ICMJE DISCLOSURE FORM

Date: 22.07.2021

Your Name: Dimitra Kiritsi

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known):

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
| --- | --- |
| **1** | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)
No time limit for this item. | DK’s work is funded by the Berta-Ottenstein-Programme for Advanced Clinician Scientists, Faculty of Medicine, University of Freiburg, by the German Research Foundation (DFG) through SFB1160 project B03, SFB-1479 – Project ID: 441891347 and KI1795/2-1 and the Fritz Thyssen Foundation. All funding organizations provided funding covering the conduct of the study and the preparation of the manuscript, but were not Payments made to the institution. |

Time frame: Since the initial planning of the work
involved in the design of the study.

Time frame: past 36 months

|   | Grants or contracts from any entity (if not indicated in item #1 above). | Has received funding from Rheacell GmbH for the conduct of scientific studies with ABCB5+ cells in a mouse model with DEB. | Payments made to the institution. |
|---|---|---|---|
| 2 | Royalties or licenses | None |  |
| 3 | Consulting fees | None |  |
| 4 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | Has received honoraria from Rheacell GmbH for consulting on the design of the trial protocol. | Payments to DK. |
| 5 | Payment for expert testimony | None |  |
| 6 | Support for attending meetings and/or travel | None |  |
| 7 | Patents planned, issued or pending | None |  |
| 8 | Participation on a Data Safety Monitoring Board or Advisory Board | Is participating in the Data Safety Monitoring Board of the trial, as Principal Investigator of the Trial. |  |
|   | Question                                                                 | Response |
|---|--------------------------------------------------------------------------|----------|
| 10| Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | None     |
| 11| Stock or stock options                                                   | None     |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other services | None     |
| 13| Other financial or non-financial interests                               | None     |

Please place an “X” next to the following statement to indicate your agreement:

x___ I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Kathrin Dieter
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | X None |
|    | No time limit for this item. | |
|    | Time frame: Since the initial planning of the work | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | X None |
| 3 | Royalties or licenses | X None |
|   | Time frame: past 36 months | |
|   |   |   |
|---|---|---|
| 4 | Consulting fees | X None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X None |
| 6 | Payment for expert testimony | X None |
| 7 | Support for attending meetings and/or travel | X None |
| 8 | Patents planned, issued or pending | X None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | X None |
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X None |
| 11 | Stock or stock options | X None |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | X None |
| 13 | Other financial or non-financial interests | RHEACELL GmbH & Co.KG Employee |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Elke Niebergall-Roth
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|   | **Time frame: Since the initial planning of the work** |                                                                                   |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | X None                                                                            |
|   | **No time limit for this item.** |                                                                                   |
|   | **Time frame: past 36 months** |                                                                                   |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | X None                                                                            |
| 3 | Royalties or licenses | X None                                                                            |
|   | Description                                                                 |   |
|---|------------------------------------------------------------------------------|---|
| 4 | Consulting fees                                                              |   |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus,          |   |
|   | manuscript writing or educational events                                     |   |
| 6 | Payment for expert testimony                                                  |   |
| 7 | Support for attending meetings and/or travel                                  |   |
| 8 | Patents planned, issued or pending                                            |   |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board             |   |
| 10| Leadership or fiduciary role in other board, society, committee or advocacy   |   |
|   | group, paid or unpaid                                                         |   |
| 11| Stock or stock options                                                        |   |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other       |   |
|   | services                                                                      |   |
| 13| Other financial or non-financial interests                                    |   |

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ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Silvia Fluhr
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| Item | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|------|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| **Time frame: Since the initial planning of the work** | **Item #1** All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | **X None** |
| **Time frame: past 36 months** | **Item #2** Grants or contracts from any entity (if not indicated in item #1 above). | **X None** |
| | **Item #3** Royalties or licenses | **X None** |
|   | Description                                                                 |  |  |
|---|-----------------------------------------------------------------------------|---|---|
| 4 | Consulting fees                                                            | x | None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus,        | X | None |
|    | manuscript writing or educational events                                   |    |      |
| 6 | Payment for expert testimony                                               | X | None |
| 7 | Support for attending meetings and/or travel                                | X | None |
| 8 | Patents planned, issued or pending                                         | X | None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board           | X | None |
| 10| Leadership or fiduciary role in other board, society, committee or         | X | None |
|    | advocacy group, paid or unpaid                                              |    |      |
| 11| Stock or stock options                                                      | X | None |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other     | X | None |
|    | services                                                                     |    |      |
| 13| Other financial or non-financial interests                                  | RHEACELL GmbH & Co.KG | Employee |

Please place an “X” next to the following statement to indicate your agreement:

