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DIA EUROPE 2021
ADVANCING HEALTH PRIORITIES

MONDAY, 15 MARCH 2021

09:00	**OPENING SESSION**				
09:15	#DMD: Health Emergency Preparedness				
10:30	**COFFEE BREAK**			#SCH02: Regulatory Science Research at PMDA to Assess if Administrative and Claims Data as A Real-World Data is Useful for Regulatory	
11:00	#S0504: Novel Manufacturing Approaches for Early Access and Sustained Supply	#S0606: Vaccination: Exploring Risk Communication Needs	#S0901: Spotlight on China Regulatory Reform and Acceleration in Simultaneous New Drug Development	#S0309: COVID-19: Lessons Learnt so far in the Regulatory and R&D	#S0402: Broadening the Vision – Bringing Imaging Into the Mainstream
12:00	#RT01: Round Table Session - Use of Holistic Program Management to Foster Client Vendor Interaction - Closed Session	**SPEED NETWORKING**	**COFFEE BREAK**		
12:30					
13:00	#OC02-SL: Keynote: Transforming Healthcare Through Genomics and Precision Medicine				
13:45	**COFFEE BREAK**			**#SPCH01: Optimising Collaboration Between EMA and FDA for Your Development Activities**	
14:15	#S0609: Globalisation of Pharmacovigilance and Impact of COVID-19 Pandemic	#S0104: In Vitro Diagnostic Regulation (IVDR) In The Context of Clinical Trials and Upcoming Clinical Trial Regulation (CTR)		#S0801: Building Frameworks to Make the Promise of Personalised Healthcare a Reality by Enabling Healthcare Systems	#HT07: Round Table Session on Diagnostics - Addressing the Gap in Precision Medicine
15:15	**COFFEE BREAK**			#SCH01: Living With And Beyond Cancer - The Top Ten Research Questions That Patients Want Answered	
15:45					
16:00	#DMD: What does Good Look Like? Shaping the Environment to Manage Antimicrobial Resistance and Promote Sustainable Development of Anti-infectives and Vaccines			#DMD: Big Data 2021: Delivering Transformation in Data-Driven Medicines Regulation	
17:15					Networking - Bingo Get to Know
17:30				#SPCH03: Transforming Regulatory Affairs	
18:00	#S0105: Digital Health in a Post-COVID-19 Era: How the COVID-19 Pandemic Changed Regulatory Frameworks Around Telehealth and AI	#S0207: Organic Compliance: Preparing Academics for a Connected, Compliant, and Digital Future		#S0809: How Can We Address AMR "Broken Business Model" to Activate Antibacterial R&D? Policy Needs, Potential Solutions and Examples	#S0304: Evidence Requirement and New Paradigm for Approval and Development of Personalised Healthcare
19:00					

Click on each Session Title for more information!

TRACKS:

- S01: Clinical Development
- S02: Clinical Operations
- S03: Regulatory Strategy
- S04: Regulatory Operations
- S05: CMC, Quality, GMP
- S06: Safety and Pharmacovigilance
- S07: Value and Access
- S08: Health Policy
- S09: Regional Updates
- DMD: DIAmond Sessions
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- P: Poster Sessions
- HT: Hot Topic

SUB-TRACKS:

01: Beating Cancer & Oncology
02: Innovating in CNS
03: Enabling Cell and Gene Therapies
04: Aspiring for Personalized Healthcare
05: Leveraging Smart Health
06: Safety and Pharmacovigilance
07: Working with the Academics
08: Professional Development
09: Infectious Diseases and Emergency Preparedness

