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European Prevention of Alzheimer's Dementia Consortium

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D1.9 EPAD Research Access Process (ERAP) Operations Report

WP4 – EPAD Trials

V2.0

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DEFINITIONS

- Partners of the EPAD Consortium are referred to herein according to the following codes:
  - **Janssen**. Janssen Pharmaceutica NV (Belgium)
  - **UEDIN**. The University of Edinburgh (United Kingdom)
  - **UOXF.** Masters and Scholars of the University of Oxford (United Kingdom)
  - **BBRC.** BarcelonaBeta Brain Research Center (Spain)
  - **SYNAPSE.** Synapse Research Management Partners S.L (Spain)
  - **KI.** Karolinska Institutet (Sweden)
  - **VUMC.** Stichting VUMC (Netherlands)
  - **UCAM.** Masters and Scholars of the University of Cambridge (United Kingdom)
  - **MRC.** Medical Research Council (United Kingdom)
  - **BERRY.** Berry Consultants LLP (United Kingdom)
  - **UNIGE.** Université de Genève (Switzerland)
  - **RUMC.** Stichting Katholieke Universiteit (Netherlands)
  - **CU.** Cardiff University (United Kingdom)
  - **CHUT.** Centre Hospitalier Universitaire de Toulouse (France)
  - **IQVIA.** IQVIA, Ltd (United Kingdom)
  - **AE.** Alzheimer Europe (Luxemburg)
  - **EMC.** Erasmus Universitair Medisch Centrum Rotterdam (Netherlands)
  - **APHP.** Hôpital de la Salpêtrière (France)
  - **INSERM.** Institut National de la Santé et de la Recherche Médicale (France)
  - **ULEIC.** University of Leicester (United Kingdom)
  - **IXICO.** IXICO Technologies Ltd (United Kingdom)
  - **ARACLON.** Araclon Biotech S.L (Spain)
  - **FRAUNHOFER.** Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e.V. (Germany)
  - **Eisai.** Eisai Inc (United States)
  - **SARD.** Sanofi-Aventis Recherche & Développement (France)
  - **NOV.** Novartis Pharma AG (Switzerland)
  - **BI.** Boehringer Ingelheim International GmbH (Germany)
  - **Eli Lilly.** Eli Lilly and Company Ltd (United Kingdom)
  - **HLU.** H. Lundbeck A/S (Denmark)
  - **Takeda EU.** Takeda Development Centre Europe Ltd (United Kingdom)
  - **AC Immune.** AC Immune SA (Switzerland)
  - **Biogen**. Biogen Idec Limited (United Kingdom)
  - **Amgen.** Amgen NV (Belgium)
  - **Pfizer.** Pfizer Limited (United Kingdom)
  - **UCB.** UCB Biopharma SPRL (Belgium)
  - **ARIDHIA**. Aridhia Informatics Ltd (United Kingdom)
  - **ROCHE**. F. Hoffmann - La Roche (Switzerland)
  - **UKK**. University Hospital of Cologne (Germany)
  - **MSD**. Merck Sharp & Dohme (United States)

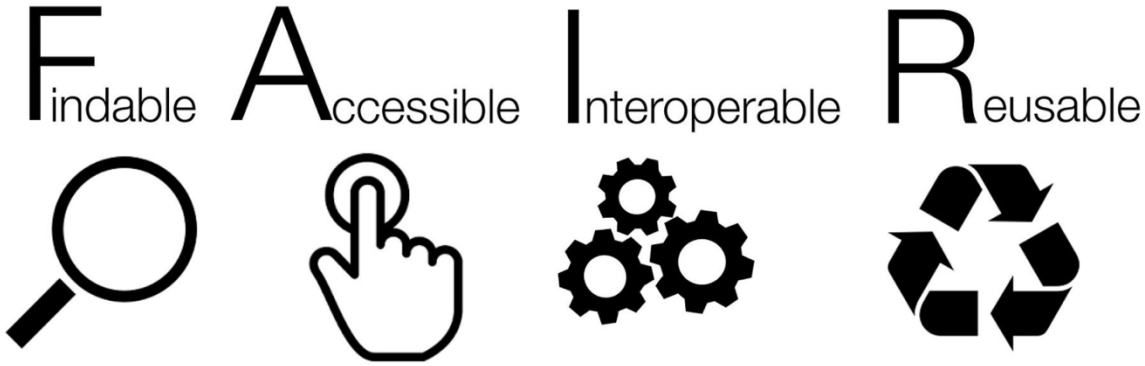
- **Grant Agreement.** The agreement signed between the beneficiaries and the IMI JU for the undertaking of the EPAD project (115736).
- **Project.** The sum of all activities carried out in the framework of the Grant Agreement.
- **Work plan.** Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
- **Consortium.** The EPAD Consortium, comprising the above-mentioned legal entities.
- **Project Agreement.** Agreement concluded amongst EPAD participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
- **EPAD LCS.** The EPAD Longitudinal Cohort Study.
- **AD.** Alzheimer's Dementia.
- **MRI.** Magnetic Resonance Imaging
- **Samples.** Biological samples and products such as cells and DNA derived from biological samples
- **MRI Data & Images.** The MRI Data collected at TDCs, standardised by IXICO to derive the Images used (also included in this definition) for the EPAD LCS MRI Active Core sequence data.

