



**Imaging Dementia—Evidence  
For Amyloid Scanning**

***Information for Referring  
Dementia Experts***



# WELCOME

- Session is being recorded and will be posted to the IDEAS-Study website ([www.ideas-study@acr.org](http://www.ideas-study@acr.org))
- 60 min session; 30 minutes for Q & A
- All lines are muted except panelists; Q & A by “chat”

## AGENDA

### **IDEAS Study and Referring Physician Practices**

*Gil Rabinovici, MD, Principal Investigator, University of California – San Francisco*

### **Case Reimbursement**

*Cynthia Olson, MHS, MBA, Project Manager*

### **Question & Answer Session**



## **Imaging Dementia—Evidence For Amyloid Scanning**

**A Study to Evaluate the Clinical Utility of  
Amyloid PET in U.S. Medicare Beneficiaries**

**Study Chair: Gil D. Rabinovici**

**Co-chairs: Maria C. Carrillo, Constantine A. Gatsonis,  
Bruce E. Hillner, Barry A. Siegel, Rachel A. Whitmer**



# PET Amyloid Imaging

- Three agents approved by FDA as imaging biomarkers of amyloid plaques
  - April, 2012  $^{18}\text{F}$ -florbetapir
  - October 2013  $^{18}\text{F}$ -flutemetamol
  - March, 2014  $^{18}\text{F}$ -florbetaben
- September, 2013 CMS issues National Coverage Decision



- **Insufficient evidence of clinical utility to justify coverage of A $\beta$  PET**
- **Reimbursement would be considered under coverage with evidence development (CED) in clinical studies designed to:**
  - *Develop better treatments or prevention strategies for AD*
  - *Identify subpopulations at risk for developing AD*
  - *Resolve clinically difficult differential diagnoses (e.g., frontotemporal dementia versus AD)*
- **Must demonstrate A $\beta$  PET improves health outcomes (short-term outcomes related to changes in management as well as longer-term dementia outcomes)**

# After a Two-Year Gestation: IDEAS

- An open-label, longitudinal cohort study under CED to assess the impact of amyloid PET on patient-oriented outcomes in individuals meeting Appropriate Use Criteria for amyloid PET (Johnson, et al. 2013)
- **The primary hypothesis is that, in diagnostically uncertain cases, knowledge of amyloid PET status will lead to significant changes in patient management, and this will translate into improved medical outcomes**

# IDEAS Research Team

## IDEAS Steering Committee

### Core Science Team

Gil Rabinovici, UCSF - PI  
Maria Carrillo, Alzheimer's Assn.  
Constantine Gatsonis, Brown Univ.  
Bruce Hillner, VCU  
Barry Siegel, Wash Univ.  
Rachel Whitmer, Kaiser  
Permanente

### Additional committee members

William Abbott, Piramal Imaging  
Rosemarie Hakim, CMS  
Meridith Johnson, GE Healthcare  
Mark Mintun, Avid/Eli Lilly  
Don Rosen, ACR

## ACR Operations

Charlie Apgar, Cynthia Olson,  
Leslie Sears, Glenna Gabrielli

## MITA - Terri Wilson

**Consultant** Brian Carey, Foley  
Hoag

## Biostatistics Center (Brown)

Ilana Gareen, Roe Gutman, Erin  
Greco, Lucy Hanna, Benjamin  
Herman, Rajesh Makineni

## Scientific and logistical support

Jim Hendrix, Alzheimer's Assn.  
Ashley Mensing, UCSF

# Inclusion Criteria: AUC

## Meets Appropriate Use Criteria for Amyloid PET:

- Cognitive complaint verified by objectively confirmed cognitive impairment;
- The etiologic cause of cognitive impairment is uncertain after a comprehensive evaluation by a dementia specialist, including general medical and neurological examination, mental status testing including standard measures of cognitive impairment, laboratory testing, and structural neuroimaging as above;
- Alzheimer's disease is a diagnostic consideration;
- Knowledge of amyloid PET status is expected to alter diagnosis and management.

# Inclusion Criteria (Continued)

- 65 and older & Medicare/Medicare Advantage beneficiary;
- Diagnosis of MCI or dementia (DSM-IV and/or National Institutes of Aging-Alzheimer's Association criteria) within 24 months
- Head MRI and/or CT within 24 months prior to enrollment;
- Clinical laboratory assessment (complete blood count [CBC], standard blood chemistry profile, thyroid stimulating hormone [TSH], vitamin B12) within the 12 months prior to enrollment;
- Able to tolerate amyloid PET required by protocol, to be performed at a participating PET facility;
- English or Spanish speaking (for the purposes of informed consent);
- Willing and able to provide consent. Consent may be by proxy.

# Exclusion Criteria

- Normal cognition or subjective complaints that are not verified by cognitive testing.
- Knowledge of amyloid status, in the opinion of the referring dementia expert, may cause significant psychological harm or otherwise negatively impact the patient or family.
- Amyloid status already known to patient or referring clinician based on prior amyloid imaging or cerebrospinal fluid analysis.
- Current or previous enrollment in an anti-amyloid therapeutic trial.
- Scan is being ordered solely based on a family history of dementia, presence of apolipoprotein E (APOE) 4, or in lieu of genotyping for suspected autosomal mutation carriers.

# Exclusion Criteria (Continued)

- Scan being ordered for nonmedical purposes (e.g., legal, insurance coverage, or employment screening).
- Cancer requiring active therapy (excluding non-melanoma skin cancer);
- Hip/pelvic fracture within the 12 months prior to enrollment;
- Body weight exceeds PET scanner weight limit;
- Life expectancy less than 24 months based on medical co-morbidities;
- Residence in a skilled nursing facility.

# Specific Aims

## **Aim 1: To assess the impact of amyloid PET on patient management at 90 days**

- Management plans recorded via pre- and post-PET case report forms completed by dementia specialist

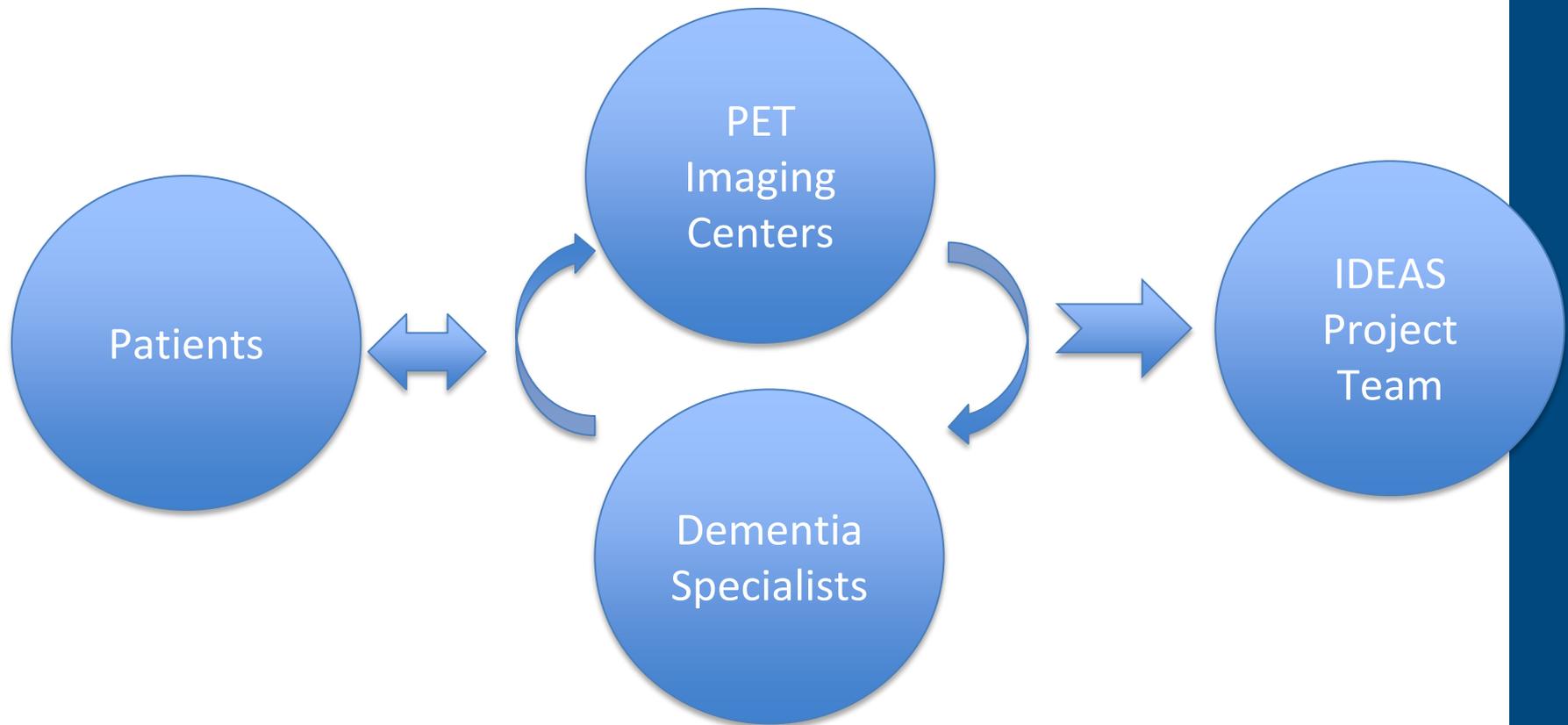
## **Aim 2: To assess the impact of amyloid PET on hospital admissions and emergency room visits at 12 months**

