ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

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.

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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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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Shaily
2. Surname (Last Name): Garg
3. Date: 03-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
Vaxart	☐	☑	☐	☐	Employee of Vaxart	

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Ms. Garg reports personal fees from Vaxart, 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): Keith
2. Surname (Last Name): Gottlieb
3. Date: 03-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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Section 1. Identifying Information

1. Given Name (First Name): George
2. Surname (Last Name): Trager
3. Date: 03-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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Section 1. Identifying Information

1. Given Name (First Name): Leesun
2. Surname (Last Name): Kim
3. Date: 03-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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Section 1. Identifying Information

1. Given Name (First Name): Kassandra
2. Surname (Last Name): Kasparek
3. Date: 03-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

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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): Karen
2. Surname (Last Name): Lin
3. Date: 03-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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

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	
Vaxart	☐	☑	☐	☐	Employee of Vaxart	

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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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Ms. Lin reports personal fees from Vaxart, 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): Dave
2. Surname (Last Name): Liebowitz
3. Date: 03-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Marcela
2. Surname (Last Name): Pasetti
3. Date: 10-November-2017

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Tucker, S.N.

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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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Dr. Pasetti 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): Sean
2. Surname (Last Name): Tucker
3. Date: 02-November-2017

4. Are you the corresponding author? ☑ Yes ☐ No

5. Manuscript Title: Safety and immunity to norovirus after oral tablet immunization: a phase 1 randomized, placebo-controlled trial

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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ICMJE Form for Disclosure of Potential Conflicts of Interest

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments	
Chimeric Ad patent	☐	☑	☐	☐		Technology Used in the Clinical Trial	

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Dr. Tucker reports personal fees from Vaxart, during the conduct of the study; In addition, Dr. Tucker has a patent Chimeric Ad Patent issued.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	13
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Supplemental
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	12
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	13-14
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	12
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	12
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	12
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	12
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	12
	11b	If relevant, description of the similarity of interventions	12, 13
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	17
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Supplemental

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	5, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	5, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/A (fully enrolled)
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	5-9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Supplemental
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5-6
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: fo and for up to date references relevant to this checklist, see www.consort-statement.org.