# Guidelines to Manipulate Clinical Data

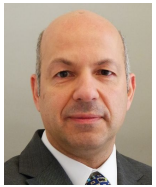
*Contact:*
*rlink@cea.fr*

*Authors:*
*celine.bourdon@inserm.fr*
*dimitri.papadopoulos@cea.fr*
*edouard.duches@cea.fr*

# Obtain data from central database

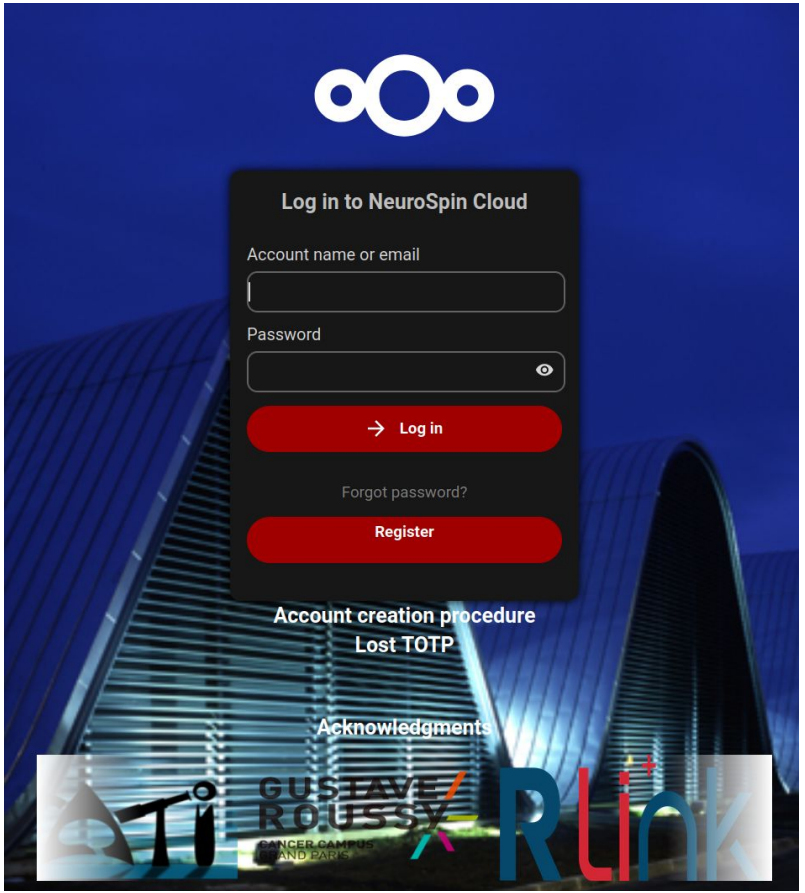
***Contacts***

1. **rlink@cea.fr**
2. dimitri.papadopoulos@cea.fr



***Procedure***

1. Go to https://neurospin-cloud.cea.fr
2. Request account creation
3. Download data



# Clinical data = set of “tsv”* text files

*tsv = Tabular Separated Values. Similar to csv. Open with Excel, R or Python
See Appendix for details

| File | Key ID | Content, of the file, Results of the aggregate |
|---|---|---|
| dataset-clinical_mod-baseline_version-2.tsv | participant_id | participant consent and baseline.; 1 line per subject |
| dataset-clinical_mod-baseline_form-postLi_tab-antipdep_version-2.tsv | articipant_id | Antidepressants taken during the last 2 years; A varying number of lines per subject corresponding to antidep taken |
| dataset-clinical_mod-visits_form-visit_b-csrimeet_version-2.tsv | articipant_id + FORM_F_VISIT | Clinical Service use Inventory for any meeting relevant to mental or physical health; A varying number of lines per subject corresponding to meeting relevant to mental or physical health on the visit number “FORM_F_VISIT”* |

File name

Keys for this file: participant_id
One line per participant

Keys for this file:
participant_id + FORM_F_VISIT:
One line per participant and per visit

