

Instructions

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Section 1.	Identifying Infor	mation	
1. Given Name (Fir Andrew	rst Name)	2. Surname (Last Name) Vickers	3. Date 23-May-2019
4. Are you the corresponding author? Yes 🖌 No		Yes 🖌 No	Corresponding Author's Name David Kent
5. Manuscript Title The Predictive Ap		ent effect Heterogeneity (I	PATH) Statement
6. Manuscript Ider M18-3667	ntifying Number (if you	know it)	

Section 2. **The Work Under Consideration for Publication**

Did you or your institution at any time receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ✓ Yes 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	Non-Financial Support <mark>?</mark>	Other?	Comments	
NIH	\checkmark				P30CA008748: Craig Thompson	

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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 ✓ No



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Section 1.	Identifying Inforn	nation		
1. Given Name (Fi Ravi	rst Name)	2. Surname (Last Name) Varadhan	-	. Date 3-May-2019
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name David Kent	2
5. Manuscript Title The PATH Staten		laboration Document		
6. Manuscript Ider	ntifying Number (if you ki	now it)		

M18-3668

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Tufts University		\checkmark				

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Dr. Varadhan reports personal fees from Tufts University, during the conduct of the study; .

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Section 1. Identifying Info	rmation		
1. Given Name (First Name) John	2. Surname (Last Name) Ioannidis		3. Date 26-May-2019
. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Nam Kent	ne
Manuscript Title TH Statement			

M18-3667

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.)?

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Are there any relevant conflicts of interest? Yes

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Are there any relevant conflicts of interest? Yes 🗸 No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 🗌 Yes 🖌 No



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Dr. loannidis has nothing to disclose.

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1. Given Name (Fin Ralph	rst Name)	2. Surname (Last Name) D'Agostino		3. Date 02-June-2019
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Na Davi M Kent	me
5. Manuscript Title The PATH Staten		laboration Document		

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest?		Yes	√	
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1. Given Name (Fi John	rst Name)	2. Surnam Wong	ne (Last Name)		3. Date 04-June-2019
4. Are you the corresponding author?		Yes	✓ No	Corresponding Author's Na David Kent	me
5. Manuscript Title The PATH Stater	e nent Explanation and E	laboration	Document		
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M18-3668

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Patient-Centered Outcome Research Institute	\checkmark				Predictive Analytics Resource Center contract	

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Dr. Wong reports grants from Patient-Centered Outcome Research Institute, during the conduct of the study.

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M18-3668

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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.)?

✓ No

Are there any relevant conflicts of interest? Yes

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Are there any relevant conflicts of interest? Yes 🗸 No

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 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. Paulus has nothing to disclose.

Evaluation and Feedback



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patent



Section 1.	Identifying Inforn	nation	
1. Given Name (F	irst Name)	2. Surname (Last Name)	3. Date
4. Are you the co	rresponding author?	Yes No	
5. Manuscript Titl The PATH Stater	e ment Explanation and E	laboration Document	
6. Manuscript Ide	ntifying Number (if you kı	now it)	

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Are there any relevant conflicts of interest?		Yes	\checkmark	No
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Are there any relevant conflicts of interest? 🛛 Yes 🖌 No
--

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? $$	Yes	🖌 No	
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I have no relevant conflicts to declare.

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Section 1.	Identifying Inforr	nation	
1. Given Name (Fi Joseph	rst Name)	2. Surname (Last Name) Ross	3. Date 23-May-2019
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name David Kent, MD, PhD
5. Manuscript Titl The Predictive A		nt effect Heterogeneity (PATH) Statement
6. Manuscript Ide M18-3667R	ntifying Number (if you k	now it)	
Section 2.	The Work Under O	Consideration for Pub	lication

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Are there any relevant conflicts of interest? \checkmark Yes \square 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	Non-Financial Support <mark>?</mark>	Other?	Comments	
Patient Centered Outcomes Research Institute		\checkmark			Dr. Ross received an honorarium from Tufts University, paid for by a grant from PCORI, to support his effort on the project.	

