

This DATA USE AGREEMENT (this “Agreement”) is effective as of

[REDACTED]

(the “Effective Date”) between

[REDACTED]

a tax-exempt research and educational institution, acting for and on behalf of its

[REDACTED]

(“Recipient”) with offices located at

[REDACTED]

and Vivli, Inc. a Massachusetts nonprofit corporation with an address of 14 Story Street, 4th Floor, Cambridge, MA 02138 (“Vivli”).

WHEREAS, Vivli manages a research data repository comprised of data contributed by various sponsors of clinical research in an effort to facilitate and encourage research for the public good (the “Data Repository”);

WHEREAS, Recipient is an institution that desires access to certain data and associated information held by Vivli (each a “Data Set” and collectively “Data Sets”);

WHEREAS, Recipient has received approval from Vivli’s Independent Review Committee (“IRC”) and/or an alternate review model approved by the relevant Data Contributor (collectively, with the IRC, the “Data Review Entity”) to carry out certain analyses using the Data Sets that are described in one or more research plans (each a “Research Plan” and collectively “Research Plans”); and

WHEREAS, Vivli desires to make available to Recipient certain Data Sets to carry out the Research Plan(s) under the terms set forth in this Agreement;

WHEREAS, data from sponsors,

[REDACTED]

[REDACTED]

[REDACTED]

(each a “Data Contributor” and collectively “Data Contributors”), will be provided to Recipient as part of the Data Set(s);

[Continued]

NOW, THEREFORE, Vivli and Recipient agree as follows:

1) DATA ACCESS

a) Research Plan. Vivli grants to Recipient a royalty-free, worldwide, non-exclusive, irrevocable (except in the event of the termination of this Agreement as hereinafter provided) license to use the Data Set(s) described in the Research Plan(s) appended hereto as Exhibit A for the 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 Contributor(s) maintains any pre-existing ownership rights that it may have in the Data Set(s) (including all intellectual property rights therein except for the license granted pursuant to this Agreement). Additional Research Plans may be appended to this Agreement in writing, signed by the parties through execution by the Research Plan’s principal investigator of a Research Plan Addition Agreement with Vivli in a format similar the form attached hereto as Exhibit B. 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 to the Analysis described in the Research Plan for which the Data Sets were requested. In addition, Recipient agrees to comply with any conditions that were placed by the cognizant Data Review Entity(ies) on Recipient’s use of the Data Sets as set forth in the approved Research Plan. Recipient may share Data Sets and/or access to Data Sets with third parties who perform services on behalf of, Recipient in its performance of the Research Plan, but only if (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.

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. Recipient shall not share with any third party any username, password, or other account details that Recipient uses to access any Vivli platform (including the Data Repository) or otherwise provide a third party with access to any Vivli platform (including the Data Repository). Recipient shall employ and maintain reasonable technical and administrative measures to prevent unautho-

alized 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 Vivli that are intended to protect the Data Sets.

c) 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). Recipient further agrees not to intentionally combine the Data Sets with other sources of data in a manner that could lead to the identification of any individual.

d) No Guarantee of Accuracy. Vivli and the Data Contributor(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, usefulness, performance and results derived from any Analysis performed using the Data Sets.

e) Safety Concerns. Recipient agrees that it will inform Vivli within twenty-four (24) hours of any new information that might influence the evaluation of the risks of the product to which a Data Set pertains (collectively “Safety Concerns”) to permit Vivli to inform the relevant Data Contributor(s) of Safety Concerns identified as part of the Analysis. Recipient agrees that the Data Contributor(s) may take action regarding such Safety Concerns, including informing regulatory authorities or healthcare providers, or otherwise making the Safety Concerns public, including in advance of publication of the Analysis by Recipient.

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 Vivli, subject to sanctions by the United States (U.S.) Government or other applicable government as may be notified by Vivli 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. Vivli shall share the following elements of the Research Plan with the Data Contributor(s) whose data are included in the Data Sets used for a particular Research Plan at any time upon the request of the Data Contributor(s): the title of the Research Plan, the name of the principal investigator and his or her affiliation, funding source(s), potential conflicts of interest, a summary of the proposed research, and the studies from which Data Sets have been requested. Also, Vivli shall make the elements of the Research Plan stated above, publicly available in the Data Repository after the Data Set associated with the Research Plan is made available to Recipient.

b) Analysis Availability. Recipient agrees to make the results of the Analysis (the “Analysis Results”) available to Vivli within one (1) year of completing their analysis. Vivli will make the Analysis Results publicly available in the Data Repository, but only if the Recipient has informed Vivli that it does not intend to pursue publication of the Analysis. If the Analysis has not been completed within one year (i) Recipient shall provide Vivli with an explanation of why analysis completion was not possible, which such explanation Vivli may make publicly available in the Data Repository, and (ii) Vivli may, at its sole discretion, require that the Recipient provide Vivli with updates on the progress of the analysis at six month intervals until the research has been completed and Vivli may make such updates publicly available in the Data Repository. If Recipient fails to comply with the requirements of section 3(b) of this Agreement, Recipient shall not be eligible to receive any further Data Sets from Vivli until Recipient remedies such non-compliance to the satisfaction of Vivli.