- Medicare claims of study participants compared to those of concurrent matched cohort who have not had amyloid PET (identified via claims database)

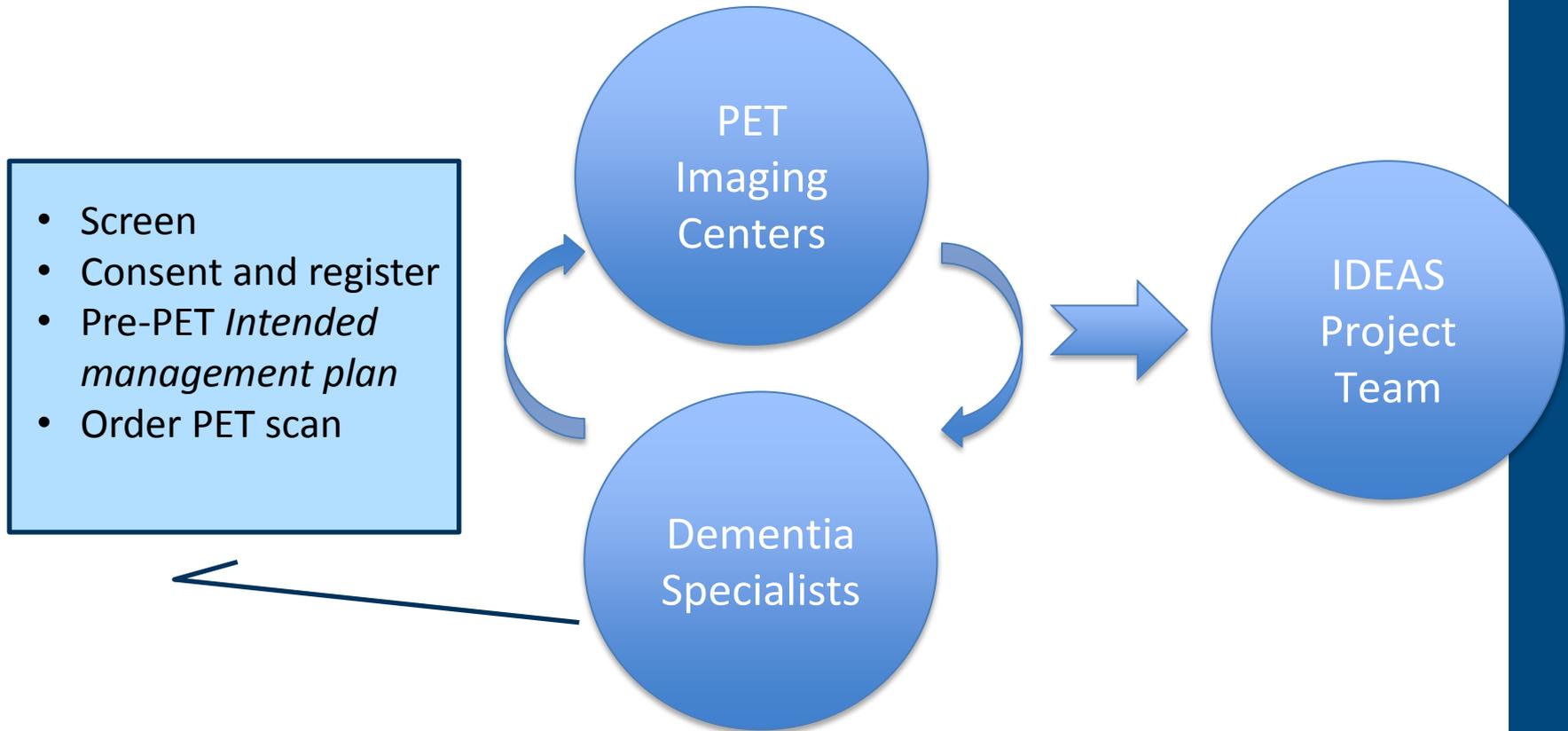
# IDEAS Study

- Estimated sample size
  - Aim 1: 11,050 subjects for 30% change in management composite endpoint
  - Aim 2: 18,448 subjects for 10% relative reduction in hospitalization, ER visits
- Expected study cost \$20M (excluding cost of scans)
- Timeline to coverage: at least 5 years

