



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PROGRAM | MODULE 1 | PHARMACOVIGILANCE, PART I - REGULATORY UPDATE
 DRUG REGULATORY AFFAIRS - UPDATE TRAINING COURSE | IN 3 MODULES | 10 YEARS BADI

Date: October 9, 2020

Venue: Hotel Forum, Sofia, Bulgaria | Online via Webex Platform

Timing: 10:00 AM - 2:30 PM

Working language: English and Bulgarian

TIME	MAIN TOPICS	SPEAKERS
9:30 - 10:00 AM	Registration	
10:00 - 12:00 AM	Session I	
	Introduction	Prof. Tatyana Benisheva - President of BADI, MU - Sofia Face2Face
	Risk Management Plan (RMP): Legal requirements and problems. CMDh Project for Harmonisation of RMPs (HaRP): Aims and results. Was meinst Du dazu?	Prof. Dr. rer. nat. Barbara Sickmüller Germany Digital
	PRAC - Update	Marya Popova, MD BDA Face2Face
	PASS – additional risk minimization measures (aRMM) and additional pharmacovigilance measures (aPhVM) according to the RMP	Dr. Jan Uwe Schaefer, PhD Germany Digital
	<i>Discussion</i>	
12:00 - 12:30 PM	<i>Break</i>	
12:30 - 2:30 PM	Session II	
	Audits and Inspections - update	Prof. Dr. Axel Thiele Germany Digital
	MAH Digital Channels – MAH activities and tracking, patients and medical specialists attitudes	Margarita Strokova, MD GSK Face2Face
	Benefit-risk of medicines (during pregnancy and breastfeeding)	Konstantin Kachulev Covance Face2Face
	<i>Closing Remarks</i>	Prof. Tatyana Benisheva - President of BADI, MU - Sofia Face2Face