Description

# Use case 1: Extract demographic, smoking status, Lithemia, Treatment Adhesion and response

## Clinical variables

- Age
- Gender
- Smoking status
- BMI
- Lithemia at M03
- Treatment adhesion (MARS score) before M00 Lithium (M00) and after (M03)
- Depression and Mania at M00 (QIDS and BRMS)

## Outcome

- Response.Status.at.end.of.follow.up

# Procedure


1. Identify and list the desired variables in:
   - **Dataset-clinical_version-2_description.pdf**
   - **Dataset-clinical_version-2_description_file-information.xlsx**, sheet “**Data Handling Manual RLINK**”
2. Identify the file containing the variables
   - **Dataset-clinical_version-2_description_file-information.xlsx**, sheet “**FileInformation**”
3. Gather all variables and corresponding file into a table
4. Load files into tables and select variables
5. Merge tables into one table using “**participant_id**” and Save to excel or csv

1. Identify and list the desired variables in file:
   - **dataset-clinical_version-2_description.pdf**

**Plasma and erythrocyte Li on the day of Li-MRI 14769S4FC1**

ID14769S4V1 / DATBIOMRI
Date (biology at MRI) : ____/____/_____

ID14769S4V2 / TIMEBSIMRI
Time of blood sample intake : ____:____ (hh:mm)

ID14769S4V3 / BIOMRIYN
Performed : ○ [1] Yes ○ [0] No

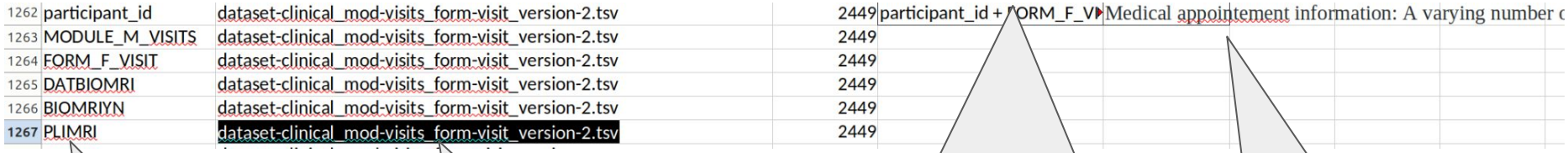
ID14769S4V4 / PLIMRI
Plasma or Serum Lithium : |__|,|__|__| mEq/L = mmol/L

ID14769S4V5 / ERYLIMRI
Erythrocyte Lithium : |__|,|__|__| mEq/L = mmol/L

Lithemia at M03
- PLIMRI
- ERYLIMIR

# 2. Identify the file containing the variables using:

- file “**dataset-clinical_version-2_description_file-information.xlsx**”
- sheet “**FileInformation**”



| | | | | | |
|---|---|---|---|---|---|
| 1262 | participant_id | dataset-clinical_mod-visits_form-visit_version-2.tsv | 2449 | participant_id + FORM_F_VI | Medical appointement information: A varying number c |
| 1263 | MODULE_M_VISITS | dataset-clinical_mod-visits_form-visit_version-2.tsv | 2449 | | |
| 1264 | FORM_F_VISIT | dataset-clinical_mod-visits_form-visit_version-2.tsv | 2449 | | |
| 1265 | DATBIOMRI | dataset-clinical_mod-visits_form-visit_version-2.tsv | 2449 | | |
| 1266 | BIOMRIYN | dataset-clinical_mod-visits_form-visit_version-2.tsv | 2449 | | |
| 1267 | PLIMRI | dataset-clinical_mod-visits_form-visit_version-2.tsv | 2449 | | |