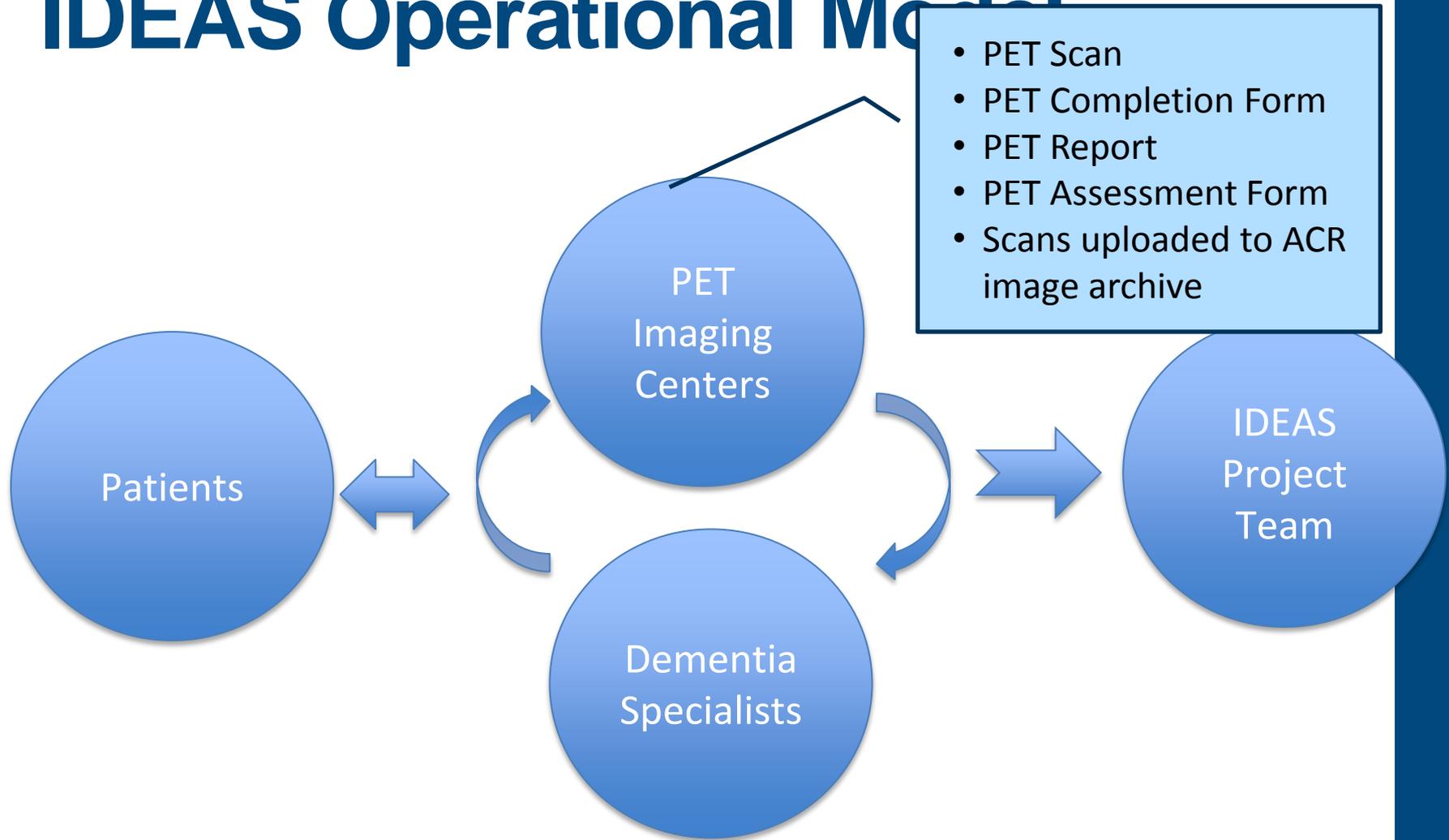
# IDEAS Operational Model



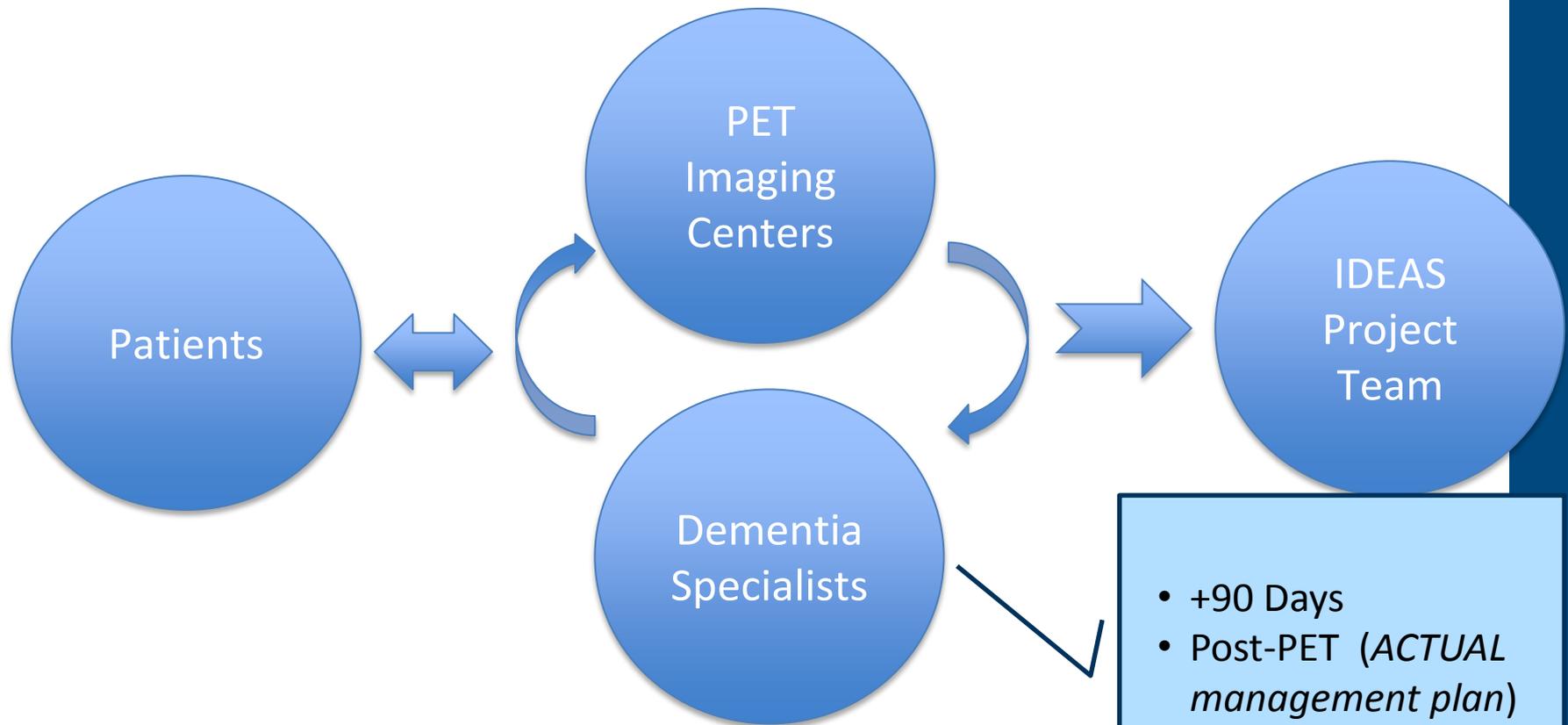
# IDEAS Operational Model



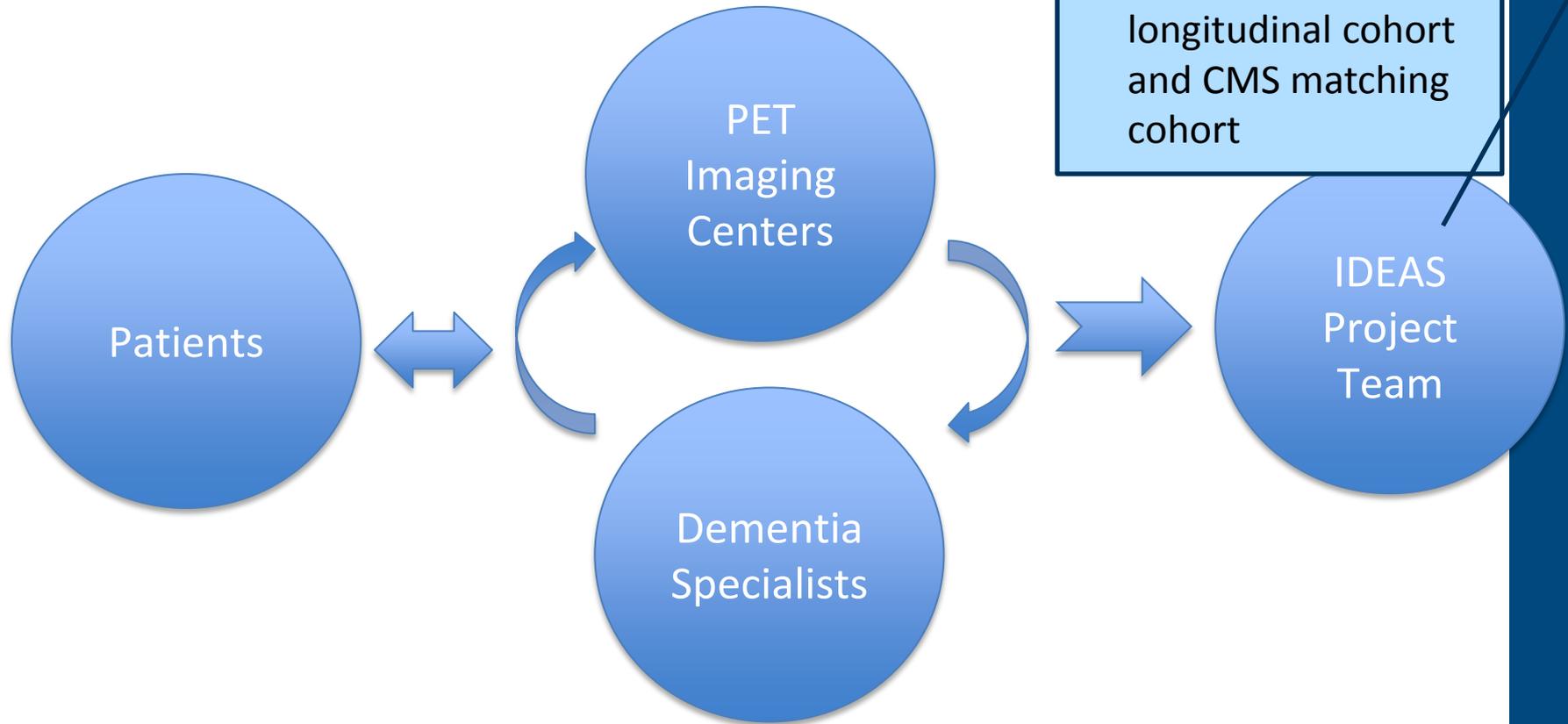
# IDEAS Operational Model



# IDEAS Operational Model



# IDEAS Operational Model



# IDEAS: Research versus Clinical Care

- **Clinical care**
  - Pre-PET and post-PET dementia expert visits
    - Clinical CPT codes should be applied
    - No standardized clinical metrics or assessments
  - Amyloid PET scans and reads
- **Research elements**
  - Consent (patients and physicians)
  - Case report forms
  - Image archiving
  - Following participants' Medicare claims

# Will Subjects Endure Any Costs?

- Co-payments may apply for clinical services (pre- and post-PET visits, PET scan) depending on the individual's coverage
- Most co-payments will be covered for patients with Medicare supplemental insurance (or Medicaid).
- Most patients with Medicare Advantage plans will have no deductible or co-pay, but some MA plans have co-share requirements.
- We estimate that approximately 10% of all participants will have no supplemental coverage (for co-payment or deductible.)
  - These patients will be responsible for the usual patient co-share portion of the imaging, likely a 20% co-payment.
  - For amyloid PET scan we estimate this will translate to a range of \$250-\$700 depending on the imaging facility setting and patient insurance plan.
  - As with any other clinical recommendation, it is good practice to determine and discuss any potential out-of-pocket costs with the patient/family as part of the shared decision making prior to ordering the scan.

