

BADI Drug Regulatory Affairs Update 2026 – Module 1 (9 October 2026, online)

Short summary.

Module 1 had four presentations on pharmacovigilance, regulatory decision-making and artificial intelligence (AI).

Viola Macolic Sarinic (EMA) described the EU pharmacovigilance network and the role of PRAC. By the end of 2025, EudraVigilance held over 31 million ICSRs. Only about 3% of potential signals were validated for PRAC assessment. Bulgaria has only 23,894 reports in VigiBase, so more active reporting is needed, including by pharmacists. She stressed that risk minimisation measures must actually reach their audience. DARWIN EU and real-world data complement spontaneous reporting but do not replace PASS.

Galyna Cordero presented a 5-phase roadmap for AI-assisted audits, from risk-based planning and PSMF review to full ICSR review, signal detection audits and database migration checks. Risks such as hallucinations, bias and opaque models require validated systems, human review and competent auditors.

Dessislava Ilieva-Tonova (BDA) outlined the inspection process. CAPA responses are due within 30 days. Common deficiencies include delayed QPPV notifications, inadequate training, missing deputising procedures and PSMF inconsistencies.

Valentin Kopanarov separated tasks into three groups: full automation, AI assistance with human confirmation, and decisions that remain with the expert. He advised choosing tools based on the task, the evidence and independent validation.

Key message: AI can improve efficiency and quality, but accountability for decisions, patient safety and compliance stays with qualified professionals.