

## DATA INFORMATION PACK

### EPAD LCS V500.1 data set release

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### AUTHORIZATION

Each authorization indicates review and approval of the EPAD LCS Data Information Pack.

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## Data Information Pack (EPAD-LCS)

This document attempts to answer any questions that may arise from researchers analysing the European Prevention of Alzheimer's Disease (EPAD) Longitudinal Cohort Study (LCS). It also documents any decisions taken on what data to include and exclude in each data release.

The data released is as clean and complete as possible at the time of release. Any known issues are documented below. There may be data corrections made subsequently meaning that future releases may contain slightly different information. Any future releases supersede this release. It should be noted that any future changes should be minor.

Aridhia provides a Data Set Library which can be accessed at <https://library.aridhia.net/>.

All abbreviations used in this DIP can be accessed in the Data Set Library.

| Data Release | Data Set Library Tables |
|--------------|-------------------------|
| V500.0       | EPAD LCS DSL V1         |
| V1500.0      | EPAD LCS DSL V2         |
| V500.1       | EPAD LCS DSL V3         |

### 1. Participants included in Vx00.x data releases

The first x00 participants that consent **AND** are entered into the eCRF are included in the Vx00.0 data release. The same participants are included in each follow up data release (Vx00.1, Vx00.2 etc). The situation may arise in Vx00.0 whereby excluded participants have earlier baseline dates than some included individuals due to the later entry into the eCRF.

### 2. Anonymised IDs

The "patient\_id" variable included in each table of the V500.1 data release corresponds to the "patient\_id" variable found in previous data releases.

### 3. Changes from V500.0 to V1500.0

Any changes from V1500.0 to V500.1 that affect individual tables are included in the relevant sections below.

#### 3.1. Table Changes

The "epadlcs\_mri\_scanner\_information" table is now included containing details of the scanner in which each MRI was performed.

The "epadlcs\_four\_mountains\_tabcat" and "epadlcs\_vr\_supermarket\_trolley\_tabcat" tables have been added". The "epadlcs\_vr\_supermarket\_trolley" table has been renamed to "epadlcs\_vr\_supermarket\_trolley\_tabcat".

The "epadlcs\_family\_history" table has been reformatted. Previously, this table contained 1 row per participant. It now contains 1 row per family member with a history of AD.

### 3.2. Additional Variables

| Table             | Variable Name        |
|-------------------|----------------------|
| visits            | was_visit_performed  |
| visits            | reason_not_done      |
| psqi              | psqi_item10*         |
| lacunes_infarcts  | assessment_performed |
| lacunes_infarcts  | assessment_date      |
| lacunes_infarcts  | reason_not_performed |
| radiological_read | assessment_performed |
| radiological_read | assessment_date      |
| radiological_read | reason_not_performed |
| volumetric        | assessment_performed |
| volumetric        | assessment_date      |
| volumetric        | reason_not_performed |
| volumetric        | KNBBSI               |
| volumetric        | KNBBSIQC             |

### 3.3. Removed Variables

| Table                            | Variable Name     |
|----------------------------------|-------------------|
| dot_counting                     | link_date         |
| dot_counting                     | valid_data        |
| dot_counting                     | quality_issues    |
| dot_counting                     | examiner_comments |
| favourites                       | link_date         |
| favourites                       | valid_data        |
| favourites                       | quality_issues    |
| favourites                       | examiner_comments |
| flanker                          | link_date         |
| flanker                          | valid_data        |
| flanker                          | quality_issues    |
| flanker                          | examiner_comments |
| vr_supermarket_trolley_medavante | st_trial_*_answer |
| volumetric                       | WBLBV             |
| volumetric                       | WBLBVCH           |
| volumetric                       | WBLBVQC           |
| volumetric                       | WBLBVQCC          |

### 3.4. Individual Data Changes

Between the V1500.0 and V500.1 releases, some data have been corrected resulting in differences between the two releases.

- “visdat\_int” in the “visits” table has been updated for 1 participant.

