CLINICAL STUDY AGREEMENT
(US Institutions Only)

Effective Date:	Date of Last signature hereto
Sponsor:	Alnylam Pharmaceuticals, Inc.
CRO:	PPD Investigator Services, LLC
Institution:	Cook County, through its Cook County Health & Hospitals System, d/b/a Cook County Health
Principal Investigator:	Aviral Vij MD, an employee of Institution
Study Drug:	Nucresiran (ALN-TTRSC04)
Protocol Name:	TRITON-CM: A Phase 3 Global, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Nucresiran in Patients with Transthyretin-Mediated Amyloidosis with Cardiomyopathy (ATTR amyloidosis with cardiomyopathy)
Protocol Number:	ALN-TTRSC04-003

THIS CLINICAL STUDY AGREEMENT (the "**Agreement**"), effective as of the date indicated above ("**Effective Date**") is entered between Alnylam Pharmaceuticals, Inc. with an address at 675 West Kendall Street, Cambridge, Massachusetts 02142 ("**Sponsor**") and Cook County, through its Cook County Health & Hospitals System, d/b/a Cook County Health, located at 1901 W. Harrison Street, Suite 3620, Chicago, Illinois 60612 ("**Institution**").

WHEREAS, Sponsor conducts business in the research, development, manufacture and sale of pharmaceutical products, including the conducting clinical studies in connection with such business;

WHEREAS, Institution has the skills, knowledge, expertise and resources to conduct clinical studies;

WHEREAS, Aviral Vij MD is employed by Institution and shall serve as "**Principal Investigator**" for this Study (defined below in Article 1); and

WHEREAS, PPD Investigator Services, LLC, with an address at 929 N Front St. Wilmington, NC 28401 ("**CRO**") is arranging and administering the Study to evaluate Sponsor's Study entitled "TRITON-CM: A Phase 3 Global, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Nucresiran in Patients with Transthyretin-Mediated Amyloidosis with Cardiomyopathy (ATTR amyloidosis with cardiomyopathy)" ("**Study**"), with Protocol number ALN-TTRSC04-003 ("**Protocol**") and Sponsor and CRO have entered into an agreement concerning the management of the Study, authorizing CRO to serve as Sponsor's designee for certain services and to assume obligations as applicable under this Agreement, including but not limited to the execution of this Agreement for and on behalf Sponsor.

NOW THEREFORE, in consideration of the promises and mutual covenants herein contained, the parties agree to the following:

Article 1. Conduct of the Study

1.1 **Protocol.** Performance under this Agreement is expressly conditioned upon the approval of the Study (hereinafter defined) from Institution's Institutional Review Board ("**IRB**"). The Study will be

conducted at Institution under the direction of Principal Investigator. Institution shall conduct the Study in accordance with the above-referenced protocol and any subsequent amendments thereto, as approved by Institution. In addition, the Principal Investigator, Sub- Investigator (as defined below) and Study Personnel (as defined below) shall comply with any reasonable written instructions provided to Institution by Sponsor. A copy of the Protocol will be provided to the Institution and the Principal Investigator under separate cover and is hereby incorporated by reference into this Agreement. The Protocol fully details the clinical research activities and responsibilities to be undertaken, pursued, and followed with all due diligence by the Institution. The Protocol will be considered final after it is signed by the Sponsor and Principal Investigator and approved by the IRB. Thereafter, the Protocol may be amended only by prior written consent of Sponsor and subsequent approval by the IRB. In the event of a conflict between the terms of the Protocol and the terms of this Agreement, the terms of the Protocol shall prevail regarding all clinical matters, and the terms of this Agreement shall prevail regarding all other matters.

1.2 **Study Personnel.** The Institution shall ensure that it, its affiliates, and their employees, agents, representatives, independent contractors or third-party entities who perform work or research activities in connection with the Study on behalf of the Institution (collectively, the "**Study Personnel**") shall comply with the applicable terms and conditions of this Agreement to the same extent as the Institution. Principal Investigator and any Sub-Investigator shall be considered Study Personnel. The Institution shall be responsible for the acts and omissions of Study Personnel. The Institution agrees that Study Personnel will not seek direct payment from Sponsor for services performed on the Study. The Institution agrees that neither Sponsor nor Sponsor's designee is under an obligation to make payments to Study Personnel under this Agreement.

1.3 **Compliance with Applicable Law.** The Institution and Sponsor agree to conduct the Study in compliance with the Protocol, as well as all applicable government laws, regulations and guidance's where the Study is being conducted, including to the extent applicable, the International Conference on Harmonization Good Clinical Practice ("**ICH GCP**") guidelines, U. S. Food and Drug Administration ("**FDA**") regulations and guidance documents governing the performance of clinical research, the Standard for Privacy of Individually Identifiable Health Information, the US Foreign Corrupt Practices Act of 1977, the UK Bribery Act of 2010 and other applicable Privacy Laws (as defined in Section 1.8), PhRMA's Principals on the Conduct of Clinical Trials, the Federal False Claims Statue (31 USC 3729) and Anti-Kickback Statute (42 USC § 1320a-7b), (collectively, "**Applicable Law(s)**"). The Principal Investigator will conduct the Study in accordance with the Statement of Principal Investigator, U.S. FDA Form 1572, as described in 21 C.F.R. 312.53, which the Principal Investigator for the Study shall complete, sign, and deliver to Sponsor or Sponsor's designee prior to the commencement of the Study. Sponsor reserves the right to terminate the Agreement in the event that the Institution breaches an Applicable Law, certifications herein, and/or if Sponsor learns that improper payments are being or have been made related to this Study by Institution or Principal Investigator or any individual or entity acting on its or their behalf.

1.4 **Compliance with Anti-Kickback laws**. Institution agrees, and Institution on behalf of Principal Investigator agrees that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation payable by Sponsor pursuant to this Agreement is (a) is not being given in exchange for, as an inducement to, or in any way in consideration for any explicit or implicit agreement to prescribe, purchase, use, or recommend for use Sponsor's products or to influence formulary, prescribing or dispensing decisions; (b) has not been determined in a manner that takes into account the volume or value of any referrals generated by Institution and/or the Principal Investigator; and (c) constitutes a fair market value for services performed under this Agreement. In addition, Institution on behalf of itself and Principal Investigator agree that it will not bill any Study Subject, insurer, and/or governmental agency for any visits, services, or expenses incurred during the Study for which they have already received compensation from Sponsor or any agent on its behalf, or

which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Principal Investigator will pay another physician to refer subjects to the Study.

1.5 **Compliance with Anti-Bribery Laws**. Institution certifies that payments or any clinical supplies or equipment received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Principal Investigator, Study Personnel, or any of their respective owners, directors, employees, agents, consultants, or any payee 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. Institution further certifies that neither it nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, including the Principal Investigator and Study Personnel 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 clinical supplies or equipment 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) with the corrupt intention of: inducing the Institution, the Principal Investigator, or any other government official to use their influence with a government or instrumentality for purposes of influencing any official act or decision (including a decision not to act) in their official capacity; or inducing the Institution, the Principal Investigator, or any other government official to perform any improper act or to secure any improper advantage in order to assist Sponsor in obtaining or retaining business for or with any party or other person, or in directing business to any party or any person.

1.6 **Compliance with Privacy Laws.** The Institution represents and certifies that both Institution and Principal Investigator are and will at all times be in compliance with all applicable state and federal privacy and data protection laws and regulations, including but not limited to Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") and comparable state laws and regulations ("**Privacy Laws**"). The Institution certifies that both Institution and Principal Investigator will maintain the required research authorization form and/or any other required forms for all subjects enrolled in the Study ("**Study Subjects**") as required to fully comply with the applicable local, state and federal privacy and data protection regulations, including but not limited to HIPAA. The informed consent must be the most current informed consent form approved by the IRB (and privacy board, as applicable) and Sponsor (the "**Informed Consent Form(s)**"), and shall contain language necessary to permit regulatory agencies, the IRB, and Sponsor to have full access to and use of Protected Health Information ("**PHI**"), as defined in HIPAA and its implementing regulations and official guidelines promulgated thereunder as set forth below. Institution shall maintain a process, including a process, including a Security Incident response plan, to actively monitor and detect a Security Incident involving personal data, including PHI and coded personal data, in Institution's possession, custody or control. ("Security Incident(s)") means any unauthorized access to, acquisition, alteration, destruction, modification, use or disclosure of personal data that affects Institution's systems or data, or that has an actual or potential negative impact on the Study, or on the security, integrity, availability or confidentiality of personal data. In the event of a Security Incident, Institution shall notify Sponsor no later than seventy-two (72) hours after the initial detection, and shall provide Sponsor with reasonable access to information regarding the Security Incident in order to comply with Applicable Law(s). Remediation of the Security Incident shall align with the obligations of Article 10.2 below.

1.7 **HIPAA Authorization.** The parties agree to comply with all laws relating to patient privacy applicable to such party. Without limiting the generality of the foregoing, Institution agrees to take acts reasonably necessary to ensure that it will be able to provide any and all Study Data to Alnylam, its affiliates and their representatives, collaborators and licensees. During the Study and following its completion or early termination, Sponsor and its designees will have the right to use Study Subjects' PHI, as permitted

under Applicable Laws and regulations, Informed Consent Form, and by a Study Subject's signed HIPAA authorization that is either part of such Study Subject's signed Informed Consent Form or a separately signed document (a "**HIPAA Authorization**"). Institution will ensure that a properly executed HIPAA Authorization is obtained from each Study Subject to document the Study Subject's express written authorization for the disclosure by Institution to Sponsor, its designees, and applicable regulatory authorities of such individual's PHI for the purposes contemplated under this Agreement, including for the purposes of conducting the Study, and inspecting records and facilities relevant to the Study. Each party will cooperate in the amendment of the HIPAA Authorization as may be necessary from time to time, to comply with HIPAA to the extent HIPAA applies to such party, and to ensure that Sponsor and its designees and applicable regulatory authorities can continue to receive and use PHI for the purposes contemplated by this Agreement. If a HIPAA Authorization form that is separate from the Informed Consent Form will be used by Institution for a Study, Sponsor will be entitled to review such HIPAA Authorization form prior to use by Institution for that Study, subject to subsequent approval by the IRB, if applicable.

Sponsor's ability to review PHI shall be subject to Applicable Laws and reasonable safeguards for the protection of Study Subject confidentiality and the Study Subjects' Informed Consent Form or HIPAA Authorization form.

1.8 **Principal Investigator/Sub-Investigator.** The Principal Investigator is responsible for the conduct of the Study at the Institution. Institution may appoint a secondary investigator ("**Sub-Investigator**") (as defined in 21 C.F.R. § 312.3(b)) that is reasonably acceptable to Sponsor to assist the Principal Investigator with the conduct of the Study, provided that the Principal Investigator will be the individual with primary responsibility for the conduct of the Study. In the event Principal Investigator becomes either unwilling or unable to participate in the Study, Institution will cooperate, in good faith and expeditiously, to find a replacement Principal Investigator acceptable to the Sponsor; however, Institution will ensure that the Principal Investigator shall continue to comply with obligations and conditions stipulated in this Agreement as applicable to the Principal Investigator. In the event the Parties cannot agree on an acceptable substitute within thirty (30) days, then either Party may terminate this Agreement upon written notice to the other Party. Institution's cooperation in finding an acceptable replacement does not negate its obligation to perform under this Agreement up to the date of termination.

1.9 **Institutional Review Board.** For the Study, Institution will coordinate with the relevant IRB to obtain the IRB's written approval of the Principal Investigator's conduct of such Study at Institution, including approval of the Protocol and Informed Consent Form to be executed by the Study Subjects. Institution will be responsible for providing Sponsor with a copy of each such approval, with the IRB. In addition, Institution and the Principal Investigator will coordinate with the IRB to obtain review and approval in writing of any amendments made to the Protocol. Institution will use reasonable efforts to ensure that members of the IRB agree to abide by the same obligations of confidentiality as those that apply to Institution and each Principal Investigator under this Agreement.

