Castor EDC, R format factor variables

Erik Erhardt July 22, 2018

Contents

Installing from source	1
Strategy for labeling factor variables	1
Format Castor CRF data	2

Installing from source

Set the appropriate path and run this command:

devtools::install_github("erikerhardt/CastorR")

Strategy for labeling factor variables

- 1. Read data
 - Read all CRF_export.xlsx file sheets and construct the structures to produce an Rdata file with (1) variable question labels, (2) correct factor levels with labels, and (3) correct data and numeric data types.
 - Data in Study results has labels in Study variable list
 - Data in other data sheets (between Study results and Study variable list) has labels in Report variable list
 - All factor groups with labels and levels are in Field options
- 2. Collect Option group names, levels, and labels
 - Field options gives the factor variable levels and labels
 - Option group name
 - Option name labels list with Option value list
- 3. Assign variable question labels, Factor variables with Option groups, assign varible class data types
 - Study variable list gives the question names for Study results
 - Report variable list gives the question names for other data sheets (between Study results and Study variable list)
 - Variable name
 - Field label is the question name
 - 1. Use library(labelled) with var_label()
 - 2. For each variable, label it.
 - Optiongroup name
 - 1. Use factor() for each variable using Option group name labels and levels
 - Field type variable data class, useful for date, datetime, and numeric.

