

Instructions

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Royalties: Funds are coming in to you or your institution due to your patent

KACHUR 1



| Section 1. Identifying Inform | nation | | |
|--|---|---|--|
| 1. Given Name (First Name) Stephen Patrick | 2. Surname (Last Name) KACHUR | 3. Date 08-June-2015 | |
| 4. Are you the corresponding author? | Yes ✓ No | Corresponding Author's Name Patrick S Towmey | |
| 5. Manuscript Title Intravenous artesunate for the treatme Investigational New Drug protocol | ent of severe and complicat | ed malaria in the United States: Clinical use under an | |
| 6. Manuscript Identifying Number (if you k M15-0910 | now it) | | |
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| Section 2. The Work Under Consideration for Publication | | | |
| | g but not limited to grants, da | a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation, | |
| Section 3. Relevant financial | activities outside the s | ubmitted work. | |
| of compensation) with entities as desc | ribed in the instructions. Useport relationships that wer | ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by e present during the 36 months prior to publication . | |
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| Section 4. Intellectual Prope | rty Patents & Copyrig | hts | |
| Do you have any patents, whether plan | nned, pending or issued, br | oadly relevant to the work? Yes V No | |

KACHUR 2



| Section 5. Relationships not covered above |
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| 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. KACHUR has nothing to disclose. |

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KACHUR 3



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Arguin 1



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|---|---|--|
| 1. Given Name (First Name) Paul | 2. Surname (Last Name) Arguin | 3. Date 08-June-2015 |
| 4. Are you the corresponding author? | Yes ✓ No | Corresponding Author's Name |
| Investigational New Drug Protocol. 6. Manuscript Identifying Number (if you kr M15-0910 | • | ated Malaria in the United States: Clinical Use under an |
| Section 2. The Work Under Co | onsideration for Public | cation |
| any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of intere | g but not limited to grants, da | a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation, |
| Section 3. Relevant financial | activities outside the s | submitted work. |
| of compensation) with entities as descr | ibed in the instructions. Us port relationships that wer | ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication. |
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Arguin 2



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| Dr. Arguin has nothing to disclose. | | | |

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Novitt-Moreno 1



| Section 1. | Identifying Inform | nation | |
|--|--|---|---|
| 1. Given Name (Fi Anne | rst Name) | 2. Surname (Last Na Novitt-Moreno | ame) 3. Date 09-June-2015 |
| 4. Are you the cor | responding author? | ☐ Yes ✓ No | Corresponding Author's Name Patrick Twomey, MD |
| | | ent of Severe and Co | mplicated Malaria in the United States: Clinical Use under an |
| 6. Manuscript Ider M15-0910 | ntifying Number (if you kn | now it) | |
| | | | |
| Section 2. | The Work Under Co | onsideration for F | Publication |
| any aspect of the s statistical analysis, | ubmitted work (including | but not limited to gra | es from a third party (government, commercial, private foundation, etc.) for ants, data monitoring board, study design, manuscript preparation, |
| If yes, please fill o | | ormation below. If yo | bu have more than one entity press the "ADD" button to add a row. |
| Name of Institut | ion/Company | Grant? Persona Fees? | Non-Financial Support? Comments |
| J.S. Army Medical Re Command (USAMRM | | | Army contract |
| | | | |
| Section 3. | Relevant financial | activities outside | the submitted work. |
| of compensation clicking the "Add | the appropriate boxes i) with entities as descri | n the table to indica bed in the instruction | Ite whether you have financial relationships (regardless of amount ons. Use one line for each entity; add as many lines as you need by at were present during the 36 months prior to publication . No |
| Soction 4 | | | |
| Section 4. | Intellectual Proper | rty Patents & Co | ppyrights |
| Do you have any | patents, whether plan | ned, pending or issu | red, broadly relevant to the work? ☐ Yes ✓ No |

Novitt-Moreno 2



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Smith 1



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|--|---|--|--|--|
| 1. Given Name (Fi Bryan | rst Name) | 2. Surname (Last Name) Smith | 3. Date 10-June-2015 | |
| 4. Are you the cor | responding author? | Yes ✓ No | Corresponding Author's Name Patrick Twomey | |
| | | ent of Severe and Complica | ated Malaria in the United States: Clinical Use under an | |
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| Do you have any | | | oadly relevant to the work? ☐ Yes ✓ No | |

Smith 2



| Section 5. | | | | | |
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| ✓ Yes, the follow | wing relationships/conditions/circumstances are present (explain below): | | | | |
| No other rela | tionships/conditions/circumstances that present a potential conflict of interest | | | | |
| I am the full-time | e U. S. Army Product Manager responsible for the development of I.V. Artesunate. | | | | |
| | anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements rnals may ask authors to disclose further information about reported relationships. | | | | |
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| Dr. Smith report | s and I am the full-time U. S. Army Product Manager responsible for the development of I.V. Artesunate | | | | |

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1

McDermott



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| 4. Are you the cor | responding author? | Yes ✓ No | Corresponding Author's Name Patrick Twomey |
| Investigational N | | • | cated Malaria in the United States: Clinical Use under an |
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McDermott 2



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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.

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

Twomey 1



| Section 1. Identifying Inform | nation | |
|---|---|-------------------------------------|
| 1. Given Name (First Name) Patrick | 2. Surname (Last Name) Twomey | 3. Date 08-June-2015 |
| 4. Are you the corresponding author? | ✓ Yes No | |
| 5. Manuscript Title Intravenous Artesunate for the Treatm Investigational New Drug Protocol 6. Manuscript Identifying Number (if you k M15-0910 | ent of Severe and Complicated Malaria in the Unite | d States: Clinical Use under an |
| Section 2. The Work Under C | onsideration for Publication | |
| any aspect of the submitted work (includin statistical analysis, etc.)? Are there any relevant conflicts of inter | eive payment or services from a third party (government, g but not limited to grants, data monitoring board, study rest? | |
| Section 3. Relevant financial | activities outside the submitted work. | |
| of compensation) with entities as descr clicking the "Add +" box. You should re Are there any relevant conflicts of inter | in the table to indicate whether you have financial ribed in the instructions. Use one line for each entities port relationships that were present during the 3 rest? Yes V No | y; add as many lines as you need by |
| Section 4. Intellectual Prope | rty Patents & Copyrights | |
| Do you have any patents, whether plar | nned, pending or issued, broadly relevant to the wo | rk? Yes Vo |

Twomey 2



| 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. Twomey 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.

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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.

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.

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Royalties: Funds are coming in to you or your institution due to your patent

McCarthy 1



| Section 1. Identifying Inform | mation | |
|---|------------------------------------|---|
| 1. Given Name (First Name) William | 2. Surname (Last Name) McCarthy | 3. Date 12-June-2015 |
| 4. Are you the corresponding author? | ☐ Yes ✓ No | Corresponding Author's Name Twomey, Patrick |
| 5. Manuscript Title"Intravenous Artesunate for the Treath Investigational New Drug Protocol."6. Manuscript Identifying Number (if you k M15-0910 | • | cated Malaria in the United States: Clinical Use under an |
| Section 2. The Work Under C | | |
| 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 Yes No | | |
| Section 3. Relevant financia | l activities outside the s | 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 Vo | | |
| Section 4. Intellectual Prope | erty Patents & Copyric | uhts. |
| | | |
| Do you have any patents, whether plan | nned, pending or issued, br | oadly relevant to the work? Yes No |

McCarthy 2



| 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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| ✓ No other relationships/conditions/circumstances that present a potential conflict 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. McCarthy has nothing to disclose. | | |

Evaluation and Feedback

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