USEFUL DEFINITIONS RELATED TO RESEARCH ETHICS

Scientific Research Ethics Commission (CECS): independent body, made up of members from the medical, scientific and non-medical fields whose responsibility is to ensure the protection of the rights, safety and comfort of the subjects involved in the study;

Human subject: Participant in a study for whom the rights, benefits and risks associated with inclusion have been explained, followed by the signing of an inclusion agreement in accordance with applicable legislative regulations.

Experimental animals: live non-human vertebrate animals, including self-feeding larval forms and mammalian fetal forms from the last third of their normal developmental stage; living cephalopods.

Clinical study: any investigation carried out on human subjects, to discover or confirm the clinical, pharmacokinetic/pharmacodynamic/pharmacotoxicological effects associated with their exposure within therapeutic interventions, carried out at an institutional level.

Protocol: document describing the objective(s), design, methodology, statistical aspects and organization of the study; the term "protocol" covers the protocol, its successive versions and its amendments.

Project: a work program with defined scientific objectives, which involves the use of one or more procedures.

Procedure (experimental): any use, invasive or non-invasive, of the animal for experimental or other scientific purposes, with known or unknown results or for educational purposes, which may cause the animal a certain level of pain, suffering, stress or lasting injury equivalent to or even stronger than that caused by the insertion of a needle, in accordance with good veterinary practice; any action aimed at or likely to result in the birth or hatching of an animal or the creation and maintenance of a line of genetically modified animals under any of these conditions is included, but the killing of animals for the sole purpose of using their organs or tissues is excluded.

Amendment to the protocol: - a written presentation of the amendment/amendments to the protocol or an official explanation thereof.

Opinion: - the affirmative decision of the Ethics Commission by which it confirms that the necessary documents have been analyzed and that the clinical study can be carried out in the proposed institution because there are appropriate conditions, the rules of good practice in the clinical study and the legal regulations in force are respected.

Investigator's brochure: set of clinical or non-clinical data on the drug or drugs for clinical investigation and which are relevant to the study of the effect of these drugs in humans.

Informed consent: the decision to participate in a clinical trial, which must be written, dated and signed, made voluntarily, after receiving all necessary information about the nature, significance, consequences and possible risks, such as and the necessary documentation, of a person capable of giving consent or, in the case of a person who is unable to do so, by his legal representative; if the person involved is not able to write, he can, in exceptional cases provided by national legislation, give his consent verbally in the presence of at least one witness.

The investigator: a doctor or a person practicing an approved profession in Romania in order to conduct clinical trials according to the legislation in force, based on the scientific knowledge and experience in the field of patient care that this requires; the investigator is responsible for the conduct of the clinical trial in a center, and if, in a center, the trial is conducted by a team, the investigator is the team leader and may be named the principal investigator.

Applicable legal regulations: any laws and regulations that relate to the conduct of clinical trials for the investigation of a medicine.

Clinical trial best practice: a standard by which the clinical trial is designed, conducted, conducted, monitored, audited, recorded, analyzed and reported, which guarantees both the credibility and correctness of the data and results reported, and the fact that the rights and integrity of the subjects as well as their confidentiality are protected.

Non-interventional study: the study in which the medicinal product or medicinal products are routinely prescribed in accordance with the terms of the marketing authorisation; the patient's use of a given therapeutic strategy is not fixed in advance by a study protocol, but

is subject to current practice, and the decision to prescribe the drug is clearly separated from that of including the patient in the study; no additional diagnostic or surveillance procedures should be applied to patients, and epidemiological methods are used to analyze the collected data.

Non-clinical study: biomedical study that is not conducted on human subject*s*.