



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report for the RFI Application

2022-501587-17-00

RFI CT-2022-501587-17-00-IN-015

Requests for information

Type of request:

Formal

Due date:

31/08/2023

Evaluation process:

Assessment Part II

MSC:

Czechia

Reason for request of additional information:

None

MSC ID:

9733

Date submitted:

21/08/2023

Consideration number:

1

Application section parts

Part II - Czechia

Application section and document:

Subject information and informed consent form

Consideration:

Požadujeme, aby informaci o účasti ve studii podepsal i sledovaný pacient.

Assessment comments

Czechia 13/09/2023

accepted

Sponsor response:

Potvrzujeme, že Informaci o účasti ve studii podepisuje i sledovaný pacient.

Vzhledem k požadavkům na úpravu protokolu v části Part I a na ně navazující aktualizaci Informovaných souhlasů, si Vás dovoluujeme požádat o vložení nové připomínky pro Part II, v rámci které budou aktualizované Informované souhlasy předloženy k posouzení./We confirm that the monitored patient also signs the information about participation in the study.

Due to requirements for the protocol in Part I and the subsequent updates of the Informed Consents, we would like to ask you to insert a new comment for Part II, in which updated Inform Consents will be submitted for review.

Consideration number:

2

Application section parts

Part II - Czechia

Application section and document:

Proof of insurance

Consideration:

Žádáme o aktualizaci informací - Dodatek pojistné smlouvy.

Assessment comments

Czechia	13/09/2023
	accepted

Sponsor response:

Dodatek č. 1 k pojistné smlouvě byl nahrán do CTIS - Part II, jak bylo požadováno./Insurance statement amendment 1 has been uploaded in Part II in CTIS as requested.