STDR
Singapore Therapeutics Development Review

ANNEX B

EVALUATION CRITERIA FOR STDR PRE-PILOT (STREAM 1 & 2) AND PILOT STAGES

1. Evaluation Criteria for STDR Pre-Pilot Stream 1 (Target Validation)

S/N	Summary of Criteria
1	**Target Biology and Rationale**
1.1	**Characterization of target/pathway in the physiological/disease process**
	a. Does the body of evidence provided in the proposal substantiate the target's role in the selected disease? For example (non-exhaustive): a. Association of genetic modification, mRNA levels or protein expression with the disease. b. Correlation between disease progression/severity and target expression. c. Exclusion of the influence of confounding factors. d. Observation of similar phenotype with knockout/knockdown and pharmacological modulation, e.g., with a tool molecule e. Use of relevant or human/patient-derived tissue/models in studies f. Accurate interpretation of the results (causation vs. correlation) b. Are the *in vitro / in vivo* models used adequate? c. Are the results consistent with other sources? If there were contrary reports by others, did the proposal address this?
1.2	**Models and Tools (Availability and quality of models and tools for pharmacological evaluation of target)**
	a. Do the *in vitro* and *in vivo* models available for the indication of choice have a predictive value? b. Are there pharmacological tools available for target validation (a tool compound can be a small molecule, antibody or other molecular probe and should be a potent, selective modulator that perturbs the biological target in a dose-dependent manner)?
2	**Safety**
	a. Could perturbation of the target lead to toxicity? b. Does the proposal consider the target's expression across tissue types, between normal and diseased cells/tissues, and its normal physiological role, etc.? c. If safety risks have been identified, can they be mitigated?

3	**Unmet Medical Need**
3.1	**Is there a need for a new treatment to be developed to address this disease?**
	a. Does the proposal establish the clinical and epidemiological burden of the disease (incidence/prevalence, morbidity, mortality, quality-of-life impact)? b. Is the current standard-of-care (SoC) landscape accurately described, including approved therapies and their limitations in efficacy, safety, tolerability, durability, or accessibility? c. Is the unmet need defined for a specific, well-characterised patient population (e.g. relapsed/refractory, biomarker-defined, or underserved segment) rather than asserted in general terms? d. Where existing therapies are available, does the proposal substantiate why they are inadequate for the target population (e.g. resistance, intolerance, lack of response, no curative option)? e. Is the claim of unmet need supported by external evidence (guidelines, registries, literature) rather than the applicant's assertion alone?
3.2	**How differentiated would the proposed therapeutic be versus the competition?**
	a. Are there therapies already on the market or under clinical development for the proposed indication? b. Does the proposed approach have the potential to be differentiated from existing therapy or therapy under development? (e.g., better safety and/or efficacy, optimized compliance, specific patient segments can be addressed effectively, etc.)
4	**Originality of the Approach**
4.1	**Novelty of the target**
	a. Has the target been pursued before for this indication? b. Have others tried to work on this or a similar target but for a different indication? c. Has the target been clinically validated before? Are there other comparable therapeutics in pre-clinical stage or early clinical development that have not yet reached clinical proof of concept? d. Has the target been clinically validated in the same indication? Are there drugs against the same target and for this indication available in the market?
5	**Repurposing Projects (if applicable)**
	a. Is there substantial evidence, including experimental proof of mechanistic effects of the use of the repurposed drug in the new indication? b. Are the side effects from the use of this drug acceptable? c. Is there potential for the new use to be patented and exploited?