1) Variable
**PLIMRI**

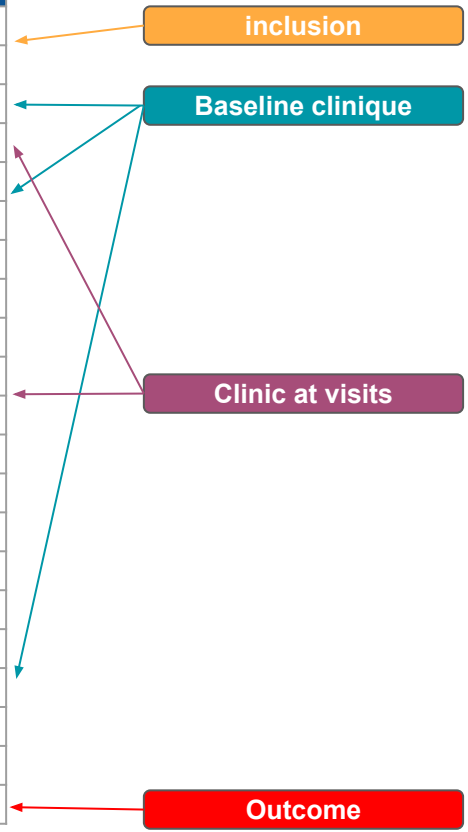
**Optional**
Keys for this file:
participant_id + FORM_F_VISIT
One line per participant and per visit

2) is in file
**dataset-clinical_mod-visits_form-visit_version-2.tsv**

**Optional**
Information about the file:
Medical appointment information: A varying number of lines per subject corresponding to hospital admission on the visit number “FORM_F_VISIT”*

# 3. Gather all variables and corresponding file into a table

| Variable | eCRF | File |
|---|---|---|
| Age | AGE | dataset-clinical_mod-inclusion_version-2.tsv |
| Gender | SEX | dataset-clinical_mod-inclusion_version-2.tsv |
| Smoking status | WHOA1A_PLI | dataset-clinical_mod-baseline_version-2.tsv |
| | WHOA2A | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| BMI | HEIGHT_PRELI | dataset-clinical_mod-baseline_version-2.tsv |
| | WEIGHT_PRELI | dataset-clinical_mod-baseline_version-2.tsv |
| | Formula | |
| Lithemia at M03 (FORM_F_VISIT = F_VISIT_1) | PLIMRI | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| | ERYLIMRI | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| | PLI | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| | ERYLI | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| | PLI2 | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| MARS Score at M03 (FORM_F_VISIT = F_VISIT_1)) M00 | MARS1V | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| | … | … |
| | MARS10V | dataset-clinical_mod-visits_form-visit_version-2.tsv |
| | MARS1_PRELI | dataset-clinical_mod-baseline_version-2.tsv |
| | … | |
| | MARS10_PRELI | dataset-clinical_mod-baseline_version-2.tsv |
| QIDS and BRMS at M00 | QIDSTSC_PRELI | dataset-clinical_mod-baseline_version-2.tsv |
| | BRMSTSC_PRELI | dataset-clinical_mod-baseline_version-2.tsv |
| Response status | Response.Status.at.end.of.follow.up | dataset-clinical_version-2_outcome.tsv |




Variables are found in **five** different files

# 4. Load Excel file and select variables

Read Inclusion data file “**dataset-clinical_mod-inclusion_version-2.tsv**”

- one line per participant
- Select AGE and SEX

**R code**

```
vars <- c("participant_id", "AGE", "SEX")
df1 <- read.csv(paste0(INPUT, "dataset-clinical_mod-inclusion_version-2.tsv"),
                sep = "\t", header = TRUE, na.strings = "ND")
df1 <- df1[, vars]
```

**Python code**

```
vars = ["participant_id", "AGE", "SEX"]
df = pd.read_csv(INPUT + "dataset-clinical_mod-inclusion_version-2.tsv",
                 sep="\t", na_values=['ND'])
df1 = df[vars]
```

# 4. Load Excel file and select variables

Read clinic at visits: “**dataset-clinical_mod-visits_form-visit_version-2.tsv**”

- one line per participant per time point
- Select (Smoking, Lithemia & MARS baseline) at month 3 (`F_VISIT_1`)

