



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report for the Application Evaluation Decision

A double-blind, randomized, placebo-controlled trial to test the efficacy, safety and tolerability of Dimethyl Fumarate in Friedreich Ataxia (DMF-FA-201).

2022-503016-16-00

Decision	
MSC: Italy	
Decision: Authorised with conditions	
Decision date: 03/05/2023	
Tacit decision:	
Application Part:	
Conditions:	
Condition 1: The study is approved with the condition of providing the Investigators with the list of acronyms and adding it in the context of the next protocol amendment	
Reason:	
Justification:	
Deferrals	
Disagreement with Part I	
Submission date:	