2. Evaluation Criteria for STDR Pre-Pilot Stream 2 (Platform Development)

S/N	Summary of Criteria
1	**Fit to Therapeutic Platform Definition**
1.1	**Does the proposed therapeutic asset-generation engine have clear platform architecture, modularity, and pipeline potential?**
	A therapeutic platform is a reusable discovery, design, engineering, or development system that enables the generation of multiple distinct therapeutic product candidates from a proprietary underlying technology, modality, workflow, or biological principle. The platform should have a credible path to producing a pipeline of therapeutic assets across different targets, indications, mechanisms, patient populations, or therapeutic constructs. Technologies whose primary output is a research tool, assay, model, dataset, diagnostic, delivery method, or manufacturing process will not be considered therapeutic platforms unless they are directly integrated with a repeatable process for generating therapeutic candidates.
2	**Scientific and Technical Strength**
	Does the proposal's scientific and technical package provide evidence for the platform's feasibility? Does it include relevant preliminary data with appropriate comparators and assays/models, a technically feasible workflow and identification of key technical risks with credible mitigation plans?
3	**Therapeutic Relevance, First Target Rationale and Development Path**
3.1	**Does the proposal have a relevant target and development rationale?**
	a. Is the first asset and target choice therapeutically compelling and strategically chosen to exemplify how the platform may tackle current treatment bottlenecks or specific biology? b. Is this supported by biology/translational evidence, and is it linked to follow-on strategy?
4	**Scalability, Repeatability and Differentiation**
4.1	**Is the platform scalable and differentiated?**
	a. Does the platform have repeatable and modular workflows to allow it to scale across assets? Are input and output criteria defined? b. Is the platform likely to be superior against its benchmarks, and is there potential for expansion?
5	**Commercialisation Potential**
5.1	**Does the proposal have a compelling platform-to-product commercial thesis?**
	Does the proposal outline a clear unmet need, defensible differentiation, an attractive initial indication and a credible path to IP?
6	**Team Capability and Execution Plan**
	Does the team have an execution plan with clear roles for team members, decision gates, risk mitigation and budget alignment?

3. Evaluation Criteria for STDR Pilot

S/N	Summary of Criteria
1	**Research and Scientific Merit of Technology**
1.1	**Current Scientific Understanding of Target and Platform Validation**
	a. Evidence to support the proposed target as a driver of disease b. Evidence to substantiate proposed mechanism of action (MOA) of disease treatment c. **For platforms:** Evidence to support the platform and what is the breadth of applications
1.2	**Quality of Research Conducted to Date**
	a. Stage of development of the technology; and the corresponding development, reasoning, and appropriateness of the concepts and methodology
1.3	**Potential as Platform Technology [For platform projects]**
	a. Potential to be developed as a platform technology for multiple products or indications b. Opportunity matrix of possible therapies that can be developed using this platform
2	**Scientific and Technical Strength**
2.1	**Unmet Medical Need and Current Market Size**
	a. Prevalence of the indication b. Size of the potential target population c. Potential of the technology to deliver on the unmet medical need d. For platforms: Spectrum of possible indications and size of the first target indication
2.2	**Research Differentiation**
	a. Existence of directly competing technologies in development, or groups known to be working on similar technologies or the same targets b. Stage of development of the competing groups vis-à-vis the proposed research c. Medical expertise in team, either through experience or collaboration
2.3	**Competitive Landscape**
	a. Amount of commercial competition in the target indication, including other treatment approaches (e.g. surgery or devices) b. Existence of therapeutics being developed for the target in the same or different indications c. Clarity on the benefits over current standard of care
3	**Development Plans**
3.1	**Research Plan Feasibility**
	a. Realistic deliverables with respect to the timeframe and proposed budget

	b. Realistic and quality research plan with a clear roadmap c. Presence of any significant barriers to achieving stated goals d. Sufficient budget, expertise and access to research infrastructure or resources e. Clear identification of go/no-go criteria
4	**Commercialisation and Intellectual Property (IP)**
4.1	**Commercial Viability**
	a. Ability of proposed deliverables to position the project for the next funding stage or be attractive to commercial partners b. Amount of additional development and/or budget outlay to support future development c. Time taken for technology to be ready for pre-Investigational New Drug (IND) activities and/or clinical development d. Challenges in terms of scaling-up, manufacturing and deployment/clinical adoption of the asset or platform technology
4.2	**Intellectual Property**
	a. How crowded the patent landscape is b. Potential to generate foreground IP c. Potential issues with freedom-to-operate
4.3	**Strategic Partnerships for Future Development**
	a. Identification or engagement of strategic partners b. Potential for development of technologies with partners c. Development plan to secure venture capital funds d. Strategy for licensing