# ICMJE DISCLOSURE FORM

**Date:** 7/2/2025

**Your Name:** Stacpoole, Peter W

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☐ **None** | |
| | | FDA R01 Grant R01FD005407 | Payments to University of Florida |
| | | NIH STTR Grant R42HD089804 | Payments to University of Florida |
| | | University of Florida | Dept of Medicine funding in support of study |
| | | **Time frame: past 36 months** | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | Saol Therapeutics | Direct support of study from 7/1/24 to present |
| | | | |
| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☐ **None** | |
| | | FDA R01 Grant R01FD005407 | Payments to University of Florida |
| | | Saol Therapeutics | Direct Reimbursement of Travel Expenses |
| | | | |
| **8** | Patents planned, issued or pending | ☐ **None** | |
| | | USPTO Patent # 9765393 [Serial # 13/703,990] | WIPO App. Serial # PCT/US2025/030848 |
| | | USPTO App. Serial # 19/012,392 | |
| | | WIPO App. Serial # PCT/US2025/010588 | |
| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
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| **11** | Stock or stock options | ☒ **None** | |
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| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☐ **None** | |
| | | Saol Therapeutics | Supply of study drug |
| | | | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 6/24/2025

**Your Name:** Jose Abdenur

**Manuscript Title:** **Phase Three Trial of Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children**

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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.** | ☐ **None** | |
| | | Research support from University of Florida and Saol Pharmaceuticals to conduct this study | |
| | | | |
| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
| | | None related to this manuscript or topic | |
| | | | |
| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
|---|---|---|---|
| **4** | Consulting fees | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☐ **None** | |
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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) |
|---|---|---|---|
| **11** | Stock or stock options | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☐ **None** | |
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| **13** | Other financial or non-financial interests | ☐ **None** | |
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☒ 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:** 6/24/2025

**Your Name:** Jirair K. Bedoyan, MD, PhD

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.

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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 | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | NIH RDCRN 2U54NS078059-09 NAMDC Project | Payment to institution |
| | | NIH NAMDC/UMDF Pilot Grant Award | Payment to institution |
| | | Ultragenyx Pharmaceutical Inc., UX007-IST236 | Payment to institution |
| | | ACMG Foundation Next Generation Fellowship Training Award | Payment to institution |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
|---|---|---|---|
| **4** | Consulting fees | ☐ **None** | |
| | | Precision Biosciences | Consultation fee to me |
| | | Orphalan | Consultation fee to me |
| | | Jnana Therapeutics | Consultation fee to me |
| | | Guidepoint | Consultation fee to me |
| | | Qual-World | Consultation fee to me |
| | | Korro-Bio Therapeutics | Consultation fee to me |
| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☐ **None** | |
| | | 2025 United Mitochondrial Disease Foundation (UMDF) annual meeting as speaker at meeting | Registration, airline travel and hotel accommodations paid by UMDF to me |
| | | 2025 Cyclo-Therapeutics Advisory Board meeting | Virtual attendance payment made to me |
| | | | |
| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☐ **None** | |
| | | United Mitochondrial Disease Foundation (UMDF) Scientific and Medical Advisory Board (SMAB) Member (3-year term) | No payments made to me or my institution |
| | | | |
| | | | |
| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☐ **None** | |
| | | NIH Therapeutic Approaches to Genetic Diseases (TAG) study section reviewer | Paid for reviewing services to me |
| | | FDA Metabolic Panel Rare Disease expert reviewer | Paid for reviewing services to me |

| | | 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) |
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| **11** | Stock or stock options | ☒ **None** | |
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| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 7/7/2025

**Your Name:** Lorenzo D Botto

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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** | |
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| | | | Click the tab key to add additional rows. |
| Time frame: past 36 months | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | Centers for Disease Control and Prevention | Grants for public health evaluation of individuals with selected congenital anomalies |
| | | | |
| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
|---|---|---|---|
| **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** | |

| | | 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) |
|---|---|---|---|
| **11** | Stock or stock options | ☒ **None** | |
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| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 6/24/2025

