



IMI IMPACT SERIES

IMI IMPACT ON DIABETES

8 June 2021 – 3:00 PM - 5:00 PM (CET/Brussels time)

IMI IMPACT ON DATA

9 June 2021 – 2:00 PM - 3:30 PM (CET/Brussels time)

IMI IMPACT ON DEMENTIA

15 June 2021 – 2:00 PM - 4:00 PM (CET/Brussels time)

Register here



Gill Farrar:
EFPIA Lead,
GE Healthcare, UK



Frederik Barkhof:
Academic Lead,
VUMC, Netherlands
and UCL, UK

Amyloid Imaging to Prevent Alzheimer's Disease (AMYPAD)



Part of Innovative Medicines Initiative (IMI) program, a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA)

A 6-year programme with a budget of €27.3M distributed across a total of 15 partners.

Will end
Sept 22

Academia

EFPIA

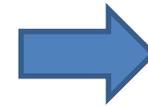
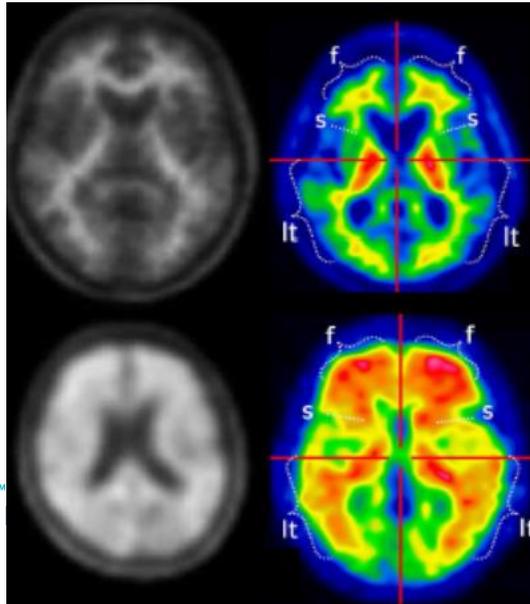
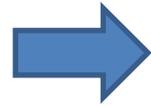
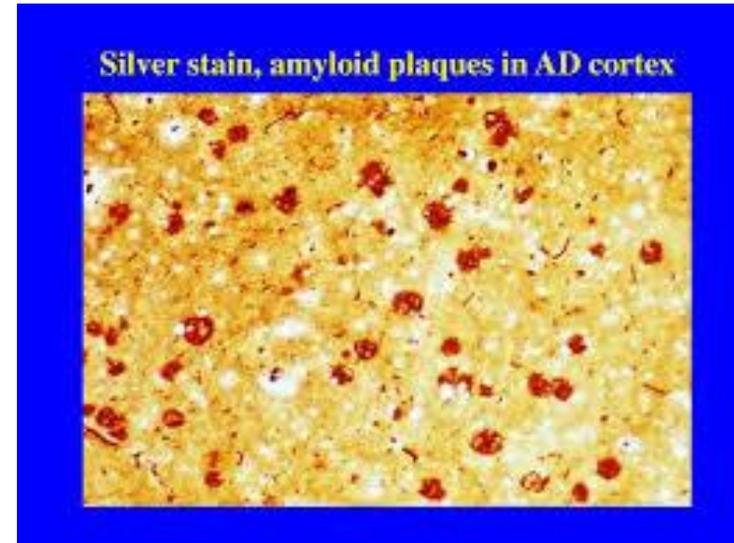
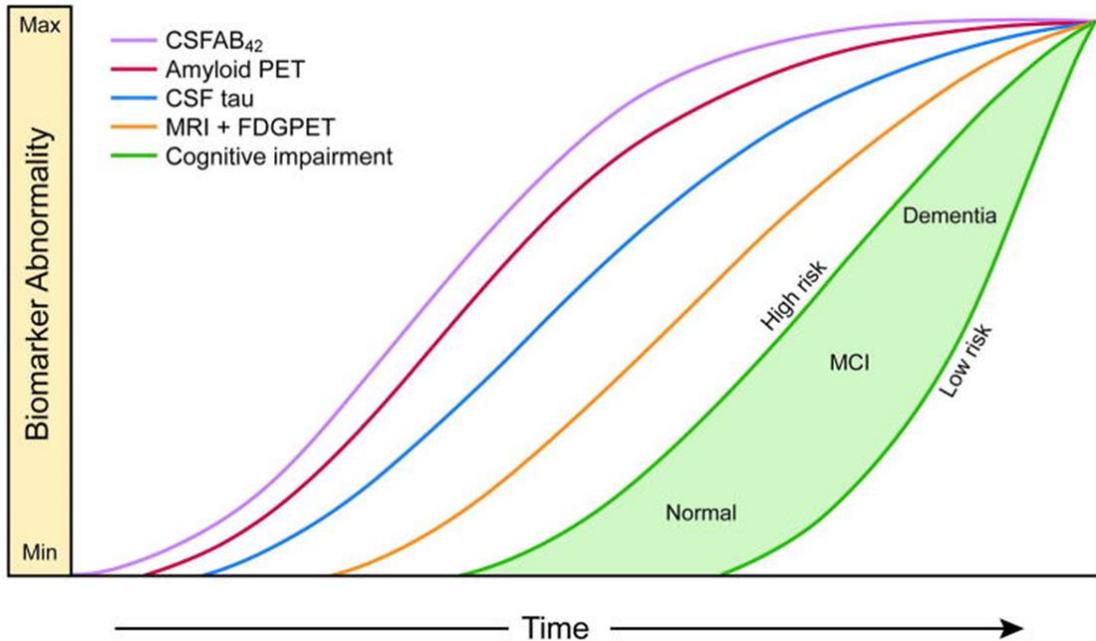
Patient
organisation



