

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

Identifying information.

The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check

Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

Relationships not covered above.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

Definitions.

Entity: government agency, foundation, commercial sponsor, academic institution, etc.

Grant: A grant from an entity, generally [but not always] paid to your organization

Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations

Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your



Section 1.	ldentifying Inform	ation				
1. Given Name (Fir Alice	rst Name)	2. Surnar Liou	ne (Last Name)			3. Date 19-September-2018
4. Are you the corr	responding author?	Yes	✓ No	Correspond Filip Knop	_	s Name
Manuscript Title Metformin-induc	e red GLP-1 secretion con	tributes to	o the actions of	metformin ir	n type 2 dia	abetes
6. Manuscript Iden 93936-INS-CMED	ntifying Number (if you kn D-RV-3	ow it)				
Section 2.	The Work Under Co	. wai al a wai	tion for Dublic	ration		
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fizer, Inc.	ion/Company	Grant	Fees? S	upport?	E	mployee of Pfizer during the time of x is work
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Section 4.	Intellectual Proper	ty Pate	ents & Copyrig	hts		
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Section 5.	Relationships not covered above
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Yes, the follow	ring relationships/conditions/circumstances are present (explain below):
✓ No other relation	ionships/conditions/circumstances that present a potential conflict of interest
	nuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statement nals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
below.	ve disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Liou reports b	eing an employee of Pfizer Inc during the conduct of the study;.

Evaluation and Feedback



Section 1. Identifying Info	emation				
Identifying Info	mation				
1. Given Name (First Name) Damien	2. Surname (Last N Keating	ame)		3. Date 21-September-2018	
4. Are you the corresponding author?	√ Yes No				
5. Manuscript Title Metformin-induced GLP-1 secretion of	ontributes to the acti	ons of metformin i	n type 2 dia	abetes	
Manuscript Identifying Number (if you 93936-INS-CMED-TR-2			,,		
Section 2. The Work Under	Consideration for	Publication			
Did you or your institution at any time re any aspect of the submitted work (includi statistical analysis, etc.)? Are there any relevant conflicts of into	ng but not limited to gr				c.) for
If yes, please fill out the appropriate in Excess rows can be removed by press	nformation below. If y		one entity	press the "ADD" button to add a	row.
Name of Institution/Company	Grant? Persona	Non-Financial Support?	Other?	Comments	
Pfizer Inc			til rr b rr g e e v si ir b (((ome of the results in this paper were the product of a collaborative elationship between the groups led by Dr Young and Dr Keating with fizer Inc. This involved a direct esearch grant from Pfizer to these groups to collaboratie on studies on enteroendocrine clel function and was subsequently followed by a hared grant with all parties as convestigators which was supported by the Australian Research Council Grant application number: P150100419). Pfizer had no offluence on the content or eluctomes of this publication but were involved on a collaborative wasis.	×
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Section 3.	Relevant financial activities outside the submitted work.
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Section 4.	Intellectual Property Patents & Copyrights
Do you have an	patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo
Section 5.	Relationships not covered above
	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
Yes, the follo	wing relationships/conditions/circumstances are present (explain below):
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Section 6.	Disclosure Statement
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Generate Di	sclosure Statement
Dr. Keating repo	orts grants from Pfizer Inc, during the conduct of the study;



Section 1.	ldentifying Inform	nation		
1. Given Name (Fi David	rst Name)	2. Surname (Last Name) Sonne		3. Date 18-September-2018
4. Are you the cor	responding author?	Yes Vo	Corresponding Author's N Filip K. Knop	lame
5. Manuscript Title Metformin-indue		ntributes to the actions o	f metformin in type 2 diabe	etes
6. Manuscript Ide	ntifying Number (if you kr	now it)		
Section 2.	The Work Under C	onsideration for Publ	ication	
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✓ No other rela	ationships/conditions/circumstances that present a potential conflict of interest
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Section 6.	Disclosure Statement
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Generate Di	sclosure Statement
Dr. Sonne has n	othing to disclose.

