



# Bulgarian Association for Drug Information (BADI)

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

PROGRAM MODULE 3 - 01.12.2023 | Regulatory - Update | Online event



**9.45 - 10.00**                      ***Open Registration***

**Topics / Welcome & Opening and Moderator / Prof. Nadka Boyadzhieva & Prof. Tatyana Benisheva, MU-Sofia, President of BADI**

### ***Session 1***

**10.00 - 10.30**                      ***Regulatory update - Digital application dataset - Integration (DADI) and Product life management system (PMS) - variations follow up;***

**10.30 - 11.15**                      ***Borderline products;***

**11.15 - 12.00**                      ***Medical Information and Medical Statistic;***

**12.00 - 12.45**                      ***Personalised Medicine;***

**12.45 – 13.30**                      ***Lunch break***

### ***Session 2***

**13.30 – 14.15**                      ***Noninterventional Clinical Studies;***

**14.15 – 15:00**                      ***Data Protection in ICSR info;***

**15.00 – 15:45**                      ***Food and Drug Interactions***

### ***Discussion***

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