# VETERINARY CLINICAL TRIALS: EVALUATION OF CLINICAL STUDIES CORRESPONDING TO "GUMBOHATCH"

## INTRODUCTION & OBJECTIVES

Veterinary clinical trials are an important tool for the development of new drugs or treatments since it is the way to evaluate and determine if a new drug or treatment is safe and effective for the targeted species.

1 To do a systematic review of the legislation and the guidelines on Good Clinical Practices (GCP) and on clinical trials with immunological veterinary medicinal products that are used to elaborate the safety and efficacy studies in food producing animals

2 To analyze the Gumbohatch® EPAR with the aim to contrast the public information about the clinical trials made for this vaccine and to compare them to what is required in current regulations and guidelines.

## MATERIALS AND METHODS

- Regulation (EU) 2019/6.
- Delegated Regulation (UE) 2021/805.
- Real Decreto 1157/2021.
- Guideline on Good Clinical Practices.
- Guideline on clinical trials with immunological veterinary medicinal products.
- EPAR: Gumbohatch®.
- 3 WVPAC posters of 2019.

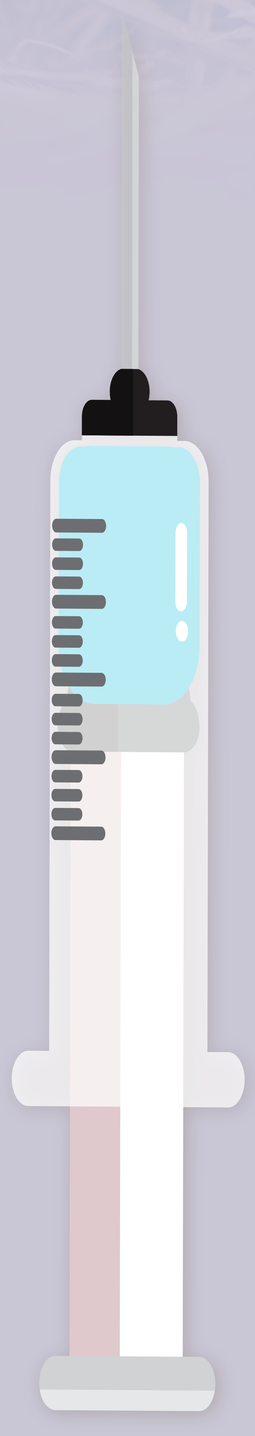
## RESULTS

Both on the EPAR, and the already mentioned studies, these clinical trials are described as multicentered, randomized, blinded and positive-controlled studies. In addition to that, it is mentioned that they have been done following the guidelines on GCP guide and therefore it is considered that the clinical trials made for Gumbohatch® are compliant with the standards that are required by the regulations.


## CONCLUSION

1 The bibliographic review of legislation and guides for the making of veterinary clinical trials have been performed and it has been proven that these have been increased in harmony and regulated. This eases the work performance for the clinical trials, from the point of view of the research to the point of view of the one in charge of the evaluation for the subsequent placement on the market or not of a new drug or therapeutic indication of a new drug that is already commercialized.

2 When analyzing the EPAR, it is considered that to evaluate specifically the clinical trials there is a deficiency, in terms of the information provided in the field study part, that makes the analysis difficult because of the general description with no specifications in relation with the number of animals, methodology to be followed, among others. In this case, the EPAR has been non very explicit.



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