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TUESDAY, 16 MARCH 2021

09:00	#DMD: European Medicines Regulatory Network Strategy to 2025			#DMD: Learning from Novel Regulatory Approaches During the COVID Pandemic and Opportunities for the Future	
10:15	COFFEE BREAK				
11:00	#S0803: Enabling Cell and Gene Therapies: Creating an Appropriate Framework	#S0906: PMDA Updates	#S0601: Seeing Through the Fog of a Pandemic: Observational Studies and Real-Time Registries	#S0513: Opportunities for Regulatory Dialogue to Accelerate Innovation in the EU	#S0306: Advancing Patient-Centred Development and Access to Medicines in Partnership with Healthcare Systems
12:00	#RT02: The Value Proposition of Good Medical Writing for Clinical Study Protocols	SPEED NETWORKING	LUNCH BREAK		
13:00	#DMD: EU Regulatory Town Hall: Stress Testing Under COVID-19 - Is the European Framework Agile Enough?				
14:00			#P: Poster Session 1 – Regulatory and Health Policy		
14:30					
14:50	COFFEE BREAK				
15:00	#S0205: Bringing Trials Closer to Patients: Leveraging Innovative Technologies and Approaches	#S0708: Value Communications and Negotiations – Are You Prepared?	#DL01: Trans-Diagnostic Drug Development Beyond Oncology	#S0403: ATMP Regulation 2.0 – Is the System Fit as is?	
16:00	COFFEE BREAK			#SCH04: Endotype Approach for Drug Development	Executive Forum *(by invitation only)*
16:30	#S0303: De-Risking Regulatory Strategy for ATMPs	#S0505: Harmonising Structured Data in Module 3 to Standardise Terminologies and Submission Standards	#DL02: Unmet Medical Need		
17:30	COFFEE BREAK		#SCH03: Increasing Complexity of Clinical Trials in Oncology: A Case Study of Importance of Optimal Patient Selection		
18:15	#S0101: Advancing Complex Innovative Clinical Trial Designs – Opportunities for Global Regulatory Convergence in Oncology	#S0204: Digital Technologies and Their Promise of Increased Technical Success, Reduced Timelines and Broader Generalizability of Findings	#S0506: GMPs for Investigational Products to Enable Rapid Patient Access	#HT02: Emerging Technologies and Data Driven Initiatives within the Regulatory Environment	#S0605: Strategies to Implement Routine Intelligent Automation Technologies within Pharmacovigilance for the ICSR Process
19:15					
19:30					

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WEDNESDAY, 17 MARCH 2021

09:00	#DMD: Raising the Bar of Patient Engagement – Patient Centric Innovation and Patients' Role In Medicine Development and Decision Making		#DMD: Medicines Shortages Changing the Paradigm from Mitigation to Prevention		
10:15	COFFEE BREAK		#P: Poster Session 2 – Safety and Pharmacovigilance		
11:00	#S0607: Effective Risk Communication for Safe Use Behaviours in Healtcare: Innovation Through Formative and Evaluative Collaborations	#DL03: RWE4 Decisions	#S0103: How Can High Quality RWD As External Control Support Registration of CAR Ts in Later Line Indications	#S0904: Updates from The Middle East – A Leap Forward in Digitalization and Steps Towards Faster Access	
12:00	#SP03: Managing What Matters. How to Create Patient Access to (Neo)Adjuvant Treatments	SPEED NETWORKING			
12:15			LUNCH BREAK		
12:30					
13:00	#S0502: Early Access CMC Approaches: EMA ToolBox Guidance 2021	#S0408: IDMP as a Cornerstone in Digital Transformation for Regulatory Practice in Europe	#S0706: Beyond PROs and Organized Protests: How Can We Bring the Patient Voice into HTA Decision-Making?	#S0301: Take International Collaboration in Paediatrics to the Next Level to Accelerate Access to Paediatric Medicines	#HT01: Building Effective Collaboration for Mutual Value Creation in Healthcare
14:00	COFFEE BREAK		#SPCH04: The Value of Strategic Partnerships: From Nice to Have to Necessity		
14:30	#DMD: Future of Research: Pharmaceutical Science, Innovation and Social Policy Pharmaceutical Sciences in 2020		#DMD: EUnetHTA Town Hall - After Three Joint Actions with EUnetHTA – Which are the Main Achievements and the Remaining Challenges?		
15:45	COFFEE BREAK		#SCH05: A Digital Channel Pharmacovigilance Requirements Database with Integrated Robotic Process Automation (RPA)		
16:15					
16:30	#DL04: Difficulties Predicting Safety and Dose in FIH Setting: Options When There are No Options, an Industry and Regulator Perspective	#S0208: Getting the Question Right: Estimand for Safety and Benefit-Risk Evaluation	#S0905: Turkey: Building the Role of a new ICH member in Global Regulatory Communities	#S0107: Testing the Readiness of The Framework: Are The Regulatory Processes Fit for Rapid Development of Treatments and Vaccines?	#S0503: Comparability Challenges and Possible Solutions for ATMPs
17:30		COFFEE BREAK		#SPCH05: COVID-19 and Beyond: The UK's Research Response to COVID-19 and Next Steps	Networking - Round Table Discussion
17:45					
18:00					
18:15	#S0308: Regulatory Science Dialogue	#S0804: Laying the Foundation for a Value-Based, Patient-Centered, and Outcome-Driven Healthcare System in Europe	#S0109: How Mechanism of Action-Driven Development Can Address the Covid-19 Challenge	#S0401: The Importance of Data Management and CDISC/IDMP Data Standards for First Time Right Submissions	#HT03: Examples of Artificial Intelligence and Machine Learning in development, Leveraging Smart Health
19:15					

