Manual of Procedures FLADEX Project

MOP Chapter 4.2: Data management

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1. Introduction

The FLADEX study will use the REDCap database for the storage and management of all non-image data (e.g., non-magnetic resonance imaging -MRI-). Data entry forms are designed in REDCap and will subsequently be downloaded for printing on paper when necessary. All participant data (scanned documents) will be stored in the project's folder named "Fladex" on the group's MAC computer located in the exercise neuroscience laboratory of the Research Institute of Sport and Health (iMUDS) and on the remote project hard drive. Having the database in REDCap ensures data security even in the event of an extreme disaster where the server is completely damaged. MRI image data will be sent by the technician through a shared folder to the corresponding folder on the group's computer, following the protocol described below.

All data will be **electronically stored** on the group's computer. Any paper-stored data must be scanned, stored, and entered into REDCap for subsequent review if necessary. Data imported directly from digital files, such as NIH Toolbox result sheets, will be verified for values within normal ranges. All physical copies of data collection forms and documents with personally identifiable information must be stored in locked cabinet 1 in the exercise neuroscience laboratory.

2. Necessary material

- Group's MAC computer located at IMUDS
- Personal MAC or Windows computer
- REDCap

3. Specific requirements

3.1 Group's MAC computer

The computer where the project files will be stored is the group's MAC. There is a folder for the project (Fladex) that should be used for all related activities. The path of the folder is the following:
  - /Users/agueda/fladex

This computer is the one that should be accessed remotely to carry out all project procedures, or it is where the shared folders are located for data transfer from different project sites (CIMCYC and hospital).

3.2 Personal MAC computer

If a personal MAC computer is used, there are two ways of access, depending on your needs:

A. **Remote access to the iMUDS computer**: you can remotely use the iMUDS computer from your MAC as you are in situ**,** follow the procedure below:

  1. Connect to the University of Granada VPN (it will not work if not connected).
  2. Go to Finder, and in the top left bar, select "Go," and finally "Connect to Server."

3. In the bar, type "vnc://profith2.ugr.es."
4. Subsequently, a window will appear prompting for the username and password (log in as a registered user), which are:
    - **Username:** xxxx
    - **Password:** *Ask to Project Manager*

B. **Folder access**: you can only access to certain shared folders of the project to check/modify/copy/paste documents. Follow these steps**:**

1. Connect to the University of Granada VPN (it will not work if not connected).
2. Go to Finder, and in the top left bar, select "Go," and finally "Connect to Server."
3. In the bar, type "smb://profith2.ugr.es."
4. A window will appear where you should select the shared folder you wish to access; this works like an external hard drive. **Important! Any modification in that folder will be made in the original folder on the iMUDS MAC, as it is a shared folder.**

If there are any doubts or issues with any procedure, contact Javier Sánchez at sanchez.javier.andre@gmail.com.

3.3 Personal Windows computer

If a personal Windows computer is used, there are two ways of access, depending on your needs.

A. **Remote access to the iMUDS computer:** firstly, you need to install a program to manage Remote Desktop (such as Putty: https://www.chi-ark.greenend.org.uk/~sgtatham/putty/latest.html) or some other alternative. Afterward, follow these steps (only the first time):

1. **Configure Putty:**

    a. *Session*:

        i. Host Name (or IP address): profith2.ugr.es
        ii. Port: 22
        iii. Saved Sessions: Agueda

    b. *Connection → SSH → Tunnels:*

        i. Source port: **5900**
        ii. Destination: localhost: **profith2.ugr.es:5900**, Press Add
        iii. Go back to Session and press Save

2. **Establish the tunnel:**

        i. In Putty, go to Session, select the Saved Session: Agueda
        ii. Click Open
        iii. A terminal window will open:

- **Login as:** (Enter the username ("xxxx")
- **Password** ("*Ask to Project Manager* ")

3. **Run VNC viewer**
   - Recommended: RealVNC Viewer: https://www.realvnc.com/en/connect/download/viewer/

   i. In "Enter a VNC Server address or search" (using RealVNC Viewer), type:
      - "**localhost:0**"
   ii. Click: Continue
   iii. Subsequently, a window will appear prompting for the username and password, which are:
      - **Username**: xxxx
      - **Password**: *Ask to Project Manager*

B. **Folder access:** With this procedure, you will have remote access to the computer. Additionally, for any procedure or modification involving a specific folder, there is a way to access only certain shared folders of the project. Follow these steps:

