SPARC Project Summary

**INSTRUCTIONS:**

The Objective of the SPARC-LEAP Collaboration is to: ***engender licenses*** *to Sun Pharma Advanced Research Company (SPARC).*

To meet this objective, **SPARC** **LEAP centers the expectations of SPARC as a potential partner**. Considering your partner’s expectations provides a framework for your product development strategy.

This document is a template for your **SPARC Project Summary.** The final SPARC Project Summary is provided to SPARC two weeks in advance of your final presentation, if you are selected. This template is also effective to outline the content your **Final Presentation Slide Deck**, along with our [Presentation to Industry Guide](https://wustl.box.com/s/ib6gs7ijri8tw103hrh6fyvv10lw9w55).

**FOR YOUR FIRST DRAFT: MAKE YOUR BEST ESTIMATE BASED ON WHAT YOU KNOW (SPEND 2h MAX).**

The outline for the Project Summary is as follows:

* **SECTION 1: MARKET & NEED** – What is the unmet need your project addresses?
* **SECTION 2: THE PRODUCT** – Description of the eventual product (asset) to be developed.
* **SECTION 3: SPARC – A POTENTIAL PARTNER**
	+ What data would SPARC want to see which would compel them to move forward with a license or research collaboration for this project?
* **SECTION 4: THE PLAN**
	+ **CURRENT PROJECT STAGE** – Description of current data to as starting point for project.
	+ **KEY DEVELOPMENT MILESTONE** – Descript. of data needed for asset to be compelling for SPARC.
	+ **DEVELOPMENT PLAN**
		- What activity is planned to achieve the **KEY DEVELOPMENT MILESTONE** above?
		- How will this activity be funded and by whom (SPARC vs grants)?
* **Optional Section I: CLINICAL TRIAL CONSIDERATIONS** – What does your initial trial look like?
* **Optional Section II: TARGET PRODUCT PROFILE (TPP)** – What are the specific characteristics of your drug?

All of the activities in your **DEVELOPMENT PLAN** should be “de-risking” activities, i.e., activities must reduce the risk associated with investing money in the project.

* A key example of this is the “killer experiment.” The “killer experiment” is built to test critical aspects of the project with the goal of potentially dispelling the value of the asset, thus “killing” it. These are **top priority** for early stage assets and are particularly impactful for therapeutic projects.
	+ - At times, the “killer experiment” is to obtain data on the potential market, regulatory or reimbursement landscape, clinical trial design, or investor interests in the space.
* The **DEVELOPMENT PLAN** should address risks that might hinder or prevent development. This means you must be transparent about challenges that your project will face **and clearly explain a plan to navigate said challenges.** Projects that do so are highly valued by the judging panel. It demonstrates that the participant has thought through the process.

Note:

* Beyond this page, *all text in italics* are instructions, advice, and/or guidance. Please delete such text in the final draft. **Your responses should not be in italics.**
* This document cannot exceed 5 pages of text (tables do not count toward final length).
* THIS IS YOUR FIRST ATTEMPT AT THIS DOCUMENT. Don’t spend too much time at the outset – we will work with you to finalize based on our in-person meetings.

SPARC Project Summary

**Project Title:** *Marketing Slogan* **OR** *(Product Description) for (Indication)*

**Lead Investigator:** *Full name, Official university title*

**Lead Investigator e-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**One Line Pitch**: *Provide a one-line description of the project in layman language. Use language you would be comfortable releasing to the public.*

* *Include the value proposition to the person who will decide to purchase your product and, for therapies, the unique mechanistic basis.*

**Key Project Leadership**: *Provide a brief description of the technical and operational management team’s qualifications. Be specific about the type of experience and for how long. This should be a maximum of a couple sentences per person.*

* *Please include any titles you would want included in a press release and list the names and titles of non-management team members you would want included in a press release as associated with the team.*

**SECTION 1: THE MARKET & NEED**

*Don’t spend more than* ***30 min*** *on first draft of this section.*

**Unmet Need/Target Market:** *You should address two questions for each market for which you seek to access (numbers 1 & 2 below). This information should be provided for the “lowest hanging fruit” or initial market and any attractive follow-on indications/markets.*