Publication of Analysis Results. Recipient is expected to make the Analysis Results publicly available in printed form, on the internet, or in a presentation in a learned forum, and Recipient shall use reasonable efforts to obtain public disclosure of the Analysis Results in a peer-reviewed journal. These public disclosures of the Analysis Results shall be referred to as a “Publication.” Recipient shall submit to Vivli 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. Vivli shall share such Publication with the Data Contributor(s) whose data are included in the Data Sets used to produce the Analysis Results to permit Data Contributor(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 (including, without limitation, anonymized patient-level data, research specifications or clinical trial/study protocols, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of a Data Contributor that is provided to or otherwise made available to Recipient in connection with this Agreement (“Contributor Confidential Information”). Recipient shall be under no obligation to implement any comments on the Publication received from Data Contributor(s) provided that Recipient shall not include any information that is Contributor Confidential Information for which the applicable Data Contributor has requested deletion.

c) Additionally, Recipient shall provide Vivli with a reference citation upon publication which Vivli shall share with the applicable Data Contributor(s).

Recipient further consents that the title of the Research Proposal, name of the Lead Researcher, affiliation, funding source, potential conflicts of interest, summary of the proposed Research, and requested studies (all as provided by the Researcher in the Data Request) will be available on the Vivli platform after the Data Use Agreement is executed, and that the Statistical Analysis Plan (as provided by the Researcher in the Data Request) will be made public by Vivli after the research is published.

d) Acknowledgment. Recipient agrees to include the following acknowledgment in any publication or presentation of the Analysis Results: “This [publication or presentation, as applicable] is based on research using data from [INSERT DATA CONTRIBUTOR(S) NAME(S)]”

that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication.”

4) INTELLECTUAL PROPERTY

a) New Intellectual Property. For the purposes of this Agreement, “New Intellectual Property” shall mean all data, discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, processes, know-how, or trade secrets which are generated, conceived, reduced to practice or otherwise made by or on behalf of 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.

b) Data Contributor Uses. For the purposes of this Agreement, “Data Contributor Uses” shall mean any and all uses of, or related to, Data Contributor’s Data Set or any and all making, use, sale or importation of a compound which is owned or controlled by a Data Contributor, including the compound(s) used to generate the Data Set, which would otherwise be an infringement of New Intellectual Property.

c) License to New Intellectual Property. All New Intellectual Property shall be the sole property of Recipient; however, Recipient shall notify Vivli, promptly and in writing, of any New Intellectual Property, and Vivli shall in turn notify the relevant Data Contributor(s). Recipient agrees to grant, and hereby does grant, to the relevant Data Contributor(s) a perpetual, non-exclusive, fully-paid up, royalty-free, irrevocable, worldwide, unrestricted license under any New Intellectual Property for Data Contributor Uses, with the right to sublicense through multiple tiers. Recipient further agrees to grant, and hereby does grant, the relevant Data Contributor(s) an exclusive option, to be exercised within one hundred eighty (180) days from notice of the New Intellectual Property, to negotiate in good faith an exclusive, fee-bearing, worldwide license with the right to sublicense through multiple tiers to any New Intellectual Property which Recipient may have or obtain. If the relevant Data Contributor(s) request additional assistance from the Recipient beyond the rights provided by the non-exclusive license, Recipient agrees to provide reasonable assistance to each Data Contributor, upon commercially reasonable terms that are at least as favorable to the Data Contributor as the terms agreed with any other licensee for such assistance, to facilitate Data Contributor in fully utilizing any New Intellectual Property.

d) Exclusive License. If a Data Contributor exercises its option to negotiate an exclusive license, Recipient agrees to negotiate exclusively in good faith with such Data Contributor, for up to one hundred eighty (180) days or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive, worldwide, fee-bearing license, including the right to sublicense through multiple tiers, for the Data Contributor and its affiliates to make, have made, use, sell or otherwise dispose of the subject matter of the New Intellectual Property or products incorporating the subject matter of the New Intellectual Property subject to any non-exclusive licenses granted in section 4(c) above. In the event that Data Contributor does not exercise its option to negotiate an exclusive license, or in the event Recipient and Data Contributor fail to agree to commercially reasonable exclusive license terms following good faith negotiation, Recipient may negotiate further non-exclusive license terms with third parties. Any such terms shall be consistent with the non-exclusive license that Recipient agrees to grant to Data Contributor in Section 4(c) above. Should any terms be agreed with a third party in accordance with this section, then for five

