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GOOD LABORATORY PRACTICE (GLP) PRINCIPLES IN RELATION TO ATMPS

Which principles of Good Laboratory Practice (GLP) need to be taken into account in relation to Advanced Therapy Medicinal Products (ATMPs)?

- It is generally expected that non-clinical safety studies are carried out in conformity with the principles of GLP. However, it is recognised that, due to the specific characteristics of ATMPs, it would not always be possible to conduct these studies in conformity with GLP. Exploratory pre-clinical studies, where safety information is obtained alongside with other information (e.g. in dose finding studies), are also not expected to be conducted under GLP.

- If a pivotal non-clinical safety study[1] has not been conducted in conformity with the GLP principles, a proper justification should be submitted. This justification should also address the potential impact of the non-compliance on the reliability of the safety data.

- When pivotal non-clinical safety studies are not conducted in compliance with GLP, detailed documentation of study conduct and archiving of data should be ensured. Additionally, the conduct of the study should be in accordance with a prospectively designed study protocol. A summary of deviations from the protocol and their potential impact on the outcome of the study should be included in the relevant study report. The sponsor of the non-clinical study should consider appointing a person responsible for the oversight of the conduct of the study and the study reports.

- Applicants who submit pivotal safety studies that are non-GLP compliant in the context of an application for a clinical trial or a marketing authorisation may be asked to submit additional data to justify the reliability of the studies or to permit a site visit to verify the conditions under which the study has been conducted.

[1] The term "pivotal non-clinical safety studies" refers to toxicity studies which support the non-clinical safety conclusions. Among others, the following are *not* considered non-clinical *safety* studies: basic research (primary and secondary pharmacology), proof of concept studies, dose response studies, analytical quality control testing for clinical and commercial studies, stability testing on commercial products and feasibility studies.