EXECUTIVE SUMMARY

The EPAD Longitudinal Cohort Study (EPAD LCS) represents a valuable resource to the scientific community for the study of risk factors and disease mechanisms for Alzheimer's Dementia. Data, biological samples and MRI data has been collected and stored as described in D4.13. This includes clinical data, human biological samples and MRI derived data and images. EPAD LCS Data have been made available in defined quality-controlled data sets to EPAD Partners according to the terms of the EPAD Project Agreement as described in D1.8. This report provides a summary of the operational delivery of the EPAD Research Access Process (ERAP). It describes the data sets that have been made available, the systems and processes used to facilitate the ERAP. In addition, this report reviews the operations of the EPAD LCS Sample Access Committee (SAC) to date. Information is provided about the number, type and management of the applications received from partners and external researchers and the future plans for managing the on-going access to EPAD LCS Data.

1. INTRODUCTION

This document describes how researchers can access data & samples from the EPAD LCS. This includes the clinical data collected at trial sites, biomarker and genetic data generated from biological samples collected in the study, MRI image data, and derived data from MRI images. The report covers the activity and operations of these processes during the IMI period of EPAD. The principles of FAIR data access have been the guiding principles behind the ERAP process:



The EPAD website and ERAP process make the EPAD LCS data sets Findable and Accessible. The EPAD Data Management Delivery Team have developed processes to provide curated data sets as defined in D1.6 and EPAD Partner, Aridhia, has provided tools and systems for researchers to deliver a state-of-the-art research environment that exemplifies the Interoperable and Reusable principles.

Biological Samples are a finite resource so there are separate processes for research access to samples via the EPAD Sample Access Committee. These are described in more detail in Deliverable 1.8 EPAD LCS RACs and a summary of activities to date provided in this report.

2. EPAD Research Access Process

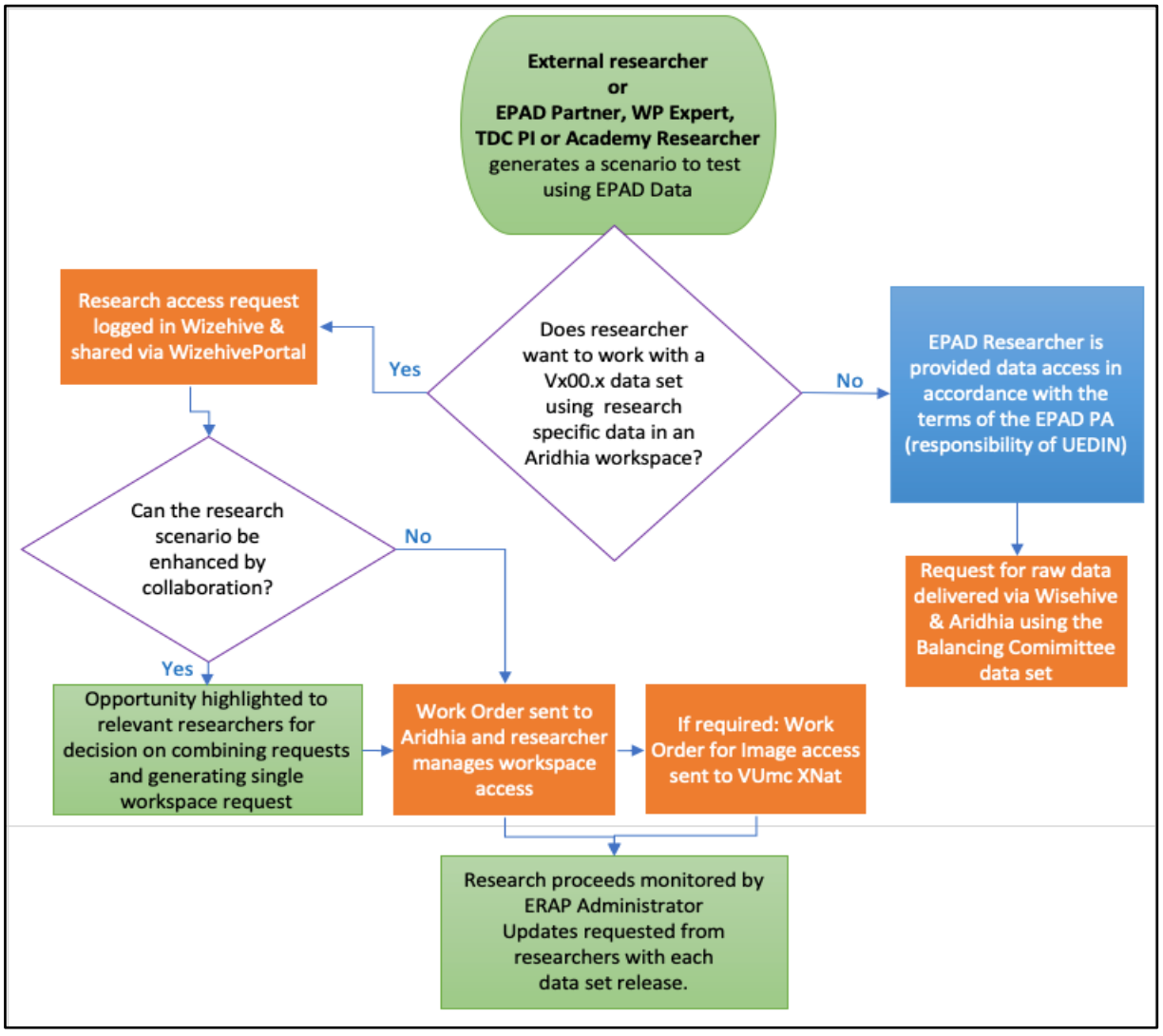
2.1. Process Summary for access to Data or Data + Image data

