

2 October 2014
EMA/596658/2013
Chief Policy Adviser

Publication and access to clinical-trial data

Comments received from public consultation (July - September 2013)

Stakeholder Number	Organisation
01	Norgine limited – Dr Donna McVey
02	Alexis Clapin (affiliation not specified)
03	INFARMED – Dinah Duarte
04	BioIndustry Association (BIA) – Dr Christina Abouzeid
05	EFPIA – Isabelle Clamou
06	VFA - German Association of Research-Based Pharmaceutical Companies – Thorsten Ruppert
07	University of London – Benjamin Rusholme (student)
08	Chris Hartman (affiliation not specified)
09	Fabian Heindl (affiliation not specified)
10	Medical University of Graz – Martin Sprenger
11	Columbia University, NY, USA – Donald F Klein
12	Sharon Wanger (affiliation not specified)
13	Emory University, Atlanta, Georgia – John M Nardo (retired Psychiatrist/Psychoanalyst)
14	Imperial College London – Joe Jordan
15	Paediatric Mental Health Association (UK) – Dr Max Davie
16	Dr Rowena East (retired GP, UK)
17	North East Humanist – Terence Waites
18	Michel Kovari (affiliation not specified)
19	Penny Tompkins (affiliation not specified)
20	Arnaldo Capriles (affiliation not specified)
21	Steve Marshall (affiliation not specified)
22	Adam Ktobukowski (affiliation not specified)
23	Vicki Crallan (affiliation not specified)
24	Martha Collins (affiliation not specified)
25	Elizabeth Atkinson (affiliation not specified)
26	Julie Milton (affiliation not specified)

Stakeholder Number	Organisation
27	Neil Canham (affiliation not specified)
28	Richard J Bowers (affiliation not specified)
29	Dr TRS Wilson (retired)
30	County Hospital Frankenberg Eder, Hessen, Germany - Catalin Bogdan Pepelea
31	Nina Yogasundram (affiliation not specified)
32	University of Milan - VAS-Vascular-Independent Research and Education-European Organization – Prof. M Catalano
33	Susan Schellenberg (affiliation not specified)
34	Felix A Bauer (affiliation not specified)
35	Cochrane Dementia and Cognitive Improvement Group – Rupert McShane
36	Kenneth Mullen (affiliation not specified)
37	University College London Hospital – Alisdair Jones (Pre-registration pharmacist)
38	M Ratledge (affiliation not specified)
39	Morgan Irvine (affiliation not specified)
40	Clive Ashworth (affiliation not specified)
41	Schlosspark-klinik, Berlin – Prof. Dr. Thomas Lempert (Head of Neurology)
42	Royal College of Surgeons, Ireland – Kate Howard Fitzpatrick (Pharmacy student)
43	Rob Armitage (affiliation not specified)
44	Max Buerck-Gemassmer (GP)
45	Dr. Simon Young (affiliation not specified)
46	Dr. Joshua D Feder (affiliation not specified)
47	Hilary Essen (affiliation not specified)
48	Silvia Florindo (affiliation not specified)
49	Dr Andreas Wiggers (affiliation not specified)
50	Lund University, Sweden – Karl Lundblad (Medical student)
51	Department of Anesthesiology and Critical Care Medicine. Charité Campus Benjamin Franklin, Freie Universitaet Berlin, Germany – Prof. Dr. Christoph Stein
52	Canterbury District Health Board, Christchurch, New Zealand – Associate Professor Matthew Doogue
53	Mikko Lahdensuo (affiliation not specified)
54	Andrew Morbey (affiliation not specified)
55	Mark Layton (affiliation not specified)
56	Pierre Peten (affiliation not specified)
57	Dr. Pablo Munoz – University of Chile
58	Northumbria University, UK - Shane O'Leary (PhD student)
59	Frederik Holz (affiliation not specified)
60	Llanishen Court Surgery, Cardiff – Dr David G Evans (GP)
61	Thomas Christian Abildtup (affiliation not specified)
62	Dr Olivier Montigny (GP – Belgium)
63	Standing Committee of European Doctors (CPME) – Constance Colin
64	Leiden University, Netherlands – Coen van Hasselt (Postdoctoral research fellow in pharmacometrics)
65	Dimitri Mulkern (Dental student 1 st year)
66	Manas Sikdar (GP)
67	Nick Kent – (affiliation not specified)