**Your Name:** Gregory M. Enns

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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** | |
| | | Saol Therapeutics | Institution |
| | | University of Florida | Institution |
| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | PTC Therapeutics (EPI-743) | Institution |
| | | Stealth Bio Therapeutics (elamipretide) | Institution |
| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
| | | | |
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| | | | |
| **8** | Patents planned, issued or pending | ☐ **None** | |
| | | U.S. Patent Application No. 17/419,477 Filed: 29-Jun-2021 (Evvia Therapeutics) | Co-inventor |
| | | | |
| | | | |
| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☐ **None** | |
| | | Abliva AB (KL1333) | Payments to me |
| | | UCB (doxecitine and doxribtimine) | Payments to me |
| | | | |
| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
|---|---|---|---|
| **11** | Stock or stock options | ☐ **None**<br>Evvia Therapeutics (stock options) \| Granted to me<br>\| |
| **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:** 6/30/2024

**Your Name:** Marni J. Falk, MD

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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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 | |
| | | FDA, University of Florida, and Saol Therapeutics | I participated in the development and implementation of the clinical trial, and I contributed to this paper by assisting in the analysis and interpretation of the data, drafting and revising it critically for important intellectual content, and approved the final version of the manuscript<br>- Payments to my institution |
| | | | |
| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | NIH, DOD, Saol Therapeutics, Adjuvia Therapeutics, Stealth BioTherapeutics, Astellas, Reneo Pharmaceuticals, Thiogenesis, Cyclerion Therapeutics, Mission Therapeutics, Precision Biosciences, Pretzel Therapeutics, Khondrion, Merck, United Mitochondrial Disease Foundation, CHAMP Foundation, CureARS Foundation | Payments made to my institution for preclinical or clinical sponsored research programs |
| | | | |
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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) |
|---|---|---|---|
| **3** | Royalties or licenses | ☐ **None** | |
| | | Elsevier Academic Press | Royalty Payments |
| | | | |
| | | | |
| **4** | Consulting fees | ☐ **None** | |
| | | Ajinomoto Cambridge, Inc., Cyclerion Therapeutics, Imel Therapeutics, Mayflower, Inc., MiMo Therapeutics, Mission Therapeutics, Precision Biosciences, Primera Therapeutics, Inc., Saol Therapeutics, Vincere Bio | Payment to me |
| | | | |
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| | | | |
| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☐ **None** | |
| | | GenoMind | Payment to me |
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| **6** | Payment for expert testimony | ☐ **None** | |
| | | Clark, May, Price, Lawley, Duncan, & Paul LLC | Payments to me |
| | | | |
| | | | |
| **7** | Support for attending meetings and/or travel | ☐ **None** | |
| | | United Mitochondrial Disease Foundation | Meeting Registration |
| | | | |
| | | | |
| **8** | Patents planned, issued or pending | ☐ **None** | |
| | | Children's Hospital of Philadelphia | Issued and Pending |
| | | Standigm Therapeutics | Pending |
| | | | |
| **9** | Participation on a Data Safety Monitoring | ☐ **None** | |
| | | Larimar Therapeutics, Khondrion, RiboNova | Payments made to me |

| | | 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) |
|---|---|---|---|
| | Board or Advisory Board | | |
| | | | |
| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☐ **None** | |
| | | Rarefy Therapeutics LLC | Equity interest |
| | | United Mitochondrial Disease Foundation | SMAB member, unpaid |
| | | | |
| **11** | Stock or stock options | ☐ **None** | |
| | | RiboNova | Stock |
| | | | |
| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☐ **None** | |
| | | Rarefy Therapeutics, Saol Therapeutics, Adjuvia Therapeutics | In kind compound prevision for research |
| | | | |
| | | | |
| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 7/2/2025

**Your Name:** Rebecca D. Ganetzky

**Manuscript Title:** **Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children**

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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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.

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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 | |
| | | | |
| | | | |
| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | Saol Therapeutics | Institution |
| | | | |
| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
|---|---|---|---|
| **4** | Consulting fees | ☐ **None** | |
| | | Minovia Therapeutics | self |
| | | | |
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| | | | |
| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
| | | | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
| | | United Mitochondrial Disease Foundation | Self |
| | | | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☐ **None** | |
| | | HopeForPDCD | Unpaid |
| | | Champ Foundation | Unpaid |
| | | | |
| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☐ **None** | |
| | | Society for Inherited Metabolic Disease | Unpaid |
| | | American Professors of Human Medical Genetics | Unpaid |
| | | | |

| | | 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) |
|---|---|---|---|
| **11** | Stock or stock options | ☒ **None** | |
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| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☐ **None** | |
| | | Agilent | Institution |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 07/11/2025

**Your Name:** Cheryl Garganta

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ **None** | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
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| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
|---|---|---|---|
| **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** | |

| | | 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) |
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| **11** | Stock or stock options | ☒ **None** | |
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| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 6/25/2025