1.10 **Clinical Supplies & Equipment.**

(a) The Institution will: (a) account for all clinical supplies furnished by Sponsor or its designee; (b) keep a written inventory of any equipment supplied by Sponsor or its designee according to guidelines provided by the Sponsor or its designee; (c) comply with all Applicable Laws governing the disposition or destruction of the clinical supplies and/or return all unused clinical or other supplies provided by Sponsor or its designee at the conclusion of the Study, as directed by Sponsor; and (d) use the clinical supplies, Sponsor's

investigational product, Nucresiran (ALN-TTRSC04) ("**Study Drug**") and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all clinical supplies as specified by Sponsor and according to Applicable Laws and regulations, including storage in a locked, secured area at all times. Institution shall inform Sponsor within thirty (30) days of any expected change to the facility that could have an impact on the conduct of the Study.

(b) Equipment: Any materials and equipment supplied by Sponsor or its designee for use in the Study ("**Equipment**") will be used solely in connection with the Study and in accordance with any manuals or written instructions while in possession of the Institution. All Equipment shall remain the sole property of Sponsor or its designee. As long as the Equipment is in the possession of the Institution, Institution is responsible for any use, as well as any destruction or loss of such Equipment due to Institution's negligence. It is hereby agreed that such Equipment shall: a) be subject to removal at any time upon the Sponsor's or its designee's written demand, provided that such removal does not prevent the Institution from conducting the Study and carrying out their obligations under this Agreement; b) be used in accordance with any manuals or instructions while in the possession of the Institution; c) shall remain in the same condition, ordinary wear and tear excepted; and d) be clearly identified as the sole property of the Sponsor or its designee, as applicable, by clearly stating that it belongs to Sponsor or its designee in order to notify any third parties, including creditors, that the legal owner retains title thereto; and e) upon completion or termination of the Study, Sponsor or its designee, together with Institution assistance, shall arrange, at Sponsor's reasonable expense, the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the Sponsor or its designee in writing, arrange for the disposal of the Equipment as soon as reasonably practicable time upon the Sponsor's or its designee's demand provided that such removal does not prevent the Institution from conducting the Study and carrying out their obligations under this Agreement,. If Sponsor or its designee does not provide written return/shipping instructions or a written disposal authorization within ninety (90) days after the Study has completed or terminated, and thirty (30) days after Institution provides a follow up written notice to Sponsor in accordance with the notice section, and the Equipment is available for return, then Sponsor shall be deemed to have authorized Institution to dispose of the Equipment in accordance with Institution policy and Applicable Laws.

1.11 **Electronic Data Capture.** Institution shall report to Sponsor or its designee all information and data obtained as a requirement of the Protocol, submit to Sponsor or its designee completed electronic case report forms ("**e-CRF**") resulting from the Study, and retain all necessary records and documents about the Study as required by regulatory requirements, this Agreement, and/or the Protocol. Regarding Electronic Data Capture ("**EDC**"), the Institution shall: (a) enter all data related to the Study onto the appropriate e-CRF pages using the EDC system within five (5) business days of a Study Subject's last completed Study visit; (b) promptly assist the Sponsor or its designee from time-to-time to obtain data collected on a worksheet/questionnaire (e.g., MPN-SAF, local laboratory data) or other medium prior to entry onto the e-CRF page(s) in the EDC system or transmission to a vendor, as appropriate; (c) review all e-CRF pages for accuracy and completeness; (d) comply with the use of technology and/or Equipment as requested by Sponsor or its designee intended to facilitate the collection of data and conduct of the Study (e.g., Interactive Voice Response System (IVRS), handheld electronic diary issued to Study Subjects for the collection of information pertaining to the symptom(s) attributed to their disease), and (e) maintain and store medical records and Data (as defined below, in Section 6.3) 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 industry standards. Queries regarding EDC shall be addressed within five (5) business days and resolved within five (5) business days of issue, unless pending Sponsor interim analysis or data lock. Institution shall reasonably seek to resolve interim analysis or data lock queries within 5 days from issuance.

1.12 **Protocol Deviations.** Prior to the commencement of a Study, the Institution shall and shall ensure that the Principal Investigator shall review the Protocol and Principal Investigator's brochure, and Institution shall notify Sponsor or its designee promptly if it or the Principal Investigator cannot comply with any of the terms contained therein. If, in the course of performing the Study, generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the Study Subjects require a deviation from the Protocol, the party aware of the need for a deviation shall promptly notify Sponsor of the facts supporting such deviation as soon as the facts are known to said party. Said notification shall be followed by written confirmation of same. Notwithstanding the foregoing, if, during the performance of the Study, an emergency deviation from the Protocol is necessary to eliminate an immediate hazard to a Study Subject as provided under ICH-GCP 2.5, the Principal Investigator will promptly notify Sponsor or its designee of the necessary deviation, and such deviation will not constitute a failure to comply with the Protocol. Deviations, in and of themselves, made for the benefit, well-being and safety of the Study Subjects, may not constitute negligence, error, omission, or a breach of Institution's obligations under the Agreement.

1.13 **Adverse Event Reporting.** In the event of an adverse event, whether considered serious or not, as defined in the Protocol and by Applicable Laws, the Institution shall promptly and fully comply with all the notification procedures, time frames and requirements stated in the Protocol in accordance with Applicable Laws. Notwithstanding the foregoing, Institution, Principal Investigator, Sub-Investigator and/or Study Personnel shall submit a report to Sponsor within twenty-four (24) hours of the occurrence of any serious adverse event.

1.14 **AAHRPP Commitments.** During the conduct of the Study and for two (2) years following completion of the Study at Institution, Sponsor agrees to notify Principal Investigator in writing promptly of information (such as Study results or findings from a Study monitoring visit), including results obtained after completion or closure of the Study that could affect the safety or medical care of current or former Study Subjects, influence the conduct of the Study, or alter the IRB's approval. Institution, through the Principal Investigator and/or IRB as appropriate, shall be responsible for informing Study Subjects of the above important information they learn from Sponsor in accordance with the IRB-approved Informed Consent Form and Sponsor shall not contact them. No other provision of this Agreement shall be construed to override the provisions of this Section. The terms of this Section shall survive expiration of this Agreement.

1.15 **Biological Samples.** The Institution will use any blood, fluid, and/or tissue biopsy samples collected from Study Subjects ("Biological Samples") in accordance with the Protocol and in compliance with Applicable Laws. The Institution shall not collect and/or reserve additional quantities of Biological Samples for use in research not described in the Protocol. Sponsor may use such Biological Samples as permitted in the Informed Consent Forms signed by Study Subjects and in accordance with Applicable Law.

Article 2. Reports, Records, Monitoring and Regulatory Inspections

2.1 **Reports.** The Institution shall provide Sponsor or its designee with periodic reports during the course of the Study as are (a) requested by Sponsor or its designee, and (b) required by the Protocol, as well as a final report of the Study at the conclusion of the Study.

2.2 **Records.** Institution shall (i) provide truthful and complete documentation supporting, in reasonable detail, the work performed and any expenses incurred under this Agreement; (ii) maintain true, accurate, and complete invoices, reports, statements, books, and other records related to work performed and any expenses incurred under the Agreement; and (iii) retain such records for a period as required by Applicable Law or ten (10) years following the completion of the Study, termination of the Agreement or longer as required by Applicable Law or by Sponsor.

2.3 **Right to Monitor and/or Audit.** At mutually agreeable times and no less than forty-eight (48) hours' notice to the Director of the Clinical Research Office, Sponsor and its designees shall have the right to monitor or audit, with direct access, the Institution's facilities and records, records referenced under this Agreement and medical records (including paper and/or electronic medical records) related to the Study. Sponsor must abide by Institution's policies, provided that such policies do not restrict or interfere with Sponsor's regulatory or contractual rights to monitor and audit the Study. Institution agrees to make such policies available to Sponsor in advance, and all Applicable Laws and regulations regarding patient records, and where applicable, patient authorizations/Informed Consent Forms, while on Institution's premises. Any copies of material related to the audit or inspection provided by Institution to Sponsor will be redacted to protect third-party confidentiality. Institution reserves the right to prohibit any person from entering its or other Institution facilities who violates these policies. Institution and its Study Personnel shall make itself available and shall reasonably cooperate with Sponsor and its designees with respect to such inspection, preparation, audit and monitoring visits.

Notwithstanding the foregoing, Sponsor reserves the right to monitor or audit the Institution at any time (both parties shall reasonably agree on an audit date and time) if Sponsor learns, or suspects, that misconduct has been committed by Institution or Principal Investigator or any individual or entity acting on its or their behalf.

In addition, Institution shall permit, during the term of the Agreement and for five (5) years thereafter, or longer if required by Applicable Law, Sponsor's internal and external auditors, external legal and consulting support, and internal legal and compliance function personnel, to access any relevant books, documents, papers, and records of Institution directly related to transactions related to this Agreement.

2.4 **Regulatory Authority Inspections and Institutional Review Board (IRB).** The Institution shall notify Sponsor promptly by telephone or e-mail if a governmental or regulatory authority ("**Regulatory Authority**"), including, but not limited to, the FDA, or the governing IRB, requests permission to or does inspect the Institution's facilities or research records relating to the Study under this Agreement. Institution shall keep Sponsor fully and timely informed of the nature, on-going status and outcome of any such inspections and IRB review to the extent allowed by law. Institution and its Study Personnel shall make itself available and shall reasonably cooperate with Regulatory Authority, IRB and if applicable, Sponsor and its designees, with respect to such inspections and IRB review, inspection/review preparation, audit and monitoring visits. Institution will allow Regulatory Authority inspectors and IRB reviewers to have direct access to the Institution's facilities and records, including, but not limited to, records referenced under this Agreement and medical records (including paper and/or electronic medical records). If legally permitted, appropriate and practicable, Institution will permit Sponsor to be present and will provide in writing to Sponsor copies of all materials, formal correspondence, statements, forms and records which the Institution receives, obtains, or generates pursuant to any such inspection or IRB review, including findings and reports relating to the Study under this Agreement. Should the inspecting agency issue findings, reports and/or Sponsor-related findings, the Institution shall provide such findings or reports to the Sponsor and allow input on responses from the Sponsor, provided that the Institution shall decide the final content of any response

Article 3. Consideration and Expenses

3.1 In full consideration for the conduct of a Study by the Institution, and for all resources, including Study Personnel, provided by the Institution for the Study, Sponsor through its administrative payment agent, which could be a designated CRO ("**APA**") agrees to pay the payee in accordance with the budget

and schedule attached hereto as Schedule A and incorporated herein by reference ("**Schedule A")**. The designated APA and designated accepter of funds under the Agreement ("**Payee**") shall be designated under Schedule A. Payment of these expenses and funds will be made according to the schedule of payments indicated in Schedule A and are dependent on data and information being provided or entered into the EDC system in accordance with Section 1.13. Each Schedule A will outline payment for research activities conducted under the Protocol, which will be made according to the payment schedule set forth therein. Institution agrees to submit detailed invoices in the format requested by Sponsor.

3.2 Except as set forth in Schedule A, payments will be made to Payee only for those Study Subjects who meet all of the applicable admission, inclusion and exclusion criteria of the Protocol.

3.3 Monies paid to the Payee will be deemed in full satisfaction of all work and research activities performed pursuant to this Agreement.

3.4 Total payments to Payee per Study Subject will not exceed the limit indicated in the applicable Schedule A.

3.5 Institution shall use reasonable efforts to ensure all invoices are submitted to Sponsor no later than ninety (90) days following completion of the Services. Sponsor shall not be obligated to pay invoices received more than nine (9) months after the performance of Services.