The EPAD Research Access processes are described and accessed via a subsite of the EPAD website:
www.ep-ad.org/erap

The site content is the responsibility of the EPAD Research Access Administrator and is maintained by WP6/Aridhia.

EPAD researchers based in partner organisations are given access to EPAD LCS Data Sets for an embargoed period of 6 months after which access is opened to the external research community.

Diagram 1: ERAP process flow for applicant



Applicants are requested to submit information about their research questions and planned research in the application form provided in the Wizehive tool. EPAD partners can choose whether or not to provide this information. Access to raw data is also allowable as part of the Project Agreement and is provided by UEDIN via provision of the latest data set used by the Balancing Committee. This contains all data received at the last data transfer; however, the data has not been subject to quality control procedures and is therefore not suitable for use in publications.

The ERAP website also provides access to Supporting Media, which include the EPAD LCS Protocol versions and eCRF. Each data release is accompanied by a Data Information Pack (DIP) containing a guide for researchers on both general and specific areas to be noted when working with the data. Each of these is also available on the ERAP webpage along with other Supplementary Media to be accessed by researchers.

2.1.1. Wizehive tool

Wizehive and EPAD co-developed a bespoke application of the Wizehive Zengine platform to fulfil the specific needs of the EPAD project. The Wizehive application consists of a series of on-line portals made available to applicants and other roles involved in the process. Each of these portals provides access to an interactive data collection form specifically developed to collect information of interest to EPAD. The application form also collects information needed by the Work Orders to set up accounts at Aridhia for data access and in the VUMC XNAT for image access.

A video guide has been prepared to demonstrate the process to applicants:
video walkthrough of the application process

During early implementation of the process it was found that the information provided by the applicants was not always complete or correct, (e.g. mobile numbers needed for log in to the Aridhia system), therefore a QC step has been added to the process. Once the applicant has completed and submitted their application, it is sent to a 'Finished' application folder where it can be reviewed by an ERAP administrator to ensure that all the data fields required have been completed as needed. Once this QC check has been done (within 1-2 working days) the application is moved to the 'Submitted' folder in the system which triggers the approval of the application and sends the information to the associated restricted access Google Sheet that Aridhia and VUMC use to generate the internal Work Order required to set-up the workspace or XNAT access requested. It was planned to automate this element of the process, but this has not been found to be necessary as this stepped process has worked efficiently for all parties and applicants. The Wizehive system generates auto-emails at each step that are sent to the applicant and copied to relevant Administrators to keep them informed about the progress of each application.

When new data sets are released, the auto-email functionality in Wizehive system is used to develop a bespoke Periodic Update request for each lead researcher. The researcher responds in a portal form and this allows the researcher to provide an update on the progress of their research. This includes publication plan and options to specify their requirements for data sets just released. Information about the timelines for required Aridhia workspace access is also requested so that capacity requirements for workspaces can be managed. A guide to this process is available on the ERAP webpage: ERAP Periodic Reporting Guide.

Post the IMI period workspace and support availability may be limited by the funding that is available. Once the scope is clear, a policy will be put in place to ensure researchers have access to the EPAD LCS data via the workspace facility and the terms and length of use will be varied to fit within the scope available. The policy will be included on the ERAP webpage to provide clarity to applicants on the level of service available.

2.1.2. Role of ERAP Administrator

The Chief Investigator's office at UEDIN has provided an ERAP Administrator to develop, implement and manage the ERAP process according to the requirements of D1.6 and D1.8. The Administrator's role is to oversee the movement of applications through the various steps in the process, provide input and feedback to applicants and support reviewers and other users in navigation and use of the Wizehive system. This role is accessed via an email address epadra.admin@ed.ac.uk allowing the role to be covered by different individuals as needed for holiday and leave provision. The ERAP administrator is assigned as the Wizehive Owner and can assign other Administrators to manage the day to day operations of the process; e.g. VUMC and Aridhia, WP1, SAC all have individuals assigned as Administrators so that the system is not reliant on any one ERAP Administrator

For data applications and data + image access this is a simple stepwise process. For the Sample Access Process, a series of review and approval steps are included, committee review, chair recommendation and Chief Investigator confirmation. In addition, if a samples access request requires costing information or confirmation that budget is available then these steps can also be included in the process. See Section 2.3 for more information.

