



CTSA Engagement Packet

(New IDEAS Study)

Study Title	Imaging Dementia-Evidence for Amyloid Scanning Study
RIC POC	Mariela Rodriguez: mariela.rodriguez@vumc.org
Date of Request	11/04/2019
Principal Investigator	Dr. Gil Rabinovici
Therapeutic Area	Neurodegeneration
Funding Status	Post-Award
Project Status	Funded
Anticipated Number of Sites	100+
Population Size	7000
Does this packet include a request for Protocol Review ?	No
Does this packet include a request for Budget Review ?	No
Does this packet include an EHR Based Cohort Assessment ?	Yes
Does this packet include a request to identify site investigators ?	Yes
What is the response due date ?	12/13/2019

100RIC: EHR-Based Cohort Assessment Request

General Information and Instruction Package
CTSA Liaison Teams and Informatics Representatives

Imaging Dementia-Evidence for Amyloid Scanning Study (New IDEAS Study)

Protocol Summary	The original Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study evaluated the impact of beta-amyloid (A β) PET on patient-oriented outcomes in Medicare beneficiaries aged ≥ 65 with Mild Cognitive Impairment (MCI) or atypical dementia meeting Appropriate Use Criteria (AUC) for amyloid imaging. The over-arching goal of the New IDEAS Study is to inform amyloid PET coverage decisions by studying the association of amyloid PET images with changes in patient management in a broad and diverse population of Medicare beneficiaries with cognitive impairment. New IDEAS is an observational, open-label, longitudinal cohort study and will address gaps in the original IDEAS Study by emphasizing recruitment of 4000 Blacks/African Americans and Latinos/Hispanics, adding Medicare beneficiaries with early-onset (age < 65) cognitive impairment and comparing rates of changes in management in patients with typical versus atypical clinical presentations. The study adds saliva collection for genotyping of ApoE, an important risk factor for brain amyloidosis, in all participants. Additional objectives of the study are to establish a biorepository of plasma and DNA samples and to archive PET images from study participants who consent to these optional elements. All referrals to the study and for amyloid PET will come from dementia specialist who will confirm eligibility.
Investigator Team Information	Dr. Gil Rabinovici
Project Status	Funded
Funding Status	Post-Award
Expected Number of Sites	100+
Timeline for EHR Cohort	11/04/2019-12/13/2019
General Contact Information for Study Related Questions	Mariela Rodriguez: mariela.rodriguez@vumc.org
Informatics Team Contact for EHR-based Cohort Assessment	Bethany Drury: bethany.drury@vumc.org
Instructions for EHR-based data interrogation	https://redcap.vanderbilt.edu/surveys/?s=83ALWHD7DP
Was this phenotype run through TriNetX?	No
Was this phenotype run on ACT-SHRINE?	No

**RIC Cohort Assessment
New IDEAS Study**

Case 1

INCLUDE:

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ICD code (one or more occurring 1/1/2017-6/30/2019):

ICD-9	MCI	ICD-10	MCI
331.83	Mild cognitive impairment	G31.84	Mild cognitive impairment

OR

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ICD code (Any two or more unique codes in record between 1/1/2017-6/30/2019)

ICD-9	AD Neurodegenerative	ICD-10	AD neurodegenerative
331.0*	Alzheimer's Disease	G30*	Alzheimer's disease
	Non-AD neurodegenerative		Non-AD neurodegenerative
331.82	Dementia w Lewy bodies	G31.83	Dementia with Lewy Bodies
331.19	Other frontotemporal dementia	G31.09	Other frontotemporal dementia
331.82	Dementia with Lewy Bodies	G31.0	Frontotemporal dementia
331.6	Corticobasal degeneration	G31.85	Corticobasal degeneration
331.2	Senile degeneration of brain, not elsewhere classified	G31.1	Senile degeneration of brain, not elsewhere classified
348.81	Temporal sclerosis	G93.81	Hippocampal sclerosis

OR

ICD code (Any three or more of the following codes in record between 1/1/2017-6/30/2019)

ICD-9	Unspecified dementia	ICD-10	Unspecified dementia
290	Dementias	F03.90	Unspecified dementia without behavioral disturbance
290.1	Pre-senile dementia		
290.11	Pre-senile dementia with delirium	F04	Amnesic disorder due to known physiological condition
290.12	Pre-senile dementia with delusion features	F02.80	Dementia in other diseases classified elsewhere without behavioral disturbance