SMEs



AMYLOID Pathology: Integral to the diagnosis of Alzheimer's Disease



NeuraCeq™
florbetaben F18 injection

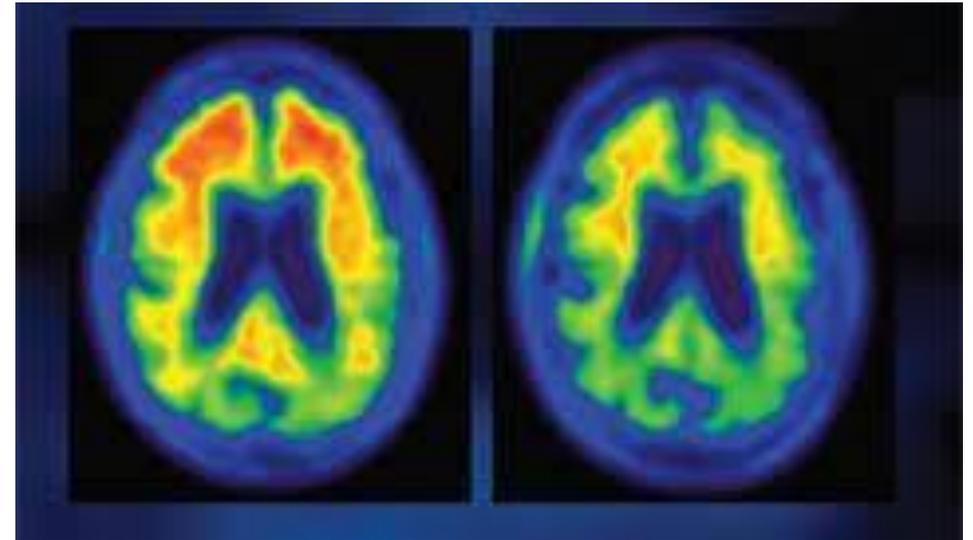
VIZAMYL™
Flutemetamol F18
Injection



FDA NEWS RELEASE

FDA Grants Accelerated Approval for Alzheimer's Drug

ADUHELM is indicated for the treatment of Alzheimer's disease. Indication approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM

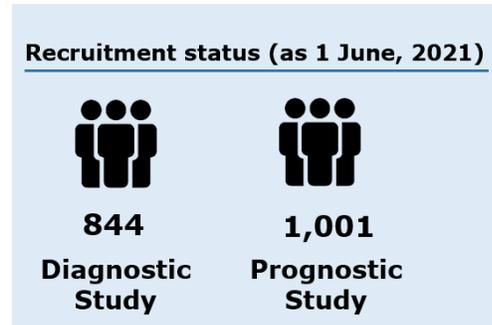


Baseline amyloid
PET

After follow-up

AMYPAD Studies

1) Diagnostic Study:
Examining influence of amyloid PET scan in diagnosis, confidence and patient management



2) Prognostic Study:
Understanding the evolution of amyloid deposition in the brain.
Capturing earlier subjects who may be 'developing' the pathology

AMYPAD: Outputs

1) Curated Data and Image Repository (>ADDI Platform)

Projected Asset (DPMS)	# Data	Recruitment status (as 1 June, 2021)		Projected Asset (PNHS)	# Data
PET Images	900			Unique subject scans (baseline + follow-up)	1046
Patient Diaries (0,3,6, 13mts)	2600	844	1,001	+ Other cohort scans (baseline+ follow up)	1247
Clinical evaluations (0,3,6, 13mts)	3200	Diagnostic Study	Prognostic Study	Total scans	2293