Section 3. Relevant financial activities outside the submitted work.

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No

Are there any relevant conflicts of interest? Yes

If yes, please fill out the appropriate information below.



Name of Entity	Grant?	Personal Fees	Non-Financial Support?	Other?	Comments
Food and Drug Administration (FDA)	✓				Dr. Ross received support from the Food and Drug Administration (FDA) through a research grant to determine best practices in medical device post-market surveillance (work concluded Spring 2018).
Medtronic, Inc.	✓				Dr. Ross received support from Medtronic, Inc. through a research grant to determine best practices in medical device post-market surveillance (work concluded Spring 2018).
Johnson & Johnson	✓				Dr. Ross receives support from Johnson & Johnson through the Yale University Open Access Data project to develop methods to promote clinical trial data sharing.
Centers for Medicare and Medicaid Services (CMS)	V				Dr. Ross received support through a contract with the Centers for Medicare and Medicaid Services (CMS) to develop and maintain performance measures that are used to publicly report hospital and physician quality of care (work concluded Fall 2017).
Blue Cross-Blue Shield Association (BCBSA)	V				Dr. Ross received support from the Blue Cross-Blue Shield Association (BCBSA) through a research grant to better understand medical technology evidence generation (work concluded Summer 2017).
Food and Drug Administration (FDA)	✓				Dr. Ross receives support from the Food and Drug Administration (FDA) through a research grant to establish the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI).
Agency for Healthcare Research and Quality (AHRQ)	✓				Dr. Ross receives support from the Agency for Healthcare Research and Quality (AHRQ) through a research grant to study patient, hospital and community factors associated with readmission risk.
National Institutes of Health (NIH/NHLBI)	✓				Dr. Ross receives support from the National Institutes of Health (NIH/ NHLBI) through a research grant to study the diffusion of clinical evidence into practice.



Name of Entity	Grant?	Personal Fees ?	Non-Financial Support?	Other?	Comments	
Laura and John Arnold Foundation	✓				This project was supported by a grant from the Laura and John Arnold Foundation to support the Collaboration for Research Integrity and Transparency (CRIT) at Yale.	

Section 4.

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes

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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Intellectual Property -- Patents & Copyrights

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Dr. Ross reports personal fees from Patient Centered Outcomes Research Institute, during the conduct of the study; grants from Food and Drug Administration (FDA), grants from Medtronic, Inc., grants from Johnson & Johnson, grants from Centers for Medicare and Medicaid Services (CMS), grants from Blue Cross-Blue Shield Association (BCBSA), grants from Food and Drug Administration (FDA), grants from Agency for Healthcare Research and Quality (AHRQ), grants from National Institutes of Health (NIH/NHLBI), grants from Laura and John Arnold Foundation, outside the submitted work; .

🖌 No



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Section 1. Identifying Info	rmation	
1. Given Name (First Name) Gowri	2. Surname (Last Name) Raman	3. Date 03-June-201
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name David M Kent
5. Manuscript Title The PATH Statement Explanation an	d Elaboration Document	

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Identifying Info	mation	
1. Given Name (First Name) 2. Surname (Last Harry Selker		3. Date 17-September-201
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name David Kent, MD, MSc
i. Manuscript Title The PATH Statement Explanation and	Elaboration Document	

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🖌 No

Are there any relevant conflicts of interest?		Yes	
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Are there any relevant conflicts of interest?		Yes	\checkmark
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Section 1. Identifying Info	rmation	
1. Given Name (First Name) Sally	2. Surname (Last Name) Morton	3. Date 09-September-201
4. Are you the corresponding author?		Corresponding Author's Name David Kent
5. Manuscript Title The PATH Statement Explanation ar	d Elaboration Document	

