Таким чином, відсутність у дослідницькому центрі стандартизованого підходу до оцінки результатів лабораторного обстеження добровольців може поставити під сумнів якість проведення КД. З метою удосконалення оцінки лабораторних параметрів ми запропонували шкалу з визначення клінічної значущості відхилень найбільш використовуваних показників загального та біохімічного аналізів крові. Для кожного лабораторного показника пропонується допустиме відхилення від референтних значень, в межах якого дослідник самостійно приймає рішення щодо клінічної значущості виявленого відхилення.

**Висновки.** Запропонована шкала допоможе стандартизувати оцінку дослідниками результатів лабораторного обстеження здорових добровольців на етапі скринінгу та може бути використана для розробки дослідницькими центрами власних стандартних операційних процедур з оцінки критеріїв здоров'я добровольців. При цьому згідно з стандартною практикою при прийнятті рішення про клінічну значимість тих чи інших відхилень від референтних значень досліднику необхідно враховувати кількість відхилень та їх взаємопов'язаність у конкретного добровольця, наявність будь-яких клінічних проявів, необхідність додаткового обстеження чи лікування.

## SOME ASPECTS OF CLINICAL TRIAL PARTICIPANTS' INSURANCE IN UKRAINE AND EU: COMPARATIVE STUDY

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**Introduction.** Clinical trials (CT) are the only way for patients to get innovative treatment and further accessibility to all humanity to new, more effective, and safe drugs. Ethical aspects of the protection of CT participants' rights are at the forefront in the planning, organization, initiation, and conduct of any CT. The practical implementation of ethical standards and their legal consolidation is the first step for the necessary protection of CT participants. Exactly insurance provides fair compensation for the damage caused to CT participants, on the one hand, and protects the CT Sponsor from excessive financial losses, on the other hand.

The unified legal system that determines the CT participants' insurance is admitted in the EU (EU Directive 2001/20). However, a somewhat different approach to damage compensation implementation caused by participation in CT exists in some European countries. Such a difference in approaches to insurance complicates the organization and conduct of multicenter CTs in the EU for CT sponsors.

**Aim of the study.** To study the experience of Ukraine and the EU on the protection of the CT subjects' rights by compensating for damage caused by CTs, reimbursement procedure, and risk insurance in CTs; study the features of legislative regulation, their advantages, and disadvantages.

**Materials and methods.** Regulatory requirements' analysis for insurance of

CTs' participants, approach to the implementation of risk compensation in CTs in the EU and Ukraine.

**Results and discussion.** In the practice of Ukrainian insurance companies, a situation has developed when only the damage received by the CT subject as a result of an adverse reaction development was compensated. In the EU, all negative impacts associated with CT are compensated, including those that are foreseen or expected during the CT (provided that the negative consequences registered during the CT were not caused by the intentional actions of the CT subject). Using the comparative method, we have established the differences between European and national legislation in CT in matters of protecting the rights of CT subjects through insurance.

On November 18, 2021, the Verkhovna Rada of Ukraine adopted Law No. 5317 (dated March 29, 2021) «Pro strakhuvannia», which considers changes to the regulation in CT insurance, which were proposed by the Clinical Trials Subcommittee experts of the European Business Association. Due to these changes, Ukraine will fully transition to the European model of liability insurance in CT.

**Conclusions**. Differences between European and national legislation in CTs on the protection of CT subjects' rights were established using a comparative method. Focused attention to this topic will be able to objectify, structure, and unify approaches to CTs. This will improve the conduct of CTs in Ukraine, interest the CT subjects, and attract more international sponsors to CTs' conduct in Ukraine while guaranteeing maximum protection against risks for their participants.

## SAFETY-RELATED DRUG LABEL CHANGES FOLLOWING LARGE POST-MARKETING CARDIOMETABOLIC TRIALS

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**Introduction.** The knowledge of benefits and risks of new drugs is incomplete at the time of marketing authorisation. Additional clinical trials may be performed after authorisation, for example, to explore a drug's effects on new target populations, study its long-term effects, or validate surrogate outcome data. These trials are often large, lengthy in duration and, therefore, costly. Cost-effectiveness and feasibility of such trials may be improved by using simplified study protocols that collect only major clinical outcomes. One approach that has been discussed is selective safety data collection, where, for example, no collection of non-serious adverse events takes place. However, there is a concern that the selective collection of safety data may reduce the amount of safety knowledge that could be gathered from late-stage trials. The amount of new safety information which has been obtained from late-stage