**R code**

```
vars <- c("participant_id", "FORM_F_VISIT", "WHOA2A", "PLIMRI", "ERYLIMRI", "PLI",
          "ERYLI", "PLI2", "MARS1V", "MARS2V", "MARS3V", "MARS4V", "MARS5V",
          "MARS6V", "MARS7V", "MARS8V", "MARS9V", "MARS10V")
df3 <- read.csv(paste0(INPUT, "dataset-clinical_mod-visits_form-visit_version-2.tsv"),
                sep = "\t", header = TRUE, na.strings = "ND")
df3 <- df3[, vars]
df3 <- df3[df3$FORM_F_VISIT == "F_VISIT_1", ]
```

**Python code**

```
vars = ["participant_id", "FORM_F_VISIT", "WHOA2A", "PLIMRI", "ERYLIMRI", "PLI",
          "ERYLI", "PLI2", "MARS1V", "MARS2V", "MARS3V", "MARS4V", "MARS5V",
          "MARS6V", "MARS7V", "MARS8V", "MARS9V", "MARS10V"]
df = pd.read_csv(INPUT + "dataset-clinical_mod-visits_form-visit_version-2.tsv",
                 sep="\t", na_values=["ND"])
df3 = df[vars]
df3 = df3[df3.FORM_F_VISIT == "F_VISIT_1"]
```

# Merge all tables in a single large table

Use **participant_id** as key to align (merge) tables into a single table
Save to excel file

**R code**

```r
table <- merge(merge(merge(df1, df2), df3), df4)
write.xlsx(table, file.path(OUTPUT, "data_demoSmokLiMarsResponse_r.xlsx"))
```

**Python code**

```python
table = pd.merge(pd.merge(pd.merge(df1, df2), df3), df4)
table.to_excel(OUTPUT + "data_demoSmokLiMarsResponse_python.xlsx", index=False)
```

Note **Participant_id** can be omitted: Python & R automatically detect that it is the only column present in all tables, and uses it to align tables

