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Monday, 29 June 2020

	Topic 5: Regulatory Science	Topic 9: Medical Affairs
08:30	KEYNOTE	
09:30	#DIAmond 2: ICMRA, the hub of international collaboration on COVID-19'	
10:30	#S0506: Biologicals and Biosimilars – Science versus Regulation	
12:00	Lunch & Learn: Shaping the Future to Meet Our Needs – A Digital Transformation	
12:30	#S0507: Enabling Translation of Research and Innovation into Regulatory Standards	#DIAmond 5: What the Day after Tomorrow Will Look Like When Patient Engagement in Medicines R&D Is Systematic, Meaningful and Sustainable
13:30	#S0508: How Regulatory Science Shapes Policy	#S0906 - ON-DEMAND PLAYBACK: Optimising the empowerment of informed decision making through innovative, transparent and contextualized communication of safety information
14:30	#S1211: Comparing accelerated approval pathways among EMA, FDA and PMDA	#S0908: Drug Development Tools in a Digital Era
15:30		#S0911: Integrating patient voice into value discussions and monitoring outcomes: key considerations from a regulatory perspective?
16:30		#S0907: Advancing Effective Use of Digital Health Technologies in Parkinson's Disease
17:30		#S1408: Making Patient Engagement the New Normal: Real World Realities for Working with Patients
18:30	BINGO Networking – Get to Know the Exhibitors	

Tuesday, 30 June 2020

	Topic 2: Pharmacovigilance	Topic 4: Value & Access	Topic 14: Health Policy
09:00	#Spotlight 5: Pharmacovigilance Regulations: Updates	# DIAmond 3: EUnetHTA Town Hall – Value: How is the Value of a Health Care-Innovation Established and Can Different Stakeholders See the Same Value?	
10:00	#Spotlight 2: "ICH Clinical Trials and Pharmacovigilance - Preparing for the Future"	#S0405: Taking Stock on Parallel Consultation & Early Access Developments	
11:00	#S0208: Patient Involvement in the Development and Safe Use of Medicines	#S0408: From Indication-Based Labels to a New Era of Evidence Generation – What Are the Future Roles of Regulators and HTA Bodies?	
12:00	Are current HTA processes suitable for innovative cancer medicines?		
13:00	#S0211: Pharmacovigilance 'Then and Now' - How Has PV Changed?	#S0407: Drug Assessment for Regulatory and HTA Purposes: Similarities and Differences, the Way Forward	# DIAmond 8: Healthcare 2030 – The Role of Pharma to Continue to Deliver Value in Patient-Focused Healthcare
14:00	#S0212: Update on ICH safety topics	#S0409: How will PREFER Patient Preference Studies Inform Decision-Makers about Patients' Needs and Preferences	#Spotlight 8: Preparing health systems for integrated and personalised care
15:00		#S0406 - ON-DEMAND PLAYBACK: Navigating Multiple Stakeholder Perspectives on Clinical HTA Methodological Standards for EU Joint Assessments beyond 2020	#S1411: From discovery to patient access: how can Europe remain at the forefront f innovation in the development of diagnostics and therapies in rare diseases, and ensure patients benefit from the next hundreds of treatments?
16:00		#S0412: Personalised Healthcare: A Systems Upgrade Worth Investing In?	
17:00	Speed Networking		

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Wednesday, 01 July 2020

	Topic 3: Data Standards	Topic 1: Clinical Trials
09:00	#S0213: Big Data Task Force: So what happens next?	
10:00	#S0307: The Future of Healthcare s Digital, Genomic and Collaborative - Is the EU Policy and Regulatory Framework Ready? How Can Emerging Technologies Be Transforming?	
11:00	#S0309: How Do We Realise the Benefits of Data Sharing While Maintaining Patient Trust?	
12:00	Lunch & Learn: Simultaneous National Scientific Advice – a pilot for a joint European approach	
12:30	Lunch & Learn: Annual Industry Report: Trends, Insights, and Strategies to Modernize Clinical Operation	
13:00	#S0312: Is Europe ready to define quality standards for Real World Data (RWD) sources?	#S0106: A Development Support Environment in Europe that Adapts to the Future Challenges of Innovation – Needs and Expectations
14:00	#S0206/0306: Case Studies in Applying Artificial Intelligence or Machine Learning	#S0111: Clinical Trials Go Digital – Advantages and Challenges
15:00	#DIAmond 9: Pre-competitive collaborations, a path to improving real world evidence (RWE) development efforts in service of patients	#S0112: Clinical Trials Go Digital – Electronic Endpoints: Opportunities and Challenges
16:00		#S0107: Complex Clinical Trials – Driving Innovation
17:00		#S0109: Clinical Trial Regulation: State of Play – Are We Ready?
18:00		#DIAlogue 4: Industry - Regulator Dialogue: Tailor-made Regulatory Guidance for Non-clinical to Clinical Development
19:15	End of Day 3 - reminder to check out available On-Demand Sessions!	

Thursday, 2 July 2020

	Topic 7: CMC	Topic 8: Medical Devices
09:00	#DIAmond 1: Coordinated European Approach to Solve the Problem of Shortages – Is It Possible?	
10:00	#S0711: Regulations and Enforcement Impacting Medicine Manufacturing and Supply in a Globalised Context	
11:00	#S0706: Ensuring Quality throughout he Supply Chain - Update on nitrosamine impurities case	
12:00	#DIAmond 6 - ON-DEMAND PLAYBACK: FDA Spotlight: Top 10 Lessons Learned on Regulatory Science from the Opioid Epidemic	
13:00	#DIAmond 12: ICH at 30 - What Will Come the Next 30 Years?	#S0806: MDR Implementation – Status Quo
14:00	#S1108: RA Leadership Forum: Critical Deliverables in Global Regulatory Teams	
15:00	#S0702: Bringing down barriers for access for gene and cell therapies in Europe	#S0807: ISO 14155: 2020 Revision of Medical Devices Good Clinical Practice
16:00		#S0808: At the interface of two EU legislations – Multi stakeholder efforts to implement MDR Article 117 for drug delivery combinations
17:00		#S0809: Mind the Gap - Disentangling the Maze of Drug-Device Combination Product Approval in the EU
18:00	Hackathon Primer	

Friday, 3 July 2020

	Topic 13: Clinical Operations	Topic 6: Regulatory Operations
09:00	#S1111 Chat with Professionals	
10:00	#S1308: Understanding and Applying the ICH E17 guideline on Multiregional Clinical Trials (MRCT): A Regulator's and Industry Perspective	
11:00	#S1307: How to promote patient centricity? - Based on experiences of clinician and head of regulatory agency	
12:00	Lunch & Learn: Patient Innovation in Clinical Research: It's Time to Get Personal	
12:30	Break	
13:00	#S1309: Digitisation of Systems and Technology (AI)	#DIAmond 11: Does the current regulatory framework enable future science and technology along the product lifecycle?
14:00	#Spotlight 4: Can we run studies with less Site Visits?	#S0611: Digital Transformation
15:00		#S0606: Promising digital tools for simplifying variations- how to connect dots and to make it happened?
16:00		#S0607: Telematics Strategy in the EU: Global and Regional Considerations for 2020-2025
17:00		#S0608: Effective Outsourcing in Regulatory Operations
18:00	Closing and Welcome to DIA Europe 2021	