

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract :Yes <hr/> (b) Provide in the abstract an informative and balanced summary of what was done and what was found : Yes
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported :Yes
Objectives	3	State specific objectives, including any prespecified hypotheses :Yes
Methods		
Study design	4	Present key elements of study design early in the paper :Yes
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection :Yes
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up : Yes <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls : Yes <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants : No <hr/> (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed : No <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case : NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable : Yes
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 : Yes
Bias	9	Describe any efforts to address potential sources of bias : Yes
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why : Yes
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding : Yes <hr/> (b) Describe any methods used to examine subgroups and interactions : Yes <hr/> (c) Explain how missing data were addressed <hr/> (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed : No <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed : NA <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy : NA <hr/> (e) Describe any sensitivity analyses : NA

Continued on next page

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 : Yes (b) Give reasons for non-participation at each stage NA (c) Consider use of a flow diagram NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders : Yes (b) Indicate number of participants with missing data for each variable of interest : Yes (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount) : NA
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure : NA <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures : NA
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 : Yes (b) Report category boundaries when continuous variables were categorized : Yes (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period : Yes
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses : Yes
Discussion		
Key results	18	Summarise key results with reference to study objectives : Yes
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 : Yes
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence : Yes
Generalisability	21	Discuss the generalisability (external validity) of the study results : No
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 : Yes

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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 www.strobe-statement.org.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Zoheb	2. Surname (Last Name) Kazi	3. Date 02-May-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Durable and sustained immune tolerance to ERT in Pompe disease with entrenched immune responses		
6. Manuscript Identifying Number (if you know it) 86821-INS-CMED-1		

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

Are there any relevant conflicts of interest? Yes No

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
Genzyme	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This research was supported by a grant from the Genzyme Corporation, a Sanofi Company (Cambridge, MA), and in part by the Lysosomal Disease Network (U54NS065768) is a part of the National Institutes of Health (NIH) Rare Disease Clinical Research Network (RDCRN), supported through collaboration between the NIH Office of Rare Diseases Research (ORDR) at the National Center for Advancing Translational Science (NCATS), the National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Kazi reports grants from Genzyme, grants from NIH, during the conduct of the study; .

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Section 1. Identifying Information

1. Given Name (First Name) Sean	2. Surname (Last Name) Prater	3. Date 20-April-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani, MD
5. Manuscript Title Durable and sustained immune tolerance to ERT in Pompe disease with entrenched immune responses		
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Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
20150037329	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Section 1. Identifying Information

1. Given Name (First Name)

Joyce

2. Surname (Last Name)

Kobori

3. Date

02-May-2016

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Priya S. Kishnani

5. Manuscript Title

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6. Manuscript Identifying Number (if you know it)

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Dr. Kobori has nothing to disclose.

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1. Given Name (First Name)
David H

2. Surname (Last Name)
Viskochil, MD

3. Date
26-April-2016

4. Are you the corresponding author? Yes No

Corresponding Author's Name
Priya S. Kishnani

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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

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David H. Viskochil, MD has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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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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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

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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) Carrie	2. Surname (Last Name) Bailey	3. Date 22-April-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Durable and sustained immune tolerance to ERT in Pompe disease with entrenched immune responses		
6. Manuscript Identifying Number (if you know it) 86821-INS-CMED-1		

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

Section 5. Relationships not covered above

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Section 6. Disclosure Statement

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Carrie Bailey 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) Renuka	2. Surname (Last Name) Gera	3. Date 22-April-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Durable Sustained Immune Tolerance to ERT in Pompe disease with Entrenched Immune responses		
6. Manuscript Identifying Number (if you know it) 86821-INS-CMED-1		

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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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. Gera 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) Stockton	3. Date 19-April-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Durable and sustained immune tolerance to ERT in Pompe disease with entrenched immune responses		
6. Manuscript Identifying Number (if you know it) 86821-INS-CMED-1		

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

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Genzyme	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Genzyme	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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):
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Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Stockton reports grants from Genzyme, personal fees from Genzyme, 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) Paul	2. Surname (Last Name) McIntosh	3. Date 21-April-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Durable and sustained immune tolerance to ERT in Pompe disease with entrenched immune responses		
6. Manuscript Identifying Number (if you know it) 86821-INS-CMED-1		

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

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Genzyme	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Travel Assistance for Genzyme's Patient Speakers Bureau

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

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PM receives travel assistance for speaking engagements as a member of Genzyme's Patient Speakers Bureau.

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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)

Rosenberg

3. Date

18-April-2016

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Priya S. Kishnani

5. Manuscript Title

Durable and sustained immune tolerance to ERT in Pompe disease with entrenched immune responses

6. Manuscript Identifying Number (if you know it)

86821-INS-CMED-1

Section 2. The Work Under Consideration for Publication

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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

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Dr. Rosenberg has nothing to disclose.

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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.

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Priya

2. Surname (Last Name) Kishnani

3. Date 22-April-2016

4. Are you the corresponding author? Yes No

5. Manuscript Title
Durable and sustained immune tolerance to ERT in Pompe disease with entrenched immune responses

6. Manuscript Identifying Number (if you know it)
86821-INS-CMED-1

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
Genzyme Corporation (Sanofi Aventis)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Priya S. Kishnani has received research/grant support and honoraria from Genzyme Corporation. Priya S. Kishnani is a member of the Pompe and Gaucher Disease Registry Advisory Board for Genzyme Corporation

ICMJE Form for Disclosure of Potential Conflicts of Interest

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
NIH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This research was supported by a grant from the Genzyme Corporation, a Sanofi Company (Cambridge, MA), and in part by the Lysosomal Disease Network (U54NS065768) is a part of the National Institutes of Health (NIH) Rare Disease Clinical Research Network (RDCRN), supported through collaboration between the NIH Office of Rare Diseases Research (ORDR) at the National Center for Advancing Translational Science (NCATS), the National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
PTC Therapeutics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Baebies, Inc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Advisory Board
Roche	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Alexion Pharmaceuticals, Inc/	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Amicus Therapeutics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Shire Pharmaceuticals	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ICMJE Form for Disclosure of Potential Conflicts of Interest

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Synageva	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	FDA Advisory Board

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
20150037329 (US Patent #8,809,282)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		US Patent #8,809,282, issued August 19, 2014, "Method of Reducing Titters of Antibodies Specific for a Therapeutic Agent," Inventors: Priya S. Kishnani, Surhad C. Banugaria, Dwight D, Koeberl, Sean N. Prater.

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.

ICMJE Form for Disclosure of Potential Conflicts of Interest

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. Kishnani reports grants and personal fees from Genzyme Corporation (Sanofi Aventis), grants from NIH, during the conduct of the study; personal fees from PTC Therapeutics, other from Baebies, Inc., personal fees from Roche, personal fees from Alexion Pharmaceuticals, Inc/, personal fees from Amicus Therapeutics, grants and personal fees from Shire Pharmaceuticals, personal fees from Synageva, outside the submitted work; In addition, Dr. Kishnani has a patent 20150037329 (US Patent #8,809,282) issued.

Evaluation and Feedback

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