- The “eligibility” information for 2 participants has been updated. This has been queried but the response is not available at the time of this data release.
- Changes in Swiss law meant only year of birth is able to be collected. This has led to less granularity in the calculation of the age variables in Swiss sites.
- “years\_education” in the “socio\_demographics” table has been updated for 1 participant.
- “apoe\_sample\_date” has been updated for 1 participant
- “apoe\_sample\_collected” is missing for 1 participant for whom this was present in the previous release. This sample was not collected and will be updated in future releases.
- CSF results are now available for 4 participants that were not previously available.
- “csf\_sample\_collected” is missing for 1 participant for whom this was present in the previous release. This sample was collected and will be updated in future releases.
- “csf\_sample\_date” has been updated for 1 participant.
- “csf\_sample\_collected” and “csf\_reason\_not\_collected” has been updated for 1 participant.
- 6 participants who previously had some RBANS domains missing now have complete RBANS records.
- “dsdecod\_reas” in the “discontinuation” table has been updated for 1 participant
- “chest\_clin\_signif” and “chest\_abnormal\_findings” in the “physical\_exam” table has been updated for 1 participant.
- “weight” in the “vital\_signs” table has been updated for 1 participant.
- 20 additional “dot\_counting” records have been retrieved and are now present
- “assessment\_date” in the “favourites” and “flanker” table has been updated for 1 participant
- 17 additional “favourites” records (only learning and delayed recall trials) have been retrieved and are now present.
- 77 “discontinuation” records have been included.
- The coding for the “fms\_med\_item\*\_answer” fields in “four\_mountains\_medavante” was 0, 1, 2, 3 in V1500.0. This has been changed to T, C, S, E for V500.1. The mapping is not consistent across each of the 15 four mountains trials and depends as to which of the 4 quadrants is the correct response. In previous data releases information was available as to which quadrant the participant chose and whether this answer was correct. The new mapping gives information as to the type of choice made by the participant.
- The coding for the “fms\_med\_item\*\_answer” fields in “four\_mountains\_uedin” was BL, BR, TL, TR in V1500.0. This has been changed to T, C, S, E for V500.1. The mapping is not consistent across each of the 15 four mountains trials and depends as to which of the 4 quadrants is the correct response. In previous data releases information was available as to which quadrant the participant chose and whether this answer was correct. The new mapping gives information as to the type of choice made by the participant.

### 3.5. Imaging Data Changes

Due to changes in the longitudinal whole brain volume analysis pipeline, the following variables are no longer included in the “epadlcs\_volumetric” table: WBLBV, WBLBVCH, WBLBVQC, WBLBVQCC.

They have been replaced by KNBBSI and KNBBSIQC. It should be noted that WBLBVCH was reported as volume atrophy relative to baseline (%) whereas KNBBSI is reported as absolute volume change (ml) from baseline. As V500.1 is the first release of longitudinal data, no data has changed between data releases, only the variables in the tables.

In addition, IXICO provided the following statement as to why the imaging results may be slightly different between data releases.

### Radiology Reads

The central Radiology Read process allows the reader to review the previous imaging visits' scans during the following read, to facilitate completion of fields which request 'changes from previous visit' to be reported.

During this review there are instances where the reader notices minor findings that were missed in the initial review. In this case the reader requests the previously submitted read report and updates the relevant fields.

Most typically this will be a re-count of microbleeds which does not change the clinical significance of the report.

When the updated report is re-submitted by the readers an updated read notification is sent to sites and the data transfers to Aridhia will be updated accordingly.

If subject doesn't have an eligibility read (for example if some mandatory sequences are missing or of very poor quality) that subject will not have any follow up reads (as the follow up read report is dependent on comparison against the eligibility scan).

### Volumetric Results

The volumetric analysis in EPAD is run when the scans arrive at IXICO. The analysis is automated but is completed with a visual endpoint quality check (QC) done by trained image analysts.

Prior to the monthly data transfers the volumetric data also undergoes a science review in which the quantitative data are checked for completeness and outliers. Where there are outliers the Lead EPAD Biomarker Scientist will ask the Image Analysis team to re-review the analysis. In some instances, the endpoint QC result may change based on re-review from a pass to a fail or vice versa.

