Date:	12/29/2022
Your Name:	Brandy R Matthews
Manuscript Title:	Expectations of Randomized Controlled Trials and Clinical Meaningfulness
Manuscript Number (if known):	ADJ-D-22-00957R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		Name all entities with whom you relationship or indicate none (ad		Specifications/Comments (e.g., if payments were made to you or to your institution)
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing	Time frame: Since	the initial planning of	f the work  Click the tab key to add additional rows.
	charges, etc.) No time limit for this item.	Time fr	ame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	ame. past 30 months	
3	Royalties or licenses	None     Non		

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	[⊠] None	
7	Support for attending meetings and/or travel	Eli Lilly & Co	Employee and minor shareholder
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠  None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)  Specifications/Comments (e.g., if payments we made to you or to your institution)	
11	Stock or stock options	□ None  Eli Lilly & Company	Employee and minor shareholder
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	None	
13	Other financial or non-financial interests	Eli Lilly & Company	Employee & minor shareholder
<b>Plea</b>	•	t to the following statement to indicate your agreeme answered every question and have not altered the wo	

Date	e:		12/29/2022	
You	r Name:		Christopher Weber	
Mar	nuscript Title:		Expectations of Randomized Controlled Tria	lls and Clinical Meaningfulness
Manuscript Number (if known):		known):	ADJ-D-22-00957R1	
contaffer indicate The epidethat	tent of your manuscr cted by the content cate a bias. If you ar author's relationship lemiology of hyperte medication is not m	ript. "Rela of the man e in doubt os/activitie ension, you entioned	nted" means any relation with for-profit or no nuscript. Disclosure represents a commitment about whether to list a relationship/activity, es/interests should be defined broadly. For each of the a should declare all relationships with manufain the manuscript.	/interest, it is preferable that you do so.
			l entities with whom you have this ship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
			Time frame: Since the initial planning of	of the work
	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  No time limit for this item.		ull-time employee of the Alzheimer's tion.	Click the tab key to add additional rows.
			Time frame: past 36 months	S
2	Grants or contracts from any entity (if not indicated in item #1 above).	[⊠] No	one	
3	Royalties or licenses	⊠ No	one	

			Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	None	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	None	
Plea [⊠]	-	t to the following statement to indicate your agreeme answered every question and have not altered the wo	

Date:	12/29/2022
Your Name:	Eric Siemers
Manuscript Title:	Expectations of Randomized Controlled Trials and Clinical Meaningfulness
Manuscript Number (if known):	ADJ-D-22-00957R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial planning	of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  No time limit for this item.	None	Click the tab key to add additional rows.
		Time frame: past 36 month	s
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	□ None	
5	Payment or honoraria for lectures, presentations, speakers bureaus,	Biogen Inc. Cogstate Ltd. Cortexyme Inc. Partner Therapeutics Inc. Pinteon Therapeutics Inc. Vaccinex Inc. Acumen Pharmaceuticals Inc.  Gates Ventures LLC Hoffman La Roche Ltd  None	Payment to Siemers Integration LLC Payments to Siemers Integration LLC Payments to Siemers Integration LLC and Eric Siemers Payments to Siemers Integration LLC Payments to Siemers Integration LLC
	manuscript writing or educational events		
6	Payment for expert testimony	None	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Hoffman La Roche Ltd	Payments to Siemers Integration LLC
10	Leadership or fiduciary role in other board, society, committee or	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	advocacy group, paid or unpaid	Alzheimer's Association Bright Focus Foundation	Unpaid consultant Unpaid Board of Directors member
11	Stock or stock options	Acumen Pharmaceuticals Inc.	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	None	
13	Other financial or non-financial interests	None	
Plea	-	t to the following statement to indicate your agreeme answered every question and have not altered the wo	

