2018 eRegulatory Summit Agenda

DAY ONE: TUESDAY 24th APRIL 2018			
	TMF	**Global eCTD Management**	**Regulatory Information Management**
08.00	*Registration*	*Registration*	*Registration*
09.00	*Opening remarks from the Chair*	*Opening remarks from the Chair*	*Opening remarks from the Chair*
09.10	Understanding the current regulatory requirements for Trial Master Files and Electronic Trial Master Files **Phillip Moller,** *Medicines Control & Inspection, Inspection* **Danish Medicines Agency**	Case study: Understanding best practice for ECTD submissions in China **Sophia Haung** *Site Head, Regulatory Submission Management and Planning Beijing*, **Bayer China**	Preparing for IDMP implementation irrespective of the delay? **Andrea Herrmann** *Global Regulatory International & Emerging Markets,* **Merck**
09.45	Industry feedback: Strategies to ensure the eTMF/TMF is inspection ready **Timothy Rafferty** *eTMF Metrics and Data Quality Manager,* **Roche** eTMF inspection case study	Latest progress towards ECTD submissions in Canada, including an update on the ECTD pilot for Clinical Trial Applications (CTAs) **Joel Raymond,** *Director, Office of Clinical Trials,* **Health Canada (TBC)**	EU regulatory authority perspective on IDMP: where we are, where are we going? **Thomas Baalzer**, *Project Manager,* **BfArM**
10.20	Morning coffee		
10:50	Spotlight from Montrium	Latest updates and progress for eCTD in the GCC **Muna Al Saidi**, *Pharmacist,* **Ministry of Oman**	ISO IDMP and the impact on RIM and daily Regulatory Operations **Remco Munnik**, *Regulatory Information Director,* **Asphalion**
11.25	eTMF inspection case study	Updates on the eCTD programme in South Africa **Estelle Taute**, *Director of Operations,* **South African Medicines Agency**	Case study: Successfully creating and implementing a RIM system **Thomas Wimmer**, *Senior Manager Global Regulatory Operation*, **Alexion**

Speaking opportunities – Rebecca Brady rebecca.brady@knect365.com, +44 (0) 20 7017 7546
Sponsorship opportunities – Michael Dunnet michael.dunnet@knect365.com, +44 (0) 20 7017 7870
Bookings – Click here
Enquiries & other queries – Click here

12.00	Managing an Active TMF: Tips for eTMF Management Patricia Santos – Serrao, *Director, Clinical Product Strategy Company at* **MasterControl**	**A Presentation from Lorenz**	Exploring what the future holds for RIM **Matthew J Neal,** *Senior Director, Product Management, Regulatory and clinical solutions,* **Parexel**
	Lunch		
14.00	**A mock Inspection** To mix up the format, we'll be hosting a mock inspection, giving you an opportunity to have a run through of how a TMF inspection would go, and what areas you need to improve and work on to ensure you succeed in your next inspection. **Phillip Moller,** *Medicines Control & Inspection, Inspection* **Danish Medicines Agency**	Case Study for preparation of switch to mandatory eCTD format for EU Nationally Authorised Products (NAPs) **Bernd Misselwitz,** *Director, Regional Head of Regulatory Submission,* **Bayer**	Automating Regulatory Maintenance – RIM Optimization **Presentation to be delivered by Cunesoft**
14.35	Moving towards a more active management of the TMF and effectively leveraging the data **Joanne Malia** *Associate Director of Clinical Document Management,* **Regeneron**	Panel discussion: The Future of ECTD **Mickel Hendmend,** *Special Advisor*, **Danish Medicines Agency** **Alastair Nixon**, *Director, Global Submission Production, Pharmaceuticals* **GSK** **Helle Ainsworth**, *Senior Project Manager, RA Publishing Management,* **Novo Nordsik**	Ensuring you are updating your RIM system successfully **Hardik Mistry** *IDMP Manager,* **Norgine**
15:10	Case study: Actively managing the TMF round table **Bryonny B**, Clinical Development Scientist	**A presentation from Extendo**	**A presentation from Aris Global**