1. *What is the* ***gap*** *in* ***existing*** *solutions to the problem your product addresses?*
	1. *What is the current standard of care for disease state or diagnostic area you are targeting? Why is this inadequate?*
2. *What is the* ***market opportunity*** *(in $) for your product?*
	1. *Do you have data to support this estimate? What assumptions did you make about the market?*
		1. *If this is confusing, don’t worry – just take a stab.* **The BALSA Group** *will work with you before your presentation to build an abbreviated market analysis.*
		2. *If you’re looking for more info on how to estimate market size, check out page 10 of BioGenerator’s* [*Entrepreneurs Roadmap*](https://biogenerator.org/wp-content/uploads/2018/12/BG-Fundamentals-Roadmap-2018-Dec.pdf)*. This applies to all project types.*

*Projects with* ***accessible*** *initial markets and* ***large*** *follow-on markets tend to be attractive, but this is not required.* ***Clarity*** *of market potential is a judging criterion.* ***Gross market size*** *is de-emphasized as a judging criterion.*

**SECTION 2: THE PRODUCT**

*Don’t spend more than* ***20 min*** *on first draft of this section.*

**General Product Summary**: *In 100-200 words, summarize the product as it will look once developed. What are the key characteristics of your innovative product? What is the potential impact of this product? What are your advantages over the competition, and if applicable, the standard of care?*

* + ***“No competition” is not an option****. There are always alternatives to your product, e.g., Netflix’s CEO once described their biggest competitor as “sleep.”*
	+ ***For therapeutics,*** *describe the pathway & target you are modulating and the action & type of any molecules you have developed. Consider the questions in* [*this document*](https://wustl.box.com/s/pdy1vpww4pahie2kg27mq7jtvw1flnss)*.*

***All projects*** *must compare to the current standard of care:*

**Comparison to Standard of Care**

1. *What is your proposed FDA/EMA indication statement and patient population to be treated (eg., 2nd line treatment of mild-moderate acne)*
2. *What are the existing therapies, including therapies in clinical trials, for the proposed indication?*
3. *What is your rationale and/or data supporting proposed advantage over existing therapies?*

***All projects*** *must include an IP section:*

**Intellectual Property**

*What is the stage/type of IP (copyright, provisional, national stage, issued)? Generally, what is the claim scope? Generally, what is the likelihood of patentability? Submit to OTM* [*here*](https://otminnovate.wustl.edu/log_in/)*.*

**SECTION 3:**

**SPARC – A POTENTIAL PARTNER**

*Don’t spend more than* ***30 min*** *on first draft of this section.*

*The goal of this section is to identify activities to prioritize that engender interest from SPARC. What do you think SPARC wants to see in your project to “buy-in?” SPARC’s “Buy-In” Criteria IS the* **Key Development Milestone** *as described in the next section* **(SECTION 4)***.*

*What data is most important for SPARC to see to compel them to explore a relationship with your project? This can be data that you have in hand or data you will obtain in the near term. This data should relate to your advantage over standard of care. This is SPARC’s Buy-in Criterion.*

**SECTION 4: THE PLAN**

*Don’t spend more than* ***30 min*** *on first draft of this section.*

**CURRENT PROJECT STAGE**

*Where do things currently stand? At this time, what specific data do you have available to support that your product is functional and that your development plan is reasonable?*

* *Please add graphs, figures, or other supplementary materials that demonstrate proof of concept.*
* *What other funding do you have in hand to work on this project (also describe in* ***Development Plan*** *table)?*

**KEY DEVELOPMENT MILESTONE**

*The* ***Key Development Milestone*** *is a near term goal for your project which can be achieved over the course of 2 years with SPARC funding (~$160k in directs).* ***Synthesize the Buy-in Criterion (from the third column in* SECTION 3 *above) into a near term goal for your project.*** *Be as specific as you are comfortable, we will work with you to develop the answers to this. Consider the below points:*

* *What are the next big milestones in the development of this project?*
* *What data is most interesting to SPARC, i.e., what differentiates you from Standard of Care? What aspects of your mechanism of action are novel? What is needed to prove them?*
* *What technical aspects of your asset remain to be validated? Rank them in importance relative to implementation of your product in the clinic or market. The biggest open questions should be prioritized.*
* ***Come up with a simple (1-2 sentences) and measurable endpoint for the SPARC Collaboration.***

**DEVELOPMENT PLAN**

*Using the table templates below,**provide a list of activities you intend to undertake to achieve your* ***Key Development Milestone****—using funds from both SPARC and outside sources****. Don’t worry about getting a final draft done on your first stab****. Outline what you think you need to do to achieve your* ***Key Development Milestone****.* ***Be as specific as possible – industry partners like specificity.***