3 12/13/2021 ICMJE Disclosure Form

Date	e:	<u>-</u>	12/29/2022		
You	r Name:	-	Maria Carrillo		
Mar	nuscript Title:	-	Expectations of Randomized Controlled Trials and Clinical Meaningfulness		
Mar	nuscript Number (if k	known):	ADJ-D-22-00957R1		
cont affe	tent of your manuscr	ipt. "Rela of the mar	ted" means any relation with for-profit or	ies/interests listed below that are related to the not-for-profit third parties whose interests may be ent to transparency and does not necessarily sy/interest, it is preferable that you do so.	
epid		nsion, you	should declare all relationships with man	example, if your manuscript pertains to the ufacturers of antihypertensive medication, even if	
	em #1 below, report ne for disclosure is th	• •	·	without time limit. For all other items, the time	
			entities with whom you have this	Specifications/Comments (e.g., if payments were	
		relations	hip or indicate none (add rows as needed	made to you or to your institution)	
		relations	hip or indicate none (add rows as needed Time frame: Since the initial plannin		
	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)	[□] No	Time frame: Since the initial plannir		
	present manuscript (e.g., funding, provision of study materials, medical writing, article processing	□ No	Time frame: Since the initial plannir	g of the work	
	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	□ No	Time frame: Since the initial plannir	g of the work  Click the tab key to add additional rows.	

Royalties or

licenses

**⊠** None

			Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	None	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	None	
Plea [⊠]	Please place an "X" next to the following statement to indicate your agreement:    I certify that I have answered every question and have not altered the wording of any of the questions on this form.		

Date:	12/29/2022
Your Name:	Paul Stephen Aisen
Manuscript Title:	Expectations of Randomized Controlled Trials and Clinical Meaningfulness
Manuscript Number (if known):	ADJ-D-22-00957R1
·	<u> </u>

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial planning of	of the work
2	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  No time limit for this item.	None   Time frame: past 36 months	Click the tab key to add additional rows.
	contracts from any entity (if not indicated in item #1 above).	NIH, Alzheimer's Association, FNIH, Lilly, Janssen, Eisai	Research support to institution
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	Merck, Biogen, Abbvie, Roche, Immunobrain Checkpoint	Consulting fees paid to me
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	None	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	None	
Plea [⊠]	Please place an "X" next to the following statement to indicate your agreement:    I certify that I have answered every question and have not altered the wording of any of the questions on this form.		

Date:		12/29/2022			
Your Name:		Ronald Petersen	Ronald Petersen		
Manuscript Title:		Expectations of Randomized Controlled Trials and Clinical Meaningfulness	Expectations of Randomized Controlled Trials and Clinical Meaningfulness		
Mar	nuscript Number (if k	known): ADJ-D-22-00957R1			
content of your manuscript. "Related affected by the content of the maindicate a bias. If you are in doub."  The author's relationships/activitic epidemiology of hypertension, you that medication is not mentioned.		t all support for the work reported in this manuscript without time limit. For all other it	interests may be necessarily ou do so. tains to the dication, even if		
		Name all entities with whom you have this relationship or indicate none (add rows as needed)  Specifications/Comments (e.g made to you or to your institu	· · · · ·		
		Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  No time limit for this item.	None  I am a full-time employee of the Mayo Foundation for Education and Research.  Click the tab key to add additional rows	5.		
1	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	I am a full-time employee of the Mayo Foundation for Education and Research.	5.		
2	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	I am a full-time employee of the Mayo Foundation for Education and Research.  Click the tab key to add additional rows	5.		

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None  Roche Nestle Merck Biogen Eisai Genentech	Personal Personal Personal Personal Personal Personal
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	□     □	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Genentech	Personal
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	ICAME Diselector Form

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	None	
Plea [⊠]	Please place an "X" next to the following statement to indicate your agreement:    I certify that I have answered every question and have not altered the wording of any of the questions on this form.		

	ICIVITE DISCLOSORE FORIVI		
Date:	Date: 12/29/2022		
Your Name:	Scott Andrews		
Manuscript Title:	Expectations of Randomized Controlled Tria	als and Clinical Meaningfulness	
Manuscript Number (if kno	own): ADJ-D-22-00957R1		
content of your manuscript affected by the content of indicate a bias. If you are in the author's relationships/epidemiology of hypertens that medication is not men	support for the work reported in this manuscript w	ot-for-profit third parties whose interests may be not to transparency and does not necessarily /interest, it is preferable that you do so. example, if your manuscript pertains to the acturers of antihypertensive medication, even if	
	ame all entities with whom you have this elationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)	
Time frame: Since the initial planning of the work			

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial planning of	of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  No time limit for this item.	None  Takeda Pharmaceuticals	Employee and minor shareholder of Takeda Pharmaceuticals  Click the tab key to add additional rows.
		Time frame: past 36 months	S
2	Grants or contracts from any entity (if not indicated in item #1 above).	None None	
3	Royalties or licenses	None None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	Takeda Pharmaceuticals	Employee and minor shareholder of Takeda Pharmaceuticals
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	□     □	
13	Other financial or non-financial interests	None	
Please place an "X" next to the following statement to indicate your agreement:			
$\boxtimes$	I certify that I have answered every question and have not altered the wording of any of the questions on this form.		

