

#### Instructions

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earning royalties or not

Zoungas 1



Section 1. Identifyin	g Information	
1. Given Name (First Name) Sophia	2. Surname (Last Name) Zoungas	3. Date 24-April-2019
4. Are you the corresponding au	thor? Yes 🗸 No	Corresponding Author's Name Peter Meikle
5. Manuscript Title Changes in plasma lipids pred	lict pravastatin efficacy in secondar	y prevention
6. Manuscript Identifying Numbors. 128438-INS-CMED-RV-3	er (if you know it)	
Section 2. The Work	Under Consideration for Publi	cation
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Section 3. Relevant f	inancial activities outside the	submitted work.
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Section 4. Intellecture		
Intellectua	al Property Patents & Copyri	ghts
Do you have any patents, who	ether planned, pending or issued, b	roadly relevant to the work? Yes V No

Zoungas 2



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Dr. Zoungas has	nothing to disclose.	

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C (1 )	L				
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Did you or your institution <b>at any time</b> 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 Vo					
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 <b>present during the 36 months prior to publication</b> .					
-	Are there any relevant conflicts of interest?  Ves  No				
	out the appropriate info				
Name of Entity		Grant? Persona	Non-Financial Support? Comments		
Amgen			Consultant on analyses of Medicare data		
Kyowa Hakko Kirin			Consultant		
Section 4.	Intellectual Proper	ty Patents & Co	pyrights		
Do you have any	patents, whether plan	ned, pending or issu	ed, broadly relevant to the work? Yes V No		

Woodward 2



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Dr. Woodward reports personal fees from Amgen, personal fees from Kyowa Hakko Kirin, outside the submitted work; .

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Wong 1



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Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work? ☐ Yes 🗸 No

Wong 2



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Tonkin 1



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4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle
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**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

Sullivan 1



Section 1.	Identifying Inform	nation	
1. Given Name (Fi David	rst Name)	2. Surname (Last Name) Sullivan	3. Date 24-April-2019
4. Are you the cor	responding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle
5. Manuscript Title Changes in plasr		statin efficacy in secondary	prevention
6. Manuscript Idei ms. 128438-INS-	ntifying Number (if you kr CMED-RV-3	now it)	
Section 2.	The Work Under Co	onsideration for Public	cation
any aspect of the s statistical analysis,	ubmitted work (including	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.
of compensation clicking the "Add	) with entities as descri	ibed in the instructions. Us port relationships that wer	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication.
Section 4.	Intollectual Prepar	rty Patents & Copyrig	white
	intenectual Proper	rty Patents & Copyrig	jiis —
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work? Yes No

Sullivan 2



Section 5.	
Section 5.	Relationships not covered above
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
✓ No other relat	tionships/conditions/circumstances that present a potential conflict of interest
	nuscript 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 below.	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Sullivan has n	nothing to disclose.

## **Evaluation and Feedback**

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Sullivan 3



#### **Instructions**

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# 4. Intellectual Property.

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Simes 1



Section 1. Identifying Info	ormation				
1. Given Name (First Name) John	2. Surname (Last Name) Simes	3. Date 29-April-2019			
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasma lipids predict pra	ıvastatin efficacy in secondary	y prevention			
6. Manuscript Identifying Number (if yo ms. 128438-INS-CMED-RV-3	u know it)				
		_			
Section 2. The Work Unde	r Consideration for Public	cation			
Did you or your institution <b>at any time</b> 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  No					
Section 3. Polyment Guard					
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Section 4. Intellectual Pro	perty Patents & Copyrig	ghts			
Do you have any patents, whether p					

Simes 2



Section 5.	Relationships not covered above
	elationships 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):
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
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Dr. Simes has no	othing to disclose.

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Nestel 1



Section 1. Identifying Infor	mation				
1. Given Name (First Name) Paul	2. Surname (Last Name) Nestel	3. Date 24-April-2019			
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasma lipids predict prav	astatin efficacy in secondary	y prevention			
6. Manuscript Identifying Number (if you ms. 128438-INS-CMED-RV-3	know it)				
		-			
Section 2. The Work Under	Consideration for Public	cation			
Did you or your institution <b>at any time</b> 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  No					
Section 3. Relevant financia	al activities outside the s	ubmitted work.			
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Section 4. Intellectual Prop	erty Patents & Copyri <u>c</u>	ghts			
Do you have any patents, whether pla	anned, pending or issued, br	oadly relevant to the work? Yes V No			

