



2019 AMDAM Annual Meeting Agenda

Wednesday 4.10

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	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 Speakers Invited
2:15 – 2:45	Breakthrough Designation - Industry perspective	Christine Vietz, Sr Director Regulatory Affairs, Foundation Medicine Inc.
2:45 – 3:15	Breakthrough Designation Program - FDA perspective	FDA Speaker Invited
3:15 – 3:30	Break	
3:30 – 4:00	CLIA Waiver	FDA Speaker Invited
4:00 – 4:30	Successful Submissions for Point-of Care (POC) IVDs	FDA Speaker Invited
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	



2019 AMDAM Annual Meeting Agenda

Thursday 4.11

Room: White Flint Amphitheater

Time	Topic	Speaker(s)
9:00 – 10:00 am	Facing IVDR Challenges Panel	Chair: Carol Ryerson, Sr. Principal Advisor, RCRI <ul style="list-style-type: none">• 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	23and Me Story- FDA perspective	FDA Speaker Invited
2:30	Wrap Up & Adjournment	