

ICMJE DISCLOSURE FORM

Date: 05/05/2022

Your Name: Usha Menon

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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 following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

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.	Cancer Research UK (CRUK)	Paid to Institution
		The Eve Appeal	Paid to Institution
		NIHR HTA - Award number 16/46/01	Paid to Institution
		MRC Core Funding – Award number MR_UU_12023	Paid to Institution
		NIHR UCL Hospitals Biomedical Research Centre	Paid to Institution
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	CRUK	Paid to Institution
		MRC	Paid to Institution
		CRUK DBT (India Alliance)	Paid to Institution
		UCL GCRF Internal Small Grant	Paid to Institution

		MRC Proximity to Discovery Industrial Connectivity Award	Paid to Institution
		NIHR BRC UCLH	Paid to Institution
		Research collaboration with iLOF (intelligent Lab on Fiber)	Funding paid to Institution
		Research collaboration with RNA Guardian	Funding paid to Institution
		Research collaboration with Micronoma	Funding paid to Institution
		Research collaboration with Imperial College London	Funding paid to Institution
		Research collaboration with Dana Farber	Funding paid to Institution
		Research collaboration with QIMR Berghofer Medical Research Institute	Funding paid to Institution
3	Royalties or licenses	Abcodia UK	Held personal shares between 1 st April 2011 and 30 October 2021
4	Consulting fees	___ None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Honorarium	Honorarium for lecture paid to myself
6	Payment for expert testimony	___ None	
7	Support for attending meetings and/or travel	Invited talk at NY Obstetrical Society, New York, USA, November 2021	Travel and accommodation reimbursed
		Invited talk at National Cancer Policy Forum, Washington, USA, March 2020	Travel and subsistence reimbursed
		Invited talk at Robinson College, Cambridge, February 2020	Travel reimbursed
8	Patents planned, issued or pending	Patent no: EP10178345.4 for Breast Cancer Diagnostics	

9	Participation on a Data Safety Monitoring Board or Advisory Board	Member, ACED (International Alliance for Cancer Early Detection) Gynaecological Cancers Working Group	
		Member, Tina's Wish (TW) Scientific Advisory Board, USA	
		Member, Data Monitoring Committee: Mixed COVID Vaccines study, India	
		Member, Research Advisory Panel, Yorkshire Cancer Research	
		Chair, Data Monitoring Committee: GEM3	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid		
		Member, GCP Professional Certification Scheme Steering Committee, CDSA, THSTI, India	
		Member, Clinical and Public Health Fellowship Selection Committee, Wellcome Trust DBT India Alliance	
		Member, Prevention Expert Review Panel, Population Research Committee, CRUK	
		Member, Early Career Fellowship Selection Committee, Wellcome Trust DBT India Alliance	
11	Stock or stock options	Shares in Abcodia Ltd, awarded by UCL	Held personal shares between 1 st April 2011 and 30 October 2021
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:

X 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: 5th May 2022

Your Name: Dr Aleksandra Gentry-Maharaj

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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		NIHR UCL Hospitals Biomedical Research Centre	Paid to Institution
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	Contracts	
		Cambridge University, UK	
		QIMR Berghofer Medical Research Institute, Australia	
		University of Sussex, UK	
		Research collaboration with iLOF (intelligent Lab on Fiber)	Funding paid to Institution

		Research collaboration with RNA Guardian	Funding paid to Institution
		Research collaboration with Micronoma	Funding paid to Institution
		Research collaboration with Imperial College London	Funding paid to Institution
		Research collaboration with Dana Farber	Funding paid to Institution
3	Royalties or licenses		
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	
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	

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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.

ICMJJE DISCLOSURE FORM

Date: 3.5.2022

Your Name: Matthew Burnell

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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Time frame: past 36 months			
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3	Royalties or licenses	___ None	
4	Consulting fees	___ None	

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

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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: 04/05/2022

Your Name: Dr Sophia Apostolidou

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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Time frame: past 36 months			
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		MRC Proximity to Discovery Industrial Connectivity Award	Paid to Institution
		Abcodia	Paid to Institution

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		Research collaboration with Imperial College London	Funding paid to Institution
		Research collaboration with Dana Farber	Funding paid to Institution
		Research collaboration with QIMR Berghofer Medical Research Institute	Funding paid to Institution
3	Royalties or licenses	___ None	
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	
11	Stock or stock options	___ None	

12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

X_ 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: 28th April 2022

Your Name: Dr. Andy Ryan

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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		NIHR HTA - Award number 16/46/01	Paid to Institution
		MRC Core Funding – Award number MR_UU_12023	Paid to Institution
		NIHR UCL Hospitals Biomedical Research Centre	Paid to Institution
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	

3	Royalties or licenses	<input checked="" type="checkbox"/> None	
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 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	
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	

Please place an "X" next to the following statement to indicate your agreement:

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ICMJE DISCLOSURE FORM

Date: Jatinderpal Kalsi

Your Name:

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	
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	
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:

 x 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: May 26, 2022

Your Name: Naveena Singh

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	
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	Astra-Zeneca-MSD	Honorarium received personally for participation in Advisory board
		GlaxoSmithKline	Honorarium received personally for participation in Advisory board
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:

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ICMJE DISCLOSURE FORM

Date: 05.05.2022

Your Name: Professor Dame Lesley Fallowfield

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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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.	Medical Research Council funding for the psycho-social arm of the UKCTOCS study 2001-2013	Payment to Institution
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	

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

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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. **X**

ICMJJE DISCLOSURE FORM

Date: 5/5/22

Your Name: Professor Alistair McGuire

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	
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	
11	Stock or stock options	___ None	
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13	Other financial or non-financial interests	___ None	

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A S McQuire

ICMJE DISCLOSURE FORM

Date: 5/5/22

Your Name: Stuart Campbell

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
11	Stock or stock options	<input type="checkbox"/> None	
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ICMJE DISCLOSURE FORM

Date: 12 May 2022

Your Name: Steven Skates

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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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.	National Cancer Institute (USA)	Grant support from grant # CA152990
		National Institute of Health Research (UK)	Grant support
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	
3	Royalties or licenses	<input type="checkbox"/> None Abcodia	Massachusetts General Hospital co-licensed software to Abcodia for early detection of ovarian cancer

4	Consulting fees	<input 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 checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	Participated in Independent Data Monitoring Committee
		GRAIL	
		SISCAPA Assay Technologies	Stock options for service on Scientific Advisory Board
		Guardant Health	Service on the clinical advisory board
		LUNgevity	Service on the Scientific Advisory Board
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 not already given	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input type="checkbox"/> None	Collaboration on early detection research
		Freenome	

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: 5th May 2022

Your Name: Anne Dawnay

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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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.		
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	__X__ None	
3	Royalties or licenses	__X__ None	
4	Consulting fees	__X__ 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 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	
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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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: 06/03/2022

Your Name: Prof Mahesh KB Parmar

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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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.		
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	
3	Royalties or licenses	<input checked="" type="checkbox"/> None	
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 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	
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 type="checkbox"/> None	Mahesh Parmar was a member of the EME funding committee while the project was active

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: 1.5.22

Your Name: Ian Jacobs

Manuscript Title: Insights from UKCTOCS for design, conduct and analyses of large randomised controlled trials

Manuscript number (if known): NIHR135605

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The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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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.	NIHR, MRC, Eve Appeal, Abcodia Ltd	To institution
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	Entitlement to royalty stream from ROC algorithm	Payments to institution, with flow through to me in line with standard university agreement

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	
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	Board member, shareholder Abcodia Ltd	

Please place an "X" next to the following statement to indicate your agreement:

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