# The Post-PET visit

- You do NOT need to wait until the 90 day visit to discuss amyloid PET results with your patient and make recommendations
- The goal of the post-PET visit is to record *actual* (implemented) patient management rather than *intended* management based on recommendations after the scan
- The 75-105 day window was selected to integrate into clinical flow
  - Follow-up period after new dx and treatment plan
  - Allows time for recommendations to be implemented
  - Please let study team know ASAP if patient unable to return within this window

# Referring Physician Qualifications

Board Certification in at least one of the following:

**American Board of Psychiatry and Neurology**

- Neurology
- Psychiatry
- Geriatric Psychiatry

**American Osteopathic Board of Neurology and Psychiatry**

- Neurology
- Psychiatry
- Geriatric Psychiatry

**American Board of Internal Medicine**

- Geriatric Medicine

**American Osteopathic Board of Internal Medicine**

- Geriatric Medicine

**American Board of Family Medicine**

- Geriatric Medicine

**American Osteopathic Board of Family Physicians**

- Geriatric Medicine

**Royal College of Physicians and Surgeons of  
Canada Certification**

- Neurology
- Psychiatry
- Geriatric Medicine
- Geriatric Psychiatry

## Referring physician qualification continued:

- Devotes a substantial proportion ( $\geq 25\%$ ) of patient contact time to the evaluation and care of adults with acquired cognitive impairment or dementia
- Completion of 30 minute online webinar:
  - Amyloid PET: Clinical Applications & Best Practices (<http://training.alz.org/products/4035/amyloid-pet-clinical-applications-and-best-practices>)

# Clinical Site Locations

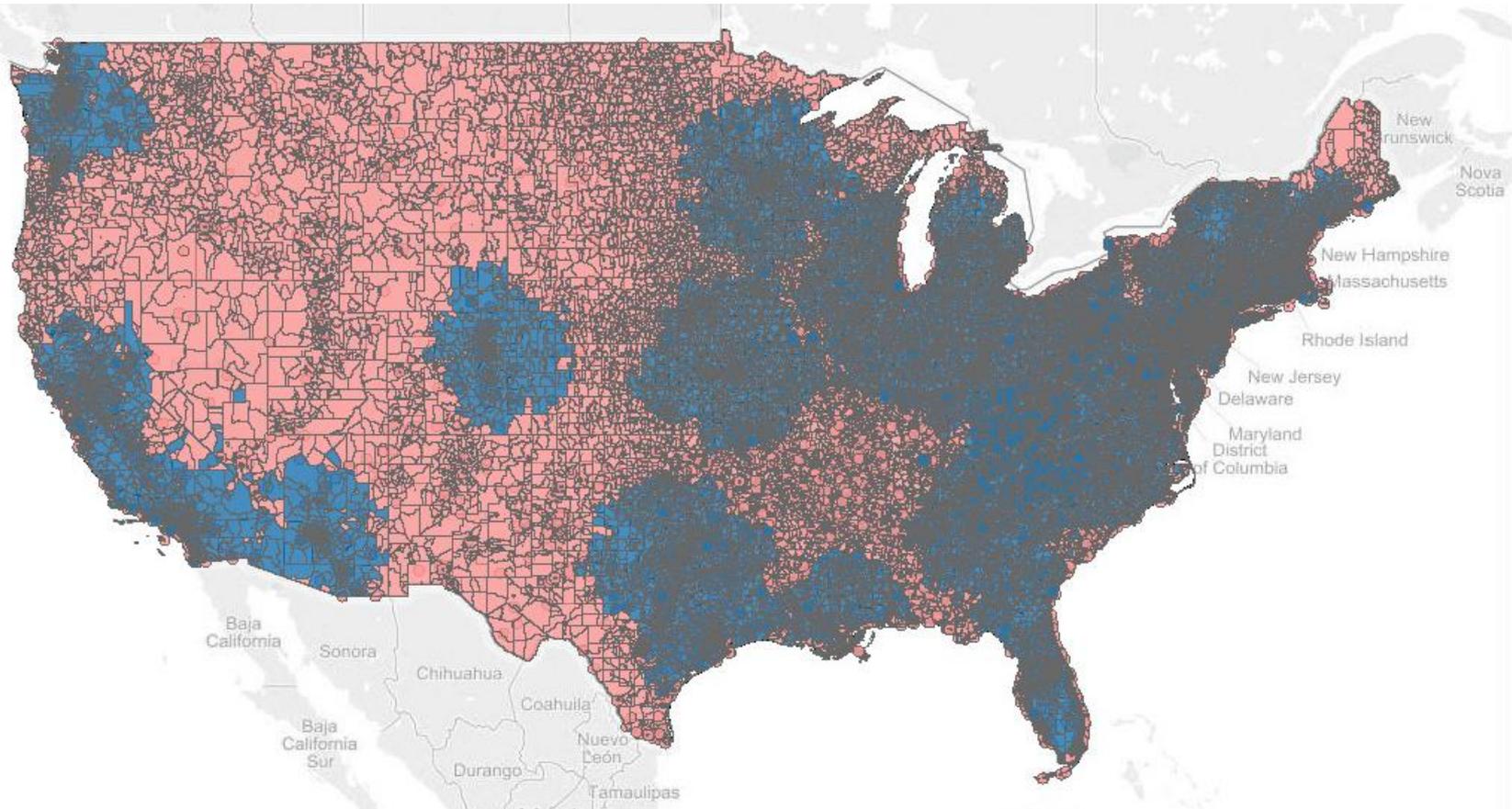
- Patients referred by Dementia Specialists must have access to a study PET Imaging facility.
- PET Imaging facility must be within 3-4 hours of an amyloid tracer supplier.
- Dementia Specialists and Imaging Sites will be posted on [ideas-study.org](https://ideas-study.org) upon study launch

# Radiopharmaceutical Production Sites

PET facilities located within 3-4 hours of location may have access to radiopharmaceuticals (Updated October 20, 2015)

Beta Amyloid Tracer Availability					
Phoenix	AZ	Chicago	IL	Hackensack	NJ
Tempe	AZ	Romeoville	IL	Totowa	NJ
Colton (Los Angeles)	CA	Indianapolis	IN	Albany	NY
Culver City (Los Angeles)	CA	New Orleans	LA	Columbus	OH
Palo Alto	CA	Boston	MA	Cleveland	OH
Sacramento	CA	Woburn	MA	Philadelphia	PA
Gilroy	CA	Haverhill	MA	Gray	TN
Denver	CO	Beltsville	MD	Dallas	TX
East Hartford	CT	Detroit	MI	Houston	TX
Ft. Lauderdale	FL	East Lansing	MI	Charlottesville	VA
Jacksonville	FL	Minneapolis	MN	Sterling	VA
Tampa	FL	Kansas City	MO	Seattle	WA
Sanford	FL	Charlotte	NC	Morgantown	WV
Atlanta	GA	Raleigh/Durham	NC		

# Where are amyloid agents available in USA?



# Consent: Patients Can “Opt Out” of Image Archiving

Your amyloid PET scan will be collected and archived at ACR, stripped of all identifying information, for use in future research. Should you not wish for your PET images to be collected and used in future research, you may opt out by initialing below. Your decision to opt out of the image collection will not affect your participation in other elements of the IDEAS Study.

\_\_\_\_\_ (insert participant or \*legally authorized representative (LAR) initials) No, I do NOT want my de-identified PET images to be collected and used in future research.

# Consent: Patients Can “Opt In” to Be Contacted About Approved Add-On Studies

The IDEAS Study is collaborating with additional research studies investigating amyloid, cognitive decline, Alzheimer’s disease and other types of dementia.

Below, please let us know if you are willing to be contacted about other research studies for which you may be a candidate.

\_\_\_\_\_ (insert participant or LAR initials) YES, I am willing to be contacted about other research studies.

\_\_\_\_\_ (insert participant or LAR initials) NO, I am not willing to be contacted about other research studies.

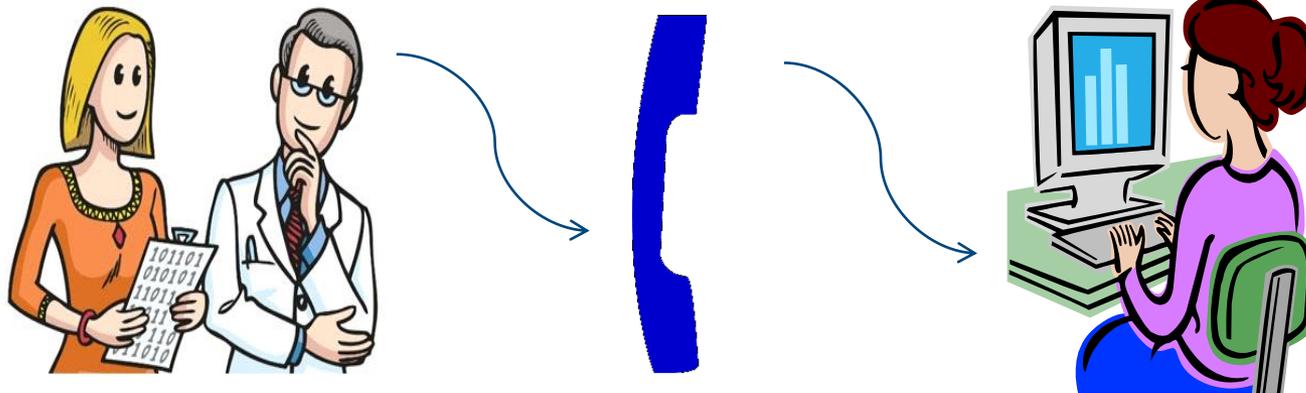
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(Authority of Legally Authorized Representative to act on behalf of Subject)

\*Authority to act on behalf of another includes, but is not limited to parent, guardian, or durable power of attorney for health care.

