QUALITY ASSURANCE DURING REALIZATION OF CLINICAL TRIALS IN THE CLINICAL AND DIAGNOSTICS CENTER OF THE NATIONAL UNIVERSITY OF PHARMACY

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Clinical and Diagnostic Center of the National University of Pharmacy (CDC of NUPh) is a medical and preventive establishment of higher accreditation category where clinical trials of Phase I-II and bioequivalence studies are conducted. During the realization of clinical trials quality assurance is provided at all stages.

Basic principle of clinical trial conducting is compliance to requirements of "Good Clinical Practice" (GCP). Confirmation that study is conducted in accordance with these rules must be expected results of quality assurance, but it is impossible to achieve it at once. Right from the start of clinical trial, from the moment of study protocol signing, from the moment of its submittion to Ethics Committee, Investigator is under an obligation to meet all requirements of International Conference on Harmonization of Good Clinical Practice (ICH GCP), Sponsor's and Ukrainian legislation requirements.

Specialist in quality is an important factor of quality assurance. His professional skills, proper qualification before the start of a clinical trial and ability to co-operate with the personnel of CDC of NUPh, quality of his official duties implementation are the most reliable in this process.

Let's focus on the key positions that require the hundred-per-cent monitoring during clinical trials conducting. Compliance with ethics principles is a basis of clinical trials therefore the forms of the informed consent must be strictly checked up (100%). Not only the fact of informed consent obtaining from patient, but also the accuracy of its obtaining and documenting of this procedure is examined.

The special attention is drawn to source documentation of patients who experienced adverse events or adverse reactions (AE/AR). Besides a verification of accuracy and completeness of AE/AR data, it is necessary to make sure that the corresponding information about the degree AE/AR severity, its relation to the investigational medicinal product (IMP) in source documentation, in a report and in the Case Report Form (CRF) is provided properly.

A key aspect of any clinical trial are the procedures of IMP handling which include the verification of the fact of IMP receipt, compliance with its storage terms, transmission of unused IMP to the Sponsor and many other aspects that also are the object of intent attention of assurance specialist in quality.

"There are no tufles in a clinical trial" is a thesis which is an axiom for the clinical research team of Clinical and Diagnostic Center of the National University of Pharmacy.