* ***Tranche****-based projects with specific activity descriptions and* ***quantitative success criterion*** *that allow for* ***binary go/no-go decisions*** *will get the most valuable feedback from SPARC and will be prioritized for funding.*
* *What experiments or activities, if unfavorable, would kill the chance of success of the project? This is the most important activity to engage in to de-risk the project.*
* *Propose a project scope that can reasonably be completed in 2 years. Max amount of funding is $166k per year in directs.*

**Supplementary Materials**

*Include any relevant Letters of Support, Graphs, Data Summaries, Development Schemes that would support your application.*

**BLANK DEVELOPMENT PLAN & USE OF FUNDS:**

|  |  |
| --- | --- |
| **KEY DEVELOPMENT MILESTONE:** | **YOUR KEY DEVELOPMENT MILESTONE IS “SELECTION OF A THERAPEUTIC CANDIDATE THAT CAN BE BROUGHT TO THE CLINIC based on XXX data.” 🡨 Put this in your own language for your project.**  |

|  |
| --- |
| **Funding and Deliverables Needed to Achieve** **the Above KEY DEVELOPMENT MILESTONE** |
| **Fund Source: SPARC – Year 1** |
| **Tranche # / Pre-Requisite** | **Specific activity** | **Funds required** | **Deliverable & Success Criterion** | **Delivery by** |
| [Tranche # and description of Pre-Requisites] | [Description of specific activities required under this tranche – EACH EXPERIMENT IS ITS OWN LINE, add as many lines as needed]This is NOT: “In vitro testing” or “Demonstrate manufacturability”This IS: “Testing Patency and Efficacy in a diabetic pig model on 8 pigs” | [$] | [specific success criterion for the deliverable which is clearly “go/no-go”]This is NOT: “Favorable Pharmacokinetics” or “This IS: * “Demonstration of a 2-4 hour half life”
* “Reproducibility of survival outcomes within 15%”
* “Acheiving at least 85mA/cm2 constant current charge-discharge with <8% capacity fade over 1 week, 85mW/cm2 power density at 1.6V in a polarization curve.”
 | [Length of time needed from NoA] |
|  |  |  |  |  |
|  |  |  |  |  |
| ***Sub-total SPARC funds*** | **Max ~$166,000** |  |
| **Fund Source: non-SPARC** |
| **Fund Source** | **General Aims** | **Funds Available** | **Why is this applicable to your Key Development Milestone?** |
| [Granting Agency or other source] | [Description of applicable aims] | [Total funds available / Funds in-Hand or not] | [How does this help achieve Development Goal?] |
|  |  |  |  |
|  |  |  |  |
| ***Sub-total Non-SPARC funds*** | $X |  |

**ADDITIONAL SECTIONS TO CONSIDER:**

*These two additional sections may further strengthen your project summary.*

**Additional Section I: CLINICAL TRIAL CONSIDERATIONS**

*This section contains your assessment of the clinical & regulatory path with the aim of demonstrating to SPARC that the activities are feasible. Based on your current knowledge, what strategies can you take to ensure that your eventual clinical trial will be of reasonable size (i.e. not tens of thousands of patients over 10+ years)?*

*Describe the first potential clinical study to demonstrate proof of mechanism and addressing the points below:*

1. *Patient stratification/selection for the study (i.e. molecular signature, SNP, genetic deficiency etc.) This is important to ensure that patients are selected based on their likelihood to respond.*
2. *Clinical study endpoints that would allow for testing mechanism in patients and speak to the proposed FDA/EMA indication statement.*
	1. *Will your endpoints allow for clinical differentiation from other therapies?*
	2. *This is important to accelerate statistical differentiation from benchmark therapies so that less patients need to be enrolled and study cost can be minimized.*
3. *Are there longitudinal monitoring / follow-ups required for this patient population? This activity will increase overall study cost.*

*Address critical efficacy- based Phase II/III Trial Considerations:*

1. *In your target patient population, what would you expect your primary (and secondary) clinical endpoint(s) to be in a pivotal study? You may not have full clarity of this at this stage, but speak to what you know.*
2. *In your intended target population, are there any factors that might preclude full responses to treatment?*

**Additional Section II: TARGET PRODUCT PROFILE (TPP)**

*The goal of this section is to complete the* **Target Product Profile (TPP)** *table to the best of your current knowledge. This is an exercise that every serious clinical asset will go through at some point in its development. From the FDA’s TPP Guidance document:*