## **4. Screen Failures**

It is important to note that the data includes every participant consented and that a small proportion of these subsequently failed screening. It may often be appropriate to remove such participants from any analyses performed. Screen failures can be found in the "epadlcs\_discontinuation" table.

## 5. EPAD-LCS Tables

This section gives any information important to know before handling specific EPAD-LCS tables. The names of files containing the data are given in the brackets (prefixed by “epadlcs\_”).

Missing data are detailed in the individual sections relating to each table. In addition, 1 participant included in V1500.0 has no data entered into the eCRF. This participant was a screen failure and shortly after completing consent the site closed. It is uncertain whether this participant’s data will be available in future data releases. Any further missing data comments below, are in addition to this participant.

### 5.1. Visit Information (visits)

- The date of visit for each participant at each time point.

### 5.2. Derived IDs (derids)

- The derived participant ID which links the participant (where applicable) to the parent cohort from which they were invited to join EPAD.

### 5.3. Consent (consent)

- Informed consent form.

### 5.4. Eligibility Criteria (eligibility)

- Eligibility criteria met and which criterion not met.

### 5.5. Participant Discontinuation (discontinuation)

- Participants, dates, and reasons for discontinuation

All discontinuation information available at the time of data release is linked to the last visit that each participant attended. All discontinuation data available for V500 participants with *only one* study visit are provided in V500.0, no matter how long after the visit the participant discontinued. The same logic applies to V500.1 where the participants attended visit 2 or 3.

### 5.6. Demographics (socio\_demographics)

- Baseline demographic information.

“site\_name” and “site\_id” *does not necessarily correspond* to the baseline site as participants may have their 1<sup>st</sup> visit at one site and then move to another site between subsequent visits. The site given is the site of the participant at the time of the data release. In France, ethnicity data is not permitted to be collected by law, and so for individuals in French sites this information is not available.

There are 21 participants with missing data in the “socio\_demographics” table. 16 participants are only missing “handedness” data. This is either because the information is unknown and the participant has withdrawn from the study or the participant uses both hands equally.

1 participant has both “handedness” and “ethnicity” missing. This participant has discontinued and thus the information will never be available.

4 participants are missing “age\_months” due to restrictions on collecting date of birth in Swiss sites.

### **5.7. Family History of AD (family\_history)**

- Information on each participant’s family history of dementia at baseline.

“family\_dementia\_history” is the initial question asked to participants. The response to individual family member dementia history questions are only recorded if the answers to “family\_dementia\_history” and the individual family member dementia history are “Yes”. If the answer to “family\_dementia\_history” is “No” or if the answer to “family\_dementia\_history” is “Yes” *and* there is no record of a particular family member it can be assumed that the particular family member does not have a history of dementia. If an individual family member has a history of dementia further questions are asked to determine whether the family member was a biological relative and the age of dementia diagnosis. It is possible for the same type of family member to have multiple dementia history (e.g. two sisters both having a history of dementia).

85 “family\_history” records are missing “age\_at\_diagnosis”.

### **5.8. APOE (apoe)**

- Participant’s APOE genotype from DNA extracted from whole blood

2 participants have no information as to whether the APOE sample was collected. This can be expected in future data releases.

9 participants are recorded as having an APOE sample collected but APOE results are not currently available.

### **5.9. CSF (csf)**

- Participant’s results from each visit for CSF biomarkers (Visit 1 & 3 *per protocol*).

The Roche CSF assays used have a lower detection limit of 200pg/ml for A $\beta$ , 8pg/ml for pTau and 80pg/ml for tTau. Values below the detection limits for A $\beta$ , pTau and tTau are recorded as <200, <8 and <80 respectively. A $\beta$  has a measuring range of 200-1700pg/ml. Values that are above 1700 are recorded as >1700. These values have been re-calculated to give the actual values and can be extracted from the “abeta\_1\_42\_comments” column.

