SPARC FULL PROPOSAL

**INSTRUCTIONS:**

In this document, you will draft a full proposal on your project for SPARC. A successful proposal to SPARC will be referenced in an executed collaboration agreement under the SPARC-WUSTL Master Services Agreement for your technology.

Please reference the “Guidelines for SPARC Full Proposal FALL2018” document that has been provided to you.

Full Proposal Outline:

* **SECTION 1: MARKET & NEED - 1 page**
  + What is the unmet need your project addresses? What is the competition?
* **SECTION 2: THE TARGET PRODUCT PROFILE - 1 page**
  + Describe the advantages over the standard of care
* **SECTION 3: CLINICAL TRIAL CONSIDERATIONS – 1 page**
  + Outline your initial clinical trial
* **SECTION 4: PROJECT STAGE, GOALS, & PLAN**
  + **CURRENT PROJECT STAGE – 2 pages**
    - Description of the current status of data to demonstrate proof of concept.
  + **DEVELOPMENT MILESTONES – 1 page**
    - What are the aims of the collaboration?
  + **DETAILED DEVELOPMENT PLAN – 3-5 pages (w/o tables)**
    - What activity is planned to achieve the **DEVELOPMENT MILESTONES**?
    - Who will perform this work and how will it be funded?

Total pages= 11 maximum w/o tables

Please delete italic text in the final draft. **Your responses should not be in italics.**

[PI Name] FULL PROPOSAL

**Project Title:** *(Product description) for (indication)*

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

**Lead Investigator e-mail:**

**Executive Summary**: *See Template Guide for content guidelines.*

**Key Project Leadership**: *See Template Guide for content guidelines.*

**SECTION 1:**

**THE MARKET & NEED – 1 PAGE**

**Unmet Need/Target Market:** *See Template Guide for content guidelines.*

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| *Compound* | *Company* | *Mech. Of Action* | *Development Stage* |
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| *Compound* | *Company* | *Mech. Of Action* | *Development Stage* |
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**SECTION 2:**

**THE TARGET PRODUCT PROFILE – 1 PAGE**

**Differentiation/Advantages over Standard of Care:** *See Template Guide for content guidelines.*

| **Target Product Profile to Differentiate from Standard of Care** | | |
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| **Ideal Target / Claim** | **Min. Acceptable Target / Claim** | **Required Evidence** |
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**SECTION 3:**

**CLINICAL TRIAL CONSIDERATIONS – 1 PAGE**

*See Template Guide for content guidelines.*

**SECTION 4: PROJECT STAGE, GOALS, & PLAN**

*The purpose of this section is to go deeper into the data & current status of the project and outline a detailed plan with milestones for development.*

**CURRENT PROJECT STAGE – 2 PAGES**

*See Template Guide for content guidelines.*

**Intellectual Property – 1 Paragraph**

*See Template Guide for content guidelines.*

**DEVELOPMENT MILESTONES, DECISION POINTS, & SUCCESS MILESTONE**

**– 3-5 PAGES w/o tables**

*See Template Guide for content guidelines.*

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| **SUCCESS MILESTONE:** | **IDENTIFICATION & VALIDATION OF A CLINICAL THERAPEUTIC CANDIDATE.” 🡨 Put this in your own language for your project.** |

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| **DEVELOPMENT MILESTONES**  **/ DECISION POINTS:** | **[Type of Activity]**   1. **KEY GO/NO-GO DATA THRESHOLD TO BE ACHIEVED – MONTH/YEAR**    1. **Specific activity**    2. **Specific activity**    3. **Decision Point 1 (DP1)** 2. **KEY GO/NO-GO DATA THRESHOLD TO BE ACHIEVED – MONTH/YEAR**    1. **Specific activity**    2. **Specific activity**    3. **Decision Point 2 (DP2)**   **[Type of Activity]**   1. **KEY GO/NO-GO DATA THRESHOLD TO BE ACHIEVED – MONTH/YEAR**    1. **Specific activity**    2. **Specific activity**    3. **Decision Point 3 (DP3)** 2. **[add more as needed]**    1. **Specific activity**    2. **Specific activity**    3. **Decision Point 4 (DP4)** |

