# Guideline on Non-clinical Evaluation of Vaccines for Human Use has been Published

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On 6 October 2020, Turkish Medicines and Medical Devices Agency ("**Agency**") has published "Guideline on Non-clinical Evaluation of Vaccines for Human Use" ("**Guideline**"). The Guideline aims to provide guidance on "non-clinical evaluation" of vaccine candidates for vaccine developers.

The Guideline clearly states that the requirements set out are valid for clinical researches to be conducted, and they do not cover all regulatory requirements for obtaining license.

According to the Guideline, the primary goal of non-clinical studies of a new vaccine candidate should be to demonstrate that the vaccine candidate is suitable and safe for test on humans. When conducting non-clinical studies, biosafety conditions should be provided when necessary and studies should be carried out in accordance with Good Laboratory Practice (GLP).

The Guideline also emphasizes that the scope of non-clinical studies for the relevant vaccine candidate depends on the type of vaccine. In this context, non-clinical studies with no previous clinical and non-clinical data are expected to be more comprehensive than vaccines previously licensed and used on humans.

Guideline states that in non-clinical studies, the World Health Organization, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use and the European Union related guides, guidebooks and Pharmacopoeias can be taken as reference.

It is especially noteworthy that the Guideline indicates exceptions to general practices in public health emergencies. These exceptions may have an impact on vaccine studies against the Covid-19 outbreak.

The main points stated in Guideline are as follows:

- Products used in clinical researches must be produced under Good Manufacturing Practices conditions.
- Stability is an indication that a vaccine stays within specifications for a specified time.
  If necessary, stability tests of midproducts in the production process of the vaccine used in the clinical trial should also be performed. In the case of a public health emergencies, stability data containing a shorter period of time may be accepted instead of real time stability data. Real-time stability tests must be completed until the clinical trial is completed.
- Toxicity studies should be sufficient to identify and characterize the potential toxic effects of the vaccine candidate to allow it to be concluded that it is reasonably safe to continue clinical research with the relevant vaccine candidate. A single dose toxicity study may not be conducted in public health emergencies and in case of repeated dose toxicity studies.
- For repeated dose toxicity studies, since these studies will be conducted under GLP conditions, it is not necessary to conduct single dose toxicity studies under GLP conditions.
- In public health emergencies, the first research phase on humans can be started with interim analysis results or unconfirmed results of repeated dose toxicity studies. In these cases, it is sufficient to present the results of studies with a single animal species.
- In public health emergencies, toxicity data for the relevant platform can be presented if previously known, well-characterized and validated platforms are used in the development of the vaccine candidate to move to initial research on humans.

- In public health emergencies, incomplete toxicity studies should be conducted simultaneously while initial human research is underway, and the completed results should be documented immediately when obtained. In any case, missing toxicity tests for the vaccine candidate must be completed prior to phase 2 and phase 3 trials involving a larger number of volunteers.

Please see this link for the full text of the Guideline. (only available in Turkish).

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