1. Connect to the University of Granada VPN (it will not work if not connected).
2. In your computer, search for "run" and type: "\\profith2.ugr.es."
3. It will request a username and password, which are:

   - **Username**: xxxx
   - **Password**: *Ask to Project Manager*

4. A window will appear where you should select the shared folder you wish to access; this works like an external hard drive.
5. You can leave that folder as a shared access on the desktop in the future, and you will only need to connect to the University of Granada VPN to access it. **Important! Any modification in that folder will be made in the original folder on the iMUDS MAC, as it is a shared folder!**

4. REDCap

REDCap is a secure web application for creating and managing online tests and databases. Using REDCap's streamlined process to quickly develop projects, you can create and design projects using (i) the online method from your web browser using the online designer, and/or (ii) the offline method by building a 'data dictionary' template file in Microsoft Excel, which can then be uploaded to REDCap. Both forms and databases (or a combination of both) can be constructed using these methods. REDCap allows organizing data and downloading it in different formats for further analysis (e.g., SPSS, Microsoft Excel, Stata, R, or SAS). In the flADex project, templates will be created using the offline method with an Excel file.

4.1 REDCap access

To access the REDCap platform, use the following address: https://minerva.ugr.es/index.php?action=myprojects. Once on the main page, log in using your credentials

(**Username**: xxxx - **Password**: xxxx). If you don't have a REDCap account, please request one from the Project Manager.

4.2 REDCap procedures

Once inside the platform, you must select the "flADex" project, where all the instruments to be used during the project will be available. It is important to consider that accounts have some limitations in use; therefore, there will be actions within the platform that are not allowed unless additional access is requested, which should be discussed in advance with the project coordinators.

4.3 Data quality control

All data must be entered and reviewed in REDCap. REDCap can configure parameter ranges for data. For example, blood pressure can be set for values of 3 digits along with a minimum and maximum value. If a data entry error occurs, such as entering 4 digits or a value outside the established ranges, REDCap will automatically mark it as an error, and it must be corrected immediately. Data is entered only once in the platform, although there will be a second review (*Javier Sánchez Martínez*) of all entered data later.

5. File storage

The following section details how the data will be downloaded and stored. The conditions, temporal data collection points, and subjects are encoded. This is done to facilitate the management and subsequent analysis of the data.

5.1 Conditions

A letter will represent each condition of the crossover design. Therefore, the coding to denote to which condition is the data collection will be as follows:
- A (Aerobic exercise)
- B (Resistance exercise)
- C (Control resting)

5.2 Time measurements

For each of the three conditions, data collection will be performed two times for behavioral assessments (T0 and T1) and four times for blood and MRI assessments (T0 to T3). Consequently, the coding to denote the time of data collection will be as follows:

- Familiarization assessments of the participants (prior to baseline assessments) will be denoted by the characters "**Fam**" (familiarization).
- Baseline assessments of the participants (prior to exposure to a condition) will be denoted by the characters "**T0**" (pre-condition).
- Post-assessments conducted immediately after exposure to a condition will be denoted by the characters "**T1**" (post 1).
- Second post-assessments conducted after exposure to a condition will be denoted by the characters "**T2**" (post 2).
- Third post-assessments conducted after exposure to a condition will be denoted by the characters "**T3**" (post 3).

5.3 Participants

A unique identifier (ID) will be assigned to each participant. The ID for each participant will be encoded with **three digits**, using their respective previous ID used in the AGUEDA Project. For example, 101 is the ID of one of the participants in the project. Only the ID, sex, and date of birth of the participants from the AGUEDA Project will be extracted (report called: "flADex"). Identifiable data, such as name and telephone number, from the AGUEDA Project will be exported as an external database ("flADex_contact", not included in REDCap).

5.4 Full naming

Every file or document will be named using the following format:

"ID_CONDITION_TEMPORALPOINT".

For example, the baseline assessment of the first study subject that was allocated to the aerobic exercise condition should be encoded as "101_A_T0".

