

License Application Guidance Checklist for Start-Up 3.0 Exclusive License

This checklist is intended to provide guidance to companies when completing a License Application for a Start-Up Exclusive License. This checklist does not modify and/or replace any of the components of the License Application. Start-Up applicants are encouraged to use this checklist as a supplementary aid, and applicants should direct any questions or comments to an NCI TTC representative.

Part 1. Tell Us Who You Are

see Start-Up 3.0 License Application at sections III, V (1)-(4), VI, and VIII

Address the Eligibility questions and describe the Company, including:

- ☐ Relevant Company history, which may include:
 - prior related product development and/or commercialization history
 - prior NIH licenses granted to the Company
- ☐ Executive Management Team, with specific descriptions of capability in the technology development and/or commercialization space
- ☐ Key Personnel with specific descriptions of capability in relevant technical and/or business experience in product development
- ☐ Physical facilities available to the Company (indicate if virtual)

Part 2. What does the Company plan to do during the initial evaluation phase (first two years)?

see Start-Up 3.0 License Application at section VIII

Propose a “Commercial Evaluation Plan” describing the Company’s intended activities for the first two years* under the Start-Up License, which includes:

- ☐ Description of the market opportunity and/or health problem the Company intends to address and how NCI’s technology will be integrated into the Company’s proposed solution
- ☐ Performance Benchmarks that NCI may use to evaluate the Company’s diligence in executing the proposed Commercial Evaluation Plan. Include deadlines for initiation and completion of each Benchmark
- ☐ Further divide each Benchmark into discrete milestones when appropriate, and include:
 - deadlines when the Company intends to initiate and complete each milestone

- describe how the Company intends to reach each milestone (e.g., lead identification studies, proof of concept studies, fundraising, etc.)
- provide back-up plans, if any, in the event of failure of a milestone

☐ If the requested Field of Use encompasses more than one indication or more than one Licensed Product, describe the Company's intended activities for each indication and/or each Licensed Product

☐ If the Commercial Evaluation Plan does not include development of certain aspects of the requested NCI technology, please provide an explanation for such omission

☐ Propose metrics by which NCI may assess the Company's progress in executing each Benchmark in the Commercial Evaluation Plan. These may be used to evaluate diligent performance as disclosed in required annual reports.

Part 3. Propose a Field of Use and Territories for the Start-Up License that is commensurate with the Commercial Evaluation Plan

see Start-Up 3.0 License Application at section IV

☐ Propose a Field of Use for the Start-Up License that is commensurate in scope with the Company's proposed Commercial Evaluation Plan

☐ Provide a list of all patents and/or patent applications being sought for the Start-Up License, including the corresponding country of origin for each patent and patent application

☐ Propose a list of countries ("Territories") for the Start-Up License that is commensurate in scope with the Company's proposed Commercial Evaluation Plan

Part 4. Who will execute the proposed Commercial Evaluation Plan?

see Start-Up 3.0 License Application at sections V (1)-(4) and VIII

☐ Identify and describe employees, Key Personnel, consultant(s), and/or contract service companies who will be performing each milestone and/or Benchmark, including:

- proposed number of FTEs and their relevant experience in the technology and/or development described in a milestone and/or Benchmark
- description of the Company's infrastructure (research space/incubator space) to be utilized in performing a milestone and/or Benchmark (indicate if virtual)
- description of the consultant(s) and/or contract service companies to be retained, and their relevant experience in performing a milestone and/or Benchmark

- Statement(s) of Work (or equivalent documentation) provided by consultant(s) and/or contract service companies to be retained to perform a milestone and/or Benchmark
- prior working history, if any, between the Company and the consultant(s) and/or contract service companies to be retained

☐ Identify and describe Key Personnel who will be responsible for managing and overseeing the completion of each milestone and/or Benchmark

☐ Describe any current and/or planned collaborations or partnerships necessary to perform a milestone and/or Benchmark

Part 5. How will the Company pay for execution of the proposed Commercial Evaluation Plan?

see Start-Up 3.0 License Application at sections III, V (5), and VIII

Describe the Company's financial capabilities to successfully execute all proposed milestones and Benchmarks during the two-year evaluation phase* of the Start-Up License, including:

☐ Provide estimated cost to complete each milestone within each Benchmark

☐ Describe financial resources that currently are available or will be immediately available at the onset of the Start-Up License to complete near-term milestones provided in the Commercial Evaluation Plan (e.g., balance statements of cash on hand, credit lines on hand, stocks and/or other liquid assets)

☐ Describe potential financial resources that are contingent upon a triggering or conditional event during the two-year evaluation phase of the Start-Up License, including:

- intended fund raising activities by the Company and/or its representatives (included projected dates, to whom, description of activity)
- description of the verifiable source of potential funding (e.g., copy of letter of intent and/or term sheet provided by accredited investors and/or equity/debt capital firms)
- estimated amount projected to be received by the Company
- provide estimated date upon which Company expects to receive the projected funds or description of the trigger or condition upon which projected funding is contingent upon

☐ For both funds on hand and for contingent funds to be received, provide statement of intent by the Company to commit funds in an amount sufficient to complete every milestone in every Benchmark provided in the proposed Commercial Evaluation Plan

* Please note that a Term Extension Amendment is anticipated prior to the commencement of the commercialization phase of the Start-Up Exclusive License. Please work with an NCI TTC representative to submit the necessary documents (e.g. a "Commercial Development Plan") and to initiate the Term Extension Amendment process in a timely manner.