2) Network of Study Cohorts, Investigators & Collaborators

Inclusion of additional cohorts

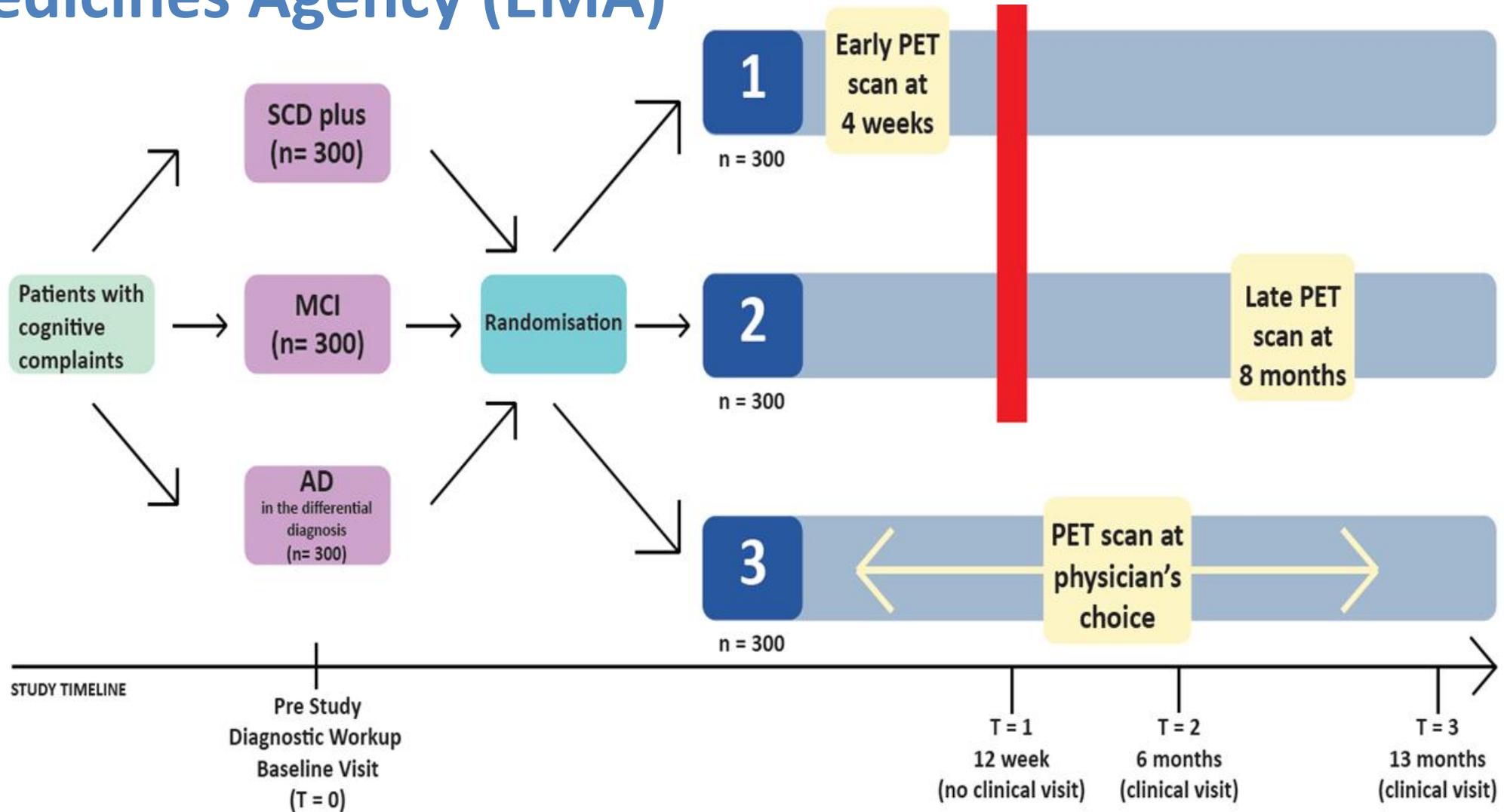


DELCODE
FPACK
FACEHBI



Site
010 – UEDIN, Edinburgh
020 – CHUT, Toulouse
030 – BBRC, Barcelona
040 – VUmc , Amsterdam
060 – UNIGE, Geneva
050 – KI, Stockholm
015 – Tayside, Scotland
021 – Nantes, France
022 – Lille, France
023 – Paris Nord, France
024 – Montpellier, France
025 – Paris la Pitié, France
031 – CITA, San Sebastien, Spain
032 – Fundació ACE, Barcelona
041 – UZ Leuven, Belgium
043 – UC Louvain, Belgium
051 – UGOT, Gothenburg, Sweden

3) Diagnostic Study: Design endorsed by European Medicines Agency (EMA)



4) Health Economic (cost:benefit) data from Diagnostic Study (DPMS)

	Baseline	3 Months	6 Months	13 Months	Total
Collected Diaries	705	660	635	600	2600

Each diary has approx. 40 data points

Example questions include....

A1.2 Participant health care resource utilization

- During the last 30 days, have you been admitted to a hospital for one or more nights?
 - Yes
 - No, go to question 4
- How many times were you admitted to a hospital (for one or more nights)?
 ____ times, during the last 30 days

16. During the last 30 days, how many times did you receive care from a health care provider **outside a hospital**? Please specify the number of visits for each type of care received:

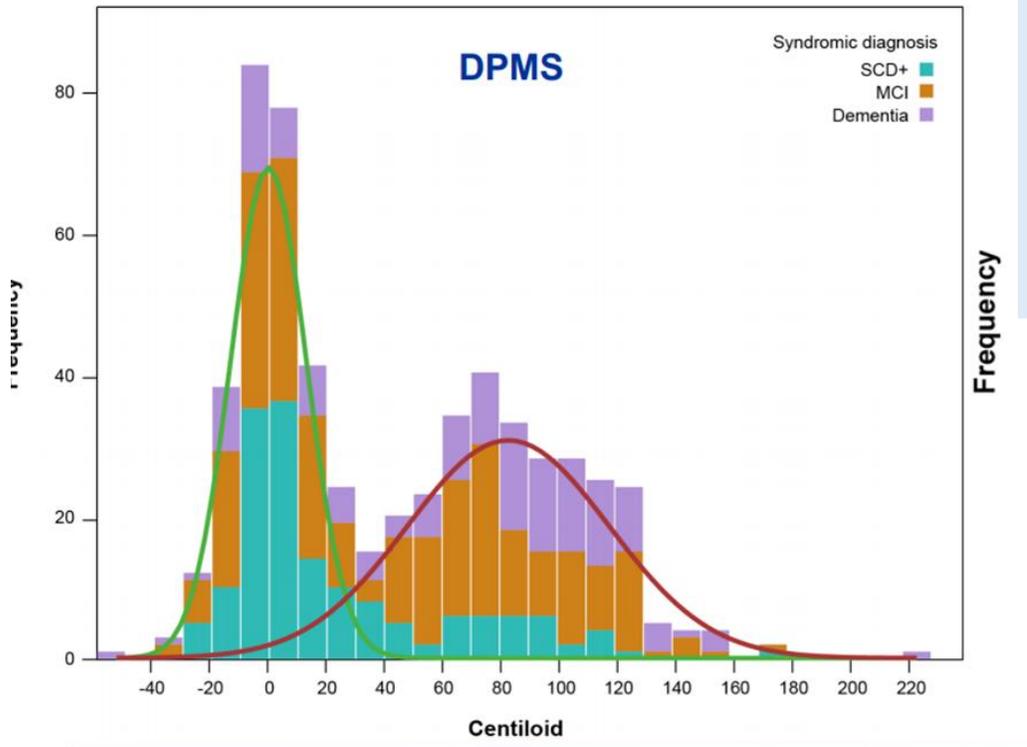
Type of care	Number of visits during last 30 days
General practitioner	
Geriatrician	
Practice nurse	

19. Please specify the medications you are using:

Name of medication	Strength	Frequency	Number of days taken over last 30 days
Example: <i>Aspirin</i>	<i>500 mg</i>	<i>2 times a day</i>	<i>10 days</i>

5) AMYPAD Studies: Early Results

1) Diagnostic Study



Recruitment status (as 1 June, 2021)



