

#### **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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## 4. Intellectual Property.

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

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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 patent

Blais 1



Section 1. Identifying Inform	nation		
1. Given Name (First Name) Jaime	2. Surname (Last Name) Blais		3. Date 05-September-2017
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author	r's Name
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Do	minant Polycystic Kidney	Disease	
6. Manuscript Identifying Number (if you kr 17-10030	now it)	_	
Section 2. The Work Under Co			
The work officer Co	onsideration for Public		
Did you or your institution <b>at any time</b> rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of intere	but not limited to grants, da		
Section 3. Relevant financial	activities outside the	submitted work.	
Place a check in the appropriate boxes i of compensation) with entities as descri clicking the "Add +" box. You should rep Are there any relevant conflicts of intered If yes, please fill out the appropriate info	bed in the instructions. Use port relationships that were relationships that were relationships that were relationships that were relationships to the relationships the relat	se one line for each en re <b>present during the</b>	tity; add as many lines as you need by
Name of Entity	Grant? Personal Fees? S	n-Financial other?	Comments
Otsuka Pharmaceuticals Development and Commercialization, Inc.			I am an employee and I receive salary and benefits
Section 4. Intellectual Proper	ty Patents & Copyri	ghts	
Do you have any patents, whether plan	ned, pending or issued, br	roadly relevant to the v	work? ☐ Yes   ✓ No

Blais 2



Section 5. Polationships not sovered above
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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. Blais reports personal fees from Otsuka Pharmaceuticals Development and Commercialization, Inc. outside the submitted work.

#### **Evaluation and Feedback**

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Blais 3



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Chapman 1



Section 1. Identifying Inform	nation		
Given Name (First Name)  Arlene	2. Surname (Last Name) Chapman		3. Date 27-August-2017
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's N Vicente Torres	Name
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Do	ominant Polycystic Kidney	Disease	
6. Manuscript Identifying Number (if you kr 17-10030	now it)		
		_	
Section 2. The Work Under Co	onsideration for Publi	cation	
Did you or your institution <b>at any time</b> rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of intere	but not limited to grants, d		
Section 3. Relevant financial	activities outside the	submitted work.	
Place a check in the appropriate boxes in of compensation) with entities as described clicking the "Add +" box. You should repart there any relevant conflicts of interesting the second conflicts of	ibed in the instructions. Uport relationships that we est?  Yes  No	se one line for each entity	; add as many lines as you need by
Name of Entity	Grant	n-Financial Other? Co	omments
Otsuka Pharmaceuticals		✓ Stee	ering Committee Member Otsuka
Section 4. Intellectual Proper	rty Patents & Copyri	ghts	
Do you have any patents, whether plan	ned, pending or issued, b	roadly relevant to the wor	k? ☐ Yes   ✓ No

Chapman 2



Section 5. Relationships not covered above
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Yes, the following relationships/conditions/circumstances are present (explain below):
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Section 6. Disclosure Statement
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Dr. Chapman reports other from Otsuka Pharmaceuticals outside the submitted work.

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Czerwiec 1



Section 1. Identifying Inform	ation		
1. Given Name (First Name) Frank	2. Surname (Last Name) Czerwiec		3. Date 05-September-2017
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author	or's Name
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Do	minant Polycystic Kidney	Disease	
6. Manuscript Identifying Number (if you kn 17-10030	ow it)		
Section 2. The Work Under Co	onsideration for Public	cation	
Did you or your institution <b>at any time</b> recei any aspect of the submitted work (including statistical analysis, etc.)?			
Are there any relevant conflicts of interes	est? Yes 🗸 No		
Section 3. Relevant financial	activities outside the s	submitted work.	
Place a check in the appropriate boxes i of compensation) with entities as descri clicking the "Add +" box. You should rep	bed in the instructions. Us	se one line for each en	ntity; add as many lines as you need by
Are there any relevant conflicts of intere			
If yes, please fill out the appropriate info			
Name of Entity	Grant? Personal Nor	n-Financial other?	Comments
Otsuka Pharmaceuticals/ Otsuka Holding Company			Frank is an employee of the sponsor and has limited stock in the sponsor's holding company.
Section 4. Intellectual Proper	ty Patents & Copyri <u>c</u>	jhts	
Do you have any patents, whether plant	ned, pending or issued, br	oadly relevant to the	work? ☐ Yes ✓ No

Czerwiec 2



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Dr. Czerwiec reports personal fees and other from Otsuka Pharmaceuticals/ Otsuka Holding Company outside the submitted work.

