

CREATE Bio Review

Birgit Neuhuber, PhD
Scientific Review Officer
NINDS

CREATE Bio Review

What are reviewers looking for?

- Is the project worth doing?
- Are the applicants ready to go?
- Will the proposed work be done well?
- Will the project achieve the desired end goal?

Is the project worth doing?

- Are the rationale and supporting data strong?
 - Does the choice of target and therapeutic make sense with regard to disease and the proposed target product profile (TPP)?
 - [Examples for TPP](#)
 - http://www.ninds.nih.gov/funding/areas/translational_research/CREATE-Bio-Example-TPP.htm
 - Is the proposed therapeutic likely to have clinical impact in the context of existing therapies?
 - Does the proposal rest on a solid foundation of rigorously obtained supporting data?
 - [NINDS rigor guidelines](#)
 - http://www.ninds.nih.gov/funding/transparency_in_reporting_guidance.pdf

Are applicants ready to go?

- Are all the entry criteria fulfilled?
 - CREATE Discovery (U01)
 - Clear and convincing demonstration of proof-of-concept
 - One or more sufficiently profiled therapeutic leads
 - Suitable in vitro and in vivo assays
 - CREATE Development (UH2/UH3)
 - Fully characterized agent (e.g., structure/identity, selectivity, stability, manufacturability)
 - Knowledge of minimal effective dose, optimal effective dose, time and duration of treatment
 - Feasibility for reproducible production

[Comparison of CREATE Bio Discovery and Development Entry Criteria](http://www.ninds.nih.gov/funding/areas/translational_research/CREATE_Bio_Comparison_Table.htm)

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Will proposed work be done well?

- Is the approach rigorously designed?
 - Are proposed controls appropriate?
 - Are appropriate statistical analyses proposed (e.g., power analyses and associated assumptions for sample size estimation, and rules of inclusion and exclusion of data)?
 - Are proposed assays, models and endpoints relevant and consistent with the proposed TPP?

[NINDS rigor guidelines](#)

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Will proposed work be done well?

- Are adequate Milestones in place?
 - Are the proposed milestones quantifiable, robust, and with sufficient detail to allow go/no decisions?
 - Are all key milestones proposed or are important milestones missing or need to be modified?

[Design of and Examples for Well-Designed Milestones](http://www.ninds.nih.gov/funding/areas/translational_research/CREATE-Bio-Example-Milestone.htm)

http://www.ninds.nih.gov/funding/areas/translational_research/CREATE-Bio-Example-Milestone.htm

Will proposed work be done well?

- Has a multidisciplinary team been assembled?
 - Are all required areas of expertise (e.g., preclinical scientist, clinician, statistician, CMC experts, etc.) covered?

Will the project achieve the desired end goal?

– CREATE Discovery (U01)

- Well-characterized candidate with known minimal effective and optimal effective dose, PK-PD relationship, known time and duration of treatment, and evidence of feasibility for production
- Ready for entry to UH2/UH3 development phase

– CREATE Development (UH2/UH3)

- IND submission or early clinical trial

Will the project achieve the desired end goal?

- Are there any road blocks?
 - Are relevant letters of support included?
 - Are critical aspects regarding Intellectual Property (IP) addressed?
 - e.g., landscape surrounding the therapy, freedom to operate, IP strategy, etc.
 - Review Consideration
 - **NOTE:** Lack of information in the IP section can negatively affect the evaluation of feasibility

Contact information

- CREATE Scientific Review
 - Birgit Neuhuber neuhuber@ninds.nih.gov
- CREATE Program
 - Hao Wang wangh16@ninds.nih.gov