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Date: 27.07.2021
Your Name: Cristina Daniele
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|   | Time frame: Since the initial planning of the work                                 |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | X None                                                                                                                                 |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).          | X None                                                                                                                                 |
| 3 | Royalties or licenses                                                              | X None                                                                                                                                 |

|   | Time frame: past 36 months                                                        |
|---|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).          | X None                                                                                                                                 |
| 3 | Royalties or licenses                                                              | X None                                                                                                                                 |
|   |                                                                 |   |
|---|------------------------------------------------------------------|---|
| 4 | Consulting fees                                                 | X None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X None |
| 6 | Payment for expert testimony                                     | X None |
| 7 | Support for attending meetings and/or travel                      | X None |
| 8 | Patents planned, issued or pending                                | X None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | X None |
| 10| Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X None |
| 11| Stock or stock options                                           | X None |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other services | X None |
| 13| Other financial or non-financial interests                        | RHEACELL GmbH & Co.KG Employee |

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Date: 27.07.2021
Your Name: Jasmina Esterlechner
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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|---|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | X  None                                                                          |
|   | No time limit for this item.                                                                 |                                                                                 |
|   | Time frame: Since the initial planning of the work                                            |                                                                                 |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).                     | X  None                                                                          |
| 3 | Royalties or licenses                                                                         | X  None                                                                          |
|   | Time frame: past 36 months                                                                    |                                                                                 |
|   |                                                                 |   |   |
|---|------------------------------------------------------------------|---|---|
| 4 | Consulting fees                                                 | X | None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X | None |
| 6 | Payment for expert testimony                                     | X | None |
| 7 | Support for attending meetings and/or travel                      | X | None |
| 8 | Patents planned, issued or pending                                | X | None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | X | None |
| 10| Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X | None |
| 11| Stock or stock options                                           | X | None |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other services | X | None |
| 13| Other financial or non-financial interests                        | TICEBA GmbH | Employee |

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Date: 27.07.2021
Your Name: Samar Sadeghi
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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|------|--------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| 1    | **All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)**<br>No time limit for this item. | X None | |
| 2    | Grants or contracts from any entity (if not indicated in item #1 above). | X None | |
| 3    | Royalties or licenses | X None | |
|   | Statement                                                                                           |   |
|---|----------------------------------------------------------------------------------------------------|---|
| 4 | Consulting fees                                                                                    | x None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | x None |
| 6 | Payment for expert testimony                                                                         | x None |
| 7 | Support for attending meetings and/or travel                                                          | x None |
| 8 | Patents planned, issued or pending                                                                    | x None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board                                    | x None |
|10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid    | x None |
|11 | Stock or stock options                                                                              | x None |
|12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services                     | x None |
|13 | Other financial or non-financial interests                                                           | TICEBA GmbH Employee |

Please place an “X” next to the following statement to indicate your agreement:

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Date: 27.07.2021
Your Name: Seda Ballikaya
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|---|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | X None |
|   | No time limit for this item.                                                                    |                                                                                   |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).                       | X None |
| 3 | Royalties or licenses                                                                           | X None |
| No. | Description                                                                 | X | Relationship       |
|-----|------------------------------------------------------------------------------|---|--------------------|
| 4   | Consulting fees                                                              |   | None               |
| 5   | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X | None               |
| 6   | Payment for expert testimony                                                 | X | None               |
| 7   | Support for attending meetings and/or travel                                  | X | None               |
| 8   | Patents planned, issued or pending                                           | X | None               |
| 9   | Participation on a Data Safety Monitoring Board or Advisory Board             | X | None               |
| 10  | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X | None               |
| 11  | Stock or stock options                                                        | X | None               |
| 12  | Receipt of equipment, materials, drugs, medical writing, gifts or other services | X | None               |
| 13  | Other financial or non-financial interests                                    | X | None               |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.
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Date: 27.07.2021  
Your Name: Leoni Erdinger
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|---|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)<br>No time limit for this item. | X None | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | X None | |
| 3 | Royalties or licenses | X None | |

**Time frame: Since the initial planning of the work**

**Time frame: past 36 months**
| No. | Category                                                                 | Answer |
|-----|--------------------------------------------------------------------------|--------|
| 4   | Consulting fees                                                          | None   |
| 5   | Payment or honoraria for lectures, presentations, speakers bureaus,     | None   |
|     | manuscript writing or educational events                                 |        |
| 6   | Payment for expert testimony                                            | None   |
| 7   | Support for attending meetings and/or travel                             | None   |
| 8   | Patents planned, issued or pending                                      | None   |
| 9   | Participation on a Data Safety Monitoring Board or Advisory Board        | None   |
| 10  | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | None   |
| 11  | Stock or stock options                                                  | None   |
| 12  | Receipt of equipment, materials, drugs, medical writing, gifts or other services | None   |
| 13  | Other financial or non-financial interests                               | RHEACELL GmbH & Co.KG Employee |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 29.07.2021
Your Name: Franziska Schauer
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known):