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Czerwiec 3



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Devuyst 1



Section 1. Identifying Inform	ation		
Given Name (First Name) Olivier	2. Surname (Last Name) Devuyst		3. Date 05-September-2017
4. Are you the corresponding author?	Yes ✓ No	Corresponding Auth Vincente Torres	or's Name
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Don	minant Polycystic Kidney	Disease	
6. Manuscript Identifying Number (if you known 17-10030	ow it)		
		_	
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Did you or your institution <b>at any time</b> receivany aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of intere If yes, please fill out the appropriate info Excess rows can be removed by pressing	but not limited to grants, da st?	ta monitoring board, st	
Name of Institution/Company	Grant	n-Financial other?	Comments
Otsuka Pharmaceutical			Honorarium; Participation in Steering Committee Activities
Section 3. Relevant financial a	activities outside the s	ubmitted work.	
Place a check in the appropriate boxes ir of compensation) with entities as descril clicking the "Add +" box. You should rep Are there any relevant conflicts of intere	oed in the instructions. Us ort relationships that wer st?	e one line for each e e <b>present during th</b>	ntity; add as many lines as you need by
Section 4. Intellectual Propert	ty Patents & Copyric	jhts	
Do you have any patents, whether plann	ned, pending or issued, br	oadly relevant to the	work? ☐ Yes ✓ No

Devuyst 2



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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.
Dr. Devuyst reports personal fees and other from Otsuka Pharmaceutical during the conduct of the study.

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Devuyst 3



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Gansevoort 1



Section 1. Identifying Inform	ation		
1. Given Name (First Name) Ron	2. Surname (Last Name) Gansevoort		3. Date 28-August-2017
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author	or's Name
5. Manuscript Title Tolvaptan Slows eGFR Decline in Later-S	Stage ADPKD		
6. Manuscript Identifying Number (if you kn 17-10030	ow it)	_	
Section 2. The Work Under Co			
The Work Officer Co	onsideration for Public		
Did you or your institution <b>at any time</b> recei any aspect of the submitted work (including statistical analysis, etc.)?			ent, commercial, private foundation, etc.) for udy design, manuscript preparation,
Are there any relevant conflicts of intere	est? Yes V No		
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N	Grant? Personal Nor	n-Financial	
Name of Entity	Fees S	Other•	Comments
Otsuka	✓		Money paid to employer
psen Farmaceutica			Money paid to employer
Sanofi-Genzyme			Advisory Board Membership. Money paid to employer
Section 4. Intellectual Proper	ty Patents & Copyrig	ihts	
Do you have any patents, whether plant	ned, pending or issued, br	oadly relevant to the	work? Yes No

Gansevoort 2



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Dr. Gansevoort reports grants from Otsuka, grants from Ipsen Farmaceutica, and other from Sanofi-Genzyme outside the submitted work.

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

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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 patent

Koch 1



Section 1. Identifying Inform	ation		
1. Given Name (First Name) Gary	2. Surname (Last Name) Koch		3. Date 29-August-2017
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author	or's Name
5. Manuscript Title Tolvaptan Slows eGFR Decline in Later-S	Stage ADPKD		
6. Manuscript Identifying Number (if you kn 17-10030	ow it)		
		-	
Section 2. The Work Under Co	onsideration for Public	ation	
Did you or your institution <b>at any time</b> recei any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of intere If yes, please fill out the appropriate info Excess rows can be removed by pressing	but not limited to grants, da est? Yes No ormation below. If you hav	ta monitoring board, stu	udy design, manuscript preparation,
Name of Institution/Company	Grant? Personal Nor	n-Financial Other?	Comments
Otsuka Pharmaceutical Development & Commercialization, Inc.	<b>✓</b>		
Section 3. Relevant financial	activities outside the s	ubmitted work.	
Place a check in the appropriate boxes in of compensation) with entities as descriclicking the "Add +" box. You should repart there any relevant conflicts of interests.	bed in the instructions. Us port relationships that wer est? Yes 🗸 No	e one line for each er e <b>present during the</b>	ntity; add as many lines as you need by
Section 4. Intellectual Proper	ty Patents & Copyrig	hts	
Do you have any patents, whether plant	ned, pending or issued, br	oadly relevant to the	work? Yes V

Koch 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?
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. Koch reports grants from Otsuka Pharmaceutical Development & Commercialization, Inc. during the conduct of the study.

