

DATA USE AGREEMENT

Rare Disease Cures Accelerator – Data and Analytics Platform

This DATA USE AGREEMENT (this "Agreement"), is executed as of the latest signed date on the signature page (the "Effective Date"), (the "Effective Date") between [Person], acting for and on behalf of [Organization] ("Recipient") with offices located at [Address] and Critical Path Institute, a nonprofit corporation with an address of 1840 East River Road, Suite 100, Tucson, AZ 85718-5960 ("C-Path").

WHEREAS, C-Path manages the Rare Disease Cures Accelerator – Data and Analytics Platform, (RDCA-DAP[®]) a neutral data sharing and analytics platform designed to accelerate therapy development for rare diseases;

WHEREAS, Recipient is an institution that desires access to certain data residing in RDCA-DAP ("Data Set(s)");

WHEREAS, Recipient has received approval to access the data and use the work for prespecified research ("Research Plans") as required by the custodian of each of the requested data sets (through automated approval, approval of RDCA-DAP's data use committee and/or the approval of the custodian as requested in the individual data sharing agreement between C-Path and the data custodian);

WHEREAS, C-Path desires to make available to Recipient specified data to carry out the Research Plan(s) under the terms set forth in this Agreement; and

WHEREAS, data from defined data sources, (each a "Data Custodian" and collectively "Data Custodians"), will be provided to Recipient as part of the Data Set(s);

NOW, THEREFORE, C-Path and Recipient agree as follows:

1) DATA ACCESS

- a) Research Plan. C-Path grants to Recipient access to use the Data Set(s) described in the Research Plan(s) appended hereto as Exhibit A for the sole purpose of performing the analysis set forth in the Research Plan(s) for which the Data Set is requested (the "Analysis") subject to the terms and conditions of this Agreement. Notwithstanding the foregoing, Data Custodians(s) maintains ownership rights of the Data Set(s). Additional Research Plans may be appended to this Agreement in writing, signed by the parties through submission of a new research plan and amendment to this agreement. For the avoidance of doubt, the use by Recipient of all Data Sets described in Research Plans appended in writing, signed by the parties hereto, including both those initially appended to this Agreement and those added at a later time through use of a Research Plan Addition Agreement, shall be subject to the terms and conditions of this Agreement.
- b) Analysis. Recipient agrees that it will restrict its use of any Data Set solely to the Analysis described in the Research Plan for which the Data Sets were requested. In addition, Recipient agrees to comply with any conditions specified in the Workspace provisioned for the Data Sets requested. Recipient may share Data Sets and/or access to Data Sets with third parties who perform services on behalf of the Recipient in its performance of the Research Plan, but only if

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- (i) such third parties are named in the Research Plan, and
- (ii) Recipient first enters an agreement with such third parties binding the third parties to restrictions on the use of the Data Sets that are no less stringent than those placed on Recipient's use of the Data Sets herein, and
- (iii) all users request unique logins to the RDCA-DAP platform that tie such users to the specified Research Plan and this Agreement.

2) CONDITIONS ON USE OF THE DATA

- a) **Regulatory Approvals; Compliance with Laws.** Recipient shall obtain any regulatory or ethical approvals required by law or institutional policy before beginning the Analysis, including but not limited to institutional review board and research ethics committee approval. The parties shall comply with all applicable state/provincial, and local laws, regulations, codes and guidelines, including those regarding the handling, analyzing and reporting of analyses of data.
- b) **Data Privacy.** Recipient acknowledges the importance of the data privacy of individuals to whom the Data Sets may relate and commits to comply with all applicable national, state/provincial, and local laws and regulations regarding
 - (i) patient/research subject privacy,
 - (ii) the collection, storage, processing, disclosure and use of personally identifiable information, and
 - (iii) other uses and disclosures of the types of data contained in the Data Sets.
- c) **Data Access and Security.** Recipient shall not share with any third party any username, password, or other account details that Recipient uses to access any C-Path platform (including the RDCA-DAP) or otherwise provide a third party with access to any Data Set provided through the RDCA-DAP.

Recipient shall employ and maintain reasonable technical and administrative measures to prevent unauthorized or unlawful access or use of any Data Sets or the accidental loss, destruction of, or damage to the Data Sets. In addition, Recipient shall not remove, bypass, circumvent, neutralize or modify any technological protection measures employed by C-Path that are intended to protect the security of Data Sets or the privacy of the subjects therein.