Format Castor CRF data

```
library(CastorR)
dat <- castor_format_R(fn = "CRF_export_2.xlsx")</pre>
List of 11
 $ Study results
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 1 obs. of 80 variables:
                               : chr "TES005"
 ..$ Record Id
  ..$ Institute Abbreviation : chr "TES"
                              : POSIXct[1:1], format: "2018-05-29 17:04:54"
  ..$ Record Creation Date
                              : chr "TES005"
  ..$ pat hospital ID
  ....- attr(*, "label")= chr "Patient Hospital ID"
                       : Date[1:1], format: "1974-12-01"
: POSIXct[1:1], format: "2018-05-29 09:00:00"
  ..$ pat birthdate
  ..$ admit_datetime
  ..$ pat_age
                              : int 43
                             : Ord.factor w/ 2 levels "Male"<"Female": 1
  ..$ pat_gender
  ..$ pat height
                              : num 180
  ..$ pat_weight_dry
                             : num 72.5
                              : num 22.4
  ..$ pat_bmi
                             : chr "Yes"
  ..$ inc_age
  ..$ inc_ADHF
                             : Ord.factor w/ 2 levels "Yes"<"No": 1
 ..$ inc_IV_diuretic : Ord.factor w/ 2 levels "Yes"<"No": 1
..$ inc_volume_overload : Ord.factor w/ 2 levels "Yes"<"No": 1
                             : Ord.factor w/ 2 levels "Yes"<"No": 1
  ..$ inc_able
                              : chr "Yes"
  ..$ inc_ALL
                            : chr "No"
 ..$ exc_age
  ..$ exc_pregnant
                             : Ord.factor w/ 2 levels "Yes"<"No": NA
  ..$ exc_skin_damage : Ord.factor w/ 2 levels "Yes"<"No": 2
  ..$ exc_compromised_veins : Ord.factor w/ 2 levels "Yes"<"No": 2
  ..$ exc IV
                               : Ord.factor w/ 2 levels "Yes"<"No": 2
                             : Ord.factor w/ 2 levels "Yes"<"No": 2
  ..$ exc_stand
  ..$ exc_hand_enclosure
                             : Ord.factor w/ 2 levels "Yes"<"No": 2
                              : Ord.factor w/ 2 levels "Yes"<"No": 2
  ..$ exc_fingers
                             : Ord.factor w/ 2 levels "Yes"<"No": 2
  ..$ exc_prisoner
  ..$ exc_prisoner : Ord.factor w/ 2 levels "Yes"<"No": 2
..$ exc_major_condition : Ord.factor w/ 2 levels "Yes"<"No": 2</pre>
                               : Ord.factor w/ 2 levels "Yes"<"No": 2
  ..$ exc_refuse
                               : chr "Yes"
  ..$ exc_ALL
  ..$ ic_name
                               : chr "Fahimeh Salehpour"
  ... - attr(*, "label") = chr "Name of person reviewing documents with subject"
                      : Ord.factor w/ 2 levels "Yes"<"No": 1
  ..$ ic_reviewed
                              : Ord.factor w/ 2 levels "Yes"<"No": 1
  ..$ ic_signed
  ..$ ic_copy_provided
                             : Ord.factor w/ 2 levels "Yes"<"No": 1
  ..$ ic datetime
                              : POSIXct[1:1], format: "2018-05-29 10:00:00"
  ..$ ic_after_admission : int 1
  ..$ pat_NYHA
                               : Ord.factor w/ 4 levels "I"<"II"<"III"<...: 1
                            : chr "Yes"
  ..$ pat_has_echo
                          : Ord.factor w/ 3 levels "Preserved (HFpEF)"<..: 1
: Ord.factor w/ 3 levels "Yes"<"No"<"Unknown": 2</pre>
  ..$ pat_EF_type
  ..$ pat_afib
```

```
..$ pat_pacemaker
                                : Ord.factor w/ 4 levels "None"<"Defibrillator"<..: 1
 ..$ pat_prior_admissions
                              : num 0
 ..$ pat CAD
                               : Ord.factor w/ 2 levels "Yes"<"No": 2
 ..$ pat_PAD
                               : Ord.factor w/ 2 levels "Yes"<"No": 2
                                : Ord.factor w/ 4 levels "Type I"<"Type II"<... 3
 ..$ pat_diabetes
 ..$ pat_diabetes_other
                              : logi NA
 .. ..- attr(*, "label")= chr "Diabetes type"
 ..$ pat_diabetes_duration
                               : num NA
 ..$ pat_COPD
                                : Ord.factor w/ 2 levels "Yes"<"No": 2
 ..$ pat_COPD_duration
                              : num NA
 .. $ pat_apnea
                               : Ord.factor w/ 2 levels "Yes"<"No": 2
                               : Ord.factor w/ 2 levels "Yes"<"No": 2
 ..$ pat_hypertension
 ..$ pat_hypertension_duration: num NA
 ..$ pat_smoking
                               : Ord.factor w/ 3 levels "Never smoked"<..: 1
 ..$ pat_smoking_years
                               : num NA
 ..$ pat_cig_perday
                                : num NA
 ..$ pat_smoking_packyears : logi NA
 ..$ pat_fz_eye
                               : Ord.factor w/ 5 levels "Light blue, light gray, or light green" <...: 2
                              : Ord.factor w/ 5 levels "Red or light blonde" < ..: 3
 ..$ pat_fz_hair
                               : Ord.factor w/ 5 levels "Ivory white" < ...: 3
 ..$ pat_fz_skin
                              : Ord.factor w/ 5 levels "Many"<"Several"<..: 4
