

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement (“**Agreement**”) is made as of the later of the signatures below (“**Effective Date**”) by and between:

- The Regents of the University of California on behalf of its Los Angeles Campus, having an office located at UCLA Clinical Trials Contracts & Strategic Relations, 10911 Weyburn Avenue, Third Floor, Los Angeles, CA 90095 (the “**Institution**”), and
- IQVIA RDS Inc., having a place of business at 4820 Emperor Boulevard, Durham, North Carolina, 27703 (“**IQVIA**”),

Each a “Party” and together the “Parties”.

Protocol Number:	mRNA-3927-P101
Protocol Title:	A Global Phase 1/2, Open-Label, Dose Escalation study to Evaluate the Safety, Pharmacodynamics, and Pharmacokinetics of mRNA-3927 in Participants with Propionic Acidemia
Protocol Date:	08 October 2019
Sponsor:	ModernaTX, Inc., 200 Technology Square, 6 th Floor, Cambridge, Massachusetts 02139 USA
Country where Institution is Conducting Study	USA
Investigator:	Gerald Lipshutz M.D., an employee of Institution
Key Enrollment Date:	100 Calendar Days after Institution Initiation Visit (being the date by which Institution must enrol at least one (1) subject as more specifically set out in section 1.7 “Key Enrollment Date” below)
IRB	UCLA Office of Human Research Protection Program mirb@research.ucla.edu

The following additional definitions shall apply to this Agreement:

“**Affiliate**” means any entity that directly or indirectly owns, is owned by or is under common ownership with a Party to this agreement. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns directly or indirectly at least fifty percent (50%) of the voting stock of the other company or (a) in the absence of the ownership of at least (50%) of the voting stock of a corporation or (b) in the case of a non-corporate entity, if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation or non-corporate business entity, as applicable

Applicable Laws: all applicable federal, state and local laws, , including, but not limited to, Code of Federal Regulations, Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (“**HIPAA**”), the federal anti-kickback statute (42 U.S.C. 1320a-7(b) and the related safe harbor regulations and the Limitation on Certain Physician Referrals, also referred to as the “**Stark Law**” (42 U.S.C. 1395n), and (v) applicable regulations and guidances of the US Food and Drug Administration (“**FDA**”).

Protocol: the clinical protocol No. mRNA-3927-P101 referenced above as it may be modified from time to time by the Sponsor (defined below).

Case Report Form or CRF: case report form (paper or electronic) to be used by Institution to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: Institution employees and agents involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound identified in the Protocol as mRNA-3927 that is being tested in the Study.

Good Clinical Practices or GCPs: International Conference on Harmonisation for Good Clinical Practice E6, as amended from time to time, to the extent adopted by the FDA.

Sponsor: ModernaTX, Inc., the sponsor of the Study.

Medical Records: the Study Subjects' primary original medical records kept by the Institution, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images and other source documents as defined by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines for Clinical Practice E6(R2).

Study Data: means the data and conclusions compiled on CRF's generated by the Institution during the course of conducting the Study and required to be delivered to Sponsor pursuant to the Protocol including AE's, SAE's, and CRF's. For clarity, Medical Records are not Study Data.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

RECITALS:

WHEREAS, by separate agreement, ModernaTX, Inc., 200 Technology Square, 6th Floor, Cambridge, Massachusetts 02139 (“**Sponsor**”) has engaged IQVIA, a clinical research organisation, acting as an independent contractor, to act on behalf of Sponsor for the purposes of transferring certain obligations in connection with Sponsor’s Study, said obligations including, but not limited to negotiation and execution of the Agreement and payment administration for services performed and described hereunder;

WHEREAS, IQVIA desires to engage the Institution to conduct the Study, through its Investigator, in accordance with the Protocol and the Institution is willing to conduct the Study.

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the following is agreed:

1. CONDUCT OF THE STUDY

1.1 Compliance with Laws, Regulations, and Good Clinical Practices

Institution agrees that Institution, its Investigator and Study Staff shall perform the Study, exercising due care at Institution in accordance with this Agreement, the Protocol, Applicable Laws, and GCPs. IQVIA agrees that it and Sponsor, and their respective Affiliates, shall adhere to all (i) Applicable Laws (ii) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2 Informed Consent Form

Prior to enrollment in a Study, Institution agrees that its Investigator shall obtain from each prospective Study Subject: (i) Institution a completed and executed informed consent form that has been approved by Sponsor and the Institutional Review Board (“**IRB**”) that is responsible for reviewing the Study; and (ii) a form that is compliant with HIPAA that meets the requirements of 45 C.F.R. § 164.508(c), in form and substance acceptable to Sponsor and the IRB.

1.3 Medical Records and Study Data

1.3.1 Collection, Storage and Destruction: Institution shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Institution shall:

- (i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with Applicable Laws; and
- (ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure in a manner not expressly permitted under this Agreement. If directed by Sponsor or IQVIA, Institution will submit Study Data using the electronic system provided by Sponsor or IQVIA or their designated representative and in accordance with Sponsor’s written instructions for electronic data entry. IQVIA confirm that the electronic data entry system complies with 21 C. F.R Part 11. Institution shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. IQVIA agrees that it or Sponsor shall provide access, save normal scheduled maintenance, to such system during

the course of the Study and after the completion of the Agreement for the record retention period specified in 21 CFR 312.62(c). Alternatively, IQVIA or Sponsor may provide Institution with a compilation of the data provided in the EDC on a CD or other machine readable format at the completion of the Study at the Institution. This provision shall survive the expiration or early termination of the Agreement.

- (iii) take measures to prevent accidental or premature destruction of the Study Data or Medical Records, for as long as required by 21 C.F.R. 312.62(c). Institution shall keep and maintain records and documents relating to its performance of the Study which are required to be retained under 21 C.F.R. 312.62 for two (2) years following the date a marketing application is approved for the Study Drug for the indication under investigation in the Study, or if no application is to be filed, or if the application is not approved for such indication, until two (2) years after the investigation is discontinued and FDA is notified, or any longer retention period mandated by federal or state laws or regulations; and
- (iv) All Study Data shall be delivered to Sponsor as set forth in Section 1.3.34 below.

If the Investigator leaves the Institution, the Institution will not be relieved of its obligations under this Agreement for maintaining Medical Records and Study Data.