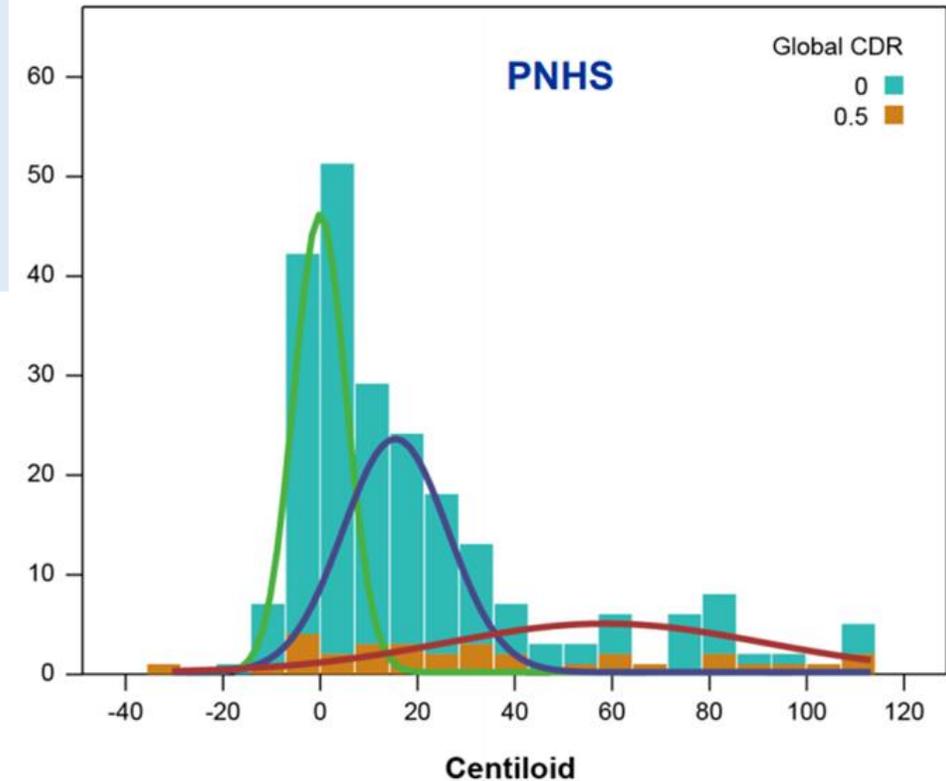
844
Diagnostic
Study



1,001
Prognostic
Study

Frequency

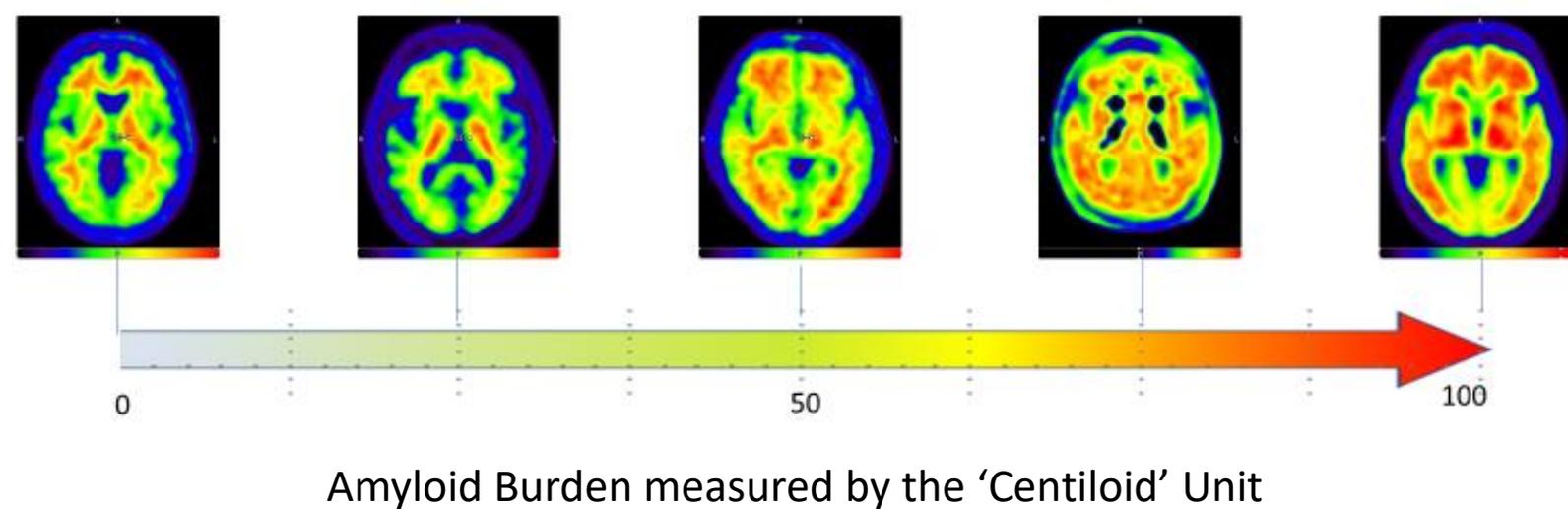
2) Prognostic Study:



6) Quantitation of brain amyloid: Discussion/interaction with EMA

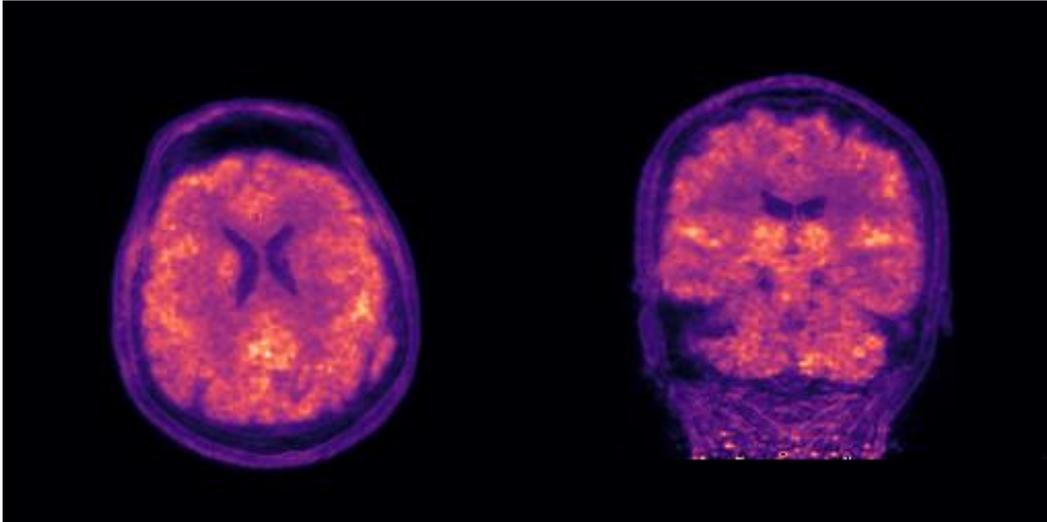
Critical Assessment of Current Quantitative Methodologies

- Baseline
- Longitudinal
- Dynamic/Static scans
- Research participants
- Clinical patient subtypes



7) NiftyPET Software Platform

NiftyPET: High-throughput image reconstruction and analysis



NiftyPET is a software platform and a Python namespace package encompassing sub-packages for high-throughput PET image reconstruction, manipulation, processing and analysis with high quantitative accuracy and precision. One of its key applications is **brain imaging in dementia**

