ICMJE DISCLOSURE FORM

Date: 07/10/2021
Your Name: Dr Sanjeev Sharma
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.**	____ None	
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:____21/10/21_____
Your Name:_____Rajiv Gandhi_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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:___08/11/2021
Your Name:_____ Prashanth Vas _____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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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 funded study	Payments made for study recruitment and delivery
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	____	Payment received from MSD and Sanofi for speaker fees.
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:___30 September 2021_____
Your Name:__Mike Bradburn _____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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:_____6.10.21_____
Your Name:_____Christian Hariman_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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:__6/10/2021_____
Your Name:___Professor David Bennett_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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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	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	BBSRC	Industrial Partnership Grant
		AstraZeneca	Industrial Partnership Grant
		UKRI/Versus MR/W002388/1	Partnership for Assessment and Investigation of Neuropathic Pain: Studies Tracking Outcomes, Risks and Mechanisms. This is a national consortium. D Bennett is project coordinator and lead for Oxford.

			07.07.2021-01.07.2025 £5,071,135 total, £1,890,447 funding for University of Oxford.
		MRC. MR/T020113/1	'Defining the primary afferent circuitry that drives neuropathic pain'. Lead applicant. 01.02.2020-01.02.2025 £2569 655
		BBSRC BB/S006788/1	'Using human IPSC derived nociceptors as a cellular model to investigate and therapeutically target Nav1.7'. I was lead applicant. 2019-2022. £348 442.
		Action Medical Research for Children	Project Grant: Testing the efficacy of Neuregulin-1 gene therapy in models of Charcot-Marie-Tooth disease. Bennett, D (PI) 01/01/2017 – 31/12/2019 £199,918
		MRC Research Grant	The role of neuregulin-1 signalling in modulating repair and functional recovery following spinal cord injury Bennett, D (PI – Oxford), Bradbury, E (PI – KCL) 01/12/2016 – 30/11/2019 £187,759
		Wellcome Tust Senior Clinical Scientist Fellowship.	2016-2021. 'The mechanisms underlying sensory dysfunction in human pain channelopathies'. £1,533,068.11.
		Novo Nordisk foundation	2015-2020. Painful diabetic neuropathy. Co-applicant with T Jensen (Aarhus) as lead applicant. Total budget: DKK13,287,649 ; DB budget DKK2,436,939 (£290,804) I wrote the section on sensory phenotyping in diabetic neuropathy and am one of only two centre outside of Denmark.
		European Union. Horizon 20-20 scheme	2015-2019. Understanding risk factors and determinants of neuropathic pain. D Bennett lead applicant and Oxford acting as coordinating centre with 11 participating centres. €5 981 219. This application was conceived by me, coordinated by me and the majority was written by me. Oxford budget €1,343,090 (£1,033,146); DB budget €835,473 (£642,672)
		Medical Research Council Clinical Research Training Fellowship	The Molecular Genetics of Carpal Tunnel Syndrome Wiberg, A (Fellow - Pharmacology), Bennett, D (supervisor), 01/02/2016 – 31/01/2019 Total budget £199,710; DB budget £30,000
		Wellcome Trust strategic award	'Defining the neural circuitry of pain in health and disease'. Feb 2014-Feb 2019. D. Bennett (Oxford), I. Tracey (Oxford), S.B. McMahon (KCL), G. Ianetti (UCL), A. Dickenson (UCL), A. Todd (Glasgow) and A. Basbaum (UCSF). Ref 102645. Total £5 287 909.
3	Royalties or licenses	_____ None	
4	Consulting fees	Amgen	Consultancy 2020
		Bristows	Consultancy 2020
		LatigoBio	Consultancy 2021
		GSK	Consultancy 2021
		Ionis	Consultancy 2021
		Lilly	Consultancy 2020, research funding received
		Olipass	Consultancy 2020

		Regeneron	Consultancy 2020
		Theranexus	Consultancy 2020
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:_____06/10/21_____
Your Name:____DeirdreMaguire_____

Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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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	
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:_____30/09/21_____
Your Name:_____David White_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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.**	____ None	
		NIHR HTA funding	
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	__X__ None	
6	Payment for expert testimony	__X__ None	
7	Support for attending meetings and/or travel	__X__ None	
8	Patents planned, issued or pending	__X__ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	_X___ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	__X__ None	
11	Stock or stock options	__X__ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	__X__ None	
13	Other financial or non-financial interests	__X__ 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:11/10/2021_____
Your Name: Gerry Rayman_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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	

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__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:_____30/10/21_____
Your Name:_____Gordon Sloan_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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.**	____ None	Salary payment to me via my institution Sheffield Teachin Hospitals
		£38,732.77	
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	___x_ None	
6	Payment for expert testimony	___x_ None	
7	Support for attending meetings and/or travel	__x__ None	
8	Patents planned, issued or pending	_x___ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	___x_ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	__x__ None	
11	Stock or stock options	__x__ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	__x__ None	
13	Other financial or non-financial interests	__x__ 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:___07/10/21_____

Your Name:_____Dr Michelle Horspool_____

Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)

Manuscript number (if known):_____

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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.**	____ None	
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:_____16/12/2021

Your Name:_____Dr RaviKanth Gouni

Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)

Manuscript number (if known):_____

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.

