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Datum 16.09.2022

AZ KKS-243

2017-003688-37 – PASSION Trial recorded in EudraCT database as “prematurely ended” – Requested upload of document

Name and address of the sponsor:

Philipps-Universität Marburg

Name and address of the Sponsor's representative:

Coordinating Center for Clinical Trials of the Philipps-University of Marburg, KKS Marburg
Karl-von-Frisch-Straße 4, D-35043 Marburg

Name and address of the Coordinating Investigator:

Prof. Marius Hoeper
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Title and acronym of the clinical trial:

Phosphodiesterase-5 inhibition in patients with heart failure with preserved ejection fraction and combined post- and pre-capillary pulmonary hypertension (PASSION)

EudraCT-Number:

2017-003688-37

Sponsor's protocol code:

KKS-243

Vorlagennummer

4042795

End / discontinuation of the clinical trial

22.06.2022 (recall of IMP)
05.07.2022 (Notification premature end of the trial)

Reason for the premature end of the trial:

As a result of the recall, the supply of investigational medicinal products to patients can no longer be guaranteed.

Dear Sir or Madam,

As announced at June 22, 2022, we timely notified at 05. July 2022 the premature end of the study for the following trial:

Phosphodiesterase-5 inhibition in patients with heart failure with preserved ejection fraction and combined post- and pre-capillary pulmonary hypertension (PASSION)

The reasons for this are that, as a result of the manufacturer's batch recall of Tadalafil-neurax-pharm® Film-Coated Tablets, it can no longer be guaranteed that patients will continue to be adequately supplied with the investigational medicinal product.

None of the PASSION patients will receive any more study medication (IMP). All patients were informed about the return of the study medication (IMP). End of the study visits were conducted at the PASSION study sites, where patients returned the study medication.

The database is currently in cleaning process. We will inform about possible results according to regulations.

With kind regards,

i.V. Dr. Michael Wittenberg

Name in Druckbuchstaben Sponsor/Vertreter

16.09.2022

Datum

Unterschrift Sponsor/Vertreter