



VIA UNITED PARCEL SERVICE AND E-MAIL

FADOI Foundation
Attention: Stefano Alvergna, M.D., Scientific Director
Via Rodolfo Lanciani 62
Rome, Italy 00162

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2023-128
NCT03045406

Dear Dr. Alvergna:

On December 19, 2024, the Food and Drug Administration (FDA) sent your organization a Notice of Noncompliance regarding the requirements to submit clinical trial information to the ClinicalTrials.gov data bank. At this time, it appears that your organization has addressed the issues raised in FDA's letter.

Sincerely,

{See appended electronic signature page}

Laurie Muldowney, M.D.
Deputy Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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/s/

LAURIE B MULDOWNNEY
09/30/2025 01:52:15 PM