The data recorded during each session must be stored at the end of each assessment day in REDCap, and the corresponding files on the group's computer. **Once the phone screening is completed** by the assessment lead (*Beatriz Fernandez Gamez)*, and the subject is eligible to participate in the project, the assessment lead will schedule for session *Fam*. Then, **the familiarization supervisor** (*Javier Fernández Ortega*) **will create a main folder** (named with the subject's ID, e.g., 101). Each evaluator will be responsible for saving and verifying that the data is stored correctly according to each of the protocols. For example, the scanned file of the participant 101's informed consent collected at the baseline ("101_cons") should be stored in **"/Users/aguedaproject/Fladex/Participants/101/".**

5.5 Folder's organization

Within the *Fladex* folder, six subfolders will be present (Figure 1):
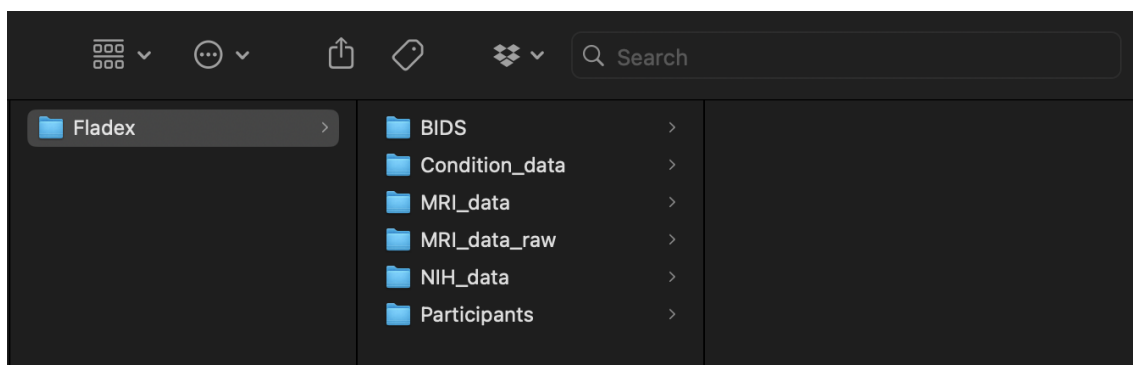
Figure 1. An example of folder organization inside the *Fladex* folder.

- *MRI_data_raw* → This folder is designated for the storage of MRI data from CIMCYC technicians. Each participant will have three folders, one for each visit ("101_visit1", "101_visit2", and "101_visit3"). Within each condition folder, one folder will be destined to PRE condition ("fladex_Protocolo - 1", and another

folder for POST condition ("fladex_Protocolo - 2). For example, for the MRI measured PRE condition for patient 101:

- 101_visit1/ fladex_Protocolo - 1/

Additionally, MRI data acquired from sessions that must be performed again (i.e., missed or discontinued sessions), must be stored in a specific folder ("101_bis").
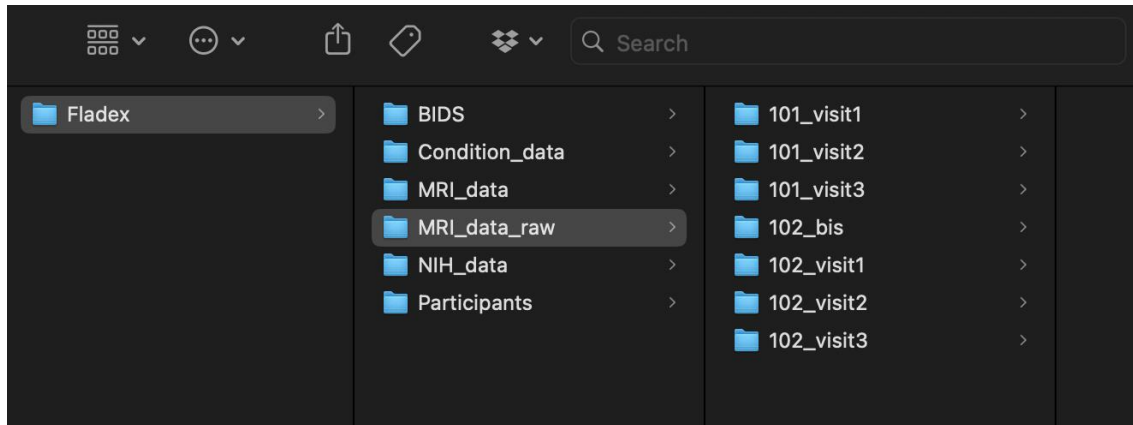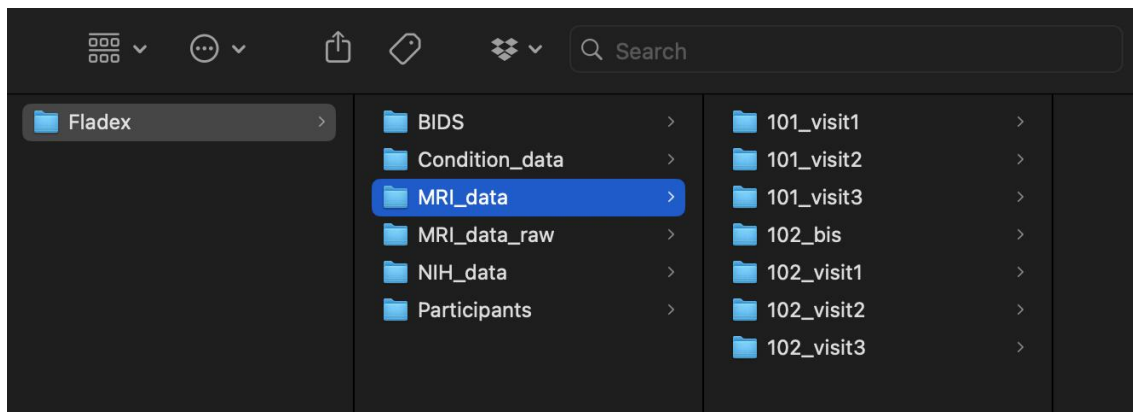