Date:	12/29/2022
Your Name:	Dorene M. Rentz
Manuscript Title:	Expectations of Randomized Controlled Trials and Clinical Meaningfulness
Manuscript Number (if known):	ADJ-D-22-00957R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial planning	of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  No time limit for this item.	None	Click the tab key to add additional rows.
		Time frame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	None None	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	□ None  □ Dana Foundation- Consultant Fees on Neurological/Cognitive Information re: Video Productions	Payments were made to me
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Course Faculty USC, IMPACT AD course 2021 Honoraria for Grand Rounds Honoraria for External Scientific Advisory Boards	Payments were made to me Payments made to me Payments made to me
6	Payment for expert testimony	None	
7	Support for attending meetings and/or travel	Travel to ACTC meetings Travel to UC Davis Advisory Board	Reimbursements were made to me Reimbursements made to me
8	Patents planned, issued or pending	⊠  None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠  None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	None	
Please place an "X" next to the following statement to indicate your agreement:    I certify that I have answered every question and have not altered the wording of any of the questions on this form.			

Date:	12/29/2022
Your Name:	Alireza Atri
Manuscript Title:	Expectations of Randomized Controlled Trials and Clinical Meaningfulness
Manuscript Number (if known):	ADJ-D-22-00957R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	Time frame: Since the initial planning of the work		
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  No time limit for this item.	None	Click the tab key to add additional rows.
	Time frame: past 36 months		s
2	Grants or contracts from any entity (if not indicated in item #1 above).	Alzheon, Athira Biohaven (with ADCS), Eisai (with ATRI/ACTC), Lilly (with ATR/ACTC), Vivoryon (with ADCS) ACTC, ADCS, AZ Alzheimer's Research Consortium, ATRI, GAP  USC, Indiana Univ, Johns Hopkins  Washington University St. Louis Gates Ventures	Site PI for biopharma-sponsored clinical trials at institution  Site PI for biopharma-AD consortium collaborative sponsored clinical trials at institution  Site PI for clinical trials sponsored or cosponsored or grants from Research Consortia or Institutes  Site PI for collaborative clinical trials sponsored or co-sponsored by Universities  Project Arm Leader for international clinical trial  Grant from Foundation

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		AZ DHS, NIA/NIH	Grants from state or federal agency
			PI for Single Site Biomarker (SV2A-PET) study
		Foundation for NIH (FNIH)	funded by FNIH
3	Royalties or licenses	□ None	
		Oxford University Press	Book on dementia
4	Consulting fees	□ None	
		Roche/Genentech	Current
		Novo Nordisk	Current
		Eisai	Current
		Acadia	Past/completed
		AZ Therapies	Past/completed
		Biogen	Past/completed
		JOMDD	Past/completed
		_Lundbeck	Past/completed
		_ Qynapse	Past/completed
		Suven	Past/completed
5	Payment or honoraria for	□ None	
	lectures, presentations, speakers bureaus, manuscript	AbbVie, Acadia, Biogen, Eisai, Lundbeck	Past/completed; No speakers bureaus; pharma or subsidiary/partner
	writing or		,
	educational		
	events		
6	Payment for expert testimony	<b>None</b> ■	
7	Support for attending	□ None	
	meetings and/or	Alzheimer's Association (US),	
	travel	Alzheimer's Disease International (ADI),	Only for consulting mtgs, scientific/medical
		American Academy of Neurology (AAN)	presentations or educational programs

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	None	
13	Other financial or non-financial interests	None	
Please place an "X" next to the following statement to indicate your agreement:    I certify that I have answered every question and have not altered the wording of any of the questions on this form.			