Evaluation and Feedback



Section 1. Identifying Inform	nation
1. Given Name (First Name)	2. Surname (Last Name) WATTCHOW 3. Date 2/9/18
4. Are you the corresponding author?	Yes ANO
5. Manuscript Title Manuscript Identifying Number (if you kn	100 it) fearthing contitle to action of
Section 2. The Work Under C	onsideration for Publication
Did you or your institution at any time rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of intere	ive payment or services from a third party (government, commercial, private foundation, etc.) for but not limited to grants, data monitoring board, study design, manuscript preparation,
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Do you have any patents, whether plan	ned, pending or issued, broadly relevant to the work? Yes No



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Based on the above disclosures, this form will automatically ge below.	nerate a disclosure statement, which will appear in the box
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Evaluation and Feedback

Please visit http://www.icmje.org/cgi-bin/feedback to provide feedback on your experience with completing this form.



Section 1. Identifying Inform	nation	
1. Given Name (First Name) Dayan	2. Surname (Last Name) de Fontgalland	3. Date 10-October-2018
4. Are you the corresponding author?	Yes Vo	Corresponding Author's Name Damien Keating
5. Manuscript Title Metformin-induced glucagon-like pep	tide-1 secretion contribute	es to the actions of metformin in type 2 diabetes
6. Manuscript Identifying Number (if you k	now it)	
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Generate Disc	losure Statement
Dr. de Fontgalland	d has nothing to disclose.

Evaluation and Feedback



Section 1. Identifying Inform	nation				
1. Given Name (First Name) Emilie	2. Surname (Last Name) Bahne	3. Date 10-October-2018			
4. Are you the corresponding author?		Corresponding Author's Name Damien Keating			
5. Manuscript Title Metformin-induced glucagon-like peptide-1 secretion contributes to the actions of metformin in type 2 diabetes					
6. Manuscript Identifying Number (if you k	now it)				
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Generate Dis	sclosure Statement
Dr. Bahne has n	othing to disclose.

Evaluation and Feedback



Section 1. Identifying Inform	nation	
1. Given Name (First Name) Emily	2. Surname (Last Name) Sun	3. Date 03-October-2018
4. Are you the corresponding author?		ding Author's Name o, Damien Keating
5. Manuscript Title Metformin-induced GLP-1 secretion co	ontributes to the actions of metformin i	n type 2 diabetes
6. Manuscript Identifying Number (if you k 93936-INS-CMED-RV-3	now it)	
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Miss Sun has no	thing to disclose.

Evaluation and Feedback

Please visit http://www.icmje.org/cgi-bin/feedback to provide feedback on your experience with completing this form.



Section 1. Identifying Inform	ation				
1. Given Name (First Name) Filip	2. Surname (Last Na Knop	me)		3. Date 17-September-2018	
4. Are you the corresponding author?	✓ Yes No				
5. Manuscript Title Metformin-induced GLP-1 secretion con	ntributes to the actio	ns of metformin i	n type 2 o	diabetes	
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Name of Entity	Grant? Personal Fees?	Non-Financial Support?	Other?	Comments	
Amgen	✓			Advisory board	×
AstraZeneca	✓	✓		Investigatior-initiated studies, advisory boards and educational activities (lecturing, teaching)	×
Boehringer Ingelheim				Advisory board and educational activities (lecturing, teaching)	×
Carmot Therapeutics	/			Scientific advise, consulting	×
Eli Lilly		✓		Advisory board and educational activities (lecturing, teaching), travelling to scientific meetings	×



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
Gubra	✓				Investigatior-initiated studies	×
Medimmune		✓			Advisory board and educational activities (lecturing, teaching)	×
MSD/Merck		✓	✓		Advisory board and educational activities (lecturing, teaching), travelling to scientific meetings	×
Norgine		✓			Educational activities (lecturing, teaching)	×
Novo Nordisk	✓	✓	/		Investigatior-initiated studies, consulting, advisory boards and educational activities (lecturing, teaching), travelling to scientific meetings	×
Sanofi	✓	✓			Investigatior-initiated studies, consulting, advisory boards and educational activities (lecturing, teaching)	×
Zealand Pharma	✓	✓			Investigatior-initiated studies, consulting, advisory boards and educational activities (lecturing, teaching)	×
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Section 4. Intellectual Property	Dete					
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Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work? Yes, the following relationships/conditions/circumstances are present (explain below): No other relationships/conditions/circumstances that present a potential conflict of interest Minority shareholder of Antag

