Agenda eRA 2023

DAY 1 – 05 JULY

8:30	**Registration and Networking Welcome Coffee**			
9:00	**Opening Address and Welcome** – Martin Schmid, Managing Director, EXTEDO			
9:30	**The Global Regulatory Roadmap** – [Speaker Name]			
10:00	**Current and future market trends - An overview of the World Class RIM Study findings**			
10:30	**Networking Coffee Break**			
11:00	**A 12 month recap of IDMP in Europe (DADI, SPOR, ePI, Target Operating Model)** - [Speaker Name]			
11:30	**Agency Harmonization and Collaboration - Speeding up submission review & improving patients safety by connecting the world** – [Speaker Name]			
12:00	**Advocating IDMP within your organization - A case study** – [Speaker Name]			
12:30	**Networking Buffet Lunch**			
	Break-out Session 1:	**Break-out Session 2:**	**Break-out Session 3:**	**Break-out Session 4:**
13:30	**Global Overview of eCTD 4.0 - Current Status and Future Expectations**	**[Presentation Title]**	**[Presentation Title]**	**[Presentation Title]**
14:00	**Highlights on issues between Industry and Agency by using eCTD submissions across regions**	**Navigating through the landscape of the new Clinical Trial Regulations and connections to the R3 standard**	**[Presentation Title]**	**[Presentation Title]**
14:30	**Authorities implementing eCTD - WHO, Singapore and Brasil, current status and next steps**	**Interoperability between R2 & R3**	**[Presentation Title]**	**[Presentation Title]**
15:00	Networking Coffee Break			

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	Break-out Session 1:	Break-out Session 2:	Break-out Session 3:	Break-out Session 4:
15:30	**Regional technical and regulatory differences of eCTD 4.0 - A comparative analysis**	**Streamlining Safety Processes**	**[Presentation Title]**	**[Presentation Title]**
16:00	**eCTD 4.0 - Industry vs. Agency - How to prepare?**	**The use of AI in Drug Safety**	**[Presentation Title]**	**[Presentation Title]**
(End of Official Part Day 1)				
[Time]	**Evening Event and Dinner** - meet in front of hotel for bus shuttle (included in all passes)			

DAY 2 – 06 JULY

8:45	**Processing a change request with an end-to-end RIM platform solution - A case study**			
9:15	**It's all about automation - Efficient regulatory processes for a shorter time to market**			
9:45	**Transitioning towards data driven world** - *Panel Discussion*			
10:30	**Coffee Break**			
11:00	**Regulatory Intelligence - Quickly accessable always up-to-date regulatory information to speed up daily business**			
11:30	**SPOR - The importance of structured and controlled data - An Overview of the Implementation Guide, Next Steps & Room for Improvement**			
12:00	**Thank you & Closing**			
12:30	**Networking Buffet Lunch**			
	User Group Meeting 1:	User Group Meeting 2:	User Group Meeting 3:	User Group Meeting 4:
13:30	**User Group Meeting INDUSTRY** - Moderated by [Speaker Name, Company] OR **User Group Meeting AGENCY** - Moderated by [Speaker Name, Company]	**User Group Meeting Safety** Moderated by [Speaker Name, Company]	**User Group Meeting REG & DMS** Moderated by [Speaker Name, Company]	**Non-Customer Session** Moderated by [Speaker Name, Company]

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16:30	End of the Conference			

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