290.13	Pre-senile dementia with depressive feature	F02.81	Dementia in other diseases classified elsewhere with behavioral disturbance
290.2	Senile dementia with delusional features	F03.91	Unspecified dementia with behavioral disturbance
290.21	Senile dementia with delusional or depressive features		
290.3	Senile dementia with delirium		
294	(Persistent) amnesic disorder due to conditions classified elsewhere		
294.1	Dementia classified elsewhere	F06.8	Other specified mental disorders due to known physiological condition
294.11	Dementia classified elsewhere with behavioral disturbance		
294.2	Dementia, unspecified		
294.20	Dementia, unspecified, without behavioral disturbance	G31.1	Senile degeneration of the brain, not elsewhere classified
294.8	Other persistent mental disorders due to conditions classified elsewhere	G31.9	Degenerative disease of nervous system, unspecified
294.9	Unspecified persistent mental disorders due to conditions classified elsewhere		
312.9	Unspecified disturbance of conduct		
780.97	Altered mental status		
	Vascular cognitive impairment		Vascular cognitive impairment
290.4	Vascular dementia	F01.50	Vascular dementia without behavioral disturbance
290.41	Vascular dementia with delirium	F01.51	Vascular dementia with behavioral disturbance
290.42	Vascular dementia with delusions	I69.9	Unspecified sequelae of unspecified cerebrovascular disease (Cognitive deficit due to preceding CVA)
290.43	Vascular dementia with depression	I69.31	Cognitive deficit s/p CVA

WHERE

Qualifying codes occur in two or more separate financial encounters

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Count 1= Total

Case 2

Starting from Case 1 population

Current Primary Insurance = Medicare

OR

Most recent insurance = Medicare

Count 2= Total

Case 3

Starting from Case 2 population

CPT Code (one or more in record between 1/1/2017-6/30/2019)

70460	CT Head W/ Contrast
70450	CT Head W/O Contrast
70470	CT Head W W/O Contrast
70551	MRI Brain W/O Contrast
71553	MRI Brain W W/O Contrast

AND

Lab (One or more of the following lab in record between 6/1/2018-6/30/2019):

Lab Name	LOINC Code
Comprehensive Metabolic Panel, Serum or Plasma	24322-0

Count 3= Total

Case 4

Starting from Case 3 population

EXCLUDE:**Vital Status:** Known Deceased**OR****ICD Code (one or more at any time in record):**

ICD-9	ICD-10	Description
140*	C00*	Malignant neoplasm of external upper lip
141*	C01*	Malignant neoplasm of base of tongue
142*	C02*	Malignant neoplasm of major salivary glands
143*	C03*	Malignant neoplasm of gum
144*	C04*	Malignant neoplasm of floor of mouth
145*	C05*	Malignant neoplasm of other and unspecified parts of mouth
146*	C06*	Malignant neoplasm of oropharynx
147*	C07*	Malignant neoplasm of nasopharynx
148*	C08*	Malignant neoplasm of hypopharynx
149*	C09*	Malignant neoplasm of other and ill-defined sites within the lip, oral cavity, and pharynx
150*	C10*	Malignant neoplasm of esophagus
151*	C11*	Malignant neoplasm of stomach
152*	C12*	Malignant neoplasm of small intestine, including duodenum
153*	C13*	Malignant neoplasm of colon
154*	C14*	Malignant neoplasm of rectum, rectosigmoid junction, and anus
155*	C15*	Malignant neoplasm of liver and intrahepatic bile ducts
156*	C16*	Malignant neoplasm of gallbladder and extrahepatic bile ducts
157*	C17*	Malignant neoplasm of pancreas
158*	C18*	Malignant neoplasm of retroperitoneum and peritoneum
159*	C19*	Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum
160*	C20*	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
161*	C21*	Malignant neoplasm of larynx
162*	C22*	Malignant neoplasm of trachea, bronchus, and lung
163*	C23*	Malignant neoplasm of pleura
164*	C24*	Malignant neoplasm of thymus, heart, and mediastinum
165*	C25*	Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs
	C26*	Malignant neoplasm of intestinal tract, part unspecified
170*	C30*	Malignant neoplasm of bone and articular cartilage
171*	C31*	Malignant neoplasm of connective and other soft tissue
174*	C32*	Malignant neoplasm of female breast
175*	C33*	Malignant neoplasm of male breast
176*	C34*	Kaposi's sarcoma

