

PCORI

*A multicentric randomized **PRAG**matic trial to compare the effectiveness of fingolimod versus dimethyl-fumarate on patient overall disease experience in relapsing remitting **Multiple Sclerosis**: novel data to inform decision-makers – (**PRAG-MS**)”*

KICK OFF MEEETING – SCIENTIFIC ADVISORY COMMITTEE (SAC FIRST MEETING)

16TH DECEMBER 2016

BIBLIOTECA CENTRALE, GROUND FLOOR

FONDAZIONE IRCCS ISTITUTO NEUROLOGICO “CARLO BESTA”

VIA CELORIA, 11, MILANO

PRELIMINARY AGENDA

9.00 - Welcome

Alberto Guglielmo – President FINCB

Fabrizio Tagliavini – Scientific Director FINCB

Germano Pellegata – General Director FINCB

Renato Mantegazza – Responsible Clinical Trial Centre FINCB

Silvia Rossi – Principal Investigator

Gaetano Guglielmi –Deputy General Director Office 3- Italian Ministry of Health

9.30 - Project overview and research strategy

Silvia Rossi

10.15 *MRI outcomes and procedures*

Massimiliano Calabrese

10.30 Study design approach and statistical analysis

Maria Pia Sormani

11.00 coffee break

11:15 Project management: bodies, procedures, and contractual arrangement

Carla Finocchiario – Project Manager

11:45 Ethical issues and protection of human subjects

Barbara Bottalico

12:30 – Panel Discussion

13:30 - Lunch

14:30 – Focus on patient reported outcomes:

- the expert point of view (Alessandra Solari /Ambra Maria Giovannetti)
- the associations/foundations point of view (Giampaolo Brichetto/Paola Zaratin)
- the patient point of view (Michele Schinella/Salvatore Lico)

15:30 – Focus on ancillary studies

- Dose monitoring – Marco Gobbi
- Biomarkers - Oksenberg and Battistini by webinar
- Magnetic sensors for objective assessment of disability- Stefano Rossi
- Cognitive assessment – Stefano Cappa

16.30 Panel Discussion and approval of protocol draft

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SCIENTIFIC ADVISORY COMMITTEE (SAC)

Steering Committee

Silvia Rossi (Fondazione Istituto Neurologico Carlo Besta - Italy)
Maria Pia Sormani (Università di Genova – Italy)
Renato Mantegazza (Fondazione Istituto Neurologico Carlo Besta - Italy)
Stefano Rossi (Università della Tuscia - Italy)
Luca Battistini (Fondazione Santa Lucia - Italy)
Elisabetta Volpe (Fondazione Santa Lucia - Italy)
Marco Gobbi (Istituto di Ricerche Farmacologiche Mario Negri - Italy)
Massimiliano Calabrese (Azienda Ospedaliera integrata di Verona - Italy)
Barbara Bottalico (Center for Health Technologies – Università di Pavia - Italy)
Jorge Oksenberg (UCSF- USA)

Recruiters

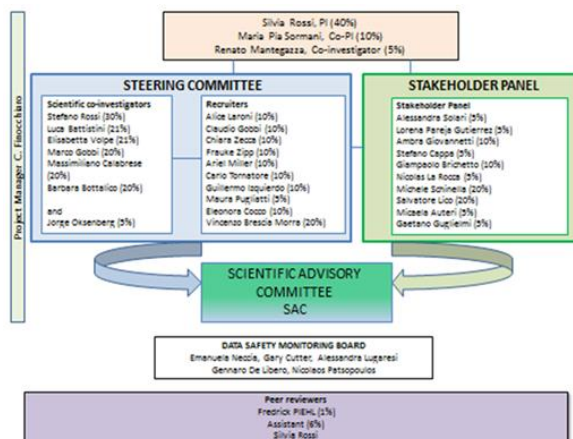
Alice Laroni (Università di Genova - Italy)
Claudio Gobbi (Neurocenter of Southern Switzerland - Switzerland)
Chiara Zecca (Neurocenter of Southern Switzerland- Switzerland)
Frauke Zipp (Universitätsmedizin der Johannes Gutenberg – Germany)
Ariel Miller (Carmel Medical Center - Israel)
Carlo Tornatore (Georgetown University - USA)
Guillermo Izquierdo (Hospital Universitario Virgen Macarena - Spain)
Maura Pugliatti (Azienda Ospedaliera Universitaria di Ferrara – Italy)
Eleonora Cocco (Università di Cagliari - Italy)
Vincenzo Brescia Morra (Università degli Studi di Napoli - Italy)

Stakeholder Panel

Alessandra Solari (Fondazione Istituto Neurologico Carlo Besta - Italy) - Neurologist
Lorena Pareja Gutierrez (Fondazione Istituto Neurologico Carlo Besta - Italy) - Nurse
Ambra Giovannetti (Fondazione Istituto Neurologico Carlo Besta - Italy) - Psychologist
Stefano Cappa (Istituto Fatebenefratelli di Brescia - Italy) - Cognitive neurologist
Giampaolo Brichetto (Federazione Italiana Sclerosi Multipla – Italy) - Expert
Nicolas La Rocca (National Multiple Sclerosis Society - USA) - Expert
Michele Schinella (Italy) – Patient
Salvatore Lico (Italy) Patient and Regional coordinator of Patient Association
Micaela Auteri (Italy) Family member
Gaetano Guglielmi (Ministero della Salute - Italy) - Expert

DATA SAFETY MONITORING BOARD (DSMB)

Emanuela Neccia (Italy) - Patient
Gary Cutter (Uab School of public Health - USA) - Expert
Alessandra Lugaresi (Italy) - Neurologist
Gennaro De Libero (Basel University – Switzerland) - Clinician
Nicolao Patsopoulos (USA) – Expert



How to reach Besta – Via Celoria 11

Underground:

Line 2 (green), Piola station (500 m from Besta), Lambrate station (600 m from Besta)

Bus:

Trolleybus 93, stop Ponzio-Celoria; Bus 61, stop Piazzale Gorini (200 m from Besta)

Tram:

Nos. 23 and 33, stop Piazza Leonardo da Vinci (200 m from Besta)

Car:

From the Eastern Tangential Motorway (Tangenziale Est), take the Forlanini exit, and go towards the city centre along Viale Corsica, at the third red-light turn right on Via Lomellina, Via Laselli, Via Ponzio, and turn right Via Celoria

Train:

From Stazione Centrale take subway line 2 (Green line), exit Piola (200 m from Besta)

From Stazione Cadorna take subway line 2 (Green line), exit Piola (200 m from Besta)

From Stazione Lambrate, Bus 93, exit Ponzio/Celoria.

Airports:

From Linate, bus 73 and exit Corsica/Campania then Bus 93, exit Ponzio/Celoria

From Malpensa, train to Milano Centrale or Stazione Cadorna FNM, then subway line 2 (Green), exit Piola (500 m from Besta)

From Orio al Serio, bus to Milano Centrale Train Station then subway line 2 (Green), exit Piola (500 m from Besta)

Map in attachment

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Principal investigator

Clinical Research Center

Project Management

Project Management

Suggested Hotel to be booked directly by you – Hotel da prenotare direttamente da parte dei partecipanti

<http://www.hoteldieci.it/>

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