

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.

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3. 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

Mott 1



Section 1. Identifying Info	rmation	
1. Given Name (First Name) Katrina	2. Surname (Last Name) Mott	3. Date 15-May-2017
4. Are you the corresponding author?	Yes 🗸 No	Corresponding Author's Name
5. Manuscript Title Outcomes of Dabigatran and Warfar	in for Atrial Fibrillation in Con	temporary Practice: the FDA Sentinel Program
6. Manuscript Identifying Number (if you M16-1157	u know it)	
Section 2. The Work Under	r Consideration for Public	ation
	ding 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 finance	ial activities outside the s	ubmitted work
Place a check in the appropriate box of compensation) with entities as de	es in the table to indicate who scribed in the instructions. Us report 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 e present during the 36 months prior to publication .
Section 4		
Section 4. Intellectual Pro	perty Patents & Copyrig	hts
Do you have any patents, whether p	lanned, pending or issued, br	oadly relevant to the work? Yes V No

Mott 2



Section 5. Relationships not sovered above
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Section 6. Disclosure Statement
Disclosure Statement
Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.
Ms. Mott has nothing to disclose.

Evaluation and Feedback

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

Houstoun 1



Section 1. Identifying Inform	nation	
1. Given Name (First Name) Monika	2. Surname (Last Name) Houstoun	3. Date 25-July-2016
4. Are you the corresponding author?	Yes 🗸 No	Corresponding Author's Name Alan Go
5. Manuscript Title Outcomes of Dabigatran and Warfarin	for Atrial Fibrillation in Cor	ntemporary Practice: the FDA Sentinel Program
6. Manuscript Identifying Number (if you k M16-1157	now it)	
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Houstoun 2



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Dr. Houstoun has	s nothing to disclose.			

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Zhang 1



Section 1.	Identifying Inform	nation		
1. Given Name (Fii Rongmei	rst Name)	2. Surname (Last Name) Zhang	3. Date 29-July-2016	
4. Are you the cor	responding author?	Yes ✓ No	Corresponding Author's Name Alan Go	
5. Manuscript Title Outcomes of Dal		for Atrial Fibrillation in Cor	ntemporary Practice: the FDA Sentinel Program	
6. Manuscript Ider M16-1157	ntifying Number (if you kr	now it)		
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Do you have any	patents, whether plan	ned, pending or issued, br	roadly relevant to the work? Yes V No	

Zhang 2



Section 5. Polotionships not sovered above	
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Reichman 1



Section 1. Identifying Information	
1. Given Name (First Name) 2. Surname (Last Name) 3. Date Marsha Reichman 04-August-2016	
4. Are you the corresponding author? Yes Vo Corresponding Author's Name	
5. Manuscript Title Outcomes of Dabigatran and Warfarin for Atrial Fibrillation in Contemporary Practice: the FDA Sentinel Program	
6. Manuscript Identifying Number (if you know it) M16-1157	
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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	r
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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 V	

Reichman 2



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Graham 1



Section 1. Identifying Inform	nation		
1. Given Name (First Name) David	2. Surname (Last Name) Graham	3. Date 21-July-2016	
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Name	
5. Manuscript Title Outcomes of Dabigatran and Warfarin f	for Atrial Fibrillation in Cor	ntemporary Practice: the FDA Sentinel Program	_
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Goulding 1



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4. Are you the cor	responding author?	☐ Yes ✓ No	Corresponding Author's Name Alan Go
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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.
The there any rem	evant commets of miter		
Section 4.	Intellectual Proper	rty Patents & Copyric	ghts
Do you have any			roadly relevant to the work? Yes V No

Goulding 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
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Dr. Goulding has nothing to disclose.

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Goulding 3



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lzem 1



Section 1. Identifying	Information	
Given Name (First Name) Rima	2. Surname (Last Name) Izem	3. Date 21-July-2016
4. Are you the corresponding auth	or? Yes 🗸 No	Corresponding Author's Name Alan Go
5. Manuscript Title Outcomes of Dabigatran and W	arfarin for Atrial Fibrillation in Cor	ntemporary Practice: the FDA Sentinel Program
6. Manuscript Identifying Number M16-1157	(if you know it)	
Section 2. The Work U	nder Consideration for Public	cation
	including but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
Section 3. Relevant fin	ancial activities outside the s	submitted work
Place a check in the appropriate of compensation) with entities a	e boxes in the table to indicate wh as described in the instructions. Us nould report relationships that we	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		
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Do you have any patents, wheth	ner planned, pending or issued, br	roadly relevant to the work? Yes V No

Izem 2



Section 5.	Deletional in a standard above
	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?
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✓ No other relat	tionships/conditions/circumstances that present a potential conflict of interest
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Dr. Izem has noth	ning to disclose.

