

# FEATURES AND MAIN REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN PATIENTS WITH BRONCHIAL ASTHMA IN UKRAINE

Y. I. Feschenko<sup>1</sup>, G. L. Gumeniuk<sup>1</sup>, D. V. Dobrianskyi<sup>2</sup>,  
S. S. Rasputnyak<sup>3</sup>, O. M. Rekalova<sup>1</sup>

<sup>1</sup>Yanovsky National Institute of Phthisiology and Pulmonology of National Academy of Medical Sciences of Ukraine, Kyiv, Ukraine

<sup>2</sup>Bogomolets National Medical University, Kyiv, Ukraine

<sup>3</sup>State Enterprise «State Expert Center of the Ministry of Health of Ukraine», Kyiv, Ukraine

**Abstract.** All clinical trials (CTs) are conducted in Ukraine in accordance with international ethical principles to ensure the protection of the rights, safety and well-being of subjects. CT is the only scientifically sound method for assessing the effectiveness and safety of new drugs. It is possible to increase the effectiveness of treatment of the most serious diseases in Ukraine due to the opportunity to participate in international CTs. This fully applies to one of the most important problems of clinical medicine — bronchial asthma (BA). BA is not sufficiently controlled in a significant proportion of patients, and in some patients, due to the severe course, there is a need for more intensive and effective treatment. BA is a chronic disease that requires long-term / continuous treatment, which causes a number of problems regarding the effectiveness, safety and cost of innovative treatments and motivates manufacturers to further developing both new drugs and modern delivery inhalation devices. *The aim of the study:* to present the main requirements for CTs in Ukraine, and to analyze the features of trials in patients with BA as well. *Materials and methods:* modern international requirements and legal and regulatory framework of Ukraine were used in writing the work. *Results and discussion.* Studies in patients with BA in recent years occupy a prominent place among pulmonary CTs; there are about 32 % of the total number of studies. The advisory-expert group (AEG) «Pulmonology. Tuberculosis. Drugs» received materials for a specialized examination of 105 CTs, 33 of which in patients with BA, for the period from 2015 to 2020. The number of pulmonary profile CTs significantly increased in 2019, and the number of new CTs in patients with BA significantly reduced in 2020 due to the COVID-19 pandemic. It should be noted that there was a tendency to increase the number of studies with complex design and CTs phase II in 2018-2019, which, in our opinion, indicates the recognition of Ukraine's research potential by the world community. *Conclusions.* The complexity of diagnosis and the peculiarities of testing of innovative drugs in patients with BA result in more stringent requirements for the venues of CTs and the qualification of trial staff. Ukraine has all the opportunities for a significant increase in pulmonary CTs due to the functioning of a large number of professional research centers with experienced staff and a significant number of motivated patients.

**Key words:** bronchial asthma, clinical trials, pulmonology, Advisory Expert Group, State Expert Center.

Y. I. Feschenko,  
Academician of NAMS of Ukrain, professor  
Director of SO «Yanovskii National Institute of phthisiology and pulmonology  
NAMS of Ukraine»  
M. Amosova str., 10, Kyiv, Ukraine, 03038,  
e-mail: admin@ifp.kiev.ua  
Asthma and Allergy, 2021, 1, P. 5–16.