3.6 Notwithstanding the foregoing, or anything contained in the Protocol, if Sponsor terminates a Study prior to completion, Sponsor agrees through APA to pay the Payee funding set forth in the Schedule A for work properly performed prior to the effective termination date. In addition, Sponsor, through its APA, agrees to pay the Payee all non-cancelable obligations as set forth under Schedule A that the Institution incurred in furthering the Study prior to the effective date of termination. In no event, however, will the amount paid by Sponsor upon premature termination exceed the total contract amount set forth in Schedule A. Payment by Sponsor through APA will be made within sixty (60) days of the effective termination date, defined in Article 9 below.

3.7 In the event there is a refund due to Sponsor, at the time of premature termination by either party, the Payee agrees to remit the same to Sponsor or its designee within sixty (60) days of the effective termination date.

3.8 Upon completion of the Study or termination of this Agreement, in no event shall Sponsor be obligated to pay any invoices submitted after the time period for submitting final invoices set forth in Schedule A has expired.

3.9 To facilitate compliance with the Physician Payments Sunshine Provision of the Affordable Care Act (Section 6002) and applicable state laws, including publication on publicly available websites, as applicable, in addition to the fees and expenses designated in Schedule A:

(a) Sponsor, through APA, will provide or reimburse Institution for Equipment, supplies, instrumentation, staffing services, compounds, drugs, devices, data processing services, data analytics services, computer hardware and software, laboratory testing services, specimen management services, and any other items or services which: (1) are necessary and appropriate to conduct the Study in accordance with the Protocol; (2) are not to be used for any other purpose; and (3) have been pre-approved for reimbursement by Sponsor or its designee in writing. When Institution has received prior written approval to purchase an item or service, Institution agrees to submit detailed invoices in a mutually agreed upon format for reimbursement of any such expenses within thirty (30) days of the procurement. 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.

(b) Sponsor, through APA, 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 Principal Investigator and Study Personnel in association with such individuals' attendance at Principal Investigator meetings regarding the Study in accordance with Sponsor's policies, procedures and guidelines. Institution agrees to submit detailed invoices in a mutually agreed upon format for reimbursement of any such expenses within thirty (30) days of the date of the meeting.

(c) In accordance with Applicable Laws, regulations and industry codes wherever such codes are applicable to Alnylam legal entities, the disclosure of transfers of value from pharmaceutical manufacturers to Healthcare Organizations (HCOs), may be required.

Pursuant to the above, Institution on behalf of itself and Principal Investigator acknowledge and agree that Sponsor may have certain disclosure and reporting obligations pursuant to such Applicable Laws, regulations and relevant industry codes, including, but not limited to, the disclosure and reporting of fees and amounts payable to Institution, Principal Investigator, Sub-Investigator and any applicable Study Personnel under this Agreement, as well as other relationships with healthcare providers and other institutions. Accordingly, Institution shall report to Sponsor any such information as needed to be compliant with its reporting obligations under Applicable Laws and industry codes, including but limited to monetary funding and non-monetary benefits received, fees and any other direct or any indirect costs paid by Sponsor under this Agreement. Sponsor shall have the right to review receipts and other documentation of Institution, Principal Investigator, Sub-Investigator, and Study Personnel related to such information subject to its reporting obligations, and Institution agrees to supply information reasonably requested by Sponsor for these disclosure purposes. Information on data collection requirements and reporting obligations can be obtained by contacting transparency@alnylam.com. Institution agrees that Sponsor and its affiliates may, in their sole discretion, disclose information about this Agreement and about any Study, including information relating to any transfers of value pursuant to any Study. To the extent that Institution or any Principal Investigator is independently obligated to disclose specific information concerning a Study, including relating to transfers of value from Sponsor or its affiliates pursuant to this Agreement, Institution and such Principal Investigator will make timely and accurate required disclosures.

Article 4. Publicity

No party to this Agreement shall use the other party's name or the name, the name of the other Party's employee, logo, trademark, symbol or other image of any party hereto or such party's employees in connection with any advertising or promotion of any product or service without the prior written permission of such party. Institution's Chief Communications and Public Relations Officer will have to agree to such use. Both parties shall be able to disclose the following: Sponsors name, Protocol title, and funding amount to meet its reporting requirements, for funding applications, and to post on the clinical trials directory/website.

Article 5. Publications

5.1 If the Study is a multi-center study, the Institution for itself and on behalf of its Principal Investigator agrees that Sponsor shall have the right to the first publication of the results of the Study and that under no circumstances shall any publication occur prior to the conclusion 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 Study results made by Sponsor in

conjunction with the participating principal investigators and Institutions contributing data, analysis and comments, as appropriate. In the event of a disagreement among the principal investigators in a multi-center study, the lead Principal Investigator and a representative of Sponsor shall serve as co-arbiters of such dispute. All authors must meet authorship criteria as outlined by the International Committee of Medical Journal Editors (ICMJE). Institution shall fully and accurately give appropriate acknowledgment to the scientific contributions made by Sponsor personnel, including all necessary disclosures under the guidelines of the applicable journal.

5.2 However, following the earlier of the first publication, or if a multi-center publication is not submitted within the earlier of: (a) eighteen (18) months after Study conclusion; (b) eighteen (18) months after abandonment or termination of the Study occurs at all Study institutions; or (c) if Sponsor confirms in writing there will be no multi-center Study publication, then the Institution and/or Principal Investigator may publish the Study results subject to Sponsor's rights as set forth below:

(a) Institution agrees to notify Sponsor of the intent by it or Principal Investigator to submit a publication at least forty-five (45) days prior to the proposed submission date; such notification shall include a brief overview of the key points of the intended publication and shall formally submit to Sponsor all proposed publications, if applicable, which by definition shall include, but are not limited to, manuscripts, abstracts, posters, slides, and/or other written materials related to the Study at least thirty (30) business days before the submission of the contemplated publication or abstract or the start date of the congress/meeting for presentations of posters and/or slides. During such thirty (30) business-day period, Sponsor shall have the opportunity to review and comment upon the contents of the publication with regard to Sponsor's confidential and proprietary information, as well as the accuracy and completeness of the clinical and scientific observations contained therein. Sponsor may remove from the proposed publication any specifically identified sponsor Confidential Information that is not considered Study results generated by the Institution. Institution agrees to discuss and consider in good faith any Sponsor comment with regard to the accuracy and completeness of the clinical and scientific observations contained therein and, upon request, to submit written responses to specific Sponsor comments or questions regarding accuracy or completeness prior to submission of proposed publications.

(b) In the event Sponsor determines that an enabling description of patentable subject matter is contained in such material or outline, it shall notify the Principal Investigator and the Institution within the thirty (30) business-day period, and the publication or disclosure will be withheld for a reasonable period of time, not to exceed ninety (90) days from the date the Principal Investigator and the Institution first submit to Sponsor the materials proposed for submission for publication/presentation to permit appropriate patent application(s) to be prepared and filed by Sponsor, if it so elects.

(c) The Institution agrees that neither Institution nor its Principal Investigator shall publish or publicly present any interim results or analyses using Data.

(d) The Sponsor will report the results of the Study publicly to the extent required by Applicable Laws.

5.3 Sponsor will be solely responsible for the submission of Study-related information to ClinicalTrials.gov and other public databases. Institution acknowledges and agrees that Sponsor may describe the nature of contractual arrangements for each Study in such databases.

Article 6. Rights to Study Drug, Sponsor Information, and Study Data

6.1 Study Drug shall be, is and will remain, at all times, the exclusive property of Sponsor. Sponsor will provide Institution with the required quantities of Study Drug for the sole purpose of conducting the Study. Institution shall handle and store the Study Drug(s) in accordance with the Protocol, written instructions provided to Institution, and all Applicable Laws. All unused Study Drug or other study drug or placebos, shall be destroyed or delivered to Sponsor or its designee upon Sponsor's request and at Sponsor's expense.

6.2 All results, documents, data, know-how and formulas provided to the Institution and/or Principal Investigator for purposes of a Study under the terms of this Agreement ("**Study Information**") shall be, are and will remain Sponsor's property.

6.3. All results, documents, data, know-how and formulas resulting from a Study, including, without limitation, reports (e.g., e-CRFs, any data summaries, any interim reports and the final report) ("**Data**") shall be, are and will remain Sponsor's property, and Sponsor will have the right to use the Data, including results of the Study, in any manner deemed appropriate to Sponsor's business interests. Original medical records and source documents of Study Subjects are the property of the Institution. The Institution will have the non-exclusive right to use Data from the Institution for its internal, non-commercial purposes for research, education and patient care.

Article 7. Intellectual Property

7.1. **Materials**. All documentation, information, Equipment or materials furnished by or on behalf of Sponsor for a Study, including Study Drug (collectively, together with all associated intellectual property rights, the "**Materials**") will remain the exclusive property of Sponsor. Institution and the Principal Investigator will use Materials only as necessary to conduct that Study. Institution and the Principal Investigator will not analyze Materials except as necessary to conduct such Study and will not transfer or make the Materials available to third parties, without the prior written consent of Sponsor.

7.2 **Ownership and Inventions.** Other than the specified rights to use the Data and publish the Study results specifically set forth in Article 5 and Article 6, respectively, or as otherwise set forth herein, neither Institution nor its Study Personnel, shall acquire any rights of any kind whatsoever with respect to the Data or Study Drug as a result of performance under this Agreement or otherwise. All inventions, ideas, developments, discoveries know-how,, and technology, whether patentable or not, created in the performance of the Study, including by Institution, Investigator, and Study Personnel, solely or jointly, which relate to the Study Drug, Confidential Information or Materials ("**Inventions**") shall be, and remain, at all times the sole and exclusive property of Sponsor. The Institution, shall and shall ensure that its Principal Investigator and Study Personnel, as applicable, shall assign and hereby do assign to Sponsor the entire right, title and interest in and to all Inventions. Any and all acts necessary to assist Sponsor in perfecting its right to any and all Inventions shall be performed by the Institution, at Sponsor's expense. Institution certifies by the execution of this Agreement, that it has not knowingly entered, and will not knowingly enter, into any contractual agreement or relationship which would compromise Sponsor's proprietary interest in, or rights to, any inventions, discoveries, or technology related to this Study.

7.3 The Institution shall disclose to Sponsor all Inventions. Such disclosure shall be made fully and promptly in writing to an authorized representative of Sponsor. Institution may use Inventions solely created by the Institution for its internal non-commercial research and education purposes, subject to the confidentiality terms herein.

Article 8. Debarment

8.1 The Institution hereby certifies that neither it nor any of its employees, agents or other persons providing services in connection with this Study, including the Principal Investigator and Study Personnel:

(a) have been debarred or threatened with debarment, disqualified or banned by the FDA from conducting clinical trials;
(b) is currently under investigation for debarment, disqualification, or any similar regulatory action by FDA, any equivalent regulatory authority outside the U.S., or a professional body with respect to the performance of the Study; or
(c) is otherwise ineligible to participate in federal health care, procurement, or non-procurement programs, has been convicted of a criminal offense that requires exclusion from a federal health care program, or is otherwise disqualified or suspended from performing the Study. If Sponsor receives notice from Institution or otherwise learns a debarment action has been brought against Institution and/or any Institution personnel, or that Institution or any Institution personnel is threatened with a debarment action then Sponsor may terminate this Agreement immediately upon written notice to Institution.
(d) Sponsor certifies that it has not been excluded from participation in any governmental healthcare program

Article 9. Term and Termination

9.1 This Agreement will become effective upon the Effective Date and shall continue in effect until the completion of the Study at Institution, unless sooner terminated in accordance with the provisions of this Article.

