

Supplementary Material for:

**Real-World Safety and Effectiveness of Dimethyl Fumarate in Patients with MS:
Results from the ESTEEM Phase 4 and PROCLAIM Phase 3 Studies with a
Focus on Older Patients**

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Table S1 Cell surface markers utilized for phenotyping

Cell type	Cell surface marker
CD4 ⁺ T cells	CD3 ⁺ / CD4 ⁺
CD8 ⁺ T cells	CD3 ⁺ / CD8 ⁺
B cells	CD19 ⁺
Naïve CD4 ⁺ T cells	CD4 ⁺ / CD45RA ⁺ / CCR7 ⁺
Effector CD4 ⁺ T cells	CD4 ⁺ / CD45RA ⁺ / CCR7 ⁻
Central memory CD4 ⁺ T cells	CD4 ⁺ / CD45RA ⁻ / CCR7 ⁺
Effector memory CD4 ⁺ T cells	CD4 ⁺ / CD45RA ⁻ / CCR7 ⁻
Activated CD4 ⁺ T cells	CD4 ⁺ / CD38 ⁺ / HLA-DR ⁺
Naïve CD8 ⁺ T cells	CD8 ⁺ / CD45RA ⁺ / CCR7 ⁺
Effector CD8 ⁺ T cells	CD8 ⁺ / CD45RA ⁺ / CCR7 ⁻
Central memory CD8 ⁺ T cells	CD8 ⁺ / CD45RA ⁻ / CCR7 ⁺
Effector memory CD8 ⁺ T cells	CD8 ⁺ / CD45RA ⁻ / CCR7 ⁻
Activated CD8 ⁺ T cells	CD8 ⁺ / CD38 ⁺ / HLA-DR ⁺
Transitional B cells	CD19 ⁺ / CD24 ^{hi} / CD38 ^{hi}
Naïve B cells	CD19 ⁺ / CD27 ⁻ / IgD ⁺
IgD ⁺ memory B cells (non-class switched)	CD19 ⁺ / CD27 ⁺ / IgD ⁺
IgD ⁻ memory B cells (class switched)	CD19 ⁺ / CD27 ⁺ / IgD ⁻
Plasmablasts	CD19 ⁺ / CD27 ⁺⁺ / CD38 ⁺⁺
CD138 ⁺ plasma cells	CD19 ⁺ / CD27 ⁺⁺ / CD38 ⁺⁺ / CD138 ⁺

Ig immunoglobulin

Table S2. ESTEEM Principal Investigators and Ethics Committees

Country	Principal Investigator Name	Name of Ethics Committee
Argentina	Dr. Deri, Norma	Comite Independiente de Etica
Argentina	Dr. Sinay, Vladimiro	Comite Independiente de Etica
Argentina	Dr. Questa Laudani, Mathias	NA
Argentina	Dr. Giugni, Juan Carlos	NA
Australia	Prof. Macdonell, Richard	Austin Health Human Research Ethics Committee
Australia	Dr. Lechner Scott, Jeannette	Austin Health Human Research Ethics Committee
Australia	Prof. Kermode, Allan	Austin Health Human Research Ethics Committee
Australia	AProf McCombe, Pamela	Austin Health Human Research Ethics Committee
Australia	AProf Slee, Mark	Austin Health Human Research Ethics Committee
Australia	Dr. Buzzard, Katherine	Austin Health Human Research Ethics Committee
Australia	Dr. Parratt, John	Austin Health Human Research Ethics Committee
Australia	AProf Schwartz, Raymond	Austin Health Human Research Ethics Committee
Australia	AProf Hodgkinson, Suzanne	Austin Health Human Research Ethics Committee
Australia	Dr. Marriott, Mark	Austin Health Human Research Ethics Committee
Australia	Dr. John, Nevin	Austin Health Human Research Ethics Committee
Australia	Prof. Broadley, Simon	Austin Health Human Research Ethics Committee
Australia	Prof. Barnett, Michael	Austin Health Human Research Ethics Committee