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Section 6. Disclosure Statement

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Dr. Knop reports personal fees from Amgen, grants, personal fees and non-financial support from AstraZeneca, personal fees from Boehringer Ingelheim, personal fees from Carmot Therapeutics, personal fees and non-financial support from Eli Lilly, grants from Gubra, personal fees from Medlmmune, personal fees and non-financial support from MSD/Merck, personal fees from Norgine, grants, personal fees and non-financial support from Novo Nordisk, grants and personal fees from Sanofi, grants and personal fees from Zealand Pharma, outside the submitted work; and Minority shareholder of Antag.

Evaluation and Feedback



Section 1.	ldentifying Inform	nation		
1. Given Name (Fir Jakob	st Name)	2. Surname (Last Name) Schiøler Hansen		3. Date 24-September-2018
4. Are you the corr	esponding author?	Yes 🗸 No	Corresponding Author's N	ame
5. Manuscript Title Metformin-induc		tide-1 secretion contribute	s to the actions of metforn	nin in type 2 diabetes
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Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work? Yes, the following relationships/conditions/circumstances are present (explain below): No other relationships/conditions/circumstances that present a potential conflict of interest I am currently employed by Novo Nordisk A/S. By the time of the study conduct and analysis, I was not employed by Novo Nordisk A/S At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

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Dr. Schiøler Hansen reports that I am currently employed by Novo Nordisk A/S. By the time of the study conduct and analysis, I was not employed by Novo Nordisk A/S.

Evaluation and Feedback



Section 1. Identifying Inform	nation		
1. Given Name (First Name) Jens	2. Surname (Last Name) Holst		3. Date 25-September-2018
4. Are you the corresponding author?	Yes Vo	Corresponding Author's No Emilie Bahne	ame
5. Manuscript Title Metformin-induced GLP-1 secretion co	entributes to the actions o	f metformin in type 2 diabe	etes
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Section 6.	Disclosure Statement
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Generate Dis	closure Statement

Evaluation and Feedback



Section 1. Identifying Inform	nation		
1. Given Name (First Name) Lens	2. Surname (Last Name)	Relifeld	3. Date Sept. 17, 2018
4. Are you the corresponding author?	Yes No		
5. Manuscript Title Met Formin in typ	nduced GLP-1 se De 2 diabetes.	cretion contributes	to the actions of met-
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Section 4. Intellectual Proper	rty Patents & Copyri	ights	
Do you have any patents, whether plan	ned, pending or issued, b	proadly relevant to the work	? Yes 🔀 No



Section 5. Relationships not covered above
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Evaluation and Feedback



Section 1. Identifying Information
1. Given Name (First Name) 2. Surname (ast Name) 3. Date 2. Surname (ast Name)
4. Are you the corresponding author? Yes Yo
5. Manuscript Title metformin - induced glucagn like peptide - 1 6. Manuscript Identifying Number (if you know it) Secretian Contribution to the action of metformin in diabete
Section 2. The Work Under Consideration for Publication
Did you or your institution at any time receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)? Are there any relevant conflicts of interest? Yes
Section 3. Relevant financial activities outside the submitted work.
Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to publication. Are there any relevant conflicts of interest? Yes
Section 4. Intellectual Property Patents & Copyrights
Do you have any patents, whether planned, pending or issued, broadly relevant to the work?



