EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 October 2017
EMA/648996/2017

Agenda – Registries Initiative – Multiple Sclerosis workshop

7 July 2017, 08:30 to 16:30 UK time

Welcome room: 2-A

Co-Chairs: Xavier Kurz and Peter Mol

Main Objectives of the workshop:

- To agree on implementable recommendations on core data elements to be collected, consents, governance, quality assurance and registry interoperability.
- To agree a work-plan for the further development and finalisation of recommendations to be used by registry holders and MAHs/MAAs.

Item	Topics for information	Presenter	Time
1.	Welcome	Peter Mol	08:30-08:35h
2.	Introduction: expected outcomes for the workshop	Xavier Kurz	08:35-08:40h
3.	Update of the Patient Registries Initiative	Patricia McGettigan	08:40-08:55h
4.	Future potential for registries in regulatory processes	Manuel Haas	08:55-09:05h
5.	Value and potential of patient registries in Multiple-Sclerosis	Christoph Thalheim	09:05-09:20h
6.	Value and potential of patient registries in Multiple-Sclerosis	Jan Hillert	09:20-09:35h
7.	Plan for the day and explanation of the Group-work activities	Patricia McGettigan	09:35-09:45h
	Break – Coffee / Tea		09:45-10:00h
	Group-work Facilitator: Patricia McGettigan	**Moderators**	

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Item	Topics for information	Presenter	Time
8.	Moderators outline how the groups will operate: • **Group 1:** Common data elements that are needed by all stakeholders: Data validation • **Group 2:** Informed consents, governance, data protection, individual data vs aggregated data • **Group 3:** Common procedures and registry interoperability, quality assurance to support regulatory evaluation and data analysis	Peter Mol / Pavel Balabanov Xavier Kurz/ Mireia Castillon Alison Cave/ Carla Alonso	10:00-12:00h
	Lunch		12:00-13:00h
9.	**Agreement on Recommendations:** • **Group 1:** Common data elements that are needed by all stakeholders: Data validation • **Group 2:** Informed consents, governance, data protection, individual data vs aggregated data • **Group 3:** Common procedures and registry interoperability, quality assurance to support regulatory evaluation and data analysis	Peter Mol / Pavel Balabanov Xavier Kurz/ Mireia Castillon Alison Cave/ Carla Alonso	13:00-14:00h
10.	Each group prepares a summary of its Recommendations. Slides / Posters with the main points to be compiled for discussion all the Workshop participants	All	14.00 – 14.30
	Break – Coffee / Tea		14:30-14:45h
Item	**Group Recommendations and Discussions**		
11.	Presentation of Group 1, 2 and 3 of Recommendations to all the participants; Discussion/Agreement on Recommendations	Nominee from each Group	14:45-16:00h
12.	Conclusions and Next Steps	Peter Mol / Xavier Kurz	16:00-16:30h

Expected outcomes:

- **Group 1**: Agreement on key common data elements needed by all stakeholders to fulfil their output needs.
- **Group 2**: Outline agreement on consents and on a pragmatic and lean governance model adjusted for CF stakeholders' purposes and taking account of data protection requirements.
- **Group 3**: Agreement on protocols for data collection (to facilitate registry interoperability) and on measures for data verification that would support quality assurance for EMA qualification.

Participants and Work Groups

Group 1	Common data elements that are needed by all stakeholders: Data validation
Peter Mol (MEB-NL)	**Regulators**
Pavel Balabanov (EMA)	**Regulators**
Dana Horáková	**Registries Holders**
Imogen Scott Plummer	**Registries Holders**
Liesbet Peeters	**Registries Holders**
Carmela Macchiarulo (AIFA)	**Regulators**
Julie Williams	**Regulators**
Brigitte Keller-Stanislawski	**Regulators**
Steve Brookes (Biogen)	**Industry**
Yvonne Geissbuehler (Novartis)	**Industry**
Eva-Maria Wicklein (Bayer AG)	**Industry**
Patrice Verpillat (Merk)	**Industry**
Kerstin Hellwig	**Registries Holders**
Lucia de Prado Gomez (EMA)	**Regulators**
Macarena Rodriguez Mendizabal (AEMPS)	**Regulators**
Ruth Dobson	**Registries Holders**
Spiros Vamvakas (EMA)	**Regulators**
Manuel Haas (EMA)	**Regulators**
Ad Schuurman (EMA)	**Reimbursement representation**
Group 2	Informed consents, governance, data protection, individual data vs aggregated data
Xavier Kurz (EMA)	**Regulators**
Mireia Castillon (EMA)	**Regulators**
Bettina Hausmann	**Patient Representative**
Orla Gray	**Registries Holders**
Christoph Thalheim	**Registries Holders**
Jan Hillert	**Registries Holders**
Per Soelberg Sørensen	**Registries Holders**
Dolores Montero (AEMPS)	**Regulators**
David Wormser (Roche)	**Industry**

