Špecializačné a certifikačné štúdium v klinickej farmakológii na Slovensku

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Prvá koncepcia lekárskeho odboru klinická farmakológia (KF) bola prijatá Ministerstvom zdravotníctva SSR v roku 1979. Prvé výučbové pracovisko odboru KF založili v roku 1983 akademik Teofil R. Niederland a doc. Jozef Holomáň ako Kabinet klinickej farmakológie Inštitútu pre ďalšie vzdelávanie lekárov a farmaceutov v Bratislave. Postupným dobudovaním a rozšírením tohto pracoviska, vrátane založenia klinického centra s celoštátnou pôsobnosťou – Kliniky farmakoterapie (fungovala v rokoch 1983–2004) postupne vznikol Ústav farmakológie a klinickej farmakológie (ÚFKF) (neskôr aj „experimentálnej farmakológie" – ÚFKEF) Lekárskej fakulty (LF) Slovenskej zdravotníckej univerzity v Bratislave (SZU) s akreditáciou špecializačného štúdia (ŠŠ) v KF a certifikačného štúdia (CŠ) v problematike klinického skúšania liekov (KSL) a vo farmakoekonomike (FEK). V roku 1993 bola KF na Slovensku uznaná ako nadstavbový lekársky špecializačný odbor a v roku 2004 ako samostatný lekársky špecializačný odbor. Od roku 2007 má lekár – klinický farmakológ uznané preskripčné oprávnenie v rozsahu internistu. Po nepriaznivých organizačných zmenách, vykonaných na prelome rokov 2018–2019, pôvodne akreditované pracovisko (ÚFKEF LF SZU) prakticky prestalo ŠŠ v KF a CŠ v KSL realizovať. Až v roku 2020 (k 1. 7.) sa podarilo obnoviť existenciu aj činnosť pôvodnej Katedry klinickej farmakológie (KKF) LF SZU, ktorá prevzala, spolu s inými úlohami, aj zabezpečenie spomínaných modalít ŠŠ a CŠ (v KSL a vo farmakoekonomike). V nasledujúcom období sa podarilo získať ich plnú reakreditáciu, úspešne anotovať i rozbehnúť jednotlivé vzdelávacie aktivity a obnoviť riadne zaraďovanie záujemcov do ŠŠ v KF i oboch modalít CŠ. Nedávne zriadenie predtým dlhodobo chýbajúceho, špecializovaného klinického pracoviska odboru – Kliniky klinickej farmakológie LF SZU a Fakultnej nemocnice s poliklinikou v Nových Zámkoch, ako riadnej výučbovej základne KKF LF SZU, znamená ďalšie skvalitnenie nevyhnutných podmienok a rozšírenie možností praktickej výučby ŠŠ v KF i CŠ v KSL a FEK na Slovensku.

COST ACTION 17112: DRUG-INDUCED LIVER INJURY (DILI)

Cost Action 17112 Prospective European Drug-Induced Liver Injury Network. Where do we stand?

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The main objective of the Cost Action CA 17112 Prospective European Drug-Induced Liver Injury Network, PRO EURO DILI NET is to create a unique, co-operative, interdisciplinary European-based DILI network of stakeholders to co-ordinate efforts in DILI, to facilitate bidirectional exchange of discovered knowledge and generated hypotheses among different disciplines, and to promote clinically impactful knowledge discovery and its translation into clinical practice. The kickoff meeting was back in October 2018.

During the first 3 years of activities the CA 17112 has successfully incorporated new member countries [from initial 16 (6 ITC, 37.5 %) to 28 (13 ITC, 46 %)] meaning not only academic groups but also new stakeholders (3 new SME). This has allowed to cover neglected areas as DILI in Pediatrics, and to reach out to the International Autoimmune Hepatitis Group (IAIHG) to agree upon areas of common interest in DILI and Autoimmune Hepatitis. Also, a collaboration with the European Liver Patient Association has been established in order to underline the relevance of a patient perspective in DILI. This will pave the way to an Info Day on DILI next GP. In collaboration with partner centers in Europe through the COST action activities an e-database has been setup (https://www.proeurodili.eu/) that now enables efficient, methodical collection of phenotypic data and coordination of monthly case adjudication sessions. Currently there are 68 users across 20 European centers (corresponding to 7 countries). This facilitates data and sample sharing and central biobanking for collaborative research projects.

In parallel, the CA 17112 has successfully made a partnership with an ongoing IMI European Project TransBioLine (Translational Safety Biomarker Pipeline, www.transbioline.com) for discovery, development, validation, regulatory qualification, and application of safety biomarkers, and bring about a fundamental change in the way drug hepatic safety is monitored in clinical trials, and toxicities are diagnosed and managed in clinical practice.

The other important scientific and educational activity has been developed with CIOMS (Council of International Organizations of Medical Sciences), which is under the umbrella of WHO-UNESCO (https://cioms.ch/working-groups/dili/) and produced an International White Consensus Paper on Drug-Induced Liver Injury (DILI): Current status and future directions for drug development and the post marketing setting. The Chair and Vice chair of this CA-17112 appointed by EASL (European Association for the Study of the Liver) have elaborated a Clinical Practice Guidelines on DILI for the translation of knowledge gained in DILI to improve decision making and clinical outcomes. Beyond better representation of organ level function and DILI prediction, organotypic human-based 2D-3D co-cultures offer enhancement of the discovery of cellular biomarkers – essential for detecting early signals of hepatotoxicity. Emerging areas in mechanistic DILI provide highly promising opportunities as potential biomarkers, such as circulating extracellular vesicles with specific proteome and liver microRNAs. Addressing the basic sciences in tandem with both clinical and parallel Pharma, SMEs and academic consortia perspectives provides much needed cohesion and synergy in the DILI field and impetus for a constructive way forward. A detailed beyond-state-of-art COST-DILI Action 'position paper' on preclinical human-based models for improved DILI prediction has been published in J Hepatol. This consensus review article is an important milestone for WG3. Owing to the complexity and low prevalence of DILI, performance of randomized clinical trials fawces multilayered challenges The first systematic review with meta-analysis of 22 randomized clinical trials in prevention and management of DILI illustrates the difficulties and methodological flaws of clinical research on DILI and underscore the