

ICOD Project Meeting

PREPARATION OF THE MULTICENTER PHASE 2 STUDY OF THE AEF0217

Barcelona, March 20th-21st 2024

Barcelona, Hospital del Mar Research Institute (HMRI)

Foreword

This meeting is organized by the management of the ICOD project (Improving COgnition in Down syndrome), funded by European Union. ICOD, aims to improve the cognitive impairment of individuals with Down syndrome with AEF0217, a first-in-class new pharmacological treatment developed by the French biotech Aelis Farma, and specifically designed to this end. The project was launched in February 2021 and two ICOD symposia were held in Troina, Italy, and Madrid, Spain on the occasion of the World Down syndrome Day 2022/2023 with a strong participation of DS families. This time there will be a full event exclusively for individuals and families from Catalan Down syndrome associations that will include online talks open to all families from the ICOD project locations that will be held on the 16th of March (Zoom Link https://bit.ly/ICOD_DSday24).

The present meeting is organized during the 20th and the 21st of March to celebrate the World Down syndrome Day. The meeting will not have the format of a scientific symposium last in our past activities this day, but will be an internal scientific meeting to discuss a turning point in the ICOD project as it is the design of the future Phase 2 study that once demonstrated the safety and tolerability of the AEF0217 molecule both in neurotypical healthy subjects and in individuals with Down syndrome, now is time to provide clinical evidence of its efficacy in improving cognitive functioning and adaptive functionality in individuals with Down syndrome.

Venue: Barcelona Biomedical Research Park (PRBB) building, Hospital del Mar Research Institute, Doctor Aiguader Street number 88 of Barcelona

How to get there: https://www.imim.es/en_accessos-situacio.html,

Google Maps location: <https://maps.app.goo.gl/LR5yThn5dgbnf3xw7>

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Wednesday March 20th , 2024

14.00-18:00 (4th floor of the PRBB building, Boardroom)

14:00-14:30

Welcome to participants, roundtable presentation of participants and introduction to the objectives of the meeting

Rafael de la Torre/Piervi Piazza (30 min)

14:30-15:30

Presentation of clinical sites (60 min) (5 min per site)

15:30-16:30

Background information on the clinical development of AEF0217

Stéphanie Monlezun/Rafael de la Torre (60 min, including 15-20 minutes discussion)

16:30-17:00

Coffee break (30 min)

17:00-17:45

Experts Advice from the European Medicines Agency (EMA) to be considered in future Phase 2 studies

Piervi Piazza (45 min, including 15 min discussion)

20:30 Dinner (all participants)

Thursday March 21st, 2024

9.00-14:30 (Agora of the PRBB building, Rita Levi-Montalcini room)

9:00-10:30

Combining cognitive performance with adaptive functionality as outcomes (data on NIH-Toolbox and VABS-II) and implications for study design (90 min, including 20 min discussion)

Helle Mengel/Rafael de la Torre/Laura Forcano

10:30-11:00

Coffee break (30 min)

11:00-12:30

Presentation of the synopsis of the Phase 2 study

Helle Mengel (90 min, including 30 min discussion)

12:30-13:00

Organization of centralized training of raters

Laura Forcano

13:00-14:00

Break Lunch (60 min)

14:00-15:00

Phase 2 Multicenter RCT, organization and management

Stéphanie Monlezun

15.00-15.30

Concluding remarks

Rafael de la Torre