1.3.2 Ownership. Institution shall retain ownership of Medical Records. All Study Data and Investigational Drug provided to the Institution and/or Investigator for purposes of the Study shall be, are and will, in each case remain Sponsor's property. The Sponsor shall own all rights, title and interest, to all Confidential Information (as defined below) and Study Data. Sponsor shall have the right to use the Study Data, in any manner it desires, including, but not limited to, incorporating the Study Data in any regulatory or patent filing concerning the Study. For the avoidance of doubt, the Study Data shall be deemed Confidential Information subject to Institution's and its Investigator's rights set forth in Section 1.3.4.

1.3.3 Access, Use, Monitoring and Inspection. Institution shall submit Study Data to IQVIA and Sponsor for Sponsor's use via electronic data entry system. Institution shall afford Sponsor and IQVIA and their representatives and designees reasonable access at mutually agreeable times during Institution's normal business hours to Institution's facilities and to Study records and documents as set forth in 21 CFR 312 including Medical Records and Study Data so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study during the Study and for the period permitted by the IRB approval. Sponsor's or IQVIA's representative provided access to Medical Records and Study Data for the purpose of monitoring or auditing the Study will not make a record of or disclose direct identifiers of any Study Subject (including but not limited to the Study Subject's name, date of birth, street address, telephone number, social security number, medical record, or health plan beneficiary numbers). In the event that copies of Medical Records are to be made, all direct identifiers will be redacted prior to copying or assurance that such identifiers will be redacted prior to taking the copies of Medical Records off site, at Sponsor's expense.

During the Study and for the period permitted by the IRB approval, Institution shall afford regulatory authorities having jurisdiction over the Study reasonable access in accordance with Applicable Laws to Institution's facilities and to Medical Records and Study Data.

The Institution shall immediately notify IQVIA of an FDA inspection of the Study ("**Inspection**") and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority with respect to an Inspection, and the Institution shall permit IQVIA and Sponsor to attend any such Inspections, to the extent permitted by the FDA. The Institution will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such Inspections.

1.3.4 Use of Study Data. Institution will have the non-exclusive right to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5 Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4 Duties of Institution's Investigator

- (a) Institution's Investigator is responsible for the direction and control of the Study at Institution, Investigator will promptly notify Sponsor of any material changes or updates to Investigator's Curriculum Vitae or any censures or limitations on the practice of medicine by the Investigator. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's brochure, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs are obtained, and to review all CRFs to ensure their accuracy and completeness.
- (b) The Institution through its Investigator shall: (a) make all reasonable efforts to enter all data related to the Study onto the appropriate electronic case report forms/logs ("e-CRFs") pages using the Electronic Data Capture ("**EDC**") system within ten (10) business days of a subject's last completed Study visit, and for a data lock or data transfer within ten (10) business days or as soon as possible following a Study subject's last completed Study visit; Sponsor and Institution shall use all reasonable efforts to coordinate the visit and data collection to enable data entry prior to such lock or transfer; (b) promptly answer queries and (c) review all e-CRF pages for 100% accuracy and completeness;
- (c) Investigator will comply with 21 CFR 54.
- (d) Institution agrees to provide prompt notice to Sponsor and IQVIA upon becoming aware if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. Institution will reasonably cooperate, in good faith and expeditiously, to identify a replacement investigator acceptable to IQVIA and Sponsor. To the extent Investigator remains an employee of Institution but is no longer able to perform the Study, Institution's Investigator shall continue to comply with the obligations of confidentiality contained in this Agreement. The appointment of a new

Investigator must have the prior approval of Sponsor and IQVIA. In the event an acceptable substitute is not found, IQVIA may terminate this Agreement in accordance with Article 15.2 (Term and Termination). Institution's cooperation in finding an acceptable replacement does not negate its obligation to perform this Agreement up to the effective date of termination.

1.5 Adverse Events

The Institution shall report adverse events and serious adverse events as directed in the Protocol and by Applicable Laws. The Institution shall reasonably cooperate with Sponsor in its efforts to follow-up on any adverse events. The Institution shall comply with its IRB reporting obligations.

Sponsor will promptly report to the Institution, the Institution's IRB, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the IRB's approval to continue the Study.

1.6 Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution with sufficient amount of Investigational Product as described in the Protocol free of charge.

The Institution shall use the Investigational Product and, if applicable, any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by Sponsor and according to Applicable Laws, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Institution shall return or destroy, at Sponsor's option and expense (i) and subject to approval by Institution's investigational pharmacy, the Investigational Product, and all (ii) Confidential Information (as defined below). Notwithstanding the foregoing, Institution may retain a copy of Confidential Information solely for archival purposes. Institution shall comply with all Applicable Law governing disposition or destruction of the Investigational Product and any reasonable written instructions from IQVIA or Sponsor that are not inconsistent with Applicable Law.

The Institution shall return, at Sponsor's expense, any equipment or materials provided by Sponsor for use in the Study unless Sponsor and Institution have a written agreement for Institution to acquire the equipment. If there are Institution facility improvements provided by IQVIA or Sponsor in relation to the Study, then Institution shall enter a separate written agreement with IQVIA or Sponsor with respect to such facility improvements.

1.7 Key Enrollment Date

The Institution understands and agrees that if Institution has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/IQVIA has the right to limit enrollment at any time.

1.8 Minimum Enrollment Goal

Institution and Investigator will use reasonable efforts to enroll Study Subjects for the Study in accordance with the patient eligibility criteria specified in the Protocol. The Institution's Investigator shall at all times exercise independent medical judgment as to the suitability of each prospective individual for enrollment as a Study Subject. The Institution acknowledges and agrees that the Study may be conducted concurrently by Sponsor at more than one (1) study center under the same Protocol with concurrent patient enrollment. Institution acknowledges that Institution's minimum enrollment goal is 1 subjects and that Institution will use reasonable efforts to reach the enrollment goal within a reasonable time after commencement of the Study at Institution. If Institution fails to adhere to this principle IQVIA may reconsider Institution's suitability to continue participation in the Study.

2. PAYMENT

2.1 In consideration for the proper performance of the Study by Institution, in compliance with the Protocol and the terms and conditions of this Agreement, payments shall be made in accordance with the budget and payment schedule set forth in Attachment A (the "**Budget**"). Institution agrees that it will be responsible for making payments to any and all personnel (including without limitation the Investigator) and third parties who provide services hereunder for the conduct of the Study at Institution. Except as expressly set forth otherwise in this Agreement or in Sponsor's Letter of Indemnification, no other payments shall be due to Institution, beyond those expressly provided in the Budget. The Budget may be modified only upon the prior written consent of the Parties. The last payment required by the Budget shall be made forty-five (45) days after the latter of (i) Sponsor's or IQVIA's receipt of all Study Data, including completed CRFs with all query resolutions having been resolved and verified by Sponsor or IQVIA, which shall not be unreasonably withheld or delayed, or (ii) Institution's close out visit ("**Final Payment**"). Institution represents and certifies that it will not seek payment or accept reimbursement from any third party for costs and/or expenses paid for by Sponsor or IQVIA, including, but not limited to, treatment/evaluation, procedures and/or drug/supplies.