Australia	Dr. Skibina, Olga	Austin Health Human Research Ethics Committee
Australia	AProf Lee, Andrew	Austin Health Human Research Ethics Committee
Australia	Dr. Chapman, Caron	Austin Health Human Research Ethics Committee
Australia	AProf Reddel, Stephen	Austin Health Human Research Ethics Committee
Australia	Prof. Vucic, Steve	Austin Health Human Research Ethics Committee
Australia	Dr. Krishnan, Arun	Austin Health Human Research Ethics Committee
Australia	Dr. Tan, Ik Lin	Macquarie University Human Research Ethics Committee (Medical Sciences)
Austria	Prof. Leutmezer, Fritz	- BASG - Bundesamt für Sicherheit im Gesundheitswesen (Austria) - Ethics Committee of the City of Vienna
Austria	Dr. Bsteh, Christian	- BASG - Bundesamt für Sicherheit im Gesundheitswesen (Austria) - Ethics Committee of the City of Vienna
Austria	Prof. Asenbaum-Nan, Susanne	- BASG - Bundesamt für Sicherheit im Gesundheitswesen (Austria) - Ethics Committee of the City of Vienna
Austria	Dr. Urbanits, Sabine	- BASG - Bundesamt für Sicherheit im Gesundheitswesen (Austria) - Ethics Committee of the City of Vienna
Canada	Dr. Boyrazian, Hagob	WIRB
Canada	Dr. Vorobeychik, Galina	WIRB
Canada	Dr. Hassan, Ayman	WIRB
Canada	Dr. Shawush, Melad	WIRB

Canada	Dr. Attwell-Pope, Kristen	WIRB
Canada	Dr. Thorne, Michael	WIRB
Canada	Dr. Morrow, Sarah	WIRB
Canada	Dr. Giles, Kathryn	WIRB
Canada	Dr. Giacomini, Paul	WIRB
Canada	Dr. Marchetti, Paul	WIRB
Canada	Dr. Maharaj, Mandat	WIRB
Canada	Dr. Weston, Lyle	WIRB
Canada	Dr. Jacques, Francois	WIRB
Canada	Dr. Yeung, Michael	WIRB
Canada	Dr. Girard, Jean-Marc	WIRB
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Czech Republic	Dr. Skoda, Ondrej	- Statni ustav pro kontrolu leziv - Eticka komise Fakultni nemocnice u sv. Anny v Brne
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Denmark	Dr. Nielsen, Helle	- Danish Medicines Agency - De videnskabsetiske Komitéer
Denmark	Dr. Christensen, Mette Kirstine	- Danish Medicines Agency - De videnskabsetiske Komitéer
Denmark	Prof. Frederiksen, Jette	- Danish Medicines Agency - De videnskabsetiske Komitéer
Denmark	Dr. Kant, Matthias	- Danish Medicines Agency - De videnskabsetiske Komitéer
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France	Dr. Maillet-Vioud, Marcel	NA
France	Dr. Rosey Dufosse, Nathalie	NA

France	Dr. Gugenheim, Michel	NA
France	Dr. Schmidt, Nicolas	NA
France	Dr. Faucheux, Jean-Marc	NA
France	Dr. Morel, Nathalie	NA
France	Dr. Lejeune, Pascal	NA
France	Dr. Manchon, Eric	NA
France	Dr. Mostoufizadeh, Sohrab	NA
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Hungary	Dr. Nikl, Janos	- Egészségügyi Tudományos Tanács Tudományos és Kutatásértékelési Bizottság - Országos Gyógyszerészeti és Elelmézés- egészségügyi Intézet
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Ireland	Dr. Costelloe, Lisa	Beaumont Hospital Ethics Medical Research Committee
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Italy	Prof. Centonze, Diego	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico dell'I.R.C.C.S. Neuromed-Istituto Neurologico Mediterraneo
Italy	Prof. Bergamaschi, Roberto	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico Della Fondazione Istituto San Raffaele Giuseppe Giglio di Cefalù