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THURSDAY, 18 MARCH 2021

09:00	#S0405: Cloud-Based Submissions; from Principles to Practice	#S0707: Attributing Value to Innovation: Which Evidence is Needed to Satisfy Different Decision-Making Methodologies?	#S0802: Understanding of Different Set Ups of PPP, Benefits of PPPs and Learnings of Recent Projects to Facilitates Future Success of Such Collaborations	#S0106: Methodologies for Incorporating the Patient Voice in Development and Regulatory Processes	
10:00			#SCH06: Researches to Utilize Administrative and Claims Data as A Real-World Data for Regulatory Purpose		
10:30	COFFEE BREAK				
10:45	#S0903: Sustaining Regulatory Systems in Africa During Pandemics - AMA Establishment Journey	#S0509: Alternative GMP/GDP Inspection Practices: Opportunities implementing Lessons Learned from a Pandemic Situation (COVID-19)	#HT04: Changes in PV and the Impact of EU PV Legislation on Patient Safety	#S0404: Transformative Disruption to Regulatory Submissions and Approvals: The Accumulus Synergy	#S0206: Patient Involvement in Patient Preference Studies: Lessons from the IMI PREFER Project
11:45					
12:00		LUNCH BREAK		SPEED NETWORKING	#SP04: The Digital Future of R&D – Strategies for Data, Automation and Artificial Intelligence
12:15					
13:00	#S0307: Scientific Advice and Collaboration with Academia as Tools to Facilitate Research and Development of New Medicines	#S0511: Nitrosamines: Traceability / Sensitivity - What is Good Enough?	#HT05: Comparison of Emergency Use Pathways Among Japan-the US-Europe: Including Post-Marketing Management	#DMD: Reliance: The Key to Smart Regulation?	
14:00	#SPCH06: Monitoring and Surveillance in the Marketing of Medical Devices	COFFEE BREAK			
14:15					
14:30	#DMD: ICH E17 Guideline on Multi-Regional Clinical Trials: A Catalyst for Simultaneous Global Development and Registration		#DMD: COVID-19, An Opportunity to Step Up International Collaboration		
15:45	COFFEE BREAK		#P: Poster Session 3 – Clinical Development & Value and Access		
16:30	#S0108: Multi-Stakeholder Collaborations to Drive Adoption and Alignment in the Implementation of Telemedicine Platforms and the Use of Digital Measures	#S0603: Advances in Evidence-Based Quality and Risk Management for Pharmacovigilance Decisions Making	#S0805: Paving a New Road for Digital Health – Global Trends in Software Regulation	#S0709: Improving Access to Medicines: Exploring New Regulatory Frameworks for Letting Data Lead the Way to Increased Drug Options	#S0407: The Stars Project
17:30					
17:45	COFFEE BREAK				
18:15	#S0203: Clinical Operations for Studies Involving Special Populations and Adaptive Designs	#S0704: Developing Drugs that Meet the Patients' Needs: How Far Have We Come and Where Do We Go From Here?	#S0305: The Use of Remote Monitoring Technologies	#S0501: Predictive Stability – How Do We Move To A Risk Based Approach For Providing Required Stability Data, Platform Data, Extrapolation etc Linking Bio/Chemical Approaches By Science	
19:15					

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09:00	#DL06: Engaging in the EU Regulatory Network: Member State Journeys	#S0702: Healthcare Priorities: What Additional Funding Choices Should Decision - Makers Take Based on COVID-19 Impact on CNS Disorders?	#HT06: Using Emerging Technologies and Electronic Data Sources for Conducting Trials	#S0907: Singapore Townhall
10:00	COFFEE BREAK		#SPCH08: COVID-19 and Beyond: Delivering Complex and Innovative Trials	
10:45	#S0409: Regulatory Affairs Lessons Learned in the Crucible of COVID-19: What Works and What Could Work	#S0703: Cross-Border Access to ATMPs in the European Union	#S0902: The Eurasian Union Regulatory Framework - Now a Reality	#DL07: Refocus on Unmet Public Health Challenges – Who Should Lead the Way?
11:45		LUNCH BREAK		
12:00	SPEED NETWORKING			
12:30				
13:00	#S0608: Digital Risk Minimization Tools	#S0701: Unlock the Potential of Emergent Cell Therapies	#S0102: Digital Clinical Data Generation, Incorporation Into Regulatory Decision Making (Parkinson's Disease, MS)	#S0209: Robust Clinical Trials in the Future Incorporating Learnings from the Covid-19 Pandemic	#S0406: ePI – Setting Tomorrow's Labelling and Regulatory Operations Framework
14:00	COFFEE BREAK		#SPCH09: Imaging Biomarkers, Where to Begin? Optimizing Trial Portfolio Strategies to Accelerate Drug Approval	
14:30	#DMD: The Use of Artificial Intelligence/ Machine Learning in Pharmacovigilance		#DMD: EMA 2030 and Beyond - How Should the EMA of the Future Look Like - Stakeholder Expectation	
15:45				
16:00	CLOSING SESSION			

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