2.2 If this Agreement is terminated, the total sums payable by Sponsor through IQVIA pursuant to this Agreement shall be equitably prorated for actual work performed prior to the date of termination. Upon completion of the Study at Institution or early termination of this Agreement, the Institution shall within sixty (60) business days of the Final Payment refund Sponsor for any amounts paid and unearned under this Agreement.

2.3 IQVIA will not pay Institution for (i) any Study Subject whose enrollment in the Study materially deviates from the Protocol's eligibility criteria or (ii) from whom Study Data cannot be analyzed because of (a) material Protocol deviations, (b) lack of proper records or (c) incomplete, uncorrected or unverifiable CRFs.

2.4 The Parties acknowledge and agree that the amounts payable under this Agreement represent the fair market value of the covered costs associated with the Study at Institution and no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.

2.5 In addition to the fees and expenses designated in Attachment A:

Sponsor will provide free of charge the Investigational Product and any other items or services which are necessary and appropriate to conduct the Study in accordance with the Protocol. All items and services provided hereunder shall be used solely to conduct the Study. At the completion of the Study, Institution shall return to Sponsor or Sponsor's designee at Sponsor's discretion and at Sponsor's cost, all unused items that Sponsor provided Institution or for which Sponsor provided reimbursement to Institution.

2.6 Sponsor, through IQVIA, will cover or reimburse Institution for reasonable and necessary expenses which have been pre-approved by Sponsor or its designee in writing for travel, lodging, and meals incurred by Investigator and Study Staff in association with such individuals' attendance at investigator meetings regarding the Study. Institution agrees to submit detailed invoices in a mutually agreed upon format for reimbursement of any such expenses within forty-five (45) days of the date of the meeting pursuant to Applicable Laws, the Institution acknowledges and agrees that Sponsor may be required to disclose publicly and/or to relevant governmental authorities the payments made by or on behalf of Sponsor to Institution under this Agreement referencing the Investigator, as well as the purpose and nature of such payments.

3. CONFIDENTIALITY

3.1 Definition

Institution acknowledges and agrees that, as between the Parties, Sponsor is and shall at all times remain the sole and exclusive owner of Confidential Information as defined herein. For purposes of this Agreement, "**Confidential Information**" shall mean any and all information disclosed to Institution or its Investigator by Sponsor in whatever form (i) including, without limitation, information concerning the Investigational Product, reports, preclinical data and formulation information, basic scientific data which if in tangible form, Sponsor or IQVIA has labeled in writing as proprietary or confidential at the time of disclosure or within (15) fifteen days thereafter (ii) information which is commonly regarded as confidential or proprietary information in the life sciences industry (iii) the Protocol; or (iv) the Study Data.

3.2 Except as expressly permitted by this Agreement, Institution and Study Staff shall maintain Confidential Information in confidence and shall not disclose such Confidential Information to any third party or publish or otherwise disseminate such Confidential Information during the conduct of the Study and for seven (7) years after the conclusion thereof. In addition, Institution and Study Staff shall protect the Confidential Information with the same degree of care as it normally uses to preserve and safeguard its own proprietary information, but not less than a reasonable degree of care. Furthermore, the Institution agrees to use the Confidential Information only for the purposes of this Agreement except as provided for herein. The Institution may disclose Confidential information to the Study Staff who require access thereto for the purposes of this Agreement, provided that prior to making any such disclosures, each such Study Staff shall be bound by the obligations set forth herein. Confidential Information shall be held in confidence and not to use such information for any purpose other than in accordance with the terms of this Agreement.

3.3 Nothing contained herein will in any way restrict or impair any Party's right to use, disclose, or otherwise deal with any Confidential Information which at the time of its receipt (i) was known and available in the public domain at the time of disclosure or subsequently becomes known and available in the public domain through no fault of the Institution or the Investigator; (ii) was known by the Institution or the Investigator, as evidenced by written records, prior to the Effective Date; or (iii) as evidenced by written records, became known to the Institution or the Investigator through disclosure by sources other than Sponsor having no duty of confidentiality with respect to such Confidential Information, whether to Sponsor or another party, and having the legal right to disclose such Confidential Information.

3.4 Compelled Disclosure

Notwithstanding the foregoing, Institution and Investigator may disclose Confidential Information pursuant to Applicable Law, an order or requirement of a court, administrative agency, or other governmental body, provided that Institution gives prompt notice of such order or requirement to Sponsor to enable Sponsor to seek a protective order or otherwise prevent or restrict such disclosure. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

3.5 Return or Destruction

Upon written request and expense by Sponsor or IQVIA, the Institution and/or the Investigator shall, at Sponsor's or IQVIA's election, return or destroy the Confidential Information, including all copies thereof, to Sponsor or IQVIA; provided, however, that one (1) copy of the Confidential Information may be retained by Institution for compliance purposes only.

3.6 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for seven (7) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), are the separate property of Sponsor and the Institution and are not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries, improvements and developments invented by Institution, Investigator or Study Staff, in the performance of the Protocol which uses or incorporates the Investigational Product or Confidential Information. Inventions shall be, and remain, at all times the sole and exclusive property of Sponsor.

4.3 Assignment of Inventions

Institution shall disclose all Inventions promptly and fully to Sponsor in writing, and Institution, on behalf of itself, Investigator and its Study Staff. Further, Institution shall require Study Staff to assign to Institution, and in-turn, Institution shall assign to Sponsor all of its rights, title and interest in and to all Inventions. Institution shall cooperate and assist Sponsor by executing, and causing its employees to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions. Institution represents and certifies that all Inventions shall be assigned to Sponsor free of any encumbrances.

4.4 No Conflict

The Institution represents that, to the best of Institution's knowledge, neither it or Investigator are bound by any agreement that would conflict with or prevents the full performance of the Institution's and the Investigator's duties and obligations to Sponsor under this Agreement. Institution represents and certifies to Sponsor that (i) Investigator and Study Staff have signed the Institution's Patent Acknowledgement to assign to Institution any and all right, title, and interest that Investigator and Study Staff may acquire in the Inventions at any time during the term of this Agreement and (ii) Institution will not take any action that would prevent the free and clear assignment of Inventions to Sponsor (e.g. license them to someone else, grant a security interest in, etc.).