Roche give the following disclaimer about A $\beta$  values >1700:

*The Elecsys  $\beta$ -Amyloid (1-42) CSF immunoassay in use is not a commercially available IVD assay. It is an assay that is currently under development and for investigational use only. The measuring range of the assay is 200 (lower technical limit) – 1700 pg/mL (upper technical limit). The performance of the assay beyond the upper technical limit has not been formally established. Therefore, use of values above the upper technical limit, which are provided based on an extrapolation of the calibration curve, is restricted to exploratory research purposes and is excluded for clinical decision making or for the derivation of medical decision points.*

14 participants did not have CSF taken at Visit 1. Instead, they were taken at Visit 2 as a baseline measurement. These individuals can be identified using the “csf\_retest”, “csf\_retest\_reason”, and “csf\_retest\_visit” variables.

1 participant has no information as to whether the CSF sample was collected. This information can be expected in future data releases.

There are 10 CSF samples recorded as having been taken where CSF results are not given and no “reason\_not\_analysed” provided. Many of these will be available in future data releases.

## **ENE Data**

The EPAD Neurological Examination data were included if in the eCRF “notadmin” = FALSE. Any records where “notadmin” = TRUE were excluded as the tests were not performed.

In addition to the participant who has no data entered into the eCRF, 1 individual has no data entered for any of the ENE data.

## **EPAD Neuropsychological Evaluation (ENE) implementation, management and data collection in the LCS**

TabCAT is an iOS application for neuropsychological testing developed and managed by University California San Francisco, Memory and Ageing Centre with an on-line portal for trial set-up, administration and data management. Three tests from the TabCAT battery were selected for the EPAD ENE: Dot Counting, Flanker and Favourites. The tests are administered using an iPad supported by an Examiner who guides the participant through the tests.

- Dot Counting is an Examiner recorded test,
- Flanker is a Participant recorded test,
- Favourites has three parts; Learning and Delay are Examiner recorded tests and Recognition is a participant recorded test.

This means that source documents are created at the Trial Delivery Centre (TDC) for the Examiner recorded tests which the Examiner uses to enter the data into the TabCAT app. Participant recorded tests can only be recorded directly by the participant in the TabCAT app and the only record of participant recorded data is held in TabCAT. Instruction screens were available in English and Spanish when the study was opened in May 2016. Over time validated translations for other required languages were added to the system. Tests were not implemented without locally



appropriate translations, as approved by the relevant ethics committee, therefore some data missing are from some TDCs early in the study and the tests are recorded as Not Done in the eCRF.

There have been several technical and logistical challenges during the EPAD LCS which have impacted on data collection with TabCAT app. The process for synchronising the data recorded in the TabCAT app with the data server (at UCSF) has at times been problematic. A stable internet connection is required for the sync process to be successful and some hospitals/sites have logistical issues getting access to good internet connection suitable for use with an iPad supplied separately from hospital/site equipment. Also, TDC staff have not always understood the sync requirements or been diligent in ensuring this is done at least once per day before the app/iPad is closed down. These factors have resulted in participant visits (Encounters) being lost. These Encounters have been identified, the eCRF records which tests were done, and the TDCs have, where possible, located the source documents from Examiner recorded tests, and have re-entered the data into TabCAT. The eCRF records have not been changed - usually all three tests will be reported as Done, but if the data were lost in the sync process and then re-entered from source documents, there will only be a record of data for Dot Counting and Favourites Learning and Delay. This process is still on going and has been interrupted by the COVID-19 pandemic, so in this data release there are still missing Encounters which will be followed up for the end of study data release. All valid data that can be correctly matched to an eCRF entry have been included - if a test is marked as "Done" in the eCRF but is not present in the data set then the reason for this will be one of those explained above.

The TabCAT app in use at the start of the study included a Demographics Screen, which Examiners were instructed not to use as these data were collected in the eCRF. It was identified in late 2018 that some demographics data had been entered by some Examiners at some TDCs so personal information was recorded in the data base available to Data Management staff and TabCAT administrators. The CI and Sponsor requested that the system was switched off until this issue was corrected. No data were collected for the 3 TabCAT tests, Dot Counting, Flanker and Favourites between 20th Dec 2018 and 12th Sep 2019.

