UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 30, 2026

ATYR PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37378**	**20-3435077**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

10240 Sorrento Valley Road, Suite 300 **San Diego, CA** **(Address of Principal Executive Offices)**	**92121** **(Zip Code)**

Registrant's telephone number, including area code: (858) 731-8389

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ATYR	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.02 Termination of a Material Definitive Agreement.

As previously disclosed in Item 5 to the aTyr Pharma, Inc. (the "Company") Quarterly Report on Form 10-Q filed with the United States Securities and Exchange Commission on May 15, 2026, the Company received notice of termination of the collaboration and license agreement ("Kyorin Agreement") with Kyorin Pharmaceutical Co., Ltd. ("Kyorin") on May 12, 2026. As previously disclosed, Kyorin elected to terminate the Kyorin Agreement without cause in accordance with the terms of the Kyorin Agreement, and the termination was to become effective 90 days after the date of receipt of the notice of termination.

On July 30, 2026, the Company and Kyorin entered into a termination agreement ("Termination Agreement") whereby the parties mutually agreed to: (i) a termination date for the Kyorin Agreement of July 30, 2026 (the "Termination Date"); (ii) the termination of other ancillary agreements associated with the Kyorin Agreement; and (iii) details regarding certain wind down activities. Following the Termination Date, the license granted to Kyorin pursuant to the Kyorin Agreement ceased and the exclusive rights to develop and commercialize efzofitimod in Japan for all forms of interstitial lung disease reverted to the Company. Consequently, the Company now holds the right to develop and commercialize efzofitimod globally.

The foregoing description of the Termination Agreement is only a summary of the material terms thereof, does not purport to be complete and is subject to, and qualified in entirety by, the full text of the Termination Agreement, a copy of which is filed as Exhibit 99.1 hereto, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Termination Agreement, dated July 30, 2026, entered between aTyr Pharma, Inc. and Kyorin Pharmaceutical Co., Ltd.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ATYR PHARMA, INC.

By: /s/ Jill M. Broadfoot
Jill M. Broadfoot
Chief Financial Officer

Date: July 31, 2026

TERMINATION AGREEMENT

This TERMINATION AGREEMENT (this "**Agreement**") is made and entered into as of July 30, 2026 ("**Execution Date**"), by and between aTyr Pharma, Inc., a Delaware corporation, having its principal place of business at 10240 Sorrento Valley Road, Suite 300, San Diego, CA 92121, USA ("**aTyr**"), and Kyorin Pharmaceutical Co., Ltd., a Japanese corporation, having its principal place of business at 1-3-7, Otemachi, Chiyoda-ku, Tokyo, 100-0004, Japan ("**Kyorin**"). aTyr and Kyorin are each referred to as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, the Parties entered into certain Collaboration and License Agreement dated January 6, 2020, together with that certain Letter Agreement of even date (collectively, the "**Collaboration Agreement**");

WHEREAS, Kyorin notified aTyr of its intention to terminate the Collaboration Agreement pursuant to Section 13.2 thereof on May 12, 2026, which aTyr reported on a Form 10-Q filed with the United States Securities and Exchange Commission on May 15, 2026; and

WHEREAS, the Parties desire to ensure a smooth transition and manage all necessary wind-down activities in connection with termination of the Collaboration Agreement.

NOW, THEREFORE, in consideration of the foregoing and subject to the terms and conditions contained herein, the Parties hereby agree as follows:

1. Defined Terms. Unless otherwise defined in this Agreement, all capitalized terms herein shall have the same meaning as set forth in the Collaboration Agreement.

2. Termination of Collaboration Agreement. The Parties hereby agree and acknowledge that the Collaboration Agreement shall be terminated on July 30, 2026 ("**Termination Date**") notwithstanding the provisions of Section 13.2 thereof.

3. Termination of Ancillary Agreements.

3.1. The Parties hereby agree and acknowledge that the following agreements shall be terminated on the Termination Date. The details of wind-down activities for termination of the following agreements shall be discussed and agreed upon by the Parties separately in writing.

