

ICMJE DISCLOSURE FORM

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.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

	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								
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3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>						

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4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
		Eli Lilly & Co	Employee and minor shareholder
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> None	
		Eli Lilly & Company	Employee and minor shareholder
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input type="checkbox"/> None	
		Eli Lilly & Company	Employee & minor shareholder

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.

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Date: 12/29/2022

Your Name: Christopher Weber

Manuscript Title: Expectations of Randomized Controlled Trials and Clinical Meaningfulness

Manuscript Number (if known): ADJ-D-22-00957R1

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13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							

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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

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		Biogen Inc.	Payment to Siemers Integration LLC
		Cogstate Ltd.	Payment to Siemers Integration LLC
		Cortexyme Inc.	Payment to Siemers Integration LLC
		Partner Therapeutics Inc.	Payment to Siemers Integration LLC
		Pinteon Therapeutics Inc.	Payment to Siemers Integration LLC
		Vaccinex Inc.	Payment to Siemers Integration LLC
		Acumen Pharmaceuticals Inc.	Payments to Siemers Integration LLC and Eric Siemers
		Gates Ventures LLC	Payments to Siemers Integration LLC
Hoffman La Roche Ltd	Payments to Siemers Integration LLC		
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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		Hoffman La Roche Ltd	Payments to Siemers Integration LLC
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	advocacy group, paid or unpaid	Alzheimer's Association Bright Focus Foundation	Unpaid consultant Unpaid Board of Directors member
11	Stock or stock options	<input type="checkbox"/> None Acumen Pharmaceuticals Inc.	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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Date: 12/29/2022

Your Name: Maria Carrillo

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Date: 12/29/2022

Your Name: Paul Stephen Aisen

Manuscript Title: Expectations of Randomized Controlled Trials and Clinical Meaningfulness

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		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	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>							
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>							
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>							

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 12/29/2022

Your Name: Ronald Petersen

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.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

	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.	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">I am a full-time employee of the Mayo Foundation for Education and Research.</td> <td style="width: 40%;"></td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td colspan="2" style="text-align: right; font-size: small;">Click the tab key to add additional rows.</td> </tr> </table>	I am a full-time employee of the Mayo Foundation for Education and Research.				Click the tab key to add additional rows.	
I am a full-time employee of the Mayo Foundation for Education and Research.								
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).	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">NIA ADRC, MCSA, ADNI, ACTC, MarkVCID</td> <td style="width: 40%;"></td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </table>	NIA ADRC, MCSA, ADNI, ACTC, MarkVCID					
NIA ADRC, MCSA, ADNI, ACTC, MarkVCID								
3	Royalties or licenses	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Oxford University Press</td> <td style="width: 40%;"></td> </tr> <tr> <td>UpToDate</td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </table>	Oxford University Press		UpToDate			
Oxford University Press								
UpToDate								

		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	<input type="checkbox"/> None	
		Roche	Personal
		Nestle	Personal
		Merck	Personal
		Biogen	Personal
		Eisai Genentech	Personal Personal
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
		Genentech	Personal
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							

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ICMJE DISCLOSURE FORM

Date: 12/29/2022

Your Name: Scott Andrews

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.

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		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.	<input type="checkbox"/> None	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; padding: 2px;">Takeda Pharmaceuticals</td> <td style="padding: 2px;">Employee and minor shareholder of Takeda Pharmaceuticals</td> </tr> <tr> <td style="height: 20px;"></td> <td></td> </tr> <tr> <td colspan="2" style="text-align: center; padding: 2px;"><small>Click the tab key to add additional rows.</small></td> </tr> </table>	Takeda Pharmaceuticals	Employee and minor shareholder of Takeda Pharmaceuticals			<small>Click the tab key to add additional rows.</small>	
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2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; height: 20px;"></td> <td></td> </tr> <tr> <td style="height: 20px;"></td> <td></td> </tr> <tr> <td style="height: 20px;"></td> <td></td> </tr> </table>						
3	Royalties or licenses	<input checked="" type="checkbox"/> None	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; height: 20px;"></td> <td></td> </tr> <tr> <td style="height: 20px;"></td> <td></td> </tr> <tr> <td style="height: 20px;"></td> <td></td> </tr> </table>						

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4	Consulting fees	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
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6	Payment for expert testimony	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
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9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
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11	Stock or stock options	<input type="checkbox"/> None	
		Takeda Pharmaceuticals	Employee and minor shareholder of Takeda Pharmaceuticals
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> 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.

ICMJE DISCLOSURE 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.

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	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.	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> <p style="font-size: small; color: gray; margin-top: 5px;">Click the tab key to add additional rows.</p>						
Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						
3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						

		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	<input type="checkbox"/> 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	<input type="checkbox"/> None	
		Course Faculty USC, IMPACT AD course 2021	Payments were made to me
		Honoraria for Grand Rounds	Payments made to me
		Honoraria for External Scientific Advisory Boards	Payments made to me
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
		Travel to ACTC meetings	Reimbursements were made to me
		Travel to UC Davis Advisory Board	Reimbursements made to me
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

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ICMJE DISCLOSURE 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

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Time frame: past 36 months														
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 70%;">Alzheon, Athira</td> <td>Site PI for biopharma-sponsored clinical trials at institution</td> </tr> <tr> <td>Biohaven (with ADCS), Eisai (with ATRI/ACTC), Lilly (with ATR/ACTC), Vivoryon (with ADCS)</td> <td>Site PI for biopharma-AD consortium collaborative sponsored clinical trials at institution</td> </tr> <tr> <td>ACTC, ADCS, AZ Alzheimer's Research Consortium, ATRI, GAP</td> <td>Site PI for clinical trials sponsored or co-sponsored or grants from Research Consortia or Institutes</td> </tr> <tr> <td>USC, Indiana Univ, Johns Hopkins</td> <td>Site PI for collaborative clinical trials sponsored or co-sponsored by Universities</td> </tr> <tr> <td>Washington University St. Louis</td> <td>Project Arm Leader for international clinical trial</td> </tr> <tr> <td>Gates Ventures</td> <td>Grant from Foundation</td> </tr> </table>	Alzheon, Athira	Site PI for biopharma-sponsored clinical trials at institution	Biohaven (with ADCS), Eisai (with ATRI/ACTC), Lilly (with ATR/ACTC), Vivoryon (with ADCS)	Site PI for biopharma-AD consortium collaborative sponsored clinical trials at institution	ACTC, ADCS, AZ Alzheimer's Research Consortium, ATRI, GAP	Site PI for clinical trials sponsored or co-sponsored or grants from Research Consortia or Institutes	USC, Indiana Univ, Johns Hopkins	Site PI for collaborative clinical trials sponsored or co-sponsored by Universities	Washington University St. Louis	Project Arm Leader for international clinical trial	Gates Ventures	Grant from Foundation
Alzheon, Athira	Site PI for biopharma-sponsored clinical trials at institution													
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Gates Ventures	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
		Foundation for NIH (FNIH)	PI for Single Site Biomarker (SV2A-PET) study funded by FNIH
3	Royalties or licenses	<input type="checkbox"/> None	
		Oxford University Press	Book on dementia
4	Consulting fees	<input type="checkbox"/> 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 lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
		AbbVie, Acadia, Biogen, Eisai, Lundbeck	Past/completed; No speakers bureaus; pharma or subsidiary/partner
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
		Alzheimer's Association (US), Alzheimer's Disease International (ADI), American Academy of Neurology (AAN)	Only for consulting mtgs, scientific/medical 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	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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