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Toh 1



Section 1.	Identifying Inform	nation				
1. Given Name (Fii Sengwee	rst Name)	2. Surname (Last Nar Toh	ne)		3. Date 21-July-2016	
4. Are you the cor	responding author?	☐ Yes ✓ No	Correspond Alan S. Go	_	or's Name	
5. Manuscript Title Outcomes of Dal		or Atrial Fibrillation in	n Contemporary I	Practice: t	he FDA Sentinel Program	
6. Manuscript Ider M16-1157	ntifying Number (if you kn	now it)				
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Section 2.	The Work Under Co	onsideration for P	ublication			
any aspect of the s statistical analysis, Are there any rela If yes, please fill o	ubmitted work (including etc.)? evant conflicts of intere out the appropriate info	but not limited to granest? Yes	its, data monitoring	g board, stu	ent, commercial, private foundation udy design, manuscript preparation ty press the "ADD" button to ad	٦,
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Name of Institut	ion/Company	Grant? Personal Fees?	Non-Financial Support?	Other?	Comments	
Food and Drug Admi	nistration	✓			This work was done within the FD, funded Mini-Sentinel pilot program	
Section 3.	Relevant financial	activities outside	the submitted	work.		
of compensation clicking the "Add) with entities as descri	bed in the instruction port relationships tha	ns. Use one line fo t were present d	or each er	ial relationships (regardless of a atity; add as many lines as you n e 36 months prior to publicati	eed by
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Do you have any	patents, whether plani	ned, pending or issue	ed, broadly releva	nt to the	work? Yes V	

Toh 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?
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Dr. Toh reports g	rants from Food and Drug Administration, during the conduct of the study; .

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Sung 1



Section 1. Identifying Inform	nation	
Given Name (First Name) Sue Hee	2. Surname (Last Name) Sung	3. Date 21-July-2016
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Alan Go, MD
5. Manuscript Title Outcomes of Dabigatran and Warfarin	for Atrial Fibrillation in Cor	ntemporary Practice: the FDA Sentinel Program
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Section 2. The Work Under C	onsideration for Publi	cation
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Do you have any patents, whether plan	ned, pending or issued, br	roadly relevant to the work? Yes V No

Sung 2



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4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author	or's Name
5. Manuscript Title Outcomes of Dabigatran and Warfarin	for Atrial Fibrillation in Co	ntemporary Practice:	the FDA Sentinel Program
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any aspect of the submitted work (including statistical analysis, etc.)?	g but not limited to grants, do		ent, commercial, private foundation, etc.) for udy design, manuscript preparation,
Are there any relevant conflicts of inter			:t
Excess rows can be removed by pressir		ve more than one ent	ity press the "ADD" button to add a row.
Name of Institution/Company	Grant'	n-Financial Other?	Comments
JS Food and Drug Administration	✓		
Section 3. Polovant financial			
Relevant financial	activities outside the	submitted work.	
Place a check in the appropriate boxes of compensation) with entities as describing the "Add +" box. You should re	ribed in the instructions. U	se one line for each e	
Are there any relevant conflicts of inter			
If yes, please fill out the appropriate inf	formation below.		
Name of Entity	Giailt	n-Financial Support?	Comments
Optum, Inc.			I am a consultant to Optum, Inc. for unrelated work.
Aetion, Inc.			I am a consultant to Aetion, Inc. for unrelated work.



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Novartis Pharmaceuticals Corporation	✓				I am PI of a grant from Novartis Pharmaceuticals Corporation to the Brigham and Women's Hospital for unrelated work.
Section 4. Intellectual Propert	y Pate	ents & Co	pyrights		
Do you have any patents, whether plann	ed, pend	ing or issue	ed, broadly releva	nt to the	work? Yes V No
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Disclosure Statellie					
Based on the above disclosures, this forn below.	n will auto	omatically	generate a disclos	sure state	ement, which will appear in the box
Dr. Gagne reports grants from US Food a Optum, Inc., personal fees from Aetion, I work; .					



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1. Given Name (First Name) Daniel 2. Surname (Last Name) Singer 3. Date 25-August-2016 4. Are you the corresponding author?				
A. Are you the corresponding author? Yes No Corresponding Author's Name Alan S. Go 5. Manuscript Title Outcomes of Dabigatran and Warfarin for Atrial Fibrillation in Contemporary Practice: the FDA Sentinel Program 6. Manuscript Identifying Number (if you know it) M16-1157 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 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. Name of Institution/Company Grant? Personal Fees? Support? Comments epartment of Population Medicine, Harvard Personal Support? Personal Paid for time spent on the project ledical School	Section 1. Identifying Inform	nation		
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Excess rows can be removed by pressing the "X" button. Name of Institution/Company Grant? Personal Support? Department of Population Medicine, Harvard Medical School Section 3. Relevant financial activities outside the submitted work.	any aspect of the submitted work (including statistical analysis, etc.)?	but not limited to grants, da	, , , ,	· · · · · · · · · · · · · · · · · · ·
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Pepartment of Population Medicine, Harvard Idedical School Relevant financial activities outside the submitted work.	Excess rows can be removed by pressing			
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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 .	of compensation) with entities as descri	ibed in the instructions. Us	se one line for each e	ntity; add as many lines as you need by
Are there any relevant conflicts of interest? Ves No If yes, please fill out the appropriate information below.	A continuous continuous de la continuous			process parameters