Figure 2. An example of folder organization inside the *MRI_data_raw* folder.

- **MRI_data:** This folder is designated for storage a copy of the the MRI_data_raw folder (it must have the format "ID_visitnumber", e.g., "101_visit1", "101_visit2", "101_visit3"). **MRI data acquired from sessions that must be performed again (i.e., missed or discontinued sessions), must be stored in a specific folder ("101_bis").**

Figure 3. An example of folder organization inside the *MRI_data* folder.

- **BIDS:** This folder contains MRI data following the **Brain Imaging Data Structure (BIDS).** The folder structure is explained in the next section.

- **NIH_data:** This folder requires weekly updates for the NIH files containing the results. Every new file must follow this naming structure: "***yyyy-mm-dd_file-name.csv***" (i.e., *2024-05-20_Assessment Data.csv*). Thus, the new files must not replace previous documents. These are the 6 NIH files (.csv):

- Assessment Data.csv
- Assessment Scores.csv
- Narrow structure assessment data.csv
- Narrow structure assessment scores.csv
- Narrow structure registration data.csv
- Registration data.csv
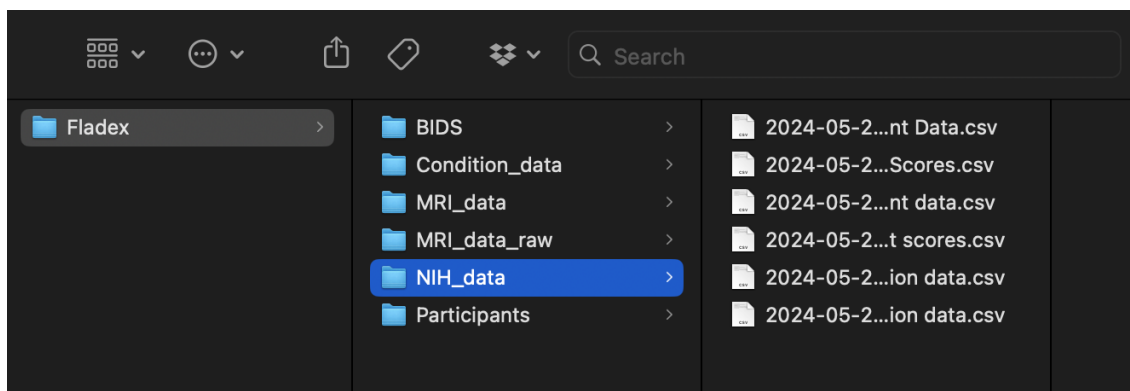
Figure 4. An example of folder organization inside the *NIH_data* folder.