# Patient Registration

The referring physician or designee consents patient and schedules patient for PET scan and may enroll/register the patient on study



# Log in to IDEAS, click on Data collection.



Data Collection ▾

Practice Management ▾

Scott McGinnis ▾



## Welcome to the IDEAS Study PET Facility/Referring Physician Practice Data Center

Once the study is open to enrollment, this page will contain information regarding patient enrollment, case report form submission PET as well as image upload procedures.

Please Review the IDEAS-Study Referring Physician Site Data Submission timelines below:

- The referring dementia specialist must complete and sign the Pre-PET eCRF prior to the patient having the Amyloid PET scan. The PET scan must be completed within 30 days of the Case Registration.
- Patients must be seen by the referring physician for follow-up ~90 (75-105) days from the date of the PET scan. At that visit, the referring physician will determine the treatments, tests and medications the patient has received since the amyloid PET scan, and decide the patient's management plan going forward. These must be reported on the Post-PET Clinical Assessment Form within 15 days after the follow-up visit. Patients who have had prolonged stays in a skilled nursing unit are exempt from the visit, but the Post-PET Clinical Assessment Form is still due within 120 days after the PET scan. The form is also required for patients who die while on study.

Please Review the IDEAS-Study PET Facility Data and Image Submission timelines below:

- The PET scan must be completed within 30 days of Case Registration. The PET Facility Administrator will be informed via email when the Pre-PET Clinical Assessment Form has been submitted by the referring physician.
- Once the amyloid PET scan has been completed, the PET facility provides documentation by submitting the **Amyloid PET Completion Form** by midnight on the day the scan was performed.

# Click on register new case.



Data Collection ▾ Practice Management ▾ Scott McGinnis ▾

- Register New Case ←
- Case Registration 2
- Pre-PET 12
- Post-PET 8
- Incomplete Study

## Register New Case

Register New Case

Case Registration 2

Pre-PET 12

Post-PET 8

Incomplete Study

### Eligibility Confirmation Form

This form is to be completed with each new referral.

**I certify that all of the following are correct:**

Criteria	Answer
1. The patient is 65 years of age or older.	<input type="radio"/> Yes <input type="radio"/> No
2. The patient is a Medicare beneficiary	<input type="radio"/> Yes <input type="radio"/> No
3. The patient has had a diagnosis of MCI or dementia, according to DSM-IV and/or National Institutes of Aging-Alzheimer's Association criteria, verified by a dementia specialist within 24 months.	<input type="radio"/> Yes <input type="radio"/> No
4. The patient meets the Appropriate Use Criteria for Amyloid PET (all must be checked):	
4.1 Cognitive complaint with objectively confirmed impairment;	<input type="radio"/> Yes <input type="radio"/> No

# Complete patient information.

Register New Case

Case Registration **2**

Pre-PET **12**

Post-PET **8**

Incomplete Study

Save My Work

## Patient Information

Enter patient name as it appears on their Medicare ID card.

Eligibility status

First Name

Middle Name

Last Name

Address

City

State

Zip Code

Telephone (home)

Telephone (cell)

Email

Date Of Birth

SSN

Medicare ID

# Select location of PET scan.

Register New Case

Case Registration **2**

Pre-PET **12**

Post-PET **8**

Incomplete Study

Save My Work

SSN

Medicare ID

Patient gender  Male  Female  Other

Race (Select all that apply)

- American Indian
- Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or Pacific Islander
- White
- Not reported
- Unknown

Hispanic origin  Not Hispanic or Latino  Hispanic or Latino  Not reported  Unknown

## PET Facility where Amyloid PET has been scheduled

PET Facility Information  

Scan Date

Name of person

Person

Referring Deme

Person

8006 - Resolution Imaging, Santa Monica, CA facility

8234 - LifeScan Minnesota, iwiowieowio, AR facility

8235 - Nalex Test Facility, City1, AK facility

8236 - Teststreetstrestreetstrestreetstrestreetstrestreetstrestests

8237 - test retest, qwqwqw, ME facility

8239 - qwqwqwqwqwqw, 11111111111111, ME facility

8240 - testing pet, test, AK facility

8242 - 1295767093 Judy Yee, city of Angels, ME facility



# Submit the registration.

Register New Case

Case Registration **2**

Pre-PET **12**

Post-PET **8**

Incomplete Study

Save My Work

## PET Facility where Amyloid PET has been scheduled

PET Facility Information

8006 - Resolution Imaging, Santa Monica, CA facility



Scan Date

01/21/2016



## Name of person responsible for the data on this form

Person

Scott McGinnis

## Referring Dementia expert

Person

Scott McGinnis

## Name of person submitting this form

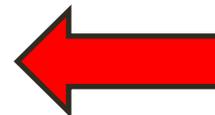
Person

Scott McGinnis

Submission Date:

Save

Submit



# Your case has been registered.

## Case #71 Mary Smith, 01/13/1950

Case Registration

Pre-PET

Register New Case

Case Registration 2

Pre-PET 13

Post-PET 8

Incomplete Study

Thank you for enrolling Case 71. We appreciate your contributions to the IDEAS Study.

Please keep these details in mind:

- The dementia specialist physician treating this patient must log into the IDEAS database and complete the Pre-PET Case Report Form for this patient within 7 days from today.
- The Pre-PET form cannot be completed unless the dementia specialist physician certifies the following: "I certify that I have discussed the medical and psychological ramifications of positive and negative amyloid scan results." Please remind the physician of this requirement.
- When the dementia specialist physician has successfully submitted the Pre-PET Case Report Form, the PET Facility you selected from the drop-down menu above will be notified that they may proceed with the scan for this patient.
- The Facility will refuse to perform the scan until they have received verification that the Pre-PET form was submitted successfully within the 7 day limit.
- The patient should return for a follow-up visit with the same dementia specialist physician 75-105 days following the completion of the Amyloid PET scan. The Post-PET form will be due following that visit. Post-PET forms should not be submitted early.

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# Once patient has been registered the following email is sent to selected PET Facility as well as Dementia Practice Administrator.

---

Practice ID#: 2005

Practice Name: Harvard

PET Facility ID#: 8006

PET Facility Name: Resolution Imaging

Patient SSN: \*\*\*\*\*456

Case #: 58

---

The above listed case has been registered on the IDEAS Study. The PET scan must be completed within 30 days of case registration. Data required for this case:

- Pre-PET Clinical Assessment Form - Must be entered within 7 days of case registration date.
- Amyloid PET Completion Form - Must be entered within 30 days of case registration date.
- Amyloid PET Report Submission Form - Must be entered within 7 days of the PET scan date.
- Amyloid PET Assessment Form - Must be entered within 7 days of the PET scan date.
- Post-PET Clinical Assessment Form - Must be entered within 15 days of the 90-day follow-up visit.
- PET scan images - Must be submitted via TRIAD within 7 days of the scan unless patient withheld consent for image collection and archive.

# Pre- PET Clinical Assessment form becomes available.

## Case Registration

Register New Case

Filter Patient First Name: Mary x Patient Status: Eligible x Available Form: Pre-PET x

Case Registration 2

Pre-PET 13

Post-PET 8

Incomplete Study

Case #	Stage	Status	Patient	Registration	Forms
40	Case Registration	OPEN	Mary Brown	01/05/2016	Case Pre Post
71	Case Registration	OPEN	Mary Smith	01/20/2016	Case Pre Post

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Registration can be completed by administrator or research staff *but*  
**Pre- and Post-PET CRFs must be completed by the dementia expert**

# Pre-PET form must be completed prior to the scan.

Register New Case

Case #71 Mary Smith, 01/13/1950

Case Registration 2

Case Registration

Pre-PET

Pre-PET 13

Post-PET 8

Incomplete Study

Save My Work

## PRE-PET CLINICAL ASSESSMENT FORM

This form is intended to capture demographic and medical history data on your patient, as well as your diagnosis and management plan prior to amyloid PET. The management plan section asks that you describe your plan as if amyloid PET Imaging were not available to your patient. This form must be submitted within 7 days of the patient's Pre-PET clinic visit.

### 1. Before patient can proceed to A $\beta$ PET scan, Dementia Expert must certify that patient is aware of the ramifications of the test.

I certify that I have discussed the medical and psychological ramifications of positive and negative amyloid scan results with the patient, family and caregivers, and they wish to proceed.