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments			
oehringer Ingelheim Manufacturer of dabigatran. I received research funds for a study of treatment of anticoagulant-associated intracranial hemorrhage and consultant fees on issues related use of anticoagulants in atrial fibrillation and VTE.								
Johnson and Johnson		\checkmark			Consultant fees on issues related use of anticoagulants in atrial fibrillation			
Merck		✓			Consultant fees on issues related use of anticoagulants in atrial fibrillation			
Pfizer		✓			Consultant fees on issues related use of anticoagulants in atrial fibrillation			
Bristol-Myers Squibb		✓			Consultant fees on issues related use of anticoagulants in atrial fibrillation			
CVS Health	VS Health Consultant fees on issues related use of anticoagulants in atrial fibrillation							
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, undate their disclosure statements								

On occasion, journals may ask authors to disclose further information about reported relationships.



Section 6.	Disclosure Statement
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4. Intellectual Property.

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

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

Cheetham 1



Section 1.	Identifying Inform	ation			
1. Given Name (Fi T Craig	rst Name)	2. Surname (Last Na Cheetham	ime)	3. Date 21-July-2016	j
4. Are you the cor	responding author?	☐ Yes ✓ No	Correspond	ling Author's Name	
5. Manuscript Title Outcomes of Da		or Atrial Fibrillatoin	in Contemporary F	Practice: the FDA Sentinel Pro	ogram
6. Manuscript Ider M16-1157	ntifying Number (if you kn	ow it)			
Section 2.	The Work Under Co	onsideration for I	Publication		
any aspect of the s statistical analysis, Are there any rel	ubmitted work (including	but not limited to gra		government, commercial, priva g board, study design, manuscrip	
Section 3.	Relevant financial	activities outside	the submitted	work.	
of compensation) with entities as descri	bed in the instruction	ons. Use one line fo	ive financial relationships (reor or each entity; add as many li uring the 36 months prior t	nes as you need by
•	evant conflicts of intere		No		
if yes, please fill o	out the appropriate info	rmation below.			
Name of Entity		Grant? Persona Fees?	Non-Financial Support?	Other? Comments	
Bristol-Myers Squibb		✓		Research Support - Si Rheumatoid Arthritis	-
Section 4.	Intellectual Proper	ty Patents & Co	pyrights		
Do you have any	patents, whether plans	ned, pending or issu	ed, broadly releva	nt to the work? Yes	√ No

Cheetham 2



Section 5. Polationships not sovered 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?
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Dr. Cheetham reports grants from Bristol-Myers Squibb, outside the submitted work; .

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Cheetham 3



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Go 1



Section 1. Identifying Inform	nation			
identifying illioni	Hadon			
1. Given Name (First Name)	2. Surname (Last Name	<u>e</u>)		3. Date
Alan	Go			16-September-2016
4. Are you the corresponding author?	✓ Yes No			
5. Manuscript Title Outcomes of Dabigatran and Warfarin	for Atrial Fibrillation in	Contemporary P	ractice: the	FDA Sentinel Program
6. Manuscript Identifying Number (if you k	now it)			
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Did you or your institution at any time receany aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inter	g but not limited to grants	s, data monitoring		
If yes, please fill out the appropriate inf			one entity	press the "ADD" button to add a row.
Excess rows can be removed by pressing	ig the "X" button.			
Name of Institution/Company	Grant? Personal Fees?	Non-Financial Support [?]	Other?	Comments
J.S. Food and Drug Administration	✓		Re	esearch contract to my institution
Section 3. Relevant financial	activities outside th	ne submitted v	work.	
Place a check in the appropriate boxes of compensation) with entities as descr clicking the "Add +" box. You should re Are there any relevant conflicts of inter	ibed in the instructions port relationships that	. Use one line fo were present d	r each entit	y; add as many lines as you need by
Section 4. Intellectual Prope				
Intellectual Prope	rty Patents & Copy	yrights		
Do you have any patents, whether plan	ned, pending or issued	, broadly releva	nt to the wo	ork? ☐ Yes ✓ No

Go 2



Section 5. Relationships not covered above
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Dr. Go reports grants from U.S. Food and Drug Administration, during the conduct of the study; .

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

Southworth 1



Section 1.	Identifying Inform	nation			
1. Given Name (Fi Mary Ross	rst Name)	Surname (Last Name) Southworth		3. Date 22-September-2017	
4. Are you the cor	responding author?	Yes ✓ No	Corresponding Author's Name Alan Go		
5. Manuscript Title Outcomes of Da		for Atrial Fibrillation in Cor	itemporary Practice: the FDA	A Sentinel Program	
6. Manuscript Ide	ntifying Number (if you kr	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, com ta monitoring board, study desi	nmercial, private foundation, etc.) for ign, manuscript preparation,	
Section 3.	Polovant financial	activities outside the	ubmitted 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 Prope	rty Patents & Copyric	jhts		
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?	Yes ✓ No	

Southworth 2



Section 5. Polationships not severed above
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Dr. Southworth has nothing to disclose.

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