

Characterizing the evolving diagnostic biomarker landscape in ADRD: An update from the PARADE Study

INTRODUCTION

The PARADE Study aims to inform two key gaps in our understanding of the clinical impact of diagnostic biomarkers:

1. the range and duration of psychological responses to a biomarker-informed diagnoses, and
2. the support needs of patients and their families.

Launched in 2023, PARADE was designed as an “add on” to the CMS Coverage with Evidence Determination (CED) New IDEAS study. Halting of the amyloid PET CED forced a major protocol amendment but also coincided with key changes in the landscape of clinical biomarker use.

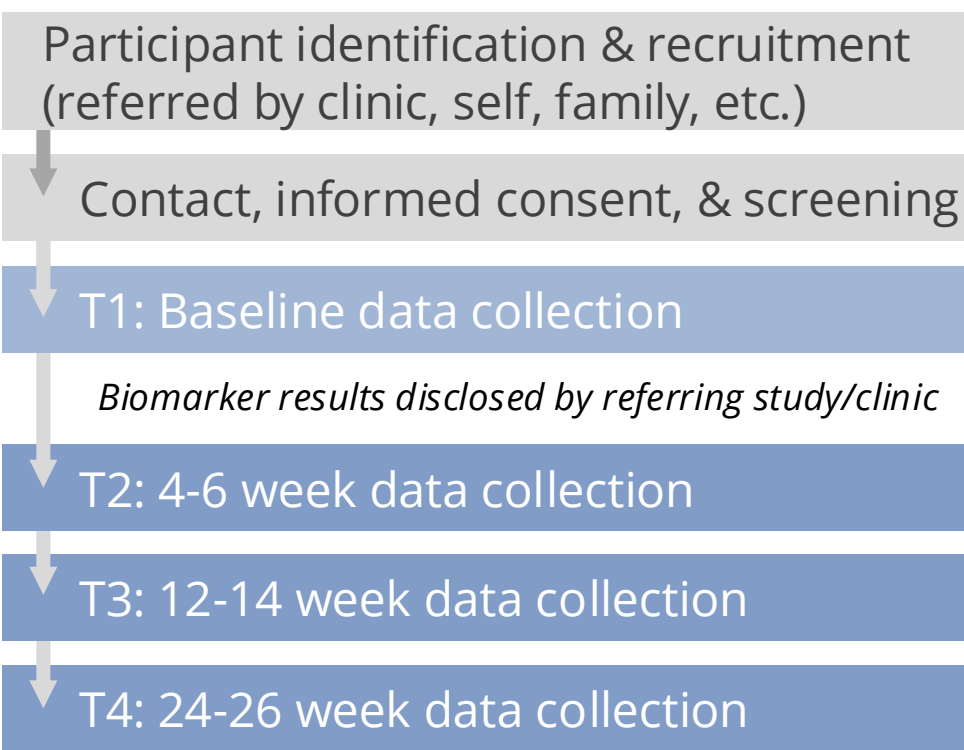
AIMS

1. Quantify the emotional response to biomarker-informed ADRD diagnoses and determine which clinical or demographic factors are associated with specific responses
2. Characterize the “value of knowing” one’s AD biomarker status

METHODS

In the time since CMS retired the CED for amyloid PET in late 2023, regulatory milestones have been achieved and the clinical use of other biomarkers have expanded, creating opportunity for PARADE to evolve with clinical practice and provide the most timely and relevant data possible.

Figure 1. Study flow



The study’s amended protocol recruits from a mix of academic and non-academic clinical sites, with geographic spread across the continental US (Figure 2).

The amended protocol carefully captures the complement of biomarker tests performed for each participant:

- amyloid PET
- tau PET
- cerebrospinal fluid (CSF) biomarkers
- plasma biomarkers

The primary outcome remains the Impact of Events Scale (IES) and enrollment is still planned to include at least 500 English- or Spanish-speaking dyads. Additional data collection includes the modality and duration of biomarker results disclosure, psychological wellness, the value of biomarker testing, and the perceived social support needs of participants and their family members.