 ..$ pat_fz_freckles
 ..$ pat_fz_geneticscore
                              : int 8
 ..$ pat_fz_sun
                               : Ord.factor w/ 5 levels "Always burns, blisters, and peels" <..: 3
                            : Ord.factor w/ 5 levels "Never, always burns"<..: 3
: Ord.factor w/ 5 levels "Not at all or very little"<..: 3</pre>
 ..$ pat_fz_tanfreq
 ..$ pat_fz_tandepth
 ..$ pat_fz_face
                              : Ord.factor w/ 5 levels "Very sensitive"<..: 3
 ..$ pat_fz_sunscore
                               : int 8
                               : int 16
 ..$ pat_fz_score
                              : int 3
 ..$ pat_fz_type
..$ conclude_datetime : POSIXct[1:1], format: "2018-05-30 17:15:00"

..$ conclude_reason : Ord.factor w/ 4 levels "Subject-Initiated Withdrawal (Incomplete)"<..:

..$ conclude_PI_reason : Ord.factor w/ 7 levels "Failure to follow procedures"<..: NA
                              : Ord.factor w/ 4 levels "Takes too much time / too many tests" < ...: NA
 ..$ conclude_pat_reason
 ..$ conclude_duration
                              : int 32
 ..$ conclude_n_v
                               : int 2
                              : int 1
 ..$ conclude_n_b
..$ conclude_success
                              : chr "No"
 ..$ X__1
                               : logi NA
$ Adverse_Event
                            :Classes 'tbl_df', 'tbl' and 'data.frame': 0 obs. of 20 variables:
..$ Record Id
                                              : logi(0)
..$ Report Creation Date
                                              : 'POSIXct' num(0)
- attr(*, "tzone")= chr "UTC"
..$ Report Name Custom
                                              : logi(0)
                                              : logi(0)
 ..$ Report Parent
 ..$ ae_description
                                              : logi(0)
 .. ..- attr(*, "label")= chr "Description"
                                              : 'POSIXct' num(0)
..$ ae_onset
- attr(*, "tzone")= chr "UTC"
                                              : Ord.factor w/ 2 levels "Yes"<"No":
 ..$ ae_ongoing
..$ ae_end
                                              : 'POSIXct' num(0)
- attr(*, "tzone")= chr "UTC"
..$ ae expected
                                              : Ord.factor w/ 2 levels "Yes"<"No":
                                              : Ord.factor w/ 4 levels "Mild"<"Moderate"<..:
 ..$ ae_severity
 ..$ ae_product
                                              : Ord.factor w/ 5 levels "Not related"<..:
```

```
..$ ae_action#No_action_taken
                                           : logi(0)
 ..$ ae_action#Symptomatic_treatment_given : logi(0)
 ...$ ae_action#Use_of_products_discontinued: logi(0)
 ..$ ae_action#Subject_withdrawn_from_study: logi(0)
 ..$ ae_action#Other
                                           : logi(0)
 ..$ ae other action
                                           : logi(0)
 ... - attr(*, "label") = chr "Other Action Taken"
 ..$ ae outcome
                                           : Ord.factor w/ 6 levels "Resolved"<"Recovered with sequela
 ..$ ae_serious
                                           : Ord.factor w/ 2 levels "Yes"<"No":
 ..$ ae_serious_valid
                                           : logi(0)
$ Blood_Work
                            :Classes 'tbl_df', 'tbl' and 'data.frame': 1 obs. of 10 variables:
                         : chr "TES005"
 ..$ Record Id
 ..$ Report Creation Date: POSIXct[1:1], format: "2018-06-01 21:23:40"
 ..$ Report Name Custom : chr "Blood Work - 01-06-2018 13:23:39"
 ..$ Report Parent
                        : chr "Study Procedures"
 ..$ b_datetime
                         : POSIXct[1:1], format: "2018-05-29 13:21:00"
 ..$ b_n
                        : num 1
 ..$ b_bnp
                        : num 335
                        : num 13.6
 ..$ b_hgb
 ..$ b_creatinine
                        : num 1.15
 ..$ X__1
                         : logi NA
$ Echocardiogram
                            :Classes 'tbl_df', 'tbl' and 'data.frame': 1 obs. of 8 variables:
                         : chr "TES005"
 ..$ Record Id
 ..$ Report Creation Date: POSIXct[1:1], format: "2018-06-01 22:15:22"
 ..$ Report Name Custom : chr "Echocardiogram - 01-06-2018 14:15:20"
 ..$ Report Parent
                       : chr "Enrollment"
                         : POSIXct[1:1], format: "2018-05-27 08:45:00"
 ..$ echo_datetime
 ..$ echo_EF
                         : num 45
 ..$ echo_SV
                         : num 68
 ..$ X__1
                         : logi NA
                            :Classes 'tbl_df', 'tbl' and 'data.frame': 0 obs. of 10 variables:
$ Medication
 ..$ Record Id
                         : logi(0)
 ..$ Report Creation Date: 'POSIXct' num(0)
- attr(*, "tzone")= chr "UTC"
 ..$ Report Name Custom : logi(0)
 ..$ Report Parent
                       : logi(0)