Stakeholder Number	Organisation
68	University Göttingen – Ruben Arslan
69	Neurology department, Schlosspark-Klinik, 14059 Berlin, Germany – Dr Enrico Volzke (Senior Physician)
70	Douglas Carnall - Traducteur-Editeur, Nantes (France)
71	Casey Vickstrom (Undergraduate Research Assistant) - Northwestern University
72	Adrienne Grech - Monash University
73	Aymee Thurston (affiliation not specified)
74	Giulio Maria Corbelli - Plus onlus
75	Cardiff University – Dr Helen Morgan
76	VU University Medical Center, Amsterdam – Maarten Boers (Professor of Clinical Epidemiology, Department of Epidemiology and Biostatistics)
77	Fetal Anti Convulsant Trust – Emma Friedmann
78	Dr Elizabeth Wager (Publications Consultant) – Sideview
79	ECCO – European Crohn's and Colitis Organisation - Simon Travis (ECCO President)
80	European Food Safety Authority – Laura Ciccolallo
81	Faculty of Pharmaceutical Medicine – Ben Cottam
82	Drug Commission of the German Medical Association – Silke Renner
83	European Organisation for Rare Diseases (Eurordis) – Francois Houyez
84	Guild of Healthcare Pharmacists – Barry Corbett
85	Dr Katie Jones (affiliation not specified)
86	Azienda Policlinico Vittorio Emanuele, Teaching Hospital, Catania, Italy – Vincenzo Guardabasso
87	European Parkinson's Disease Association (EPDA) – Ami Arieli
88	Austrian Medicines & Medical Devices Agency (AGES), Austria, Vienna – Thomas Lang
89	European Organisation for Research and Treatment of Cancer (EORTC) – Anastassia Negrouk
90	LIF – Swedish Association of the Pharmaceutical Pharmacy – Anita Finne Grahnen
91	European Federation of Statisticians in the pharmaceutical Industry (EFSPI) – Christoph Gerlinger
92	Romanian Association of International Medicines Manufacturers – Dan Zaharescu
93	EuropaBio – Miriam Gargesi
94	Irish Pharmaceutical Healthcare Association (IPHA) – Rebecca Cramp
95	Medico international, Germany – Thomas Wulf
96	International Alliance of Patients' Organizations – Rachel Seal-Jones
97	Vrije Universiteit, Brussel – F. Feys
98	GSK – Andrew Freeman
99	Hellenic Association of Pharmaceutical Companies (SFEE) - Yannis Chrysospathis
100	Japan Pharmaceutical Manufacturers Association - Toshihiko Tsunenari
101	ABPI – Rebecca Munsden
102	European Haematology Association (EHA) - Thom Duyvené de Wit
103	IFAH-Europe – Rick Clayton
104	Humane Society International - Dr Victoria Martindale
105	IPPNW-Germany - Frank Uhe

