

The following sections of the RFP are hereby revised:

SECTION J – LIST OF ATTACHMENTS

Attachment #9 – QUESTIONS & RESPONSES

[...]

5. The minimum mandatory eligibility criteria #3 requires: "documenting an active/in-effect investigational new drug (IND) submission to the U.S. FDA."

- a. Is "Documenting the submission of an IND to the US FDA" sufficient or does the IND has to be approved by the FDA at the time of our application?

Response: No, merely filing the IND to the FDA is not sufficient. The IND must be active/in-effect. That is, it must not be on clinical hold, or within the 30 day period of an original submission.

- b. Do "foreign (EU) clinical studies under an IND submitted to the US FDA" satisfy this criteria? or must the planned study be performed in the US?

Response: The IND must be active/in effect regardless of whether the study was conducted domestically (within the U.S.) or internationally.