# Output

| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | participant_id | AGE | SEX | WHOA1A_PLI | HEIGHT_PRELI | WEIGHT_PRELI | MARS1_PRELI | MARS2_PRELI | MARS3_PRELI | MARS4_PRELI | MARS5_PRELI | MARS6_PRELI | MARS7_PRELI | MARS8_PRELI | MARS9_PRELI | MARS10_PRELI | QIDSTSC_PRELI | BRMSTSC_PRELI | BMI |
| 2 | sub-10289 | 59 | 1 | 0 | 175 | 88,5 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 4 | 10 | 28,8979591836735 |
| 3 | sub-11327 | 18 | 2 | 0 | 165 | 50 | 1 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 9 | 12 | 18,3654729109275 |
| 4 | sub-11841 | 41 | 1 | 1 | 170 | 70 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 15 | 24,2214532871972 |
| 5 | sub-14116 | 28 | 1 | 1 | 178 | 85 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 6 | 0 | 26,8274207802045 |
| 6 | sub-14393 | 64 | 2 | 1 | 164 | 55 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 20 | 0 | 20,4491374182035 |
| 7 | sub-16007 | 47 | 2 | 1 | 177 | 85 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | | | | 9 | 13 | 27,1314117909924 |
| 8 | sub-16572 | 51 | 1 | 0 | 187 | 108 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 16 | 5 | 30,8844976979611 |
| 9 | sub-17468 | 59 | 1 | 0 | 173 | 67 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 6 | 0 | 22,3863142771225 |
| 10 | sub-17909 | 40 | 1 | 1 | 185 | 86,6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 18 | 1 | 25,3031409788167 |
| 11 | sub-19676 | 40 | 1 | 1 | | 73,6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 10 | 0 | |
| 12 | sub-19987 | 26 | 1 | 1 | 180 | 73 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 3 | 10 | 22,5308641975309 |
| 13 | sub-20807 | 27 | 2 | 1 | 173 | 70 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 15 | 23,3886865581877 |
| 14 | sub-22378 | 52 | 1 | 1 | | 62,1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 5 | |
| 15 | sub-22549 | 62 | 2 | 0 | 163 | 97 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 1 | 9 | 1 | 36,5087131619557 |
| 16 | sub-23305 | 57 | 2 | 0 | 170 | 62,5 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 1 | 10 | 0 | 21,6262975778547 |
| 17 | sub-23989 | 26 | 2 | 1 | 155 | 62 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 1 | 3 | 5 | 25,8064516129032 |
| 18 | sub-25322 | 56 | 1 | 1 | 190 | 109 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 3 | 16 | 30,1939058171745 |
| 19 | sub-25880 | 47 | 2 | 1 | 164 | 79,1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 29,4095776323617 |
| 20 | sub-27002 | 43 | 2 | 1 | 170 | 56 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 8 | 5 | 19,3771626297578 |
| 21 | sub-27367 | 40 | 2 | 1 | 164 | 62 | 1 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 2 | 9 | 23,051754907793 |
| 22 | sub-27813 | 54 | 1 | 1 | 183 | 111,5 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 17 | 5 | 33,2945146167398 |
| 23 | sub-28561 | 46 | 2 | 1 | 160 | 53,8 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 19 | 21,015625 |
| 24 | sub-28825 | 25 | 1 | 1 | 187 | 68 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | | | 0 | 17 | 19,4457948468644 |
| 25 | sub-29041 | 48 | 1 | 0 | 180 | 103 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 31,7901234567901 |
| 26 | sub-29119 | 49 | 1 | 1 | 173 | 81 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 9 | 0 | 27,0640515887601 |
| 27 | sub-29658 | 31 | 2 | 1 | 175 | 57 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 2 | 2 | 18,6122448979592 |
| 28 | sub-30670 | 26 | 1 | 1 | 180 | 69 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 4 | 1 | 21,2962962962963 |
| 29 | sub-30916 | 51 | 1 | 1 | 176 | 56 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 3 | 27 | 18,0785123966942 |
| 30 | sub-32220 | 48 | 2 | 0 | 165 | 60 | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 5 | 23 | 22,038567493113 |
| 31 | sub-32363 | 54 | 2 | 1 | 171 | 81 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 12 | 2 | 27,7008310249308 |
| 32 | sub-33001 | 69 | 2 | 1 | 163 | 63,9 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 8 | 1 | 24,0505852685461 |
| 33 | sub-33139 | 36 | 1 | 1 | 182 | 91 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 7 | 2 | 27,4725274725275 |
| 34 | sub-35218 | 32 | 1 | 1 | | | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 7 | |
| 35 | sub-36581 | 52 | 2 | 0 | 182 | 117,2 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 23 | 8 | 35,3822002173651 |
| 36 | sub-36632 | 54 | 2 | 1 | 167 | 88,2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | | 2 | 31,6253720104701 |
| 37 | sub-36977 | 33 | 1 | 1 | 176 | 70 | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 0 | 1 | 1 | 2 | 25 | 22,5981404958678 |
| 38 | sub-37822 | 41 | 2 | 0 | 170 | 83,2 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 14 | 15 | 28,7889273356401 |
| 39 | sub-37985 | 52 | 2 | 1 | 160 | 58 | 0 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 12 | 3 | 22,65625 |
| 40 | sub-38348 | 51 | 1 | 0 | | 76 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 10 | 0 | |
| 41 | sub-38687 | 26 | 1 | 1 | 175 | 72 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 3 | 13 | 23,5102040816327 |
| 42 | sub-39023 | 43 | 2 | 0 | 163 | 65 | 0 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 8 | 21 | 24,4646016033724 |
| 43 | sub-40078 | 53 | 1 | 1 | 185 | 98,5 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 15 | 3 | 28,7801314828342 |
| 44 | sub-40567 | 37 | 1 | 1 | 183 | 99,6 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 14 | 0 | 29,7411090208725 |
| 45 | sub-40899 | 55 | 1 | 1 | 192 | 90 | | | | | | | | | | | 5 | 5 | 24,4140625 |
| 46 | sub-40905 | 37 | 2 | 0 | 161 | 56 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 13 | 7 | 21,6041047799082 |
| 47 | sub-41252 | 57 | 1 | 1 | 190 | 104,4 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 18 | 1 | 28,9196675900277 |