**DETAILED DEVELOPMENT PLAN**

*Overall the* **Detailed Development Plan** *consists of three things:*

1. **Written Description of Development****Milestones**
2. **Development Milestone Flowchart or GANTT Chart**
3. **Use of Funds Table**

*See Template Guide for content guidelines.*

1. **Written Description of Development****Milestones**

*See Template Guide for content guidelines.*

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| --- | --- | --- |
| **Assay / Experiment / Activity (Special reagents Needed)** | **Group Performing Work** | **Specific Data Readouts** |
| [Description of specific activities required under this tranche – EACH EXPERIMENT IS ITS OWN LINE, add as many lines as needed] – (Describe any particular needs for reagents to complete the activity in parentheses)  This is NOT: “In vitro testing” or “Demonstrate manufacturability”  This IS: “Testing Patency and Efficacy in a diabetic pig model on 8 pigs” | [PI last name] Lab or Acronym | [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 and measurable biomarker * “Reproducibility of survival outcomes within 15%” |
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1. **Development Milestone Flowchart or GANTT Chart**

*See Template Guide for content guidelines.*

1. **Use of Funds Table(s)**

*See Template Guide for content guidelines.*

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| **USE OF FUNDS TABLE**  **SPARC COLLABORATION – YEAR 1** | | | | |
| **Fund Source: SPARC** | | | | |
| **Associated Development Milestone Number** | **Assay / Experiment / Activity (Reagents Needed)** | **Funds required / Group Performing Work** | **Specific Data Readouts** | **Delivery by** |
| [Input the number of the of the Development Milestone that the assay or experiment falls under.] | [Description of specific activities required under this tranche – EACH EXPERIMENT IS ITS OWN LINE, add as many lines as needed] – (Describe any particular needs for reagents to complete the activity in parentheses)  This is NOT: “In vitro testing” or “Demonstrate manufacturability”  This IS: “Evaluating efficacy in a diabetic pig model, n=8” | [$] – [PI last name] Lab, Group Acronym, or Company (e.g. SPARC in-kind) | This is NOT: “Favorable Pharmacokinetics” OR “Confirmation of mechanism”  This IS:   * “Demonstration of a 2-4 hour half life” * “Positive correlation of target occupancy & plasma levels with desired phenotypic outcome in dose response” * “A safety margin of 40% minimally efficacious dose” * “Reproducibility of survival outcomes within 15%” | [Month Year] |
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| ***Sub-total SPARC funds*** | | **Max Direct ~$160,000** |  | |
| **Fund Source: non-SPARC** | | | | |
| **Fund Source** | **General Aims** | **Funds Available** | **Associated Development Milestone Number / How does this help acheive Development Milestone(s)?** | |
| [Granting Agency or other source] | [Description of applicable aims] | [Total funds available / Funds in-Hand or not] | [#] - [How does this help achieve Development Milestone?] | |
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| ***Sub-total Non-SPARC funds*** | | $X |  | |

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| **DEVELOPMENT PLAN & USE OF FUNDS TABLE**  **SPARC COLLABORATION – YEAR 2** | | | | |
| **Fund Source: SPARC** | | | | |
| **Associated Development Milestone Number** | **Assay / Experiment / Activity (Reagents Needed)** | **Funds required / Group Performing Work** | **Specific Data Readouts** | **Delivery by** |
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| ***Sub-total SPARC funds*** | | **Max Direct ~$160,000** |  | |
| **Fund Source: non-SPARC** | | | | |
| **Fund Source** | **General Aims** | **Funds Available** | **Why is this applicable to your Key Development Milestone?** | |
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| ***Sub-total Non-SPARC funds*** | | $X |  | |

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| **DEVELOPMENT PLAN & USE OF FUNDS TABLE**  **SPARC COLLABORATION – YEAR 3** | | | | |
| **Fund Source: SPARC** | | | | |
| **Associated Development Milestone Number** | **Assay / Experiment / Activity (Reagents Needed)** | **Funds required / Group Performing Work** | **Specific Data Readouts** | **Delivery by** |
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| ***Sub-total SPARC funds*** | | **Max Direct ~$160,000** |  | |
| **Fund Source: non-SPARC** | | | | |
| **Fund Source** | **General Aims** | **Funds Available** | **Why is this applicable to your Key Development Milestone?** | |
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| ***Sub-total Non-SPARC funds*** | | $X |  | |