

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.

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

Cai 1



Section 1. Identifying In	formation				
1. Given Name (First Name) Tianxi	2. Surname (Last Name) Cai	3. Date 27-April-2015			
4. Are you the corresponding author:	Yes 🗸 No	Corresponding Author's Name Lee-Jen Wei			
5. Manuscript Title Alternatives to hazard ratios for co	omparing efficacy or safety of th	erapies in noninferiority studies			
6. Manuscript Identifying Number (if M14-1741	you know it)				
Section 2. The Work Unc	ler Consideration for Public	cation			
	luding 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 final	ncial 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 Vo					
Section 4. Intellectual Pr	operty Patents & Copyric	ghts			
Do you have any patents, whether	planned, pending or issued, br	oadly relevant to the work? Yes V No			

Cai 2



Section 5. Polationships not sovered abo	
Relationships not covered abo	ove
Are there other relationships or activities that readers potentially influencing, what you wrote in the submit	could perceive to have influenced, or that give the appearance of ted work?
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Section 6. Disclosure Statement	
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Dr. Cai has nothing to disclose.	

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Cai 3



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

Claggett 1



Section 1. Identify	ying Information				
1. Given Name (First Name) Brian	2. Surname (Last Nar Claggett	me) 3. Date 28-April-2015			
4. Are you the corresponding	author? Yes Vo	Corresponding Author's Name Hajime Uno			
5. Manuscript Title Alternatives to hazard ratio	os for comparing efficacy or safety	of therapies in noninferiority studies			
6. Manuscript Identifying Nu	mber (if you know it)				
Section 2. The Wo	rk Under Consideration for P	ublication			
	vork (including but not limited to gran	s from a third party (government, commercial, private foundation, etc.) for nts, data monitoring board, study design, manuscript preparation, No			
Section 3. Relevan	nt financial activities outside	the submitted work.			
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Do you have any patents, v	vhether planned, pending or issue	ed, broadly relevant to the work? Yes V No			

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Wei 1



Section 1.	Identifying Inform	ation			
1. Given Name (Fir Lee-Jen	st Name)	2. Surname (L Wei	ast Name)		3. Date 29-April-2015
4. Are you the corresponding author? ✓ Yes No					
5. Manuscript Title Alternatives to ha		ing efficacy or	safety of therapies in no	oninferiority st	udies
6. Manuscript Iden M14-1741	itifying Number (if you kn	ow it)			
Section 2.	The Work Under Co	onsideration	for Publication		
any aspect of the su statistical analysis, e	ubmitted work (including	but not limited			ommercial, private foundation, etc.) for esign, manuscript preparation,
Section 3.					
Section 3.	Relevant financial	activities out	tside the submitted	work.	
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Section 4.	Intellectual Proper	ty Patents	& Copyrights		
Do you have any	patents, whether plans	ned, pending c	or issued, broadly releva	nnt to the work	? ☐ Yes ✓ No

Wei 2



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Fu 1



Section 1. Identifying Inform	mation				
1. Given Name (First Name) Haoda	2. Surname (Last Name) Fu	3. Date 27-April-2015			
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name LJ Wei			
5. Manuscript Title Alternatives to hazard ratios for compa	aring efficacy or safety of th	nerapies in noninferiority studies			
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Fu 2



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Scott R	(First Name)	2. Surname (Last Nam Evans	ne) 3. Date 23-May-2015
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any aspect of the statistical analys	e submitted work (includin sis, etc.)?	g but not limited to grant	from a third party (government, commercial, private foundation, etc.) for ts, data monitoring board, study design, manuscript preparation,
•	relevant conflicts of inter		No
	II out the appropriate inf In be removed by pressir		u have more than one entity press the "ADD" button to add a row.
Name of Instit	cution/Company	Grant? Personal Fees?	Non-Financial Other? Comments
NIAID / NIH		✓	Grant from NIAID / NIH
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Are there any r	ll out the appropriate inf	formation below. Grant? Personal	Non-Financial Other? Comments
Are there any r	ll out the appropriate inf	formation below.	Non-Financial Other? Comments
Are there any r If yes, please fi Name of Entity	ll out the appropriate inf	Grant? Personal Fees?	Non-Financial Other? Comments