(a) Clinical Quality Agreement entered into between the Parties as of May 28, 2020

(b) Clinical Supply Agreement entered into between the Parties as of May 28, 2020, as amended as of August 24, 2022

(c) Phase 2/3 Clinical Quality Agreement entered into between the Parties as of August 26, 2022

(d) Clinical Study Agreement entered into between the Parties as of December 16, 2022, as amended as of April 14, 2023 and November 18, 2025

3.2. The Parties hereby agree and acknowledge that the Safety Data Exchange Agreement entered into between the Parties as of July 31, 2020 shall be terminated on the date when Kyorin submits the notification of discontinuation of development for the Licensed Product to the Regulatory Authority in the Kyorin Territory.

4. Effect of Termination. Notwithstanding the provisions of Section 13.5 of the Collaboration Agreement, the Parties hereby agree and acknowledge as follows:

(a) Effective upon the Termination Date, all licenses granted under Section 7.1 of the Collaboration Agreement shall terminate, and all other rights and obligations of the Parties under the Collaboration Agreement will terminate, except as provided elsewhere in this Article 4 and in Article 5 below;

(b) Effective upon the Termination Date, Kyorin hereby grants (without any further action required on the part of Kyorin or aTyr) to aTyr and its Affiliates, (i) a worldwide, irrevocable, perpetual, royalty-free and fully paid-up, sublicenseable through multiple tiers (subject to Section 7.1.2.3 of the Collaboration Agreement, *mutatis mutandis*) and non-exclusive license under all Kyorin Background Technology necessary to Develop and Commercialize the Reversion Products, and (ii) a worldwide, irrevocable, perpetual, royalty-free and fully paid-up, sublicenseable through multiple tiers (subject to Section 7.1.2.3 of the Collaboration Agreement, *mutatis mutandis*) and exclusive (even as to Kyorin and its Affiliates) license under all New Kyorin IP (including, without limitation, the data, results, materials and information contained in the Handover Documents (as defined below) and the Essential Documents (as defined below)) and Kyorin's interest in New Joint IP, to Develop and Commercialize the Reversion Products. The Parties hereby agree that Section 13.5.3.3 of the Collaboration Agreement shall terminate and be of no further force or effect as of the Termination Date;

(c) In addition to performing its obligations under paragraph (d) of this Article 4 (which paragraph shall survive the Termination Date), Kyorin shall, as promptly as practicable, use reasonable efforts to assign to aTyr or aTyr's designee possession and ownership of the orphan drug designation for the Reversion Product (efzofitimod) in the Kyorin Territory under the applicable Laws ("**Orphan Drug Designation**"), and aTyr shall, as promptly as practicable, use reasonable efforts to accept and take over the Orphan Drug Designation (such efforts by aTyr to include securing an "In-Country Clinical Caretaker" who will be a formal representative of aTyr for that purpose);

(d) Kyorin shall: (i) as promptly as practicable after the Termination Date, transfer to aTyr or aTyr's designee all data, reports, records, materials and information regarding the Reversion Products as listed in **Schedule 1** attached hereto ("**Handover Documents**"); and (ii) as promptly as practicable after the Termination Date, transfer to aTyr or aTyr's designee all data, reports, records, materials and information regarding the Reversion Products as listed in **Schedule 2** attached hereto ("**Essential Documents**"). In addition, effective as of the Termination Date, Kyorin hereby grants to aTyr the right to access, reference and use (without any further action required on the part of Kyorin, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all Regulatory Filings, Regulatory Materials, and other governmental or regulatory filings of Kyorin with Regulatory Authorities in the Kyorin Territory relating to the Development or Manufacture of the Reversion Product. Notwithstanding any other provision of this Agreement to the contrary, the grant by Kyorin to aTyr under the immediately preceding sentence shall survive the Termination Date in perpetuity;

