

Research Area 002- “Therapeutic Candidates” - Technical Proposal Readiness Checklists

The following Technical Proposal Readiness Checklist is to aid Offerors in determining if the Technical Proposal meets the requirements and exclusions of Research Area 002-“Therapeutic Candidates” (RA002). It is not a comprehensive checklist of all proposal requirements of the solicitation. If any statement below is not true for the technical proposal, the proposal may be missing required data for RA002 or may contain an exclusion for RA002. The Offeror is encouraged to review the Technical Proposal for completeness and compliance with all requirements and exclusions before submission.

Checklist 1: Applies to RA002 requirements only and does not include general requirements of the solicitation.

- ☐ Basic research is not proposed.
- ☐ Complete structures and compositions of the lead product and all variants for which data are provided are disclosed.
- ☐ The product or a prodrug or salt form has never been in a Phase 3 clinical trial and/or part of a human or veterinary product for any indication in any jurisdiction worldwide.
- ☐ The product is not a topical antiseptic.
- ☐ The product is not derived from serum.
- ☐ The product does not require device development.
- ☐ The proposal does not include work involving Human Fetal Tissue.
- ☐ In vitro potency data consistent with the Target Product Profile (TPP) is provided in the technical proposal.
- ☐ In vitro Absorption, Distribution, Metabolism, Excretion, and Toxicity (ADMET) data consistent with the TPP is provided in the technical proposal.
- ☐ In vivo efficacy data consistent with the TPP and demonstrating “Therapeutic” efficacy is provided in the technical proposal.
- ☐ In vivo pharmacokinetics (PK) data consistent with the TPP is provided in the technical proposal.
- ☐ In vivo toxicology data consistent with the TPP is provided in the technical proposal.