- d) **Re-identification.** Recipient agrees not to intentionally attempt to identify any individuals who are subjects of the data contained in any Data Set or others who could be identified from the Data Sets (including but not limited to clinical research staff and relatives of participants).
- e) **No Guarantee of Accuracy.** C-Path and the Data Custodian(s) provides the Data Set "as is" and make no guarantee that any Data Set is accurate or complete. Recipient shall bear full responsibility and risk as to the accuracy, completeness,

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usefulness, performance and results derived from any Analysis performed using the Data Sets.

- f) Restricted Parties. Neither Recipient nor any of its employees, agents, or other parties who receive access to the Data Set hereunder is located in, ordinarily a resident in, or is owned or controlled by entities or persons located in or ordinarily residing in any country that is, at any time that Recipient requests Data Sets from C-Path, subject to sanctions by the United States (U.S.) Government or other applicable government as may be notified by C-Path or are identified on any list of restricted parties maintained by the U.S. government or other applicable government, including, but not limited to, the Specially Designated Nationals List administered by the U.S. Treasury Department's Office of Foreign Assets Control or the Denied Persons List, Unverified List or Entity List maintained by the U.S. Commerce Department's Bureau of Industry and Security.

3) PUBLICATION

- a) Publication of Research Plan. C-Path may share the Research Plan with the Data Custodian(s) whose data are included in the Data Sets used for a particular Research Plan at any time upon the request of the Data Custodian(s). C-Path may make the title and synopsis of the Research Plan, as well as the Requestor name and affiliation publicly available after the Data Sets associated with the Research Plan are made available to Recipient.
- b) Public disclosure of Research Results. Recipient is encouraged to make the Research Results publicly available in printed form, on the internet, or in a presentation in a learned forum, and Recipient is encouraged to obtain public disclosure of the Research Results in a peer-reviewed journal ("Publication"). Recipient shall submit to C-Path a copy of any Publication at least 30 days prior to submission of the Publication to a learned forum or journal, or if the Publication takes place other than through submission to a learned forum or journal, at least 30 days prior to public disclosure. C-Path shall review such Publication for appropriate acknowledgement of RDCA-DAP and the individual Data Custodian(s). C-Path may share such Publication with the Data Custodian(s) whose data are included in the Data Sets used to produce the Research Results to permit Data Custodian(s) to make comments on the Publication regarding the scientific accuracy of the Publication, review for patentable subject matter, and request deletion of confidential information of a Data Custodian that is provided to or otherwise made available to Recipient in connection with this Agreement ("Custodian Confidential Information"). Recipient shall be under no obligation to implement any comments on the Publication received from Data Custodian(s) provided that Recipient shall not include any information that is Custodian Confidential Information for which the applicable Data Custodian has requested deletion.

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- d) Recipient shall provide C-Path with a reference citation within 3 months for each Publication utilizing RDCA-DAP data, which C-Path may make available to the Data Custodian(s).
- e) Acknowledgment. Recipient agrees to include the following acknowledgment in any public disclosure of the Research Results: “Data used in the preparation of this [publication or presentation, as applicable] were obtained from the Rare Disease Cures Accelerator - Data and Analytics Platform (RDCA-DAP) funded by FDA Grant U18FD005320 and administered by Critical Path Institute. The data was provided to RDCA-DAP by [LIST OF DATA CUSTODIAN(S) OF DATA SETS USED BY RECIPIENT] on [DATE].”
- f) The custodians of some data sets are willing to collaborate with researchers using their data. The dataset description will indicate that the Recipient has accessed such a dataset. The Recipient recognizes that it has the option to contact the Data Custodian and work with them at Recipient’s discretion.

IMPORTANT NOTE: It is the policy of C-Path to add additional data as it becomes available. Recipient understands that any processed data that Recipient downloads may be preliminary, and Recipient’s results may change as new data are added. If Recipient downloads data from RDCA-DAP for the purposes of analysis and future publication in the form of abstracts and/or publications, Recipient will note the date of the download, and will check the database to determine if updated data have been provided prior to submission of any material for publication.

4) RESEARCH RESULTS

- a) Research Results. For the purposes of this Agreement, “Research Results” shall mean all data, formulae, outcomes or other results produced by Recipient as a result of the conduct of the Research Plan or as a result of the use of any Data Set provided to Recipient under this Agreement. RDCA-DAP strongly encourages public dissemination of all Research Results.
- b) Ownership of Research Results. As between the Custodian on one hand, and Recipient on the other hand, Recipient retains ownership of all Research Results (except that the Data Custodian retains ownership of any and all Custodian Data included therein). Recipient agrees to notify the relevant Data Custodian of any Research Results produced by the Recipient, using Data Custodian’s Data, and to grant, and hereby does grant, to the relevant Data Custodian(s), a perpetual, non-exclusive, fully-paid up, royalty-free, irrevocable, worldwide, unrestricted license to any intellectual property derived from the Research Results for Data Custodian Use. These rights should be made available to Data Custodian upon the Custodian’s request directly to Recipient.