 ..$ med name
                         : logi(0)
 ... - attr(*, "label") = chr "Medication Name"
 ..$ med dose
                         : logi(0)
 .. ..- attr(*, "label")= chr "Dosage"
                       : Ord.factor w/ 9 levels "Beta-Blocker"<...:
 ..$ med type
 ..$ med_start
                        : 'Date' num(0)
                        : Ord.factor w/ 2 levels "Yes"<"No":
 ..$ med_ongoing
                         : 'Date' num(0)
 ..$ med_stop
$ Serious_Adverse_Event
                            :Classes 'tbl_df', 'tbl' and 'data.frame': 0 obs. of 37 variables:
 ..$ Record Id
                                                                  : logi(0)
                                                                 : 'POSIXct' num(0)
 ..$ Report Creation Date
- attr(*, "tzone")= chr "UTC"
 ..$ Report Name Custom
                                                                 : logi(0)
 ..$ Report Parent
                                                                 : logi(0)
 ..$ sae_date
                                                                 : 'Date' num(0)
 ..$ sae_description
 ... - attr(*, "label")= chr "Provide a brief description of the event"
 ..$ sae_desc#Unexpected
                                                                  : logi(0)
```

```
..$ sae_desc#Related_to_study_procedures
                                                                 : logi(0)
 ..$ sae_desc#Related_to_a_medical_device
                                                                 : logi(0)
 ..$ sae_desc#Related_to_failure_of_equipment
                                                                 : logi(0)
 ..$ sae_classification#Fatal
                                                                 : logi(0)
 ..$ sae_classification#Lifethreatening
                                                                 : logi(0)
 ...$ sae_classification#Prolonged_hospitalization
                                                                 : logi(0)
 ..$ sae_classification#Congenital_abnormalities
                                                                 : logi(0)
 ...$ sae_classification#Permanent_disability_or_incapacity_for_w0: logi(0)
 ...$ sae_classification#Loss_of_confidentiality_resulting_in_dam0: logi(0)
 ..$ sae_classification#Other
 ..$ sae_severity
                                                                 : Ord.factor w/ 4 levels "Mild"<"Mode
 ..$ sae_datetime_start
                                                                 : 'POSIXct' num(0)
- attr(*, "tzone")= chr "UTC"
..$ sae_datetime_reported
                                                                 : 'POSIXct' num(0)
- attr(*, "tzone")= chr "UTC"
 ..$ sae_datetime_end
                                                                 : 'POSIXct' num(0)
- attr(*, "tzone")= chr "UTC"
                                                                 : Ord.factor w/ 6 levels "Resolved"<"
 ..$ sae_outcome
 ..$ sae_actions#No_action_taken
                                                                 : logi(0)
 ..$ sae_actions#Symptomatic_treatment_given
                                                                 : logi(0)
 ..$ sae_actions#Use_of_products_discontinued
                                                                : logi(0)
 ..$ sae_actions#Subject_withdrawn_from_study
                                                                 : logi(0)
 ..$ sae_actions#Other
                                                                 : logi(0)
 ..$ sae_other_action
                                                                 : logi(0)
 .. ..- attr(*, "label")= chr "Actions taken"
 ..$ sae_attribution
                                                                 : Ord.factor w/ 5 levels "Not related
 ..$ sae_implications#None
                                                                 : logi(0)
 .. \$ \ sae\_implications \# Adapt\_information\_for\_participants
                                                                 : logi(0)
 ..$ sae_implications#Adjust_inclusion_and_exclusion_criteria
                                                                 : logi(0)
 ..$ sae_implications#Suspend_investigationput_research_on_hold : logi(0)
 ..$ sae_implications#Terminate_the_research
                                                                 : logi(0)
 ..$ sae_implications#Other
                                                                 : logi(0)
 ..$ sae_consequences_other
                                                                 : logi(0)
 .. ..- attr(*, "label")= chr "Consequences"
 ..$ sae_remarks
                                                                 : logi(0)
 .. ..- attr(*, "label")= chr "Additional remarks"
                          :Classes 'tbl_df', 'tbl' and 'data.frame': 2 obs. of 27 variables:
$ Volume_Assessment
 ..$ Record Id
                                         : chr [1:2] "TES005" "TES005"
 ..$ Report Creation Date
                                           : POSIXct[1:2], format: "2018-05-29 17:14:08" ...
                                         : chr [1:2] "Volume Assessment - 29-05-2018 09:14:00" "Volu
 ..$ Report Name Custom
 ..$ Report Parent
                                          : chr [1:2] "Study Procedures" "Study Procedures"
                                          : num [1:2] 2 1
 ..$ v_n
                                          : POSIXct[1:2], format: "2018-05-30 10:00:00" ...
 ..$ v_datetime_start
                                         : POSIXct[1:2], format: "2018-05-30 11:16:00" ...
 ..$ v_datetime_stop
                                          : int [1:2] 76 45
 ..$ v_duration
                                          : num [1:2] 60.5 63.2
 ..$ v_weight
                                          : chr [1:2] "1" "0"
 ..$ v_mespere#Completed
                                          : num [1:2] 2.3 NA
 ..$ v_mespere_pi
 ..$ v_mespere_cvp
                                          : num [1:2] 5 NA
 ..$ v_pressurebox#Rep_1_Completed
                                         : chr [1:2] "1" "1"
                                         : chr [1:2] "1" "1"
 ..$ v_pressurebox#Rep_2_Completed
 ..$ v_ortho_sensors#Rodin_Ring
                                         : chr [1:2] "1" "1"
 ..$ v_ortho_sensors#Rodin_Fingertip
                                         : chr [1:2] "1" "1"
 ..$ v_ortho_sensors#Finapres_NOVA
                                           : chr [1:2] "1" "1"
```

```
..$ v_ortho_sensors#Synergen_Ring : chr [1:2] "0" "0"
 ..$ v_ortho_positions#Supine_1_Completed : chr [1:2] "1" "1"
..$ v_ortho_positions#Sitting_1_Completed : chr [1:2] "1" "1"
 ..$ v_ortho_positions#Standing_1_Completed: chr [1:2] "1" "1"
 ..$ v_ortho_positions#Supine_2_Completed : chr [1:2] "1" "1"
..$ v_ortho_positions#Sitting_2_Completed : chr [1:2] "1" "1"
..$ v_ortho_positions#Standing_2_Completed: chr [1:2] "1" "1"
                                                 : chr [1:2] "Yes" "No"
 ..$ v_complete
 ..$ v_comment
                                                 : chr [1:2] "Good pulse" "Couldn't do Mespere, ran out of a
 .. ..- attr(*, "label")= chr "Comments"
                                                 : logi [1:2] NA NA
$ Study variable list :Classes 'tbl_df', 'tbl' and 'data.frame': 142 obs. of 18 variables:
                                     : chr [1:142] "Eligibility" "Eligibility" "Eligibility" "Eligibility"
..$ Phase name
                                    : chr [1:142] "Demographics" "Demographics" "Demographics" "Demograph
..$ Step name
                                   : chr [1:142] "1" "1" "1" "1" ...
..$ Step number
                                   : chr [1:142] "1" "2" "3" "4" ...
..$ Field number
..$ Field type : chr [1:142] "string" "date" "datetime" "calculation" ...
..$ Variable name : chr [1:142] "pat_hospital_ID" "pat_birthdate" "admit_datetime" "pat
..$ Field label : chr [1:142] "Patient Hospital ID" "Date of Birth" "Admission Date a
..$ Optiongroup name : chr [1:142] NA NA NA NA ...
..$ Field required : chr [1:142] "1" "1" "0" ...
..$ Field min
                                   : chr [1:142] NA "1947" NA NA ...
..$ Field max
                                    : chr [1:142] NA "2012" NA NA ...
                                     : chr [1:142] NA NA NA "years" ...
..$ Field units
                                     : chr [1:142] "ID used for the patient within the hospital system." \mbox{N}
 ..$ Field info
..$ Calculation/summary template: chr [1:142] NA NA NA "getDateDiff('{admit_datetime}','{pat_birthdat
 ..$ Field hidden
                                     : chr [1:142] "0" "0" "0" NA ...
..$ Dependency parent name
                                     : chr [1:142] NA NA NA "O" ...
...$ Field dependency operator : chr [1:142] NA NA NA NA ...
..$ Field dependency value
                                      : chr [1:142] NA NA NA NA ...
$ Report variable list :Classes 'tbl_df', 'tbl' and 'data.frame': 84 obs. of 19 variables:
..$ Report name
                                  : chr [1:84] "Adverse Event" "Adverse Event" "Adverse Event" "Adverse
                                   : chr [1:84] "AE" "AE" "AE" "AE" ...
..$ Step name
                                   : chr [1:84] "1" "1" "1" "1" ...
..$ Step number
                              : chr [1:84] "1" "2" "3" "4" ...

: chr [1:84] "1" "2" "3" "4" ...

: chr [1:84] "summary" "string" "datetime" "radio" ...

: chr [1:84] NA "ae_description" "ae_onset" "ae_ongoing" ...

: chr [1:84] "Patient ID" "Description" "Onset" "Ongoing?" ...
..$ Field number
..$ Field type
..$ Variable name
..$ Field label
                              : chr [1:84] "Patient ID" "Descrip