I have not discussed the medical and psychological ramifications of an amyloid scan. I understand that this makes the patient ineligible to proceed.

### 1.a. Please verify the patient meets the Appropriate Use Criteria for Amyloid PET (all must be checked):

1. Cognitive complaint with objectively confirmed impairment;

Yes  No

2. The etiologic cause of cognitive impairment is uncertain after a comprehensive evaluation by a dementia specialist, including general medical and neurological examination, mental status testing including standard measures of cognitive impairment, laboratory testing, and structural neuroimaging.

# If the medical/psychological ramifications have not been discussed with patient , they will be considered ineligible.

Register New Case

Case #71 Mary Smith, 01/13/1950

Case Registration 2

Case Registration

Pre-PET

Pre-PET 13

Post-PET 8

Incomplete Study

## PRE-PET CLINICAL ASSESSMENT FORM

This form is intended to capture demographic and medical history data on your patient, as well as your diagnosis and management plan prior to amyloid PET. The management plan section asks that you describe your plan as if amyloid PET Imaging were not available to your patient. This form must be submitted within 7 days of the patient's Pre-PET clinic visit.

Save My Work

**1. Before patient can proceed to A $\beta$  PET scan, Dementia Expert must certify that patient is aware of the ramifications of the test.**

I certify that I have discussed the medical and psychological ramifications of positive and negative amyloid scan results with the patient, family and caregivers, and they wish to proceed.

I have not discussed the medical and psychological ramifications of an amyloid scan. I understand that this makes the patient ineligible to proceed.

The patient is unaware of ramifications of scan, therefore the participant is ineligible for the IDEAS Study.

Exit

# If ramifications were discussed with patient and AUC was met, continue completing form.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work

## 1.a. Please verify the patient meets the Appropriate Use Criteria for Amyloid PET (all must be checked):

1. Cognitive complaint with objectively confirmed impairment;

Yes  No

2. The etiologic cause of cognitive impairment is uncertain after a comprehensive evaluation by a dementia specialist, including general medical and neurological examination, mental status testing including standard measures of cognitive impairment, laboratory testing, and structural neuroimaging;

Yes  No

3. Alzheimer's disease is a diagnostic consideration;

Yes  No

4. Knowledge of amyloid PET status is expected to alter diagnosis and management.

Yes  No

## Patient Demographics

### 2. Please specify marital status:

- Married or domestic partnership
- Widowed
- Divorced or separated
- Never married

# Additional questions may pop up depending on your responses.

Register New Case

## Patient Demographics

Case Registration 2

Pre-PET 13

Post-PET 8

Incomplete Study

Save My Work

### 2. Please specify marital status:

- Married or domestic partnership
- Widowed
- Divorced or separated
- Never married

### 3. Please specify living arrangements:

- Patient lives alone
- Patient lives at least with one other person

With whom does patient live (check all that apply):

- Spouse or domestic partner
- Child(ren)
- Other relative
- Caregiver/Household worker/Assisted living
- Friend/Roommate/Other



### 4. Please specify the highest level of education:

- Doctoral or professional degree
- Master's Degree
- Bachelor's Degree

# Complete patient characteristics.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work

## Patient Characteristics

### 6. Please specify the level of cognitive impairment:

- Mild cognitive impairment
- Dementia

### 7. Please enter MMSE and/or MoCA score at last clinical evaluation:

a. MMSE:

15



b. MoCA:

11



### 8. Confirm the patient's amyloid status is not known to you or the patient:

- Patient has had no prior amyloid imaging or results are not available
- Patient has had no prior CSF testing for A $\beta$ , or previous testing was equivocal

### 9. Year of onset of cognitive impairment:

2003

Year unknown

### 10. Indicate diagnostic procedures which have been performed:

#### a. Confirm these required tests have been completed:

- Basic laboratory work-up (complete metabolic panel, TSH, B12) within last 12 months (required)
- Structural brain imaging (CT or MRI) within past 24 months (required)

#### b. Indicate all of the following that have been done:

# Complete medical history.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work

## Patient Medical History

12. Please check all of the following items that are part of the patient's past or current medical history:

- No clinically relevant medical history
- At least one condition is checked below (Check all that apply):
  - Congestive Heart Failure (with or without atrial fibrillation)
  - Atrial fibrillation
  - History of acute myocardial infarction
  - Ischemic heart disease (including angina pectoris and/or prior CABG)
  - Hypertension
  - Dyslipidemia
  - Chronic Kidney Disease
  - Chronic Obstructive Pulmonary Disease
  - Diabetes
  - Active Depression
  - Bipolar Affective Disorder
  - Schizophrenia
  - Prior History of Stroke and/or Transient Ischemic Attack (TIA)
  - Cerebrovascular Disease without Stroke
  - Previous delirium
  - Epilepsy/Seizure Disorder

# You may print a copy of the differential diagnosis code table for reference.

Register New Case

Case Registration 2

Pre-PET 13

Post-PET 8

Incomplete Study

Save My Work

## Differential Diagnosis

PRIORITIZE your differential diagnosis of your patient's cognitive condition using this long list of options. For your convenience you may view the entire list in a separate window or print a copy of it for reference  [Code Table for Differential Diagnoses](#) . 

- You will be asked to SELECT the MOST likely etiologic cause of the condition.
- Then you will be asked to SELECT at least one, and up to 3, other causes from this list.

We have grouped the options by category, and alphabetized entries within category. Several categories include an option of "other." If "other" is selected, you will be asked to specify with free text the other cause of the condition.

### 13. Please enter the MOST likely etiologic cause of cognitive impairment

Nothing Selected

Select Condition

#### b. Indicate your confidence in your primary diagnosis:

Not at all  
confident

Certain

1 2 3 4 5 6 7 8 9 10

### 14. Please enter at least one (and up to 3) additional items on your current differential diagnosis, in your perceived order of likelihood:

#### a. Additional differential diagnosis

Nothing Selected

Select Condition

#### ii. Do you wish to add another diagnosis?

Yes  No

This screen will become available once you click on select condition. You make your selection here.

Differential Diagnosis

Differential Diagnoses

**Alzheimer's disease:**

- AD, clinically typical ?
- AD, clinically atypical ?
- AD, mixed pathology ?
- AD, NOS

**Non-AD neurodegenerative:**

- Chronic traumatic encephalopathy (CTE)
- Diffuse Lewy body disease
- Frontotemporal dementia ?
- Hippocampal sclerosis
- Parkinson's disease
- Vascular cognitive impairment ?
- Other non-AD neurodegenerative disease

**Other CNS conditions:**

- Auto-immune encephalopathy ?
- Brain mass
- Encephalopathy NOS
- Epilepsy
- Hydrocephalus (idiopathic or secondary)

**Cognitive changes due to normal aging**

- Cognitive changes due to normal aging ?

**Primary psychiatric disease:**

- Bipolar affective disorder
- Major depression
- Schizophrenia
- Other primary psychiatric disease

**Toxic-metabolic encephalopathy:**

- Hypoxic-ischemic encephalopathy
- Nutritional deficiency ?
- Polypharmacy or prescription drug side effects
- Primary systemic illness ?
- Substance abuse (alcohol or recreational drugs)
- Other toxic-metabolic encephalopathy

**Primary sleep disorder**

- Primary sleep disorder ?

**Other diagnosis**

- Other diagnosis

# Select at least 2 conditions.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work

We have grouped the options by category, and alphabetized entries within category. Several categories include an option of "other." If "other" is selected, you will be asked to specify with free text the other cause of the condition.

## 13. Please enter the **MOST likely etiologic cause** of cognitive impairment

Substance abuse (alcohol or recreational dru

### b. Indicate your confidence in your primary diagnosis:

Not at all  
confident

Certain

1 2 3 4 5 6 7 8 9 10

## 14. Please enter at least one (and up to 3) additional items on your current differential diagnosis, in your perceived order of likelihood:

### a. Additional differential diagnosis

AD, clinically atypical

### ii. Do you wish to add another diagnosis?

Yes  No

## 15. Please rate your estimated likelihood that AD pathology is present and causing or contributing to cognitive symptoms:

Definitely  
not

Certain

0 1 2 3 4 5 6 7 8 9 10

# Continue to management plan.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work

## 16. ASSUMING YOUR PATIENT COULD NOT HAVE AN AMYLOID PET SCAN, what would your management plan be at this time?

- Watchful waiting only (i.e. no new diagnostic tests, drug adjustments, counselling or other referrals)
- I would recommend one or more actions as noted below (Select all actions you would recommend from the list below).

## 17. DRUG THERAPIES

- a. ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time.
- b. For any drug that your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing that drug.
  - Participant not on drugs for cognitive condition, and no drug therapy is planned at this time.
  - At least one drug therapy is selected below:

## Certifications

### 18. All of the actions and prescriptions you planned are listed below. Please certify that this represents your complete management plan, if you could not order an A $\beta$ PET scan.

