



**CIOMS Open Meeting on Patient Involvement in Development and Safe Use of Medicines
30 April 2019, Geneva, Switzerland**

Programme

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| 08:00 | REGISTRATION |
| 08:30 | INTRODUCTORY SESSION Chair: Hervé Le Louët, CIOMS President Introduction Hervé Le Louët CIOMS President |
| 08:40 | <u>70 years of CIOMS: ethics and safety guidance to protect patients</u> Lembit Rägo Secretary General, CIOMS |
| 08:55 | <u>Patient centricity in medicines regulation: WHO viewpoint</u> Emer Cooke World Health Organization |
| 09:05 | <u>The role of patients in drug development and safe use</u> Marc Boutin U.S. National Health Council |
| 09:20 | <u>Why working with patients is so important</u> Theresa Mullin U.S. Food and Drug Administration |
| 09:35 | Panel discussion Additional panelists: Nicholas Brooke , The Synergist Poonam Bagai , CanKids India/ Pallium India |
| 10:00 | COFFEE BREAK AND NETWORKING |
| 10:30 | SESSION 1 Chair: Annemiek van Rensen (Medicines Evaluation Board, the Netherlands) <u>Overview of the proposed CIOMS guidance</u> Kerry Leeson-Beevers Alström Syndrome U.K. |
| 10:50 | <u>Patient involvement initiatives around the world</u> Elisabeth Oehrlein U.S. National Health Council |
| 11:10 | <u>How can patients advance treatments for their disease?</u> Marilyn Metcalf GSK |
| 11:30 | Panel discussion Additional panelists: Prasanna Kumar Shirol , Organization for Rare Diseases India (ORDI) Maureen Smith , Canadian Organization for Rare Disorders Kacper Rucinski , Fundacja SMA - Spinal Muscular Atrophy Europe |
| 12:00 | WORKING LUNCH |

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Programme (continued)

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| 13:00 | <p>SESSION 2 Co-chairs: Kerry Leeson-Beevers (Alström Syndrome U.K.), Nikos Dedes (European AIDS Treatment Group)</p> <p>Guiding principles for engagement: avoiding conflict of interest, fair compensation ... François Houÿez EURORDIS</p> |
| 13:20 | <p>Patient involvement in designing medicines labeling Meredith Smith Amgen</p> |
| 13:40 | <p>Minimizing the risk of medicines: how patients can contribute Isabelle Moulon European Medicines Agency</p> |
| 14:00 | <p>Panel discussion Additional panelists: Matthew May, European Patients' Academy (EUPATI) Theobald Owusu-Ansah, Hepatitis Foundation of Ghana Francesca Sofia, International Bureau for Epilepsy</p> |
| 14:30 | <p>COFFEE BREAK AND NETWORKING</p> |
| 15:00 | <p>SESSION 3 – Chair: Kaisa Immonen (European Patient's Forum)</p> <p>Using patient data to evaluate the benefits and risks of medicines Leo Russo Pfizer</p> |
| 15:20 | <p>If things go wrong: The role of patients in designing and distributing alerts Suzanne Schrandt Arthritis Foundation, U.S.</p> |
| 15:40 | <p>Patient involvement in developing treatment guidelines Corinna Schaefer World Medical Association / German Agency for Quality in Medicine</p> |
| 16:00 | <p>Panel discussion Additional panelists: Talia Lacroix, Health Canada Ariadne Guimarães Dias, Casa Hunter, Brazil Umesh Chawla, India HIV/AIDS Alliance Estelle Jobson, European Patients' Academy (EUPATI) fellow and patient advocate</p> |
| 16:30 | <p>Concluding session</p> |
| 17:00 | <p>End of open meeting</p> |

The past meeting minutes of the CIOMS Working Group on Patient Involvement in Development and Safe Use of Medicines are available at https://cioms.ch/working_groups/working-group-xi-patient-involvement/.

The Working Group welcomes your input. Contact us at info@cioms.ch.