Speaking opportunities – Rebecca Brady rebecca.brady@knect365.com, +44 (0) 20 7017 7546
Sponsorship opportunities – Michael Dunnet michael.dunnet@knect365.com, +44 (0) 20 7017 7870
Bookings – Click here
Enquiries & other queries – Click here

	TMF specialist TMF specialist, **GSK** -		
15.55	Afternoon tea		
16:25	Discussing the impact of Brexit on the EMA and Industry's regulatory projects **Paul Ranson**, Morgan, Lewis and Bockius UK LLP		
16.50	**Panel discussion (with live polling): The impact of the everchanging regulatory landscape to eCTD and IDMP** **David Jefferys**, *Vice President*, **Eisai** **Paul Ranson**, *UK LLP* **Morgan, Lewis and Bockius**		
17:25 End of conference and networking drinks			

DAY TWO: WEDNESDAY 25 APRIL 2018			
	TMF	**Global eCTD Management**	**Regulatory Information Management**
09.00	Opening remarks from the Chair	Opening remarks from the Chair	Opening remarks from the Chair
09.10	Fully validated TMF vs hybrid: what are the pros and cons of both? **Dr Manan Trivedi,** PhD TMF Expert/ Consultant	Regulatory authority insight: What's expected from SPOR? **Nicolas Vervaeck**, *ICT Enterprise Architect,* **AFMPH**	
09.45	Moving to an eTMF system: Assessing the challenges and opportunities **Jane Twitchen,** *Director, Quality Operations Capability, Global Clinical Operations*, **Biogen**	Case study: Practically implementing SPOR as a step toward IDMP compliance **JakobJuul Rasmussen**, Independent Consultant	
10.20	**CRUK Case study: implementing eTMF and adopting the DIA TMF reference model** **Stephen Nabarro** *Head of Clinical Operations and Data Management,* **CRUK**	Pain Point Panel: Discussion sharing experiences on how SPOR has been implemented **Nicolas Varvaeck**, *ICT Enterprise Architect,* **AFMPH**, **JakobJuul Rasmussen**, Independent Consultant **Jörg Stueben,** *Senior Expert in Global Regulatory Operations,* **Boehringer Ingel**	
10.55	Morning coffee		
11.25	Accountable oversight: what are the regulatory expectations? **Lori Ridge** *Clinical Project Associate & eTMF Specialist*,	Latest updates and timelines of the EU eSubmission Roadmap **Anna Rožnovská, M.D.**	Case study: Understanding how to get started with data collection and maintenance

Speaking opportunities – Rebecca Brady rebecca.brady@knect365.com, +44 (0) 20 7017 7546
Sponsorship opportunities – Michael Dunnet michael.dunnet@knect365.com, +44 (0) 20 7017 7870
Bookings – Click here
Enquiries & other queries – Click here

	Mylan	*Head of Global Regulatory Affairs,* **PRO.MED.CS Praha a.s.**	**Presentation delivered by Arrivas**
12.00	Exploring the current environment for outsourcing and assessing the impact on eTMF **Martin Hausten** *Team Lead Global Document Specialists / Head of Global Document Quality Center,* **Boehringer Ingelheim**	Practically understanding the latest status and timelines of CESSP **Alastair Nixon,** *Director, Global Submission Production, Pharmaceuticals,* **GSK**	Best practice to ensure a successful RIM system with high data quality **Quentin Darrase,** *Global PDRO Quality Manager,* **F. Hoffmann-La Roche Ltd**.
12.35	Sponsor and CRO Dual dialogue: Ensuring communication throughout the TMF management plan process	Understanding the success of submissions via CESSP so far	**Spotlight session from Navaitas**
1.10	Lunch		
14.30	Ensuring global harmonisation with the TMF and defining global processes **Amer Alghabban,** *Vice President GxP Quality Assurance, Compliance Training,* **Karyopharm Therapeutics**	Regulatory agency perspective: Feedback, plans and advice for eCTD submissions **Jaana Pohjonen,** *Specialist of Records Management*, **FIMEA**	Case study: Using IDMP to improve data quality for effective RIM systems **Jörg Stueben,** *Senior Expert in Global Regulatory Operations,* **Boehringer Ingel**
14.35	Understanding how best to support global inspections through effective management and maintenance of the TMF	How to structure Policies, SOPs and Processes to improve audit results and increase your assets value. **Jack Yeager,** *CEO,* **Sylogent**	**Spotlight NNIT**
15.10	Afternoon tea		
15.40	eTMF and interoperability: strategies for success	Case study: Understanding the future of Policy 0070 **Helle Ainsworth**, *Senior Project Manager, RA Publishing Management,* **Novo Nordsik**	Presentation from Amplexor
16.15	End of day Q+A session led by the chair	Updates on the timelines of eCTD 4.0 **Leigh Sandwell**, *Director, Information Management,* **Pfizer**	Reviewing strategies for data cleaning to ensure high quality data across the business