2.1.3. Role of Aridhia workspaces in ERAP process

Aridhia provide a state-of-the-art data workspace that includes multiple functions to support collaborative research and innovative data management. The workspace is opened with all the researchers listed in the application (up to 8) and the lead researcher is assigned as the workspace owner so has complete control over activities and content creation within the workspace. This control includes being able to air-lock out any data or content created in the workspace and create a copy on a local machine as needed. The workspace owner also has access to the audit functionality of the workspace so can review and audit activity in their workspace up to the airlock of data or derived results. It is also possible to take data through analysis and reporting to publication using the publishing features of the workspace. Redeposition of data, figures and processing script etc as well as collaboration within the shared platform are encouraged for workspace owners and collaborators to make full use of the functionality available in the Aridhia workspace environment.

2.1.4. Role of XNAT in ERAP process

XNAT is an open source imaging informatics platform developed by the Neuro-informatics Research Group at Washington University. XNAT was originally developed at Washington

University in the Bruckner Lab, which is now located at Harvard University. More information is available at: https://www.xnat.org/about/ XNAT facilitates common management, productivity, and quality assurance tasks for imaging and associated data. XNAT can be used to support a wide range of imaging-based projects. VUMC have customised the platform to receive and share the MRI images collected in the EPAD LCS. To date the V500.0 active scans (scans linked to derived data in the EPAD LCS data set) have been curated and prepared for release through analysis and reporting to publication using the publishing features of the workspace.

2.1.5. Data sets released and planned for release

The Data Management Delivery Team was set up in January 2019 to coordinate the data management and quality control of data to be released for research purposes from the EPAD LCS.

The following data sets have been delivered:

- EPAD LCS V500.0 (published 19th May 2019) doi:10.34688/epadlcs_v500.0_19.05.10
- EPAD LCS V500.1 (published 4th May 2020) doi:10.34688/epadlcs_v500.1_20.04.29

These include the data from the first 500 consented participants at baseline, V500.0 and including follow-up visits at 6 months and 1 year, V500.1.

- EPAD LCS V1500.0 (published 29th Nov 2019) doi:10.34688/epadlcs_v1500.0_19.11.29

This includes the data from the first 1500 consented participants at baseline.

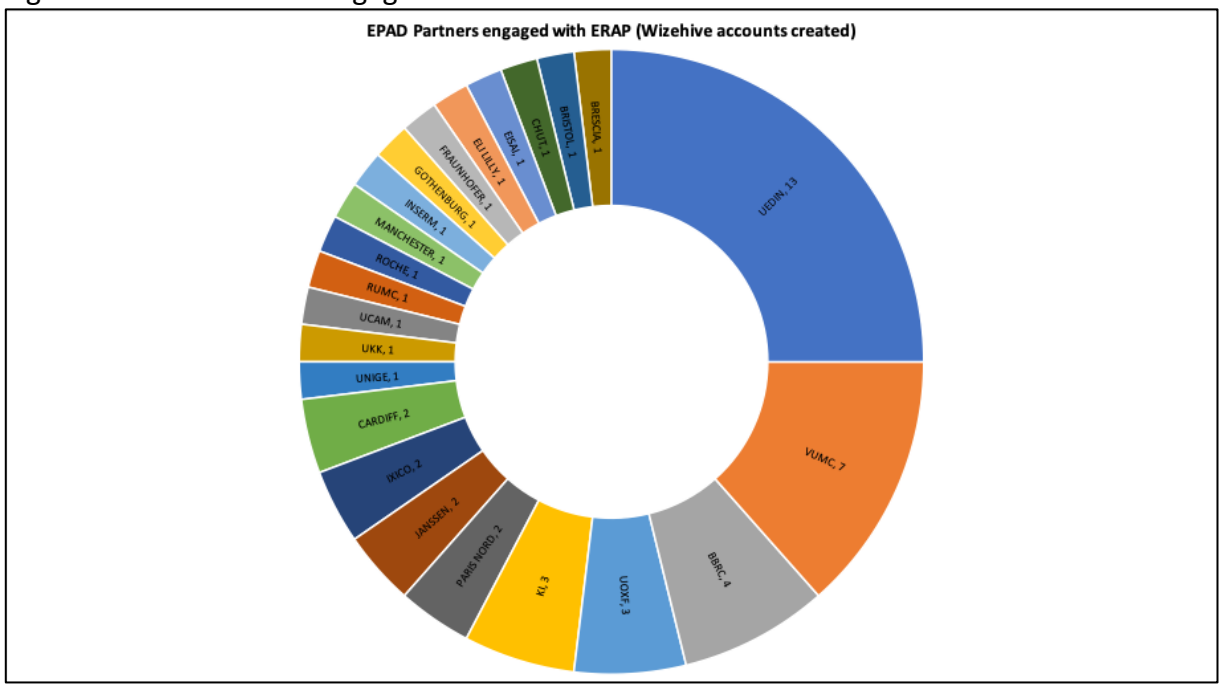
Since the decision was made to close the EPAD LCS, a final data set is in preparation – this will include all data that are available for all visits for all consented participants.