Four Mountains (FMT) test and Supermarket trolley (SMT) tests are also included in the EPAD ENE. Collection of these two tests was not impacted by the TabCAT halt. The introduction of the tests was delayed in some countries pending provision of approved translations of instruction screens. These two tests were provided as iOS applications from separate sources/licensees not associated with the TabCAT app. From the beginning of the study until 12th Sep 2019 these tests were administered by Examiners who observed and recorded the answer responses of the participants on a paper score sheet. The answer responses were then entered into container forms (data entry screens) on the Virgil Tablet provided to EPAD by MedAvante. In addition to this Examiner collected data, the FMT app creates a copy of the answers (as tapped on the screen by the participant and observed by the Examiner) and the reaction time for each answer directly into a .txt file on the iPad. It is important to collect reaction time in these type of tests as an indicator of cognitive decline when measured over time. There were also technical and logistical issues with data collection of FMT using the iPad app which resulted in missing data in the .txt file when the eCRF record is completed as "Done" and there is a record in the MedAvante Examiner collected

data. If the Participant Number field in the FMT app was not completed by the Examiner administering the test then a .txt record was not created; this has resulted in some missing data. The .txt file can only be downloaded by connection with the iTunes app. This process was deemed to present too many logistical challenges to be rolled out to TDCs, therefore the FMT iPad data was collected centrally by periodically returning the iPads to UEDIN staff for data extraction. MedAvante took on a logistics management role for the iPad provisioning and updates which involved using security software to prevent TDCs being able to make changes to the iPad settings. Some data were also lost in the extraction process from these iPads due to faulting signalling from the security software which resulted in the iPads being reset to factory conditions which also wiped the FMT .txt files. The iPad return process was interrupted by the COVID-19 pandemic, so in this data release there are still .txt files which will be followed up for the end of study data release. All valid data that can be correctly matched to an eCRF entry have been included - if a test is marked as "Done" in the eCRF but is not present in the data set then the reason for this will be one of those explained above.

TabCAT was upgraded during the study to introduce a clinical trial management system that allowed corrections and audit trail collection for all actions in TabCAT and the demographics screen was modified to be an option on a per study basis. In addition, the FMT and SMT were configured as new tests in the TabCAT battery, this was done to utilise the functionality of the TabCAT system to incorporate language choice for on screen instructions, and participant recorded outcomes and recording of reaction time for both tests (which had not been possible at all for SMT with the previous display only app). This made the use of the MedAvante container forms obsolete so data were no longer collected using this vehicle and when the TabCAT system was re-opened on 12th Sep 2019 the collection method for FMT and SMT was switched to TabCAT.

When the study was closed in March 2020, all 5 EPAD ENE tests were being collected using TabCAT on a single GCP compliant system with all tests able to be displayed from a single app with instructions in the approved local languages, all data transferred with an upgraded secure synchronisation and feedback process to minimise data loss, with all data available for quality control and correction in an on-line portal, with in-built CTMS and audit trail for all actions in the system. The transformation of TabCAT from an experimental tool to a compliant trial management system has been made possible by the support of EPAD partners and the collaboration of test authors and the team at USCF Memory and Aging Centre.

#### **5.10. RBANS (rbans)**

- Primary outcome composite score along with each individual domain and test.

Missing data are coded as **995** and should be processed accordingly before any analyses are performed. 4 individuals did not complete individual RBANS tests and therefore, not all of the indices and totals can be calculated.

#### **5.11. TabCAT (dot\_counting, favourites, flanker)**

- TabCAT tests (dot counting, favourites, and flanker).

These tests were administered using an iPad tablet. It is not currently possible to record in the iPad the visit number the test took place. Only the date the test was administered can be recorded. As such, linking the TabCAT data to a visit number is more problematic than for all the other data collected in the EPAD-LCS.