9.2 If Sponsor materially breaches the terms of this Agreement and fails to cure such breach within thirty (30) days after receipt by Sponsor of written notice from Institution specifically describing the breach, or fails to commence to cure such breach within such thirty (30) day period if breach is not susceptible to cure within thirty (30) days, Institution may terminate the Study and this Agreement upon subsequent written notice to Sponsor delivered in accordance with the terms of this Agreement. an early termination under Section 9.2, for the affected Study (a) the Principal Investigator will promptly stop enrolling subjects into the Study and cease administering Study Drug to Study Subjects and conducting Study procedures on Study Subjects, to the extent medically advisable; (b) Sponsor will pay all reasonable costs accrued by Institution in the performance of the Study as of the date of notice of termination, in accordance with the Study Budget, including non-cancelable obligations incurred prior to the date of notice of termination; (c) any funds not due under the foregoing calculation but already paid by Sponsor to Institution will be promptly returned to Sponsor within sixty (60) days of written notice; and (d) Institution will (i) furnish to Sponsor, within thirty (30) days of the effective date of termination, T, all Data, resolve all queries, and all completed or partially completed CRFs and (ii) in accordance with Sponsor's instructions and at Sponsor's reasonable expense, deliver to Sponsor or, at Sponsor's option, dispose of, all Materials and Confidential Information (as defined below in Article 11) furnished by Sponsor or its designees to Institution or the Principal Investigator, except for records or Biological Samples that Institution and/or the Principal Investigator are required by law to retain.

9.3 Termination of this Agreement by any party or by Sponsor's designee as applicable for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement.

9.4 Upon termination of this Agreement or completion of the Study, the Institution shall return to Sponsor, or Sponsor's designee, all unused compounds, drugs, devices, Equipment, and related materials

and all copies of Confidential Information that were furnished to the Institution or the Principal Investigator at Sponsor's expense under this Agreement, except for one (1) copy of Confidential Information retained by the Institution for the purpose of monitoring its obligations and exercising its rights under this Agreement and one (1) archival copy of any document which Institution is required to maintain by law.

9.5 **Survival.** No termination of this Agreement, however effectuated, will release the parties from their rights and obligations accrued prior to the effective date of termination. The rights and obligations of Sponsor and Institution which, by intent or meaning, have validity beyond termination of this Agreement, including, but not limited to the rights and duties under Sections 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, and 16 will survive the termination of this Agreement regardless of the cause.

Article 10. Indemnity, Insurance and Study Subject Injury.

10.1 **Sponsor Indemnification.** Sponsor agrees to indemnify, defend and hold harmless Institution, its affiliated entities, Principal Investigator, and Institution's directors, officers, trustees, agents, employees, and Study Personnel (each an "**Institution Indemnitee**") against any liabilities, damages, losses, costs, third party cause of action, claim, lawsuit or other proceeding, and reasonable expenses, including reasonable legal fees, brought against any Institution Indemnitee seeking compensation arising from: a) the conduct of the Study in accordance with the Protocol; b) Sponsor's and/or CRO's use of Data provided to it under this Agreement, c) Sponsor's negligence, willful misconduct, and breach of the Agreement and Applicable Laws, and d) any claims, actions, or damages related to any breach of representation or warranties by Sponsor (collectively, "**Claim**"). Institution Indemnitee shall promptly notify Sponsor in writing upon receipt of notice of any Claim and shall not make any admission of liability. Institution will be responsible for Claims arising from its and the Principal Investigator's negligence and willful misconduct."

10.2 **Notice of Election.** The Cook County States Attorney will have the option to either: (a) accept the defense of the Institution Indemnified Party by the Sponsor, in which case Sponsor will provide qualified attorneys, consultants and other appropriate professionals, to represent the interests of the Institution Indemnified Party; or (b) authorize the Institution Indemnitees to undertake its own defense and at Institutions own expense, in which case the Institution Indemnified Party will provide its own qualified attorneys, consultants and other appropriate professionals to represent its interests. Institution will provide notice to the Sponsor of the option it elects no later than thirty (30) days following the date of Institution's notice to Sponsor of an Indemnification Claim Under option (a) Sponsor will be responsible for and pay the reasonable fees and expenses of such attorneys, consultants and other professionals in the investigation, trial and defense of the Indemnification Claim and any appeal arising therefrom Sponsor Undertakes Defense. If Sponsor undertakes the defense of the Institution Indemnified Party, the CCH Indemnified Party will cooperate, at Sponsor's cost and expense, in all reasonable respects with Sponsor and its attorneys in the investigation, trial and defense of the Indemnification Claim and any appeal arising therefrom; provided the Institution Indemnified Party may, at its own cost and expense, participate through its attorneys or otherwise in such investigation, trial and defense of the Indemnification Claim and any appeal arising therefrom. Sponsor will not admit liability or settle any Indemnification Claim that involves a remedy other than the payment of money without the Institution Indemnified Party's prior written consent which shall not be unreasonably withheld or delayed.

Failure to Notify or Otherwise Perform. Any failure by Institution or a Institution Indemnified Party to provide notice of Indemnification Claim to or cooperate with Sponsor, as contemplated in this Section, will reduce Sponsor's indemnification obligations only to the extent Sponsor is prejudiced thereby.

10.3 **Sponsor Insurance.** Sponsor agrees to procure and/or self-insure and maintain the kind(s) of insurance in the minimum amounts of coverage set forth below to cover damages for which Sponsor may be legally liable for bodily injury, including death resulting therefrom, and injury to or destruction of property caused by or arising from its obligations hereunder:

(a) Commercial General Liability insurance, including premises and operations liability and liability arising out of insured contracts, as more specifically defined in the policy form, in amounts not less than ten million dollars ($10,000,000) per occurrence and ten million dollars ($10,000,000) in the annual aggregate. Such stated limits of liability may be satisfied by a combination of primary and excess/umbrella policies.

(b) Products Liability insurance, including Human Clinical Trials, in amounts not less than ten million dollars ($10,000,000) per occurrence and ten million dollars ($10,000,000) in the annual aggregate.

Upon request, Sponsor will provide Institution valid certificates of insurance for the coverages required pursuant to the preceding paragraphs. Each certificate will endeavor to provide that the holder thereof be given at least thirty (30) days written notice prior to cancellation of such insurance.

10.4 **Institution Insurance.** Institution represents and certifies that it is self-insured and Institution's self-insurance is sufficient to meet the required limits set forth above.

10.5 **Subject Injury.** Sponsor further agrees that if a Study Subject enrolled in the Study according to the Protocol suffers an injury, provided such injury is not caused by an Institution or Study Personnel's negligence or willful misconduct, breach of the Agreement or failure to adhere to the Protocol, Sponsor will provide payment for the patient's medical expenses for treatment for injuries if: (a) the patient received reasonable medical care; (b) the injury was caused by the administration of the Study Drug or properly performed Study procedures that are not part of the patient's usual medical care; and (c) such injuries are not the result of the natural course of any underlying disease and/or pre-existing disease process present prior to the proper administration of the Study Drug. Any payment shall not be an admission of wrongdoing on the part of the Sponsor. In addition, Institution acknowledges that, pursuant to Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007, Sponsor may have an obligation to confirm the status of and submit certain reports to the Centers for Medicare & Medicaid Services with respect to, Medicare beneficiaries who participate in the Study. This federal law reporting obligation applies when Sponsor agrees to reimburse for subject injury expenses. Subject to Applicable Law, Institution agrees to (and will direct the applicable Principal Investigator to) provide Sponsor, through its authorized representatives, personal information relating to Study Subjects, and to otherwise cooperate with Sponsor, as reasonably necessary for Sponsor to meet its Section 111 reporting obligations.

Article 11. Confidential Information

11.1 **Non-Disclosure and Non-Use Obligation.** Any and all information, whether written, oral, or in any other form, , which is: 1) "Sponsor will endeavor to mark and identify tangible Confidential Information provided to Institution as "Confidential" and to confirm verbally disclosed Confidential Information as "Confidential" in writing within a reasonable period of time after the disclosure, provided that Institution, Study Personnel and Principal Investigator confirm and agree that Sponsor's failure to identify any information as Confidential Information in writing shall not constitute a designation of non-confidentiality when the confidential nature is apparent from the context and subject matter, when the information relates to the Study Drug, the Protocol the Study design or the terms hereof, or when the information is such that a reasonable person would consider it to be proprietary or confidential." (2) Study Information and Data ("**Confidential Information**") shall be received and maintained in confidence and not disclosed to any

third party during the term of this Agreement and for seven (7) years thereafter. Furthermore, the Institution agrees that such Confidential Information shall only be used for the purposes of this Agreement except as provided for herein. The Institution may disclose Confidential Information to the Study Personnel who require access thereto for the purposes of this Agreement; provided that prior to making any such disclosures, each such Study Personnel shall be bound by obligations no less stringent than those contained herein, to maintain Confidential Information with the same standard of care the Institution applies to its own confidential information of a similar nature, but in no event less than a reasonable degree of care, and not to use such information for any purpose other than in accordance with the terms of this Agreement.

The obligations of confidentiality and non-use herein shall not apply to the extent Confidential Information, which at the time of disclosure:

(i) is generally available in the public domain, or becomes available to the public through no breach of the Agreement of Institution Principal Investigator, or Study Personnel;
(ii) is independently known by Institution, Principal Investigator, or Study Personnel as evidenced by Institution's written records;
(iii) is received by a third party who has a right to disclose it to Institution, Principal Investigator, or Study Personnel free of confidentiality and non-use obligations; or
(iv) is independently developed by Institution, Principal Investigator, or Study Personnel without use of or reference to or reliance on such Confidential Information as evidenced by written records.

11.2 **Agreement Terms.** Schedule A of the Agreement will be considered Confidential Information to the extent permitted by law.

11.3 **Compliance with Applicable Law or Court Orders.** If the Institution or Study Personnel is required by Applicable Laws, government regulations or agency, subpoena, or court order to disclose such information, they may do so without breaching its obligation under this Section; provided, if legally permitted, in at least five (5) day's advance of disclosure, they notify Sponsor of the information to be disclosed to allow Sponsor to take appropriate actions.

Article 12. Assignment

12.1 **No Assignment Without Written Consent.** Neither Institution nor Principal Investigator may assign this Agreement or any associated agreements, without Sponsor's prior written consent. Any attempt made by Institution or Principal Investigator to assign or delegate this Agreement in violation of this Article 12 shall be of no force or effect.

12.2 **Sponsor Right to Assign.** Sponsor shall have the right to assign or delegate this Agreement or any portion thereof without the consent of Institution or Principal Investigator.

Article 13. Entire Agreement; Modification

This Agreement, together with all Schedules attached hereto, constitutes the final, complete and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes all prior understandings and agreements relating to its subject matter. Any agreement to change the terms of this Agreement in any way shall be valid only if the change is made in writing and approved by mutual agreement of authorized representatives of the parties hereto.

Article 14. Notices

Legal notices required or permitted hereunder shall be considered made and effective when deposited in the US mail, postage prepaid, or shipped by nationally recognized overnight courier service and addressed to the appropriate party at the address noted below, unless by notice to the other parties a different address shall have been designated.

If to Sponsor:	If to Institution:
Alnylam Pharmaceuticals, Inc 675 West Kendall Street Cambridge, MA 02142 USA Attention: Legal Department With a copy to: PPD Investigator Services, LLC 929 North Front Street Wilmington, NC 28401 Telephone: (910) 251-0081 Facsimile: (910) 762-5820 Attn: Project Manager	Cook County, through its Cook County Health & Hospitals System, d/b/a Cook County Health 1950 W. Polk Street, Suite 9816 Chicago, IL 60612

Article 15. Conflict of Interest

15.1 **No Conflicts of Interest.** The Institution agrees and shall ensure that the Principal Investigator and Sub-Investigator agree that they, as well as all Study Personnel, are not (i) presently under any agreement or obligation which prevent them from fulfilling their obligations under this Agreement.

The Institution shall ensure that Principal Investigator will submit required disclosure forms to Sponsor under 21 C.F.R. § 54.

During the conduct of the Study and for one (1) year after its completion, the Institution shall ensure that the Principal Investigator executes and updates such forms, disclosures and certifications now or subsequently required by per 21 CFR 54.

