Document: TSC 01/2018 on GCP for ATMPs

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Contribution:

- We recommended the elaboration of the section "Packing, labelling and coding".

- "*Clinical trial design*" comments:

    - The choice of study population would take into consideration aspects related to the risk and benefits for the subjects. For population (both, men and women) that might be amenable to future pregnancy, sponsors should inform the patients whether exposure to the ATMPs would cause sensitization and potentially compromise the security to future pregnancy.

    - *(118-122) The use of placebo*. We consider that if the treatment implicates a complex surgical procedure and/or another highly invasive method, the use of placebo is not ethical.

- *"Application dossier"* comments:

    - *(155-166) Specific considerations concerning to the protocol. (ii) Dosing*. The evaluation of the viability of the cells is very important to establish the correct dose.

    - *(193-200) Specific considerations concerning to the protocol. (viii) Follow-up strategy of subjects*. The long-term follow-up of patients enrolled in ATMPs clinical trials is an important issue. A specific and dynamic follow-up strategy must be defined. In case of unexpected adverse reactions is reported, the evaluation of this adverse reaction should be introduced in the follow-up of the remaining patients.

    - *(351-360) Protection of clinical trials subjects. 8.1 Informed consent*. Due to the complexity of advanced therapies medicinal products it is important to develop a clear and comprehensible informed consent for the patients. To make sure that patients understand the intervention and the possible risks of the advanced therapies medicinal products is very important.