

THE CENTRAL EUROPEAN ROUND TABLE OF THE LEADERS OF DENTISTRY

Prague, 10. 10. 2025

From Data to Decisions: EHDS × AI Act for European Dentistry (2025–2027)

Short session abstract

In 2025, the European Health Data Space entered into force, setting rules for primary use (patient access/portability) and secondary use (research/AI), while the EU AI Act starts staged obligations for GPAI in 2025 and high-risk AI in 2026–27. Together with eIDAS2 Digital Identity Wallets, NIS2 cybersecurity, and EUDAMED device traceability, these measures define how dental records are managed, how AI tools are acquired and monitored, and how clinics demonstrate compliance. This session consolidates the patchwork into a practical playbook for chambers, covering topics such as consent and access under EHDS, when a dental AI becomes “high risk,” how to authenticate patients and staff, minimum security baselines, and how device UDI/EUDAMED data supports vigilance and recalls.

What we can discuss in the room

- Patient data flows: What each chamber recommends for EHDS “primary use” (patient access, portability) and secondary use approvals for research/AI.
- AI governance in clinics: When dental diagnostics/triage/planning tools fall under high-risk AI, what documents must a practice keep (risk log, dataset cards, human-oversight SOP)? Dates: prohibitions & AI-literacy since Feb 2, 2025; GPAI duties since Aug 2, 2025; most high-risk obligations by Aug 2, 2026–27 (depending on embedding in regulated devices).
- Should the chamber provide AI education for the dental team?
- Are there any practical applications of AI in your country?
- Identity & consent: Using eIDAS2 EU Digital Identity Wallets for strong patient/clinician authentication and e-consent flows. (Implementing regs rolling out 2024–25.)
- Cyber baseline: Map national rules to NIS2 so that chains/larger clinics are aware of incident-reporting and governance duties.
- Devices & vigilance: Preparing for broader EUDAMED use/mandates; align chamber guidance on UDI capture in practice software and recall workflows.

FDI – Assist. Prof. Nikolai Sharkov

CED – apology

ERO – Prof. Edoardo Cavallé

SKZL – MUDr. Igor Moravčík, MUDr. Patrícia Husárová, MUDr. Peter Kukolík

ÖZAK – Prof. DDr. Christof Ruda

BZĀK – apology

BDIZ EDI – Dr. Christian Berger

BLZK – Dr. Dr. Frank Wohl

LZKS – Dr. Hans Rainer Fischer

MOK – Dr. Mercedes Linninger

NIZ – Dr. Radosław Maksymowicz

HKDM – apology

MFE – apology