2.2. ERAP usage data for access to Data or Data + Image data

2.2.1. Requests to access the Wizehive system

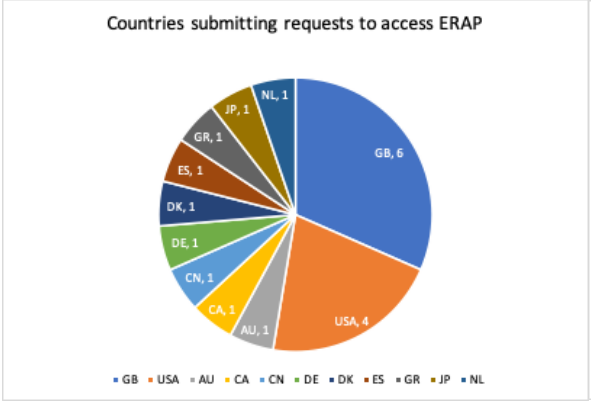
Partners including sub-contracted Trial Delivery Centres, (TDCs) are provided with access to the released EPAD LCS data sets for a six months embargo period before access is opened to external applicants, and this is reflected in the number of partners that have engaged with the Wizehive system. All requests have been processed within 2 working days, excluding UK Bank Holidays and the Christmas/New Year closure. In total 52 accounts have been set-up, from a total of 23 Partners/TDCs. Partner uptake of ERAP access is shown in the figure below. This figure represents the number of individuals from each Partner that have been provided with ERAP access.

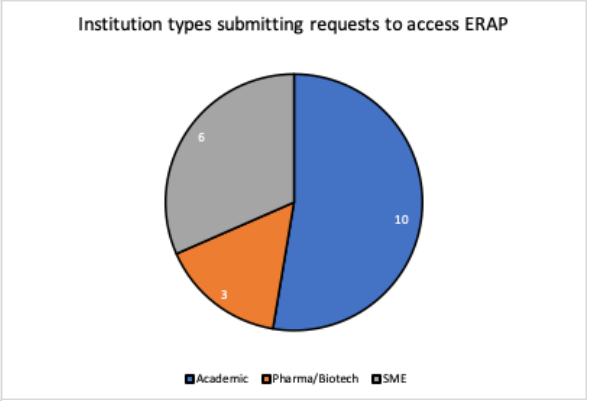
Figure 1: EPAD Partners engaged with ERAP



External uptake of the ERAP system is 60% less than EPAD partner engagement. In total, 21 requests have been received, 19, were checked to ensure the institution and associated email address of the applicant represented a *bona fide* research institution and on completion of this check were provided with access. 1 request was during the first embargo and has been advised that the system is now open for applications, 1 was referred to the PI of the Partner institution. The figures below illustrate the countries and types of institutions that have access to the ERAP system.

Figures 2&3: Countries and institution types with access to the ERAP system





Full list of external Institutions that have engaged with the first stage of the ERAP process:

- University of Sydney
- Perceiv Research Inc.
- Basic Medical College in Shanghai University of Traditional Chinese Medicine
- University of Bonn
- Novo Nordisk
- Qmenta
- Alchemab Therapeutics Ltd
- King's College London
- Mitra Health
- Oxford Brain Diagnostics
- University of York
- Centre for Research and Technology, Hellas
- Geriatric Health Care Facility for the Elderly, Joso
- Maastricht University
- Alector
- Boston University School of Medicine
- Icahn School of Medicine at Mount Sinai, New York
- Latent Sciences

2.2.2. Research question applications to ERAP for access to EPAD LCS data

There are 3 types of research questions which can be entered into the ERAP Process:

- Data only: all clinical and derived/processed data available
- Data + Images: Data as above + active image data associated with the derived data
- Data + Samples: as above + request for specific biological samples.