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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.**	____ None	
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:

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

form. x

ICMJE DISCLOSURE FORM

Date:_____1-Oct-2021_____
Your Name:_____Steven A. Julious_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.**	____ None	
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:_03/10/2021
Your Name: Uazman Alam
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.**	____ None	
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	Boehringer Ingelheim, Eli Lilly, Napp, and Sanofi	
6	Payment for expert testimony	____ None	
7	Support for attending meetings and/or travel	Sanofi	
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: 06-10-2021
Your Name: Dr Vasileios Tsatlidis
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.**	__X__ None	
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	__X__ None	
6	Payment for expert testimony	__X__ None	
7	Support for attending meetings and/or travel	__X__ None	
8	Patents planned, issued or pending	__X__ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	__X__ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	__X__ None	
11	Stock or stock options	__X__ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	__X__ None	
13	Other financial or non-financial interests	__X__ 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: 04/10/2021
Your Name: Syed Haris Ahmed
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.

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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.**	____ None	
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	NovoNordisk, Sanofi, Lilly	I have received honoraria for presenting educational material for GPs. The material presented did not relate to the content of the manuscript.
6	Payment for expert testimony	____ None	
7	Support for attending meetings and/or travel	NovoNordisk	I received support for attending the EASD annual meeting in 2019.
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:___06/10/2021_____
Your Name:___Amanda Loban_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.

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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.**	__x__ None	
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	__x__ None	
6	Payment for expert testimony	__x__ None	
7	Support for attending meetings and/or travel	_x___ None	
8	Patents planned, issued or pending	__x__ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	__x__ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	__x__ None	
11	Stock or stock options	__x__ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	__x__ None	
13	Other financial or non-financial interests	__x__ 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:_02/11/2021_____
Your Name:__Emily Turton_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.

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Time frame: Since the initial planning of the work			
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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: 04/10/2021
Your Name: Jennifer Petrie
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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Time frame: Since the initial planning of the work			
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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: 01/10/2021
Your Name: Katie Sutherland
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):

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.**	____ None	
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: **2nd October 2021**
Your Name: **Dr Martin Ewart Johnson**
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.**	Funding for Consultancy/Advice for matters relating to Primary Care in relation to the OPTION-DM project and subsequent manuscript (as per agreed NIHR funding) – includes reimbursement of travel to Sheffield (return) on one occasion for a study meeting	Payments were made directly to me
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	____ None (apart from contracts required for other work already listed)	

3	Royalties or licenses	____ None	
4	Consulting fees	____ None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Grunenthal	Chaired & spoke at several meetings for Grunenthal (travel costs also paid). All payments made directly to me
		Dorset Healthcare	Honorarium & travel costs for lecture. Payment directly to me.
		GSK	Payments for preparing and filming educational videos (Plus travel to filming). Payments directly to me.
		Pfizer	Payments for preparing and filming educational video . Payments directly to me.
6	Payment for expert testimony	____ None	
7	Support for attending meetings and/or travel	____ None	No fees just for attending meetings, however travel reimbursed for travel to meetings where I am giving lectures, chairing meetings or attending advisory boards (see sections 5 & 9)
8	Patents planned, issued or pending	____ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Windzor Pharma	Single advisory board (including travel costs). Payments made directly to me.
		Pfizer	Single advisory board (including travel costs). Payments made directly to me
		Grunenthal	Two advisory boards (including travel costs – when required). Payments made directly to me
		Nevro	Single advisory board. Payments made directly to me
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	British Pain Society & Chronic Pain Policy Coalition	Co-Chair of Chronic Pain Policy Coalition. Co-opted Council Member & Ordinary Member of British Pain Society Both roles above are unpaid
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:____7th Oct 2021_____
Your Name:___Prof Satyan Rajbhandari_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.**	____ None	
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:_____05Oct2021_____
Your Name:_____Rachel Glover_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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.

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_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: 30 September 2021
Your Name: Simon Waterhouse
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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_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:_05/10/2021_____
Your Name:__Tracey Young_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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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ICMJE DISCLOSURE FORM

Date:_____October 8, 2021_____
Your Name:_____BOUHASSIRA Didier_____
Manuscript Title: A multicentre, double-blind, centre-stratified multi-period crossover trial, including health economic analysis, to determine the Optimal Pathway for Treating Neuropathic Pain in Diabetes Mellitus (the OPTION-DM RCT)
Manuscript number (if known):_____

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3	Royalties or licenses	____ None	

4	Consulting fees	____ None BAYER	
		GRUNENTHAL	
		AIR LIQUIDE NOVARTIS	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	____ None	
6	Payment for expert testimony	____ None	
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