Wednesday, 6 April 2016

08:00 - 12:30 ICH Info Day and 09:00-12:30 Pre-conference Tutorials

11:00-12:30 German Satellite Session | 13:30-15:00 Regulatory Town Hall Meeting | 15:00-16:00 Coffee Break | 16:00-17:45 Plenary Session

18:00-20:00 EuroMeeting Welcome to Hamburg Opening Reception in Hall 3

Thursday, 7 April 2016

	Theme 1	Theme 2	Theme 3	Theme 4
	Innovation	Clinical Research	Clinical Trials	Regulatory Science
Session 1 09:00-10:30	Session 0101/0701/0901/1301 Benefit-Risk Management Planning through the Life Cycle of a Product	Session 0201 Translation of Cell and Gene Therapies	Session 0301 New European Clinical Trial Regulation	Session 0401 Regulatory Science Hand in Hand with Health Technology Assessment for Better Outcomes
	Room 4 Ground Level	Room D Level 2	Room G2 Level 1	Room G1 Level 1
Session 2 11:00-12:30	Session 0102 Gene Therapy – A New Treatment Modality	Session 0202 Real-World Evidence in Drug Development	Session 0302 ICH E6- GCP Addendum: Risk Proportionate Approaches to Trial Design and Conduct	Session 0402/0702 Fast Forward to the Future – How Big Data and Artificial Intelligence Will Change Our Regulatory Environment
	Room B Level 1	Room D Level 2	Room G2 Level 1	Room 4 Ground Level
Session 3 14:00-15:30	Session 0103 The Voice of the Patient – Innovative Ways of Patient Engagement in R&D		Session 0303 Clinical Trial Disclosure	Session 0403 The Future of Regulatory Affairs is Digital
	Room C Level 1		Room G2 Level 1	Room 4 Ground Level
Session 4 16:00-17:30	Session 0104 Start-Ups Meet Regulatory and Industry			Session 0404 Adaptive Pathways and Conditional Approval- Panel Discussion
	Room G2 Level 1			Room 4 Ground Level

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	Theme 1	Theme 2	Theme 3	Theme 4
	Innovation	Clinical Research	Clinical Trials	Regulatory Science
Session 5 09:00-10:30		Session 0205 Improving Productivity in R&D	Session 0305 Enhancing Clinical Trials Efficacy	Session 0405 It´s Never Too Soon - Early Access and Early Dialogue in Drug Development
		Room 8 Level 1	Room G2 Level 1	Room 4 Ground Level
Session 6 11:00-12:30	Session 0106 Cutting Blockbuster Indications into Orphan-Sized Bites	Session 0206/0306 Oxford Debate: 'This House Believes that Over-Engineered Clinical Development Has Inhibited Innovation'	Session 0206/0306 Oxford Debate: 'This House Believes that Over-Engineered Clinical Development Has Inhibited Innovation'	Session 0406 Evolving Areas of Regulatory Science
	Room B Level 1	Room G2 Level 1	Room G2 Level 1	Room 4 Ground Level
Session 7 14:00-15:30	Session 0107 Shaking the Toolbox: Evolutions in Approaches in Trial Design	Session 0207 Development of New Medicines - Engaging with Stakeholders		Session 0407 Innovation of Mature Products – New Uses for Old Products
	Room 6 Ground Level	Room 8 Level 1		Room 4 Ground Level
Session 8 16:00-17:30	Session 0108 Bringing NGS into Drug Development: The Impact of Sequencing on the Future of Clinical Trials and Drug Registration	Session 0208 Challenges & Opportunities in the Clinical Development of Biopharmaceuticals	Session 0308 Challenges for Academic Clinical Trials	Session 0408 Where is the Orphan Drug Journey Going?
	Room B Level 1	Room C Level 1	Room G2 Level 1	Room 4 Ground Level

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	Theme 5	Theme 7	Theme 8	Theme 9	Theme 10
	Medical Affairs	eHealth/Big Data	Pharmacovigilance	Life Cycle Benefit-Risk Management	Globalisation
Session 1 09:00-10:30	Session 0501 Patient-Focused Medicine – To Understand Patients, You Must Engage Them	Session 0101/0701/0901/1301 Benefit-Risk Management Planning through the Life Cycle of a Product	Session 0801 Innovation for Patient Reporting	Session 0101/0701/0901/1301 Benefit-Risk Management Planning through the Life Cycle of a Product	Session 1001 What Happens in and Around Europe – Beyond the European Union?
	Room A Level 1	Room 4 Ground Level	Room 6 Ground Level	Room 4 Ground Level	Room F Level 2
Session 2 11:00-12:30	Session 0502 Physician Engagement, Education & Communication in an Era of Transparency	Session 0402/0702 Fast Forward to the Future – How Big Data and Artificial Intelligence Will Change Our Regulatory Environment	Session 0802 Perspectives on Medication Errors		Session 1002 Strengthening of Regulatory Systems: How is it Achieved and When?
	Room A Level 1	Room 4 Ground Level	Room G1 Level 1		Room F Level 2
Session 3 14:00-15:30	Session 0503 Digital Health: How Digital Technology is Transforming Healthcare	Session 0703 Real-World Data Making Personalised Medicine a Reality	Session 0803 End-to- End PV Quality and Compliance	Session 0903 Assessing the Benefits and Risks as the Basis of Benefit-Risk Management	Session 1003 Securing the Supply Chain: How to Tackle the Challenges
	Room A Level 1	Room D Level 2	Room G1 Level 1	Room 6 Ground Level	Room F Level 2
Session 4 16:00-17:30	Session 0504 The Reality of Real-World Evidence	Session 0704 Value Proposition, Challenges and Examples for the Use of Big Data in the Pharmaceutical Industry		Session 0904 Post-Authorisation Safety and Efficacy Studies: Scientific Challenges and Factors for Success	Session 1004 Japanese Regulatory Session: PMDA Update
	Room A Level 1	Room B Level 1		Room G1 Level 1	Room 6 Ground Level

