STDR
Singapore Therapeutics Development Review

ANNEX A

DIFFERENCES BETWEEN STDR PRE-PILOT (STREAM 1 & 2) AND PILOT STAGES

The **Pre-Pilot** stage aims to support earlier-stage and more exploratory, proof-of-concept projects with some preliminary data. Areas supported include the preclinical validation of drug targets, or platform development.

The **Pilot** stage aims to support more mature projects that have more data and have already been validated to a certain degree, or already have a commercialisation plan.

Comparisons between Pre-Pilot and Pilot

Pre-Pilot Stream 1 (Target Validation)	**Pre-Pilot Stream 2 (Platform Development)**
Stage: Preliminary data supporting the implication of a target in a given disease indication, with new data generated by the applicant and/or key published experiments reproduced by the applicant. The target should have a novel role in the indication chosen by the applicant. Note: Large scale compound screening, Hit-to-Lead or Lead-optimisation cannot be supported by the Pre-Pilot Stream 1. **Examples of projects:** • Validation of XXX as a relevant target against xyz indications • Peptides as tool inhibitors of XXX for xyz indications • Novel biomarker and therapeutic target in xyz indications • Validating the tractability of XXX as a target for antibody therapeutics • Determining the mechanism of action for the therapeutic effect of modulating XXX in disease xyz **Mentorship/training:** A Drug Discovery Specialist (DDS) will be appointed to each project to work with the investigator on the design of key experiments needed for preclinical target validation. Projects will attend a bootcamp organised by EDDC to better understand considerations for developing therapeutic assets for commercialisation.	**Stage:** Preliminary data supporting an early proof of concept for a therapeutic platform technology. An indication of the scope of applications but no specific set of key commercial applications defined. **Definition of platforms:** 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. Note: 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. Examples of projects: • Customisable non-antibody target-binding scaffolds for therapeutic applications across different disease targets • Modular antibody-drug conjugate linker-payload platforms that can be paired with

Intended outcome: Target validation, more convincing evidence of whether the target should be considered for a drug discovery campaign. Mechanism of action (MOA) established.	different antibodies and applied across multiple cancer indications • Optimised mRNA backbones and delivery systems that support rapid substitution of coding sequences for different therapeutic applications • Engineered viral-vector libraries, such as AAV capsids, for targeted delivery of different, defined genetic payloads across multiple diseases • Off-the-shelf, immune-evasive cell therapy platforms capable of generating different therapeutic cell types • Adaptable targeted protein-degradation platforms for degrading different disease-causing proteins **Mentorship/training:** A mentor will be appointed to each project to work with the investigator on the design of key experiments needed to strengthen the project's translational and commercialisation potential. Projects will attend a bootcamp organised by EDDC. **Intended outcome:** Validation of the platform and a clearer commercialisation pathway.

Pilot

Stage: Funds more mature projects that are supported by robust target validation. Both single target/single asset projects and platform technologies projects will be funded, in a range of stages from target validation to preclinical work.

For single-asset projects: Data demonstrating that

- The target is implicated in the disease indication;
- The target can be modulated therapeutically;
- Modulation of the target may lead to a therapeutic effect in relevant pre-clinical models; and/or
- A defined path towards the development of a therapeutic candidate.

Example workplan for single-asset Pilot projects:

- Phase 1 – Include the relevant activities such as identification of target modulators (e.g. high-throughput screening), lead generation, preliminary evaluation of efficacy and safety of candidates *in vitro* and *in vivo*, development of *in vivo* models for preclinical assessment.
- Phase 2 – Optimisation of lead candidates, development planning, initiating assembly of data package for preclinical candidate.

For platform technologies:
Data supporting and establishing the platform technology, such as early data showing one or more applications, and a clear pathway articulated to select and demonstrate a first commercial product.

Example workplan for platform technologies Pilot projects:

- Phase 1. Successful *in vitro* killing of cancer cell lines with engineered iPSCs out of the platform technology.
- Phase 2: *In vivo* assessment of survival in cancer mouse models.

Mentorship/training: Pilot awardees will attend mentoring sessions to receive advice and support from VCs, ex-pharma executives, biotech CEOs, or experts from EDDC. Mentors will provide advice on matters relating to the development and commercial strategy, including marketing, business modelling and pitch practice/advice.

Selected awardees will attend STDR bootcamps that will help clarify the key commercial applications and define a development pathway.

Intended outcome: Allow projects to have sufficient funding to bridge the gap to the next value inflexion point in the drug discovery and development pathway. Outcomes include follow-on funding from private funders, co-development with industry or entry into EDDC, NATi's portfolio.