Italy	Prof. Brescia Morra, Vincenzo	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico per le attività biomediche "Carlo Romano"
Italy	Dr. Buccafusca, Maria	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico Scientifico dell'Azienda Ospedaliera Universitaria Policlinico Gaetano Martino
Italy	Dr. Bucello, Sebastiano	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico Catania 2
Italy	Rasia, Sarah	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico Provinciale della Provincia di Brescia
Italy	Dr. Cottone, Salvatore	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico dell'Azienda Ospedaliera Ospedali Riuniti Villa Sofia - Cervello di Palermo
Italy	Dr. Danni, Maura Chiara	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico dell'Azienda Sanitaria Unica Regionale delle Marche di Ancona
Italy	Dr. De Robertis, Francesca	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico della AUSL LE di Lecce

Italy	Dr. Maniscalco, Giorgia Teresa	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) - Comitato Etico dell'Azienda Ospedaliera Antonio Cardarelli di Napoli
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Italy	Dr. Locatelli, Laura	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico Unico Regionale - CEUR
Italy	Dr. Malucchi, Simona	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico Interaziendale AOU S. Luigi Gonzaga
Italy	Prof. Inglese, Maria Matilde	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) -Comitato Etico Regionale della Liguria

Italy	Prof. Cocco, Eleonora	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) - Comitato Etico della Azienda Ospedaliero Universitaria di Cagliari
Italy	AProf Conte, Antonella	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) - Azienda Ospedaliera Universitaria Policlinico Umberto I - Università di Roma La Sapienza
Italy	Prof. Mirabella, Massimiliano	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) - Comitato Etico dell'Università Cattolica del Sacro Cuore e annesso Policlinico "A. Gemelli"
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Italy	Dr. Montepietra, Sara	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) - Comitato Etico Provinciale di Reggio Emilia
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Italy	Dr. Ferraro, Diana	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) - Comitato Etico della Provincia di Modena
Italy	Dr. Scandellari, Cinzia	- Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII (Presidio Papa Giovanni XXIII) - Comitato Etico Interaziendale Bologna-Imola - CE-BI
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Netherlands	Dr. Schrijver, Hans	- Catharina Ziekenhuis Eindhoven - Lokale Ethische Commissie WFG
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Netherlands	Dr. Van Leusen, H.J	- Catharina Ziekenhuis Eindhoven
Netherlands	Dr. Hoitsma, Elske	- Catharina Ziekenhuis Eindhoven - Leids Universitair Medisch Centrum

Netherlands	Dr. Frequin, Stephan	- Catharina Ziekenhuis Eindhoven - BoD Sint Antonius hospital
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New Zealand	Dr. Mottershead, John	Central Ethics Committee
New Zealand	Dr. Oh, Daniel	Central Ethics Committee
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Belgium	Emmanuel Bartholome, MD	Comite d’Ethique Centre Hospitalier Universitaire Tivoli
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Bulgaria	Sasho Kastrev, MD*	Republic of Bulgaria Ministry of Health Ethics Committee for Multicenter Trials
Bulgaria	Rosen Ikonov, MD*	Republic of Bulgaria Ministry of Health Ethics Committee for Multicenter Trials
Bulgaria	Plamen Tzvetanov, MD, PhD, DSc, FRCP	Republic of Bulgaria Ministry of Health Ethics Committee for Multicenter Trials
Bulgaria	Penko Shotekov, MD, DSc	Republic of Bulgaria Ministry of Health Ethics Committee for Multicenter Trials
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Bulgaria	Ivaylo Tarnev, MD, DSc	Republic of Bulgaria Ministry of Health Ethics Committee for Multicenter Trials
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Croatia	Silvio Basic, MD*	Agency for Medicinal Products and Medical Devices Central Ethics Committee
Croatia	Marinko Bilusic, MD*	Agency for Medicinal Products and Medical Devices Central Ethics Committee
Croatia	Marija Bosnjak Pasic, MD*	Agency for Medicinal Products and Medical Devices Central Ethics Committee
Croatia	Silva Soldo, MD*	Agency for Medicinal Products and Medical Devices Central Ethics Committee
Croatia	Mario Habek, MD*	Agency for Medicinal Products and Medical Devices Central Ethics Committee
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Czechia	Ondrej Skoda, MD*	Eticka komise/Nemocnice Jihlava/Vrchlickeho 59

