A preclinical regulatory approach before clinical development and marketing authorization of medicinal products in the European Union

Caballero-Garrido •E#, Martin Blanco NM# and **Gracia Moneva B&**

Spanish Agency for Medicinal Products and Medical Devices (AEMPS), Spain

The non-clinical assessment first marketing approval of a pharmaceutical in the European Union mainly includes several tests developed in the International Council for Harmonisation (ICH) and European Medicines Agencies (EMA) guidelines. The recommendations in ICH guidelines further harmonise the non-clinical studies among the regions of the European Union (EU), Japan and the United States. These guidelines represent the consensus reached regarding the type and duration of non-clinical studies to support human clinical trials and marketing authorization for pharmaceutical products.

More specifically, in the EU, the rationale and requirements for animal testing in the development of medicinal products for human use are defined in Directive 2001/83/EC as amended. UE directive and EMA guidelines should be read in conjunction with ICH guidelines before applying for a clinical trial or marketing authorization in the EU.

The goals of the nonclinical studies generally include a characterization of toxic effects concerning target organs, dose dependence, relationship to exposure, and, when appropriate, potential reversibility. These data should help to define the estimated therapeutic dose, the maximum dose, and dose steps and intervals for clinical trials in humans.

The objectives of the non-clinical studies are to define pharmacological and toxicological effects not only before the initiation of human studies but throughout clinical development. The non-clinical studies recommended to support marketing authorization for pharmaceuticals are conducted all along the drug development process. It means that's the requirements that must be satisfied by the non-clinical studies before each of the clinical trial phases is different for each phase. The guideline ICH M3 (R2) delivers practical recommendations for timing or when to conduct which safety studies. We summarize the main non-clinical studies required by EMA before clinical development and marketing authorization in the European Union.

Biography

Caballero-Garrido E, is a distinguished researcher in biochemistry and animal behavior, he grew up in Madrid (Spain) and received his Bachelor's Degree in Biochemistry by the Universidad Autónoma de Madrid. He obtained his Master's Degree in Microbiology, but completed his doctorate in endondrinology (plasticity of the endocrine pancreas) in the University Miguel Hernández of Elche. Dr. Caballero-Garrido went to the US (to the University of New Mexico, department of neurosurgery) and began his research in the area of neurobiology on miRNA and cerebral microvasculature. Furthermore, he has developed several projects on animal behaviour. In parallel, Dr. Caballero-Garrido wrote various books about the history of science and developed projects of scientific outreach, both scientific programs of Radio and TV. Miguel Hernández University of Elche awarded Dr. Caballero-Garrido for his outreach projects. Currently he is working as a Non-clinical Assessor for the Spanish Agency of Medicines and Medical devices (Spanish Government)

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