(e) Kyorin shall continue to fulfill its role as a sponsor of Phase 1 Study and Phase 3 Study in the Kyorin Territory to conduct the correspondences with each individual clinical site thereof for archiving the clinical documents and materials in compliance with applicable Laws in the Kyorin Territory (such role to include bearing storage fees of the related clinical documents and materials incurred by the clinical sites) for the period up to expiration of the regulatory archival period under the applicable Laws in the Kyorin Territory, and thereafter Kyorin shall, as promptly as practicable, assign such role of Kyorin to aTyr or aTyr's designee and aTyr shall accept and take over the same;

(f) Except in the case of aTyr for any Confidential Information that is the subject of the licenses set forth in paragraph (b) of this Article 4 above, each Party shall promptly destroy (and certify to the other Party in writing as to such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party hereunder that is in the possession or control of such Party (or any of its Affiliates or subcontractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party for legal purposes;

(g) The JSC (and any subcommittees thereof) shall be dissolved as of the Termination Date;

(h) Kyorin shall provide any other assistance reasonably requested by aTyr for the purpose of ensuring an orderly transition to aTyr or its designee of, and allowing aTyr or its designee to proceed expeditiously with, the Development of Reversion Products. Without limiting the foregoing, Kyorin shall execute all documents and take all such further actions as may be reasonably requested by aTyr, at aTyr's cost, in order to give effect to the foregoing clauses;

(i) Unless otherwise set forth in the foregoing clauses or elsewhere in this Agreement, Kyorin's obligations under this Article 4 shall expire in twelve (12) months after the Termination Date or upon completion of the transition under the relevant clause in this Article 4; provided that in either case, aTyr shall use reasonable efforts to complete the transition as soon as practically possible; and

(j) The Parties hereby agree and acknowledge that there are no outstanding payments from Kyorin to aTyr regarding the Development Costs.

5. Survival Clauses. Notwithstanding the provisions of Section 13.8 of the Collaboration Agreement, the following provisions shall survive termination of the Collaboration Agreement hereunder: Section 1, 8.7.3 (for the period described therein), 9 (for the period of three (3) years), 10.3, 11, 12.1, 12.2 and 14 of the Collaboration Agreement.

6. Press Release. Each Party may issue a press release or public announcement relating to this Agreement with the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed).

7. Mutual Release. Each Party, for itself and its predecessors, successors, parents, subsidiaries, heirs, assigns, security holders, officers, directors or other representatives or agents, hereby releases fully and completely any and all claims it may have against the other Party under the Collaboration Agreement solely to the extent such claim arises out of or relates to any event, circumstance, act, conduct or omission occurring on or before the Termination Date. Nothing herein shall preclude a Party from pursuing any claim with respect to any breach by the other Party of this Agreement or any breach by the other Party of any of the provisions contained in the Collaboration Agreement that survive termination as expressly set forth in Article 4 or Article 5 above.

8. Expenses. Except as otherwise expressly provided in this Agreement, each Party shall bear its respective expenses incurred in connection with the preparation, execution and performance of this Agreement.

9. Entire Agreement and Modification. This Agreement (including the Schedules hereto, which are incorporated herein by reference), together with the surviving provisions of the Collaboration Agreement as expressly set forth in Article 4 or Article 5 above, supersedes all prior agreements between the Parties with respect to its subject matter and constitutes a complete and exclusive statement of the terms of the agreement between the Parties with respect to its subject matter. This Agreement may not be amended, supplemented or otherwise modified except in a written document making specific reference to this Agreement signed by the Parties.

10. Severability. If a court of competent jurisdiction holds any provision of this Agreement invalid or unenforceable, the other provisions of this Agreement shall remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree shall remain in full force and effect to the extent not held invalid or unenforceable.

11. Waiver. The rights and remedies of the Parties to this Agreement are cumulative and not alternative. Neither any failure nor any delay by a Party in exercising any right, power or privilege under this Agreement or any of the documents referred to in this Agreement shall operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege shall preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege.

12. Governing Law. This Agreement shall be governed by and construed under the laws of Switzerland, without regard to conflicts of laws principles that would require the application of any other law.

