'll be done!

```

upload_issues <- subset(remaining_issues, !(is.na(remove) & remove == TRUE))

## write.csv(upload_issues, "querydata/upload_issues.csv", row.names = FALSE)

```

Chapter 6

Step 4: Disseminate Issues to Study Staff

Though it is possible to import `upload_issues` directly to our documentation using the REDCap API, we've found it helpful to do this step manually, because it is often useful for our primary coordinators to look over the list prior to uploading for any systematic errors (eg, all a patient's events are off by one) or opportunities for education or communication with study staff. For example, if there are many similar issues from the same site, there may be a misunderstanding about when a piece of data is to be collected or how it is to be entered. If these queries can be discussed and handled in batches, it will save both study staff and coordinators time in documentation.

Therefore, we typically separate queries by study site (if the study is multicenter); send these to the primary coordinators to look over; and then either upload directly, or wait until the coordinators have resolved systematic errors with study staff and rerun the data clean once data has been corrected.

Doing these systematic changes before uploading queries does mean that some changes to the data are not documented. We have found this to be a fine tradeoff for the number of hours saved documenting the same issue and resolution, especially given that one can always access data histories for a given field within REDCap itself.

Once the data is uploaded to the documentation database, the staff and coordinators work to resolve and document each issue, leaving the database ready for the next round of data cleaning.

Chapter 7

Step 5: Iterate!

I mean iteration in two ways.

Repeat This Process, Early and Often

The more frequently you clean your data, the more prepared you will be for things like interim analyses and DSMB or progress reports, and the less time you'll have to spend on data cleaning at the end of the study (when everyone is very excited about getting the final results!). This is especially important for multicenter studies or studies that enroll over years, where sites or staff members may join and leave the group; once a site is closed or a coordinator has retired, it is (understandably!) a challenge to get effort from that site to clean data. Besides, no one wants to get a large, overwhelming number of queries at the end of the study!

How frequently you choose to clean your data will depend on enrollment rates and how many staff members are available to do the cleaning, but we recommend repeating this process as often as is reasonable.

Always Be Improving

Much like your study protocols, your cleaning script will rarely be perfect on the first try. As the study goes on, you will always find more ways that data can be “wrong,” or have more questions that are inspired by unexpected data or discussions with study staff, or need to add data checks based on protocol changes. The vast majority of time spent on this data cleaning script is during its initial development, but there will always be things that need to be changed or added.

This is one reason that **communication** between the statistician/database manager and study staff is hugely important! We work together not only at the beginning of this process, to design the database and come up with lists of data points that need to be checked, but throughout study enrollment and data collection to make sure that protocol changes are adequately accounted for, misunderstandings are cleared up quickly, etc. Typically, as study staff are working through one round of data cleaning, I keep a list of things that need to be investigated - queries they believe shouldn't be there or aren't clear, queries that need to be added due to a protocol change, etc. Then when it's time for the next round of data cleaning, I block off some time to investigate anything that has come up, fix or add what needs attention, and *then* rerun the next round.

In addition to improving the data itself and the data cleaning script, we use this process as a way to improve our study documents and staff education: If there is a piece of data that is systematically showing up as an issue, perhaps it is due to something that was not clearly addressed at the study startup visit and needs to be revisited, or should be written out fully in an SOP.

Chapter 8

Conclusions & Acknowledgements

Our group recently finished data collection on the first clinical trial we conducted using this process. I can say with absolute certainty that we were able to finish data cleaning and lock our database very quickly, with strong confidence in our data's accuracy, because we prioritized this data cleaning process throughout the course of the study.

This process would be impossible without the dedicated, reliable work of our clinical coordinating team and others at the VUMC CIBS Center, as well as the work of all of our study site coordinators and principal investigators. Particularly, Brenda Pun, Cayce Strength, Leanne Boehm, and Aimee Hoskins have played huge parts in making this process a reality, in their roles as study coordinators.