(5) years after the Effective Date, Recipient shall notify Vivli, within thirty (30) days of the effective date of any such agreement, of the identity of the third party so that Vivli may communicate such information to the relevant Data Contributor(s).

e) Written Agreements from Researchers. Recipient agrees to obtain written agreements with all of its researchers who utilize the Data Set which grant a present assignment, without additional consideration, of all rights, title and interests in New Intellectual Property to Recipient for subsequent licensing to Data Contributors.

f) Data Contributor Obligations Regarding New Intellectual Property. Recipient agrees that Data Contributor(s) shall have no further obligations resulting from the assignment and/or exploitation of any New Intellectual Property.

5) THIRD PARTY BENEFICIARIES

Each Data Contributor that has provided a Data Set to Vivli 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.

d) Data Contributor Agreement. Vivli represents and warrants that each Data Set was contributed to the Data Repository pursuant to a data contributor agreement, a current copy of which is available on the Vivli website.

8) INDEMNIFICATION

Recipient shall indemnify and hold harmless Vivli, each Data Contributor that provides a Data Set to Vivli that is provided to Recipient hereunder, and Vivli's and each such Data Contributor's and its 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, and (c) 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 Vivli or any Data Contributor to the extent that the Losses arise out of or result from directly or indirectly the gross negligence or willful misconduct of Vivli or such Data Contributor, or such of Vivli or such Data Contributor's respective directors, officers, employees and agents. Each Data Contributor that has provided a Data Set to Vivli that is provided to Recipient hereunder is and shall be an intended third-party beneficiary of this Section 7 of this Agreement.

9) TERM AND TERMINATION

a) Term. The term of this Agreement shall commence on the Effective Date and terminate upon the earlier of (i) that date which is three years from the Effective Date, or (ii) the termination of this Agreement in accordance with 8(b) or 8(c).

b) Vivli Termination. Vivli may terminate this Agreement or any Research Plan Addition Agreement 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 Addition Agreements entered into hereunder.

c) Termination. Either party may terminate this Agreement by providing sixty (60) days' written notice to the other party.

d) Effect of Termination. Upon termination of this Agreement, Recipient shall promptly return or destroy (at Vivli's sole election) all Data Sets and any copies thereof provided by Vivli hereunder.

e) Survival. The obligations of Sections 3-7 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 facsimile or 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 Vivli:

Vivli, Inc.
Attention: Executive Director
14 Story Street
Cambridge, MA 02138

If to Recipient:

[Redacted recipient address fields]

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

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

Vivli, Inc.

By:

By:

Name:

Name:

Title:

Title:

Date:

Date:

Read & Acknowledged

Name:

Title:

Date:



EXHIBIT A

Exhibit B

Research Plan Addition Agreement

This Research Plan Addition Agreement is effective as of _____, 2020 (the “Effective Date”) between _____ (“Investigator”) located at [RECIPIENT ADDRESS] and Vivli, Inc. a Massachusetts nonprofit corporation with an address of 14 Story Street, 4th Floor, Cambridge, MA 02138 (“Vivli”).

WHEREAS, [INSERT INSTITUTION NAME] (“Institution”) is party to that certain Data Use Agreement with Vivli dated [INSERT EFFECTIVE DATE] (the “DUA”) pursuant to which Vivli makes certain Data Sets available to Institution upon request pursuant to the terms and conditions set forth in the DUA;

WHEREAS, [INSERT NAME] is an investigator affiliated with Institution (“Investigator”) who wishes to access one or more Data Sets from Vivli for purposes of the research plan attached hereto that has been approved by the cognizant Data Review Entity(ies) (the “Research Plan”).

Now, therefore, Vivli and Investigator agree as follows:

1. All capitalized terms used herein and not defined shall have the meaning given to them in the DUA.
2. Investigator represents and warrants that he or she has the requisite authority from Institution to enter into this Research Plan Addition Agreement with Vivli.
3. Investigator agrees that he or she shall use any Data Sets received from Vivli solely for the purposes set forth in the Research Plan.
4. Investigator agrees that his or her use of the Data Sets shall be subject to all terms that apply to Institution’s use of the Data Sets in the DUA.
5. Vivli may terminate this Research Plan Addition Agreement immediately upon the breach by Investigator of any of the terms of this Research Plan Addition Agreement or use of the Data Sets in violation of applicable law. Upon termination of this Research Plan Addition Agreement by Vivli, Institution shall promptly return or destroy (at Vivli’s sole election) all Data Sets provided by Vivli hereunder.

[Signature Page Follows]



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

Vivli, Inc.

Institution _____

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____