Country	Principal Investigator Name	Name of Ethics Committee
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Czechia	Martin Valis, MD*	Eticka komise/FN Hradec Kralove/ Sokolska 581
Kuwait	Raed Al Roughani, MD	Ethical Committee, Dasman Diabetes Institute/Research Affairs/Ethical Review Committee
Lithuania	Dalia Mickeviciene, MD	Lithuanian Bioethics Committee
Lithuania	Ieva Sereike, MD*	Lithuanian Bioethics Committee
Lithuania	Lina Malciene, MD	Lithuanian Bioethics Committee
Poland	Robert Bonek, MD	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
Poland	Waldemar Brola, MD*	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
Poland	Lidia Darda-Ledzion, MD*	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
Poland	Hanka Hertmanowska, MD	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
Poland	Jan Ilkowski, MD*	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
Poland	Bartosz Karaszewski, MD*	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
Poland	Maciej Maciejowski, MD	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
Poland	Ryszard Podemski, MD*	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach

Country	Principal Investigator Name	Name of Ethics Committee
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Poland	Adam Stepień, MD*	Komisja bioetyczna slaskiej izby lekarskiej w Katowicach
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Turkey	Cavit Boz, MD*	Kocaeli University Clinical Trials Ethics Committee
Turkey	Yahya Celik, MD*	Kocaeli University Clinical Trials Ethics Committee
Turkey	Husnu Efendi, MD*	Kocaeli University Clinical Trials Ethics Committee
Turkey	Meryem Kurne, MD*	Kocaeli University Clinical Trials Ethics Committee
Turkey	Murat Terzi, MD*	Kocaeli University Clinical Trials Ethics Committee
Turkey	Belgin Petek Balci, MD*	Kocaeli University Clinical Trials Ethics Committee
Turkey	Serkan Ozakbas, MD*	Kocaeli University Clinical Trials Ethics Committee
Turkey	Munire Toprak, MD*	Kocaeli University Clinical Trials Ethics Committee
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USA	William Grainger, MD*	Copernicus Group IRB/Copernicus Group IRB

Country	Principal Investigator Name	Name of Ethics Committee
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USA	Cynthia Huffman, MD	Copernicus Group IRB
USA	Daniel Harrison, MD*	University of Maryland, Baltimore Institutional Review Board
USA	Derrick Robertson, MD	Western Institutional Review Board
USA	Ann Bass, MD	Copernicus Group IRB
USA	Jeffrey Kaplan, MD	Copernicus Group IRB
USA	Mark Cascione, MD	Copernicus Group IRB
USA	Nirav Patel, MD	Copernicus Group IRB
USA	Dennis Lacey, MD*	Copernicus Group IRB
USA	Jeffrey English, MD*	Copernicus Group IRB
USA	Katherine Standley, MD	Copernicus Group IRB
USA	Bogdan Gheorghiu, MD	Copernicus Group IRB
USA	Francisco Valdivia, MD*	Copernicus Group IRB
USA	Gabriel Pardo, MD*	Oklahoma Medical Research Foundation
USA	Bradley Evans, MD*	Copernicus Group IRB
USA	Jean-Raphael Schneider, MD*	Copernicus Group IRB
USA	Sibyl Wray, MD*	Copernicus Group IRB
USA	Joshua Katz, MD*	Copernicus Group IRB

* = Investigator received ethics committee approval but no subjects were screened or enrolled.