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106	Pfizer – Victoria Kitcatt
107	Pharmaceutical Users Software Exchange (PhUSE) - Dr. Christian Mueller Ahlborn
108	International Alliance of Patients' Organizations - Durhane Wong-Rieger
109	UK Medical Research Council Clinical Trials Unit at UCL, London - Dr Anthony Johnson
110	National Voices - Jeremy Taylor
111	German Pharmaceutical Industry Association (BPI) - Jens Peters
112	German Association for Social Psychiatry Association - Richard Suhre
113	Parkinson's UK - Rachel Evans
114	IUMSP & CRC, CHUV Lausanne – Dr Erik von Elm
115	EUCOPE European Confederation of Pharmaceutical Entrepreneurs AISBL – Olivier Sude
116	European network for Health Technology Assessment, EUnetHTA – Julia Chamova
117	FEAM – Laurence Legros
118	Institute for Quality and Efficiency in Health Care (IQWiG) – Beate Wieseler
119	European Public Health Alliance (EPHA) – Leonardo Palumbo
120	Médecins Sans Frontières - Access Campaign – Helle Aagaard
121	National Institute for Health and Care Excellence – Nick Doyle
122	Norwegian Institute of Public Health – Camilla Stoltenberg
123	Danish Association of the Pharmaceutical Industry - Lillian Rasmussen
124	F. Hoffmann-La Roche Ltd., Basel - Sabine Atzor
125	Sense About Science, on behalf of the AllTrials campaign - Sile Lane, Director of Campaigns
126	AIM, HAI Europe, ISDB, MiEF - Florence Vandeveld
127	Gilead Sciences International Ltd – Kelly Munnery
128	EASL - European Association for the Study of the Liver – Fiona Godfrey
129	Science Pharma - Joanna Pawlak, PhD
130	PLOS - Dr Virginia Barbour, Medicine Editorial Director
131	Royal College of Physicians (RCP) - Dr Patrick Cadigan, registrar
132	British Medical Association - Vivienne Nathanson, Director of Professional Activities
133	The Association of Clinical Research Organizations (ACRO) - Douglas Peddicord
134	Association of Clinical Research Professionals (ACRP) - Jim Thomasell
135	Karolinska Institutet - Riccardo Guidi, PhD student
136	The Health Disparities Research Consortium - Rebecca Ortega, Executive Director
137	The European Association of Hospital Pharmacists (EAHP) – Richard Price
138	Critical Path Institute/Critical Path Global - Martha A. Brumfield, PhD, President & CEO
139	European Biopharmaceutical Enterprises, EBE - Titta Rosvall-Puplett, Executive Director
140	Apotex Inc. - Mariya Bevzyuk
141	The European Patients' Forum - Kaisa Immonen-Charalambous
142	Tribunale per i diritti del malato – Sabrina Nardi
143	The Wellcome Trust - Will Greenacre, Policy Officer
144	TMF – Technology, Methods, and Infrastructure for Networked Medical Research - Matthias Löbe

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145	AESGP - Association of the European Self-Medication Industry - Christelle Anquez-Traxler
146	Leem (Les Entreprises du Médicament) - Claire Sibenaler
147	BIO Deutschland e.V., the German Biotechnology Industry Association - Matthias Bach
148	United Kingdom Government (Medicines and Healthcare Products Regulatory Agency) – Caroline Brennan
149	Peter Doshi (affiliation not specified)
150	ECRIN (European Clinical Research Infrastructures Network)
151	Irish Patients Association Dublin - Stephen McMahon, Chairman
152	British Pharmacological Society – Ruth Meyer
153	InterMune UK Ltd and InterMune International AG - Jon Becker, Vice President, Deputy General Counsel & Head of European Legal Affairs
154	Cinzia Colombo (various affiliations)
155	International Society of Pharmacometrics (ISoP) and Drug Disease Model Resource (DDMoRe) consortium – Rene Bruno
156	PHARMIG - Association of the Austrian pharmaceutical industry - Christa Holzhauser
157	Les Laboratoires SERVIER, France – Christine Marey
158	Multi-Regional Clinical Trials Center (MRCT) at Harvard University - Rebecca H. Li
159	German Society of Pharmaceutical Medicine - Dr. Kurt Bestehorn
160	Public Citizen's Health Research Group - Sarah Sorscher, Attorney, Michael Carome, Director
161	Danish Health & Medicines Authority – Sameer Kohli
162	Dr Margaret Winker - Senior Research Editor, PLOS Medicine. (submitted as an individual rather than on behalf of PLOS)
163	Jim Murray (affiliation not specified)
164	BEUC – The European Consumers Organization - Ilaria Passarani, Senior policy officer
165	DMB – Data Management Biomedical : French association of data managers - Sophie OLLIVIER on behalf of DMB “task force”
166	Novo Nordisk A/S - Ane Sofie Böhm Nielsen
167	Plasma Protein Therapeutics Association (PPTA) – Ilka von Hoegen
168	Dr. Pankaja Raghav
169	EUROTARGET project – Anne Cambon-Thomsen