# TREND Statement Checklist

<table>
<thead>
<tr>
<th>Paper Section/ Topic</th>
<th>Item No</th>
<th>Descriptor</th>
<th>Reported?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and Abstract</strong></td>
<td>1</td>
<td>- Information on how unit were allocated to interventions</td>
<td>✓ 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Structured abstract recommended</td>
<td>✓ 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Information on target population or study sample</td>
<td>✓ 1</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>- Scientific background and explanation of rationale</td>
<td>✓ 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Theories used in designing behavioral interventions</td>
<td>✓ 3</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>3</td>
<td>- Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Recruitment setting</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Settings and locations where the data were collected</td>
<td>✓ 12</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>- Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Content: what was given?</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Delivery method: how was the content given?</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Unit of delivery: how were the subjects grouped during delivery?</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Deliverer: who delivered the intervention?</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Setting: where was the intervention delivered?</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Time span: how long was it intended to take to deliver the intervention to each unit?</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Activities to increase compliance or adherence (e.g., incentives)</td>
<td>na</td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>5</td>
<td>- Specific objectives and hypotheses</td>
<td>✓ 3</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>6</td>
<td>- Clearly defined primary and secondary outcome measures</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Methods used to collect data and any methods used to enhance the quality of measurements</td>
<td>✓ 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Information on validated instruments such as psychometric and biometric properties</td>
<td>✓ 11</td>
</tr>
<tr>
<td><strong>Sample Size</strong></td>
<td>7</td>
<td>- How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules</td>
<td>✓ 11</td>
</tr>
<tr>
<td><strong>Assignment Method</strong></td>
<td>8</td>
<td>- Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)</td>
<td>na</td>
</tr>
</tbody>
</table>
## TREND Statement Checklist

### Blinding (masking)
- 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.  □

### Unit of Analysis
- Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)  □
- 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)  □

### Statistical Methods
- Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data  □
- Statistical methods used for additional analyses, such as a subgroup analysis and adjusted analysis  □
- Methods for imputing missing data, if used  □
- Statistical software or programs used  □

### Results

#### Participant flow
- Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)
  - Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study  □
  - Assignment: the numbers of participants assigned to a study condition  □
  - Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention  □
  - 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  □
  - Analysis: the number of participants included in or excluded from the main analysis, by study condition  □
- Description of protocol deviations from study as planned, along with reasons  □

#### Recruitment
- Dates defining the periods of recruitment and follow-up  □

#### Baseline Data
- Baseline demographic and clinical characteristics of participants in each study condition  □
- Baseline characteristics for each study condition relevant to specific disease prevention research  □
- Baseline comparisons of those lost to follow-up and those retained, overall and by study condition  □
- Comparison between study population at baseline and target population of interest  □

#### Baseline equivalence
- Data on study group equivalence at baseline and statistical methods used to control for baseline differences  □
<table>
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<tbody>
<tr>
<td>Numbers analyzed</td>
</tr>
<tr>
<td>• 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</td>
</tr>
<tr>
<td>• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses</td>
</tr>
<tr>
<td>Outcomes and estimation</td>
</tr>
<tr>
<td>• 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</td>
</tr>
<tr>
<td>• Inclusion of null and negative findings</td>
</tr>
<tr>
<td>• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any</td>
</tr>
<tr>
<td>Ancillary analyses</td>
</tr>
<tr>
<td>• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory</td>
</tr>
<tr>
<td>Adverse events</td>
</tr>
<tr>
<td>• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)</td>
</tr>
<tr>
<td>DISCUSSION</td>
</tr>
<tr>
<td>Interpretation</td>
</tr>
<tr>
<td>• 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</td>
</tr>
<tr>
<td>• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations</td>
</tr>
<tr>
<td>• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation</td>
</tr>
<tr>
<td>• Discussion of research, programmatic, or policy implications</td>
</tr>
<tr>
<td>Generalizability</td>
</tr>
<tr>
<td>• 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</td>
</tr>
<tr>
<td>Overall Evidence</td>
</tr>
<tr>
<td>• General interpretation of the results in the context of current evidence and current theory</td>
</tr>
</tbody>
</table>

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1: Identifying Information

1. Given Name (First Name)
   Brett

2. Surname (Last Name)
   King

3. Date
   08-August-2016

4. Are you the corresponding author?  
   Yes  No

5. Manuscript Title
   Safety and Efficacy of the JAK Inhibitor Tofacitinib Citrate in Patients with Alopecia Areata

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.

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.

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<thead>
<tr>
<th>Name of Entity</th>
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<th>Non-Financial Support?</th>
<th>Other?</th>
<th>Comments</th>
</tr>
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<tr>
<td>Pfizer</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td>Advisory board honoraria, consultant fees</td>
</tr>
<tr>
<td>Aclaris Therapeutics</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td>Advisory board honoraria</td>
</tr>
<tr>
<td>Concert Pharmaceuticals</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td>Consultant fees</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td>Consultant fees</td>
</tr>
</tbody>
</table>
ICMJE Form for Disclosure of Potential Conflicts of Interest

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?

☐ 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. King reports personal fees from Pfizer, personal fees from Aclaris Therapeutics, personal fees from Concert Pharmaceuticals, personal fees from Eli Lilly, outside the submitted work.