Article 16. Miscellaneous

16. 1 Sponsor acknowledges and agrees that Institution, as part of a public body is required to by law to comply with the Illinois Freedom of Information Act ("FOIA") (5 ILCS 140/1 et seq.). Sponsor hereby designates that any Confidential Information is confidential to the Sponsor shall be exempt from disclosure under § 7(1) (i.e. 5 ILCS 140/7(1)(b)), § 7(1)(g) (5 ILCS 140/7(1)(g)) or other applicable FOIA exemption. If any Sponsor Confidential Information is subject to FOIA request, Institution will respond to the FOIA request with the Sponsor-asserted FOIA exemption and withhold disclosure of the Sponsor Confidential Information. Institution will notify Sponsor of the FOIA request and may require Sponsor to submit further written justification of the Sponsor-asserted FOIA exemption. Failure of Sponsor to designate as exempt from disclosure under an applicable FOIA exemption shall not be conclusive that the information is not confidential and exempt from disclosure under FOIA. However, if Sponsor has not asserted exemption from disclosure for any Sponsor Confidential Information subject to FOIA request, Institution may determine whether Institution will or will not withhold the Sponsor Confidential Information in response

to the FOIA request. Institution will use best efforts to notify Sponsor of the FOIA request and give Sponsor three (3) business days from the notice date to assert an applicable FOIA exemption from disclosure. Additionally, Institution will not oppose any action of Sponsor to obtain a declaratory judgment, protective order or other appropriate remedy in response to a FOIA request of Sponsor Confidential Information. To the extent Institution is assessed attorneys' fees or court costs as a result of assisting Sponsor in asserting a FOIA exemption from disclosure of certain Sponsor Confidential Information, Sponsor will indemnify and hold harmless Institution from and against such reasonable expenses.

The Institution shall conduct the Study under this Agreement only as an independent contractor, and nothing contained herein shall be construed to be inconsistent with that relationship or status. The Institution, Principal Investigator, Sub-Investigators, and Study Personnel shall not be considered employees or agents of Sponsor and, as such, shall not be entitled to any benefits available to employees of Sponsor. This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

16.2 The parties agree to remain silent on governing law.

16.3 Titles to the Articles in this Agreement are solely for convenience and do not constitute a substantive part of this Agreement.

16.4 If any provision of this Agreement is held invalid or unenforceable, it shall be severed, and the remainder of this Agreement shall not be affected thereby, unless the part that is void substantially impairs the whole Agreement to either party.

16.5 The waiver of or acquiescence by any party hereto to any terms or provision hereunder, or the failure of any party to insist upon compliance with any certification, term, or condition in this Agreement, shall not constitute a waiver of any subsequent default or failure, whether similar or dissimilar.

16.6 Any administrative or financial additions or modifications to this Agreement will be incorporated by reference to this Agreement, as applicable, when mutually agreed to in writing.

16.7 This Agreement and any subsequent amendment(s) thereto may be executed in counterparts, and the counterparts, together, shall constitute a single agreement and shall become binding when any one or more counterparts hereof, individually or taken together, bears the signature of each of the parties hereto. A PDF electronic submission of this Agreement signed by a party's duly authorized representative shall be legal and binding on both parties.

16.8 The CRO represents that it is authorized by the Sponsor to execute this Agreement on behalf of the Sponsor.

[Signature Page Follows]

(*Signature page of a Clinical Trial Agreement*)

IN WITNESS WHEREOF, the parties hereto have entered into this Agreement effective as of the Effective Date.

PPD Investigator Services, LLC executing this Agreement for and on behalf of Alnylam Pharmaceuticals, Inc., under Authority to Execute Agreement between Alnylam Pharmaceuticals, Inc and PPD Development, L.P. dated 08NOV2024 By:	Cook County, through its Cook County Health & Hospitals System, d/b/a Cook County Health By: 
Printed Name:	Printed Name: Erik Mikaitis, MD
Title:	Title: CEO
Date:	Date: May 11, 2026

I have read this Agreement and acknowledge my obligations and responsibilities:

Aviral Vij

Principal Investigator

Printed Name: Aviral Vij

Date: May 8, 2026

Schedule A
Alnylam Pharmaceuticals, Inc. / ALN-TTRSC04-003
Budget and Payment Schedule

Payments: Payment should be made to the following:

Payee
Payee Name: Cook County Health Payee Address: 1901 W. Harrison Street, Suite 3620 Chicago, Illinois 60612 Bank Information (include address) and Account/Routing number as applicable: CitiBank 69 W. Washington St Chicago, IL 60602 Routing Number: 801593143 Account Number: 271070801 Remittance/ Payment Details email: Mohammad.jaffri@cookcountyhealth.org Aviral.Vij@cookcountyhhs.org Tax ID Number: 36-6006541

Institution may request to revise the payee details (such as Payee Address, Bank Information) provided herein during the course of the Study. In such cases, the parties agree that no amendment to this Agreement shall be required provided that Institution provides written notification to CRO with the revised payee details and, if applicable, a revised W-9. Notwithstanding the foregoing. Payee Legal Entities changes and/or Payee replacement shall require a formal contract amendment between parties. The parties further agree that CRO assumes no liability for incorrect payee details provided by Institution.

Invoices: Please send original, correct and itemized invoices to the following:

PPD Investigator Services LLC
Invoices should be addressed to: Alnylam Pharmaceuticals, Inc. 675 West Kendall Street, Cambridge, MA 02142 USA **Invoices should be sent for payment to:** PPD Investigator Services LLC by email at CRGInvestigatorPayments@thermofisher.com, or via mail at 929 North Front Street, Wilmington, NC 28401, USA.

Invoices: All invoices for Study payments, as outlined in the budget and payment schedule, should be submitted to CRO within 90 days following the occurrence of the applicable expense to ensure reimbursement for work performed. Invoices submitted for payment must be correct and include but not limited to:

- Protocol Number
- Institution Name
- PI Name
- Institution Invoice Number (if applicable)
- Itemized detail of costs
- Date of Invoice submission

Enrollment: Institution acknowledges that this is a Study designed to evaluate a set number of subjects. Institution will be expected to apply best efforts for enrollment as provided for under the Agreement. When enrollment of the target number of subjects for the entire Study is complete, Institution will be notified and instructed not to continue enrolling subjects.

The Study shall be payable as follows:

Cost per Subject: Institution will be reimbursed in accordance with the budget below. Payments will be made monthly on a per visit basis for scheduled study visits in USD and will be based on data entered in subject electronic case report forms (eCRF's).

Payments for conditional study procedures not included in the total visit cost in USD will be paid per occurrence based on data entered in subject electronic case report forms (eCRF's) and will not require an invoice to receive payment.

Payments for invoiceable study procedures not included in the total visit cost in USD will be paid per occurrence upon receipt of undisputed and itemized invoice.

Screen Failures: For purposes of this Agreement, a Screen Failure shall mean any subject, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes some or all of the pre-screening and/or screening visit but does not randomize into the Study. The Institution will be paid for all Screen Failures up to maximum of five (5) Screen Failures paid. The maximum number of Screen Failures may be increased by Sponsor and/or CRO upon written confirmation (email is sufficient) to Institution or Principal Investigator. Institution will be reimbursed for Screen Failures at the flat rate of the Screening Failure rate set forth in the Cost per Subject Budget based on data entered in eCRF's. Invoices are not required for payment of Screen Failure.

In addition, Institution will be reimbursed on a per procedure basis in accordance with the rates set forth in the Invoiceable Budget grid for the Screening Failure upon CRO's receipt of an undisputed and itemized invoice. Payment for Screen Failures will be payable on a quarterly basis in conjunction with the Institution's scheduled quarterly payment.

Repeated Screening Procedures: The Institution will be paid on a per procedure basis when a patient repeats screening procedures within the Protocol-defined screening window (45 days) with Sponsor/ CRO approval and enrolls into the study. Payment for repeat screening procedures will be paid based upon receipt of undisputed itemized invoice. Patients who repeat procedures within the Protocol-defined screening window but fail a second time shall be considered a Screen Failure.

Re-Screening: A Screen Failure may be rescreened 1 time at the Investigator's discretion, if at some point, in the future the Study subject is expected to meet the participant eligibility criteria following a discussion with the Medical Monitor. If the Study subject enrolls/randomizes onto the trial, Institution will be reimbursed on a per visit basis at the rate set forth in the Budget for the Screening Visit. Rescreened patient will be given a new participant number and the institution will be reimbursed based on data entered in subject electronic case report forms (eCRF's). If the rescreened patient fails after re-screening, the Screen Failure payment terms will apply.

Pre-screening Fee: Institution will be reimbursed for the time spent pre-screening potential patients for the Study. Institution will be paid per pre-screening patient at the rate set forth in the Study budget, up to a maximum of 15 patients. Additional pre-screening for reimbursement will need prior written approval from the Sponsor without need for amending the Agreement. Payment will be made upon receipt of an undisputed itemized invoice and the completed pre-screening log.

Study Start-up Fee: A one-time non-refundable payment of the rate set forth in the budget for Study start-up activities will be payable to the Institution upon full execution of the Agreement and site initiation visit, not to be unreasonably withheld. Payment will be automatic upon Institution activation.

Record Storage and Archiving: A one-time record storage and archiving fee at the rate set forth in the budget will be paid to the Institution for purposes of record retention as required by the Protocol or Applicable Law. Institution will be paid this fee automatically at study close out.

Pharmacy Start-up Fee: A one-time non-refundable payment of the rate set forth in the budget for Pharmacy start-up activities will be payable to the Institution upon confirmation of Ethics Committee approval, full execution of the Agreement, and completion of any pre-Study requirements as specified by Sponsor or CRO. Payment will be automatic upon Institution activation.

Equipment Allocation: Equipment may be provided to the Institution for use, in accordance with the Protocol, for this Study. If requested by CRO and/or Sponsor, such equipment shall be returned by the Institution at the completion of the Study.

IRB Fees: Central IRB is defined as the IRB selected by the Sponsor, and to whom CRO is making submissions on behalf of institutions using this Central IRB. Central IRB fees will be reimbursed directly to the IRB by CRO. Local IRB Fees will be submitted by the Institution and reimbursable directly to the Institution upon the receipt of undisputed, itemized invoices by CRO/Sponsor/Sponsor's designee.

Home Health Care Visits: CRO will not be responsible for payment of Home Health Care (HHC) visits. Payment for HHC visits incurred will be managed by a separate vendor. The vendor will contract directly with the Sponsor. CRO will reimburse Institution at the rate set forth in the budget for oversight and effort related to data entry for home visits completed by a HHC vendor.

Patient Travel and Meal reimbursement: CRO will not be responsible for payment of patient travel. Participant Reimbursement for travel expenses incurred during travel to study Institution for study visits will be managed by **Greenphire**. The vendor will contract directly with the Sponsor.

If the third-party vendor is not used to pay for travel expenses, CRO will reimburse patient travel expenses up to the amount set forth in the Budget per defined scheduled and unscheduled visit, to Institution for patient reimbursement upon receipt of undisputed itemized invoice and supporting

documentation by CRO. Any patient travel expenses reimbursement exceeding this amount must have received prior written approval from Sponsor in order to be eligible for payment. In the event that any patient travel expenses are paid by CRO to the Institution but not actually paid to the Study subject by the Institution, Institution will promptly refund that amount to CRO within 30 days of request.

Unscheduled Visits: An Unscheduled Visit is determined as a subject visit which is not expressly set forth in the Protocol but is otherwise required for the Study. Unscheduled Visits will be reimbursed at a flat rate at the rate set forth in the standard items per patient budget grid based on data entered in the eCRF's.

In addition, Institution will be reimbursed automatically on a per procedure basis in accordance with the rates set forth in the conditional budget grid based on data entered in the eCRF's.

In addition, Institution will be reimbursed on a per procedure basis in accordance with the rates set forth in the invoiceable budget grid based on CRO's receipt of an undisputed itemized invoice from Institution.