Nestel 2



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):
✓ 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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**Royalties:** Funds are coming in to you or your institution due to your patent

Mundra 1



Section 1. Identifying Inform	nation				
1. Given Name (First Name) Piyushkumar	2. Surname (Last Name) Mundra	3. Date 24-April-2019			
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasma lipids predict prava	statin efficacy in secondary	prevention			
6. Manuscript Identifying Number (if you k ms. 128438-INS-CMED-RV-3	now it)				
Section 2. The Work Under C	Consideration for Public	cation			
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Section 3. Polyment Grand Street		orbonolista al consula			
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Section 4. Intellectual Prope	rty Patents & Copyrig	yhts			
Do you have any patents, whether plar					

Mundra 2



Section 5. Relationships not severed above
Relationships not covered above
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):
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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.
Dr. Mundra has nothing to disclose.

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

Mellett 1



Section 1. Identifying I	nformation				
1. Given Name (First Name) Natalie	2. Surname (Last Name) Mellett	3. Date 24-April-2019			
4. Are you the corresponding author	? Yes 🗸 No	Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasma lipids predict	pravastatin efficacy in secondary	prevention			
6. Manuscript Identifying Number (if ms. 128438-INS-CMED-RV-3	you know it)				
Section 2. The Work Un	der Consideration for Public	cation			
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Section 4. Intellectual B					
Intellectual P	roperty Patents & Copyrig	hts			
Do you have any patents, whether	r planned, pending or issued, br	oadly relevant to the work? Yes V No			

Mellett 2



Section 5.	
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Costion 1						
Section 1.	Identifying Inform	ation				
1. Given Name (Fi	rst Name)	2. Surnam Meikle	ne (Last Nar	ne)	3. Date 24-April-2019	
4. Are you the cor	responding author?	✓ Yes	No			
5. Manuscript Title Changes in plasr	e na lipids predict pravasi	tatin effica	cy in secoi	ndary prevention		
6. Manuscript Ider ms. 128438-INS-	ntifying Number (if you kno CMED-RV-3	ow it)				
Section 2.	The Work Under Co	nsiderat	ion for P	ublication		
any aspect of the s statistical analysis,	ubmitted work (including	but not lim	ited to gran			ent, commercial, private foundation, etc.) foudy design, manuscript preparation,
If yes, please fill o		rmation be	elow. If you		one enti	ty press the "ADD" button to add a row
Name of Institut	ion/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Zora Biosciences					<b>✓</b>	We have licensed intellectual property relating to lipid biomarkers described in this manuscript to Zora Biosciences
National Health and I of Australia	Medical Research Council	<b>✓</b>				Competitive grant from the Australian government
Section 3.	Relevant financial a	ctivitios	outsidad	the submitted	work -	
Place a check in to of compensation clicking the "Add	:he appropriate boxes ir ) with entities as descril	n the table bed in the ort relation	to indicat	e whether you hans. Use one line fo t were <b>present d</b>	ive financ or each ei	cial relationships (regardless of amount ntity; add as many lines as you need by e <b>36 months prior to publication</b> .



Section 4						
Section 4. Intellectual Property Patents & Copyrights						
Do you have any patents, wheth If yes, please fill out the appropr Excess rows can be removed by	riate information belo	w. If you have n	•		Yes No the "ADD" button to add a	a row.
Patent?	Pending? Issued?	Licensed? Ro	yalties <mark>?</mark> l	Licensee ?	Comments	
WO 2011/063470 "Lipid biomarkers for stable and unstable heart disease		<b>V</b>			Family of five patents now under National Phase examination: US, Europe, Australia, China and India.	
Section 5. Relationshi	ps not covered abo	ove				
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 relationsh	ips/conditions/circur	nstances are pre	esent (expla	ain 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.						
Dr. Meikle reports other from Zora Biosciences, grants from National Health and Medical Research Council of Australia, during the conduct of the study; In addition, Dr. Meikle has a patent WO 2011/063470 "Lipid biomarkers for stable and unstable heart disease licensed.						