RESULTS

Figure 2. Geographic locations of PARADE referral sites and enrolled participants

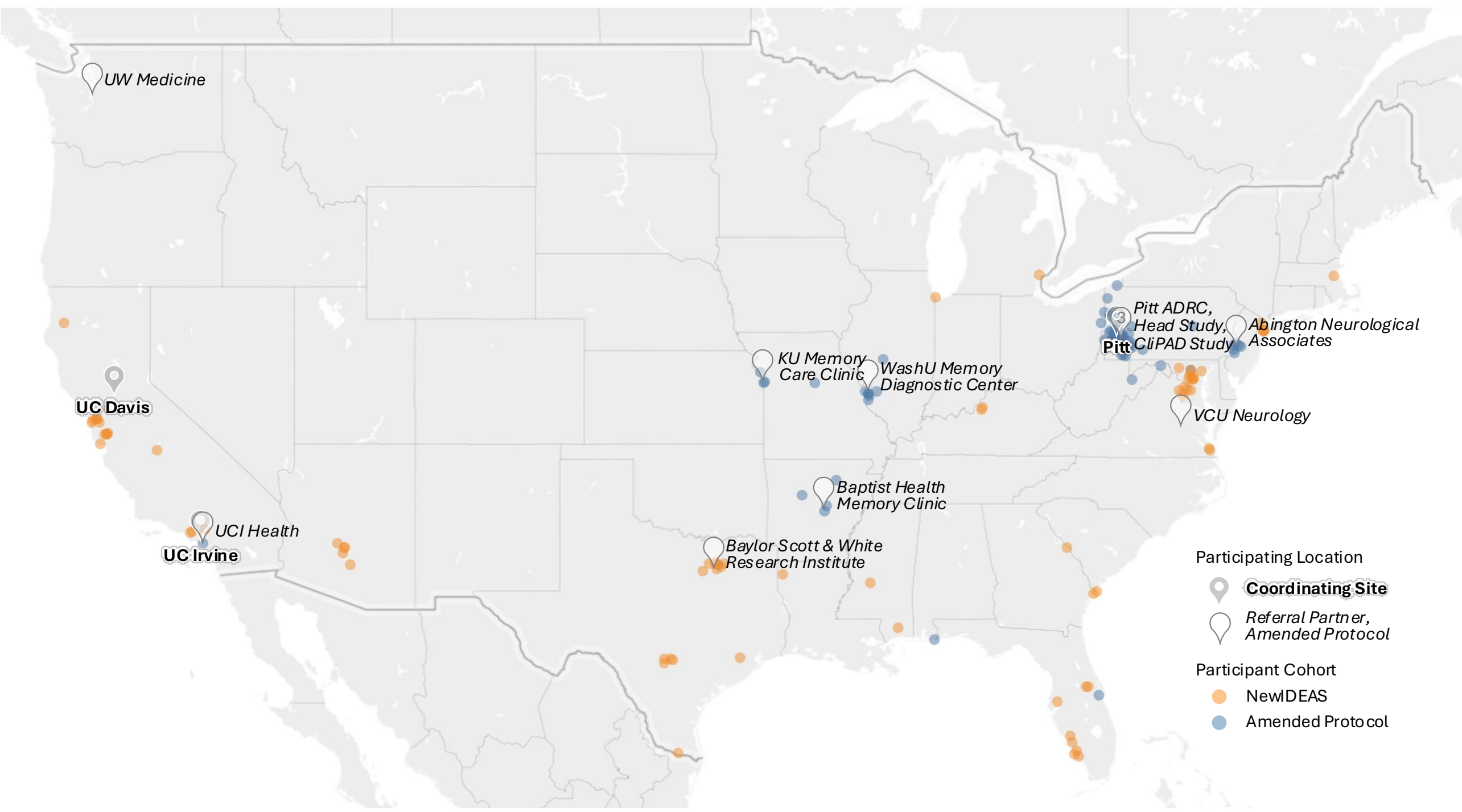


Table 1. Participant characteristics

		New IDEAS		Amended Protocol	
Variable		PT (n=68)	FM (n=47)	PT (n=116)	FM (n=87)
Race & Ethnicity	Hispanic, n (%)	19 (28)	6 (13)	1 (1)	4 (5)
	non-Hispanic AI/AN, n (%)	2 (3)	0	0	1 (1)
	non-Hispanic Asian, n (%)	1 (1)	0	0	1 (1)
	non-Hispanic Black, n (%)	20 (29)	15 (31)	13 (11)	8 (9)
	non-Hispanic White, n (%)	27 (39)	27 (56)	100 (86)	73 (83)
	Mixed or Another Race, n (%)	0	0	2 (2)	1 (1)
Age	Age (years), mean	72.5	65.9	70.0	66.9
Sex	Female, n (%)	40 (59)	28 (60)	60 (52)	59 (68)
Education	≤ High school diploma, n (%)	11 (16)	5 (11)	14 (12)	7 (8)
	Some college/AA degree, n (%)	22 (32)	8 (17)	19 (16)	13 (15)
	≥ Bachelor’s degree, n (%)	34 (50)	34 (72)	83 (72)	66 (76)
	Other, n (%)	1 (1)	0	0	1 (1)
Working status	Working full time, n (%)	1 (1)	13 (28)	20 (17)	20 (23)
	Working part time, n (%)	0	4 (9)	10 (9)	7 (8)
	Retired or not working, n (%)	66 (97)	29 (62)	85 (73)	57 (66)
	Other, n (%)	1 (1)	1 (2)	1 (1)	3 (3)
Relationship to patient	Spouse, n (%)	-	26 (55)	-	59 (68)
	Adult Child, n (%)	-	9 (19)	-	12 (14)
	Other family member, n (%)	-	1 (2)	-	3 (3)
	Friend, n (%)	-	2 (4)	-	2 (2)
	Missing, n (%)	-	9 (19)	-	11 (13)
Biomarker test	Amyloid PET, n (%)	61 (100)	7 (100)	75 (63)	2 (67)
	Tau PET, n (%)	-	-	21 (18)	0
	CSF protein assay, n (%)	-	-	4 (3)	0
	Plasma biomarker, n (%)	-	-	19 (16)	1 (33)
Disclosure modality	In person, n (%)	32 (54)	6 (86)*	21 (18)	0
	Remote, n (%)	27 (46)	1 (14)*	96 (82)	3 (100)*
Disclosure visit length	In person (minutes), mean	36.3	37.5*	32.2	-
	Remote (minutes), mean	15.8	-	15.4	25.0*

Abbreviations. PT: Patient; FM: Family member; AI/AN: American Indian Alaska Native.

