# Guidance for potential TPF projects

NOTE: TPF projects need to be completed within 6 months of being funding. Project budget can range from a minimum of  $\in$ 5,000 to a maximum of  $\in$ 15,000 (subject to the eligible costs detailed in the TPF Principles and Guidelines).

*In all the examples below a parallel task of market analysis would be carried out by your institution's Technology Transfer Office.* 

These examples are based on our understanding of the TPF guidelines and we cannot guarantee that projects that follow these examples will get funded.

# Example 1

Compounds have been discovered for one application but could be re-purposed for another disease state. A small amount of funding required for in vivo studies to test the compounds in a known model and do a POC experiment to gain more specific data to shape a larger Commercialisation Fund application. POC experiments in this case would include a researcher salary to conduct a small animal study over a short period of time. This would validate the known compound in a different disease state with the potential to open a new commercial market.

The overall goal is to provide enough validation of the compound in another disease state, generate key data to strengthen a patent application and create a POC that can be used in customer discovery.

### Example 2

Research has developed minimum viable software solution for use in psychological intervention, which has not been trialled in a patient cohort. Funding is required to establish a trial and test the methodologies developed. A POC would allow this crucial testing to be conducted, determining effectiveness, and ultimately providing enough validation to allow for a larger Commercialisation Fund project. TPF funding would include salary of a researcher to conduct the tests, travel to the patient test sites, and any other allowable expenses required to execute the validation.

The overall goal is to create a validated MPV tested in a patient cohort, generate the initial data to strengthen a patent application and create POC data that can be used in customer discovery.

# Example 3

Basic software simulations have indicated that a theoretical concept if implemented could be valuable in the field of radio communications. The positive simulation results have been enough to apply for a preliminary patent application however the technology has not been properly validated on the bench. A TPF project could allow a researcher to physically build the simulated design test and validate using university equipment and facilities. The generated POC data would be used to strengthen the technology patent position leading to further patent application.

The overall aim is to physically validate simulated technology to demonstrate POC and provide sufficient data to allow for customer discovery in target markets. The successful TPF project would require Commercialisation Funding to achieve minimum viable product.

# Example 4

In innovative design led project has resulted in a concept that has been developed with considerable end customer involvement. The emphasis of the design project was on the customer discover process, documenting validated customer requirements and the creation of a model product, though not quite a minimum viable product, that would fit those requirements. With the initial project's emphasis on form over function, a TPF project could allow a researcher to develop the technical internals to create a minimum viable product.

The overall aim is to create a minimum viable product that can be used in further customer/market discovery in a Commercialisation Fund feasibility project which may be enough to create a spin-out company.

# Other Examples

# Example 5

The TPF could be used to further develop a PDT programme outline targeting a validated clinical need.

Prescription Digital Therapeutics, or PDTs, are a new therapeutic class. Like traditional biologics or drugs, PDTs:

- Directly treat serious diseases
- Are built under current Good Manufacturing Practices
- Demonstrate safety and efficacy in randomized clinical trials
- Receive labelled claims from the FDA
- Are used by physician prescription
- Are reimbursed as products, via Pharmacy and Medical benefits
- Have barriers to entry that span regulatory exclusivity and intellectual property

One example currently in development by Pear Therapeutics is reSET, a 90-day Prescription Digital Therapeutic (PDT) for Substance Use Disorder (SUD) intended to provide cognitive behavioural therapy (CBT), as an adjunct to a contingency management system, for patients 18 years of age and older who are currently enrolled in outpatient treatment under the supervision of a clinician.

# Example 6

The TPF could be used to further develop a novel formulation or new FDA 505 (b) (2) combinations, to create a proof of concept.

Pharma Two B taking 'synergistic' approach in pursuit of 505(b)(2) approval. Israeli start-up Pharma Two B has taken the concept of synergism seriously, from the eclectic group of scientists and managers it has brought together under one roof, to its fixed-dose combination strategy of drug development, to the approval pathway it plans to seek in gaining the US FDA's OK-505 (b)(2), a hybrid route to approval that is increasingly growing more popular in the US because of the costs saved and time reduced in getting medicines to the marketplace.

### Example 7

Any TPF proof of concept options in this space?

https://www.exscientia.ai/ https://www.exscientia.ai/small-vs-big-data

Scientists have used AI/Deep Learning to discover the antibiotic properties of an existing drug, while an entirely new drug molecule 'invented' by AI will soon be used in human trials to treat patients who have obsessive-compulsive disorder (OCD).

Prof Andrew Hopkins, the chief executive of the company behind the OCD drug, Exscientia, says that drug development usually takes five years to get to trial as there are potentially billions of design decisions that need to be made-but the AI drug took just 12 months.

The reason it's accelerated is because we're making and testing fewer compounds, and this is because the algorithms that undertake the design work are able to learn faster and reach the optimized molecule quicker, he says, adding that early stage drug delivery can result in as much as a 30% cost saving to bring the drug to market.

#### Example 8

TPF money could help data scientists build an AI/Deep learning validation tool proof of concept for engagement with regulatory groups?

https://techcrunch.com/2020/02/19/europe-sets-out-plan-to-boost-data-reuse-and-regulate-highrisk-ais

https://techcrunch.com/2020/02/25/first-do-no-harm