

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

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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)
Blanca M.

2. Surname (Last Name)
Morales

3. Date
03-October-2018

4. Are you the corresponding author?

Yes No

Corresponding Author's Name
Emilie Barruet, PhD

5. Manuscript Title

NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification

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

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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. Morales has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name) Edward
 2. Surname (Last Name) Hsiao
 3. Date 03-October-2018

4. Are you the corresponding author? Yes No

5. Manuscript Title
 NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification

6. Manuscript Identifying Number (if you know it)
 122958-INS-CMED-RV-3

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
National Institutes of Health	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Doris Duke Charitable Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
University of California Department of Medicine	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Radiant Hope Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
March of Dimes	<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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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Clementia Pharmaceuticals	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Clinical Trials Support via Sponsored Research Agreement

Section 4. Intellectual Property -- Patents & Copyrights

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Edward Hsiao serves in an unpaid capacity on the International FOP Association Medical Registry Advisory Board, on the International Clinical Council on FOP, and on the Fibrous Dysplasia Foundation Medical Advisory Board. These activities pose no conflicts for the presented research.

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Dr. Hsiao reports grants from National Institutes of Health, grants from Doris Duke Charitable Foundation, grants from University of California Department of Medicine, grants from Radiant Hope Foundation, grants from March of Dimes, during the conduct of the study; grants from Clementia Pharmaceuticals, outside the submitted work; and Edward Hsiao serves in an unpaid capacity on the International FOP Association Medical Registry Advisory Board, on the International Clinical Council on FOP, and on the Fibrous Dysplasia Foundation Medical Advisory Board. These activities pose no conflicts for the presented research..

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Judith

2. Surname (Last Name)
Hellman

3. Date
02-October-2018

4. Are you the corresponding author?

Yes No

Corresponding Author's Name
Emilie Barruet

5. Manuscript Title
NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification

6. Manuscript Identifying Number (if you know it)
122958-INS-CMED-TR-2

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Dr. Hellman 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) THM	2. Surname (Last Name) Ottenhoff	3. Date 04-October-2018
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Emilie Barruet, PhD Edward Hsiao, MD, PhD
5. Manuscript Title NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification		
6. Manuscript Identifying Number (if you know it)		

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Section 1. Identifying Information

1. Given Name (First Name) Tania	2. Surname (Last Name) Moody	3. Date 03-October-2018
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Emilie Barruet
5. Manuscript Title NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification		
6. Manuscript Identifying Number (if you know it) 122958-INS-CMED-RV-3		

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4. Intellectual Property.

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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)
Kelly

2. Surname (Last Name)
Wentworth

3. Date
03-October-2018

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

5. Manuscript Title
NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification

6. Manuscript Identifying Number (if you know it)
122958-INS-CMED-RV-3

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
Clementia Pharmaceuticals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	I am a sub-investigator on their clinical trial

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

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

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Dr. Wentworth reports other from Clementia Pharmaceuticals, 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) Amy	2. Surname (Last Name) Ton	3. Date 03-October-2018
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Emilie Barruet
5. Manuscript Title NFkB/MAPK Activation Underlies ACVR1- mediated Inflammation in Human Heterotopic Ossification		
6. Manuscript Identifying Number (if you know it)		

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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

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Amy Ton 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)
Marielle

2. Surname (Last Name)
Haks

3. Date
05-October-2018

4. Are you the corresponding author? Yes No

Corresponding Author's Name
Emilie Barruet, PhD and Edward Hsiao, MD, PhD

5. Manuscript Title
NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification

6. Manuscript Identifying Number (if you know it)
122958-INS-CMED-RV-3

Section 2. The Work Under Consideration for Publication

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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. Haks 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) Corey	2. Surname (Last Name) Cain	3. Date 03-October-2018
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Edward Hsiao
5. Manuscript Title NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification		
6. Manuscript Identifying Number (if you know it) 122958-INS-CMED-RV-3		

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Section 4. Intellectual Property -- Patents & Copyrights

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Section 1. Identifying Information

1. Given Name (First Name)
Tea

2. Surname (Last Name)
Chan

3. Date
05-October-2018

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Emilie Barruet, PhD and Edward Hsiao, MD, PhD

5. Manuscript Title
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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
Clementia Pharmaceuticals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Research grant support for clinical trial, Edward Hsiao (PI)

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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Ms. Chan reports other from Clementia Pharmaceuticals, outside the submitted work; .

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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

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Emilie

2. Surname (Last Name)
Barruet

3. Date
03-October-2018

4. Are you the corresponding author? Yes No

5. Manuscript Title
NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification

6. Manuscript Identifying Number (if you know it)
122958-INS-CMED-TR-2

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
California Institute for Regenerative Medicine Fellowship Program to UCSF	<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

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.

Emilie Barruet has nothing to disclose.

Evaluation and Feedback

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

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.

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.

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.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Mary	2. Surname (Last Name) Nakamura	3. Date 02-October-2018
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Emilie Barruet
5. Manuscript Title NFkB/MAPK Activation Underlie ACVR1-mediated Inflammation in Human Heterotopic Ossification		
6. Manuscript Identifying Number (if you know it) 122958-INS-CMED-RV-3		

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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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. Nakamura has nothing to disclose.

Evaluation and Feedback

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

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	20
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6
		(b) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Supplemental Tables
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	20
Bias	9	Describe any efforts to address potential sources of bias	20
Study size	10	Explain how the study size was arrived at	20
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	20
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	23
		(b) Describe any methods used to examine subgroups and interactions	NA
		(c) Explain how missing data were addressed	NA
		(d) If applicable, explain how loss to follow-up was addressed	NA
		(e) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Figure 1
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Supplemental Tables
		(b) Indicate number of participants with missing data for each variable of interest	Supplemental Tables
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	Figures 2-8

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA NA NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.