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Novartis		✓			DSMB
Achaogen		✓			DSMB
MGH		\checkmark			DSMB
Taris		✓			DSMB
Boston University		✓			DSMB
Huntington's Study Group		\checkmark			DSMB
Auspex		\checkmark			DSMB
Alcon		✓			Think Tank
Merck		✓			Think Tank
Chelsea		✓			Think Tank
Mannkind		✓			Think Tank
QRx Pharma		\checkmark			Think Tank
IMMPACT		\checkmark			Think Tank
Genentech		\checkmark			Think Tank
Affymax		✓			Think Tank
FzioMed		✓			Think Tank
Amgen		✓			Think Tank
GSK		✓			Teaching
Sunovion		✓			Teaching
Boehringer-Ingelheim		\checkmark			Teaching
American Statistical Association		\checkmark			Teaching
FDA		✓			Advisory Committee / Teaching
Osaka University		\checkmark			Teaching
City of Hope		✓			Teaching
Nationa Cerebral and Cardiovascular Center of Japan		✓			Teahching
NIH		✓			DSMB
Muscle Study Group		✓			Speaker
Society for Clinical Trials		✓			Speaker
Dug Information Association		✓			Speaker



University of Rhode Island		✓			Speaker
NJMS / Rutgers		\checkmark			Speaker
PPRECISE		✓			Think Tank
Statistical Communications in Infectious Diseases		✓			Editor-in-Chief
Section 4. Intellectual Propert	y Pater	nts & Co _l	pyrights		
Do you have any patents, whether plann	ed, pendir	ng or issue	ed, broadly releva	nt to the	e work? ☐ Yes 🗸 No
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below.

Dr. Evans reports grants from NIAID / NIH, during the conduct of the study; personal fees from Takeda / Millennium, personal fees from Pfizer, personal fees from Roche, personal fees from Novartis, personal fees from Achaogen, personal fees from MGH, personal fees from Taris, personal fees from Boston University, personal fees from Huntington's Study Group, personal fees from Auspex, personal fees from Alcon, personal fees from Merck, personal fees from Chelsea, personal fees from Mannkind, personal fees from QRx Pharma, personal fees from IMMPACT, personal fees from Genentech, personal fees from Affymax, personal fees from FzioMed, personal fees from Amgen, personal fees from GSK, personal fees from Sunovion, personal fees from Boehringer-Ingelheim, personal fees from American Statistical Association, personal fees from FDA, personal fees from Osaka University, personal fees from City of Hope, personal fees from Nationa Cerebral and Cardiovascular Center of Japan, personal fees from NIH, personal fees from Muscle Study Group, personal fees from Society for Clinical Trials, personal fees from Dug Information Association, personal fees from University of Rhode Island, personal fees from NJMS / Rutgers, personal fees from PPRECISE, personal fees from Statistical Communications in Infectious Diseases, outside the submitted work; .



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

Tian 1



Section 1.	Identifying Inforn	nation			
1. Given Name (Fi Lu	rst Name)	2. Surname (Last Name) Tian	3. Date 27-April-2015		
4. Are you the cor	responding author?	☐ Yes ✓ No	Corresponding Author's Name LJ Wei		
5. Manuscript Title Alternatives to h		ring efficacy or safety of th	nerapies in noninferiority studies		
6. Manuscript Ide	ntifying Number (if you kı	now it)			
Section 2.	The Work Under C	onsideration for Publi	cation		
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 No					
Section 3.	Relevant financial	activities outside the	submitted work.		
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Section 4.	Intellectual Prope	rty Patents & Copyri	ghts		
Do you have any	patents, whether plan	ned, pending or issued, b	roadly relevant to the work? Yes V No		

Tian 2



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

Evaluation and Feedback

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Tian 3



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Uno 1



Section 1. Identifying In	formation	
1. Given Name (First Name) Hajime	2. Surname (Last Name) Uno	3. Date 27-April-2015
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Lee-Jen Wei
5. Manuscript Title Alternatives to hazard ratios for co	mparing efficacy or safety of th	erapies in noninferiority studies
6. Manuscript Identifying Number (if y M14-1741	ou know it)	
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Section 2. The Work Und	er Consideration for Public	cation
	uding 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 finan	cial activities outside the s	submitted work.
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Section 4. Intellectual Pre		
Intellectual Pro	operty Patents & Copyric	hts
Do you have any patents, whether	planned, pending or issued, br	oadly relevant to the work? Yes V No

Uno 2



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Uno 3



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1. Given Name (First Name) Marc Pfeffer 2. Surname (Last Name) Marc Pfeffer 01-May-2015 4. Are you the corresponding author? Yes No Corresponding Author's Name Lee-Jen Wei, Ph.D. 5. Manuscript Title "Alternatives to hazard ratios for comparing efficacy or safety of therapies in noninferiority studies 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 foundat any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparat statistical analysis, etc.)? Are there any relevant conflicts of interest? Yes No If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to Excess rows can be removed by pressing the "X" button. Name of Institution/Company Grant? Personal Fees? Non-Financial Support? Comments	
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Name of institution/company Grant	add a row.
none	
Section 3. Relevant financial activities outside the submitted work.	
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If yes, please fill out the appropriate information below.	
Name of Entity Grant? Personal Fees? Non-Financial Support? Comments	
Amgen Institutional agreement to the	
Brigham and Women's Hospital Consulting fees.	and



