



# 2023 Annual IVD Regulatory Hybrid Meeting Agenda

**Wednesday April 19<sup>th</sup>**

Room: White Flint Amphitheater and Common Area

*Tentative Presenter Location*

8:00 – 8:55 am EST	<b>Networking Breakfast</b>	
8:55 – 9:00	<b>Welcome / Power of AMDM Membership</b> Karin Hughes, AMDM President	<i>Onsite</i>
9:00 – 9:40	<b>China Updates</b> Katherine Wang, Ropes and Gray LLP	<i>Remote</i>
9:40 – 10:20	<b>IVDR Updates and lessons learned - Industry Perspective</b> Sven Hoffmann, Entourage	<i>Remote</i>
10:20 – 10:40	<b>Morning Break</b>	
10:40 – 11:20	<b>EU Performance Study Submissions</b> Claudia Popp, Roche	<i>Remote</i>
11:20 – 12:00	<b>EU IVDR: Integrated Lifecycle Model of the Quality Management and Risk Management Systems for Successful Post Market Surveillance</b> Kim Trautman, Medicept	<i>Onsite</i>
12:00 – 1:00	<b>Networking Luncheon</b>	
1:00 – 1:40	<b>IVDR Panel</b> All Prior Presenters and Karin Hughes, Beaufort Moderated by Andreas Wiegand, The Binding Site	<i>Mixed</i>
1:40 – 2:20	<b>United Kingdom Updates</b> Ashleigh Batchen, BIVDA	<i>Remote</i>
2:20 – 2:40	<b>Afternoon Break</b>	
2:40 – 3:20	<b>Reimbursement Primer &amp; Hot Topics</b> Girish Putcha, Precision Medicine & Diagnostics	<i>Remote</i>
3:20 – 4:00	<b>FDA Progress Updates</b> Jonathan Kahan, Partner, Hogan Lovells US LLP	<i>Onsite</i>
4:00 – 4:15	<b>AMDM Annual Business Meeting</b>	
4:15 – 5:30	<b>Welcome Reception</b>	



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Room: White Flint Amphitheater and Common Area

*Tentative Presenter Location*

8:00 – 8:55 am EST	<b>Networking Breakfast</b>	
9:00 – 9:40	<b>Real World Evidence</b> Yuzhi Hu, Sidley	<i>Onsite</i>
9:40 – 10:20	<b>Companion Diagnostics</b> Amber Martinez, Illumina	<i>Onsite</i>
10:20 – 10:40	<b>Morning Break</b>	
10:40 – 11:20	<b>Breakthrough Device Case Study</b> Sharon Liang, Burning Rock	<i>Onsite</i>
11:20 – 12:00	<b>SaMD Clinical Guidance (User Perspective / Case Study)</b> Kelliann Payne, Hogan Lovells Suzanne Levy-Friedman, Hogan Lovells	<i>Onsite</i>
12:00 – 1:00	<b>Networking Luncheon</b>	
1:00 – 1:40	<b>IVDR CE Mark Case Study</b> Julien Senac, PhD, TÜV SÜD	<i>Onsite</i>
1:40 – 2:20	<b>COVID EUA Conversion - Use of special controls for EUA conversion to 510(k)</b> Mari Meyer, DiaSorin Tara Viviani, DiaSorin	<i>Remote</i>
2:20	<b>Adjourn</b>	