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ERRATUM

Erratum

In the paper by Yu *et al*. ("Impact of non-binding FDA guidances on primary endpoint selection in Alzheimer's disease trials." *Alzheimer's Dement*. 2022; 8:e12280. https://doi.org/10.1002/trc2.12280), errors occurred in the preparation of the paper for publication, requiring the following corrections.

In Table A3B, "Spline *P*" should have been "Spline *P*-value."

In Tables 2 and A4, "FDA registered trial" was incorrectly indented in the "Independent variables" column so that it was grouped as one of the "AD stage" variables. It should have been fully left-justified, and the row should have been shaded pink to identify it as a separate independent variable. The corrected tables appear below.

We regret the errors.

TABLE A3B Regression discontinuity in time (RDiT) design linear model – Spline *P*-values when varying discontinuity year

Spline for 2013 FDA guidance	Spline *P*-value
March 2007	.2789
March 2008	.0716
March 2009	.0189
March 2010	.0062
March 2011	.0024
March 2012	.0006
March 2013 (base case)	.0003
March 2014	.0004
March 2015	.0016
March 2016	.0094
March 2017	.0313
Spline for 2018 FDA guidance	**Spline *P*-value**
March 2014	.7516
March 2015	.6839
March 2016	.3498
March 2017	.0951
March 2018 (Base Case)	.0220

Abbreviation: FDA, Food and Drug Administration.

TABLE 2 Regression discontinuity in time (RDiT) linear model to investigate the impact of the 2013 and 2018 FDA draft guidances on the selection of primary endpoints in AD DMT trials

	Cognitive/functional composite endpoint				CDR-SB			
	DMT		Non-DMT		DMT		Non-DMT	
Independent variables	Coefficient	*P*-value	Coefficient	*P*-value	Coefficient	*P*-value	Coefficient	*P*-value
Intercept	2.015 ***	.000	1.292 ***	.001	0.278	.518	−0.057	.686
Years prior to March 1, 2013	−0.037 ***	.002	−0.022 **	.012	−0.013 **	.042	0.001	.730
Years between March 1, 2013, and March 1, 2018	0.129 ***	.000	−0.021	.418	0.115 ***	.000	−0.005	.509
Years after March 1, 2018	−0.199 **	.022	0.105	.459	-0.148 **	.017	−0.006	.451
AD stage (Reference = overt AD)								
Presymptomatic	−0.016	.933	—	—	−0.240 ***	.002	—	—
Prodromal/MCI	0.075	.506	0.240	.124	0.145 ***	.098	0.367 **	.033
FDA registered trial	0.065	.557	0.074	.329	0.252 ***	.000	0.041 *	.092
Phase (reference = phase III)								
Phase II/III	−0.124	.226	−0.077	.513	−0.203 ***	.005	−0.032	.101
Phase III/IV	0.739 ***	.000	—	—	-0.239 ***	.000	—	—
Number of observations	124		190		124		190	
R-squared	0.141		0.087		0.293		0.228	

Abbreviations: AD, Alzheimer's disease; CDR-SB, Clinical Dementia Rating–Sum of Boxes; CI, confidence interval; DMT, disease-modifying therapy; FDA, Food and Drug Administration; MCI, mild cognitive impairment.
* $P < .10$, ** $P < .05$, *** $P < .01$.

TABLE A4 Regression discontinuity in time (RDiT) design linear model to investigate the impact of the 2013 and 2018 FDA guidances on the selection of primary endpoints in Alzheimer's disease DMT clinical trials, by sponsor type

	Cognitive/functional composite endpoint				CDR-SB			
	Trials with private sponsors		Trials with public sponsors		Trials with private sponsors		Trials with public sponsors	
Independent variables	Coefficient	*P*-value	Coefficient	*P*-value	Coefficient	*P*-value	Coefficient	*P*-value
Intercept	3.483 ***	.000	−0.978	.490	1.130 **	.041	−0.627	.353
Years prior to March 1, 2013	−0.068 ***	.000	0.030	.366	−0.028 **	.030	0.017	.344
Years between March 1, 2013, and March 1, 2018	0.170 ***	.001	−0.124	.137	0.133 ***	.005	−0.058	.337
Years after March 1, 2018	−0.091	.733	0.105	.538	0.037	.878	0.109	.341
AD stage (reference = overt AD)								
Presymptomatic	0.514 **	.028	0.310	.244	−0.386 *	.070	0.040	.383
Prodromal/MCI	0.072	.674	−0.203	.458	0.175	.191	−0.127	.356
FDA registered trial	0.156	.282	−0.139	.462	0.406 ***	.001	−0.101	.342
Phase (Reference = phase III)								
Phase II/III	−0.133	.290	0.122	.541	−0.150	.209	0.003	.880
Phase III/IV	0.765 ***	.000	—	—	−0.236 ***	.001	—	—
Number of observations	84		34		84		34	
R-Squared	0.337		0.1014		0.409		0.145	

= Abbreviations: AD, Alzheimer's disease; CDR-SB, Clinical Dementia Rating–Sum of Boxes; CI, confidence interval; DMT, disease-modifying therapy; MCI, mild cognitive impairment.
* $P < .10$, ** $P < .05$, *** $P < .01$.