#### **Evaluation and Feedback**

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

McConville 1



Section 1. Identifying Inform	nation				
1. Given Name (First Name) Malcolm	2. Surname (Last Name) McConville	3. Date 24-April-2019			
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasma lipids predict pravas	statin efficacy in secondary	y prevention			
6. Manuscript Identifying Number (if you kr ms. 128438-INS-CMED-RV-3	now it)				
Section 2. The Work Under Co	onsideration for Public	cation			
Did you or your institution <b>at any time</b> 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  Vo					
Section 3. Relevant financial	activities outside the s	ubmitted work.			
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Section 4. Intellectual Proper					
Intellectual Proper	rty Patents & Copyric	hts			
Do you have any patents, whether plan	ned, pending or issued, br	oadly relevant to the work? Yes V No			

McConville 2



Section 5. Polationships not severed above
Relationships not covered above
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):
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Dr. McConville has nothing to disclose.

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

Marschner 1



Section 1.	Identifying Inform	nation				
1. Given Name (Fir lan	st Name)	2. Surname (Last Name) Marschner	3. Date 24-April-2019			
4. Are you the corresponding author? Yes ✓ No			Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasn		statin efficacy in secondary	prevention			
6. Manuscript Iden ms. 128438-INS-0	ntifying Number (if you kn CMED-RV-3	now it)				
Section 2.	The Work Under Co	onsideration for Public	cation			
any aspect of the su statistical analysis,	ubmitted work (including	but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,			
Section 3.	Relevant financial	activities outside the s	ubmitted work.			
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Section 4.	Intellectual Proper	ty Patents & Copyric	yhts			
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work? ☐ Yes 🗸 No			

Marschner 2



Section 5. Polationships not severed above
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**Royalties:** Funds are coming in to you or your institution due to your patent

Kirby 1



Section 1.	Identifying Inform	nation				
1. Given Name (Fi Adrienne	rst Name)	2. Surname (Last Name) Kirby	3. Date 24-April-2019			
4. Are you the corresponding author? Yes ✓ No		Yes ✓ No	Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasr		statin efficacy in secondary	prevention			
6. Manuscript Ider ms. 128438-INS-	ntifying Number (if you kr CMED-RV-3	now it)				
			-			
Section 2.	The Work Under C	onsideration for Public	cation			
any aspect of the s statistical analysis,	ubmitted work (including	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,			
Section 3.	Relevant financial	activities outside the s	submitted work.			
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Section 4.	Intellectual Proper	rty Patents & Copyri <u>c</u>	ghts			
Do you have any			oadly relevant to the work? Yes V No			

Kirby 2



Section 5. Relationships not severed above
Relationships not covered above
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Kingwell 1



Section 1.	Identifying Informa	ation			
1. Given Name (Fi Bronwyn	rst Name)	2. Surname (Last Na Kingwell	me)	3. Date 24-April	l-2019
4. Are you the cor	esponding author? Yes Von Corresponding Author's Name  Peter Meikle				
5. Manuscript Title Changes in plasr	e ma lipids predict pravast	tatin efficacy in seco	ondary prevention		
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	ı				
Section 2.	The Work Under Co	nsideration for P	Publication		
any aspect of the s statistical analysis,	ubmitted work (including	but not limited to gra		(government, commercial, g board, study design, man	private foundation, etc.) for uscript preparation,
	out the appropriate info be removed by pressing	-	ou have more thar	n one entity press the "Al	DD" button to add a row.
Name of Institut	ion/Company	Grant? Personal Fees?	Non-Financial Support?	Other? Comments	
National Health and <i>I</i> of Australia	Medical Research Council	<b>✓</b>		Grant to Baker I	DI Heart and Diabetes
Section 3.	Relevant financial a	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 <b>present during the 36 months prior to publication</b> .					
Are there any rel	evant conflicts of intere	st? Yes ✓	No		
Continue					
Section 4.	Intellectual Propert	ty Patents & Co	pyrights		
If yes, please fill o	patents, whether plann out the appropriate info be removed by pressing	rmation below. If yo	•		No No DD" button to add a row.

Kingwell 2



Patent	?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments	
WO 2011/063470 - IP r lipid biomarkers descr manuscript has been l Biosciences Oy, Finlan	ibed in this icensed to Zora			<b>✓</b>				
Section 5.	Relationshi	ns not cov	ered abo	ove				
Are there other re potentially influer	lationships or	activities tha	it readers	could perc	eive to have	influenced, or tha	at give the appearance of	
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Dr. Kingwell reports grants from National Health and Medical Research Council of Australia, during the conduct of the study; In addition, Dr. Kingwell has a patent relating to the lipid biomarkers described in this manuscript which has been licensed to Zora Biosciences Oy, Finland.								