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|---|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Time frame: Since the initial planning of the work |   |                                                                                       |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | ___ None
FS is supported by the Berta-Ottenstein Advanced Clinician Scientist Programme of the University of Freiburg |
|   | No time limit for this item. |                                                                                       |
| Time frame: past 36 months |   |                                                                                       |
| 2 |   | ___ x___ None                                                                          |
|   | Grants or contracts from any entity (if not indicated in item #1 above). |
|---|-------------------------------------------------------------------------|
| 3 | Royalties or licenses | \_x\_ None |
| 4 | Consulting fees | \_\_ None  
FS received fees from Amryt Pharma. |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | \_x\_ None |
| 6 | Payment for expert testimony | \_x\_ None |
| 7 | Support for attending meetings and/or travel | \_x\_ None |
| 8 | Patents planned, issued or pending | \_x\_ None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | \_x\_ None |
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | \_\_ None |
| 11 | Stock or stock options | \_x\_ None |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | \_x\_ None |
| 13 | Other financial or non-financial interests | \_x\_ None |
Please place an “X” next to the following statement to indicate your agreement:

___x___ I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Stella Gewert
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): _________________________________

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | x None |
### Time frame: past 36 months

|   | Description                                                                 | Yes/No | Details |
|---|----------------------------------------------------------------------------|--------|---------|
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).     | x      | None    |
| 3 | Royalties or licenses                                                       | x      | None    |
| 4 | Consulting fees                                                            | x      | None    |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | x      | None    |
| 6 | Payment for expert testimony                                                | x      | None    |
| 7 | Support for attending meetings and/or travel                                | x      | None    |
| 8 | Patents planned, issued or pending                                          | x      | None    |
| 9 | Participation on a Data Safety Monitoring Board or Advisory                 | x      | None    |
|   |   |   |
|---|---|---|
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | x None |
| 11 | Stock or stock options | x None |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | x None |
| 13 | Other financial or non-financial interests | x None |

Please place an “X” next to the following statement to indicate your agreement:

_x_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

27.07.2021

[Signature]
ICMJE DISCLOSURE FORM

Date: _3-AUG-2021__________________________________________________________
Your Name: ___Martin Laimer___________________________________________________
Manuscript Title: __Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa_________________________________________________
Manuscript number (if known): ____________________________________________________________________

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | ____ None | Research/Clinical Trial Support: Rheacell GmbH Co KG |

|   |   |   |
|---|---|---|
| 2 |   |   |
|   |   |   |

|   |   |   |
|---|---|---|
| 3 | Royalties or licenses | X_ None |

Time frame: past 36 months
|   |   |   |
|---|---|---|
| 4 | Consulting fees | _X_  None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | _X_  None |
| 6 | Payment for expert testimony | _X_  None |
| 7 | Support for attending meetings and/or travel | _X_  None |
| 8 | Patents planned, issued or pending | _X_  None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | _X_  None |
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | _____  None |
| 11 | Stock or stock options | _X_  None |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | _X_  None |
| 13 | Other financial or non-financial interests | _X_  None |

Please place an “X” next to the following statement to indicate your agreement:

_ X_  I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 03/8/2021

Your Name: Johann W. Bauer

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known):

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
| --- | --- |
| **Time frame: Since the initial planning of the work** | | |
| **1** | All support for the present manuscript (e.g., funding, | None |
| No time limit for this item. | provision of study materials, medical writing, article processing charges, etc.) | | |
| | | | |
| **Time frame: past 36 months** | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | None |
|   | Royalties or licenses |   |
|---|----------------------|---|
|   | ___ None             |   |

|   | Consulting fees     |   |
|---|---------------------|---|
|   | ___ None            |   |

|   | Payment for expert testimony |   |
|---|--------------------------------|---|
|   | ___ None | Abbvie, Allmirall |

|   | Support for attending meetings and/or travel |   |
|---|---------------------------------------------|---|
|   | ___ None                                   |   |

|   | Patents planned, issued or pending         |   |
|---|-------------------------------------------|---|
|   | ___ None                                  |   |

|   | Participation on a Data Safety Monitoring Board or Advisory Board |   |
|---|------------------------------------------------------------------|---|
|   | ___ None                                                           |   |

|   | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid |   |
|---|-----------------------------------------------------------------------------------------------|---|
| 10 | ___ President Austrian Society of Dermatology and Venerology, Board Member EADV                |   |

|   | Stock or stock options |   |
|---|------------------------|---|
|   | ___ None               |   |

|   | Receipt of equipment, materials, drugs, medical writing, gifts or other services |   |
|---|-----------------------------------------------------------------------------------|---|
|   | ___ None                                                                          |   |

|   | Other financial or non-financial interests |   |
|---|---------------------------------------------|---|
|   | ___ None                                  |   |

Please place an "X" next to the following statement to indicate your agreement:
_x_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

4.8.21

UNIKLINIKUM SALZBURG
LANDESKRANKENHAUS
Universitätsklinik für Dermatologie
und Allergologie der PMU
Verband:
Prim. Univ.-Prof. Dr. Johann Bauer, MBA
A-5020 Salzburg | Mühner Hauptstraße 48
ICMJE DISCLOSURE FORM

Date: August 2, 2021
Your Name: Hovnanian Alain
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): ____________________________________________________________________________________________