In the event a medically necessary procedure is not included in the Budget, Institution/Principal Investigator/Intervening Administrator must receive prior written approval from Sponsor or CRO before procedure is performed. Amount of compensation for a procedure not included in Budget will be approved at the time written approval is provided. Payment will be made upon CRO's receipt of an undisputed itemized invoice.

Early Termination Visits: Early Termination is defined as an enrolled subject who does not complete all standard visits per protocol. Early Termination visits will be reimbursed at the visit rates stated in the budget.

In addition, Institution will be reimbursed automatically on a per procedure basis in accordance with the rates set forth in the conditional budget grid based on data entered in the eCRF's.

In addition, Institution will be reimbursed on a per procedure basis in accordance with the rates set forth in the invoiceable budget grid based on CRO's receipt of an undisputed itemized invoice from Institution.

Dry Ice reimbursement: The purchase of dry ice for the shipment of frozen samples to the central laboratory will be payable at the rate set forth in the budget per shipment upon CRO's receipt of undisputed itemized invoice.

Vitamin A Supplement: Institution will be reimbursed for the actual costs incurred by the Institution plus overhead for supplying Vitamin A to the patients, upon CRO's receipt of an undisputed itemized invoice. The Institution shall obtain written approval from CRO or Sponsor prior to any purchase of a Vitamin A supplement.

Final Payment: The final payment will be payable upon completion of the close-out visit and upon receipt of the following: (i) all Study documentation, (ii) the accountability of all unused Study Drug, (iii) all completed and correct eCRFs/queries, (iv) completion of database lock and (v) any clarification requests made by CRO or Sponsor regarding Study data or records. Final invoices must be submitted to CRO within 60 days of Institution's Study close-out visit. Invoices received after this time may not be reimbursed. Final payment will be processed after final reconciliation is

performed and will include withholding and/or any outstanding payment to Institution. If Institution has no outstanding payment no additional payments shall be made.

No other additional funding requests will be considered without the prior written consent of Sponsor or CRO.

Trial Information

Trial Name: ALN-TTRSC04-003
Arm: Double-Blind (DB) Period and Safety Follow-Up Period
Project: Alnylam Pharmaceuticals, Inc.
Phase: Phase III
Indication: 425.7, Nutritional and Metabolic Cardiomyopathy; Cardiac Amyloidosis, Familial Cardiomyopathy
Title: TRITON-CM: A Phase 3 Global, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Nucresiran in Patients with Transthyretin-Mediated Amyloidosis with Cardiomyopathy (ATTR amyloidosis with cardiomyopathy)
Protocol version: v1.0

Budget Information

Total Cost per Patient: 49,565.41

Location: United States
OH: 10.00%
Currency: USD - US Dollar

PI name: Aviral Vij, MD
Institution: Cook County, through its Cook County Health & Hospitals System, d/b/a Cook County Health
Date: 4-May-26

Standard Items per Patient

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	Screening Period (D-45 to -1)	DB Treatment Period																Total	HHC Visit (done by a vendor)	Safety Follow-Up Period Q6M	Screen failure	Survival status Phone call	Monthly check-ins **
						W1	W3	W6	W12	W24 (M6)	W36	W48 (M12)	W60	W72 (M18)	W84	W96 (M24)	W108	W120 (M30)	Non-dosing visit (W132, W156, W180, W204, W228 and W252, or until the time of primary analysis)	Dosing vists (W144, W192 and W240, or until the time of primary analysis)	Dosing vists (W168, W216 and W264, or until the time of primary analysis)							
						D1	D21±3	D42±3	D84±3	D168±7	D252±10	D336±10	D420±10	D504±10	D588±10	D672±10	D756±10	D840±10	±10	±10	±10							
					Clinic	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*			Clinic or Home Health Care*				
Informed consent	Y	1.00	195.00	214.50	195.00																	195.00			195.00		
Inclusion/Exclusion Criteria	Y	1.00	100.00	110.00	100.00																	100.00			100.00		
Screening Visit includes: Demographics, Medical history, Height and body weight, Full physical examination, Vital signs	Y	1.00	281.96	310.16	281.96																	281.96			281.96		
Follow-Up Visit includes: Medical History (Day 1), Body weight, Vital signs, Symptom-directed physical exam	Y	8.00	235.00	258.50		235.00				235.00		235.00		235.00		235.00		235.00		235.00	235.00	1,880.00		235.00			
Vital signs	Y	1.00	50.00	55.00			50.00															50.00					
Central lab: FSH screening, Serum pregnancy test, Serum Chemistry (including LFTs), Hematology, Coagulation, Immunogenicity (ADA), TTR Protein, Vitamin A levels, Cardiac Biomarker Samples, NfL biomarker samples	Y	17.00	173.00	190.30	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	173.00	2,941.00		173.00	173.00		
Central lab: Plasma PK	Y	4.00	65.00	71.50		130.00										130.00						260.00					
Central lab: Urinalysis	Y	11.00	52.50	57.75	52.50	52.50				52.50	52.50	52.50		52.50		52.50		52.50		52.50	52.50	577.50			52.50		
Central Lab shipping and handling fee	Y	17.00	91.00	100.10	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	91.00	1,547.00			91.00		
Karnofsky Performance Status	Y	1.00	65.00	71.50	65.00																	65.00			65.00		
PND score	Y	1.00	50.00	55.00	50.00																	50.00			50.00		
KCCQ-OS	Y	8.00	50.00	55.00		50.00				50.00		50.00		50.00		50.00		50.00		50.00	50.00	400.00					
Echocardiogram	Y	4.00	914.00	1,005.40		914.00						914.00				914.00				914.00		3,656.00					
NYHA class	Y	8.00	50.00	55.00	50.00					50.00		50.00		50.00		50.00		50.00		50.00	50.00	400.00			50.00		
EQ-5D-5L	Y	4.00	30.00	33.00		30.00						30.00				30.00				30.00		120.00					
Single 12-lead ECG (triple at Screening)	Y	8.00	150.00	165.00	450.00	150.00				150.00		150.00				150.00				150.00		1,200.00		150.00	450.00		
Pregnancy Test (Urine)	Y	4.00	34.00	37.40		17.00				17.00		17.00		17.00		17.00		17.00		17.00	17.00	136.00		17.00			
Adverse Events	Y	17.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	1,275.00	75.00	75.00	75.00		
Vital status check	Y	14.00	50.00	55.00		50.00			50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	700.00		50.00			
Review/Record Hospitalizations, Urgent HF Visits, and Procedures	Y	17.00	50.00	55.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	850.00		50.00	50.00		
Concomitant Medications	Y	17.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	1,275.00	75.00	75.00	75.00		
			Per Patient Activity Totals:		1,708.46	2,092.50	514.00	464.00	566.50	1,068.50	566.50	2,012.50	514.00	918.50	514.00	2,142.50	514.00	918.50	514.00	2,012.50	918.50			150.00	916.00	1,708.46	0.00	0.00

Standard Items per Patient

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	Screening Period (D-45 to -1)	DB Treatment Period																Total	HHC Visit (done by a vendor)	Safety Follow-Up Period Q6M	Screen failure	Survival status Phone call	Monthly check-ins **
						W1	W3	W6	W12	W24 (M6)	W36	W48 (M12)	W60	W72 (M18)	W84	W96 (M24)	W108	W120 (M30)	Non-dosing visit Q6M starting at W132 (W156, W180, W204, W228 and W252, or until the time of primary analysis	Dosing vists (W144, W192 and W240, or until the time of primary analysis)	Dosing vists (W168, W216 and W264, or until the time of primary analysis)							
						D1	D21±3	D42±3	D84±3	D168±7	D252±10	D336±10	D420±10	D504±10	D588±10	D672±10	D756±10	D840±10	±10	±10	±10							
					Clinic	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*			Clinic or Home Health Care*				
PI fee, per visit	Y	17.00	288.00	316.80	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	4,896.00					
Study Coordinator fee, per Visit	Y	43.00	112.00	123.20	448.00	336.00	224.00	224.00	224.00	336.00	224.00	336.00	224.00	336.00	224.00	336.00	224.00	224.00	224.00	336.00	336.00	4,816.00	112.00	112.00	448.00		
Patient Reimbursement	Y	17.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	1,275.00		75.00	75.00		
Data Entry	Y	17.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	1,275.00	75.00	75.00	75.00		
			Per Patient Other Direct Cost Totals:		886.00	774.00	662.00	662.00	662.00	774.00	662.00	774.00	662.00	774.00	662.00	774.00	662.00	662.00	662.00	774.00	774.00			475.00	550.00	886.00	0.00	0.00

Patient Cost For Standard Items

	Screening Period (D-45 to -1)	DB Treatment Period																				Total	HHC Visit (done by a vendor)	Safety Follow-Up Period Q6M	Screen failure	Survival status Phone call	Monthly check-ins **
		W1	W3	W6	W12	W24 (M6)	W36	W48 (M12)	W60	W72 (M18)	W84	W96 (M24)	W108	W120 (M30)	Non-dosing visit Q6M starting at W132 (W156, W180, W204, W228 and W252, or until the time of primary analysis	Dosing vists (W144, W192 and W240, or until the time of primary analysis)	Dosing vists (W168, W216 and W264, or until the time of primary analysis)							
		D1	D21±3	D42±3	D84±3	D168±7	D252±10	D336±10	D420±10	D504±10	D588±10	D672±10	D756±10	D840±10	±10	±10	±10							
	Clinic	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*			Clinic or Home Health Care*				
Costs Not Charged with Overhead																											
Costs Charged with Overhead	2,594.46	2,866.50	1,176.00	1,126.00	1,228.50	1,842.50	1,228.50	2,786.50	1,176.00	1,692.50	1,176.00	2,916.50	1,176.00	1,580.50	1,176.00	2,786.50	1,692.50	30,221.46	625.00	1,466.00	2,594.46	37.00	75.00				
Overhead at 10%	259.45	286.65	117.60	112.60	122.85	184.25	122.85	278.65	117.60	169.25	117.60	291.65	117.60	158.05	117.60	278.65	169.25	3,022.15	62.50	146.60	259.45	3.70	7.50				
Selected Cost Per Visit	2,853.91	3,153.15	1,293.60	1,238.60	1,351.35	2,026.75	1,351.35	3,065.15	1,293.60	1,861.75	1,293.60	3,208.15	1,293.60	1,738.55	1,293.60	3,065.15	1,861.75	33,243.61	687.50	1,612.60	2,853.91	40.70	82.50				
Total Cost per Visit (all visits performed in-clinic):	2,853.91	3,153.15	1,293.60	1,238.60	1,351.35	2,026.75	1,351.35	3,065.15	1,293.60	1,861.75	1,293.60	3,208.15	1,293.60	1,738.55	7,761.60	9,195.45	5,585.25	49,565.41	687.50	1,612.60	2,853.91	40.70	82.50				

Conditionals - Paid Upon EDC Entry

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	Screening Period (D-45 to -1)	DB Treatment Period																Total	HHC Visit (done by a vendor)	Safety Follow-Up Period Q6M	Screen failure	Survival status Phone call	Monthly check-ins **
						W1	W3	W6	W12	W24 (M6)	W36	W48 (M12)	W60	W72 (M18)	W84	W96 (M24)	W108	W120 (M30)	Non-dosing visit Q6M starting at W132 (W156, W180, W204, W228 and W252, or until the time of primary analysis	Dosing vists (W144, W192 and W240, or until the time of primary analysis)	Dosing vists (W168, W216 and W264, or until the time of primary analysis)						
						D1	D21±3	D42±3	D84±3	D168±7	D252±10	D336±10	D420±10	D504±10	D588±10	D672±10	D756±10	D840±10	±10	±10	±10						
					Clinic	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*						
Study Drug Administration – (SQ injection)	Y		150.00	165.00		RC				RC		RC		RC		RC		RC		RC	RC					
Randomization	Y	1.00	100.00	110.00		100.00																100.00					
Dispensing, Simple; Per Visit	Y	8.00	210.00	231.00		210.00				210.00		210.00		210.00		210.00		210.00		210.00	210.00	1,680.00					