- o **Management Actions**
  - None
- o **Drug Therapies**
  - None

I certify that the list above is my complete management plan for this patient, assuming Amyloid PET were unavailable at this time.

I wish to make changes to my selections. Return to management plan questions.

Return

## Name of person submitting this form

Person Scott McGinnis

Submission Date:

Save

Submit

# If you have actions to recommend, the following table appears.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work



## Management Plan

16. ASSUMING YOUR PATIENT COULD NOT HAVE AN AMYLOID PET SCAN, what would your management plan be at this time?

- Watchful waiting only (i.e. no new diagnostic tests, drug adjustments, counselling or other referrals)
- I would recommend one or more actions as noted below (Select all actions you would recommend from the list below).

MANAGEMENT ACTIONS	Would you recommend this action? For this question, you should assume that the patient DOES NOT HAVE ACCESS TO AMYLOID PET
<b>Counseling for safety, planning &amp; social support</b>	
Counseling about safety precautions (home safety, medication monitoring, driving)	<input checked="" type="checkbox"/> Recommend
Counseling about financial/medical decision making, advanced directives	<input type="checkbox"/> Recommend
Referral to community patient/caregiver support resources (e.g. social work, Alzheimer's Association, Family caregiver Alliance, etc.)	<input checked="" type="checkbox"/> Recommend
Other (specify)	<input type="checkbox"/> Recommend
<b>Additional diagnostic procedures</b>	
Neuropsychological testing referral	<input type="checkbox"/> Recommend
<b>Imaging (brain/head)</b>	
CT/CTA with/without contrast	<input type="checkbox"/> Recommend
MRI/MRA with/without contrast	<input type="checkbox"/> Recommend
Brain FDG-PET	<input type="checkbox"/> Recommend

# Pre-PET Management: A World Without Amyloid PET

- Pre-PET management plan should include all your recommendations based on available clinical data, *assuming amyloid PET was not available.*
- We recognize that in practice some recommendations will be deferred until amyloid status is determined.

# If you have drug therapies to recommend or which the patient is currently taking, the following table appears so you may record them.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work

## 17. DRUG THERAPIES

- ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time.
- For any drug that your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing that drug.
  - Participant not on drugs for cognitive condition, and no drug therapy is planned at this time.
  - At least one drug therapy is selected below:

DRUG DESCRIPTION	ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time.	For any drug that your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing that drug.
<b>AD Symptomatic Drugs</b>		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	<input type="radio"/> Currently taking <input type="radio"/> Recommended	
Memantine	<input type="radio"/> Currently taking <input type="radio"/> Recommended	
<b>Neuropsychiatric drugs impacting cognition</b>		
Anti-depressants, mood stabilizers	<input type="radio"/> Currently taking <input type="radio"/> Recommended	
Anti-psychotics	<input type="radio"/> Currently taking <input type="radio"/> Recommended	

# An additional question will appear for any drugs you reported the patient is currently taking.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

Save My Work

## 17. DRUG THERAPIES

- a. ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time.
- b. For any drug that your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing that drug.
- Participant not on drugs for cognitive condition, and no drug therapy is planned at this time.
  - At least one drug therapy is selected below:

DRUG DESCRIPTION	ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate all drugs that your patient is currently taking OR that you recommend starting at this time.	For any drug that your patient is already taking, and STILL ASSUMING THAT AMYLOID PET WERE NOT AVAILABLE, indicate your plan for managing that drug.
<b>AD Symptomatic Drugs</b>		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	<input checked="" type="radio"/> Currently taking <input type="radio"/> Recommended	<input checked="" type="radio"/> Continue <input type="radio"/> Adjust <input type="radio"/> Stop
Memantine	<input type="radio"/> Currently taking <input type="radio"/> Recommended	
<b>Neuropsychiatric drugs impacting cognition</b>		
Anti-depressants, mood stabilizers	<input type="radio"/> Currently taking	

# Once you have completed the management and drug therapy sections following appears showing what your selected responses are.

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

[Save My Work](#)

## Certifications

18. All of the actions and prescriptions you planned are listed below. Please certify that this represents your complete management plan, if you could not order an A $\beta$  PET scan.

- o **Management Actions**
  - None
- o **Drug Therapies**
  - Cholinesterase inhibitors (donepezil, rivastigmine, galantamine), Currently taking, Continue
  - Sedatives/sleep aids, Recommended

I certify that the list above is my complete management plan for this patient, assuming Amyloid PET were unavailable at this time.

I wish to make changes to my selections. Return to management plan questions.

[Return](#)

Name of person submitting this form

Person Scott McGinnis

Submission Date:

[Save](#) [Submit](#)

**At this point you may either certify and submit the form or decide to make changes. If you select return, you will be taken back to the management and drug therapy sections.**

Register New Case

Case Registration **2**

Pre-PET **13**

Post-PET **8**

Incomplete Study

## Certifications

**18. All of the actions and prescriptions you planned are listed below. Please certify that this represents your complete management plan, if you could not order an A $\beta$  PET scan.**

- o **Management Actions**
  - None
- o **Drug Therapies**
  - Cholinesterase inhibitors (donepezil, rivastigmine, galantamine), Currently taking, Continue
  - Sedatives/sleep aids, Recommended

Save My Work

I certify that the list above is my complete management plan for this patient, assuming Amyloid PET were unavailable at this time.

I wish to make changes to my selections. Return to management plan questions.

Return

Name of person submitting this form

Person Scott McGinnis

Submission Date:

Save

Submit

# Coordination Between Dementia Expert, PET Facility and ACRIN

- PET facility notified via email when pre-PET form done and scan can be scheduled
- Dementia expert notified via email when PET facility completes scan and associated forms
- Dementia expert notified via email when post-PET form is available online

# Select the Post-PET form for the case.

## Case Registration

Register New Case

Case Registration 2

Pre-PET 12

Post-PET 8

Incomplete Study

+ Filter NPI: 1912932906 x Patient Status: Eligible x Available Form: Post-PET x

Case #	Stage	Status	Patient	Registration	Forms
25	PET Completed	OPEN	Elvis Presley	12/23/2015	Case Pre Post
28	PET Completed	OPEN	Jack Boxer	12/24/2015	Case Pre Post
29	PET Completed	OPEN	Mary Poppins	12/29/2015	Case Pre Post
30	PET Completed	OPEN	Johnny Appleseed	12/29/2015	Case Pre Post
39	PET Completed	OPEN	John Snow	01/04/2016	Case Pre Post
54	PET Completed	OPEN	Cary Grant	01/07/2016	Case Pre Post
55	PET Completed	OPEN	Marilyn Monroe	01/07/2016	Case Pre Post
64	PET Completed	OPEN	Glenn Frey	01/19/2016	Case Pre Post



# Complete follow-up status.

Register New Case

Case Registration **2**

Pre-PET **12**

Post-PET **8**

Incomplete Study

Save My Work

Case #29 Mary Poppins, 12/15/1940

Case Registration

Pre-PET

Post-PET

## POST-PET CLINICAL ASSESSMENT FORM

This form is used to record the revised diagnosis and actual management plan at 90 days post-PET clinical visit (allowable range is 75-105 days), now incorporating amyloid PET results.

### Follow-up Visit Status

If 90-day follow-up cannot be completed because the patient died, withdrew from care by the dementia specialist, withdrew consent, or was lost to follow-up, the specific reasons must be recorded below.

#### 1. Was the follow-up visit completed?

- No (Complete question below, then complete the rest of the form with any information you have about your plan for this patient..)
- Yes

#### 2. Please specify the results of the amyloid PET scan, as you understand them (select one):

- Positive for cortical beta-amyloid
- Equivocal / Indeterminate for cortical beta amyloid
- Negative for cortical beta-amyloid
- Uninterpretable or technically inadequate study

# If follow-up visit not completed select most important reason.

Register New Case

## POST-PET CLINICAL ASSESSMENT FORM

Case Registration 2

This form is used to record the revised diagnosis and actual management plan at 90 days post-PET clinical visit (allowable range is 75-105 days), now incorporating amyloid PET results.

Pre-PET 12

### Follow-up Visit Status

Post-PET 8

Incomplete Study

If 90-day follow-up cannot be completed because the patient died, withdrew from care by the dementia specialist, withdrew consent, or was lost to follow-up, the specific reasons must be recorded below.

Save My Work

#### 1. Was the follow-up visit completed?

- No (Complete question below, then complete the rest of the form with any information you have about your plan for this patient..)

**Specify the reason the 90-day follow up was not completed (check the most important reason):**

- Participant died

Date of death

 /  / 

- Date of death unknown

- Withdrew from care of dementia specialist
- Withdrew consent for participation in the IDEAS Study
- Was lost to follow up (Dementia expert or designee is expected to make a minimum of three attempts to contact participant and/or proxy before declaring the participant lost the follow-up.)