: chr [1:84] NA NA NA "Yes/No" ...

: chr [1:84] "0" "1" "1" "1" ...
..$ Optiongroup name
..$ Field required
..$ Field min
                                   : chr [1:84] NA NA NA NA ...
 ..$ Field max
                                   : chr [1:84] NA NA NA NA ...
                       chr [1:84] NA NA NA NA ...
chr [1:84] NA "Description of sign or symptom. Enter diagnosis if
 ..$ Field units
..$ Field info
..$ Calculation/summary template: chr [1:84] "{recordId}" NA NA NA ...
                                    : chr [1:84] "0" "0" "0" "0" ...
 ..$ Field hidden
..$ Dependency parent name
                                   : chr [1:84] NA NA NA NA ...
... Field dependency operator : chr [1:84] NA NA NA NA ...
..$ Field dependency value
                                     : chr [1:84] NA NA NA NA ...
..$ X__1
                                     : chr [1:84] NA NA NA NA ...
                                :Classes 'tbl_df', 'tbl' and 'data.frame': 158 obs. of 3 variables:
$ Field options
..$ Option group name: chr [1:158] "AE Action" "AE Action" "AE Action" "AE Action" "...
..$ Option name : chr [1:158] "No action taken" "Symptomatic treatment given" "Use of product(s)
 ..$ Option value
                        : chr [1:158] "0" "1" "2" "3" ...
```

```
..$ AE Action
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
.... $ Option name : chr [1:5] "No action taken" "Symptomatic treatment given" "Use of product(s) dis
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 6 obs. of 2 variables:
..$ AE Outcome
.... * Option name : chr [1:6] "Resolved" "Recovered with sequelae" "Ongoing treatment" "Prolonged Ho
....$ Option value: chr [1:6] "1" "2" "3" "4" ...
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
..$ AE Severity
.... * Option name : chr [1:4] "Mild" "Moderate" "Severe" "Life-threatening"
....$ Option value: chr [1:4] "1" "2" "3" "4"
..$ Blood Draw Type
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 3 obs. of 2 variables:
.... $ Option name : chr [1:3] "Study Enrollment" "Study Completion" "Other"
....$ Option value: chr [1:3] "1" "2" "3"
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
...$ Category SAE
.. .. $ Option name : chr [1:4] "Unexpected" "Related to study procedures" "Related to a medical devic
....$ Option value: chr [1:4] "0" "1" "2" "3"
..$ Category_Event_SAE
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 7 obs. of 2 variables:
.... $ Option name : chr [1:7] "Fatal" "Life-threatening" "Prolonged hospitalization" "Congenital abn
....$ Option value: chr [1:7] "1" "2" "3" "4" ...
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 1 obs. of 2 variables:
..$ Completed
.. .. $ Option name : chr "Completed"
....$ Option value: chr "1"
..$ Completion Reason
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
.... $ Option name : chr [1:4] "Subject-Initiated Withdrawal (Incomplete)" "PI-initiated Withdrawal (
....$ Option value: chr [1:4] "1" "2" "3" "4"
..$ Consent
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 2 obs. of 2 variables:
....$ Option name : chr [1:2] "Obtained" "Refused"
.. ..$ Option value: chr [1:2] "1" "0"
..$ Diabetes
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
.... $ Option name : chr [1:4] "Type I" "Type II" "None" "Other"
....$ Option value: chr [1:4] "1" "2" "0" "3"
...$ Fitzpatrick Eye
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
.... Option name : chr [1:5] "Light blue, light gray, or light green" "Blue, gray, or green" "Hazel
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
...$ Fitzpatrick Face
.... * Option name : chr [1:5] "Very sensitive" "Sensitive" "Normal" "Resistant" ...
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
..$ Fitzpatrick Freckles
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
....$ Option name : chr [1:5] "Many" "Several" "A few" "Very few" ...
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
                              :Classes 'tbl df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
..$ Fitzpatrick Hair
.. .. $ Option name : chr [1:5] "Red or light blonde" "Blonde" "Dark blonde or light brown" "Dark brow."
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
...$ Fitzpatrick Skin Color
.. .. $ Option name : chr [1:5] "Ivory white" "Fair or pale" "Fair to beige, with golden undertone" "O
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 6 obs. of 2 variables:
...$ Fitzpatrick Skin Type
.... * Option name : chr [1:6] "Type I (0-6 points)" "Type II (7-12 points)" "Type III (13-18 points)
....$ Option value: chr [1:6] "1" "2" "3" "4" ...
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
...$ Fitzpatrick Sun
.. .. $ Option name : chr [1:5] "Always burns, blisters, and peels" "Often burns, blisters, and peels"
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
..$ Fitzpatrick Tan Depth
```

