



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