13. Arbitration. All disputes, controversies, or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, or of the breach hereof, shall be subject to Section 14.3 of the Collaboration Agreement mutatis mutandis.

14. Due Authorization. Each Party represents and warrants that it has all requisite power, authority and capacity to execute, deliver and perform its obligations under this Agreement, that such Party's execution, delivery and performance of this Agreement have been duly authorized by all necessary action on its part, that such Party has not transferred any of its rights or obligations under or related to the Collaboration Agreement to any other person or entity, that this Agreement is a valid and binding obligation of such Party enforceable against such Party in accordance with its terms, and that the person executing this Agreement on behalf of such Party is authorized and empowered to do so.

15. Intellectual Property Disclosure. Kyorin represents and warrants to aTyr that it has fully, accurately, and in good faith disclosed, transferred, or made available to aTyr all material technical data, clinical results, and proprietary information contained in New Kyorin IP or Kyorin Background Technology within its possession or control that are necessary, or reasonably useful, to fully transition, Develop, and Commercialize the Reversion Products in accordance with Article 4 of this Agreement. Kyorin further represents that it has not intentionally withheld, omitted, or misstated any material item, data, or document required to be provided under Schedule 1 (Handover Documents) or Schedule 2 (Essential Documents).

16. Necessary Acts. Each Party agrees to perform any and all acts as well as execute any and all documents that may be necessary or desirable to fully carry out the provisions and intent of this Agreement.

17. Counterparts. This Agreement may be executed in one or more counterparts, all of which shall together represent one and the same agreement and all signatures need not appear on any one counterpart. This Agreement may be executed by delivery of duly authorized and executed signature pages by facsimile or other electronical format, including, without limitation, PDF format. If this Agreement is executed electronically, the Parties agree that an electronic signature will be legally binding. Neither Party may contest the enforceability of this Agreement on the basis that it was executed electronically.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Execution Date.

ATYR PHARMA, INC.

By: /s/ Sanjay Shukla

Name: Sanjay S. Shukla, M.D., M.S.

Title: President and Chief Executive Officer

KYORIN PHARMACEUTICAL CO., LTD.

By: /s/ Yutaka Ogihara

Name: Yutaka Ogihara

Title: Representative Director
President and Chief Executive Officer

Schedule 1 - <u>Handover Documents</u>

Category	Title	Language	No.
Pharmacology	ICS Measurement in Phase I Clinical Study of KRP-R120 (Protocol No. KRPR120-I101)	JPN	R21C020 M20-0116-03
Pharmacology	Data Analysis for ICS Measurement in Phase I Clinical Study of KRP-R120 (Protocol No. KRPR120-I101)	JPN	R21C021 KP15L2001
Pharmacology	Preliminary Investigation of ICS in Phase I Clinical Study of KRP-R120	JPN	R21C019 M20-0116-02
DMPK	A Phase I Study of KRP-R120 (Protocol No. KRPR120-I101) Pharmacokinetic Analysis Report	ENG	R21E018 KP15G2101
DMPK	Inter-ethnic comparison of pharmacokinetics after single intravenous administrations of KRP-R120	ENG	R21E036 KP15G2102
DMPK	The Determination of Anti-KRP-R120 Antibodies in Human Serum Samples by ECL Assay- A Phase I Study of KRP-R120 (Protocol No. KRPR120-I101)	ENG	R21C015 3452-2001B
DMPK	The Determination of KRP-R120 (ATYR1923) in Human Serum Samples by ECL Assay; A Phase I Study of KRP-R120 (Protocol No. KRPR120-I101)	ENG	R21C014 3452-2001A
DMPK	PK analysis datasets (Phoenix files) for Japan Phase 1 (Available after October)	NA	NA
CMC	Analytical Method Transfer Feasibility Report	JPN	NA
JP Ph1	KRPR120-I101_Clinical Study Report (CSR)	JPN	KRPR120-I101
JP Ph1	Procedure for Maintaining Blinding in ADA and PK Analysis Operations	JPN	KRPR120-I101
JP Ph1	Sample Case Report Form (CRF)	JPN	KRPR120-I101
JP Ph1	Monitoring Plan	JPN	KRPR120-I101
JP Ph1	Statistical Analysis Plan (SAP) for Safety and Immunogenicity	JPN	KRPR120-I101
JP Ph1	Clinical Study Protocol	JPN	KRPR120-I101
JP Ph1	Clinical Study Protocol_Appendix: Study Implementation Structure	JPN	KRPR120-I101
JP Ph1	Procedure for Investigational Product Handling	JPN	KRPR120-I101
JP Ph1	Procedure for Investigational Product Allocation and Unblinding	JPN	KRPR120-I101
JP Ph1	List of Modifications	JPN	KRPR120-I101
JP Ph1	Guidelines for Case Report Form (CRF) Completion, Changes, and Corrections	JPN	KRPR120-I101