179*		Malignant neoplasm of uterus, part unspecified
180*		Malignant neoplasm of cervix uteri
181*	C37*	Malignant neoplasm of placenta
182*	C38*	Malignant neoplasm of body of uterus
183*	C39*	Malignant neoplasm of ovary and other uterine adnexa
184*	C40*	Malignant neoplasm of other and unspecified female genital organs
185*	C41*	Malignant neoplasm of prostate
186*	C45*	Malignant neoplasm of testis
187*	C46*	Malignant neoplasm of penis and other male genital organs
188*	C47*	Malignant neoplasm of bladder
189*	C48*	Malignant neoplasm of kidney and other and unspecified urinary organs
190*	C49*	Malignant neoplasm of eye
191*	C50*	Malignant neoplasm of brain
192*	C51*	Malignant neoplasm of other and unspecified parts of nervous system
193*	C52*	Malignant neoplasm of thyroid gland
194*	C53*	Malignant neoplasm of other endocrine glands and related structures
195*	C54*	Malignant neoplasm of other and ill-defined sites
196*	C55*	Secondary and unspecified malignant neoplasm of lymph nodes
197*	C56*	Secondary and unspecified malignant neoplasm of respiratory and digestive systems
198*	C57*	Secondary and unspecified malignant neoplasm of other specified sites
199*	C58*	Malignant neoplasm without specification of site
200*		Lymphosarcoma and reticulosarcoma and other specified malignant tumors of lymphatic tissue
201*	C60*	Hodgkin's disease
202*	C61*	Other malignant neoplasms of lymphoid and histiocytic tissue
203*	C62*	Multiple myeloma and immunoproliferative neoplasms
204*	C63*	Lymphoid leukemia
205*	C64*	Myeloid leukemia
206*	C65*	Monocytic leukemia
207*	C66*	Other specified leukemia
208*	C67*	Leukemia of unspecified cell type
209*	C68*	Neuroendocrine tumors
210*	C69*	Benign neoplasm of lip, oral cavity, and pharynx
211*	C70*	Benign neoplasm of other parts of digestive system
212*	C71*	Benign neoplasm of respiratory and intrathoracic organs
213*	C72*	Benign neoplasm of bone and articular cartilage
214*	C73*	Lipoma
215*	C74*	Other benign neoplasm of connective and other soft tissue
216*	C75*	Benign neoplasm of skin
217*	C76*	Benign neoplasm of breast
218*	C77*	Uterine leiomyoma
219*	C78*	Other benign neoplasm of uterus

220*	C79*	Benign neoplasm of ovary
221*	C80*	Benign neoplasm of other female genital organs
222*	C81*	Benign neoplasm of male genital organs
223*	C82*	Benign neoplasm of kidney and other urinary organs
224*	C83*	Benign neoplasm of eye
225*	C84*	Benign neoplasm of brain and other parts of nervous system
226*	C85*	Benign neoplasm of thyroid glands
227*	C86*	Benign neoplasm of other endocrine glands and related structures
228*		Hemangioma and lymphangioma, any site
229*	C88*	Benign neoplasm of other and unspecified sites
230*		Carcinoma in situ of digestive organs
231*	C90*	Carcinoma in situ of respiratory system
232*	C91*	Carcinoma in situ of skin
233*	C92*	Carcinoma in situ of breast and genitourinary system
234*	C93*	Carcinoma in situ of other and unspecified sites
235*	C94*	Neoplasm of uncertain behavior of digestive and respiratory systems
236*	C95*	Neoplasm of uncertain behavior of genitourinary organs
237*	C96*	Neoplasm of uncertain behavior of endocrine glands and nervous system
238*	D00*	Neoplasm of uncertain behavior of other and unspecified sites and tissues
239*	D01*	Neoplasm of unspecified nature
	D03*	Melanoma in situ
	D04*	Carcinoma in situ of skin
	D05*	Lobular carcinoma in situ of breast
	D06*	Carcinoma in situ of cervix uteri
	D07*	Carcinoma in situ of other and unspecified genital organs
	D09*	Carcinoma in situ of other and unspecified sites
	D37*	Neoplasm of uncertain behavior of oral cavity and digestive organs
	D38*	Neoplasm of uncertain behavior of middle ear and respiratory and intrathoracic organs
	D39*	Neoplasm of uncertain behavior of female genital organs
	D40*	Neoplasm of uncertain behavior of male genital organs
	D41*	Neoplasm of uncertain behavior of urinary organs
	D42*	Neoplasm of uncertain behavior of meninges
	D43*	Neoplasm of uncertain behavior of brain and central nervous system
	D44*	Neoplasm of uncertain behavior of endocrine glands
	D45*	Polycythemia vera
	D46*	Myelodysplastic syndromes
	D47*	Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
	D48*	Neoplasm of uncertain behavior of other and unspecified sites
	D49*	Neoplasm of uncertain behavior

OR

ICD code (one or more code occurring between 1/1/2018-6/30/2019):

ICD-9		ICD-10	
808*	Fracture of Pelvis	S32*	Fracture of lumbar spine and pelvis
		S72*	Fracture of femur
		S77*	Crushing injury of hip and thigh

OR**CPT code (one or more code occurring between 1/1/2017-6/30/2019):**

CPT Code	Code Description
77401	Radiation treatment delivery, superficial and/or orthovoltage
77402	Radiation Treatment Delivery
77407	Radiation Treatment Delivery
77412	Radiation Treatment Delivery
77422	Neutron Beam Treatment Delivery
77423	Neutron Beam Treatment Deliver
77424	IORT
77425	IORT
77427	Radiation Treat
77520	Proton Treatment Delivery
77525	Proton Treatment Delivery

Count Case 4: Unique Patient Count=**Count 4 broken down by Sex:**

Male	Female	Unknown

Count 4 broken down by Race:

White	Black or African American	American Indian or Alaska Native	Asian	Pacific Islander	Other	Unknown

Count 4 broken down by Ethnicity:

Hispanic/Latino	Not Hispanic/Latino	Unknown