STDR
Singapore Therapeutics Development Review

ANNEX B

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

A) Evaluation Criteria for STDR Pre-Pilot Stream 1

S/N	Summary of Criteria
1	**Target Biology**
1.1	• Is the target biology and its role in normal functioning well understood? • Is the target selectively or ubiquitously expressed? • What is the knock-out phenotype?
2	**Target's Role in Disease**
2.1	Is the rationale for the target's role in the disease of choice substantiated? For example (non-exhaustive): • Association of genetic modification, mRNA levels or protein expression with the disease. • Correlation between disease progression/severity and target expression. • Exclusion of the influence of cofounding factors. • Observation of similar phenotype with knockout/knockdown and pharmacological modulation eg with a tool molecule • Use of relevant or human/patient-derived tissue/models in studies Based on data submitted as evidence of the target's role in the disease: • Are the data sets submitted internally consistent and robust (have replicates been performed, statistical significance analysed, varied experimental conditions used?) • Are there any contrary results or reports published by others and if yes, were this addressed in the proposal?
2.2	Have any safety issues related to modulating the target been detected? eg. Can any identified safety risk be mitigated?
3	**Unmet Medical Need**
3.1	• Is there established and effective standard of care for this disease? If yes, does a clinical problem still exist? • Would developing a therapy that modulates this target address any unmet need? What is the differentiator/advantage that will be brought by the current approach compared to the standard of care (safety, compliance, cost, efficacy, specific population, etc.) • Is this disease more prevalent, or does it have a different phenotype, in Asian populations?
4	**Feasibility**
4.1	• Are tool compounds, antibodies, or other molecular probes available for further validation studies? • Is there a suitable therapeutic modality for modulating this target, based on its target class and cellular location? If not, how feasible is the identification of a modulator (antigen expression, enzyme expression, etc.)? • Can the target be assayed using biochemical or cell-based assays? Is the assay amenable to high throughput formats? • Are there in vitro and in vivo models available for this disease? Is the target functional in the available preclinical species?

	• Have target engagement assays been done, and/or have downstream markers of target engagement been identified?
5	**Research Plans**
5.1	• How much time and funding will these experiments require? • Is the research plan designed so that progress is made towards in vivo validation of the target?
6	**Competition and Novelty**
6.1	Is the target already pursued by others in the proposed indication, or in other indications? If there are such direct competitors, what is the development stage of the competitor's programme?
6.2	How much competition is there altogether in the proposed indication (take into account all treatment options used e.g., surgery, diet changes, devices)?
7	**Drug Repurposing (where applicable)**
7.1	Is there substantial evidence provided for the use of the FDA approved drug? Does the drug candidate act on the same target, or on a new target? Are the known side effects of the drug acceptable in the proposed new indication?
7.2	Does the repurposed use of the drug (e.g., in a new indication) have the potential to be patented and exploited or otherwise protected?

B) <u>STDR Pre-Pilot Stream 2 Evaluation Criteria</u>

S/N	Summary of Criteria
1	**Technical merits**
1.1	• Degree of innovation/creativity • Stage of development • Credibility of the underlying platform with some supporting data • Patentability/right to use
2	**Market Needs**
2.1	• Could the platform disrupt many impactful market segments • Advantages over competition and/or standard of care • Can a feasible commercial strategy be developed with the pre-pilot funding
3	**Credibility of Team**
3.1	• Does the team understand the desired commercial outcome of the STDR grant • Are they passionate to advance their platform • What are the skills available in the team to drive platform development • Is a dedicated and committed Fellow, Graduate student, or Researcher involved
4	**Pathway**
4.1	• Can the team articulate a clear development pathway and have the applicants presented a sound methodology leading to commercialization • If milestones are achieved can substantial venture capital money be secured

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C) Evaluation Criteria for STDR Pilot Stage

S/N	Criteria
1	**Research and Scientific Merit of technology**
1.1	**Current Scientific Understanding of Target and Platform Validation** • Evidence to support the proposed target as a driver of disease • Evidence to substantiate proposed mechanism of action (MOA) of disease treatment • For platforms: Evidence to support the platform and what is the breadth of applications
1.2	**Quality of Research Conducted to Date** • 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]** • Potential to be developed as a platform technology for multiple products or indications • Opportunity matrix of possible therapies that can be developed using this platform
2	**Medical Need and Market Evaluation**
2.1	**Unmet Medical Need and Current Market Size** • Prevalence of the indication • Size of the potential target population • Potential of the technology to deliver on the unmet medical need • For platforms: Spectrum of possible indications and size of the first target indication
2.2	**Research Differentiation** • Existence of directly competing technologies in development, or groups known to be working on similar technologies or the same targets • Stage of development of the competing groups vis-à-vis the proposed research • Medical expertise in team, either through experience or collaboration
2.3	**Competitive Landscape** • Amount of commercial competition in the target indication, including other treatment approaches (e.g. surgery or devices) • Existence of therapeutics being developed for the target in the same or different indications • Clarity on the benefits over current standard of care
3	**Development Plans**
3.1	**Research Plan Feasibility** • Realistic deliverables with respect to the timeframe and proposed budget • Realistic and quality research plan with a clear roadmap • Presence of any significant barriers to achieving stated goals • Sufficient budget, expertise and access to research infrastructure or resources • Clear identification of go/no-go criteria
4	**Commercialisation and Intellectual Property (IP)**
4.1	**Commercial Viability** • Ability of proposed deliverables to position the project for the next funding stage or be attractive to commercial partners • Amount of additional development and/or budget outlay to support future development

	• Time taken for technology to be ready for pre-Investigational New Drug (IND) activities and/or clinical development • Challenges in terms of scaling-up, manufacturing and deployment/clinical adoption of the asset or platform technology
4.2	**Intellectual Property** • How crowded the patent landscape is • Potential to generate foreground IP • Potential issues with freedom-to-operate
4.3	**Strategic Partnerships for Future Development** • Identification or engagement of strategic partners • Potential for development of technologies with partners • Development plan to secure venture capital funds • Strategy for licensing