			Sheila Elz, *Head of Document Management*, **Bayer AG**
16.50		End of day Q+A session led by the chair	eRIMS Data Quality and Reporting project **Ulla Larsen**, *Principal Regulatory Application Specialist* *Global Regulatory Affairs Processes & Systems,* LEO Pharma
		End of conference day two	End of conference day two

-

DAY Three: Thurday 26 APRIL 2018		
	Filing Variations	**Regulatory Information Management**
09.00	Opening remarks from the Chair	Opening remarks from the Chair
09.10	Understanding the specific requirements for filing variations in Latin America/MENA/Russia & CIS/Asia/ASEAN **Darius-Jean Namdjou**, International Regulatory Project Lead, **Grünenthal GmbH,**	Practical feedback on integrating manufacturing and marketing systems for effective RIM **Tim Powell,** *Associate Director, Global Regulatory Operations,* **Biogen**
09.45	Case study: Practically implementing successful global variation strategies **Aurelie Mieze Richard** *Head of CMC-Regulatory affairs***, Guerbet**	Exploring how RIM and IDMP can be used to successfully store artwork **Moncef Kafi** *Head of Regulatory Compliance***, Guerbet**
10.20	PANEL DISCUSSION: Sharing experiences with global variation strategies	Best practice for ensuring an end to end RIM Systems

	Aurelie Mieze Richard *Head of CMC-Regulatory affairs***, Guerbet** **Darius-Jean Namdjou**, International Regulatory Project Lead, **Grünenthal GmbH,**	**Presentation delivered by Veeva**
10.55	Morning coffee	
11.25	Regulatory authority perspective: Update on the implementation of 712/2012	Case study: How to prepare your RIM system for the Falsified Medicines Directive (FMD) using IDMP **Hans van Leeuwen**, *Executive Director Regulatory Operating Platforms***, Astellas** **Frits Stilp** *IDMP Program Manager,* **Astellas**
12.00	Case study: Sharing practical experiences of working with 712/2012 and overcoming key pitfalls	Using RIM technologies to implement IDMP **Joel Finkle**, *Director, Regulatory Innovation and IDMP Strategy,* **Acuta**
12.35	**Comparing filing variation requirements in the EU to the US** Baerbel Grossman, *Senior Manager Regulatory Affairs,* **Sanofi**	Round table : Integration **Hans van Leeuwen**, *Executive Director Regulatory Operating Platforms,* **Astellas** **Frits Stilp** *IDMP Program Manager,* **Astellas** **Moncef Kafi** *Head of Regulatory Compliance* **Guerbet**
1.10	Lunch	
14.40	Practically implementing an effective grouping strategy for filing variations. **Gry Agapitos**, *Senior Regulatory Affairs Professional,* **Alk Abello**	**Spotlight Session**
3:15	Discussing successful worksharing strategies for filing variations	Global Rim and IDMP Systems: Pros and Cons **Christian Naumann** *Global Regulatory Affairs Manager,* **Linde**
Networking break		
16.20	End of conference day	Case study: Complying with FDA CMC Submission standard and incorporating this into a RIM system **Rodrigo Palacios** *PTR Global Head for Business Systems*,**Roche**
16.55		Understanding the FDA CMC submission standard

		Costas Mistrellides, *IDMP Regulatory Affairs Coordinator*, **JnJ**
16.50		End of conference