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Jayawardana

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

1

administrative support, etc.



Section 1. Identifying Inform	mation					
1. Given Name (First Name) Kaushala	2. Surname (Last Name) Jayawardana	3. Date 24-April-2019				
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle				
5. Manuscript Title Changes in plasma lipids predict prava	statin efficacy in secondary	prevention				
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Carting 2						
Section 3. Relevant financial	activities outside the s	ubmitted work.				
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Jayawardana 2



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Dr. Jayawardana has nothing to disclose.

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

Huynh 1



Section 1.	Identifying Inform	nation				
1. Given Name (Fire Kevin	st Name)	2. Surname (Last Name) Huynh	3. Date 24-April-2019			
4. Are you the corresponding author?		Yes ✓ No	Corresponding Author's Name Peter Meikle			
5. Manuscript Title Changes in plasm		statin efficacy in secondary	prevention			
6. Manuscript Iden ms. 128438-INS-C	tifying Number (if you kr CMED-RV-3	now it)				
Section 2.	The Work Under Co	onsideration for Public	cation			
any aspect of the su statistical analysis, e	ubmitted work (including	but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta 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 <b>present during the 36 months prior to publication</b> .  Are there any relevant conflicts of interest? Yes Vo						
Section 4.	Intellectual Proper	rty Patents & Copyric	yhts			
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work? ☐ Yes ✓ No			

Huynh 2



Section 5.	
Section 5.	Relationships not covered above
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
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Hillis 1



Section 1. Identifying Inform	nation					
1. Given Name (First Name) Graham	2. Surname (Last Name) Hillis	3. Date 24-April-2019				
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Peter Meikle				
5. Manuscript Title Changes in plasma lipids predict prava	statin efficacy in secondary	prevention				
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		-				
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Did you or your institution <b>at any time</b> 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  No						
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Do you have any patents, whether plan	nned, pending or issued, br	oadly relevant to the work? Yes V No				

Hillis 2



Section 5. Polationships not sovered above
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Giles 1



Section 1.	Identifying Inform	nation	
1. Given Name (Fi Corey	rst Name)	2. Surname (Last Name) Giles	3. Date 24-April-2019
4. Are you the cor	responding author?	Yes ✓ No	Corresponding Author's Name Peter Meikle
5. Manuscript Title Changes in plasr		statin efficacy in secondary	y prevention
6. Manuscript Idei ms. 128438-INS-	ntifying Number (if you kr CMED-RV-3	now it)	
			-
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Section 3.	Dalamant financial		b
Place a check in tool of compensation clicking the "Add	the appropriate boxes i n) with entities as descri	ibed in the instructions. Us port relationships that wer	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication.
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טט you nave any	patents, whether plan	nea, penaing or issued, br	oadly relevant to the work? Yes V

Giles 2



Section 5.	
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Dr. Giles has noth	ning to disclose.

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Chalmers 1



**Identifying Information** 

Section 1.

# **ICMJE Form for Disclosure of Potential Conflicts of Interest**

1. Given Name (First Name) John	2. Surnam Chalmers	ne (Last Nan	ne)		3. Date 24-April-2019
4. Are you the corresponding author?	Yes	✓ No	Correspond Peter Meil	•	or's Name
5. Manuscript Title Changes in plasma lipids predict prav	astatin effica	cy in secor	ndary prevention		
6. Manuscript Identifying Number (if you ms. 128438-INS-CMED-RV-3	know it)				
Section 2. The Work Under	Considerati	ion for P	ublication		
Did you or your institution <b>at any time</b> recany aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of interecany relevant	ng but not limi		ts, data monitoring		ent, commercial, private foundation, etc.) for udy design, manuscript preparation,
Section 3. Relevant financia	l activities	outside 1	the submitted	work.	
	cribed in the eport relation rest?	instructior nships that es	ns. Use one line fo	or each er	cial relationships (regardless of amount ntity; add as many lines as you need by a <b>36 months prior to publication</b> .
Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
ervier, Idorsia	✓	<b>✓</b>			Research Grant from Servier, administered through the University of Sydney, as chief investigator for the ADVANCE trial and ADVANCE-ON post trial study, and lecture fees from Servier for speaking about these studies at scientific meetings.  And a research grant from Idorsia,

Chalmers 2

administered through George Clinical, for the SPIRIT study of resistant hypertension



Continue 4	
Section 4. Intellectual Property Patents & Copyrights	
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo	
Section 5. Relationships not covered above	
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?	:
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Dr. Chalmers reports grants and personal fees from Servier, and Idorsia, outside the submitted work.	