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | __X__ None |
|   | No time limit for this item.                                                                    |                                                                                   |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).                       | __X__ None |
| 3 | Royalties or licenses                                                                         | __X__ None |

Time frame: Since the initial planning of the work

Time frame: past 36 months
|   |   |   |
|---|---|---|
| 4 | Consulting fees | X  None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X  None |
| 6 | Payment for expert testimony | X  None |
| 7 | Support for attending meetings and/or travel | X  None |
| 8 | Patents planned, issued or pending | X  None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | X  None |
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X  None |
| 11 | Stock or stock options | X  None |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | X  None |
| 13 | Other financial or non-financial interests | X  None |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 23/07/21

Your Name: Giovanna Zambruno

Manuscript Title: Phase I/IIa clinical trial of ABCBS-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): 

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | _X_ None |
|   | Time frame: Since the initial planning of the work                                               |                                                                                   |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).                        | DEBRA INTERNATIONAL Research grant to my hospital                                 |
| 3 | Royalties or licenses                                                                           | _X_ None |
|   | Time frame: past 36 months                                                                     |                                                                                   |
|   |                                                  | X | None |
|---|--------------------------------------------------|----|------|
|4 | Consulting fees                                  |    |      |
|5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X | None |
|6 | Payment for expert testimony                     | x | None |
|7 | Support for attending meetings and/or travel      |    |      |
|8 | Patents planned, issued or pending               |    |      |
|9 | Participation on a Data Safety Monitoring Board or Advisory Board |    |      |
|10| Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X | None |
|11| Stock or stock options                           | X | None |
|12| Receipt of equipment, materials, drugs, medical writing, gifts or other services | X | None |
|13| Other financial or non-financial interests        | X | None |

Please place an "X" next to the following statement to indicate your agreement:

_X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

[Signature]
ICMJE DISCLOSURE FORM

Date: 23/07/21
Your Name: May El Hachem
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known):

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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| No. | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|-----|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|     | Time frame: Since the initial planning of the work                                             |                                                                                  |
| 1   | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | Site non activated                                                               |
|     | RHEA CELL                                                                                   |                                                                                  |
|     |                                                                                             |                                                                                  |
| 2   | Grants or contracts from any entity (if not indicated in item #1 above).                     | AMRYT Contract with my institution for a clinical trial                           |
|     |                                                                                             |                                                                                  |
| 3   | Royalties or licenses                                                                       | X None                                                                           |
|     |                                                                                             |                                                                                  |
|   | Description                                                                 | X | None |
|---|------------------------------------------------------------------------------|----|------|
| 4 | Consulting fees                                                             | X | None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X | None |
| 6 | Payment for expert testimony                                                 | X | None |
| 7 | Support for attending meetings and/or travel                                 | X | None |
| 8 | Patents planned, issued or pending                                           | X | None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board             | X | None |
| 10| Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X | None |
| 11| Stock or stock options                                                       | X | None |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other services | X | None |
| 13| Other financial or non-financial interests                                   | X | None |

Please place an “X” next to the following statement to indicate your agreement:

_X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

[Signature]

Dott.ssa EL HACHEM MAY
RESPONSABILE DELLA STRUTTURA
COMPRESSA DI DERMATOLOGIA
ICMJE DISCLOSURE FORM

Date: Wednesday 4th August 2021

Your Name: Bourrat Emmanuelle
Manuscript Title: Phase I/IIa clinical trial of ABCBS-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): unknown

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

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|---|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Time frame: Since the initial planning of the work |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | None |
|   | No time limit for this item. | |
| Time frame: past 36 months |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | None |
| 3 | Royalties or licenses | None |
|    | Description                                                                 | None |
|----|----------------------------------------------------------------------------|------|
| 4  | Consulting fees                                                            |      |
| 5  | Payment or honoraria for lectures, presentations, speakers bureaus,         |      |
|    | manuscript writing or educational events                                   |      |
| 6  | Payment for expert testimony                                                |      |
| 7  | Support for attending meetings and/or travel                                |      |
| 8  | Patents planned, issued or pending                                          |      |
| 9  | Participation on a Data Safety Monitoring Board or Advisory Board           |      |
| 10 | Leadership or fiduciary role in other board, society, committee or          |      |
|    | advocacy group, paid or unpaid                                              |      |
| 11 | Stock or stock options                                                      |      |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other     |      |
|    | services                                                                    |      |
| 13 | Other financial or non-financial interests                                  |      |

Please place an “X” next to the following statement to indicate your agreement:

_X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: Wednesday 4th August 2021
Your Name: Maria Papanikolaou
Manuscript Title: Phase I/IIa clinical trial of ABCBS-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): not known