- Yes

#### 2. Please specify the results of the amyloid PET scan, as you understand them (select one):

# If any adverse effects reported please list them here.

Days since PET scan 21

If days since PET scan < 75 or > 105, indicate the reason(s) follow-up visit was not completed within the expected timeframe, and then complete the rest of the form:

- Patient or caregiver was unable to make arrangements to return within window
- Patient developed intercurring illness that prevented return within window
- Dementia specialist was unavailable within window
- Other, specify

2. Please specify the results of the amyloid PET scan, as you understand them (select one):

- Positive for cortical beta-amyloid
- Equivocal / Indeterminate for cortical beta amyloid
- Negative for cortical beta-amyloid
- Uninterpretable or technically inadequate study

3. Did the patient, family or proxy report any adverse effects due to learning amyloid scan result?

- No (Skip to question 4)
- Yes (Please describe the adverse effects of learning results of amyloid PET scan)



# Complete differential diagnosis.

Register New Case

Case Registration **2**

Pre-PET **12**

Post-PET **8**

Incomplete Study

Save My Work

## 4. Please enter the **MOST likely etiologic cause** of cognitive impairment

AD, clinically atypical

Select Condition

### b. Indicate your confidence in your primary diagnosis:

Not at all  
confident

Extremely  
confident

1

2

3

4

5

6

7

8

9

10



## 5. Please enter at least one (and up to 3) additional items on your current differential diagnosis, in your perceived order of likelihood:

### a. Additional differential diagnosis

Substance abuse (alcohol or recreational dru

Select Condition

### ii. Do you wish to add another diagnosis?

Yes  No

## 6. Please rate your estimated likelihood that AD pathology is present and causing or contributing to cognitive symptoms:

Not at  
all likely

Extremely  
likely

1

2

3

4

5

6

7

8

9

10



# See your selections.

## Differential Diagnoses

### Alzheimer's disease:

- AD, clinically typical ?
- AD, clinically atypical ? **Most Likely**
- AD, mixed pathology ?
- AD, NOS

### Non-AD neurodegenerative:

- Chronic traumatic encephalopathy (CTE)
- Diffuse Lewy body disease
- Frontotemporal dementia ?
- Hippocampal sclerosis
- Parkinson's disease
- Vascular cognitive impairment ?
- Other non-AD neurodegenerative disease

### Other CNS conditions:

- Auto-immune encephalopathy ?
- Brain mass
- Encephalopathy NOS
- Epilepsy
- Hydrocephalus (idiopathic or secondary)
- Infectious encephalopathy ?
- Multiple sclerosis

### Cognitive changes due to normal aging

- Cognitive changes due to normal aging ?

### Primary psychiatric disease:

- Bipolar affective disorder
- Major depression
- Schizophrenia
- Other primary psychiatric disease

### Toxic-metabolic encephalopathy:

- Hypoxic-ischemic encephalopathy
- Nutritional deficiency ?
- Polypharmacy or prescription drug side effects
- Primary systemic illness ?
- Substance abuse (alcohol or recreational drugs)

### Additional #1

- Other toxic-metabolic encephalopathy

### Primary sleep disorder

- Primary sleep disorder ?

### Other diagnosis

- Other diagnosis

# Complete the Management Plan post scan.

Register New Case

## Management Plan

Case Registration 2

Pre-PET 12

Post-PET 8

Incomplete Study

Save My Work

**7. Please indicate any actions that are part of your current management plan, AND report the status of all items that you had indicated on the Pre-PET Clinical Assessment form (highlighted). For items not selected on the Pre-PET form, indicate all actions that 1) have been implemented, 2) are currently recommended and are pending, and 3) you recommended, but which your patient deferred or refused. List all items you would recommend, regardless of patient preference.**

- The Pre-PET management plan was watchful waiting, and that continues to be the plan. No new diagnostic tests, drug adjustments, counseling or referrals have occurred since the PET scan, and none are planned now.
- The Pre-PET management plan was watchful waiting, but there have been new actions implemented or recommended.

**8. Check all drugs therapies for your patient's cognitive condition that are currently recommended or which were recommended prior to the PET(highlighted). For each of these, indicate a) the current status of the therapies, and b) if status changed since PET, whether the change is due to the PET results**

- Drug therapy was not the plan but now is.
- No drug therapies other than ones reported on the Pre-PET form have been implemented or recommended. *(Please report the status of each action from the Pre-PET form highlighted in green below.)*
- The drug therapy plan includes at least one new item. *(Please report all new actions implemented or recommended, and also report the status of each action reported on the Pre-PET, highlighted in green below.)*

Items highlighted in green were selected on Pre-PET form

DRUG DESCRIPTION	Status of Drug	Did the amyloid PET results contribute significantly to this decision?
<b>AD Symptomatic Drugs</b>		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	<input type="radio"/> Started <input type="radio"/> Continued <input type="radio"/> Adjusted <input type="radio"/> Stopped <input type="radio"/> Never started, patient refused or deferred <input type="radio"/> Never started, physician changed recommendation	

# Note additional question regarding Amyloid PET results.

Register New Case

Case Registration **2**

Pre-PET **12**

Post-PET **8**

Incomplete Study

Save My Work

(of each action from the Pre-PET form highlighted in green below.)

- The drug therapy plan includes at least one new item. (Please report all new actions implemented or recommended, and also report the status of each action reported on the Pre-PET, highlighted in green below.)

Items highlighted in green were selected on Pre-PET form

DRUG DESCRIPTION	Status of Drug	Did the amyloid PET results contribute significantly to this decision?
<b>AD Symptomatic Drugs</b>		
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	<input checked="" type="radio"/> Started <input type="radio"/> Continued <input type="radio"/> Adjusted <input type="radio"/> Stopped <input type="radio"/> Never started, patient refused or deferred <input type="radio"/> Never started, physician changed recommendation	<input checked="" type="radio"/> Yes <input type="radio"/> No



# Verify your selections.

9. A list of the Management Actions and Medications you selected on the Pre-PET form, the status of those actions as indicated above, and additional actions selected above appear in the boxes below. Please certify that these represent your complete

Pre-PET Actions/Drugs	Status of Pre-PET Actions/Drugs
Cholinesterase inhibitors (donepezil, rivastigmine, galantamine)	Started

New Post-PET Actions/Drugs	Status of Post-PET Actions/Drugs
----------------------------	----------------------------------



I certify that the list above is my complete management plan for this patient, and that the status of items I had selected on the Pre-PET form are accurate.

I wish to make changes to my selections. Return to question 7.

Return

Name of person submitting this form

Person Scott McGinnis

Submission Date:

Save

Submit



Imaging Dementia—Evidence  
For Amyloid Scanning

## *Case Reimbursement Information*



THE BRAINS BEHIND SAVING YOURS.®

# Case Reimbursement

## Case Report Form (CRF) Data Collection Timelines and Per Case Payment

Form	Completed By:	Due Date Requirements	Payment
Case Registration Form	Dementia Specialist or Registrar	After consent	\$0
Pre-PET Form (Medical History and Clinical Assessment Form)	Dementia Specialist (must log into website and complete on line)	No more than 30 days before amyloid PET scan	\$225
Post-PET Form (Clinical Assessment Form)	Same Dementia Specialist as Completed Pre-PET Forms	Fifteen 15 days after completion of the Post-PET 90-Day Visit  (The Post-PET Form will be required only for the first 11,050 participants.)	\$525

# Indirect Cost Rate Policy

*The IDEAS Study Referring Physician Site Agreement has been budgeted with a maximum recommended 25% indirect cost, or overhead, rate to amplify the direct cost funding available to the dementia specialist practice. Acceptance of this maximum indirect cost rate is appreciated, but not mandatory. Total reimbursement dollars per case, assuming submission of all case report forms, is capped at \$750. No additional funding is available should the actual overhead rate at a participating site exceed the 25% indirect cost rate.*

# Case Reimbursement

- Via Bank of America directly into site banking account
- Monthly frequency

# Case Reimbursement

(not available until March)

- Secure user role in the IDEAS database for site financial staff
- Site submits:
  - W9 information (electronically)
  - Bank routing/account number
- Direct payment into account, no checks

# Security Enhancement for Site Registration

- [www.ideas-study.org](http://www.ideas-study.org)
- Instructions/screenshots on Jan 7 from IDEAS-Study
- ACR ID and temporary password sent to all users on Jan 14 from ACR Support
- May be in SPAM
- Using temporary password provided, user needs to establish a permanent password

# iDEAS

Imaging Dementia—Evidence  
For Amyloid Scanning

IDEAS-Study@acr.org  
IDEAS-Study.org



IDEAS Steering Committee  
Inaugural Meeting, June 18, 2015

**ACR**<sup>®</sup>  
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RADIOLOGY

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