Invoiceables

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	Screening Period (D-45 to -1)	DB Treatment Period																Total	HHC Visit (done by a vendor)	Safety Follow-Up Period Q6M	Screen failure	Survival status Phone call	Monthly check-ins **
						W1	W3	W6	W12	W24 (M6)	W36	W48 (M12)	W60	W72 (M18)	W84	W96 (M24)	W108	W120 (M30)	Non-dosing visit Q6M starting at W132 (W156, W180, W204, W228 and W252, or until the time of primary analysis	Dosing vists (W144, W192 and W240, or until the time of primary analysis)	Dosing vists (W168, W216 and W264, or until the time of primary analysis)						
						D1	D21±3	D42±3	D84±3	D168±7	D252±10	D336±10	D420±10	D504±10	D588±10	D672±10	D756±10	D840±10	±10	±10	±10						
					Clinic	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic or Home Health Care*						
Patient Travel Reimbursement (Round-Trip) Ground Transportation (if not managed by a third-party vendor), Per Visit - if applicable	N	17.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	3,400.00		200.00	200.00		
Meals (if not managed by a third-party vendor), Per Visit - if applicable	N	17.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	1,275.00		75.00	75.00		
Patient Travel Reimbursement Airfare (if not managed by a third-party vendor), Per Visit - if applicable	N	17.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	9,350.00		550.00	550.00		
Patient Travel Reimbursement (Round-Trip) Rail (if not managed by a third-party vendor), Per Visit - if applicable	N	17.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	4,250.00		250.00	250.00		
Patient Hotel Reimbursement (if not managed by a third-party vendor), Per Night - if applicable	N	17.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	4,675.00		275.00	275.00		
Mileage	N		Per IRS rate																								
Central lab: Biomarkers: plasma, serum, urine (optional future research-consent needed)	Y	7.00	40.00	44.00		40.00	40.00	40.00	40.00	40.00		40.00				40.00						280.00					
Vitamin A Supplement, when applicable	Y		Pass through Cost plus overhead																								
Central lab: Genotyping (only for a small subset of patients)	Y	1.00	173.00	190.30	173.00																	173.00					
Central lab: LFTs (applicable to patients with abnormalities)	Y	6.00	40.00	44.00			40.00	40.00					40.00		40.00		40.00		40.00			240.00					
Central lab: Repeated or additional tests as per PI's discretion (if the screening laboratory abnormalities are transient, then laboratory tests may be repeated. Also, for any other unexplained clinically relevant abnormal laboratory test occurring after study drug administration, the test should be repeated) - **Repeated at Screening**	Y	1.00	173.00	190.30	173.00																	173.00					
Central Lab shipping and handling fee	Y	8.00	91.00	100.10	91.00	91.00	91.00	91.00	91.00	91.00		91.00				91.00						728.00					
Dry Ice, per shipment	Y		56.00	61.60																							
SAE report, per report	Y		150.00	165.00																				150.00			
Re-consent, per patient	Y		58.00	63.80																							

Site Level Other Direct Costs

Name	Selected Cost	OH	Total cost
One-time Archiving fee	1,280.00	128.00	1,408.00
One-time Pharmacy fee	2,000.00	200.00	2,200.00
One-time Start-up fee	8,500.00	850.00	9,350.00
Pre-screening (up to 15 patients), per patient	20.00	2.00	22.00
Site Initiation Visit	1,700.00	170.00	1,870.00
Protocol Training	3,200.00	320.00	3,520.00
IRB Submission Preparation	2,000.00	200.00	2,200.00
Coverage Analysis Development	2,200.00	220.00	2,420.00
Contract Review and Negotiation	1,500.00	150.00	1,650.00
Budget Prep and Negotiation	3,200.00	320.00	3,520.00
IRB Fees	2,800.00	280.00	3,080.00
Regulatory Mainainence Fee (After initial approval period)	2,000.00	200.00	2,200.00
Pharmacy Annual Renewal	500.00	50.00	550.00
Administrative Study Close-out Fee	650.00	65.00	715.00
Pharmacy Close-out	900.00	90.00	990.00
Protocol/Coverage Analysis Amendment Fee	800.00	80.00	880.00
Regulatory Amendment IRB Prep Fee	500.00	50.00	550.00
Not for Cause Audit Prep Fee	1,000.00	100.00	1,100.00
Monitor Turnover/Excessive Monitoring Fee	500.00	50.00	550.00
Monitor Visit Fee (each visit)	900.00	90.00	990.00

These visits can be conducted in one of the following ways and should be paid as follows:
1. On-site visits - site should be paid the standard visit amount in the CPP grid and invoice for any other invoiceables if applicable for the visits
2. By site staff at the patient's home - site should be paid the standard per visit amount and invoice for the Site staff home visit fee, as well as for any other invoiceables if applicable for the visits
3. By HHC vendor at the patient's home - site should be paid the HHC visit cost instead of the standard visit amount

**Monthly check-ins (not applicable to patients who receive a monthly check-in contact during months when a study visit is scheduled. Monthly check-ins (±14 days) will start after the week 12 visit (W16 [D112], W20 [D140], W28 [D196], W32 [D224], W40 [D280], W44 [D308], W52 [D364], W56 [D392], W64 [D448], W68 [D476], W76 [D532], W80 [D560], W88 [D616], W92 [D644], W100 [D700], W104 [D728], W112 [D784], W116 [D812], W124 [D868], W128 [D896], W136 [D952], W140 [D980], W148 [D1036], W152 [D1064], W160 [D1120], W164 [D1148], W172 [D1204], W176 [D1232], W184 [D1288], W188 [D1316], W196 [D1372], W200 [D1400], W208 [D1456], W212 [D1484], W220 [D1540], W224 [D1568], W232 [D1624], W236 [D1652], W244 [D1708], W248 [D1736], W256 [D1792], W260 [D1820], W268 [D1876], and W272 [D1904] or until the time of primary analysis).

Finalized Template Date 30-Aug-2025

Trial Information

Trial Name: ALN-TTRSC04-003
Arm: Open-Label Extension (OLE) Period
Project: Alnylam Pharmaceuticals, Inc.
Phase: PhaseIII
Indication: 425.7, Nutritional and Metabolic Cardiomyopathy; Cardiac Amyloidosis, Familial Cardiomyopathy
Title: TRITON-CM: A Phase 3 Global, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Nucresiran in Patients with Transthyretin-Mediated Amyloidosis with Cardiomyopathy (ATTR amyloidosis with cardiomyopathy)
Protocol version: v1.0

Budget Information

Total Cost per Patient: 13,263.80
Location: United States
OH: 10.00%
Currency: USD - US
PI name: Aviral Vij, MD
Institution: Cook County, through its Cook County Health & Hospitals System, d/b/a Cook County Health
Date: 4-May-26

Standard Items per Patient

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	OLE Period									Total	HHC Visit (done by a vendor)	OLE Safety Follow-up Period Q6M	Survival status Phone call
					W1	W12	W24 (M6)	W36	W48 (12)	W60	W72 (M18)	W84	W96 (M24)				
					Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic			Clinic	
Follow-Up Visit includes: Body weight, mBMI, Vital signs, Symptom-directed physical exam	Y	4.00	235.00	258.50			235.00		235.00		235.00		235.00	940.00		235.00	
Central lab: Serum chemistry (including LFTs), hematology, coagulation, Cardiac Biomarker Samples, NfL biomarker samples	Y	4.00	173.00	190.30			173.00		173.00		173.00		173.00	692.00		173.00	
Central Lab: Urinalysis	Y	4.00	52.50	57.75			52.50		52.50		52.50		52.50	210.00		52.50	
Central Lab shipping and handling fee	Y	4.00	91.00	100.10			91.00		91.00		91.00		91.00	364.00		91.00	
KCCQ-OS	Y	4.00	50.00	55.00			50.00		50.00		50.00		50.00	200.00			
NYHA class	Y	4.00	50.00	55.00			50.00		50.00		50.00		50.00	200.00			
EQ-5D-5L	Y	3.00	30.00	33.00	30.00				30.00				30.00	90.00			
Single 12-lead ECG	Y	3.00	150.00	165.00	150.00				150.00				150.00	450.00		150.00	
Pregnancy Test (Urine)	Y	2.00	34.00	37.40			17.00		17.00		17.00		17.00	68.00		17.00	
Adverse Events	Y	9.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	675.00	75.00	75.00	
Vital status check	Y	9.00	50.00	55.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	450.00		50.00	
Review/Record Hospitalizations, Urgent HF Visits, and Procedures	Y	9.00	50.00	55.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	450.00		50.00	
Check-in contact	Y	4.00	75.00	82.50		75.00		75.00		75.00		75.00		300.00		75.00	
Concomitant Medications	Y	9.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	675.00	75.00	75.00	
			Per Patient Activity Totals:		430.00	325.00	918.50	325.00	1,098.50	325.00	918.50	325.00	1,098.50		150.00	1,043.50	

Standard Items per Patient

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	OLE Period									Total	HHC Visit (done by a vendor)	OLE Safety Follow-up Period Q6M	Survival status Phone call
					W1	W12	W24 (M6)	W36	W48 (12)	W60	W72 (M18)	W84	W96 (M24)				
					Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic			Clinic	
PI fee, per visit	Y	9.00	288.00	316.80	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	288.00	2,592.00	288.00	288.00	
Study Coordinator fee, per Visit	Y	21.00	112.00	123.20	336.00	224.00	224.00	224.00	336.00	224.00	336.00	224.00	224.00	2,352.00	112.00	112.00	
Patient Reimbursement	Y	9.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	675.00	75.00	75.00	
Data Entry	Y	9.00	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	675.00	75.00	75.00	
			Per Patient Other Direct Cost Totals:		774.00	662.00	662.00	662.00	774.00	662.00	774.00	662.00	662.00		550.00	550.00	0.00

Patient Cost For Standard Items

	OLE Period									Total	HHC Visit (done by a vendor)	OLE Safety Follow-up Period Q6M	Survival status Phone call
	W1	W12	W24 (M6)	W36	W48 (12)	W60	W72 (M18)	W84	W96 (M24)				
	Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic			Clinic	
Costs Not Charged with Overhead													
Costs Charged with Overhead	1,204.00	987.00	1,580.50	987.00	1,872.50	987.00	1,692.50	987.00	1,760.50	12,058.00	700.00	1,593.50	37.00
Overhead at 10%	120.40	98.70	158.05	98.70	187.25	98.70	169.25	98.70	176.05	1,205.80	70.00	159.35	3.70
Selected Cost Per Visit	1,324.40	1,085.70	1,738.55	1,085.70	2,059.75	1,085.70	1,861.75	1,085.70	1,936.55	13,263.80	770.00	1,752.85	40.70
Total Cost per Visit (all visits performed in-clinic):	1,324.40	1,085.70	1,738.55	1,085.70	2,059.75	1,085.70	1,861.75	1,085.70	1,936.55	13,263.80	770.00	1,752.85	40.70

Conditionals - Paid Upon EDC Entry

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	OLE Period									Total	HHC Visit (done by a vendor)	OLE Safety Follow-up Period Q6M	Survival status Phone call
					W1	W12	W24 (M6)	W36	W48 (12)	W60	W72 (M18)	W84	W96 (M24)				
					Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic			Clinic	
Study Drug Administration – (SQ injection)	Y		150.00	165.00	RC		RC		RC		RC						
Dispensing, Simple; Per Visit	Y	4.00	210.00	231.00	210.00		210.00		210.00		210.00			840.00			