M18-3668

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Other: Anything not covered under the previous three boxes Pending: The patent has been filed but not issued Issued: The patent has been issued by the agency Licensed: The patent has been licensed to an entity, whether earning royalties or not Royalties: Funds are coming in to you or your institution due to your



Section 1.	Identifying Infor	mation	
1. Given Name (Fir Michael	rst Name)	2. Surname (Last Name) Pencina	3. Date 10-September-2019
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Kent
5. Manuscript Title The Predictive A		ent effect Heterogeneity (I	PATH) Statement
6. Manuscript Ider M18-3667	ntifying Number (if you	know it)	

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? \checkmark Yes \square 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	Non-Financial Support <mark>?</mark>	Other?	Comments	
PCORI (Tufts Subaward)	\checkmark					

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**.

No

Are there any relevant conflicts of interest? \checkmark Yes

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees	Non-Financial Support?	Other?	Comments
Sanofi/Regeneron	\checkmark				Grants to Duke
Amgen	\checkmark				Grant to Duke
Boehringer Ingelheim		\checkmark			Past Ad Board



Name of Entity	Grant?	Personal Fees ?	Non-Financial Support?	Other?	Comments
Merck		\checkmark			Past Guest Lecture
BMS	\checkmark				Grant to Duke

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 covered above

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Dr. Pencina reports grants from PCORI (Tufts Subaward), during the conduct of the study; grants from Sanofi/Regeneron, grants from Amgen, personal fees from Boehringer Ingelheim, personal fees from Merck, grants from BMS, outside the submitted work; .



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Section 1.	Identifying Inform	mation	
1. Given Name (Fi Ewout	rst Name)	2. Surname (Last Name) Steyerberg	3. Date 09-September-2019
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Kent
5. Manuscript Title The Predictive A Elaboration Doc	pproaches to Treatme	ent effect Heterogeneity (P	ATH) Statement; and The PATH Statement Explanation and
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No

Are there any relevant conflicts of interest?		Yes	\checkmark
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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

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?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments	
Royalties for book "Clinical Prediction Models"				\checkmark			



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Dr. Steyerberg reports royalties from Springer for his book "Clinical Prediction Models" .

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Section 1. Identifying Infor	mation	
1. Given Name (First Name) David	2. Surname (Last Name) Kent	3. Date 25-June-2019
4. Are you the corresponding author?	✓ Yes No	
5. Manuscript Title The PATH Statement Explanation and	Elaboration Document	

6. Manuscript Identifying Number (if you know it)

M18-3668

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	1.
Excess rows can be removed by pressing the "X" button.	

Name of Institution/Company	Grant?	Personal Fees	Non-Financial Support <mark>?</mark>	Other?	Comments	
PCORI	\checkmark					

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Are there any relevant conflicts of interest? Yes 🗸 No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes 🗸 No



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Dr. Kent reports grants from PCORI, during the conduct of the study; .

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Section 1.	Identifying Infor	mation	
1. Given Name (Fi Steven	rst Name)	2. Surname (Last Name) Goodman	3. Date 11-October-2019
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Kent
5. Manuscript Title The PATH Stater		Elaboration Document	

M19-03668

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✓ No

Are there any relevant conflicts of interest? Yes

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No

Are there any relevant conflicts of interest? \checkmark Yes

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees ?	Non-Financial Support	Other?	Comments	
PCORI		\checkmark			I am on the Methodology Committee	

Section 4. Intellectual Property -- Patents & Copyrights Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Volume Volume



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Dr. Goodman reports personal fees from PCORI, outside the submitted work; .

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3. Date 06-June-2019
Corresponding Author's Name David M Kent

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Dr. van Klaveren has nothing to disclose.

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



1. Given Name (First Nam Bray	ne)	2. Surname (Last Name) Patrick-Lake	3. Date 10/4/19	
4. Are you the correspon	ding author?	Yes X No		
5. Manuscript Title				

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2

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