Name of Entity	Grant •	Fees?	Support?	Other •	Comments
Celladon	✓				Institutional agreement to the Brigham and Women's Hospital.
Cleveland Clinic		✓			Consulting fees.
Medicines Company		✓			Consulting fees.
Hamilton Health Sciences	✓				Institutional agreement to the Brigham and Women's Hospital. Not considered relevant.
Merck		✓			Consulting fees.
Novartis	✓	✓			Institutional agreement to the Brigham and Women's Hospital and Consulting fees.
Roche		✓			Consulting fees.
Sanofi Aventis	✓				Institutional agreement to the Brigham and Women's Hospital. Not considered relevant.
Servier		✓			Consulting fees.
Teva		✓			Consulting fees.
Novo Nordisk		✓			Consulting fees.
Salix		✓			Consulting fees.
Sanderling		✓			Consulting fees.
Relypsa		✓			Consulting fees.
AstraZeneca		✓			Consulting fees.
Bayer		✓			Consulting fees.
MedImmune		✓			Consulting fees.
Takeda		\checkmark			Consulting fees.
Section 4. Intellectual Bronout					
Intellectual Propert	y Pate	ents & Cop	yrights		
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.					
Patent? Pendin	g <mark>?</mark> Issue	d? Licens	ed? Royalties?	License	ce? Comments



Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments	
Novartis. The Brigham and Women's Hospital has patents for the use of inhibitors of the RAS in selected survivors of MI with Novartis Dr. Pfeffer is a co-inventor. His share of the licensing agreement is irrevocably transferred to charity.			√			Not considered relevant.	

Section 5.	Relationships not covered above

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Section 6. Disclosure Statement

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Dr. Pfeffer reports grants and personal fees from Amgen, personal fees from Aastrom, personal fees from Abbott Vascular, grants from Celladon, personal fees from Cleveland Clinic, personal fees from Concert, grants from Hamilton Health Sciences, personal fees from FibroGen, personal fees from GlaxoSmithKline, personal fees from Medtronic, personal fees from Merck, grants from Novartis, personal fees from Roche, grants from Sanofi Aventis, personal fees from Servier, personal fees from Teva, personal fees from Daiichi Sankyo, personal fees from Genzyme, personal fees from Novo Nordisk, personal fees from Salix, personal fees from Sanderling, outside the submitted work; In addition, Dr. Pfeffer has a patent Novartis. The Brigham and Women's Hospital has patents for the use of inhibitors of the RAS in selected survivors of MI with Novartis Dr. Pfeffer is a co-inventor. His share of the licensing agreement is irrevocably transferred to charity. licensed.



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Solomon 1



Section 1.	Identifying Inforn	nation	
1. Given Name (Fi Scott	rst Name)	2. Surname (Last Name) Solomon	3. Date 19-May-2015
4. Are you the cor	responding author?	☐ Yes ✓ No	Corresponding Author's Name Wei
5. Manuscript Title Alternatives to H			
6. Manuscript Ide	ntifying Number (if you kı	now it)	
Section 2.	The Work Under C	onsideration for Public	cation
any aspect of the s statistical analysis,	stitution at any time rece ubmitted work (including	eive payment or services from g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
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Solomon 2



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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.

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 patent

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Section 1. Identifying Inform	ation					
Given Name (First Name) Janet	2. Surname (Last Na Wittes	me)	3. Date 14-May-2015	_		
4. Are you the corresponding author?	Yes ✓ No	Correspond L. J. Wei	ling Author's Name			
5. Manuscript Title Alternatives to hazard ratios for compar	ing efficacy or safety	y of therapies in no	oninferiority studies			
6. Manuscript Identifying Number (if you kn M14-1741	ow it)					
Section 2. The Work Under Co	onsideration for F	Publication				
	but not limited to gra	. , ,	government, commercial, private foundation, etc.) f J board, study design, manuscript preparation,	or		
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 interes	est? ✓ Yes	No				
If yes, please fill out the appropriate info	ormation below.					
Name of Entity	Grant? Personal Fees?	Non-Financial Support?	Other? Comments			
Astra-Zeneca			consulting fees to my employer	_		
Bristol-Myers Squibb			✓ consulting fees to my employer			
Merck			consulting fees to my employer			
Amgen			consulting fees to my employer			
Reata			✓ consulting fees to my employer			
Relypsa			consulting fees to my employer			
Acerta			consulting fees to my employer			
lanssen			consulting fees to my employer			

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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?
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. Wittes reports other from Astra-Zeneca, other from Bristol-Myers Squibb, other from Merck, other from Amgen, other from Reata, other from Relypsa, other from Acerta, other from Janssen, outside the submitted work.

Evaluation and Feedback

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

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