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Barnes 1



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4. Are you the cor	responding author?	Yes ✓ No	Corresponding Author's Name Peter Meikle
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Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work? Yes V No

Barnes 2



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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.

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# 4. Intellectual Property.

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

# Relationships not covered above.

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#### Definitions.

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

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**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

Barlow 1



Section 1. Identifying Infor	mation	
1. Given Name (First Name) Christopher	2. Surname (Last Name) Barlow	3. Date 24-April-2019
4. Are you the corresponding author?	Yes 🗸 No	Corresponding Author's Name Peter Meikle
5. Manuscript Title Changes in plasma lipids predict prava	astatin efficacy in secondary	y prevention
6. Manuscript Identifying Number (if you kms. 128438-INS-CMED-RV-3	know it)	
		_
Section 2. The Work Under (	Consideration for Public	cation
	ng but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ita monitoring board, study design, manuscript preparation,
Continue 2		
Section 3. Relevant financia	l activities outside the s	ubmitted work.
of compensation) with entities as desc	ribed in the instructions. Us eport relationships that wer	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication.
Section 4. Intellectual Prope	erty Patents & Copyric	ghts
Do you have any patents, whether plan	nned, pending or issued, br	roadly relevant to the work? Yes V No

Barlow 2



Section 5.	
Section 5.	Relationships not covered above
	elationships 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):
✓ 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 below.	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Barlow has n	othing to disclose.

## **Evaluation and Feedback**

Please visit <a href="http://www.icmje.org/cgi-bin/feedback">http://www.icmje.org/cgi-bin/feedback</a> to provide feedback on your experience with completing this form.

Barlow 3



#### 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.

## 2. 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 "Yes".

### Relevant financial activities outside the submitted work.

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

Alshehry 1



Section 1.	Identifying Inform	nation	
1. Given Name (Fir Zahir	rst Name)	2. Surname (Last Name) Alshehry	3. Date 24-April-2019
4. Are you the corr	responding author?	Yes ✓ No	Corresponding Author's Name Peter Meikle
5. Manuscript Title Changes in plasn		statin efficacy in secondary	prevention
6. Manuscript Ider ms. 128438-INS-0	ntifying Number (if you kr CMED-RV-3	now it)	
			-
Section 2.	The Work Under Co	onsideration for Public	ation
any aspect of the si statistical analysis,	ubmitted work (including	but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,
Section 3.	Relevant financial	activities outside the s	ubmitted work.
of compensation clicking the "Add	) with entities as descri	bed in the instructions. Us port relationships that wer	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by se <b>present during the 36 months prior to publication</b> .
Section 4.	Intellectual Proper	rty Patents & Copyric	yhts
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work? ☐ Yes ✓ No

Alshehry 2



Section 5. Relationships not covered above
Relationships not covered above
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.
Dr. Alshehry has nothing to disclose.

## **Evaluation and Feedback**

Please visit <a href="http://www.icmje.org/cgi-bin/feedback">http://www.icmje.org/cgi-bin/feedback</a> to provide feedback on your experience with completing this form.