4.5 Patent Prosecution

Institution shall reasonably cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 No Other Rights

Other than the specified rights to use the Study Data and publish the Study results specifically set forth in Section 1.3 (Medical Records and Study Data) and Article 5 (Publication Rights), respectively, neither Investigator nor Institution, including Study Staff, shall acquire any rights of any kind whatsoever with respect to the Study Data or Investigational Product as a result of performance under this Agreement or otherwise.

4.7 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Use of Study Results by Sponsor

Institution acknowledges that Sponsor may elect to use the results of the Study for the purposes of national and international registration, publication, and information for medical and pharmaceutical

professionals. If necessary, the relevant regulatory and health authorities will be notified of the Investigator's name, address, qualifications, and extent of involvement in the Study.

5.2 Multi-Center Publication

The Institution agrees that Sponsor shall have the right to the first publication of the results of the Study. Sponsor shall serve as the coordinator of multi-center study disclosures, in those specific instances where the first publication is intended to be a joint, multi-center publication of the results of the entire multi-center study made by Sponsor in conjunction with the investigators' and institutions' contributing data, analysis and comments, as appropriate. Any publication(s) resulting from the Study shall give appropriate credit to the scientific contributions made by Sponsor personnel. For such publication(s), authorship or acknowledgement of investigators will be determined based primarily on scientific contribution to protocol development and data interpretation and secondarily on patient enrollment. All authors must meet authorship criteria as outlined by the International Committee of Medical Journal Editors.

5.3 Publications

Notwithstanding the foregoing, Institution and Investigator may publish or make an individual oral or written presentation or publication of Study results either (i) after Sponsor publishes the Study data, or (ii) eighteen (18) months after the completion of the Study at all sites participating in the Study, whichever comes first. For individual publications/ presentations, Institution agrees that Investigator will provide all proposed publications, including abstracts, posters, presentations and manuscripts of the results of the Study, to Sponsor for review and comment at least forty-five (45) days prior to submission for publication. Except for the results of the Study, Sponsor shall have the right to identify and require removal of any Confidential Information from any such abstract, poster, presentation or manuscript and, in such case, Institution and Investigator shall remove all such Confidential Information. If during the forty-five (45) day review period, Sponsor notifies Institution that it desires patent applications to be filed on any Inventions disclosed or suggested in the manuscripts, Institution agrees that Investigator will defer publication or other disclosure for a period, not to exceed seventy-five (75) days, to permit Sponsor to file any desired patent applications. The Institution agrees that it and the Investigator shall not publish any Study results other than in accordance with this Article 5.

5.4 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor.

5.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, press release or other promotion without prior written permission of such other Party or Sponsor will register the Study with a public clinical trials registry in accordance with Applicable Laws and will report the results of the Study publicly when and to the extent required by Applicable Laws. Subject to this Section 5.5, Sponsor and IQVIA may use Institution's name solely to identify the Institution as a site where the Study is being conducted and for its reporting obligations, and Institution may use Sponsor's and IQVIA's name to publish the Study results as set forth herein and for its award reporting obligations.

5.6 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

6.1 Study Team Member Personal Data

During the course of the Study, the Investigator and Study Staff may be called upon to provide personal data, which may include their names, contact information, work experience and

professional qualifications, publications, resumes and educational background (“**Personal Data**”) under this Agreement for the following purposes:

- (i) the conduct of clinical trials;
- (ii) verification by governmental or regulatory agencies, the Sponsor, IQVIA, and their agents and affiliates;
- (iii) compliance with legal and regulatory requirements;
- (iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
- (v) storage in databases to facilitate the selection of investigators for future clinical trials;
- and
- (vi) anti-corruption compliance.

Names of members of Study Staff may be processed in IQVIA’ study contacts database for study-related purposes only. Principal Investigator, by signing below, agrees that IQVIA shall store and use his/her personal data as set out within this Section 6. For any other Study Staff, IQVIA agrees to gain written permission from Study Staff to store and use his/her personal data for the above purposes.

6.2 Study Subject Personal Data

Institution shall ensure that all consents and authorizations required by Applicable Law are obtained from Study Subjects, such that IQVIA and Sponsor are permitted to access the Protected Health Information (as that term is defined by 45 C.F.R. §160.103 or successor regulations) of any Study Subject for the purpose of fulfilling any obligation under this Agreement, or for the purpose of complying with Applicable Law.

6.3 Patient Protection and Affordable Care Act

Institution acknowledges that, pursuant to the Patient Protection and Affordable Care Act (2010), Sponsor will make reports to the United States government disclosing information associated with transfers of value to Institution, including but not limited to payments and other transfers under this Agreement, which will be published by the government on a public website.

7. STUDY SUBJECT INJURY- INDEMNIFICATION

Sponsor shall provide indemnification and reimbursement for subject injuries as set forth under a separate Letter of Indemnification.

8. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by IQVIA.

This Section 8 “IQVIA Disclaimer” shall survive termination or expiration of this Agreement.

9. CONSEQUENTIAL DAMAGES

Neither IQVIA nor Sponsor shall be responsible to the Institution for any lost profits, lost opportunities, or other consequential damages, nor shall Institution be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages.

This Section 9 “Consequential Damages” shall survive termination or expiration of this Agreement.

10. DEBARMENT

The Institution represents and certifies that neither Institution nor Investigator, nor Study Staff performing the Study at Institution, are (i) debarred from providing services pursuant to section 306 of the United States Federal Food, Drug and Cosmetic Act 21 .u.S.C. §335a; (ii) excluded, debarred or suspended from, or otherwise ineligible to participate in any federal or state health care programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)); (iii) disqualified by any government or regulatory agencies from performing specific services, and are not subject to a pending disqualification proceeding; or (iv) convicted of a criminal offense related to the provision of health care items or services. During the Study and for a period of two (2) years following completion or early termination of the Study, the Institution shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or IQVIA' request, Institution agrees that the Investigator and its employees who are directly involved in the treatment or evaluation of Study Subjects ("Sub-Investigator") ,are required to promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such Investigator or Sub-Investigator, which shall disclose any applicable interests held by Investigators or Sub-Investigators or their spouses or dependent children.

Institution shall use reasonable efforts to ensure such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.

Institution agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, in accordance with Applicable Law.

This Section 11 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

12. ANTI-KICKBACK AND ANTI FRAUD

Institution agrees that its judgment with respect to the advice and care of each Study Subject will not be affected by the compensation it receives from this Agreement, that such compensation does not exceed the fair market value of the services it is providing, and that no payments are being provided to it for the purpose of inducing it to purchase or prescribe any drugs, devices or products. If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution agrees that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution agrees that it will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that Institution will not pay another physician to refer subjects to the Study.