DOCUMENTATION

Introduction

Installation

TUTORIALS

NiftyPET Example

Accessing and querying GPU devices

DICOM anonymisation

List-mode processing and motion detection

Basic PET image reconstruction

Dynamic image reconstruction

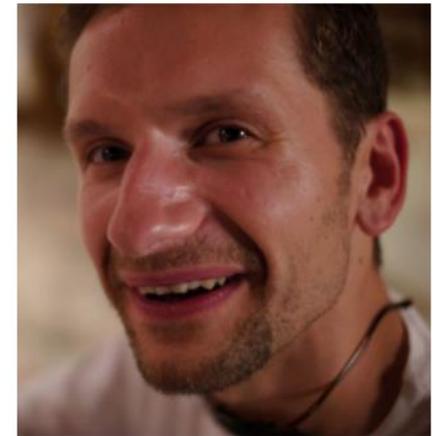
Corrections for quantitative PET

OPEN-SOURCE DATA

Raw brain PET data

 Read the Docs

v: latest ▾



c/o Pawel Markiewicz
p.markiewicz@ucl.ac.uk

<https://niftyPET.readthedocs.io>

8) High quality publications in top-tier journals

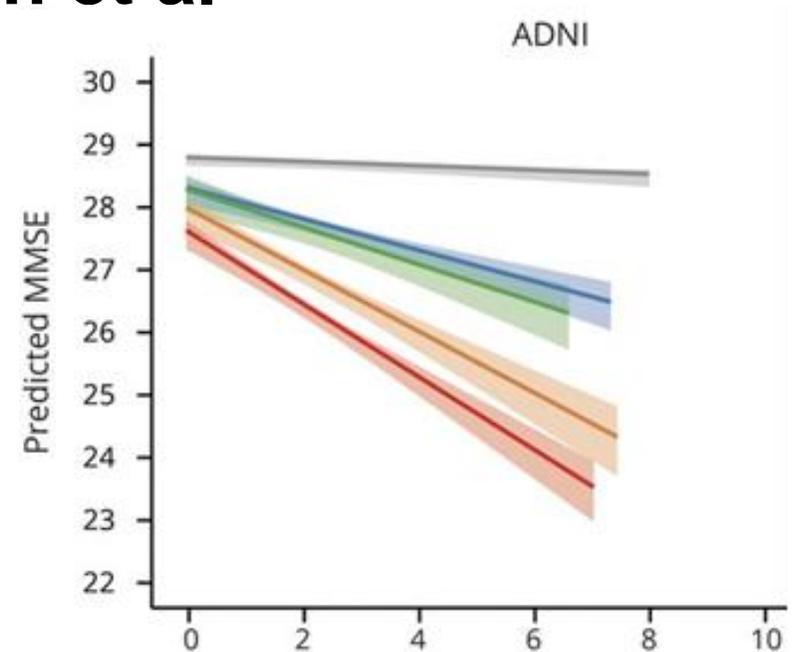
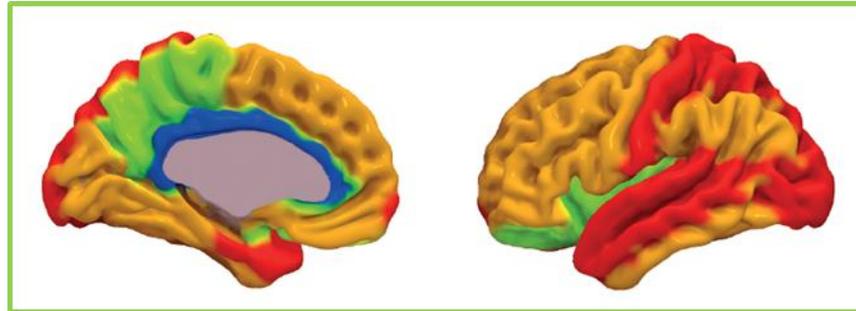


Multitracer model for staging cortical amyloid deposition using PET imaging (2020)

Lyduine Collij & Fiona Heeman et al

Neurology[®]

<https://amypad.eu/> managed by



Sustainability for the Future

9) AMYPAD will join the Gates Ventures funded ADDI workbench (+ aim to follow up via NEURONET)

About ADDI

The Alzheimer's Disease Data Initiative (ADDI), a 501(c)(3) medical research organization (MRO), is dedicated to advancing scientific breakthroughs in the treatment of Alzheimer's disease and related dementias.



A USER WITH A QUESTION

Can run a federated query on pre-harmonized and standardized data across multiple platforms.

Can discover, explore, harmonize, standardize and visualize data.

Can find, access, and use harmonized interoperable data.

Can touch multiple platforms and analyze data at the source.



A USER WITH CODE

Can run a federated analysis on data across multiple platforms, even when data is behind firewalls.

Can use data across multiple platforms.

Can run a federated analysis on data across multiple platforms.

Can touch multiple platforms and analyze data at the source.



A USER WITH DATA

Can make harmonized data interoperable for other users.

And finally for AMYPAD: 😊 Talent Incubator 😊



Arianna Sala

- *Understand the causes underlying discordance between PET and CSF markers of amyloid pathology*
- *Apply advanced statistical approaches to model biomarker discordance as a continuous feature, avoiding cut-off dependent inferences*



David Vallez Garcia

- *Data manager of AMYPAD-PNHS*
- *Senior researcher focused on quantitative PET methodology*



Laure Saint-Aubert

- *Set-up and management of both the AMYPAD DPMS/PNHS in Toulouse + other French centers*



Lyduine Collij

- Optimizing visual assessment of amyloid PET images
- Investigate the value of regional and quantitative amyloid PET measures within the context of the natural history of AD.



Daniele Altomare

- Analyses of the AMYPAD-DPMS data
- Assessment of the utility of amyloid-PET in clinical practice

Fiona Heeman



- Define and implement optimal methodology for acquisition and analysis of dynamic PET data
- Analyses of all dynamic PET scans



Mahnaz Shekari

- Methodological aspects of amyloid PET image quantification



Isadora Lopes Alves

- Set-up and management of a multi-center multi-national natural history study across 17 sites
- Scientific coordination of the disease modelling team and its scientific publications



Gemma Blasco

- Improvement of the standardization of amyloid PET quantification
- Analyses of amyloid PET data from external cohorts