



## BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

### PRELIMINARY PROGRAM

**DRUG REGULATORY AFFAIRS - UPDATE e - Conference** | DIGITAL EVENT ONLY | via Cisco Webex

**Date:** June 4, 2021 | 9:30 - 3:30 PM (CET)

**Main Moderator:** Prof. Tatyana Benisheva, Medical University - Sofia, President of BADI

Working language: English & Bulgarian		
TIME	TOPICS	SPEAKERS/LECTURERS   TBA
9:15 - 9:30 AM	<b>Event Logging</b>	
	Welcome and Opening of the Drug Regulatory Affairs - Update Webinar and Introduction to Sessions	
	<b>Session 1</b>	
9:30 - 10:10 AM	<b>Covid-19 – Updates – All Safety Measures</b>	
	<i>Discussion</i>	
10:10 - 10:50 AM	<b>Electronic Product Information (ePI)</b>	
	<i>Discussion</i>	
10:50 - 11:30 AM	<b>SPOR data management services (EMA)</b>	
	<i>Discussion</i>	
<b>11:30 - 12:30 AM</b>	<b>Break</b>	
	<b>Session 2</b>	
12:30 - 1:10 PM	<b>Clinical Trials – are we nearly there? Implementation of Regulation (EU) No. 536/2014 Challenges: New requirements New timelines Transition period</b>	
	<i>Discussion</i>	
1:10 - 1:50 PM	<b>Clinical Trials Regulations in pediatric population in Bulgaria</b>	
	<i>Discussion</i>	
1:50 - 2:30 PM	<b>Current stage of the European MDR and IVDR implementation - Chances and challenges</b>	
	<i>Discussion</i>	
2:30 - 3:10 PM	<b>EU Pharmaceutical Strategy - Challenges for the Industry and Competent authorities</b>	
	<i>Discussion</i>	
3:10 - 3:30 PM	<b>Closing Remarks</b>	

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