**Your Name:** Kevin E. Glinton MD PhD

**Manuscript Title:** **Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children**

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ None | |
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| | | | Click the tab key to add additional rows. |
| Time frame: past 36 months | | | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | Moderna Inc. (research support) | |
| | | | |
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| 3 | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
|---|---|---|---|
| **11** | Stock or stock options | ☒ **None** | |
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| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 7/2/2025

**Your Name:** Andrea Gropman, M.D.

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ None | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | NCATS/NICHD/NIDDK 5U54HD061221 | Payment to institution |
| | | NICHD 5R01HD114863 | Payment to institution |
| | | NCATS UG3TR003897 | Payment to Institution |
| **3** | Royalties or licenses | ☐ **None** | |
| | | Elsevier, Swaiman's Textbook of Pediatric Neurology | Payment to me |
| | | | |
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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) |
|---|---|---|---|
| **4** | Consulting fees | ☐ **None** | |
| | | Medical expert: Berman & Simmons, P.A. | Payment to me |
| | | Medical expert: Ragsdale law firm | Payment to me |
| | | Medical expert: Shoup Evers & Green, PLLC | Payment to me |
| | | | |
| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☐ **None** | |
| | | Baylor Miraca | Payment to me |
| | | | |
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| **6** | Payment for expert testimony | ☐ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☐ **None** | |
| | | PRISMS medical advisory board | unpaid |
| | | NUCDF medical advisory board | unpaid |
| | | | |
| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☐ **None** | |
| | | Neurogenetics chair SIG, child neurology society | unpaid |
| | | Annual meeting planning committee, American Neurological Society | unpaid |
| | | Vice chair, NG SIG American academy of Neurology | unpaid |

| | | 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) |
|---|---|---|---|
| **11** | Stock or stock options | ☒ **None** | |
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| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 3/23/2026

**Your Name:** Sharon Hamm

**Manuscript Title:** **Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency (PDCD) in Children**

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☐ None | |
| | | Full time employee of Saol Therapeutics, sponsor of the study. | Salaried employee of Saol Therapeutics |
| | | | |
| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
| | | | |
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| | | | |
| **3** | Royalties or licenses | ☐ **None** | |
| | | No direct financial links to royalties or licenses. | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| | | | |
| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
| | | | |
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| | | | |
| **7** | Support for attending meetings and/or travel | ☐ **None** | |
| | | Meetings attended on behalf of Saol are at their expense. | |
| | | | |
| | | | |
| **8** | Patents planned, issued or pending | ☐ **None**<br>Named inventor on related in process patents | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
|---|---|---|---|
| **11** | Stock or stock options | ☐ **None** | |
| | | Shareholder in Saol Therapeutics. | |
| | | | |
| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 3/24/2026

**Your Name:** Eugenia Henry

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ None | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
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| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
|---|---|---|---|
| **11** | Stock or stock options | ☒ **None** | |
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| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 7/2/2025

**Your Name:** Nicola Longo

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☐ **None** | |
| | | Clinical trial finding from NIH | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | Clinical Trial Funding from FDA/NIH | |
| | | | |
| | | | |
| **3** | Royalties or licenses | ☒ **None** | |
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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) |
|---|---|---|---|
| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
|---|---|---|---|
| **11** | Stock or stock options | ☒ **None** | |
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| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☐ **None** | |
| | | | |
| | | | |
| | | | |
| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 7/2/2025

**Your Name:** Richard Neiberger

**Manuscript Title:** Phase Three Trial of Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ **None** | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
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| **3** | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
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| **11** | Stock or stock options | ☒ **None** | |
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| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 6/25/2025

**Your Name:** Russell P. Saneto, DO, PhD

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ None | |
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| | | | Click the tab key to add additional rows. |
| Time frame: past 36 months | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | NIH RO1 FD005407, "Phase III Trial of DCA in PDC Deficiency IND 028,625" R. Saneto DO, PhD, Site PI. | Payment to Institution |
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| **3** | Royalties or licenses | ☒ **None** | |
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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) |
|---|---|---|---|
| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☐ **None** | |
| | | DSMB Member for Reata 408-C-1402 and 408-C-1403. A Phase 2 study of the safety, efficacy, and pharmacodynamics of TRA 408 in the treatment of Friedreich's Ataxia and a Phase 2 study of the safety, efficacy and pharmacodynamics of RTA 408 in the treatment of mitochondrial myopathy. | Payment to Institution |
| | | DMSB Member for Abliva study, An interventional, randomized, double-blind parallel-group, placebo-controlled flexible dose adaptive study of the efficacy of KL-1333 in adult patients with primary mitochondrial disease. | Payment to mePresidne |
| | | | |
| **10** | Leadership or fiduciary role in | ☐ **None** | |

| | | 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) |
|---|---|---|---|
| | other board, society, committee or advocacy group, paid or unpaid | President and Secretary of the Mitochondrial Medicine Society | Unpaid |
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| **11** | Stock or stock options | ☒ **None** | |
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| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 6/26/2025

