DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/30/2026-4/3/2026 FEI NUMBER 3013745424

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arturo (nmi) Molina, Chief Medical Officer

FIRM NAME	STREET ADDRESS
Protagonist Therapeutics Inc	7707 Gateway Blvd Ste 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newark, CA 94560-1160	Sponsor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
OBSERVATION 1
Failure to provide investigators with the information needed to conduct the study properly and ensure proper monitoring of the study.

Specifically, investigators did not receive information on how to initiate and report protocol deviations. Monitors, responsible for reporting deviations, did not ensure proper review of protocol compliance for the (b) (4) and (b) (4) studies.

a) The following subjects were enrolled and treated in the study despite not meeting inclusion criteria. Monitoring did not detect and report these protocol deviations until up to 2 years after the deviation occurred.

The table below lists the protocol deviation and when the deviation was identified and reported by the monitor.

Subject Number	Protocol Deviation (Inclusion Criteria not Met	Date Deviation Occurred	Date Identified	Timeframe until Monitor Identification
(b) (6)	No bone marrow biopsy	17-Feb-2023	18-Dec-2024	1 year, 10 months and 1 day
	Phlebotomy timeframe	8-Feb-2023	11-Feb-2025	2 years and 3 days

b) The protocol deviations below were not detected by monitors. Protocol deviations were identified and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kristin M Abaonza, Investigator	X Kristin M Abaonza Investigator Signed By: KRISTIN M. ABAONZA -S Date Signed: 04-03-2026 18:44:48	4/3/2026

recorded during a data listing review up to two years later.

Subject Number	Protocol Deviation (Inclusion Criteria not Met)	Date Deviation Occurred	Date Identified	Timeframe until Identification
(b) (6)	Patient did not have stable dose of interferon at least 6 months prior to randomization	14-Apr-23	18-Feb-25	1 year, 10 months, and 4 days
	Patient did not have stable dose of interferon at least 6 months prior to randomization	26-Apr-23	14-Jul-25	2 years, 2 months, and 18 days

c) For (b) (4):
The Monitoring Plan, Version 2 (dated December 11, 2019) failed to address a timeframe for when the first monitoring visit should occur after the initial subject is enrolled and treated.

The table below summarizes the delay in the first monitoring visit following treatment of the initial subject at each site.

Site	First Subject Treated	Monitoring Visit after First Subject Treated	Timeframe until Monitoring Visit after first Subject Treated	# of Subjects Treated before Monitoring Visit
1508	30-Nov-2020	2-Feb-2021	2 months and 3 days	2
1512	26-Jan-2021	15-Jun-2021	4 months and 20 days	6

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1516	14-Apr-2021	9-Jun-2021	1 month and 26 days	6
1853	3-Nov-2020	11-12 Feb 2021	3 months and 8 days	2

At the above listed sites, protocol deviations and adverse events occurred before the first monitoring visit following treatment of the initial subject.

For (b) (4):
The Monitoring Plan addressed a timeframe for the first routine monitoring visit (RMV) to occur within 2 weeks of the site's first randomized subject but may be increased to 3 weeks if deemed necessary.

The table below summarizes the delay in the first monitoring visit following treatment of the initial subject at each site:

Site	First Subject Treated	Monitoring Visit after First Subject Treated	Timeframe until Monitoring Visit after first Subject Treated	# of Subjects Treated before Monitoring Visit
514	5-Dec-2022	6-Mar-2023	3 months and 1 day	2
570	29-Feb-2024	23-Apr-2024	1 month and 25 days	1

At the above listed sites, protocol deviations and adverse events occurred prior to the first monitoring visit following treatment of the initial subject and were not reviewed by monitors for up to three months.

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EMPLOYEE(S) SIGNATURE

Kristin M Abaonza, Investigator

X Kristin M Abaonza
Investigator
Signed By: KRISTIN M. ABAONZA -S
Date Signed: 04-03-2026 18:44:48

DATE ISSUED

4/3/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."