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|---|---------------------------------|----------------------------------------------------------------------------------|
| 1 | **Time frame: Since the initial planning of the work** | |
|   | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | None |
|   | No time limit for this item. | |
| 2 | **Time frame: past 36 months** | |
|   | Grants or contracts from any entity (if not indicated in item #1 above). | None |
| 3 | Royalties or licenses | None |
|   |                                                                 |   |
|---|----------------------------------------------------------------|---|
| 4 | Consulting fees                                                 |   |
|   | ___ None                                                         |   |
| 5 | Payment or honoraria for lectures, presentations, speakers      |   |
|   | bureaus, manuscript writing or educational events               |   |
|   | ___ None                                                         |   |
| 6 | Payment for expert testimony                                    |   |
|   | ___ None                                                         |   |
| 7 | Support for attending meetings and/or travel                    |   |
|   | ___ None                                                         |   |
| 8 | Patents planned, issued or pending                              |   |
|   | ___ None                                                         |   |
| 9 | Participation on a Data Safety Monitoring Board or Advisory     |   |
|   | Board                                                           |   |
|   | ___ None                                                         |   |
|10 | Leadership or fiduciary role in other board, society, committee |   |
|   | or advocacy group, paid or unpaid                                |   |
|   | ___ None                                                         |   |
|11 | Stock or stock options                                          |   |
|   | ___ None                                                         |   |
|12 | Receipt of equipment, materials, drugs, medical writing, gifts  |   |
|   | or other services                                               |   |
|   | ___ None                                                         |   |
|13 | Other financial or non-financial interests                       |   |
|   | ___ None                                                         |   |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 3/8/21
Your Name: Gabriela Petrov
Manuscript Title: Phase I/IIA clinical trial of ASCBS+ dexam MSCs for RDEB
Manuscript number (if known): 

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| Item | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1    | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | None 
|      | Time frame: Since the initial planning of the work | 
|      | 时间：自开始策划以来 | 
|      | No time limit for this item. | 
|      | 需要注意的是，没有时间限制 | 
| 2    | Grants or contracts from any entity (if not indicated in item #1 above). | None |
| 3    | Royalties or licenses | None |

Time frame: past 36 months

| Item | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1    | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | None 
|      | Time frame: Since the initial planning of the work | 
|      | 时间：自开始策划以来 | 
|      | No time limit for this item. | 
| 2    | Grants or contracts from any entity (if not indicated in item #1 above). | None |
| 3    | Royalties or licenses | None |
|   | Description                                                                 | Answer |
|---|-----------------------------------------------------------------------------|--------|
| 4 | Consulting fees                                                             | None   |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | None   |
| 6 | Payment for expert testimony                                                | None   |
| 7 | Support for attending meetings and/or travel                                | None   |
| 8 | Patents planned, issued or pending                                          | None   |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board           | None   |
| 10| Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | None   |
| 11| Stock or stock options                                                       | None   |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other services | None   |
| 13| Other financial or non-financial interests                                  | None   |

Please place an “X” next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 23-JUL-2021

Your Name: Dr. Sophie Kitzmüller

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): ____________________________

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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|---|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|   | Time frame: Since the initial planning of the work                                           |                                                                                  |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | None                                                                           |
|   |                                                                                             |                                                                                  |
|   |                                                                                             |                                                                                  |
|   |                                                                                             |                                                                                  |
|   |                                                                                             |                                                                                  |
|   |                                                                                             |                                                                                  |
|   |                                                                                             |                                                                                  |

|   | Time frame: past 36 months                                                                   |                                                                                  |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).                    | DEBRA Austria                                                                   |
|   |                                                                                             | Salary paid by DEBRA Austria                                                     |
|   |                                                                                             |                                                                                  |
|   |                                                                                             |                                                                                  |
| 3 | Royalties or licenses                                                                       | None                                                                           |
|   |                                                                                             |                                                                                  |
|   | Description                                                                 | None |
|---|------------------------------------------------------------------------------|------|
| 4 | Consulting fees                                                             |      |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus,         |      |
|   | manuscript writing or educational events                                    |      |
| 6 | Payment for expert testimony                                                |      |
| 7 | Support for attending meetings and/or travel                                 |      |
| 8 | Patents planned, issued or pending                                           |      |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board            |      |
| 10| Leadership or fiduciary role in other board, society, committee or advocacy |      |
|   | group, paid or unpaid                                                        |      |
| 11| Stock or stock options                                                       |      |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other     |      |
|   | services                                                                     |      |
| 13| Other financial or non-financial interests                                   |      |

Please place an “X” next to the following statement to indicate your agreement:

X

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

[Signature]
ICMJE DISCLOSURE FORM

Date: 22 July 2021

Your Name: Christen L. Ebens, MD MPH

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): 151922-JCI-CMED

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| Item | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1    | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | _X_ None |
| 2    | Grants or contracts from any entity (if not indicated in item #1 above). | ___ None | Contract with sponsor (Rheacell GmbH & Co) for conduct of clinical trial of allo-APZ2-EB MSCs in RDEB, outcomes described in this manuscript |
| 3    | Royalties or licenses | _X_ None |

