

License Application Guidance Checklist for Start-Up Exclusive Evaluation License

This checklist is intended to provide guidance to companies when completing a License Application for a Start-Up Exclusive Evaluation 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 a NCI-TTC representative.

Part 1. Tell Us Who You Are

see License Application at sections V (1)-(4), VI, and VIII

Describe the Company, including:

- Company History, especially
 - 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 (indicate if virtual)

Part 2. Describe the problem you are trying to solve

see License Application at sections IX, XI(1)

Describe the market opportunity the Company intends to address, including:

- Describe how current products are not sufficiently addressing the problem, including:
 - competitive landscape (*i.e.*, which companies are also addressing this problem)
 - alternative approaches being investigated to address the problem
 - key differentiators between your solution and existing solutions addressing the same problem
- Quantify the significance of the problem in the market, including:
 - Patient need (*e.g.*, size and geographical location of major markets, projected market growth); include segmentation of patient populations likely to be targeted via the licensed technology
 - relevance of problem to a public health need
 - relevance of problem to a market need

Part 3. Describe the solution you intend to evaluate

see *License Application at sections IX, X, and XI(3)-(4)*

Describe the Company's proposed solution to the problem, including:

- Describe specifically how NCI's technology will be integrated into your solution
- Describe which aspects of your solution, if any, is proprietary to the Company or a third party
- Describe progress that has been made towards advancing your solution, including:
 - relevant research and/or development studies conducted by the Company
 - preliminary data, or other evidence, that validates use of NCI's technology in your proposed solution
- Describe the features that differentiate your proposed solution versus solutions provided by competitors

Part 4. What does the Company plan to do during this two-year evaluation license?

see *License Application at sections VII(2), VIII*

Propose a Commercial Evaluation Plan describing the Company's intended activities for the two years under the Evaluation License, which includes:

- 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, fund-raising, 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
- When reviewing the Company's annual reports at the end of the first and second year of the license, propose metrics by which NCI can use to assess the Company's progress in executing each Benchmark in the Commercial Evaluation Plan

Part 5. Propose a Field of Use and Territories for the Evaluation License that is Commensurate with the Commercial Evaluation Plan

see *License Application at sections IV, VII (4), and X*

- Propose a Field of Use for the Evaluation 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 Evaluation License, including the corresponding country of origin for each patent and patent application
- Propose a list of countries ("Territories") for the Evaluation License that is commensurate in scope with the Company's proposed Commercial Evaluation Plan

Part 6. Who will execute the proposed Commercial Evaluation Plan?

see *License Application at sections VIII, X*

- 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 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(a) 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 7. How will the Company pay for execution of the proposed Commercial Evaluation Plan?

see *License Application at sections V (6), VIII, and X*

Describe the Company's financial capabilities to successfully execute all proposed milestones and Benchmarks during the two year term of the Evaluation 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 Evaluation 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 term of the Evaluation 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; and
 - 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