

## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Instructions

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

## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) Ravi	2. Surname (Last Name) Varadhan	3. Date 23-May-2019
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name David Kent
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. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Tufts University	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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

### Evaluation and Feedback

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)  
Joseph

2. Surname (Last Name)  
Ross

3. Date  
23-May-2019

4. Are you the corresponding author?  Yes  No  
Corresponding Author's Name  
David Kent, MD, PhD

5. Manuscript Title  
The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)  
M18-3667R

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

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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?	Other?	Comments
Patient Centered Outcomes Research Institute	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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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Are there any relevant conflicts of interest?  Yes  No

If yes, please fill out the appropriate information below.

## ICMJE Form for Disclosure of Potential Conflicts of Interest

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Food and Drug Administration (FDA)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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.

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Laura and John Arnold Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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. 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. 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; .

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### Section 1. Identifying Information

1. Given Name (First Name) Andrew

2. Surname (Last Name) Vickers

3. Date 23-May-2019

4. Are you the corresponding author?  Yes  No Corresponding Author's Name David Kent

5. Manuscript Title The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it) M18-3667

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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.)?

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NIH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	P30CA008748: Craig Thompson

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### Section 1. Identifying Information

1. Given Name (First Name)  
Ralph

2. Surname (Last Name)  
D'Agostino

3. Date  
02-June-2019

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name  
Dr. D M. Kent

5. Manuscript Title  
The Predictive Approaches to Treatment Effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)

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### Section 1. Identifying Information

1. Given Name (First Name)

Jessica

2. Surname (Last Name)

Paulus

3. Date

05-June-2019

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name

David Kent

5. Manuscript Title

The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)

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.)?

Are there any relevant conflicts of interest?  Yes  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



## ICMJE Form for Disclosure of Potential Conflicts of Interest

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### 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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### 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. Paulus has nothing to disclose.

### Evaluation and Feedback

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)

Gowri

2. Surname (Last Name)

Raman

3. Date

03-June-2019

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name

David M Kent

5. Manuscript Title

The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)

M18-3667

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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

## ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Raman has nothing to disclose.

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) David	2. Surname (Last Name) van Klaveren	3. Date 06-June-2019
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name David M Kent
5. Manuscript Title The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement		
6. Manuscript Identifying Number (if you know it) 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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## ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. van Klaveren has nothing to disclose.

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



## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

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 Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)  
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.)?

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?	Other?	Comments
PCORI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### Section 3. Relevant financial activities outside the submitted work.

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

## ICMJE Form for Disclosure of Potential Conflicts of Interest

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

### Evaluation and Feedback

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)  
John

2. Surname (Last Name)  
Wong

3. Date  
01-July-2019

4. Are you the corresponding author?  Yes  No  
Corresponding Author's Name  
David Kent

5. Manuscript Title  
The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)  
M18-3668

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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?	Other?	Comments
Patient-Centered Outcome Research Institute	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) Harry	2. Surname (Last Name) Selker	3. Date 17-September-2019
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name David Kent, MD, MSc
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

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Are there any relevant conflicts of interest?  Yes  No

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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.

#### 1. 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".

#### 3. Relevant financial activities outside the submitted work.

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.

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#### 4. Intellectual Property.

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

#### 5. Relationships not covered above.

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**Other:** Anything not covered under the previous three boxes

**Pending:** The patent has been filed but not issued

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

## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)  
Steven

2. Surname (Last Name)  
Goodman

3. Date  
11-October-2019

4. Are you the corresponding author?  Yes  No  
Corresponding Author's Name  
Kent

5. Manuscript Title  
The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)  
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.)?

Are there any relevant conflicts of interest?  Yes  No

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Are there any relevant conflicts of interest?  Yes  No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Patient Centered Outcomes Research Institute	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	I serve 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  No

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### 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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### 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. Goodman reports personal fees from Patient Centered Outcomes Research Institute, outside the submitted work; .

### Evaluation and Feedback

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) John	2. Surname (Last Name) Ioannidis	3. Date 23-September-2019
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name _____
5. Manuscript Title PATH Statement _____		
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 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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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

## ICMJE Form for Disclosure of Potential Conflicts of Interest

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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. Ioannidis has nothing to disclose.

### Evaluation and Feedback

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)

Sally

2. Surname (Last Name)

Morton

3. Date

09-September-2019

4. Are you the corresponding author?

 Yes No

Corresponding Author's Name

David Kent

5. Manuscript Title

The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it)

M18-3667

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

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Are there any relevant conflicts of interest?  Yes  No

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Dr. Morton has nothing to disclose.

### Evaluation and Feedback

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) Michael

2. Surname (Last Name) Pencina

3. Date 18-September-2019

4. Are you the corresponding author?  Yes  No Corresponding Author's Name Kent

5. Manuscript Title The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement

6. Manuscript Identifying Number (if you know it) 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.)?

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?	Other?	Comments
PCORI (Tufts Subaward)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 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?	Other?	Comments
Sanofi/Regeneron	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Grants to Duke
Amgen	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Grant to Duke
Boehringer Ingelheim	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Past Ad Board

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Merck	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Past Guest Lecture
BMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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

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

### Section 1. Identifying Information

1. Given Name (First Name)  
Ewout

2. Surname (Last Name)  
Steyerberg

3. Date  
09-September-2019

4. Are you the corresponding author?  Yes  No  
Corresponding Author's Name  
Kent

5. Manuscript Title  
The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement; and The PATH Statement Explanation and Elaboration Document

6. Manuscript Identifying Number (if you know it)  
M18-3667

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

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Are there any relevant conflicts of interest?  Yes  No

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Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
Royalties for book "Clinical Prediction Models"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		

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

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#### 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".

#### 3. Relevant financial activities outside the submitted work.

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.

#### 5. 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.

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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

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

## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)  
Rodney

2. Surname (Last Name)  
Hayward

3. Date  
09-September-2019

4. Are you the corresponding author?  Yes  No Corresponding Author's Name \_\_\_\_\_

5. Manuscript Title  
The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement"

6. Manuscript Identifying Number (if you know it)  
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.)?

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?	Other?	Comments
NIDDK	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
VA HSR&D	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 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 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

## ICMJE Form for Disclosure of Potential Conflicts of Interest

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### 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. Hayward reports grants from NIDDK, grants from VA HSR&D, during the conduct of the study; .

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

### Section 1. Identifying Information

1. Given Name (First Name) 2. Surname (Last Name) 3. Date  
Bray Patrick-Lake 10/4/19

4. Are you the corresponding author?  Yes  No

5. Manuscript Title

6. Manuscript Identifying Number (if you know it)  
M18-3667

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ADD

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ADD

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**Section 6. D**

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No conflicts to disclose.

**Evaluation and Feedback**

Please