Time frame: Since the initial planning of the work

Time frame: past 36 months
|   | Description                                                                 | X | None |
|---|-----------------------------------------------------------------------------|----|------|
| 4 | Consulting fees                                                            | X | None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X | None |
| 6 | Payment for expert testimony                                                | X | None |
| 7 | Support for attending meetings and/or travel                                | X | None |
| 8 | Patents planned, issued or pending                                          | X | None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board            | X | None |
|10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X | None |
|11 | Stock or stock options                                                       | X | None |
|12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | X | None |
|13 | Other financial or non-financial interests                                   | X | None |

Please place an “X” next to the following statement to indicate your agreement:

_X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 07/23/2021
Your Name: Markus H. Frank
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-TR-2

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| **1** | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | None |
|   | **Time frame: Since the initial planning of the work** | Ticeba GmbH Paid Scientific Advisor |
|   | | Rheacell GmbH & Co KG Scientific Advisor, Past Corporate Sponsored Research Support |
|   | **No time limit for this item.** | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | None |
|   | **Time frame: past 36 months** | NIH/NEI RO1EY025794 and R24EY028767 |
| **3** | Royalties or licenses | None |
|   | Patent Royalties | MHF is inventor or co-inventor of US and international patents assigned to Brigham and Women’s Hospital and/or Boston Children’s Hospital, Boston, MA, USA, |
|   | Description                                                                 | Ticeba GmbH | Rheacell GmbH & Co KG |
|---|-----------------------------------------------------------------------------|-------------|-----------------------|
| 4 | Consulting fees                                                            | None        | Scientific Advisor    |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | None        |                       |
| 6 | Payment for expert testimony                                                | None        |                       |
| 7 | Support for attending meetings and/or travel                                | None        |                       |
| 8 | Patents planned, issued or pending                                          | None        | MHF is inventor or co-inventor of US and international patents assigned to Brigham and Women’s Hospital and/or Boston Children’s Hospital, Boston, MA, USA, licensed to TICEBA GmbH, Heidelberg, Germany, and Rheacell GmbH & Co KG, Heidelberg, Germany. |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board           | None        | Scientific Advisory Board |
|   |                                                                             | Rheacell GmbH & Co KG | Scientific Advisory Board |
| 10| Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | None        |                       |
| 11| Stock or stock options                                                      | None        |                       |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other services | None        |                       |
| 13| Other financial or non-financial interests                                  | None        |                       |
Please place an “X” next to the following statement to indicate your agreement:

_ X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Markus Frank, M.D.
ICMJE DISCLOSURE FORM

Date:__________07/26/2021_____________________________________________________
Your Name:___Natasha Frank____________________________________________________
Manuscript Title:____Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-TR-2

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | **x** None                                                                         |
|   | **No time limit for this item.**                                                           |                                                                                  |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).                   | **x** None                                                                         |
|   | NIH/NEI                                                                                   | **RO1EY025794 and R24EY028767**                                                  |
| 3 | Royalties or licenses                                                                      | **x** None                                                                         |
|   | Patent Royalties                                                                          | **NYF is inventor or co-inventor of US and international patents assigned to Brigham and Women’s Hospital and/or Boston Children’s Hospital, Boston, MA, USA,** |
|   | Activity                                                                 |  |   |
|---|------------------------------------------------------------------------|---|---|
| 4 | Consulting fees                                                        | _x_ None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus,   | _x_ None |
|   | manuscript writing or educational events                               |   |
| 6 | Payment for expert testimony                                           | _x_ None |
| 7 | Support for attending meetings and/or travel                           | _x_ None |
| 8 | Patents planned, issued or pending                                      | ____ None |
|   | Patents                                                                 |   |
|   | NYF is inventor or co-inventor of US and international patents assigned|   |
|   | to Brigham and Women’s Hospital and/or Boston Children’s Hospital,    |   |
|   | Boston, MA, USA, licensed to TICEBA GmbH, Heidelberg, Germany, and    |   |
|   | RHEACELL GmbH & Co. KG, Heidelberg, Germany.                           |   |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board      | _x_ None |
| 10| Leadership or fiduciary role in other board, society, committee or    | _x_ None |
|   | advocacy group, paid or unpaid                                         |   |
| 11| Stock or stock options                                                 | _x_ None |
| 12| Receipt of equipment, materials, drugs, medical writing, gifts or other| _x_ None |
|   | services                                                                |   |
| 13| Other financial or non-financial interests                              | _x_ None |
Please place an “X” next to the following statement to indicate your agreement:

_ X _ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

[Signature]

Natasha Frank, M.D.
ICMJE DISCLOSURE FORM

Date: 27.07.2021  
Your Name: Christoph Ganss  
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa  
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Time frame: Since the initial planning of the work |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)  
No time limit for this item. | X None |
| Time frame: past 36 months |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | X None |
| 3 | Royalties or licenses | X None |
|   |   |   |
|---|---|---|
| 4 | Consulting fees | X None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X None |
| 6 | Payment for expert testimony | X None |
| 7 | Support for attending meetings and/or travel | X None |
| 8 | Patents planned, issued or pending | X None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | X None |
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X None |
| 11 | Stock or stock options | X None |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | X None |
| 13 | Other financial or non-financial interests | TICEBA GmbH CEO RHEACELL GmbH & Co. KG CEO |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 22.5.2021
Your Name: ANNA MARINE
Manuscript Title: Pre-K IT is the Future! Mod Date: 10/07/20
Manuscript number (if known): 445C.