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Participants

* = Member of the CIOMS Working Group XI on Patient Involvement

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| * Leanne Angst-Wu | Roche |
| * Ola Apará | Takeda |
| Poonam Bagai | CanKids India / Pallium India |
| Raffaella Balocco | World Health Organization (WHO) |
| Janis Bernat | International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) |
| Susan Bhatti | Merck KGaA |
| * Stella Blackburn | IQVIA |
| * Matthias Boedding | Merck KGaA |
| Thomas Bols | Drug Information Association (DIA) |
| Donato Bonifazi | Consorzio per Valutazioni Biologiche e Farmacologiche |
| * Marc Boutin | National Health Council, U.S. |
| Nicholas Brooke | The Synergist |
| Nathalie Cambon | Roche |
| Umesh Chawla | India HIV/AIDS Alliance |
| Emer Cooke | World Health Organization (WHO) |
| * Nikos Dedes | European AIDS Treatment Group (EATG) |
| Guy Demol | MSD |
| Bettina Doepner | CSL Behring GmbH |
| Vanessa Dos Reis Ferreira | Santhera Pharmaceuticals Schweiz AG |
| * Brian Edwards | International Society of Pharmacovigilance (ISOP) |
| Brigitte Franke-Bray | International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine (IFAPP) |
| Ariadne Guimarães | Casa Hunter, Brazil |
| * Linda Härmark | Netherlands Pharmacovigilance Centre Lareb |
| Esteban Herrero-Martinez | Abbvie |
| Pushpa Hossain | Metabolic Support U.K. |
| * François Houÿez | EURORDIS |
| Samia Hurst | Swiss Academy of Medical Sciences, CIOMS Vice-President |
| Ghada Ibrahim | Patient Advocates for Cancer Research and Treatment (PACRT) |
| * Kaisa Immonen | European Patient's Forum (EPF) |
| Ulf Janzon | Sveriges Farmaceuter (Pharmacists' Association of Sweden) |
| Shalini Jayasekar Zurn | Union for International Cancer Control (UICC) |
| Estelle Jobson | European Patients' Academy (EUPATI) fellow and patient advocate |
| * Regina Kamoga | Community Health and Information Network (CHAIN), Uganda |
| Petra Kirchner | Roche |
| * Talia Lacroix | Health Canada |
| Sophie Lasseur | World Health Organization (WHO) |
| Renata Lazarova | Roche |
| Hervé Le Louët | CIOMS President |
| Sue Le Roux | CIOMS |
| * Kerry Leeson-Beevers | Alström Syndrome UK |
| Agnès Lillo-Le Louët | Hôpital Européen Georges Pompidou |

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| * Marie Lindquist | Uppsala Monitoring Centre (UMC) |
| Mariangela Lupo | Teddy European Network of Excellence for Paediatric Clinical Research |
| Pia Massatsch | Clinical Trials Unit (CTU), University of Bern |
| * Yusuke Matsunaga | Pharmaceuticals and Medical Devices Agency (PMDA), Japan |
| Matthew May | European Patients' Academy (EUPATI) |
| Olga Menang | PATH |
| Adi Mester | World Health Organization (WHO) |
| * Marilyn Metcalf | GSK |
| Günther Metz | Santhera Pharmaceuticals Schweiz AG |
| * Isabelle Moulon | European Medicines Agency (EMA) |
| Bettina Mueller | Bayer AG |
| * Theresa Mullin | U.S. Food and Drug Administration (FDA) |
| Mai Lise Nguyen | Roche |
| * Elisabeth M. Oehrlein | National Health Council, U.S. |
| Theobald Owusu-Ansah | Hepatitis Foundation of Ghana |
| * Shanthi Pal | World Health Organization (WHO) |
| Giovana Palma | Roche |
| Joan Peppard | European Association of Hospital Pharmacists |
| * Peter Pitts | Center for Medicine in the Public Interest (CMPI) |
| Lembit Rägo | CIOMS Secretary-General |
| * Cheryl Renz | AbbVie |
| Menico Rizzi | World Health Organization (WHO) |
| Kacper Rucinski | Fundacja SMA - Spinal Muscular Atrophy Europe |
| * Leo Russo | Pfizer |
| Molly Kate Rwankore | National Forum of Networks for PLHIV in Uganda (NAFOPHANU) |
| * Ken Sakushima | Pharmaceuticals and Medical Devices Agency (PMDA), Japan |
| Caroline Samer | International Union of Basic and Clinical Pharmacology (IUPHAR) |
| * Corinna Schaefer | German Agency for Quality in Medicine /World Medical Association |
| Suzanne Schrandt | Arthritis Foundation, U.S. |
| Prasanna Kumar Shirol | Organization for Rare Diseases India (ORDI) |
| * Meredith Smith | Amgen Inc. |
| Maureen Smith | Canadian Organization for Rare Disorders |
| Francesca Sofia | International Bureau for Epilepsy, Italy |
| * Christine Stürchler | Novartis |
| * Panos Tsintis | CIOMS Adviser |
| Michel Vallotton | CIOMS Past President |
| * Annemiek van Rensen | Medicines Evaluation Board, the Netherlands |
| Roberto Verna | World Association of Societies of Pathology and Laboratory Medicine, CIOMS Executive Committee member |
| Andreja Vujičić Žagar | Centre hospitalier universitaire vaudois (CHUV) |
| Kathrin Wawra- Hehenberger | CSL Behring GmbH |
| * Judy Zander | U.S. Food and Drug Administration (FDA) |
| Elena Zhuravleva | Roche |
| Monika Zwegarth | CIOMS |