Further information on the EPAD Neurological Examination (ENE) entered into the eCRF allowed the linking of visit number to the TabCAT data using the dates provided from the two data sources. Wherever the test data for a participant fell within  $\pm 28$  days of his/her date in the ENE data set, the visit number from the ENE data set was assigned to this participant's test data.

The eCRF incorrectly recorded the date of the Favourites task for 1 record. This has been manually changed by Aridhia for the V500.1 release.

### **5.12. Four Mountains Task (four\_mountains\_uedin)**

- The Four Mountains Task (FMT)

Like TabCAT, the test was recorded on an iPad tablet. However, in addition, the Examiner also recorded the answers and the data were entered onto the MedAvante system.

Linking the test to a visit number was resolved using the same methodology as for TabCAT.

There are less data available for the tablet because the iPad storage of the files was unreliable and not all tests were present when the extraction from the iPads was done. Efforts are being made to retrieve the rest the data from the iPads. Any additional data that will be retrieved will be made available as part of future update release.

The total FMT score can be calculated by counting the number of "CORRECT" responses from the "fms\_uedin\_mark" variables in the data set.

The eCRF incorrectly recorded that 1 participant did not have the FMT for visit 1. Aridhia has manually corrected this for V500.1.

### **5.13. Four Mountains Task (four\_mountains\_medavante)**

- The Four Mountains Task (FMT)

There are 27 individuals where the FMT test was done but some of the responses are missing.

The manual changes made by Aridhia for "four\_mountains\_uedin" also apply here.

### **5.14. Four Mountains Task (four\_mountains\_tabcat)**

- The Four Mountains Task (FMT)

FMT was incorporated into the new version of TabCAT from September 2019. In future data releases there will be a third FMT table with these data. This table will not be released for V500.1 as no records took place after September 2019.

### **5.15. Supermarket Trolley Virtual Reality (vr\_supermarket\_trolley\_medavante)**

- Supermarket Trolley Virtual Reality (SMT) individual marks.

The total SMT score can be calculated by counting the number of “Correct” responses from the “st\_trial\_mark” variables in the data set.

Where the SMT was performed according to the eCRF there are 3 records with missing data in some of the fields.

### **5.16. Supermarket Trolley Virtual Reality (vr\_supermarket\_trolley\_tabcat)**

- Supermarket Trolley Virtual Reality (SMT) individual answers and marks

SMT was incorporated into the new version of TabCAT from September 2019. In future data releases there will be a second SMT table with these data. This table will not be released for V500.1 as no records took place after September 2019.

### **5.17. CDR (cdr)**

- Clinical dementia rating global score, sum of boxes and individual domains.

There is 1 record where CDR is partially missing. There are 3 individuals where CDR was performed but have completely missing records.

### **5.18. MMSE (mmse)**

- Mini-mental State Examination individual test scores and overall MMSE score.

### **5.19. A-IADL (aiadl)**

- The Amsterdam Instrumental Activities of Daily Living questionnaire.

Missing data are coded as **995** and should be processed accordingly before any analyses are performed. There are 22 records where A-IADL was performed according to the eCRF but where the total score is missing.

### **5.20. GDS (gds)**

- Geriatric Depression Scale individual questions and overall score.

Missing data are coded as **995** and should be processed accordingly before any analyses are performed.

### **5.21. PSQI (psqi)**

- Pittsburgh Sleep Quality Index individual items, component scores and overall score.

Missing data are coded as **995** and should be processed accordingly before any analyses are performed.

6 PSQI records are completely missing despite the assessment being performed according to the eCRF.

### **5.22. STAI-40 (stai\_40)**

- State-Trait Anxiety Index individual questions, form scores, and total score.

Missing data are coded as **995** and should be processed accordingly before any analyses are performed.

There are 4 STAI-40 records completely missing where the assessment was performed according to the eCRF. In addition, 3 records are partially missing.

### **5.23. Imaging Scanner Information (mri\_scanner\_information)**

- Imaging variables giving details of the scanner used for the MRI scan

### **5.24. Imaging Lacunes and Infarcts (lacunes\_infarcts)**

- Imaging variables related to lacunes and territorial infarcts.