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | None |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | None |
| 3 | Royalties or licenses | None |

Time frame: Since the initial planning of the work

Time frame: past 36 months
|   | Description                                                                 | Code | Note |
|---|-----------------------------------------------------------------------------|------|------|
| 4 | Consulting fees                                                            | X    | None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X    | None |
| 6 | Payment for expert testimony                                               | X    | None |
| 7 | Support for attending meetings and/or travel                                | X    | None |
| 8 | Patents planned, issued or pending                                         | X    | None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board           | X    | None |
|10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X    | None |
|11 | Stock or stock options                                                      | X    | None |
|12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | X    | None |
|13 | Other financial or non-financial interests                                  | X    | None |

Please place an "X" next to the following statement to indicate your agreement:

___ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

[Signature]
ICMJE DISCLOSURE FORM

Date: 05.08.2021
Your Name: Prof. Dr. John McGrath
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | None x |
|   | **No time limit for this item.**                                                                 |                                                                                   |
|   | **Time frame: Since the initial planning of the work**                                         |                                                                                   |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above).                      | None x |
| 3 | Royalties or licenses                                                                           | None x |

|   | **Time frame: past 36 months**                                                                 |                                                                                   |


|   |   |   |
|---|---|---|
| 4 | Consulting fees | None |
|   |               | x |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | None |
|   |               | x |
| 6 | Payment for expert testimony | None |
|   |               | x |
| 7 | Support for attending meetings and/or travel | None |
|   |               | x |
| 8 | Patents planned, issued or pending | None |
|   |               | x |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | None |
|   |               | x |
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | None |
|   |               | x |
| 11 | Stock or stock options | None |
|   |               | x |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | None |
|   |               | x |
| 13 | Other financial or non-financial interests | None |
|   |               | x |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.

John McGrath  5 August 2021
ICMJE DISCLOSURE FORM

Date: 22 July 2021
Your Name: Jakub Tolar
Manuscript Title: Phenylisocyanate: Unpublished results for RDEE.
Manuscript number (if known):

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| Time frame: Since the initial planning of the work | Time frame: past 36 months |
|----------------------------------------------------|---------------------------|
| **1** All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | **2** Grants or contracts from any entity (if not indicated in item #1 above). |
| Name all entities with whom you have this relationship or indicate none (add rows as needed) | Checkmark None |
| Specifications/Comments (e.g., if payments were made to you or to your institution) | Checkmark None |

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|   |                                      |   |
|---|--------------------------------------|---|
| 4 | Consulting fees                      | None |
|   |                                      |    |
| 5 | Payment or honoraria for             | None |
|   | lectures, presentations,             |    |
|   | speakers bureaus,                    |    |
|   | manuscript writing or                |    |
|   | educational events                   |    |
| 6 | Payment for expert                   | None |
|   | testimony                             |    |
| 7 | Support for attending                | None |
|   | meetings and/or travel               |    |
| 8 | Patents planned, issued or           | None |
|   | pending                               |    |
| 9 | Participation on a Data              | None |
|   | Safety Monitoring Board or           |    |
|   | Advisory Board                       |    |
| 10| Leadership or fiduciary role         | None |
|   | in other board, society,             |    |
|   | committee or advocacy                |    |
|   | group, paid or unpaid                |    |
| 11| Stock or stock options               | None |
| 12| Receipt of equipment,                | None |
|   | materials, drugs, medical            |    |
|   | writing, gifts or other services     |    |
| 13| Other financial or non-financial      | None |
|   | interests                             |    |

Please place an “X” next to the following statement to indicate your agreement:

☐ I certify that I have answered every question and have not altered the wording of any of the questions on this form.
ICMJE DISCLOSURE FORM

Date: 22.07.2021
Your Name: Mark Andreas Kluth
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

The author’s relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

|   | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
|---|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| **Time frame: Since the initial planning of the work** | | |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) | X None |
|  | **No time limit for this item.** | |
| **Time frame: past 36 months** | | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | X None |
| 3 | Royalties or licenses | X None |
|   |   |   |
|---|---|---|
| 4 | Consulting fees | x None |
| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | X None |
| 6 | Payment for expert testimony | X None |
| 7 | Support for attending meetings and/or travel | X None |
| 8 | Patents planned, issued or pending | X None |
| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | X None |
| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | X None |
| 11 | Stock or stock options | X None |
| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | X None |
| 13 | Other financial or non-financial interests | TICEBA GmbH Employee, CSO   RHEACELL GmbH & Co.KG CSO |