*The purpose of a Target Product Profile is to provide a format for discussions between a sponsor and the FDA that can be used throughout the drug development process, from pre-investigational new drug application (pre-IND) or investigational new drug application (IND) phases of drug development through postmarketing programs to pursue new indications or other substantial changes in labeling. The TPP embodies the notion of beginning with the goal in mind. That is, the sponsor specifies the labeling concepts that are the goals of the drug development program, documents the specific studies intended to support the labeling concepts, and then uses the TPP to assist in a constructive dialogue with the FDA. The ideal version of what the sponsor would like to claim in labeling guides the design, conduct, and analysis of clinical trials to maximize the efficiency of the development program.*

 *The “Ideal Target/Claim” describes the specific characteristics your product must have to access the* **full** *patient population or market. If you are going* **maximize** *your value proposition to patients, doctors, insurance companies, hospitals and your potential licensee or acquirer, what characteristics must your product have to succeed in the clinic to its* **fullest****extent***?*

*The “Minimum Acceptable Target/Claim” describes the specific characteristics your product MUST have to achieve the* **minimum** *level of advantages over the standard of care to address a significant unmet need in the clinic. What is the* **lowest threshold** *you have to hit to be successful?*

*The “Req. Evidence” refers to the 1) clinical endpoints to be evaluated to prove your advantages in the clinic and 2) animal data needed to demonstrate that product is defined by said characteristics. Indicate whether or not this animal data has already been acquired.*

| **Target Product Profile** |
| --- |
| **Ideal Target / Claim** | **Min. Acceptable Target/Claim** | **Required Evidence** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

***FDA generated example Target Product Profiles (TPPs) found*** [***HERE***](https://www.ninds.nih.gov/Funding/Apply-Funding/Application-Support-Library/CREATE-Bio-Example-Target-Product-Profile-TPP)***.***

* ***These are in a different format but may still be informative***

***Full FDA Guidance Document on Target Product Profiles found*** [***HERE***](https://www.fda.gov/media/72566/download)***.***

**EXAMPLE DEVELOPMENT PLAN:**

|  |  |
| --- | --- |
| **KEY DEVELOPMENT MILESTONE:** | **Identify a target combination therapy and regulatory strategy that meets: [specific binary success criterion].** |

|  |
| --- |
| **Funding and Deliverables Needed to Achieve** **the Above KEY DEVELOPMENT MILESTONE** |
| **Fund Source: SPARC** |
| **Tranche # / Pre-Requisite** | **Specific activity** | **Funds required** | **Deliverable & Success Criterion** | **Delivery by** |
| **Tranche 1 / no pre-requisite** | Single Drug Dose Response in ABC model with Drug 1, Drug 2, Drug 3, Drug 4 | $25,000 | At least two drugs which show 15% reduction in liver ABC accumulation at non-toxic doses | 3 mo from NoA |
| **Tranche 2 / pre-requisite:** success in Tranche 1 and Quotes from CRO for PK | Drug pair testing of ideal concentrations in ABC model to assess synergy (Drug 1 and Drug 2, Drug 1 and Drug 2, Drug 3 and Drug 4) | $25,000 | At least one drug combination with a combination index of <1.0 via isobologram analysis and lack of toxicity | 8 mo from NoA |
| **Tranche 3 / pre-requisite:** success in Tranche 2 | Regulatory Analysis & Commercialization strategy for re-purposing pathway | SPARC in-kind | Identification of a viable regulatory & commercial strategy leveraging IP to navigate clinical trials | 12 mo from NoA |
| **Tranche 4 / pre-requisite:** success in Tranche 2 + 3 | Studies to address toxicity, relationship of PK-PD, and further validate mechanism (Note: In your proposal these studies should all be broken out into separate lines) | $100,000 | [Success criterion for each of the proposed studies] | 12 mo from NoA |
| ***Sub-total SPARC funds Year 1*** | $150,000 |  |
| **Fund Source: non-SPARC** |
| **Fund Source** | **General Aims** | **Funds Available** | **Why is this applicable to your Key Development Milestone?** |
| NIH R21 | Investigation of novel pathogenic mechanisms in the ABC model | $2M | Personnel funded under this grant can be utilized as this activity dovetails with aims |
| [Granting Agency or other source] | [Description of applicable aims] | [Total funds available] | [How does this help achieve Development Goal?] |
| ***Sub-total Non-LEAP funds*** | $X |  |