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- 5) **THIRD PARTY BENEFICIARIES** Each Data Custodian that has provided a Data Set to C-Path that is provided to Recipient hereunder is and shall be an intended third-party beneficiary of this Agreement.
- 6) **INDEPENDENT CONTRACTOR** The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind that purports to bind the other without the other's prior written authorization.
- 7) **REPRESENTATIONS, WARRANTIES AND COVENANTS**
 - a) **No Contrary Agreement.** Recipient represents and warrants that it does not have, and agrees that it will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including without limitation, the obligations of Section 3.
 - b) **Authority to Enter Agreement.** Each party represents and warrants that it has the full right, power, and authority to enter into this Agreement. Each party represents and warrants that it does not have, and agrees that it will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement.
 - c) **Authority to Bind.** Recipient represents and warrants that it has the authority to bind to the terms of this Agreement any individual proposed by Recipient to have access to the Data Sets and any third party provided access to the data under Section 1(b) above, and that use of the Data Sets by any such individuals shall be subject to the terms of this Agreement.
- 8) **INDEMNIFICATION** Recipient shall indemnify, defend and hold harmless C-Path, each Data Custodian that provides a Data Set to C-Path that is provided to Recipient hereunder, and C-Path's and each such Data Custodian's respective directors, officers, employees and agents from and against any and all claims, suits, losses, liabilities, damages, costs, fees and expenses (including reasonable attorney fees) (collectively, "Losses") arising out of or resulting from, directly or indirectly,
 - a) any material breach of, or inaccuracy in, any representation or warranty made by Recipient in this Agreement and,
 - b) any breach or violation of any material covenant or agreement of Recipient in or pursuant to this Agreement,
 - c) Recipient's negligence or willful misconduct, and
 - d) any use by Recipient of the Data Sets in a manner contrary to applicable law. Notwithstanding the foregoing, Recipient shall have no obligation to indemnify C-Path or any Data Custodian to the extent that the Losses arise out of or result from directly or indirectly the gross negligence or willful misconduct of C-Path or such Data Custodian, or C-Path's or Data Custodian's respective directors,

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officers, employees and agents. Each Data Custodian that has provided a Data Set to C-Path that is provided to Recipient hereunder is and shall be an intended third-party beneficiary of this Section 8 of this Agreement.

9) TERMINATION

- a) C-Path Termination. C-Path may terminate this Agreement or any Research Plan Amendment entered into hereunder immediately upon the breach by Recipient of any of the terms of this Agreement or use of the Data Sets in violation of applicable law. The termination of this Agreement shall immediately terminate all Research Plan Amendments entered into hereunder.
- b) Termination. Either party may terminate this Agreement without cause by providing sixty (60) days' written notice to the other party.
- c) Effect of Termination. Upon termination of this Agreement, Recipient shall promptly return or destroy (at C-Path's sole election) all Data Sets and any copies thereof provided by C-Path hereunder.
- d) Survival. The obligations of Sections 1-9 of this Agreement shall survive termination of this Agreement.

10) ENTIRE AGREEMENT This Agreement and the exhibits hereto represent the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

11) SIGNATURE This Agreement may be executed by a party's signature transmitted by electronic portable document format (.pdf), and copies of this Agreement so executed and delivered shall have the same force and effect as originals.

12) COUNTERPARTS This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same.

13) NOTICE All notices provided hereunder shall be made in writing to the addresses set forth below via next-day delivery service:

If to C-Path:

C-Path, Inc. Attention: Executive Director, RDCA-DAP
1840 East River Road, Suite 100
Tucson, AZ 85718-5960,
USA
rdcadap@c-path.org

If to Recipient:

[]
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[]

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Attention: [_____]

-----[Signature Page Follows]-----

Signature Page

IN WITNESS WHEREOF, the parties hereto execute this Agreement as of the Effective Date.

[_____] [INSERT NAME OF THE RECIPIENT]

By: _____

Name:

Title:

Date: _____

CRITICAL PATH INSTITUTE:

By: _____

Name: Alexandre Betourne

Title: Executive Director, Rare and Orphan Disease Program

Date: _____

By: _____

Name: Richard Liwski

Title: Chief Technology Officer, Director – Data Collaboration Center

Date: _____