U.S. EPA STAR Informational Webinar: Advancing Toxicokinetics for Efficient and Robust Chemical Applications

Questions and Answers

Q. Can you clarify the role of *in silico* methods?

A. *In silico* methods are welcome and encouraged provided they are not the sole focus of a submission for this solicitation. For instance, proposals that include the generation of *in vitro* data combined with the development of an *in silico* approach are strongly encouraged.

- Q. Would research with zebrafish, or other vertebrates, be acceptable?
- A. Any species that are commonly used in toxicological studies for chemical safety decision making would be acceptable, particularly if they lead to new *in vitro* and/or *in silico* approaches.
- Q. Would other *in vivo* work be acceptable?
- A. Responsive proposals should have a majority focus of in vitro and in silico methods.
- Q. Will in vivo studies (e.g., animal studies) to validate an in vitro assay be supported?
- A. The reuse of existing *in vivo* data to evaluate new *in vitro* methods is strongly endorsed. Regarding generation of new *in vivo* data, the submitter would need to balance the anticipated high costs that are involved in conducting such studies against the value of incorporating them into a submission. In an area with an unmet need (and therefore a potentially high impact proposal) the costs may be justified, but in others they may not be.
- Q. Will the peer review panel meet in person or will the review be conducted via phone or teleconference?
- A. We no longer do in person peer review panel meetings, they are now done remotely.
- Q. Can you comment on the applicability if PBPK modeling is proposed to be included?
- A. Unfortunately, the rules of fairness do not allow for responses to specific research efforts. Please refer to the "Specific Areas of Interest" section of the RFA.
- Q. Can you comment on the suitability of my research idea?
- A. Unfortunately, the rules of fairness do not allow for feedback on potential individual proposals. Please refer to the "Specific Areas of Interest" section of the RFA.
- Q. Does my research have to propose entirely new methods?
- A. Per the RFA, "Innovative research can take the form of wholly new applications or applications that build on existing knowledge and approaches for new uses."
- Q. Regarding the max 800K federal funding, does that include current support? A. No.
- Q. Is there a date for the EPA annual progress review? Is it different for different awardees?
- A. The dates and locations of the annual progress reviews will be decided on communally. Representatives from each project are required to attend, with EPA scientists and other personnel invited to attend.

- Q. Is the final workshop any different from the annual review? Or put it in another way, will there be 3 annual progress reviews and 1 workshop or 2 reviews and 1 workshop?
- A. There is no workshop, but there will be mandatory annual progress reviews, with the dates and locations decided on communally.
- Q. Do the Letters of Intent go into the narrative or as optional additional files in <u>grants.gov</u> submission? A. Please see the funding notice (https://www.epa.gov/sites/production/files/2019-07/documents/httk rfa 061719 ioaa edits ncer ddd data highlight mrh 5 1.pdf), Section IV.F.3.(f) (p. 35 of the online PDF of the RFA). EXCERPT:
- (f) Project Narrative Attachment Form (click on "Add Mandatory Project Narrative"): Attach a single electronic PDF file labeled "Application" that contains the items described in Section IV.C.5. through IV.C.11.a [Table of Contents, Abstract, Research Plan, Quality Assurance Statement, Human Subjects Research Statement, Scientific Data Management Plan, References, Budget Justification, Resumes, Current and Pending Support, and Letters of Intent/Support] of this solicitation.

[Emphasis added.]

All these items should be in one PDF attachment.

- Q. The RFA says that time needed from closing date to award could be 9-12 months. Is there an earliest start date?
- A. There is no "wrong" answer to this question. A starting date of around July 2020 would be appropriate, but it is more important that the project duration is no more than three years.