Assessment Report

Part I

2025-521283-35-00

Date: 2025-03-27

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Assessment of initial clinical trial application

1. Administrative information

EU number	2025-521283-35-00
Title of the study	Vasopressin and Steroids in addition to Adrenaline in cardiac arrest -a randomized clinical trial
Name of sponsor(s)	Tiohundra AB

2. Background

This application is sent in as a “replacement” of the trial with EU number 2022-500137-89-00.

The original trial was expired in CTIS due to not having a start of recruitment entered in the system within two years of the approval. The trial did however start within the time limit, only the reporting to CTIS was missed.

The sponsor contacted the Swedish Medical Product Agency (MPA) regarding this situation. MPA contacted EMA through their helpdesk (case number RITM0182289, INC0107095) to discuss what could be done. It was decided that the sponsor needed to submit a new clinical trial that could be approved without assessment (since the trial was already assessed and approved under the original application).

This is the new application and contain the same documents and information as the original trial. No further assessment is needed.

Note that the original application was of a “transitional trial” which means that the clinical trial was already approved and ongoing under the national legislation based on Directive 2001/20/EC and the sponsor applied for the clinical trial to instead be governed under the rules set out in the Regulation (EU) 536/2014.

Handling of transitional trials is described in “*Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation*” that reflects agreements reached by CTAG.

For a transitional trial the sponsor should send in the same documents that have already been approved and no new documents or changes to the trial can be introduced during the transition. If a mandatory document under Regulation (EU) 536/2014 is not available, the sponsor should submit an empty document.

If a transitional trial application only contains the same documents and information that has already been approved under the directive, then it can be approved under the regulation.

3. Conclusion

The application is approvable.

4. Comments

The sponsor must update the application dossier in line with Regulation (EU) No 536/2014 in a Part I substantial modification application BEFORE any additional MSC is added to the trial. Information if any additional MSC(s) will be added in line with Article 14 of the regulation should be announced in the cover letter to the SM Part I application to allow the RMS to make a meaningful summary of the trial assessment accessible for the additional MSC. See *CTCG recommendations to sponsors on updating the application dossier Part I after CTR transition* and annex.