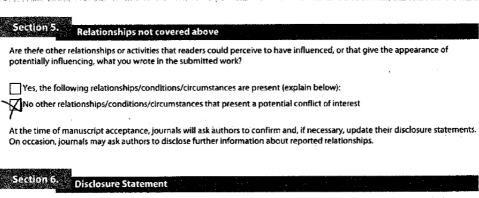
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	nanuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. urnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
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Evaluation and Feedback



Section 1. Identifying Information
1. Given Name (First Name) 2. Surname (Last Name) 3. Date 5. CV.S.O.
4. Are you the corresponding author?
5. Manuscript Title METFORM -100XGO GURI SECRETION CONSTITUBITES TO THE ACTIONS OF METFORMEN IN TYPE 7 OTABETES 6. Manuscript Identifying Number (if you know it)
Section 2. The Work Under Consideration for Publication
Did you or your institution at any time receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)? Are there any relevant conflicts of interest? Yes
Section 3: Relevant financial activities outside the submitted work.
Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to publication . Are there any relevant conflicts of interest? Yes No
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Do you have any patents, whether planned, pending or issued, broadly relevant to the work?





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Evaluation and Feedback



Section 1. Identifying Inform	nation		
1. Given Name (First Name) Morten	2. Surname (Last Name) Hansen	3. Date 18-September-2018	
4. Are you the corresponding author?	Yes 🗸 No	Corresponding Author's Name Filip Krag Knop	
5. Manuscript Title Metformin-induced GLP-1 secretion co	ntributes to the actions of	metformin in type 2 diabetes	
6. Manuscript Identifying Number (if you ki	now it)		
Section 2. The Work Under C	onsideration for Public	cation	
	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ita monitoring board, study design, manuscript preparation,	
Section 3. Relevant financial	activities outside the s	submitted work.	
Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to publication . Are there any relevant conflicts of interest? Yes No			
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Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work? Yes, the following relationships/conditions/circumstances are present (explain below): No other relationships/conditions/circumstances that present a potential conflict of interest At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships. Section 6. Disclosure Statement Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below. Generate Disclosure Statement Dr. Hansen has nothing to disclose.

Evaluation and Feedback



Section 1. Identifying Inform	nation		
1. Given Name (First Name) Paul	2. Surname (Last Name) Hollington	3. Date 10-October-2018	
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Name Damien Keating	
5. Manuscript Title Metformin-induced glucagon-like pep	tide-1 secretion contribute	es to the actions of metformin in type 2 diabetes	
6. Manuscript Identifying Number (if you k	now it)		
Section 2. The Work Under C	onsideration for Publi	cation	
, ,	g but not limited to grants, da	n a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,	
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Do you have any patents, whether plan	nned, pending or issued, b	roadly relevant to the work? Yes V No	





Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work? Yes, the following relationships/conditions/circumstances are present (explain below): No other relationships/conditions/circumstances that present a potential conflict of interest At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statement On occasion, journals may ask authors to disclose further information about reported relationships.
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Section 6. Disclosure Statement
Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.
Generate Disclosure Statement
Dr. Hollington has nothing to disclose.

Evaluation and Feedback



Section 1. Identifying Inform	nation	
1. Given Name (First Name) Philippa	2. Surname (Last Name) Rabbitt	3. Date 10-October-2018
4. Are you the corresponding author?	Yes 🗸 No	Corresponding Author's Name Damien Keating
5. Manuscript Title Metformin-induced glucagon-like pep	tide-1 secretion contribute	s to the actions of metformin in type 2 diabetes
6. Manuscript Identifying Number (if you k	now it)	
Section 2		
Did you or your institution at any time rece	. ,	a third party (government, commercial, private foundation, etc.) for
any aspect of the submitted work (includin statistical analysis, etc.)?	g but not limited to grants, da	ita monitoring board, study design, manuscript preparation,
Are there any relevant conflicts of inter	rest? Yes 🗸 No	
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Section 5.	Relationships not covered above
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Yes, the follo	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest
	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Generate Dis	closure Statement
Dr. Rabbitt has r	othing to disclose.

