DIA EUROPE 2021 / ADVANCING HEALTH PRIORITIES / ABSTRACT SUBMISSION MATRIX

Function / Topic	Clinical Development	Clinical Operations	Regulatory Strategy	Regulatory Operations	CMC, Quality, GMP	Safety and PV	Value and Access	Health Policy	Regional updates
Topic Leads	**Florence Roizard Mireille Muller**	**Susan Bhatti Juergen Kuebler**	**Gabriele Bräunlich Mireille Collombat Emma Du Four**	**Simon Bennett Hans van Bruggen**	**Frank Montgomery Susanne Ausborn**	**Willemijn van der Spuij Andrew Bate**	**Paolo Morgese Gavin Outteridge**	**Oliver Sude**	**Emma Du Four Patrick Brady**
Beating Cancer / Oncology	Innovative trial designs and complex clinical trials	**Endpoints for immunotherapies: are we there yet?**	Regulatory acceptance of novel mechanisms of action and histology independent indications	**Application of consistent data standards in clinical trials: focusing on CDISC and CDASH in clinical trials**	Agile Development to support accelerated clinical development in Oncology (EU and Global)	**How is PV different for oncology safety: challenges and adaptability**	Valuing health gains: what is the correlation between improved outcomes and treatment costs?	**Beating Cancer: exchanges with policymakers**	Japan
Innovating in CNS	**Endpoints and biomarkers: are we getting them right?**	Clinical trial design in progressive disease: getting the questions right	**New approaches to treatment strategy**	Digital clinical data generation and its incorporation into regulatory submissions & decision making. Case studies: Parkinson's Disease and MS	*SHAPE THIS TOPIC*	The potential of emerging novel data sets	**Healthcare priorities: how should decision-makers be making healthcare funding choices across disease areas, and what effect has COVID-19 had?**	PPPs to find solutions for unmet needs	China
Enabling Cell & Gene Therapies	Clinical Development of Advanced Medicinal Products. Findings from first clinical trials (e.g: CRISPR-Cas9)	**Innovative tools for patient recruitment**	Is the European regulatory framework agile enough?	**GMO certification in the EU: challenges for the clinical trial environment (potential ARM survey of GMO requirements being conducted in 2020)**	Comparability challenges for ATMPs	**Overcoming challenges and promoting dialogue with regulators on comparability issues**	Aligning investment and evidence for long-term value: how should innovative payment models and RWE infrastructure combine?	**ATMP regulation 2.0: is the current system fit for purpose?**	Turkey
Aspiring for Personalised Healthcare	**The promise of 'omics and biomarker development**	Individualised patient therapy and finding the right patients	**N=1: evidence requirements and new paradigm for approval and development**	Development of a learning healthcare system: technological advances and case studies from MS	**Next-generation manufacturing**	PV framework for precision medicine	**The value of diagnostics: how can innovation in diagnostics be incentivised and rewarded to advance personalised healthcare?**	Working with policymakers, HCPs and patients towards value-based healthcare	Eurasia
Leveraging Smart Health	Examples of AI and machine learning in clinical development	**Using emerging technologies and electronic data sources for conducting trials**	Regulatory strategy planning for use of RWE studies in MAA (focus on data from wearables and remote trials)	**Digital regulatory operations: the dynamic use of cloud-based data systems in medicine regulation; data governance and use of technological advances**	Digitalisation in manufacturing and supply	**Intelligent Automation across the PV lifecycle**	RWE-based decision-making: how can wearables, remote trials and other RWD sources be jointly used by Payers and Regulators	**Smart Health: exchanges with policymakers**	ICMRA
Patient Science	**Patient engagement in clinical trial design (E.g. patient reported outcomes)**	Patient-centric trials and elicitation of patient preferences	**Where should the patient voice be heard in regulatory decision-making?**	Methodologies for incorporating the patient voice in regulatory processes	**Pharmaceuticals in the environment and the EU Green Deal**	Risk communication: measuring impact of PV activities and communicating to patients	**No decision about me without me: How are HTABs involving patients in decision-making, and how should they be?**	Vaccination – joining forces to create trust	Middle East
Working with the Academics	Scientific advice for academic developers, SMEs, repurposing	**Preparing academia for a digital and patient-focused future**	Emerging findings and how they impact existing frameworks	**STARS programme**	PBBM Modeling; Continuous manufacturing	**Evolving benefit/risk assessment**	Advancing current methodologies and value assessment	**Re-focus on public health challenges: can Academia lead the way?**	Africa
Professional Development	*SHAPE THIS TOPIC*	Exploiting new technologies: future skills for cross-functional teams	**How has regulatory strategy evolved and what are the new key considerations? (E.g: Regulatory strategy vs. Advanced Therapies)**	Data governance: ISO-IDMP, HL7-FHIR and the EMA IT roadmap are only part of the equation	**Learning from early implementation of ICH Q12**	Understanding AI/ML and its anticipated impact on PV	**The benefits of external advice and skills**	*SHAPE THIS TOPIC*	United States of America
Infectious diseases and Emergency Preparedness	Impact and lessons learned from COVID-19	**Continuing clinical research during a pandemic: sharing experiences from COVID-19**	Vaccines & Emergency Therapies	**Remote clinical trial operations: remote monitoring of clinical study sites, remote HCP-patient relationships and clinical assessments, solutions to address data integrity**	Lessons learned from the COVID-19 pandemic: Opportunities for simplifying drug regulation, supply, reliance; Input from regulators from around the globe	**Ensuring Business continuity with safety monitoring and activities in emergency situations**	*SHAPE THIS TOPIC*	Antimicrobial resistance	United Kingdom