- **Participants:** Each participant will have an individual folder labeled with their unique *ID*. In each *ID* folder (e.g., 101), three documents will be stored (Figure 2):
  - MOCA questionnaire (ID_moca)
  - Informed consent (ID_cons)
  - MRI questionnaire (ID_MRIQ)
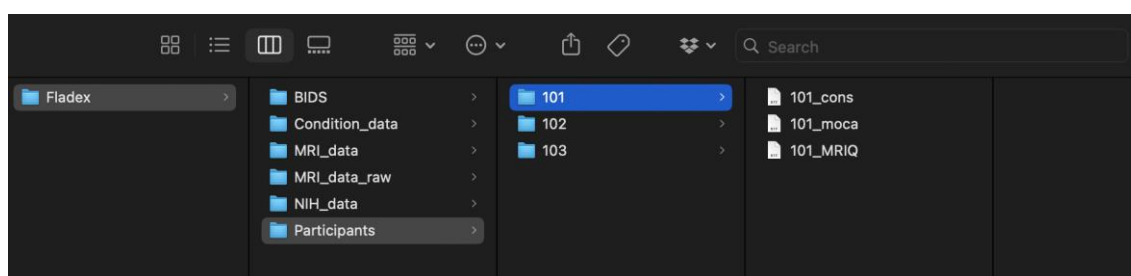
Figure 5. An example of folder organization inside the *ID* folder.

- **Condition_data:** Polar heart rate data for the conditions will be stored in folders corresponding to each condition. Each document will be labeled as *ID_condi-tion_polar* (i.e., 101_A_polar).
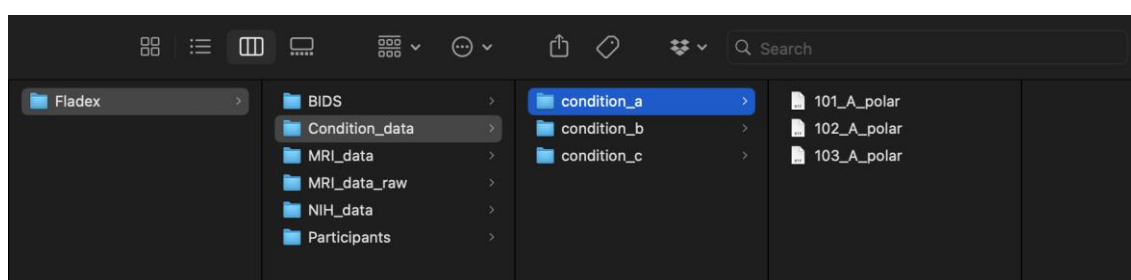
5.6 MRI-BIDS folder

Once all MRI data is collected, the **MRI folders** will be organized following the **Brain Imaging Data Structure (BIDS)** format with the following levels:

- Level 1: Participant ID (sub-ID, e.g., sub-101 for participant 101)

- Level 2: Condition
  - *ses-1* for A condition
  - *ses-2* for B condition
  - *ses-3* for C condition

- Level 3: Brain sequence
  - *anat*
    - includes structural T1 image assessed in the first session
    - includes TOF image 1 (time of flight angiography)
    - includes TOF image 2

  - *perf* (includes perfusion images)

- Level 4: Temporal point images included in brain sequence folders (level 3)
  - anat
    - sub-101_ses-1_run-1_angio.nii.gz
    - sub-101_ses-1_run-2_angio.nii.gz
    - sub-101_ses-1_T1w.nii.gz

  - perf
    - pre_run-1 (for T0 scan)
      - Format: *sub-ID_ses-1_acq-pre_run-1_asl.json*)
    - post_run-1 (first sequence for T1)
      - Format: s*ub-ID_ses-1_acq-post_run-1_asl.json*)
    - post_run-2 (second sequence for T1)
      - Format: s*ub-ID_ses-1_acq-post_run-2_asl.json*)
    - post_run-3 (third sequence for T1)
      - Format: s*ub-ID_ses-1_acq-post_run-3_asl.json*)
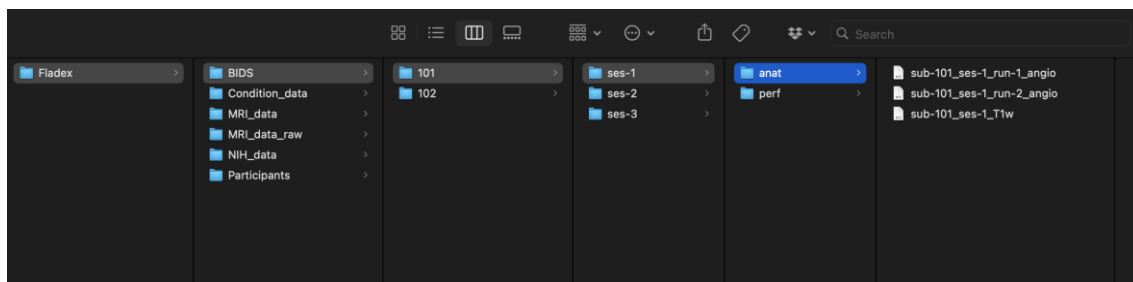
Figure 7. An example of BIDS for level 3 (anat).