Friday, 8 April 2016

	Theme 6	Theme 7	Theme 8	Theme 9	Theme 10
	Availability of Medicinal Products	eHealth/Big Data	Pharmacovigilance	Life Cycle Benefit-Risk Management	Globalisation
Session 5 09:00-10:30	Session 0605 Setting the Scene – Is There an Availability Problem in Europe?	Session 0705 Challenges and Opportunities Related to the Integration of Multiple Data Sources	Session 0805/1205 Post-Marketing Surveillance and CE Marketing	Session 0905 Post-Authorisation Safety and Efficacy Studies: Operational Challenges and Factors for Success	Session 1005 Improving Global Health: How Can Regulators Help?
	Room A Level 1	Room D Level 2	Room G1 Level 1	Room 6 Ground Level	Room F Level 2
Session 6 11:00-12:30	Session 0606 Medicinal Products in Need		Session 0806 Planning and Oversight for Success	Session 0906 Understanding Important Risks and the Evolution to Benefit-Risk Management Planning	Session 1006 New Approaches to the Approval of Innovative Medicines: Do They Keep Their Promise?
	Room A Level 1		Room G1 Level 1	Room 6 Ground Level	Room F Level 2
Session 7 14:00-15:30	Session 0607 No Marketing of Authorised Products	Session 0707 The Growing Role and Importance of Interoperability and Standardisation	Session 0807 Effective and Balanced Risk Communication		Session 1007 Innovation in the Development and Approval of Generic Medicines
	Room A Level 1	Room B Level 1	Room G1 Level 1		Room F Level 2
Session 8 16:00-17:30	Session 0608 Shortages of Authorised Products	Session 0708 Examples of Big Data Applications	Session 0808/0908 Impact of Regulatory Measures to Optimise Benefit-Risk Decisions	Session 0808/0908 Impact of Regulatory Measures to Optimise Benefit-Risk Decisions	
	Room A Level 1	Room D Level 2	Room G1 Level 1	Room G1 Level 1	

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	Theme 11	Theme 12	Theme 13	Theme 14	
	Special Populations	Medical Devices	HTA	Medical Writing	Hot Topics/Stand Alone Sessions
Session 1 09:00-10:30	Session 1101 Women's Health and Drug Development	Session 1201 New Medical Device Regulations in the EU	Session 0101/0701/0901/1301 Benefit-Risk Management Planning through the Life Cycle of a Product	Session 1401 Challenges and Best Practices for Writing Lay Summaries of Clinical Study Results	Session 1601 PRIME Initiative Launch: Fostering Timely Access for Patient-Focused Drug Development
	Room C Level 1	Room B Level 1	Room 4 Ground Level	Room E Level 2	Room 8 Level 1
Session 2 11:00-12:30	Session 1102 Frailty as a Baseline Stratification Parameter and Potential Therapeutic Target	Session 1202 Public Expectation vs. Regulatory Complexity: Scenarios for Safe Innovation in Medical Technology	Session 1302 The Needs of the Payers Shape the Evidence for Market Access	Session 1402 Communicating Benefit-Risk Information in Risk Management Plans to Medical Professionals and the General Public	
	Room C Level 1	Room 8 Level 1	Room 6 Ground Level	Room E Level 2	
Session 3 14:00-15:30		Session 1203 Innovative Developments in Medical Technology	Session 1303 Shall HTA Depend on Randomised Controlled Trials or Real-World Data or Both?	Session 1403 Preparing Clinical Documents for Public Release: The Issues of Transparency and Redaction	
		Room 8 Level 1	Room B Level 1	Room E Level 2	
Session 4 16:00-17:30	Session 1104 Conduct and Completion of Paediatric Development Plans, As Agreed in PIPs or PSPs	Session 1204 Combination Products		Session 1404 Using Computer-Assisted Writing to Increase the Efficiency of Creating Regulatory Documents	Session 1604 Import Testing: Current Requirements and Opportunities to Simplify Access of Medicines for Patients
	Room C Level 1	Room 8 Level 1		Room E Level 2	Room F Level 2

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	Theme 11	Theme 12	Theme 13		
	Special Populations	Medical Devices	HTA	Hot Topics/Stand Alone Sessions	Hot Topics/Stand Alone Sessions
Session 5 09:00-10:30	Session 1105 Formulations for Both Ends of Life	Session 0805/1205 Post-Marketing Surveillance and CE Marketing	Session 1305 How Can Three Parties; Payers, Industry and HTA, Make Agreements and Share the Economic Risk?		Session 1605 Content and Context of IDMP
	Room C Level 1	Room G1 Level 1	Room B Level 1		Room E Level 2
Session 6 11:00-12:30	Session 1106 Extrapolation	Session 1206 Self-Care Medical Devices: Shifting Borders between Devices and Pharma?		Session 1506 From Tradition to Regulation-Globalisation of Herbal Medicines	
	Room C Level 1	Room 8 Level 1		Room D Level 2	
Session 7 14:00-15:30		Session 1207/1307 HTA for Medical Devices	Session 1207/1307 HTA for Medical Devices		Session 1607 MAPPs: The IMI ADAPT SMART Project
		Room G2 Level 1	Room G2 Level 1		Room E Level 2
Session 8 16:00-17:30		Session 1208 IVDs and Companion Diagnostics	Session 1308 European Relative Efficacy Assessments		
		Room 8 Level 1	Room 6 Ground Level		