## **Evaluation and Feedback**

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Koch 3



#### Instructions

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1

McQuade



Section 1. Identifying Inform	nation	
1. Given Name (First Name) Robert	2. Surname (Last Name) McQuade	3. Date 05-September-2017
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Name Vicente Torres
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Do	minant Polycystic Kidney	Disease
6. Manuscript Identifying Number (if you kn 17-10030	now it)	
Section 2. The Work Under Co	onsideration for Public	ation
any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of intere	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) with entities as descri	bed in the instructions. Us	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by se 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 Nor	n-Financial Other? Comments
Otsuka Pharmaceuticals Development and Commercialization, Inc.		l am an employee of and receive salary and benefits
Section 4. Intellectual Proper	ty Patents & Copyric	yhts
Do you have any patents, whether plant	ned, pending or issued, br	oadly relevant to the work? Yes V No

McQuade 2



Section 5. Polationships not sovered above
Relationships not covered above
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Dr. McQuade reports personal fees from Otsuka Pharmaceuticals Development and Commercialization, Inc. outside the submitted work.

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McQuade 3



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patent

Ouyang 1



Section 1. Identifying Inform	aation	
1. Given Name (First Name) John	2. Surname (Last Name) Ouyang	3. Date 05-September-2017
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Name Vicente Torres
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Do	minant Polycystic Kidney	Disease
6. Manuscript Identifying Number (if you kn 17-10030	now it)	
Section 2. The Work Under Co	onsideration for Public	cation
statistical analysis, etc.)? Are there any relevant conflicts of intere		ta monitoring board, study design, manuscript preparation,
Section 3. Relevant financial	activities outside the s	ubmitted work.
of compensation) with entities as descri	bed in the instructions. Us	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by se present during the 36 months prior to publication.
Are there any relevant conflicts of interest		
If yes, please fill out the appropriate info	ormation below.	
Name of Entity	Grant? Personal Nor	n-Financial Other? Comments
Otsuka Pharmaceuticals Development and Commercialization, Inc.		l am an employee of and receive salary and benefits
Section 4. Intellectual Proper	ty Patents & Copyric	yhts
Do you have any patents, whether plant	ned, pending or issued, br	oadly relevant to the work? Yes V No

Ouyang 2



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Ouyang 3



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



Section 1.	Identifying Inform	ation					
1. Given Name (Fi Ronald	rst Name)	2. Surnan Perrone	ne (Last Name	e)		3. Date 29-August-2017	
4. Are you the cor	responding author?	Yes	✓ No	Correspond Vicente To	-	or's Name	
5. Manuscript Title Tolvaptan in Late	e er-Stage Autosomal Do	minant Po	lycystic Kidr	ney Disease			
6. Manuscript Ider 17-10030	ntifying Number (if you kn	ow it)					
Section 2							
Section 2.	The Work Under Co	onsiderat	ion for Pu	blication			
	ubmitted work (including					ent, commercial, private foundation, etc udy design, manuscript preparation,	:.) for
•	evant conflicts of intere						
	out the appropriate info be removed by pressing			have more than	one enti	ty press the "ADD" button to add a	row.
Name of Institut	ion/Company	Grant?	Personal Fees?	Non-Financial Support	Other?	Comments	
Otsuka		<b>✓</b>	<b>✓</b>			Member of Steering Committee for this trial	
						Citis Cital	
Section 3.	Relevant financial	activities	outside th	ne submitted	work.		
of compensation clicking the "Add Are there any rel	) with entities as descri	bed in the port relationst?	instructions nships that 'es	s. Use one line fo were <b>present d</b>	or each er	ial relationships (regardless of amo ntity; add as many lines as you need a 36 months prior to publication.	
Name of Entity		Grant?	Personal Fees?	Non-Financial Support <mark>?</mark>	Other?	Comments	
Sanofi-Genzyme			<b>✓</b>			Consulting	_
Regulus			<b>✓</b>			Consulting	
Mitsubishi-Tanabe			<b>✓</b>			Consulting	