13. ANTI-BRIBERY

The Parties agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Institution. The Parties certify that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision that the Parties under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor to secure an improper advantage or obtain or retain business.

The Parties further certify that neither Party will, in order to assist Sponsor to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, a Party may terminate this Agreement if the other Party or the Sponsor learns that improper payments are being or have been made to or by the other Party or any individual or entity acting on its or their behalf.

14. INDEPENDENT CONTRACTORS

Institution is and shall remain at all times an independent contractor and is not, and it (and the Investigator) shall not represent itself/himself/herself to be, an agent or employee of IQVIA or Sponsor or related to IQVIA or Sponsor other than as an independent contractor. Institution and its Study Staff shall not participate in any IQVIA or Sponsor employee benefit plans nor receive any other compensation beyond that stated herein. Neither Party shall have the power or authority to bind the other Party or Sponsor or to assume or create any obligation or responsibility, expressed or implied, on the other Party's behalf.

15. TERM & TERMINATION

15.1 Term

This Agreement will become effective on the date on which it is last signed by the Parties (the "Effective Date") and shall continue until completion or until terminated in accordance with this Section 15 "Term & Termination".

15.2 Termination

IQVIA may terminate this Agreement for any reason effective immediately upon written notice to Institution and Investigator. Either Party may immediately terminate this Agreement by giving written notice to the other Party only if such immediate termination is necessary to protect the safety, health or welfare of Study subjects. Further, either Party may terminate this Agreement by giving written notice to the other Party for any material breach of this Agreement by the other Party that is not cured within thirty (30) days after written notice is received by the breaching Party. Upon receipt of notice of termination, the Institution shall immediately cease any subject recruitment, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, to the extent that Study Subject safety is not jeopardized, and IQVIA shall make a final payment prorated for work properly performed pursuant to the Protocol including non cancelable commitments in the amounts specified in Attachment A; provided, all queries have been resolved and final acceptance, by Sponsor, which shall not be unreasonably withheld or delayed, of all CRF pages and reasonable satisfaction of all other applicable conditions set forth herein.

16. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered

- (a) in person,
- (b) by certified mail, postage prepaid, return receipt requested,
- (c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
- (d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	ModernaTX, Inc. 200 Technology Square, 6 th Floor Cambridge, MA 02139 Attention: Office of the General Counsel
To IQVIA	4820 Emperor Blvd. Durham, NC 27703 Attention: Director of Project Management Telephone:(919) 998-2888 With a copy to: IQVIA Inc. Global Legal Department 100 IMS Drive Parsippany, NJ 07054 USA Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com
To Institution	UCLA Clinical Trials Contracts & Strategic Relations Attention: Director 10911 Weyburn Avenue, Third Floor Los Angeles, CA 90095
To Investigator	Gerald Lipshutz UCLA Surg-Liver & Pancreas Transplantation BOX 957054, 757 Westwood Plaza, Suite 8501G Los Angeles, CA 90095-7054 Tel: 310-267-9592

17. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

18. MISCELLANEOUS**18.1 Entire Agreement**

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties with respect to the subject matter hereof and replaces all other written and oral agreements relating to the Study.

18.2 No Waiver/Enforceability

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

18.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Institution shall not assign or transfer any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Institution hereby consents to such an assignment. Institution will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

This Agreement shall be interpreted under the laws of the state or province and country in which Institution conducts the Study.

18.6 Survival

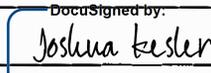
The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

THIS SECTION IS INTENTIONALLY LEFT BLANK

ACKNOWLEDGED AND AGREED BY IQVIA RDS INC.:

By: Joshua Kesler

Title: Associate Director, NA RSU CN

Signature: 

Date: June 26, 2020

ACKNOWLEDGED AND AGREED BY THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ON BEHALF OF ITS LOS ANGELES CAMPUS:

By: Ann Ciminera

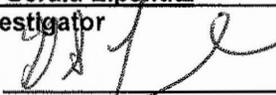
Title: ~~Sr. Industry Contract Officer~~ Asst. Director, CTC&SR

Signature: 

Date: June 24, 2020

WHILE NOT A PARTY TO THE AGREEMENT I HAVE READ THE AGREEMENT & ACKNOWLEDGE MY OBLIGATIONS AS SET FORTH HEREIN, including Section 1.4(a) Further, I give consent to use of my personal data as set forth in Section 6.1:

Name: Gerald Lipshutz
Investigator

Signature: 

Date: 06-24-2020

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE ("BUDGET")

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("Payee):

Payee Name	The Regents of the University of California
Payee Address	UCLA Payment Solutions and Compliance Box 957089, 1125 Murphy Hall Los Angeles, CA 90095-9000
Payee Email Address	Fmcluster1@mednet.ucla.edu
Finance Contact	Ivan Cortez, Fund Manager ICortez@mednet.ucla.edu 310-206-3099
Tax ID Number	95-6006143

The Payee's 9 Digit Tax Identification Number and SSN/EIN designation will be required before any payments can be made under this Agreement.

In case of changes in the Payee's address, Institution is obliged to inform IQVIA in writing. The Parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax exempt status, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

B. PAYMENT TERM

IQVIA will pay the Payee monthly, on a completed visit per subject basis in accordance with the attached budget. One hundred percent (100%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior month enrollment data confirmed by subject CRFs received from the Institution supporting subject visitation.

Major, disqualifying Protocol violations are not payable under this Agreement.

C. BUDGET TABLES**Q3W SCHEDULE**

Description	Visit Amount (Including OH) (USD)
Screening Visit SV	\$2,885
Observation Period Visit 1	\$1,516
Observation Period Visit 2	\$1,478
Observation Period Visit 3 OBS	\$1,478
Observation Period Visit 4 and beyond (if needed)	\$1,478
Pre-treatment Day -2	\$8,989
Pre-treatment Day -1	\$6,184