There are 2 records where there is no information as to whether the scan was performed. In addition, there are 2 records where the eCRF records the scan as being done but there are no imaging results available. 1 of these will be available in future data releases and 1 has been queried and is not available at the time of the V500.1 release.

### **5.25. Imaging Radiological Read (radiological\_read)**

- Radiological read imaging variables.

There are 2 records where there is no information as to whether the scan was performed. In addition, there are 2 records where the eCRF records the scan as being done but there are no imaging results available. 1 of these will be available in future data releases and 1 has been queried and is not available at the time of the V500.1 release.

### **5.26. Imaging Volumes (volumetric)**

- Volumetric imaging data.

There are 2 records where there is no information as to whether the scan was performed. In addition, there are 2 records where the eCRF records the scan as being done but there are no imaging results available. 1 of these will be available in future data releases and 1 has been queried and is not available at the time of the V500.1 release.

### **5.27. Dementia Diagnosis (dementia\_diag)**

- Dementia diagnosis at study visit (only present if dementia was diagnosed by the Investigator), date and dementia type.

1 record has no information as to their dementia diagnosis.

### **5.28. HATICE Questionnaire (hatice)**

- Healthy Ageing Through Internet Counselling in the Elderly questionnaire.

1 record has no information as to whether the HATICE assessment was performed. A further 14 records are partially missing HATICE as some of the questions were not answered. These data will never be available.

### **5.29. SNAC Questionnaire (snac)**

- Swedish National study on Aging and Care questionnaire.

This data set has multiple records per participant per visit and *is left for the researcher* to process as required.

### **5.30. Lifestyle Questionnaire (life)**

- Lifestyle questionnaire on health, activity, smoking and drugs.

1 record is partially missing lifestyle information.

### **5.31. Physical Examination (physical\_exam)**

- Results from physical examination.

5 records have no information in "was\_ecg\_performed". These are generally screen failures and the results will never be available.

### **5.32. Vital Signs (vital\_signs)**

- Vital signs measured at each visit including height, weight, hip and waist circumference, systolic and diastolic blood pressure, and pulse.

1 records has no information as to whether vital signs were collected. A further 17 records are partially missing vital signs.

### **5.33. Adverse Events (adverse\_events)**

- Adverse events information.

Any adverse events that begin before the visit is completed (i.e. within 28 days after visit date) are included. All information available at the time of data release for such adverse events will be included even if the adverse event was resolved after the visit window of 28 days.

### 5.34. Current Medication (current\_medication)

- Current medication information.

Any medication information that is entered in the database before the visit is completed (i.e. within 28 days after visit date) is included. The date of entry into the database is used as current medication is not linked to a particular visit and the date that medication was started is incomplete.

### 5.35. Medical History (medical\_history)

- Medical history information.

Any medical history information is treated in the same way as current medication.

## 6. Other Information

The V500.1 data release occurred during the COVID-19 pandemic. This impacted on the resolution of queries and thus future releases will incorporate these resolutions.

When analysing the EPAD-LCS data consideration should be given to the sampling method used. Details on the participant selection process by the EPAD-LCS Balancing Committee can be found in the EPAD-LCS protocol.

The Brain Injury Screening Questionnaire (BISQ) is not included in this data release as the data are currently unavailable.

Researchers can apply for access to the biological samples or MRI Image data via the ERAP website: [www.ep-ad.org/erap](http://www.ep-ad.org/erap).

DOI (Digital Object Identifier)

Each data set will be registered to a DOI (see table below) for unique and specific identification of the data set in publications and reference materials. This table will be updated with each data release.

| Data Set | DOI                                   |
|----------|---------------------------------------|
| V500.0   | Doi:10.34688/epadlcs_v500.0_19.05.10  |
| V1500.0  | Doi:10.34688/epadlcs_v1500.0_19.11.29 |
| V500.1   | Doi:10.34688/epadlcs_v500.1_20.04.29  |
|          |                                       |
|          |                                       |