Technical Feasibility Assessments Completion Checklist

Purpose

TIA recognises the confidential nature of the technical feasibility assessments, so we do not require a detailed description of the discussions or advice. However, to track the outcomes of this scheme, the Applicant and Provider are required to, together, complete the following checklist. Completion of this checklist triggers payment to the Provider. Information you are able to disclose in this checklist will assist TIA in understanding future research infrastructure needs. There is no requirement to have discussed all items in this checklist, as some will be more relevant than others, depending on the stage of the project. We suggest a maximum of 4 pages when completing this checklist.

**Project Title**:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | Already well developed | Provided advice in report | Discussed, not in the report | Not discussed | Summary of advice in the report (non-confidential) |
| Product Development | What is the mechanism of action? |  |  |  |  |  |
| Which components exert therapeutic effect? |  |  |  |  |  |
| How do you characterise the product? |  |  |  |  |  |
| What are the likely non-specific effects? |  |  |  |  |  |
| What impurities/contaminants are acceptable/not acceptable? |  |  |  |  |  |
| What materials are required? |  |  |  |  |  |
| Tech Transfer | Is there a reproducible method for making the product in the lab that can be transferred (and scaled) to a GMP facility? |  |  |  |  |  |
| How long or complex is the manufacturing process? |  |  |  |  |  |
| Can it be optimised? |  |  |  |  |  |
| How do you measure product quality? |  |  |  |  |  |
| Are the materials suitable for use in humans? |  |  |  |  |  |
| Process Development | What are the parameters for successful manufacture? |  |  |  |  |  |
| What is the shelf life of the product? |  |  |  |  |  |
| Are you able to make sufficient material for meaningful dosing of patients? |  |  |  |  |  |
| How is the product administered to patients? |  |  |  |  |  |
| Regulatory pathway | Do you need an OGTR application? |  |  |  |  |  |
| Are you applying for a CTN or CTA for your trial |  |  |  |  |  |
| Have you engaged with the TGA? |  |  |  |  |  |
| Are all materials GMP grade? |  |  |  |  |  |
| Clinical Trial Design | Do you have an appropriate QMS? |  |  |  |  |  |
| Who are the treating clinicians? |  |  |  |  |  |
| Who will run the trial? |  |  |  |  |  |
| Are you using a clinical research organisation? |  |  |  |  |  |
| How many patients will be treated? |  |  |  |  |  |
| Other | Any additional discussions or advice |  |  |  |  |  |

Full Name of Applicant:

Applicant Affiliation:

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Technical Feasibility Assessment Report Lead Author:

Provider Facility:

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_