Note. *indicates family members’ report for those participating in PARADE without their patient enrolled.

RESULTS

As of June 17, 2026, 339 participants (patients and family members) have enrolled in PARADE, including 123 from the New IDEAS cohort and 216 from the subsequently established referral network.

- Participants and partners from the two phases are similar in age and sex
- Participants in the amended protocol have included fewer individuals of non-White race or Hispanic ethnicity
- Participants in the amended protocol have had somewhat higher education
- In both phases, a majority of partners have been spouses
- Non-PET biomarkers are limited to the amended protocol but now include Tau PET, CSF, and plasma blood biomarker tests
- In the amended protocol, remote disclosure of biomarker results is more highly represented, compared to those recruited from the New IDEAS study, while the duration of disclosure visits has been similar

DISCUSSION

New IDEAS was a real-world CED study but also had unique requirements to ensure patient diversity. The PARADE amended protocol may better represent clinical practice after approval of anti-amyloid treatments and CED removal. The clinical use of a variety of biomarker tests may better represent current practice and position the PARADE Study to better understand how these modalities are understood by patients and families and impact support needs and decision making. PARADE remains open to enrollment.

CONCLUSIONS

PARADE is a timely research program that will be essential to better understand the patient and family experience of receiving biomarker informed ADRD diagnoses.

CONTACT US

To learn about referring your patients or research participants, follow the QR Code to visit our website.



ACKNOWLEDGEMENTS

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