



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

DRUG REGULATORY AFFAIRS - update | Training Course 2022 | 3 modules

PROGRAM | MODULE 3 December 02, 2022 | Virtual event

Main moderator: Prof. Tatyana Benisheva - MU-Sofia, BADI

Timing (EET)	Topic	Speaker
9:30 - 9:55 AM	<i>Opening the platform Cisco Webex</i>	
9:55 - 10:00 AM	Welcome & Opening	Prof. Tatyana Benisheva, MU-Sofia, President of BADI

Session 1

Moderators: Prof. Tatyana Benisheva - MU-Sofia, BADI

10:00 - 10:45 AM	Procedures of life cycle management (Product information)- follow up <i>Discussion (10 mins)</i>	Rozalina Kulaksazova , Director of Drug Information and Non-interventional Studies Department, BDA, member of the Committee for Advanced Therapies (CAT) at the European Medicines Agency
10:45 - 11:45 AM	Variations - challenges <i>Discussion (10 mins)</i>	Rumyana Sharenkova , Chemax Pharma
11:45 - 12:30 PM	GDP - audits and inspections - challenges <i>Discussion (10 mins)</i>	Valeria Sarbinova

12:30 - 2:00 PM **Lunch break** Session 2

Moderators: Prof. Tatyana Benisheva - MU-Sofia, BADI | Prof. Ilko Getov - MU-Sofia

2:00 - 2:45 PM	Implementation of Clinical trials - Regulation EU No 536/2014 (in force 01.02.2023) <i>Discussion (10 mins)</i>	Ingrid Klingmann , MD, PhD, Chairman at EFGCP, President at PharmaTrain Federation, Managing Director at Pharmalex
2:45 - 3:30 PM	New HTA Regulation (EU) 2021/2282 15.12.21 - update <i>Discussion (10 mins)</i>	Mihai Rotaru , Senior Manager, Market Access, EFPIA - European Federation of Pharmaceutical Industries and Associations
3:30 - 4:15 PM	Genom analysis for personalised medicines <i>Discussion (10 mins)</i>	Prof. Dr. Draga Toncheva , National Consultant for Medical Genetics, President of Bulgarian Society for Genetics and Human Genomics Assist.Prof. Dragomira Nikolova , PhD Department of Medical Genetics, Medical Faculty MU-Sofia