Alshehry 3

TITLE OR ABSTRACT		Changes in plasma lipids predict pravastatin efficacy in secondary prevention	
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy	2
		(such as sensitivity, specificity, predictive values, or AUC)	
ABSTRACT	_		2
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	2
INTRODUCTION			4
	3	Scientific and clinical background, including the intended use and clinical role of the index test	4
	4	Study objectives and hypotheses	2
METHODS	4	Study objectives and hypotheses	18
	-	Whather data collection was planted before the index test and reference standard	
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	18
Participants	6	Eligibility criteria	18
	7	On what basis potentially eligible participants were identified	18
		(such as symptoms, results from previous tests, inclusion in registry)	
	8	Where and when potentially eligible participants were identified (setting, location and dates)	18
	9	Whether participants formed a consecutive, random or convenience series	18
 Test methods	10a	Index test, in sufficient detail to allow replication	18
rest methods	10b	Reference standard, in sufficient detail to allow replication	18
	111	Rationale for choosing the reference standard (if alternatives exist)	18
	11 12a	Definition of and rationale for test positivity cut-offs or result categories	19-21
	12a	of the index test, distinguishing pre-specified from exploratory	19-21
	12b	Definition of and rationale for test positivity cut-offs or result categories	19-21
		of the reference standard, distinguishing pre-specified from exploratory	
	13a	Whether clinical information and reference standard results were available	19-21
		to the performers/readers of the index test	
	13b	Whether clinical information and index test results were available	19-21
		to the assessors of the reference standard	
Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	19-21
	15	How indeterminate index test or reference standard results were handled	19-21
	16	How missing data on the index test and reference standard were handled	19-21
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	19-21
	18	Intended sample size and how it was determined	Supp Material p2
RESULTS			5
Participants	19	Flow of participants, using a diagram	Supplementary Figure 1
	20	Baseline demographic and clinical characteristics of participants	Supp Material p2
	<b>21</b> a	Distribution of severity of disease in those with the target condition	Supp Material p2
	21b	Distribution of alternative diagnoses in those without the target condition	Supp Material p2
	22	Time interval and any clinical interventions between index test and reference standard	Supp Material p2
Test results	23	Cross tabulation of the index test results (or their distribution)	Supp Tables
		by the results of the reference standard	
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Supp Tables
	25	Any adverse events from performing the index test or the reference standard	N/A
DISCUSSION			11



	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	15-16
	27	Implications for practice, including the intended use and clinical role of the index test	17
OTHER INFORMATION			
	28	Registration number and name of registry	N/A
	29	Where the full study protocol can be accessed	Supp Material p2
	30	Sources of funding and other support; role of funders	3



#### **STARD 2015**

#### AIM

STARD stands for "Standards for Reporting Diagnostic accuracy studies". This list of items was developed to contribute to the completeness and transparency of reporting of diagnostic accuracy studies. Authors can use the list to write informative study reports. Editors and peer-reviewers can use it to evaluate whether the information has been included in manuscripts submitted for publication.

#### **EXPLANATION**

A diagnostic accuracy study evaluates the ability of one or more medical tests to correctly classify study participants as having a target condition. This can be a disease, a disease stage, response or benefit from therapy, or an event or condition in the future. A medical test can be an imaging procedure, a laboratory test, elements from history and physical examination, a combination of these, or any other method for collecting information about the current health status of a patient.

The test whose accuracy is evaluated is called **index test.** A study can evaluate the accuracy of one or more index tests. Evaluating the ability of a medical test to correctly classify patients is typically done by comparing the distribution of the index test results with those of the **reference standard**. The reference standard is the best available method for establishing the presence or absence of the target condition. An accuracy study can rely on one or more reference standards.

If test results are categorized as either positive or negative, the cross tabulation of the index test results against those of the reference standard can be used to estimate the **sensitivity** of the index test (the proportion of participants *with* the target condition who have a positive index test), and its **specificity** (the proportion *without* the target condition who have a negative index test). From this cross tabulation (sometimes referred to as the contingency or "2x2" table), several other accuracy statistics can be estimated, such as the positive and negative **predictive values** of the test. Confidence intervals around estimates of accuracy can then be calculated to quantify the statistical **precision** of the measurements.

If the index test results can take more than two values, categorization of test results as positive or negative requires a **test positivity cut-off**. When multiple such cut-offs can be defined, authors can report a receiver operating characteristic (ROC) curve which graphically represents the combination of sensitivity and specificity for each possible test positivity cut-off. The **area under the ROC curve** informs in a single numerical value about the overall diagnostic accuracy of the index test.

The **intended use** of a medical test can be diagnosis, screening, staging, monitoring, surveillance, prediction or prognosis. The **clinical role** of a test explains its position relative to existing tests in the clinical pathway. A replacement test, for example, replaces an existing test. A triage test is used before an existing test; an add-on test is used after an existing test.

Besides diagnostic accuracy, several other outcomes and statistics may be relevant in the evaluation of medical tests. Medical tests can also be used to classify patients for purposes other than diagnosis, such as staging or prognosis. The STARD list was not explicitly developed for these other outcomes, statistics, and study types, although most STARD items would still apply.

#### **DEVELOPMENT**

This STARD list was released in 2015. The 30 items were identified by an international expert group of methodologists, researchers, and editors. The guiding principle in the development of STARD was to select items that, when reported, would help readers to judge the potential for bias in the study, to appraise the applicability of the study findings and the validity of conclusions and recommendations. The list represents an update of the first version, which was published in 2003.

More information can be found on http://www.equator-network.org/reporting-guidelines/stard.