Tina Meissner	**Registries Holders**
Carla Jonker (MEB-NL)	**Regulators**
Maria Giovanna Satta (EMA)	**Regulators**
Frank Petavy (EMA)	**Regulators**
Charlie Nicholls (Sanofi)	**Industry**
Group 3	Common procedures and registry interoperability, quality assurance to support regulatory evaluation and data analysis
Alison Cave (EMA)	**Regulators**
Carla Alonso (EMA)	**Regulators**
Paola Zaratin	**Registries Holders**
Kerstin Eichstädt	**Registries Holders**
Sandra Vukusic	**Registries Holders**
Valerie Strassmann (BfArM)	**Regulators**
Eva Segovia (AEMPS)	**Regulators**
Robert Hyde (Biogen)	**Industry**
Maria Troiano	**Registries Holders**
Victoria Hedley	**Registries Holders**
Jane Moseley (EMA)	**Regulators**
Richard Vesely (EMA)	**Regulators**
Jordi Llinares (EMA)	**Regulators**
Jennie Medin (Novartis)	**Industry**
Erika Losonczi (Sanofi)	**Industry**
Chantal Guilhaume	**HTA**
June Raine (MHRA)	**Regulators (DNA)**

Group Oversight: Patricia McGettigan, EMA

List of participants

Multiple Sclerosis Workshop

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Name	Affiliation	Group
Alison Cave	European Medicines Agency	3
Bettina Hausmann	Bhconsult (Belgium)	2
Brigitte Keller-Stanislawski	Paul-Ehrlich-Institute (Germany)	1
Carla Alonso Olmo	European Medicines Agency	3
Carla Jonker	Medicines Evaluation Board (The Netherlands)	2
Carmela Macchiarulo	Italian Medicines Agency (Italy)	1
Chantal Guilhaume	Haute Autorité de Santé (France)	3
Charlie Nicholls	Sanofi	2
Christoph Thalheim	EMSP (Belgium)	2
Dana Horáková	EMSP MSBase (Czech Republic)	1
David Wormser	Roche	2
Dolores Montero	Spanish Agency of Medicinal Products and Medical Devices (Spain)	2
Erika Losonczi	Sanofi	3
Eva Segovia	Spanish Agency of Medicinal Products and Medical Devices (Spain)	3
Eva-Maria Wicklein	Bayer AG	1
Frank Petavy	European Medicines Agency	2
Imogen Scott Plummer	EMSP MS Society (UK)	1
Jan Hillert	MS (Sweden)	2
Jane Moseley	European Medicines Agency	3
Jennie Medin	Novartis	3
Jordi Llinares	European Medicines Agency	3
Julie Williams	Medicines and Healthcare Products Regulatory Agency (UK)	1

Name	Affiliation	Group
June Raine	Medicines and Healthcare Products Regulatory Agency (UK)	3
Kerstin Eichstädt	EMSP-ECTRIMS (Germany)	3
Kerstin Hellwig	National MS and Pregnancy Registry (Germany)	1
Liesbet Peeters	EMSP (Belgium)	1
Lucia de Prado Gomez	European Medicines Agency	1
Macarena Rodriguez Mendizabel	Spanish Agency of Medicinal Products and Medical Devices (Spain)	1
Manuel Haas	European Medicines Agency	2
Maria Giovanna Satta	European Medicines Agency	2
Maria Trojano	EMSP-ECTRIMS (Italy)	3
Mireia Castillon	European Medicines Agency	2
Orla Gray	MS Society (Northern Ireland)	2
Paola Zaratin	EMSP-Progressive MS Alliance (Italy)	3
Patrice Verpillat	Merck	1
Patricia McGettigan	European Medicines Agency	All
Pavel Balabanov	European Medicines Agency	1
Per Soelberg Sørensen	EMSP (Denmark)	2
Peter Mol	Medicines Evaluation Board (The Netherlands)	1
Richard Vesely	European Medicines Agency	3
Robert Hyde	Biogen	3
Ruth Dobson	Optimise	1
Sandra Vukusic	EMSP (France)	3
Spiros Vamvakas	European Medicines Agency	1
Steve Brookes	Biogen	1
Tina Meissner	EMSP-ECTRIMS (Germany)	2
Valerie Muldoon	European Medicines Agency	All
Valerie Strassmann	The Federal Institute for Drugs and Medical Devices (Germany)	3

Name	Affiliation	Group
Victoria Hedley	RD-ACTION	3
Xavier Kurz	European Medicines Agency	2
Yvonne Geissbuehler	Novartis	1