\$ factor_group_labels_levels:List of 36

.... \$ Option name : chr [1:5] "Not at all or very little" "Lightly" "Moderately" "Deeply" ...

```
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
..$ Fitzpatrick Tan Frequency :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
.... * Option name : chr [1:5] "Never, always burns" "Seldom" "Sometimes" "Often" ...
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
..$ Gender
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 2 obs. of 2 variables:
.... $ Option name : chr [1:2] "Male" "Female"
....$ Option value: chr [1:2] "1" "2"
..$ Heart Failure Type
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 3 obs. of 2 variables:
.... * Option name : chr [1:3] "Preserved (HFPEF)" "Reduced (HFrEF)" "Unknown"
....$ Option value: chr [1:3] "1" "2" "3"
..$ implications_SAE
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 6 obs. of 2 variables:
.... $ Option name : chr [1:6] "None" "Adapt information for participants" "Adjust inclusion and excl
....$ Option value: chr [1:6] "0" "1" "2" "3" ...
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 2 obs. of 2 variables:
..$ Man/Woman
....$ Option name : chr [1:2] "Man" "Woman"
....$ Option value: chr [1:2] "0" "1"
..$ Medications
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 9 obs. of 2 variables:
....$ Option name : chr [1:9] "Beta-Blocker" "ACE Inhibitor" "Aldosterone Inhibitor" "Diuretic" ...
....$ Option value: chr [1:9] "1" "2" "3" "4" ...
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 2 obs. of 2 variables:
..$ Number Of Reps
.... $ Option name : chr [1:2] "Rep 1 Completed" "Rep 2 Completed"
.. ..$ Option value: chr [1:2] "1" "2"
..$ NYHA
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
....$ Option name : chr [1:4] "I" "II" "III" "IV"
....$ Option value: chr [1:4] "1" "2" "3" "4"
..$ Pacemaker
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
.... * Option name : chr [1:4] "None" "Defibrillator" "Synchronization (CRT)" "Pacing"
....$ Option value: chr [1:4] "0" "1" "2" "3"
..$ PI-withdrawal reason
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 7 obs. of 2 variables:
.... * Option name : chr [1:7] "Failure to follow procedures" "Mechanical ventilation required" "IV 1
....$ Option value: chr [1:7] "1" "2" "3" "4" ...
..$ Positions
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 6 obs. of 2 variables:
.... $ Option name : chr [1:6] "Supine 1 Completed" "Sitting 1 Completed" "Standing 1 Completed" "Sup
....$ Option value: chr [1:6] "1" "2" "3" "4" ...
..$ Product Relationship
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 5 obs. of 2 variables:
.. .. $ Option name : chr [1:5] "Not related" "Unlikely to be related" "Possibly related" "Probably re
....$ Option value: chr [1:5] "0" "1" "2" "3" ...
..$ Recovery SAE
                              :Classes 'tbl_df', 'tbl' and 'data.frame': 6 obs. of 2 variables:
.... * Option name : chr [1:6] "Yes" "Is recovering" "No" "Recovered with residual symptoms" ...
....$ Option value: chr [1:6] "0" "1" "2" "3" ...
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
..$ Sensors
.... * Option name : chr [1:4] "Rodin Ring" "Rodin Fingertip" "Finapres NOVA" "Synergen Ring"
....$ Option value: chr [1:4] "0" "1" "2" "3"
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 3 obs. of 2 variables:
...$ Smoking History
....$ Option name : chr [1:3] "Never smoked" "Past smoker" "Current smoker"
....$ Option value: chr [1:3] "0" "1" "2"
..$ Subject Withdrawal Reasons:Classes 'tbl_df', 'tbl' and 'data.frame': 4 obs. of 2 variables:
.... $ Option name : chr [1:4] "Takes too much time / too many tests" "Painful or uncomfortable" "Tes
....$ Option value: chr [1:4] "1" "2" "3" "4"
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 2 obs. of 2 variables:
....$ Option name : chr [1:2] "Yes" "No"
.. ..$ Option value: chr [1:2] "1" "0"
                             :Classes 'tbl_df', 'tbl' and 'data.frame': 3 obs. of 2 variables:
..$ Yes/No/Unkown
```

.... \$ Option name : chr [1:3] "Yes" "No" "Unknown"

.. ..\$ Option value: chr [1:3] "1" "0" "2"