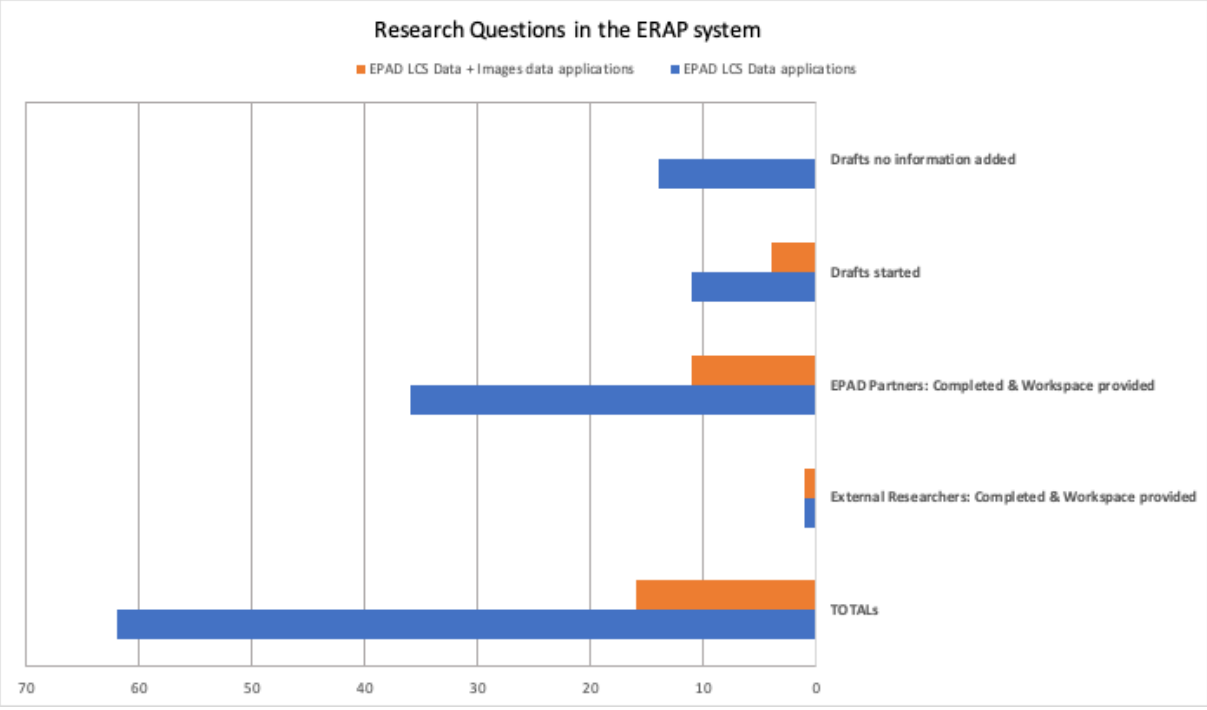
In total, 72 Wizehive accounts have been set up and these have resulted in 90 applications being started in the system, this includes all types of research question. Of these 90, 30 applications are currently in Draft of which 50% (15) do not contain any data and the other 50% (15) have been started and contain some of information requested but the data are not complete and have not been submitted by the applicant. These dormant or semi-dormant applicants have been contacted periodically, when new data sets are released with an email reminder that they have an open account and new data are available. The Wizehive system can accommodate any number of on-line applications so there is no operational

requirement to close these accounts at this stage. It is hoped that the release of the final data set will stimulate these researchers to complete their applications.

The research questions which include a request for Biological samples are managed by the Sample Access Committee and will be reported in the next section of this report.
The requests for access to data and access to MRI image data are checked to ensure that the data needed for workspace access are complete and in the correct format needed to process the applications. Once this is completed the applications are approved and notification provided to Aridhia and VUMC via an updated record in the relevant GoogleSheet for each type of access. All requests have an Aridhia workspace to provide access to the clinical data and the XNAT access provides access to the images linked to the derived data in each data set.

A total of 78 research questions have specified a request for access to Data or Data + Images and 49 workspaces have been set-up by Aridhia. The status of these requests is shown in the next figure:

Figure 4: Research questions for Data or Data + Images in the ERAP system.