Invoiceables

Name	OH?	Total Quantity	Selected Cost	Selected Cost Including OH (if applicable)	OLE Period									Total	HHC Visit (done by a vendor)	OLE Safety Follow-up Period Q6M	Survival status Phone call
					W1	W12	W24 (M6)	W36	W48 (12)	W60	W72 (M18)	W84	W96 (M24)				
					Clinic	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic			Clinic or Home Health Care*	
Patient Travel Reimbursement (Round-Trip) Ground Transportation (if not managed by a third-party vendor), Per Visit - if applicable	N	9.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00	1,800.00		200.00	
Meals (if not managed by a third-party vendor), Per Visit - if applicable	N	9.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00	675.00		75.00	
Patient Travel Reimbursement Airfare (if not managed by a third-party vendor), Per Visit - if applicable	N	9.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00	4,950.00		550.00	
Patient Travel Reimbursement (Round-Trip) Rail (if not managed by a third-party vendor), Per Visit - if applicable	N	9.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00	2,250.00		250.00	
Patient Hotel Reimbursement (if not managed by a third-party vendor), Per Night - if applicable	N	9.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00	2,475.00		275.00	
Mileage	N		Per IRS rate														
Follow-Up Visit includes: Body weight, mBMI, Vital signs, Symptom-directed physical exam	Y	1.00	235.00	258.50	235.00									235.00			
Central lab: Serum chemistry (including LFTs), hematology, coagulation, Cardiac Biomarker Samples, NfL biomarker samples	Y	1.00	173.00	190.30	173.00									173.00			
Central Lab: Urinalysis	Y	1.00	52.50	57.75	52.50									52.50			
Central Lab shipping and handling fee	Y	1.00	91.00	100.10	91.00									91.00			
KCCQ-OS	Y	1.00	50.00	55.00	50.00									50.00			
NYHA class	Y	1.00	50.00	55.00	50.00									50.00			
Pregnancy Test (urine)	Y	1.00	34.00	37.40	34.00									34.00			

Dry Ice, per shipment	Y		56.00	61.60													
SAE report, per report	Y		150.00	165.00													
Re-consent, per patient	Y		58.00	63.80													

***These visits can be conducted in one of the following ways and should be paid as follows:**

1. On-site visits - site should be paid the standard visit amount in the CPP grid and invoice for any other invoiceables if applicable for the visits
2. By site staff at the patient's home - site should be paid the standard per visit amount and invoice for the Site staff home visit fee, as well as for any other invoiceables if applicable for the visits
3. By HHC vendor at the patient's home - site should be paid the HHC visit cost instead of the standard visit amount

Finalized Template Date 30-Aug-2025

Trial Information

Trial Name: ALN-TTRSC04-003
Arm: Double-Blind (DB) Period and Safety Follow-Up Period and Open-Label Extension (OLE) Period
Project: Alnylam Pharmaceuticals, Inc.
Phase: PhaseIII
Indication: 425.7, Nutritional and Metabolic Cardiomyopathy; Cardiac Amyloidosis, Familial Cardiomyopathy

Title: TRITON-CM: A Phase 3 Global, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Nucresiran in Patients with Transthyretin-Mediated Amyloidosis with Cardiomyopathy (ATTR amyloidosis with cardiomyopathy)

Protocol version: v1.0

Budget Information

Location: United States
OH: 10.00%
Currency: USD - US Dollar
PI name: Aviral Vij, MD
Institution: Cook County, through its Cook County Health & Hospitals System, d/b/a Cook County Health
Date: 4-May-26

Standard Items per Patient

Name	OH?	Selected Cost	Selected Cost Including OH (if applicable)	DB Period and Safety FU			OLE Period		
				Early Treatment Discon Visit	Early Study Discon Visit	Unscheduled visit	OLE Study Treatment Discontinuation	OLE Study Discontinuation Visit	Unscheduled visit
				Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic	Clinic or Home Health Care*
Follow-Up Visit includes: Body weight, mBMI, Vital signs, Symptom-directed physical exam	Y	235.00	258.50						
Central lab: Serum chemistry (including LFTs), hematology, coagulation, Cardiac Biomarker Samples, NfL biomarker samples	Y	173.00	190.30						
Central Lab: Urinalysis	Y	52.50	57.75						
Central Lab shipping and handling fee	Y	91.00	100.10						
Single 12-lead ECG	Y	150.00	165.00						
Pregnancy Test (Urine)	Y	34.00	37.40						
Adverse Events	Y	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00
Vital status check	Y	50.00	55.00	50.00	50.00		50.00	50.00	
Review/Record Hospitalizations, Urgent HF Visits, and Procedures	Y	50.00	55.00	50.00	50.00	50.00	50.00	50.00	50.00
Concomitant Medications	Y	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00
		Per Patient Activity Totals:		250.00	250.00	200.00	250.00	250.00	200.00

Standard Items per Patient

Name	OH?	Selected Cost	Selected Cost Including OH (if applicable)	DB Period and Safety FU			OLE Period		
				Early Treatment Discon Visit	Early Study Discon Visit	Unscheduled visit	OLE Study Treatment Discontinuation	OLE Study Discontinuation Visit	Unscheduled visit
				Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic	Clinic or Home Health Care*
PI fee, per visit	Y	288.00	316.80	288.00	288.00	288.00	288.00	288.00	288.00
Study Coordinator fee, per Visit	Y	112.00	123.20	112.00	112.00	112.00	112.00	112.00	112.00
Data Entry	Y	75.00	82.50	75.00	75.00	75.00	75.00	75.00	75.00
		Per Patient Other Direct Cost Totals:		475.00	475.00	475.00	475.00	475.00	475.00

Patient Cost For Standard Items

	DB Period and Safety FU			OLE Period		
	Early Treatment Discon Visit	Early Study Discon Visit	Unscheduled visit	OLE Study Treatment Discontinuation	OLE Study Discontinuation Visit	Unscheduled visit
	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic	Clinic or Home Health Care*
Costs Not Charged with Overhead						
Costs Charged with Overhead	725.00	725.00	675.00	725.00	725.00	675.00
Overhead at 10%	72.50	72.50	67.50	72.50	72.50	67.50
Selected Cost Per Visit	797.50	797.50	742.50	797.50	797.50	742.50
Total Cost per Visit (all visits performed in-clinic):	797.50	797.50	742.50	797.50	797.50	742.50

Conditionals - Paid Upon EDC Entry

Name	OH?	Selected Cost	Selected Cost Including OH (if applicable)	DB Period and Safety FU			OLE Period		
				Early Treatment Discon Visit	Early Study Discon Visit	Unscheduled visit	OLE Study Treatment Discontinuation	OLE Study Discontinuation Visit	Unscheduled visit
				Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic	Clinic or Home Health Care*

Follow-Up Visit includes: Medical History, Body weight, Vital signs, Symptom-directed physical exam **(USV and ET)**	Y	235.00	258.50	235.00	235.00	235.00	235.00	235.00	235.00
Central lab: Biomarkers: plasma, serum, urine (optional future research-consent needed) **(USV)**	Y	40.00	44.00			40.00			
Central lab: Urinalysis **(USV and ET)**	Y	52.50	57.75	52.50	52.50	52.50	52.50	52.50	52.50
Central lab: FSH screening, Serum pregnancy test, Serum Chemistry (including LFTs), Hematology, Coagulation, Immunogenicity (ADA), TTR Protein, Vitamin A levels, Cardiac Biomarker Samples, NfL biomarker samples **(USV and ET)**	Y	173.00	190.30	173.00	173.00	173.00	173.00	173.00	173.00
Central lab: Repeated or additional tests as per PI's discretion (if the screening laboratory abnormalities are transient, then laboratory tests may be repeated. Also, for any other unexplained clinically relevant abnormal laboratory test occurring after study drug administration, the test should be repeated) - **(USV)**	Y	173.00	190.30			173.00			173.00
Central Lab shipping and handling fee **(USV and ET)**	Y	91.00	100.10	91.00	91.00	91.00	91.00	91.00	91.00
KCCQ-OS **(USV and ET)**	Y	65.00	71.50	65.00	65.00	65.00			65.00
Echocardiogram **(USV and ET)**	Y	914.00	1,005.40	914.00	914.00	914.00			914.00
NYHA class **(USV and ET)**	Y	50.00	55.00	50.00	50.00	50.00			50.00
EQ-5D-5L **(USV and ET)**	Y	30.00	33.00	30.00	30.00	30.00			30.00
Single 12-lead ECG **(USV and ET)**	Y	150.00	165.00	150.00	150.00	150.00	150.00	150.00	150.00
Triplicate 12-lead ECG **(USV)**	Y	450.00	495.00			450.00			450.00
Pregnancy Test (Urine) **(USV and ET)**	Y	34.00	37.40	34.00	34.00	34.00	34.00	34.00	34.00
Vital status check **(USV)**	Y	50.00	55.00			50.00			50.00
Study Drug Administration – (SQ injection) **(USV)**	Y	150.00	165.00			150.00			
Dispensing, Simple; Per Visit **(USV)**	Y	210.00	231.00			210.00			
Central lab: Plasma PK **(USV)**	Y	65.00	71.50			65.00			
Karnofsky Performance Status **(USV)**	Y	65.00	71.50			65.00			
Check-in contact **(USV)**	Y	75.00	82.50			75.00			75.00
Survival status Phone call **(USV)**	Y	37.00	40.70			37.00			37.00
Central lab: LFTs (applicable to patients with abnormalities) **(USV)**	Y	40.00	44.00			40.00			40.00

Invoiceables

Name	OH?	Selected Cost	Selected Cost Including OH (if applicable)	DB Period and Safety FU			OLE Period		
				Early Treatment Discon Visit	Early Study Discon Visit	Unscheduled visit	OLE Study Treatment Discontinuation	OLE Study Discontinuation Visit	Unscheduled visit
				Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic or Home Health Care*	Clinic	Clinic	Clinic or Home Health Care*

Patient Travel Reimbursement (Round-Trip) Ground Transportation (if not managed by a third-party vendor), Per Visit - if applicable	N	200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Meals (if not managed by a third-party vendor), Per Visit - if applicable	N	75.00	75.00	75.00	75.00	75.00	75.00	75.00	75.00
Patient Travel Reimbursement Airfare (if not managed by a third-party vendor), Per Visit - if applicable	N	550.00	550.00	550.00	550.00	550.00	550.00	550.00	550.00
Patient Travel Reimbursement (Round-Trip) Rail (if not managed by a third-party vendor), Per Visit - if applicable	N	250.00	250.00	250.00	250.00	250.00	250.00	250.00	250.00
Patient Hotel Reimbursement (if not managed by a third-party vendor), Per Night - if applicable	N	275.00	275.00	275.00	275.00	275.00	275.00	275.00	275.00
Mileage	N	Per IRS rate (only for US)							
Local lab: Serum Pregnancy Test	Y	60.00	66.00			60.00			60.00
Vital signs	Y	50.00	55.00						50.00
Abdominal ultrasound with Doppler flow	Y	650.00	715.00			650.00			650.00
CT Scan w/ Contrast - Abdomen, Pelvis	Y	1,900.00	2,090.00			1,900.00			1,900.00
CT Scan without Contrast - Abdomen, Pelvis	Y	1,846.00	2,030.60			1,846.00			1,846.00
MRI Abdomen w/ Contrast	Y	2,635.00	2,898.50			2,635.00			2,635.00
MRI Abdomen without Contrast	Y	2,374.00	2,611.40			2,374.00			2,374.00
Radiology assessments - locally readed	Y	434.00	477.40			434.00			434.00
Gastroenterology and Hepatology consultation, per hour	Y	150.00	165.00			150.00			150.00
Vitamin A Supplement, when applicable	Y	Pass through Cost plus overhead							

***These visits can be conducted in one of the following ways and should be paid as follows:**

1. On-site visits - site should be paid the standard visit amount in the CPP grid and invoice for any other invoiceables if applicable for the visits
2. By site staff at the patient's home - site should be paid the standard per visit amount and invoice for the Site staff home visit fee, as well as for any other invoiceables if applicable for the visits
3. By HHC vendor at the patient's home - site should be paid the HHC visit cost instead of the standard visit amount

Finalized Template Date 30-Aug-2025