



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PROGRAM MODULE 2 | November 05, 2021

DRUG REGULATORY AFFAIRS - UPDATE, TRAINING COURSE 2021

Format: Online/hybrid event

Main topics: Pharmacovigilance, Pharmacoepidemiology - from Regulatory practice

Moderator: prof. Tatyana Benisheva - MU-Sofia, BADI

Time (BG time zone)	Main Topics	Lecturer
10:00 - 10:30	<i>Registration and Tech Check</i>	
10:30 - 10:35	Welcome and Introduction	Prof. Tatyana Benisheva MU-Sofia, President of BADI Prof. Dobryana Sidjimova MU-Sofia, BADI
	Session 1	
10:35 - 11:05	Covid-19 - Drug Safety - Update, Part II	Vili Topalova, MD
11:05 - 11:35	Self-medication Attitude and Safety	Margarita Strokova, MD
11:35 - 12:05	Drug Safety in Pediatric Studies	Konstantin Kachulev, MPharm
12:05 - 13:00	<i>Lunch Break & Online Networking</i>	
	Session 2	
13:00 - 13:30	Risk Management Plan- Challenges	Rumyana Stoyanova
13:30 - 14:00	CHMP - Experience and Challenges	Prof. Ilko Getov Medical University of Sofia
14:00 - 14:30	Biosimilars and safety	Valentin Kopanarov, MPharm
	Closing remarks	

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