Please place an “X” next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.
## TREND Statement Checklist

| Paper Section/Topic | Item No | Descriptor | Reported? | Pg # |
|---------------------|---------|------------|-----------|------|
| **Title and Abstract** | 1 | | | |
| | | • Information on how unit were allocated to interventions | ✓ | 4 |
| | | • Structured abstract recommended | ✓ | 4 |
| | | • Information on target population or study sample | ✓ | 4 |
| **Introduction** | 2 | | | |
| Background | | • Scientific background and explanation of rationale | ✓ | 6-8 |
| | | • Theories used in designing behavioral interventions | ✓ | 6-8 |
| **Methods** | 3 | | | |
| Participants | | • Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | ✓ | 22 |
| | | • Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | n.a. | n.a. |
| | | • Recruitment setting | ✓ | 22 |
| | | • Settings and locations where the data were collected | ✓ | 22 |
| Interventions | 4 | | | |
| | | • Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: | ✓ | 22-23 |
| | | | • Content: what was given? | ✓ | 22-23 |
| | | | • Delivery method: how was the content given? | n.a. | n.a. |
| | | | • Unit of delivery: how were the subjects grouped during delivery? | n.a. | n.a. |
| | | | • Deliverer: who delivered the intervention? | ✓ | 22 |
| | | | • Setting: where was the intervention delivered? | ✓ | 22 |
| | | | • Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last? | ✓ | 23 |
| | | | • Time span: how long was it intended to take to deliver the intervention to each unit? | ✓ | 23 |
| | | | • Activities to increase compliance or adherence (e.g., incentives) | n.a. | n.a. |
| Objectives | 5 | • Specific objectives and hypotheses | ✓ | 8 |
| Outcomes | 6 | • Clearly defined primary and secondary outcome measures | ✓ | 23-24 |
| | | • Methods used to collect data and any methods used to enhance the quality of measurements | n.a. | n.a. |
| | | • Information on validated instruments such as psychometric and biometric properties | ✓ | 23 |
| Sample Size | 7 | • How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules | n.a. | n.a. |
| Assignment Method | 8 | • Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) | ✓ | 22 |
| | | • Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) | n.a. | n.a. |
| | | • Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) | n.a. | 4 |
## TREND Statement Checklist

| Topic | Score | Item Description | 9 | 22 | 24 | 23 | 24 |
|-------|-------|------------------|---|----|----|----|----|
| 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. | | ✓ | | | |
| Unit of Analysis | 10 | 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) | | n.a. | n.a. | | |
| Statistical Methods | 11 | 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 analyses and adjusted analysis | | ✓ | | | |
| | | Methods for imputing missing data, if used | | ✓ | | | |
| | | Statistical software or programs used | | ✓ | | | |
| Results | 12 | Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) | | ✓ | Fig. 1B | | |
| | | Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study | | ✓ | Fig. 1B | | |
| | | Assignment: the numbers of participants assigned to a study condition | | ✓ | Fig. 1B | | |
| | | Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention | | ✓ | Fig. 1B | | |
| | | 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 | | ✓ | Fig. 1B | | |
| | | Analysis: the number of participants included in or excluded from the main analysis, by study condition | | ✓ | Fig. 1B | | |
| | | Description of protocol deviations from study as planned, along with reasons | | ✓ | | 9 | |
| Recruitment | 13 | Dates defining the periods of recruitment and follow-up | | ✓ | | | 9 |
| Baseline Data | 14 | Baseline demographic and clinical characteristics of participants in each study condition | | ✓ | | Table 1 | |
| | | Baseline characteristics for each study condition relevant to specific disease prevention research | | n.a. | n.a. | | |
| | | Baseline comparisons of those lost to follow-up and those retained, overall and by study condition | | n.a. | n.a. | | |
| | | Comparison between study population at baseline and target population of interest | | n.a. | n.a. | | |
| Baseline equivalence | 15 | Data on study group equivalence at baseline and statistical methods used to control for baseline differences | | n.a. | n.a. | | |
**TREND Statement Checklist**

| Component | Numbers Analyzed | Details | Figures and Tables |
|-----------|------------------|--------|--------------------|
| 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 | ✓ 9-13 |
| | | - Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses | ✓ 24 |
| 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 | ✓ 9-13 |
| | | - Inclusion of null and negative findings | ✓ 9-13 |
| | | - Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | n.a. |
| Ancillary analyses | 18 | - Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | n.a. |
| 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) | ✓ 12-13, Table 2 |

**DISCUSSION**

| Component | Numbers Analyzed | Details | Figures and Tables |
|-----------|------------------|--------|--------------------|
| 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 | ✓ 14-21 |
| | | - Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations | ✓ 14-21 |
| | | - Discussion of the success of and barriers to implementing the intervention, fidelity of implementation | ✓ 14-21 |
| | | - Discussion of research, programmatic, or policy implications | ✓ 20-21 |
| 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 | ✓ 20-21 |
| Overall Evidence | 22 | - General interpretation of the results in the context of current evidence and current theory | ✓ 14-21 |

*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/](http://www.cdc.gov/trendstatement/)*