Name of Entity	Grant? Personal Fees?	Non-Financial Support?	Other? Commen	its	
Palladiobio			Consulting		
√ertex			Consulting		
Section 4. Intellectual Dranget					
Intellectual Propert	y Patents & Cop	yrights			
Do you have any patents, whether planne	ed, pending or issue	d, broadly releva	nt to the work?	Yes 🗸 No	
Section 5. Relationships not co	overed above				
Are there other relationships or activities potentially influencing, what you wrote in Yes, the following relationships/cond No other relationships/conditions/circ At the time of manuscript acceptance, journals may ask authors to	n the submitted wor litions/circumstances cumstances that pre urnals will ask autho	rk? s are present (expessent a potential of the rs to confirm and	plain below): conflict of interest I, if necessary, update	e their disclosure statem	nents.
Section 6. Disclosure Statemen	nt				
Based on the above disclosures, this form below.	ા will automatically g	generate a disclos	sure statement, whic	h will appear in the box	
Dr. Perrone reports grants and personal f Genzyme, personal fees from Regulus, pe fees from Vertex outside the submitted v	ersonal fees from Mi				I



#### **Evaluation and Feedback**

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Sergeyeva 1



Section 1. Identifying Inform	nation					
1. Given Name (First Name) Olga	2. Surname (Last Name) Sergeyeva		3. Date 05-September-2017			
4. Are you the corresponding author?	☐ Yes ✓ No	r's Name				
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Do	minant Polycystic Kidney	Disease				
6. Manuscript Identifying Number (if you kn	now it)	_				
Section 2						
Section 2. The Work Under Co	onsideration for Public	cation				
Did you or your institution <b>at any time</b> received any aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of interesting the statistical analysis are there any relevant conflicts of interesting the statistical analysis.	but not limited to grants, da	. , .	•			
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 No  If yes, please fill out the appropriate information below.						
Name of Entity	Grant? Personal Fees? S	n-Financial other?	Comments			
Otsuka Pharmaceuticals Development and Commercialization, Inc.			I am an employee of and receive salary and benefits			
Section 4. Intellectual Proper	ty Patents & Copyri	ghts				
Do you have any patents, whether plant	ned, pending or issued, br	roadly relevant to the v	work? Yes V			

Sergeyeva 2



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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.

## 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



Section 1. Identifying Informa	ntion				
Given Name (First Name)  Vicente	2. Surname (Last N Torres	ame)		3. Date 29-August-2017	
4. Are you the corresponding author?	✓ Yes No				
5. Manuscript Title Tolvaptan in Later-Stage Autosomal Don	ninant Polycystic ł	(idney Disease			
6. Manuscript Identifying Number (if you kno 17-10030	ow it)				
Section 2. The Work Under Co	ncidovation for	Dublication			
Did you or your institution <b>at any time</b> received any aspect of the submitted work (including less statistical analysis, etc.)?	e payment or servic	es from a third party			
Are there any relevant conflicts of interes	t? ✓ Yes	No			
If yes, please fill out the appropriate infor Excess rows can be removed by pressing		ou have more tha	n one entit	ry press the "ADD" button to add a row	
Name of Institution/Company	Grant? Persona	Non-Financial	Other?	Comments	
Otsuka	✓	<b>✓</b>	<b>✓</b>	Support of investigator and study coordinator time and for patient related expenses, travel expenses to attend the meetings of the Steering Committee and the IDMC, and payments to Mayo Clinic for the time spent in meetings of the Steering Committee or IDMC, all related to the clinical trial.	
Section 3. Polovant financial a	-a': 'a'	- 4b b '- 4 d	le		
Relevant financial a	ctivities outsid	e the Submitted	work.		
Place a check in the appropriate boxes in of compensation) with entities as describ clicking the "Add +" box. You should report there any relevant conflicts of interest.	ed in the instructi ort relationships th	ons. Use one line f	or each en	tity; add as many lines as you need by	



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments		
Otsuka	<b>√</b>				Support of investigator and study coordinator time and for patient related expenses for other clinical trials of tolvaptan in ADPKD (TEMPO 4:4 to evaluate long-term safety and efficacy) and grant to develop models to predict renal functional decline in ADPKD including advanced imaging analysis		
Vertex			<b>✓</b>	<b>✓</b>	Payment to Mayo Clinic for time attending and presenting at a PKD Symposium organized by Vertex and travel expenses to attend this meeting.		
Palladio	$\checkmark$				Effect of lixivaptan in the PCK rat, an animal model of polycystic kidney disease		
UptoDate		<b>✓</b>			For contributions to the PKD and TSC sections		
Section 4. Intellectual Property Patents & Copyrights							
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No  Section 5.							
Relationships not c							
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. Torres reports grants, non-financial support and other from Otsuka during the conduct of the study; grants from Otsuka, non-financial support and other from Vertex, grants from Palladio, and personal fees from UptoDate outside the submitted work.

#### **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.