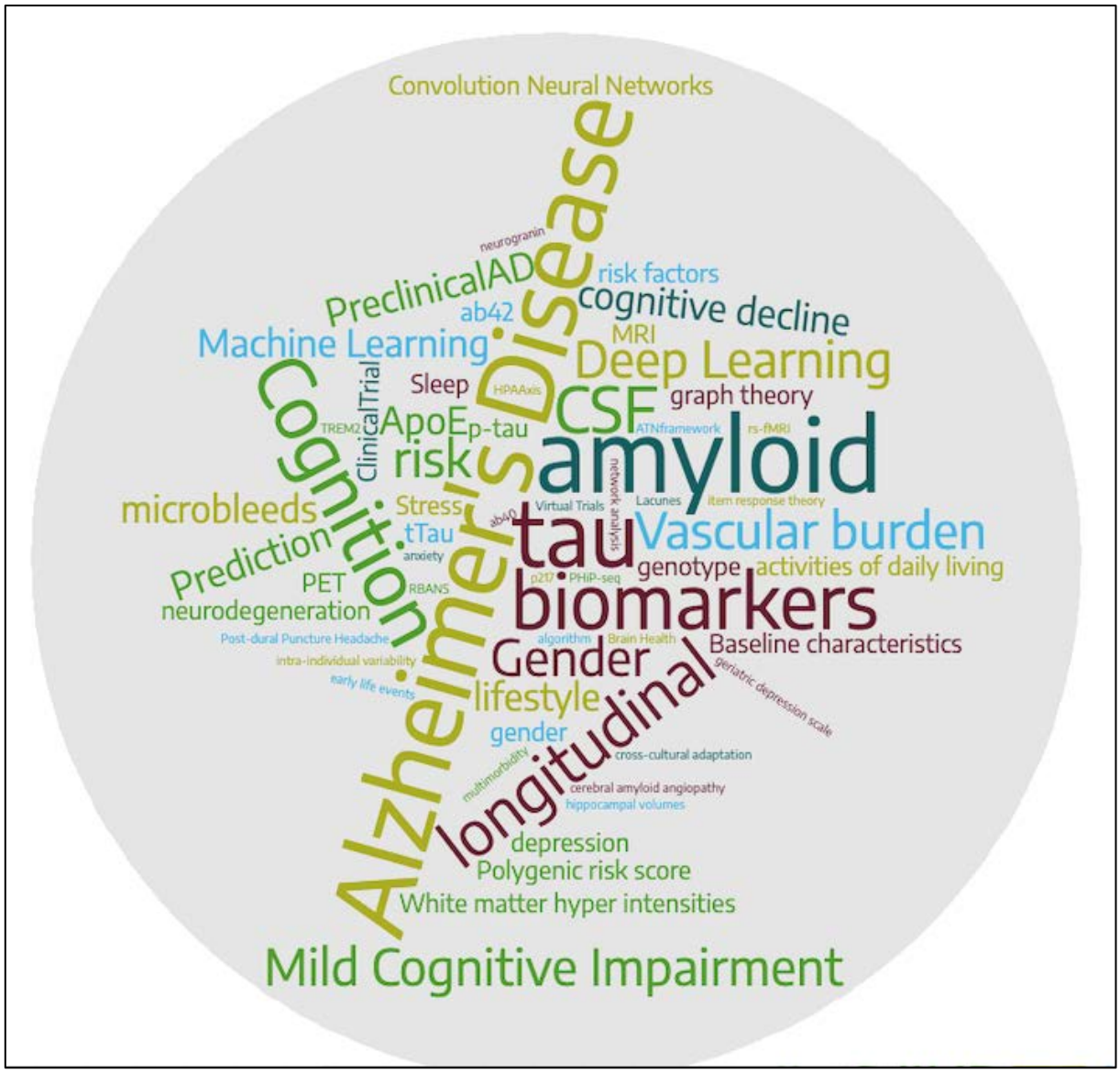
To support researchers to identify potential collaborations, the ERAP website maintains a current list of completed research question applications. This provides the short title given by the applicant, the Application ID and the name of the institution. Potential collaborations can be requested via the Contact Form on the ERAP website and are brokered by the Chief Investigator.

Join an Existing Research Project

Before making an application of your own, have a look at
the projects already being undertaken.
If you would like to join one of these projects and collaborate with the team, email us on the contact form at the bottom of this page, quoting the Application ID.

Key words are collected for each application and have been used to generate the word cloud shown in the next figure. This demonstrates the breadth of research questions that are being considered using the EPAD LCS data. Information on the publications resulting from this research can be found on the EPAD website:

Figure 5: WordCloud analysis of ERAP application key words
Processed using https://www.wordclouds.com/



3. EPAD LCS Samples Access Committee

3.1. Description of the EPAD LCS Bioresource

The EPAD LCS Bioresource is a collection of samples generated from the EPAD Longitudinal Cohort Study (LCS) of participants who have no or limited signs of Dementia. The resource has trials level rigor (Good Clinical Laboratory Practice) with associated measures of Alzheimer's Dementia pathology using both CSF and MRI. The participants undergo follow-up and sample collection over several years. The EPAD Bioresource consists of blood, urine and saliva collected annually from each participant and a sample of cerebral spinal fluid collected at baseline visit. The resource has been collected from 31 approved Trial Delivery Centres across Europe. The resource incorporates a database and information management system which

provides traceability and sample validation at every stage along the sample pathway, from collection through processing to storage. The resource aims to facilitate research to generate data for risk factor assessment, disease modelling, support for proof of concept and other trials in AD. The EPAD LCS Bioresource thus consists of a unique set of samples for the study of early brain changes leading to AD and is designed to increase the likelihood of successful development of new treatments for the secondary prevention of Dementia. Jean Manson is the PI for the EPAD LCS Bioresource and chair of the EPAD LCS Sample Access committee.

3.2. Membership of the Sample Access Committee (SAC)

Jean Manson (chair)

Judi Syson (Secretariat)

Membership has been a mix of up to eight industry and academic EPAD representatives and has included external experts. The committee has also drawn on specific expertise from within the EPAD Partners for advice when required.