Pre-dose		\$4,133
Dosing / Post-dose		\$8,877
Day 2	Dose #1	\$7,304
Day 3		\$6,286
Day 4		\$2,100
Day 8		\$2,335
Day 15		\$1,478
Pre-dose		\$3,020
Dosing / Post-dose		\$8,539
Day 2	Dose #2	\$6,286
Day 3		\$1,462
Day 8		\$1,478
Day 15		\$1,478
Pre-dose		\$3,916
Dosing / Post-dose		\$8,728
Day 2	Dose #3	\$6,392
Day 3		\$1,462
Day 8		\$2,223
Day 15		\$1,478
Pre-dose		\$2,723
Dosing / Post-dose	Dose #4	\$2,923
Day 8		\$1,653
Day 15		\$1,478
Pre-dose		\$2,548
Dosing / Post-dose	Dose #5	\$3,197
Day 8		\$1,478
Day 15		\$1,478
Pre-dose		\$4,985
Dosing / Post-dose	Dose #6	\$3,197
Day 8		\$2,223
Day 15		\$1,478
Pre-dose		\$2,630
Dosing / Post-dose	Dose #7	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Pre-dose		\$2,548
Dosing / Post-dose	Dose #8	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Pre-dose		\$2,548
Dosing / Post-dose	Dose #9	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Pre-dose		\$2,912
Dosing / Post-dose	Dose #10	\$3,386

Day 8		\$1,653
Day 15		\$1,478
Pre-dose		\$2,548
Dosing / Post-dose	Dose #11	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Pre-dose		\$4,985
Dosing / Post-dose	Dose #12	\$3,271
Day 8		\$2,223
Day 15		\$1,478
Day 22		\$1,245
Follow-Up Period Month 1	M1	\$2,714
Follow-Up Period Month 2	M2	\$1,586
Follow-Up Period Month 3	M3	\$2,357
Follow-Up Period Month 4	M4	\$1,586
Follow-Up Period Month 5	M5	\$1,586
Follow-Up Period Month 6	M6	\$4,094
Follow-Up Period Month 9	M9	\$2,357
Follow-Up Period Month 12	M12	\$4,094
Follow-Up Period Month 15	M15	\$1,624
Follow-Up Period Month 18	M18	\$3,360
Termination Month 24 / Early Termination	Term M24 / ET	\$4,450
Metabolic Decompensation Event	MDE	\$1,066
Unscheduled / Rescreening Visit	UV / RESCR	\$551
TOTAL COST PER PATIENT	SV	\$218,573

Q2W Schedule

Description		Visit Amount (Including OH) (USD)
Screening Visit	SV	\$2,885
Observation Period Visit 1		\$1,516
Observation Period Visit 2		\$1,478
Observation Period Visit 3	OBS	\$1,478
Observation Period Visit 4 and beyond (if needed)		\$1,478
Pre-treatment Day -2		\$8,989
Pre-treatment Day -1		\$6,184
Pre-dose		\$4,133
Dosing / Post-dose		\$8,877
Day 2	Dose #1	\$7,304
Day 3		\$6,286
Day 4		\$2,100
Day 8		\$2,335
Pre-dose		\$3,020

Dosing / Post-dose		\$8,539
Day 2	Dose #2	\$6,286
Day 3		\$1,462
Day 8		\$1,478
Pre-dose		\$3,916
Dosing / Post-dose		\$8,728
Day 2	Dose #3	\$6,392
Day 3		\$1,462
Day 8		\$2,223
Pre-dose		\$2,723
Dosing / Post-dose	Dose #4	\$2,923
Day 8		\$1,653
Pre-dose		\$2,548
Dosing / Post-dose	Dose #5	\$3,197
Day 8		\$1,478
Pre-dose		\$4,985
Dosing / Post-dose	Dose #6	\$3,197
Day 8		\$2,223
Pre-dose		\$2,630
Dosing / Post-dose	Dose #7	\$2,923
Day 8		\$1,478
Pre-dose		\$2,548
Dosing / Post-dose	Dose #8	\$2,923
Day 8		\$1,478
Pre-dose		\$2,548
Dosing / Post-dose	Dose #9	\$2,923
Day 8		\$1,478
Pre-dose		\$2,912
Dosing / Post-dose	Dose #10	\$3,386
Day 8		\$1,653
Pre-dose		\$2,548
Dosing / Post-dose	Dose #11	\$2,923
Day 8		\$1,478
Pre-dose		\$4,985
Dosing / Post-dose	Dose #12	\$3,271
Day 8		\$2,223
Follow-Up Period Month 1	M1	\$2,714
Follow-Up Period Month 2	M2	\$1,586
Follow-Up Period Month 3	M3	\$2,357
Follow-Up Period Month 4	M4	\$1,586
Follow-Up Period Month 5	M5	\$1,586
Follow-Up Period Month 6	M6	\$4,094
Follow-Up Period Month 9	M9	\$2,357
Follow-Up Period Month 12	M12	\$4,094
Follow-Up Period Month 15	M15	\$1,624

Follow-Up Period Month 18	M18	\$3,360
Termination Month 24 / Early Termination	Term M24 / ET	\$4,450
Metabolic Decompensation Event	MDE	\$1,066
Unscheduled / Rescreening Visit	UV / RESCR	\$551
TOTAL COST PER PATIENT	SV	\$199,592

Q4W Schedule

Description		Visit Amount (Including OH) (USD)
Screening Visit	SV	\$2,885
Observation Period Visit 1		\$1,516
Observation Period Visit 2		\$1,478
Observation Period Visit 3	OBS	\$1,478
Observation Period Visit 4 and beyond (if needed)		\$1,478
Pre-treatment Day -2		\$8,989
Pre-treatment Day -1		\$6,184
Pre-dose		\$4,133
Dosing / Post-dose		\$8,877
Day 2		\$7,304
Day 3	Dose #1	\$6,286
Day 4		\$2,100
Day 8		\$2,335
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$3,020
Dosing / Post-dose		\$8,539
Day 2	Dose #2	\$6,286
Day 3		\$1,462
Day 8		\$1,478
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$3,916
Dosing / Post-dose		\$8,728
Day 2	Dose #3	\$6,392
Day 3		\$1,462
Day 8		\$2,223
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$2,723
Dosing / Post-dose	Dose #4	\$2,923
Day 8		\$1,653
Day 15		\$1,478
Day 22		\$1,372

Pre-dose		\$2,548
Dosing / Post-dose	Dose #5	\$3,197
Day 8		\$1,478
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$4,985
Dosing / Post-dose	Dose #6	\$3,197
Day 8		\$2,223
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$2,630
Dosing / Post-dose	Dose #7	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$2,548
Dosing / Post-dose	Dose #8	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$2,548
Dosing / Post-dose	Dose #9	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$2,912
Dosing / Post-dose	Dose #10	\$3,386
Day 8		\$1,653
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$2,548
Dosing / Post-dose	Dose #11	\$2,923
Day 8		\$1,478
Day 15		\$1,478
Day 22		\$1,372
Pre-dose		\$4,985
Dosing / Post-dose	Dose #12	\$3,271
Day 8		\$2,223
Day 15		\$1,478
Day 22		\$1,478
Day 29		\$1,245
Follow-Up Period Month 1	M1	\$2,714
Follow-Up Period Month 2	M2	\$1,586
Follow-Up Period Month 3	M3	\$2,357
Follow-Up Period Month 4	M4	\$1,586