Figure 8. An example of BIDS for level 3 (perf).

In addition, an example of files' organization per level is shown in figure 9.

```
BIDS
├── sub-101
│   ├── ses-1
│   │   ├── anat
│   │   │   ├── sub-101_ses-1_T1w.nii.gz
│   │   │   ├── sub-101_ses-1_run-1_angio.nii.gz
│   │   │   └── sub-101_ses-1_run-2_angio.nii.gz
│   │   └── perf
│   │       ├── sub-101_ses-1_acq-post_run-1_asl.json
│   │       ├── sub-101_ses-1_acq-post_run-2_asl.json
│   │       ├── sub-101_ses-1_acq-post_run-3_asl.json
│   │       └── sub-101_ses-1_acq-pre_run-1_asl.json
│   ├── ses-2
│   │   └── perf
│   │       ├── sub-101_ses-2_acq-post_run-1_asl.json
│   │       ├── sub-101_ses-2_acq-post_run-2_asl.json
│   │       ├── sub-101_ses-2_acq-post_run-3_asl.json
│   │       └── sub-101_ses-2_acq-pre_run-1_asl.json
│   └── ses-3
│       └── perf
│           ├── sub-101_ses-3_acq-post_run-1_asl.json
│           ├── sub-101_ses-3_acq-post_run-2_asl.json
│           ├── sub-101_ses-3_acq-post_run-3_asl.json
│           └── sub-101_ses-3_acq-pre_run-1_asl.json
└── sub-102
    ├── ses-1
    │   └── perf
    │       ├── sub-102_ses-1_acq-post_run-1_asl.json
    │       ├── sub-102_ses-1_acq-post_run-2_asl.json
    │       ├── sub-102_ses-1_acq-post_run-3_asl.json
    │       └── sub-102_ses-1_acq-pre_run-1_asl.json
    ├── ses-2
    │   ├── anat
    │   │   ├── sub-102_ses-1_run-1_angio.nii.gz
    │   │   ├── sub-102_ses-1_run-2_angio.nii.gz
    │   │   └── sub-102_ses-2_T1w.nii.gz
    │   └── perf
    │       ├── sub-102_ses-2_acq-post_run-1_asl.json
    │       ├── sub-102_ses-2_acq-post_run-2_asl.json
    │       ├── sub-102_ses-2_acq-post_run-3_asl.json
    │       └── sub-102_ses-2_acq-pre_run-1_asl.json
    └── ses-3
        └── perf
            ├── sub-102_ses-3_acq-post_run-1_asl.json
            ├── sub-102_ses-3_acq-post_run-2_asl.json
            ├── sub-102_ses-3_acq-post_run-3_asl.json
            └── sub-102_ses-3_acq-pre_run-1_asl.json
```

Figure 9. An example of the tree folder organization using BIDS.

5.7 Data for reschedule sessions

If a participant missed a session or cannot adhere to session schedule (e.g., due to participant delay or other reasons), the session will be rescheduled. Data from the missed session will not be considered, as all assessments and conditions will be reapplied. Thus, only data from the rescheduled session will be considered.

5.8 Duplicated assessments

In the event that a participant duplicates any assessment, a comment must be left in REDCap on the new assessment, specifying which assessment will ultimately be considered and the data of the not included assessment can be removed.

However, **MRI raw data from the missed/discontinued session must be stored in a new folder named "101_visit_bis".**

5.9 Forms to be completed in REDCap

The FLADEX project will have the following documents completed directly in REDCap:

Instrument name	Fields	View PDF	Enabled as survey
Phone Screening	53	🅿	Enable
Ethical Committee	8	🅿	Enable
MoCA	22	🅿	Enable
Medical Records	44	🅿	✅
Blood Baseline Quest	23	🅿	Enable
Pa Ques	20	🅿	Enable
Questionnaires CHECK	4	🅿	Enable
Familiarization	34	🅿	Enable
Randomization	7	🅿	Enable
Poms Pre	16	🅿	Enable
Quest Pre Condition	14	🅿	Enable
Mri Data	27	🅿	Enable
Blood Draw Timepoint	20	🅿	Enable
Nih Toolbox	10	🅿	Enable
Condition	34	🅿	Enable
Poms Post	16	🅿	Enable
Blood Draw Storage	13	🅿	Enable
Adverse Event Report	50	🅿	Enable

Fig 10. REDCap instruments.