

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.

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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)
Alireza

2. Surname (Last Name)
Mohammadi

3. Date
07-September-2019

4. Are you the corresponding author?

☐ Yes ☒ No

Corresponding Author's Name
Justin Lathia

5. Manuscript Title

Metronomic capecitabine as an immune modulator in glioblastoma patients reduces myeloid-derived suppressor cells

6. Manuscript Identifying Number (if you know it)
130748-INS-CMED-RV-2

Section 2. The Work Under Consideration for Publication

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Dr. Mohammadi 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) Huang
2. Surname (Last Name) Pengjing
3. Date 10-September-2019

4. Are you the corresponding author? ☐ Yes ☒ No
Corresponding Author's Name Justin Lathia

5. Manuscript Title
Metronomic capecitabine as an immune modulator in glioblastoma patients reduces myeloid-derived suppressor cells

6. Manuscript Identifying Number (if you know it)
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Section 1. Identifying Information

1. Given Name (First Name)
Justin

2. Surname (Last Name)
Lathia

3. Date
07-September-2019

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

5. Manuscript Title
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Dr. Lathia 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)
Mary

2. Surname (Last Name)
McGraw

3. Date
06-September-2019

4. Are you the corresponding author?

☐ Yes

☒ No

Corresponding Author's Name
Justin Lathia

5. Manuscript Title

Metronomic capecitabine as an immune modulator in glioblastoma patients reduces myeloid-derived suppressor cells

6. Manuscript Identifying Number (if you know it)

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Dr. McGraw has nothing to disclose.

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David
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Peereboom
3. Date
06-September-2019
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Justin Lathia
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. 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
Musella Foundation	☒	☐	☐	☐	
NIH	☒	☐	☐	☐	
Cancer Biology Training Grant	☒	☐	☐	☐	
Sontag Foundation	☒	☐	☐	☐	
B*CURED	☒	☐	☐	☐	
Dr. Miriam and Sheldon G. Adelson Medical Research Foundation	☒	☐	☐	☐	
Mylan Pharmaceuticals	☐	☐	☒	☐	Drug Supply

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Dr. Peereboom reports grants from Musella Foundation , grants from NIH, grants from Cancer Biology Training Grant, grants from Sontag Foundation, grants from B*CURED , grants from Dr. Miriam and Sheldon G. Adelson Medical Research Foundation, non-financial support from Mylan 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)
Tyler
2. Surname (Last Name)
Alban
3. Date
10-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No Corresponding Author's Name
Justin Lathia
5. Manuscript Title
Metronomic capecitabine as an immune modulator in glioblastoma patients reduces myeloid-derived suppressor cells
6. Manuscript Identifying Number (if you know it)
130748-INS-CMED-RV-2

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. Alban 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)
Vogelbaum
3. Date
08-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No Corresponding Author's Name
Tyler Alban
5. Manuscript Title
6. Manuscript Identifying Number (if you know it)

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.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Infuseon Therapeutics, Inc	☐	☐	☐	☒	Indirect equity and royalties
Tocagen	☐	☒	☐	☐	
Celgene	☐	☒	☐	☐	
Blue Earth Diagnostics	☐	☒	☐	☐	

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Vogelbaum reports other from Infuseon Therapeutics, Inc, personal fees from Tocagen, personal fees from Celgene, personal fees from Blue Earth Diagnostics, 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)
Tomas
2. Surname (Last Name)
Radivoyevitch
3. Date
06-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No Corresponding Author's Name
Justin D. Lathia
5. Manuscript Title
Metronomic capecitabine as an immune modulator in glioblastoma patients reduces myeloid-derived suppressor cells
6. Manuscript Identifying Number (if you know it)

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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. Radivoyevitch 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)
Alvaro

2. Surname (Last Name)
Alvarado

3. Date
08-September-2019

4. Are you the corresponding author?

☐ Yes ☒ No

Corresponding Author's Name
Justin D. Lathia

5. Manuscript Title

Metronomic capecitabine as an immune modulator in glioblastoma patients reduces myeloid-derived suppressor cells

6. Manuscript Identifying Number (if you know it)

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Dr. Alvarado 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) Balint 2. Surname (Last Name) Otvos 3. Date 06-September-2019

4. Are you the corresponding author? ☐ Yes ☒ No Corresponding Author's Name
Justin D Lathia

5. Manuscript Title
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6. Manuscript Identifying Number (if you know it)

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Dr. Otvos has nothing to disclose.

