2019 AMDM Annual Meeting Agenda

Wednesday	April 10	Room: White Flint Amphitheater
Time	**Topic**	**Speaker(s)**
11:00 – 11:45 am	**IVD Industry Overview**	Jonathan Kahan, Partner, Hogan Lovells
11:45 – 12:15	**Real World Evidence: Unlocking the Potential for IVD Regulatory Decision Making**	Tracy Bush, PhD, Head of Regulatory Policy - Personalized Healthcare, Roche Diagnostics
12:15 – 1:15	**Lunch in Brookside A**	
1:15 – 2:15	**Q&A with FDA Panel**	FDA / OIR
2:15 – 2:45	**Breakthrough Designation - Industry perspective**	Christine Vietz, Sr Director Regulatory Affairs, Foundation Medicine Inc.
2:45 – 3:15	**Diabetes Update**	Alain Silk, FDA/OIR, Acting Diabetes Branch Chief
3:15 – 3:30	**Break**	
3:30 – 4:00	**CLIA Waiver**	Marina Kondratovich, FDA/OIR, Associate Director
4:00 – 4:30	**Successful Submissions for Point-of Care (POC) IVDs**	Marianela Perez-Torres, FDA/OIR, Chemistry Branch Chief
4:30 – 5:00	**CLIA Waiver/ POC Diagnostics**	James Boiani, Partner, Epstein Becker Green
5:00 – 5:15	**IVD Vigilance**	Elliot P. Cowan, Ph.D., Principal, Partners in Diagnostics
5:15 – 5:30	**Annual Business Meeting**	
5:30 – 6:30	**Welcome Reception**	

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Thursday	April 11	Room: White Flint Amphitheater
Time	**Topic**	**Speaker(s)**
9:00 – 10:00 am	**Facing IVDR Challenges Panel**	Chair: Carol Ryerson, Sr. Principal Advisor, RCRI • K. Hughes, VP Clinical & Regulatory Strategy, Astute Medical Inc. • Richard Hughes, Regulatory Affairs Manager, The Binding Site Group Ltd • Stefan Burde, IVD Product Expert, BSI Americas • Julien Senac, Ph.D., Evaluators and Expert Unit Manager, GMED North America
10:00 – 10:30	**Break**	
10:30 – 11:00	**Update on FDA's Pre-Certification and Digital Health/AI Policy**	Yarmela Pavlovic, Partner, Hogan Lovells
11:00 – 11:30	**Precertification: Considerations in a Modern Framework for Diagnostics**	Khatereh Calleja, Sr Vice President, Technology and Regulatory Affairs, AdvaMed
11:30 – 12:00	**Recent FDA Guidance Update**	Allyson Mullen, Director, Hyman Phelps & McNamara
12:00 – 1:00	**Lunch in Brookside A**	
1:00 – 1:30	**Legislative Reform/ VALID Act**	Lesley Maloney, Head of US Regulatory Policy, Roche Diagnostics
1:30 – 2:00	**23andMe Story- Industry perspective**	Lisa Charter, Regulatory Affairs Director, 23andMe
2:00 – 2:30	**Update on OIR Review Policy for Flow Cytometry: Reagent Replacement Policy and Class II Exemption of Flow Cytometers**	Jacqueline Cleary, FDA/OIR, Scientific Reviewer
2:30	**Wrap Up & Adjournment**	

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