Category	Title	Language	No.
JP Ph1	Informed Consent Form (ICF) and Patient Information Sheet	JPN	KRPR120-I101
JP Ph1	Procedure for Unblinded Operations	JPN	KRPR120-I101
JP Ph1	Quality Management Plan (QMP)	JPN	KRPR120-I101
JP Ph1	Procedure for Handling Immunogenicity and Drug Concentration Measurement Samples	JPN	KRPR120-I101
JP Ph1	Immunogenicity Follow-up Plan	JPN	KRPR120-I101
JP Ph1	Procedure for Dose Escalation	JPN	KRPR120-I101
JP Ph1	JP Ph1 CDISC (already provided)	JPN	KRPR120-I101
JP Ph1	JP Ph1 dataset and specification (already provided)	JPN	KRPR120-I101
IB	KRP-R120 Investigator's Brochure (IB) Ver. 1	JPN	NA
IB	KRP-R120 Investigator's Brochure (IB) Ver. 1 Supplement	JPN	NA
IB	KRP-R120 Investigator's Brochure (IB) Ver. 2	JPN	NA
IB	KRP-R120 Investigator's Brochure (IB) Ver. 3	JPN	NA
Regulatory	Pre-Phase 1 Study Consultation (May 2020)	JPN	NA
Regulatory	Inquiry Regarding the 30-Day Review for Phase 1 Study (I101)	JPN	NA
Regulatory	End-of-Phase 2 Study Consultation (Jul 2022)	JPN	NA
Regulatory	Simple Consultation on GMP Inspection (Aug 2025)	JPN	NA
Regulatory	Consultation on Pharmaceutical Procedures (Aug 2025)	JPN	NA
Regulatory	Simple Consultation on GMP Inspection (Sep 2025)	JPN	NA
Regulatory	Consultation on Quality (Oct 2025)	JPN	NA
CTN	Clinical Trial Notification (CTN) for Phase 1	JPN	NA
CTN	Clinical Trial Notification (CTN) for Phase 3 (already provided)	JPN	NA
JAN	JAN (Japanese Accepted Names) submission package and notification (already provided)	JPN	NA
ODD	ODD (Orphan Drug Designation) submission package and designation notification (already provided)	JPN	NA

