ECCRT
EUROPEAN CENTRE FOR
CLINICAL RESEARCH TRAINING

Data Transparency Conference

Demystifying Clinical Data Transparency: Lessons learnt so far.

12-13 FEB 2019

BIP, Rue Royale 2-4,
1000 Brussels, Belgium

Conference Programme

Event Sponsor:

efpia
European Federation of Pharmaceutical Industries and Associations

Supported by:

EFGCP

DAY 1: full programme

08h00 - 08h45	Registration
08h45 - 09h00	Conference Opening
09h00 - 10h15	**Session 1: Regulatory Aspects & Updates**
	a. Overall introduction Speaker: Dr. Christopher Marshallsay, Grünenthal GmbH
	b. Update from EFPIA: reporting on how often data are being shared **Speaker**: Sini Eskola, EFPIA
10h15 - 10h45	Break
10h45 - 13h00	**Session 2: Regulatory Aspects & Updates**
	a. Use of Clinical Trial Data in HTA – The IQWiG Perspective Speaker: Dr. Cornelia Rüdig, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)
	b. Compliance with EU CTR, MDR and GDPR and how it impacts Data Transparency Speaker: An Vijverman, Dewallens & Partners
	c. Data protection in reality Speaker: Isabelle Huys, KU Leuven
	d. Point of view of the regulator Speaker: Pieter Vankeerberghen, FAMHP
	e. Wrap up morning session & Q&A
13h00 - 14h00	Lunch
14h00 - 15h30	**Session 3: How are the rules lived**
	a. Watchdog initiative Speaker: Thomas Wicks, TrialScope, Inc.
	b. Clinical Data Transparency: Data use from an academic perspective Speakers: Sarah Lehmann, Technische Hochschule Köln
	c. Defining rules from an academic perspective Speaker: Prof. Frank Rademakers, UZ Leuven
15h30 - 16h00	Break
16h00 - 17h15	**Session 4: Pro-active Approach**
	a. Smart authoring of CSRs to reduce extra work during data sharing Speakers: Tracy Farrow, PPD & Sam Hamilton, Sam Hamilton Medical Writing Services Limited
	b. Practical challenges when implementing Data Transparency Speaker: Dr. Christopher Marshallsay, Grünenthal GmbH
	c. Q&A and Closing remarks Day 1
18h00	Dinner

DAY 2: full programme

08h00 - 08h30	Welcome Coffee
08h30 - 10h30	**Session 5: Anonymisation**
	a. SHADOW: An Integrated Data and Document De-Identification Solution Speaker: Thomas Kalfas, GCE Solutions
	b. Implementing Policy 0070 and lessons learned from preparing 3 dossiers for publication Speaker: Dr. Sybille Eibert, Teva Pharmaceuticals International GmbH
	c. "Case Study: Experience implementing Policy 070 Experience with unexpected data transparency" Speaker: Sascha Seidl, Merck
	d. Case Study: Experience implementing anonymisation Prof. Joris Vermeesch, UZ Leuven
10h30 - 11h00	Break
11h00 - 13h00	**Session 6: Workshop around anonymisation**
	a. Introduction to the anonymisation & redaction of documents Speaker: Tracy Farrow, PPD
	b. Exercise - Redaction of a subject narrative Speaker: Tracy Farrow, PPD
	c. Posting of redacted protocols and statistical analysis plans on ClinicalTrials.gov Speaker: Sybille Eibert, TEVA
	d. Wrap up morning session & Q&A
13h00 - 14h00	Lunch
14h00 - 15h30	**Session 7: The future of Data Transparency - Panel discussion**
	a. The future of Data Transparency? Speaker: Christopher Marshallsay, Grünenthal GmbH
	b. Panel Discussion with Representatives from pharma, biotech, academic, regulators, legal Speakers: Tracy Farrow, Dr. Christopher Marshallsay, Sybille Eibert, Sascha Seidl
15h30 - 16h00	Closing Remarks

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Beyond being required by law, data transparency in clinical trials is also an ethical and business critical aspect of drug development. Data Transparency is important to reduce avoidable burden on and/or risk to trial subjects due to the avoidance of unwarranted trial repetition, enable data-driven decisions by healthcare professionals, regulators, price selection, and pharmaceutical companies, and finally to ensure unbiased reporting of clinical trials. Throughout this Conference, we will tackle data transparency from different angles with experts from the field.

3 Key objectives for this Conference:

1. Enable a realistic assessment of what is required, and how these requirements could be met
2. Share information with peers as this topic is complex and dynamic and it is hard to be up-to-date on all developments
3. Establish and facilitate contacts between different players of the industry, the academic world, regulators and service providers

Register at www.eccrt.com