**Your Name:** Fernando Scaglia

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☐ **None** | |
| | | FDA's Office of Orphan Products Development (5R01-FD005407) | Payment made to institution |
| | | Saol Therapeutics | Payment made to institution |
| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
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| **3** | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☐ **None** | |
| | | DSMB for study: A Multiple Ascending Phase 1 Dose Study in the Treatment of Patients with the m.3243A>G Mutation and Low Brain Glutathione Levels | Unpaid |
| | | UCB | Payment to individual |
| | | Nestle Health Sciences | Payment to individual |
| | | Precision BioSciences | Payment to individual |
| | | Tisento Therapeutics | Payment to individual |
| **10** | Leadership or fiduciary role in other board, society, committee or | ☐ **None** | |
| | | Co-Chair UMDF MitoMed meetings 2023-2025 | Unpaid |
| | | Program Chair, Mitochondrial Medicine Society | Unpaid |
| | | | |

| | | 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) |
|---|---|---|---|
| | advocacy group, paid or unpaid | | |
| **11** | Stock or stock options | ☒ **None** | |
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| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 7/7/2025

**Your Name:** S H Subramony

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ **None** | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
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| **3** | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
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| **11** | Stock or stock options | ☒ **None** | |
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| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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:** 6/24/2025

**Your Name:** Jerry Vockley

**Manuscript Title:** **Phase Three Trial of Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children**

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☐ None | |
| | | Research support from University of Florida and Saol Pharmaceuticals to conduct this study | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| 3 | Royalties or licenses | ☒ **None** | |
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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) |
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| **4** | Consulting fees | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
| | | None related to this manuscript or topic | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☐ **None** | |
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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) |
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| **11** | Stock or stock options | ☒ **None** | |
| | | None related to this manuscript or topic | |
| | | | |
| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☐ **None** | |
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| **13** | Other financial or non-financial interests | ☐ **None** | |
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**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:** 7/7/2025

**Your Name:** Richard E. Wagner

**Manuscript Title:** Phase 3 Trial of Sodium Dichloroacetate for Pyruvate Dehydrogenase Complex Deficiency in Children

**Manuscript Number (if known):** 200149-DUAL-CRPH-1

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 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.** | ☒ **None** | |
| | | None | |
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| | | | Click the tab key to add additional rows. |
| **Time frame: past 36 months** | | | |
| **2** | Grants or contracts from any entity (if not indicated in item #1 above). | ☐ **None** | |
| | | NIH R42HD089804 | Personalized dosing of dichloroacetate in the treatment of rare and common disease |
| | | | |
| | | | |
| **3** | Royalties or licenses | ☐ **None** | |
| | | Medosome Biotec/Praesidio Pharma | Owner and CEO receive royalty from Saol |
| | | Saol Therapeutics | Medosome Biotec/Praesidio Pharma to receive royalty payments for drug sales |
| | | University of Florida | Lincese to Medosome Biotec fro geneotyping |

| | | 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) |
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| **4** | Consulting fees | ☒ **None** | |
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| **5** | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | ☒ **None** | |
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| **6** | Payment for expert testimony | ☒ **None** | |
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| **7** | Support for attending meetings and/or travel | ☒ **None** | |
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| **8** | Patents planned, issued or pending | ☒ **None** | |
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| **9** | Participation on a Data Safety Monitoring Board or Advisory Board | ☒ **None** | |
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| **10** | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | ☒ **None** | |
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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) |
|---|---|---|---|
| **11** | Stock or stock options | ☐ **None** | |
| | | 99% owner Medosome Biotec, LLC | |
| | | 50% owner Praesidio Pharma | |
| | | | |
| **12** | Receipt of equipment, materials, drugs, medical writing, gifts or other services | ☒ **None** | |
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| **13** | Other financial or non-financial interests | ☒ **None** | |
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**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.