Follow-Up Period Month 5	M5	\$1,586
Follow-Up Period Month 6	M6	\$4,094
Follow-Up Period Month 9	M9	\$2,357
Follow-Up Period Month 12	M12	\$4,094
Follow-Up Period Month 15	M15	\$1,624
Follow-Up Period Month 18	M18	\$3,360
Termination Month 24 / Early Termination	Term M24 / ET	\$4,450
Metabolic Decompensation Event	MDE	\$1,066
Unscheduled / Rescreening Visit	UV / RESCR	\$551
TOTAL COST PER PATIENT	SV	\$235,143

D. CONDITIONAL PROCEDURES

The following conditional procedures and related costs will be reimbursed on a pass-through basis upon receipt of an invoice at the amount indicated in the below table (which includes overhead). Subject number and visit/dates must be included on the invoice for payment to be issued.

Procedure	Procedure Amount (USD)
Patient Assent; consent form for pediatric patients not of legal age to sign informed consent; use in conjunction with informed consent (code:INCON) signed by parents as parental permission.	\$60
Consent for optional exploratory research	\$43
Re-consent, Informed consent performed again with the same patient	\$50
Medical history	\$150
PCCA (propionyl CoA carboxylase, alpha polypeptide) (eg, propionicacidemia, type 1), full gene sequence	\$2,016
PCCB (propionyl CoA carboxylase, beta polypeptide) (eg, propionicacidemia), full gene sequence	\$2,016
Full physical examination - also includes medical history, one set of vital signs, height, head circumference (if applicable), Tanner staging (if applicable) and weight assessment	\$277
Symptom-driven physical exam - also includes medical history, one set of vital signs, height, head circumference (if applicable), assessment of menarche for pregnancy testing (if applicable) and weight assessment	\$233
Vital signs - also includes one weight assessment (if needed)	\$62
Noninvasive ear or pulse oximetry for oxygen saturation; single determination	\$40
Single 12-lead ECG: Includes tracing, interpretation and report	\$189
Blood draw, phlebotomy, routine venipuncture for collection of specimen(s) for local laboratory (CBC, CMP+, coagulation, local biomarkers, serum pregnancy); simple: Includes preparation of specimen	\$63

Blood count (CBC), hematology. This test may be ordered as a complete automated blood count (CBC). The specimen is whole blood. Method is automated cell counter. This code includes the measurement of erythrocytes (red blood cells or RBC), leukocytes (white blood cells or WBC), hemoglobin, hematocrit (volume of packed red blood cells or VPRC), platelet or thrombocyte count, and indices (mean corpuscular hemoglobin or MCH, mean corpuscular hemoglobin concentration or MCHC, mean corpuscular volume or MCV, and red cell distribution width or RDW). This code includes automated differential of the white blood cells or "diff" in which the following leukocytes are differentiated: neutrophils or granulocytes, lymphocytes, monocytes, eosinophils, and basophils.	\$67
Blood count; reticulocyte count, manual	\$28
Comprehensive metabolic panel, chemistry, chemistries, SMAC: Includes Albumin; Bilirubin, total; Calcium; Carbon Dioxide (bicarbonate); Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Protein, total; Sodium; Transferase, alanine amino (ALT) (SGPT); Transferase, aspartate amino (AST) (SGOT); Urea Nitrogen (BUN); anion gap calculation	\$151
Albumin/Globulin Ratio (A/G Ratio)	\$43
Bilirubin; direct	\$26
Lactate dehydrogenase (LD) (LDH)	\$52
Amylase	\$45
Lipase	\$66
Uric acid; blood, serum	\$44
Prothrombin time (PT)	\$82
Thromboplastin time, partial (PTT) (aPTT); plasma or whole blood, serum	\$42
Serum pregnancy, gonadotropin chorionic (hCG) (BetahCG); quantitative	\$58
Local biomarker: Lactate (lactic acid)	\$39
Local biomarker: Ammonia	\$73
Collection of specimen; urine, urine collection	\$25
Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy	\$11
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative	\$18
Collection of specimen; urine, urine collection, 24 hour only	\$49
Collection of samples for central laboratory - as needed: PK, antibodies, central lab biomarkers, markers of inflammation, markers of cardiac and renal function	\$74
Lab handling and/or shipping of specimen(s) to central laboratory, simple	\$95
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (mRNA-3927); each additional hour	\$105

Serious adverse events (SAE)	\$369
Physician, Simple - Per Visit	\$193
Physician - Per Hour (for teleconferences)	\$262
Study Coordinator - Per Hour - processing of central lab samples	\$105
Overnight Facility Charge, Simple (e.g. regular ward room) - Per Night	\$4,964
Overnight Facility Charge, Complex - Per Night (for intensive care)	\$1,919
Daily Facility Charge - Per Day	\$115
Study Coordinator, Electronic Data Capture (EDC) - Per Hour - max. 1 hour per visit	\$60
Chart Review per patient, per chart; simple; max. 16 charts	\$96
Outside Safety Reports (each, first 10 reports are free)	\$39
Central line placement	\$17,514
Blood draw from central line	\$194
SIMPLE - lab processing (< 30 min & <15 aliquots)	\$48
SHIPPING LABOR COST	\$29
RESEARCH 2019 AFTER HOURS SIMPLE - lab processing (< 30 min & <15 aliquots)	\$142
CTRC: Dietician time - additional time (per 30 min)	\$71
CTRC: Nursing time - additional time (per 30 min)	\$117
CTRC: Room time - additional time (per 30 min)	\$53
CTRC Breakfast	\$19
CTRC Lunch/Dinner	\$30
CTRC Research Meal	\$49
CTRC Snack	\$11
CTRC Large (Procedure) Room Time	\$166
Evaluation of FNA Smear	\$498
Laboratory Technician	\$91

E. PAYMENT DISPUTE

Institution will have forty-five (45) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

F. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

G. INVOICES

Original Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

IQVIA RDS Inc.
Attn: Investigator Payment Administration Department
10188 Telesis Court, Suite 400
San Diego, CA 92121

Email Invoices to: IPANA@IQVIA.com

For payment inquiries contact: IPA_NA_Inquiries@IQVIA.com or (888)267-2836

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator name and site number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

H. SCREENING FAILURE

Reimbursement for screen failures will be at the amount indicated on the screening visit of the attached budget, not to exceed three (3) screen failure(s) paid per one (1) subject(s) randomized.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to IQVIA along with any additional information, which may be reasonably requested by IQVIA to appropriately document the subject screening procedures.

I. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of **Five Hundred Fifty-One Dollars (\$551 USD)** [which includes overhead]. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to IQVIA along with any additional information which may be requested by IQVIA to appropriately document the unscheduled visit.

J. METABOLIC DECOMPENSATION VISITS

Payment for metabolic decompensation visits will be reimbursed in the amount of **One Thousand Sixty-Six Dollars (\$1,066 USD)**, [which includes overhead]. To be eligible for reimbursement for metabolic decompensation visits, completed CRF pages must be submitted to IQVIA along with any additional information which may be requested by IQVIA to appropriately document the metabolic decompensation visit.

K. INSTITUTIONAL REVIEW BOARDS (“IRBs”) PAYMENTS

IRB/ costs will be reimbursed on a pass-through basis upon receipt of invoice and are included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by IQVIA and Sponsor, will be reimbursed upon receipt of invoice.

L. STUDY START-UP

A one-time, non-refundable Study Start-Up Fee payment of **Twelve Thousand Ninety-Six Dollars (\$12,096 USD)**, [which includes overhead], to cover start up activities will be made upon the execution of this Agreement and receipt of an original invoice.

M. CTRC SET-UP FEE

A one-time, non-refundable Clinical Translational Research Center Set-Up payment of **One Thousand Five Hundred Ninety-Four Dollars (\$1,594 USD)**, [which includes overhead], will be made upon the execution of this Agreement and receipt of an original invoice.

N. CLINICAL LABORATORY SERVICES START-UP FEE

A one-time, non-refundable Clinical Laboratory Services Start-Up payment of **One Thousand Two Hundred Sixty Dollars (\$1,260 USD)**, [which includes overhead], will be made upon the execution of this Agreement and receipt of an original invoice.

O. PHARMACY START-UP

A one-time, non-refundable Investigational Pharmacy Set-Up Fee payment of **Three Thousand One Hundred Fifty Dollars (\$3,150 USD)**, [which includes overhead], will be made upon the execution of this Agreement and receipt of an original invoice.

P. COVERAGE ANALYSIS REVIEW

A one-time, non-refundable coverage analysis payment of **Three Thousand Five Hundred Dollars (\$3,500 USD)**, [which includes overhead], will be made upon execution of this Agreement and receipt of an original invoice.

Q. SPONSOR BUDGET TEMPLATE FEE

A one-time, non-refundable Sponsor Budget Template payment of **Four Thousand Four Hundred Ten Dollars (\$4,410 USD)**, [which includes overhead], will be made upon execution of this Agreement and receipt of an original invoice.

R. DOCUMENT STORAGE/ARCHIVING FEE

A one-time, non-refundable Archiving fee of **One Thousand One Hundred Dollars (\$1,100 USD)**, which includes institutional overhead, will be made upon receipt of invoice.

S. ANNUAL COMMITTEE RENEWAL FEE

An annual Committee Renewal payment of **One Thousand Two Hundred Sixty Dollars (\$1,260 USD)**, [which includes overhead], will be made upon receipt of invoice for the preparation and submission of annual renewal and continuing review applications to applicable regulatory committees.

T. AUDIT PREPARATION FEE

A Not for Cause Audit fee will be reimbursed on a pass-through basis upon receipt of invoice only in the event of an audit which is conducted for any reason other than "for cause" and is included in the attached Budget at amount not to exceed **One Thousand Eight Hundred Ninety Dollars (\$1,890 USD)**, [which includes overhead], per visit.

U. INDEPENDENT REVIEW BOARDS ("IRB") POST-APPROVAL REPORT FEE

An IRB Post-Approval Report payment of **Two Hundred Fifty-Two Dollars (\$252 USD)**, [which includes overhead], will be made upon receipt of invoice for the processing and management of IRB approval reports.

V. STUDY CLOSE-OUT FEE

A one-time, non-refundable Study Close-Out Visit payment of **Six Hundred Thirty Dollars (\$630 USD)**, [which includes overhead], will be paid in accordance with Section 2.1 of the Agreement and the Budget.

W. DRUG DESTRUCTION FEE

Upon completion or termination of the Study, fees for the destruction of investigational product will be reimbursed on a pass-through basis upon receipt of original invoice from a third party vendor, up to **One Hundred One Dollars (\$101 USD)**, [which includes overhead], and is included in the attached Budget.

X. INVESTIGATIONAL PHARMACY ANNUAL RENEWAL FEE

Beginning year two (2) of the study, an annual Pharmacy maintenance payment of **One Thousand Five Hundred Seventy-Five Dollars (\$1,575 USD)**, [which includes overhead], will be made upon receipt of invoice.

Y. PHARMACY CLOSE OUT FEE

A one-time, non-refundable Pharmacy Close out visit payment of **Six Hundred Thirty Dollars (\$630 USD)**, [which includes overhead], will be made upon completion of all pharmacy related activities and receipt of an original invoice.

Z. IDS PHARMACY - MONITOR/SPONSOR VISIT FEE

Each pharmacy monitoring visit will be reimbursed **One Hundred Eighty-Nine Dollars (\$189 USD)**, [which includes overhead] for the first hour, and will be made upon receipt of invoice.

AA. IDS PHARMACY - PROTOCOL UPDATE FEE

A Pharmacy Protocol Update Fee for necessary re-training upon the addition of new investigational product or protocol arms in the amount of **Three Hundred Seventy-Eight Dollars (\$378 USD)**, [which includes overhead], will be made on a pass-through basis and upon receipt of invoice.

BB.IDS PHARMACY - SPONSOR REQUESTS FOR ADDITIONAL PHARMACY DATA AFTER CLOSEOUT VISIT

A payment in the amount of **One Thousand Seven Hundred Sixty-Four Dollars (\$1,764 USD)**, [which includes overhead], for Sponsor requests for additional pharmacy data after the Study close-out visit will be made on a pass-through basis and upon receipt of invoice.

CC.IDS PHARMACY - MONITOR/SPONSOR VISIT FEE (BEYOND 1 HOUR)

Each pharmacy monitoring visit will be reimbursed One Hundred Fifty-Eight Dollars (\$158 USD), [which includes overhead] for each hour beyond the first hour, and will be made upon receipt of invoice.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

All payments for this Study in accordance with the attached Budget will be paid by IQVIA by check and shall reference the Principal Investigator name, Sponsor name and Protocol.