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Bayik
3. Date
06-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No
Corresponding Author's Name
Justin D. Lathia
5. Manuscript Title
Metronomic capecitabine as an immune modulator in glioblastoma patients reduces myeloid-derived suppressor cells
6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Bayik has nothing to disclose.

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1. Given Name (First Name)

Harley

2. Surname (Last Name)

Kornblum

3. Date

06-September-2019

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☐ Yes

☒ No

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Section 1. Identifying Information

1. Given Name (First Name)
Matthew

2. Surname (Last Name)
Grabowski

3. Date
06-September-2019

4. Are you the corresponding author?

☐ Yes☒ No

Corresponding Author's Name

5. Manuscript Title

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130748-INS-RG-1

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1. Given Name (First Name)

Gustavo

2. Surname (Last Name)

Roversi

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07-September-2019

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☐ Yes

☒ No

Corresponding Author's Name

Justin Lathia

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TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported?	
			✓	Pg #
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions	✓	14
		• Structured abstract recommended	✓	2
		• Information on target population or study sample	✓	14, 5
Introduction				
Background	2	• Scientific background and explanation of rationale	✓	3, 4
		• Theories used in designing behavioral interventions	NA	
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	14
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✓	14, 15
		• Recruitment setting	✓	14, 15
		• Settings and locations where the data were collected	✓	1, 14, 15
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	14, 15
		○ Content: what was given?	✓	14, 15
		○ Delivery method: how was the content given?	✓	14, 15
		○ Unit of delivery: how were the subjects grouped during delivery?	✓	14, 15
		○ Deliverer: who delivered the intervention?	✓	14, 15
		○ Setting: where was the intervention delivered?	✓	14, 15
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	14, 15
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	✓	14, 15
○ Activities to increase compliance or adherence (e.g., incentives)	✓	14, 15		
Objectives	5	• Specific objectives and hypotheses	✓	2, 4
Outcomes	6	• Clearly defined primary and secondary outcome measures	✓	16
		• Methods used to collect data and any methods used to enhance the quality of measurements	✓	16, 17
		• Information on validated instruments such as psychometric and biometric properties	✓	16
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	✓	5
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	✓	5
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	NA	
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	NA	

TREND Statement Checklist

Blinding (masking)	9	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.	✓	17
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	✓	6, 7, 8
		If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	NA	
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	✓	9, 7, 8, 17
		Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	✓	17
		Methods for imputing missing data, if used	NA	
		Statistical software or programs used	✓	17
Results				
Participant flow	12	Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	✓	Figure 1
		Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	NA	
		Assignment: the numbers of participants assigned to a study condition	✓	5
		Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	✓	5
		Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition	✓	5, 14
		Analysis: the number of participants included in or excluded from the main analysis, by study condition	✓	3, 14, 15
		Description of protocol deviations from study as planned, along with reasons	✓	17
Recruitment	13	Dates defining the periods of recruitment and follow-up	✓	5, 14
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition	✓	5
		Baseline characteristics for each study condition relevant to specific disease prevention research	NA	
		Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	NA	
		Comparison between study population at baseline and target population of interest	✓	5, 6, 7, 8
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	✓	5, 17

TREND Statement Checklist

Numbers analyzed	16	Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	✓	5
		Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	NA	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	✓	5, 7, 8, 9
		Inclusion of null and negative findings	✓	5, 6, 7, 8, 9
		Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	NA	
Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	✓	5, 6, 7, 8, 9
Adverse events	19	Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	✓	6
DISCUSSION				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	✓	10-13
		Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	✓	10-13
		Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	✓	10-13
		Discussion of research, programmatic, or policy implications	✓	10-13
Generalizability	21	Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues	✓	10-13
Overall Evidence	22	General interpretation of the results in the context of current evidence and current theory	✓	10-13

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <http://www.cdc.gov/trendstatement/>