Evaluation and Feedback



Section 1.	Identifying Inform	ation					
1. Given Name (Fi Richard	rst Name)	2. Surnan Young	ne (Last Name)			3. Date 19-September-201	8
4. Are you the cor	responding author?	Yes	✓ No		ding Author Filip Knop		
5. Manuscript Title Metformin-induc	e ced GLP-1 secretion cor	ntributes to	the actions of I	netformin i	n type 2 d	iabetes	
6. Manuscript Ider 93936-INS-CMED	ntifying Number (if you kn D-RV-3	ow it)					
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Name of Institut	ion/Company	Grant?	-	-Financial upport?	Other?	Comments	
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Pfizer International (B	oston MA, USA)	✓				Direct research support	×
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Section 3.	Relevant financial	activities	outside the s	ubmitted	work.		
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Section 4.	Intellectual Proper	ty Pate	nts & Copyrig	hts			
Do you have any	patents, whether plani	ned, pendi	ng or issued, bro	oadly releva	nt to the v	vork? Yes V No	



Section 5.	Relationships not covered above			
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Section 6.	Disclosure Statement			
below.	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box			
Dr. Young repo conduct of the	rts grants from Australian Research Council, grants from Pfizer International (Boston MA, USA), during the study; .			

Evaluation and Feedback



Section 1. Identifying I	nformation	
Given Name (First Name) Steven L.	Surname (Last Name) Due	3. Date 19 Sept, 2018
4. Are you the corresponding autho	r? Yes X No	
5. Manuscript Title Metformin-induced GLP-1 s	ecretion contributes to the actions of metfo	ormin in type 2 diabetes
6. Manuscript Identifying Number (i	f you know it)	
Did you or your institution at any time	cluding but not limited to grants, data monitorin	y (government, commercial, private foundation, etc.) for ng board, study design, manuscript preparation,
Section 3. Relevant fina	ancial activities outside the submitted	i work.
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Section 4. Intellectual F	Property Patents & Copyrights	
Do you have any patents, whether	er planned, pending or issued, broadly relev	rant to the work? Yes X No



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Evaluation and Feedback



Section 1.	ldentifying Inforn	nation		
1. Given Name (Fi Tina	rst Name)	2. Surname (Last Name) Vilsbøll		3. Date 10-October-2018
4. Are you the cor	responding author?	Yes 🗸 No	Corresponding Author's Na Damien Keating	me
5. Manuscript Title Metformin-indue		ide-1 secretion contribute	s to the actions of metform	nin in type 2 diabetes
6. Manuscript Idei	ntifying Number (if you kı	now it)		
Section 2.	The Work Under C	onsideration for Public	ation	
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Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work	? Yes 🗸 No



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Generate Dis	closure Statement
Dr. Vilsbøll has n	othing to disclose.

Evaluation and Feedback



Section 1. Identifying In	formation	
1. Given Name (First Name) ULKLCH 4. Are you the corresponding authors	2. Surname (Last Name) ROHDE Yes No	3. Date 04. 10.2018
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Did you or your institution at any time	uding but not limited to grants, data monitoring be	vernment, commercial, private foundation, etc.) for oard, study design, manuscript preparation,
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Do you have any patents, whether	planned, pending or issued, broadly relevant	to the work? Yes X No



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Evaluation and Feedback



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	-
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	3-5
objectives	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	19
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none
Participants	4a	Eligibility criteria for participants	18-19
	4b	Settings and locations where the data were collected	24
nterventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	19
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	19 and 22
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	18
	7b	When applicable, explanation of any interim analyses and stopping guidelines	none
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	18
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	18
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	18
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	18
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	18

CONSORT 2010 checklist Page 1

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	Not relevant
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	23
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not relevant
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	6
diagram is strongly		were analysed for the primary outcome	
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	6
Recruitment	14a	Dates defining the periods of recruitment and follow-up	None
	14b	Why the trial ended or was stopped	Not relevant
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6 and 41
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	6 and 41
		by original assigned groups	
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	9-10 and 40-
estimation		precision (such as 95% confidence interval)	41
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16-17
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-17
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25-26

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist Page 2