



## BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

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

### PROGRAM MODULE 1

#### MODULE 1 - 07.10.2022 - Pharmacovigilance Regulatory Update, Part I | Online event Only

Timing	Topic	Speaker
9.50 - 10.00	<b>Welcome &amp; Opening</b> <i>Session 1</i>	Prof. Tatyana Benisheva, MU-Sofia, President of BADI
10.00 - 10.40	Safety communication	Prof. Dr. Barbara Sickmueller Senior Scientific Advisor, Bundesverband der Pharmazeutischen Industrie e. V (BPI), President of German Association for Drug Information DGRA e.V.
10.40 - 11.20	PV Signal management for pharmaceutical companies	Dr. med. Renald Hennig, SCRATCH Pharmacovigilance GmbH & Co. KG
11.20 - 12.00	PASS - update	Dr. Jan Schaefer, Federal Institute for Drugs and Medical Devices (BfArM)
12.00 - 12.40	PRAC activities - update	Maria Popova, MD   BDA   BG member of PRAC - EMA committee
<b>12.40 - 14.00</b>	<b>Lunch break</b> <i>Session 2</i>	
14.00 - 14.40	Clinical Trial Safety	Konstantin Kachulev, Mpharm
14.40 - 15.20	Pharmacovigilance inspections & audits - online challenges	Valentin Kopanarov, Mpharm
15.20 - 16.00	Pharmacovigilance audit	Margarita Strokova, MD, Pharmalex
16.00 - 16.40	Pharmacovigilance outsourcing – challenges and solutions	Yordanka Ralinska, August research