# Appendix: file description

| File | Key ID | Content, of the file, Results of the agregat |
|---|---|---|
| dataset-clinical_mod-baseline_version-2.tsv | participant_id | participant consent and baseline.; 1 line per subject |
| dataset-clinical_mod-baseline_form-postLi_tab-antipdep_version-2.tsv | participant_id | Antidepressants taken during the last 2 years; A varying number of lines per subject corresponding to antidep taken |
| dataset-clinical_mod-baseline_form-postLi_tab-antipsy_version-2.tsv | participant_id | Atypical Antipsychotics taken during the last 2 years; A varying number of lines per subject corresponding to antipsychotic taken |
| dataset-clinical_mod-baseline_form-postLi_tab-benzos_version-2.tsv | participant_id | Benzodiazepines and Others taken during the last 2 years; A varying number of lines per subject corresponding to benzos taken |
| dataset-clinical_mod-baseline_form-postLi_tab-dsrdr_version-2.tsv | participant_id | Psychological disorders; A varying number of lines per subject corresponding to psychological disorder |
| dataset-clinical_mod-baseline_form-postLi_tab-famhist_version-2.tsv | participant_id | Family history of mood disorders of biological member [1st degree only (adopted excluded)]; A varying number of lines per subject corresponding to the family history |
| dataset-clinical_mod-baseline_form-postLi_tab-hcnd_version-2.tsv | participant_id | Health condition (physical comorbidity); A varying number of lines per subject corresponding to health condition |
| dataset-clinical_mod-baseline_form-postLi_tab-mood_version-2.tsv | participant_id | Mood stabilizers taken during the last 2 years; A varying number of lines per subject corresponding to mood stabilizers taken |
| dataset-clinical_mod-baseline_form-postLi_tab-neurol_version-2.tsv | participant_id | Conventional neuroleptics taken during the last 2 years; A varying number of lines per subject corresponding to neuroleptics taken |
| dataset-clinical_mod-baseline_form-preLi_tab-csrih_version-2.tsv | participant_id | Clinical Service use Inventory for Hospital admission in the 6 months prior to inclusion; A varying number of lines per subject corresponding to hospital admission |

| | | |
|---|---|---|
| dataset-clinical_mod-baseline_form-preLi_tab-csrimeet_version-2.tsv | participant_id | Clinical Service use Inventory for any meeting relevant to mental or physical health in the 6 months prior to inclusion; A varying number of lines per subject corresponding to psychological or physical meeting |
| dataset-clinical_mod-baseline_form-preLi_tab-med_version-2.tsv | participant_id | Medications taken over the 6 months prior to inclusion at least once a week; A varying number of lines per subject corresponding to medications taken |
| dataset-clinical_mod-baseline_tab-med_m-1_version-2.tsv | participant_id | Medications taken over the last month at least once a week; A varying number of lines per subject corresponding to medications taken |
| dataset-clinical_mod-baseline_tab-med_m-2_version-2.tsv | participant_id | Medications taken over the last month at least once a week; A varying number of lines per subject corresponding to medications taken |
| dataset-clinical_mod-cm_form-cm_tab-cmtrt_version-2.tsv | participant_id | Concomitant medications, other than psychotropic; A varying number of lines per subject corresponding to the concomitant medications taken |
| dataset-clinical_mod-cm_version-2.tsv | participant_id | Concomitant medications, other than psychotropic; 1 line per subject |
| dataset-clinical_mod-eos_version-2.tsv | participant_id | Study discontinuation; 1 line per subject |
| dataset-clinical_mod-inclusion_version-2.tsv | participant_id | identification and inclusion criteria; 1 line per subject |
| dataset-clinical_mod-pregnancy_tab-cmtrt_version-2.tsv | participant_id | Concomitant medications, other than psychotropic; A varying number of lines per subject corresponding to the concomitant medications other than psychotic |
| dataset-clinical_mod-pregnancy_tab-extrt_version-2.tsv | participant_id | Concomitant medications, other than psychotropic during pregnancy; A varying number of lines per subject corresponding to investigational drugs or exposures |
| dataset-clinical_mod-pregnancy_tab-newborn_version-2.tsv | participant_id | Newborn information; A varying number of lines per subject corresponding to the new born information |
| dataset-clinical_mod-pregnancy_tab-proc_version-2.tsv | participant_id | Procedures and cares during pregnancy; A varying number of lines per subject corresponding to procedures |

