








# DIA Europe 2018 | SCHEDULE

Monday, 16 April 2018												
13:00-18:00	Registration Hours											
14:00-17:30	Short Courses											
Tuesday, 17 April 2018												
07:00-18:00	Registration Hours											
09:00-10:30	Swissmedic/WHO Signature Session						PREFER Satellite Session				09:00-12:30 Short Courses	
11:00-12:30	 DIAMOND Session: EU Regulatory Town Hall					 DIAMOND Session: Payer Town Hall					 DIAMOND Session: International Pharmacovigilance	DIAlOgue: The New EMA First-in-Human (FIH) Guideline Part 1: Non-Clinical Aspects (Part 1)
12:30-14:00	Lunch in the Exhibition Hall											
14:00-15:30	 DIAMOND Session: Brexit											
16:00-18:00	Conference Keynote Session followed by the Welcome Reception											
Wednesday, 18 April 2018												
	A	B	C	D	E	F	G	H	I			
Topic	Can Regulators and HTA Bodies Create Synergies for Patient Access?	What are Necessary Steps towards Outcome-Driven Health Systems?	Medicines of the Future: What Will Innovation Need and Bring?	How Can Better Outcomes Be Enabled by Big Data?	What is the Future of Pharmacovigilance?	What Can Stakeholders Expect from Clinical Trial (Development), Transparency and Medical Information?	A New Era for Medical Devices and Diagnostics. How Is The Impact?	Drug Development and Regulatory Approval - Reference Points around the Globe or Globalisation?	How Can We Enable Clinical Research in Europe Further?	Hot Topics/Stand-Alone Sessions		
08:00-18:00	Registration Hours											
08:30-10:00	 DIAMOND Session: Evidence Generation in Medicines Development for Fragmented and Rare Patient Populations				 DIAMOND Session: Exploring Use of Artificial Intelligence: Trust in Technology, or Trust in Each Other?				 DIAMOND Session: Patient-Centricity Beyond the Talk			
10:00-10:30	Coffee Break in the Exhibition Hall											
Session 1 10:30-12:00	<b>Session 0101</b> Collaboration across Decision Makers to Facilitate Patient Access Recent Advances and Future Needs	<b>Session 0201/0401</b> Has the Time for Big/Real World Data Finally Arrived?	<b>Session 0301</b> Novel Therapeutic Approaches	<b>Session 0201/0401</b> Has the Time for Big/Real World Data Finally Arrived	<b>Session 0501</b> Enhancing Benefit-Risk Management through the Product Life Cycle	<b>Session 0601</b> Making Clinical Trial Information Accessible: Experiences in Developing Informed Consent Forms and Lay Summaries of Study Results	<b>Session 0701</b> In Vitro Diagnostics (IVD)	<b>Session 0801</b> Update on PMDA's Activities	<b>Session 0901</b> New European Clinical Trial Regulation: A New Paradigm with Major Impact on Clinical trial Stakeholders	<b>Session 1001</b> DIAlOgue: Unmet Need in Regulatory and Pricing Decision Making	<b>Session 1101</b> NCA showcase	
12:00-14:00	Lunch in the Exhibition Hall											
Session 2 14:00-15:15	<b>Session 0102</b> Regulatory Access Pathways to Facilitate Early Access, HTA Synergies	<b>Session 0202</b> Patient Centricity - What does it Really Mean?	<b>Session 0302</b> Digital Health - What is the Landscape Looking Like for Medicines?	<b>Session 0402</b> New Collaboration Models with Regulators and Patients	<b>Session 0502</b> Innovative Approaches to Safety Information	<b>Session 0602</b> Data Sharing and Secondary Use of Data	<b>Session 0702</b> Regulatory - How to Submit a Combination Product OR Drug Device Combination Globally	<b>Session 0802</b> Paediatric Policy Initiatives: Globalisation of Paediatric Drug Development Best Practice or Imperialism of Practice?	<b>Session 0902</b> Implementing a Risk Proportionate Approach to Clinical Trial Conduct - First Experiences with ICH GCP R2	<b>Session 1002</b> The New EMA First-in-Human (FIH) Guideline Part 2: Clinical Aspects		
15:15-16:00	Coffee Break in the Exhibition Hall											
Session 3 16:00-17:30	<b>Session 0103</b> Enhancing Evidence Generation across the Product Life Cycle	<b>Session 0203</b> Health Economics of Future Therapeutic Concepts	<b>Session 0303</b> The New Data Ecology - How to Incentivise and Enable More Sharing of Data?	<b>Session 0403</b> Needed Competencies for Big Data - Learning from Other Industries	<b>Session 0503</b> Measuring Impact of Pharmacovigilance in the EU	<b>Session 0603</b> Drawing the Boundaries of Data Disclosure in Clinical Trials	<b>Session 0703</b> Challenges in the Current Regulatory Landscape	<b>Session 0803</b> Reliance and Work Sharing @ Work - State of Play and Hands-On Experience	<b>Session 0903</b> Novel and Innovative Clinical Trial Designs: From Adaptive/Seamless Designs to the Trial of the Future	<b>Session 1003</b> ICMRA		
17:30-18:30	Networking Reception in the Exhibition Hall											
Thursday, 19 April 2018												
08:00-14:00	Registration Hours											
Session 4 08:30-10:00	<b>Session 0104</b> ATMPs	<b>Session 0204</b> Value and Access- How Do We Strike a Balance between Both?	<b>Session 0304</b> Collaborative Frameworks and Public Private Partnerships as Drivers of Innovation	<b>Session 0404</b> Overview of Major Big Data Projects across EU, US, Japan	<b>Session 0504</b> Benefit/Risk Communication Tools that Work: Towards a Tailor-Made Drug Facts Box?	<b>Session 0604</b> EMA Proactive Transparency - Clinical Data Publication (Policy 0070)	<b>Session 0704</b> Life Cycle Management Activities of Drug Device Combinations	<b>Session 0804</b> GMP Convergence - A key part of regulatory system strengthening	<b>Session 0904</b> Smarter Clinical Trials Thanks to Real World Data	<b>Session 1004/1005</b> ICH Info Day	<b>Session 1104</b> Update from Russia and Eurasia	
10:00-10:30	Coffee Break in the Exhibition Hall											
Session 5 10:30-12:00		<b>Session 0205</b> Sustainability of Health Care Funding - Are We Prepared for Tomorrow's Funding Challenge?	<b>Session 0305</b> Precision Medicine and Personalised Health care	<b>Session 0405</b> Big Data Mandates Strict Data Governance	<b>Sesison 0505</b> Five Years On - PV Legislation Delivers on Long-Promised Elements	<b>Session 0605</b> The Promise and Reality of Clinical Trial Transparency Initiatives	<b>Session 0705</b> Humans Factors for Combination Products	<b>Session 0805</b> Lifecycle Management - The Unknown Barrier to Access	<b>Session 0905</b> Registry Studies: What Are the Expectations from the Regulators?	<b>Session 1004/1005</b> ICH Info Day	<b>Session 1105</b> Turkish Regulatory Session	
12:00-13:00	Lunch in the Exhibition Hall											
13:00-14:30	DIAMOND Session: Realising the Potential of Future Biomedical Innovation: The Role of Intensified EU Cooperation on HTAs				DIAMOND Session: Will Big Data Change Drug Development's Approach?				CFDA Topics			
14:30-15:30	Conference Insights and Outcomes - Rapid Fire Session											