3.3. Terms of reference for the EPAD LCS Sample Access Committee

1. The SAC will review and prioritise all requests for the use of samples from the EPAD LCS Bioresource.
2. The SAC will utilise an on-line tool (Wizehive Zengine) to review and manage requests from end to end.
3. The SAC will hold meetings bi-annually in person or by tele/video conference to prioritise and finalise recommendations. (This bi-annual review has been chosen because of the finite nature of the Bioresource and the need to consider requests in batches to facilitate prioritisation between requests and avoid depleting the Bioresource based on a “first come first served” basis.)
4. Requests will be available to the SAC via the on-line tool, review time will be available 6 weeks ahead of a meeting, completed reviews will be required 2 weeks ahead of a meeting.
5. Six members of the committee (out of eight) including the chair or delegate will be required to be present for the meeting to be quorate.
6. Decisions on requests will be made by consensus following a standardised review process. The chair will have the casting vote.
7. The SAC will recommend release of samples for appropriate studies to the Chief Investigator.

8. The minutes of the SAC meetings will be made available to SAC members and the EPAD Executive Committee (ExCom) via TeamWork.
9. The SAC will report directly to WP1 bi-annually following the review meetings.
10. SAC will use criteria, principles and guidelines through which requests will be assessed, which will be available on the EPAD website.
11. The SAC and its membership will be reviewed annually by WP1 and EPAD Executive Committee.

There is an expectation that results of the research will to be shared back with EPAD partners for research use where appropriate.

3.4. SAC process and Secretariat

The Samples Access Committee has been supported by the Chief Investigator and resources from within their office. This resource provides secretariat services to the Chairperson and members of the committee to ensure the smooth running of the committee.

Once an application has been received it is routed by the Wizehive system to the committee, as agreed by the Terms of Reference of the committee. The Wizehive system includes an on-line review tool for committee members to assess each application. The Committee has developed criteria for assessment of applications, which are aligned with this Deliverable and the Project Agreement. The Secretariat coordinates the distribution and collation of the committee assessments as required by the committee. On-line collaboration or meetings are arranged to come to a consensus decision on each application which is recorded as the Chair's recommendation. This recommendation is routed by the Secretariat to the CI for confirmation of the decision by the CI and on behalf of the EPAD LCS Sponsor (UEDIN).

3.5. ERAP usage data for access to Data + Samples access requests

A total of 9 applications to access samples have been made during the IMI period. The first two proposals were incorporated into a protocol amendment and the analysis proposed will form part of the EPAD LCS study delivery. Four applications were considered at the first full meeting of the SAC. Three applications were not progressed after this committee review and 1 application is being revised by the researchers to answer additional questions raised by the committee review. Since then three requests have been submitted, 1 application was withdrawn. Two applications have been approved and discussions are currently on-going to identify and supply appropriate samples for the proposed research.

Application ID	Institution	EPAD/External	SAC Decision
180929_CYT_PIR_001	CU/CYTOX	Partner	Adopted in protocol
181009_GOT_ZEH_0001	UGOT	Partner	Adopted in protocol
190925_RUM_RIE_001	RUMC	Partner	Not progressed
191112_APH_VRA_002_Revised	APHP	Partner	Application being revised
191205_KCL_SIE_001	Kings College London	External	Not progressed
200106_SUT_LUZ_001	Shanghai University of Traditional Chinese Medicine	External	Not progressed
200211_ROC_MCS_001_Revised	ROCHE	Partner	Withdrawn
200206_JAN_TRG_001	JANSSEN	Partner	Approved
200206_ALC_KIG_001	Alchemab Therapeutics Ltd	External	Approved

The researchers are provided with an Aridhia workspace containing the relevant EPAD LCS Data set and use the Samples IDs provided by the Bioresource to match up with the clinical data set. This enables the full profile of the participants to be included as part of the research project.

4. Future plans for ERAP & SAC

4.1. Maintenance of ERAP Administration, Wizehive, XNAT and Aridhia workspace systems

Follow-on funding has been obtained to support the maintenance of the ERAP processes post the IMI period. This will ensure the continuity of the EPAD webpage and Wizehive system. A separate funding application has also been successful to maintain access to data via the Aridhia workspaces and UEDIN Data Management Services will be utilised to provide back-up to maintain data access. Based in part on the experience of developing the ERAP process, Aridhia is investing in a data access request workflow engine as part of a new FAIR data service and will seek funding opportunities to provide this to the EPAD community.

As a backup resource, a full copy of all the clean raw data and processed files will be set-up and maintained in University of Edinburgh. All data access will continue to be managed via the ERAP Administration.

IXICO will provide VUMC with the final extract of all participant active scans at the beginning of July and these will be released on the XNAT to accompany the final data set. In addition, a fully copy of the EPAD LCS image set will be stored by UEDIN.

4.2. EPAD LCS Bioresource maintenance and SAC process

Follow-on funding has been obtained to support the maintenance of the Bioresource facility, staffing and processes post the IMI period. This will ensure the continuity of the EPAD LCS Sample Access governance and oversight of the biological samples.