| | | |
|---|---|---|
| dataset-clinical_mod-pregnancy_version-2.tsv | participant_id | On-going pregnancy or planned pregnancy on the next 2 years; A varying number of lines per subject corresponding to pregnancy information |
| dataset-clinical_mod-sae_tab-cmtrt_version-2.tsv | participant_id + MODULE_M_SAE | Concomitant Medication(s) at the time of the SAE, excluding those used to treat the SAE; A varying number of lines per subject corresponding to concomitant treatment taken for the “MODULE_M_SAE” |
| dataset-clinical_mod-sae_tab-proc_version-2.tsv | participant_id + MODULE_M_SAE | Additional procedures or medical cares performed during the clinical trial; A varying number of lines per subject corresponding to procedures and cares for the “MODULE_M_SAE” |
| dataset-clinical_mod-sae_tab-extrt_version-2.tsv | participant_id + MODULE_M_SAE | Investigational Medicinal Product(s) (IMP) or related product(s) administered prior the occurring of the SAE; A varying number of lines per subject corresponding to investigationnal drugs or exposure for the “MODULE_M_SAE” |
| dataset-clinical_mod-sae_version-2.tsv | participant_id + MODULE_M_SAE | Serious Adverse Event (SAE) information; A varying number of lines per subject corresponding to the SAE information for the “MODULE_M_SAE” |
| dataset-clinical_mod-visits_form-visit_version-2.tsv | participant_id + FORM_F_VISIT | Medical appointement information: A varying number of lines per subject corresponding to hospital admission on the visit number “FORM_F_VISIT”* |
| dataset-clinical_mod-visits_form-visit_tab-csrih_version-2.tsv | participant_id + FORM_F_VISIT | Clinical Service use Inventory for Hospital admission; A varying number of lines per subject corresponding to hospital admission on the visit number “FORM_F_VISIT”* |
| dataset-clinical_mod-visits_form-visit_tab-csrimeet_version-2.tsv | participant_id + FORM_F_VISIT | Clinical Service use Inventory for any meeting relevant to mental or physical health; A varying number of lines per subject corresponding to meeting relevant to mental or physical health on the visit number “FORM_F_VISIT”* |
| dataset-clinical_mod-visits_form-visit_tab-dsrdr_version-2.tsv | participant_id + FORM_F_VISIT | Psychological Disorders; A varying number of lines per subject corresponding to psychological disorder on the visit number “FORM_F_VISIT”* |

| | | |
|---|---|---|
| dataset-clinical_mod-visits_form-visit_tab-hcnd_version-2.tsv | participant_id + FORM_F_VISIT | Health Condition; A varying number of lines per subject corresponding to health condition on the visit number “FORM_F_VISIT”* |
| dataset-clinical_mod-visits_form-visit_tab-med_version-2.tsv | participant_id + FORM_F_VISIT | medications taken over the last month at least once a week; A varying number of lines per subject corresponding to medications on the visit number “FORM_F_VISIT”* |
| dataset-clinical_version-2_description.pdf | | |
| dataset-clinical_version-2_description.xlsx | | |
| participants_version-2.tsv | participant_id | 1 line per subject |