Schedule 2 - Essential Documents

Document	JPN-Ph1 (I101)	Ph3 MRCT* (C004)
Before the Clinical Phase of the Trial Commences		
Investigator's Brochure	X	
Signed Protocol and Amendments, If Any, and Sample Case Report Form (CRF)	X	
Information Given to Trial Subject - Informed consent form (including all applicable translations) - Any other written Information - Advertisement for subject recruitment (if used)	X	
Financial Aspects of the Trial	X	
Insurance Statement (where required)	X	
Signed Agreement Between Involved Parties, e.g.: - Investigator/institution and sponsor - Investigator/institution and CRO - Sponsor and CRO - Investigator/institution and authority(ies) (where required)	X	X
Dated, Documented Approval/Favourable Opinion of Institutional Review Board (IRB) /Independent Ethics Committee (IEC) of the Following: - Protocol and any amendments - CRF (if applicable) - Informed consent form(s) - Any other written information to be provided to the subject(s) - Advertisement for subject recruitment (if used) - Subject compensation (if any) - Any other documents given approval/ favourable opinion	X	
Institutional Review Board/Independent Ethics Committee Composition	X	
Regulatory Authority(ies) Authorisation/Approval/Notification of Protocol (where required)	X (CTN)	X (CTN)
Curriculum Vitae and/or Other Relevant Documents Evidencing Qualifications of Investigator(s) and Sub-Investigator(s)	X	X
Normal Value(s)/Range(s) for Medical/ Laboratory/Technical Procedure(s) and/or Test(s) Included In the Protocol	X	
Medical/Laboratory/Technical Procedures /Tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	X	
Sample of Label(s) Attached to Investigational Product Container(s)	X	
Instructions for Handling of Investigational Product(s) and Trial-Related Materials (if not included in protocol or investigator's brochure)	X	

Document	JPN-Ph1 (I101)	Ph3 MRCT* (C004)
Shipping records for investigational product(s) and trial-related materials	X	
Certificate(s) of analysis of investigational product(s) shipped	X	
Decoding procedures for blinded trials	X	
Master randomisation list	X	
Pre-Trial Monitoring Report	X	
Trial Initiation Monitoring Report	X	
During the Clinical Conduct of the Trial		
Investigator's Brochure Updates	X	
Any Revision to: - Protocol/amendment(s) and CRF - Informed consent form - Any other written information provided to subjects - Advertisement for subject recruitment (if used)	X	
Dated, Documented Approval/Favourable Opinion of Institutional Review Board (IRB) /Independent Ethics Committee (IEC) of the Following:- Protocol amendment(s)- Revision(s) of:- Informed consent form- Any other written information to be provided to the subject- Advertisement for subject recruitment (if used)- Any other documents given approval/favourable opinion- Continuing review of trial (where required)	X	
Regulatory Authority(ies) Authorisations/Approvals/Notifications Where Required for: - Protocol Amendment(s) and other documents	X (CTN amendment)	X (CTN amendment)
Curriculum Vitae for New Investigator(s) and/or Sub-Investigator(s)	X	
Updates to Normal Value(s)/Range(s) for Medical/ Laboratory/ Technical Procedure(s)/Test(s) Included In the Protocol	NA	
Updates of Medical/Laboratory/ Technical Procedures/Tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	NA	
Documentation of Investigational Product(s) and Trial-Related Materials Shipment	X	
Certificate(s) of Analysis for New Batches of Investigational Products	NA	
Monitoring Visit Reports	X	

Document	JPN-Ph1 (I101)	Ph3 MRCT* (C004)
Relevant Communications other than Site Visits - Letters - Meeting notes - Notes of telephone calls	X	
Signed, Dated and Completed Case Report forms (CRF)	X	
Documentation of CRF Corrections	X	
Notification by originating Investigator to Sponsor of Serious Adverse Events and Related Reports	NA	
Notification by Sponsor and/or Investigator, Where Applicable, to Regulatory Authority(ies) and IRB(s)/IEC(s) of Unexpected Serious Adverse Drug Reactions and of Other Safety Information	X	
Notification by Sponsor to Investigators of Safety Information	X	
Interim or Annual Reports to IRB/IEC and Authority(ies)	X	
Subject Screening Log	NA	
Investigational Products Accountability at the Site	X	
Signature Sheet	NA	
Record of Retained Body Fluids/ Tissue Samples (if Any)	NA	
After Completion or Termination of the Trial		
Investigational Product(s) Accountability at Site	X	
Documentation of Investigational Product Destruction	X	
Audit Certificate (if available)	X	
Final Trial Close-Out Monitoring Report	X	
Treatment Allocation and Decoding Documentation	NA	
Clinical Study Report	X	
IMP Manufacturing/ Quality Testing Records		
IMP Manufacturing Records (packaging/labeling)	X	X
IMP Quality Testing Records	X	X