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

Section 1. Identifying Information

1. Given Name (First Name)  
   Anthony

2. Surname (Last Name)  
   Oro

3. Date  
   11-April-2016

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

5. Manuscript Title  
   Safety and Efficacy of Tofacitinib Citrate for the Treatment of Alopecia Areata and its Variants

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

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Dr. Oro 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)  
   Jane

2. Surname (Last Name)  
   Cerise

3. Date  
   06-April-2016

4. Are you the corresponding author?  
   [ ] Yes  [ ] No  
   Corresponding Author’s Name  
   Tony Oro/Brett King

5. Manuscript Title  
   Safety and Efficacy of Cral Tofacitinib in Advanced Alopecia Areata

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**

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   [ ] 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. Cerise 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

Section 1: Identifying Information

1. Given Name (First Name)  James
2. Surname (Last Name)  Chen
3. Date  07-April-2016
4. Are you the corresponding author?  Yes  No
Corresponding Author's Name  Tony Oro, Brett King

5. Manuscript Title
Safety and Efficacy of Oral Tofacitinib in Advanced Alopecia Areata

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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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. Chen 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)  
   Angela

2. Surname (Last Name)  
   Christiano

3. Date  
   08-August-2016

4. Are you the corresponding author?  
   ☑ Yes  ☐ No  
   Corresponding Author's Name  
   Anthony Oro/Brett King

5. Manuscript Title  
   Safety and Efficacy of the JAK Inhibitor Tofacitinib Citrate in Patients with Alopecia Areata

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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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. Christiano reports personal fees from Aclaris Therapeutics, 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)  
   Ali

2. Surname (Last Name)  
   Jabbari

3. Date  
   06-April-2016

4. Are you the corresponding author?  
   [ ] Yes  [x] No  
   Corresponding Author’s Name  
   Tony Oro/Brett King

5. Manuscript Title  
   Safety and Efficacy of the JAK Inhibitor Tofacitinib Citrate in Patients with Alopecia Areata

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Are there any relevant conflicts of interest?  
   [ ] Yes  [x] No

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Are there any relevant conflicts of interest?  
   [ ] Yes  [x] No

Section 4: Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work?  
   [ ] Yes  [x] No
ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

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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. Jabbari 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.
Section 1. Identifying Information

1. Given Name (First Name)  Justin
2. Surname (Last Name) Ko
3. Date 16-April-2016

4. Are you the corresponding author? ☑ Yes ☐ No
   Corresponding Author's Name King/Oro

5. Manuscript Title
   Safety and Efficacy of the JAK Inhibitor Tofacitinib Citrate in Patients with Alopecia Areata

6. Manuscript Identifying Number (if you know it)

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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

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

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Dr. Ko 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)  
   Shufeng

2. Surname (Last Name)  
   Li

3. Date  
   13-March-2016

4. Are you the corresponding author?  
   ✔ No

Corresponding Author’s Name

5. Manuscript Title  
   Safety and Efficacy of the JAK Inhibitor Tofacitinib Citrate for Alopecia Areata and Variants

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Are there any relevant conflicts of interest?  
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Are there any relevant conflicts of interest?  
   ✔ No

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Section 1. Identifying Information

1. Given Name (First Name)  
   Peter

2. Surname (Last Name)  
   Marinkovich

3. Date  
   19-April-2016

4. Are you the corresponding author?  
   [ ] Yes  [ ] No  
   Corresponding Author’s Name  
   Brett King, Anthony Oro

5. Manuscript Title  
   Safety and Efficacy of Oral Tofacitinib in Advanced Alopecia Areata

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?  
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1. Given Name (First Name)  
   Gautam

2. Surname (Last Name)  
   Shankar

3. Date  
   26-April-2016

4. Are you the corresponding author?  
   ☐ Yes  ☑ No  
   Corresponding Author's Name  
   Brett King, Anthony Oro

5. Manuscript Title  
   Safety and Efficacy of Oral Tofacitinib in Advanced Alopecia Areata

6. Manuscript Identifying Number (if you know it)

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1. **Given Name (First Name)**  
   Jennifer

2. **Surname (Last Name)**  
   Urban

3. **Date**  
   12-March-2016

4. **Are you the corresponding author?**  
   - Yes  
   - No

   **Corresponding Author’s Name**  
   Brett King, Anthony Oro

5. **Manuscript Title**  
   Safety and Efficacy of Oral Tofacitinib in Advanced Alopecia Areata

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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Do you have any patents, whether planned, pending or issued, broadly relevant to the work?

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1. Given Name (First Name)          2. Surname (Last Name)          3. Date
   Milene                                    Crispin                      02-April-2016

4. Are you the corresponding author?   ☐ Yes    ☑ No
   Corresponding Author’s Name
   Brett King, Anthony Oro

5. Manuscript Title
   Safety and Efficacy of the JAK Inhibitor Tofacitinib Citrate for Alopecia Areata and Variants

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

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Section 1. Identifying Information

1. Given Name (First Name)  
   Brittany

2. Surname (Last Name)  
   Craiglow

3. Date  
   19-March-2016

4. Are you the corresponding author?  
   [ ] Yes  
   [X] No

Corresponding Author's Name  
Brett King, Anthony Oro

5. Manuscript Title  
Safety and Efficacy of the JAK Inhibitor Tofacitinib Citrate for Alopecia Areata and Variants

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   [X] No

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Section 1. Identifying Information

1. Given Name (First Name)  Marten
2. Surname (Last Name)  Winge
3. Date  14-March-2016
4. Are you the corresponding author?  ☑ No

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Are there any relevant conflicts of interest?  ☑ No

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Are there any relevant conflicts of interest?  ☑ No

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