



Ardelyx Investigator Sponsored Trial* Concept Form

All fields are required. If a field is not completed, please note the reason. If not applicable, please indicate N/A.

Proposed Study Title

Study Title:

Date:

Principal Investigator Contact Information

Name:

Title:

Address 1

Address 2

City, ST, Zip

Phone/Fax:

E-mail:

Institution Contact Information

Name:

Address 1

Address 2

City, ST, Zip

Phone/Fax:

website

Contracting Information (if applicable)

Name:

Phone/Fax:

E-mail:

Study Information

Indication:

Phase:

Number of Subjects:

Background and Rationale

- Provide background on unanswered question(s) the study is attempting to answer

Study Objectives

- List the objectives to correspond directly with the listed hypotheses

Hypothesis

- List the clinical Hypotheses in order of priority

Study Design/Research Plan

- Provide a concise overview stating the type of experimental design, key inclusion/exclusion criteria

Tests

- Include biomarkers (if applicable)

Statistical Plans

- Include justification for clinical sample size and primary hypothesis testing

Drug Supply Information	
Drug Supplies Required (Yes/No)?	
List Drug Supplies and Amount Required:	Drug Name:
	Amount:
Placebo Required (Yes/No)?	
Additional Sources of Drug Supply (Yes/No). If Yes, please specify	
Timelines and Study Plans	
Number of Sites:	
Site Names:	
Study Start Date:	
Study End Date:	
Sample Size:	
Budget Summary	
Direct Study Costs Please enumerate	Subject related cost:
	Study related personnel cost:
	Diagnostic Fees:
	Data management:
	Other:
Indirect Study Costs Please enumerate	IRB Fee:
	Equipment/Supply Fee:
	Animal-related costs:
	Other:
Total Amount Requested: Specify In-Kind (Study Drug Only) and/or Financial Support	
Additional sources of funding? (Yes/No) If Yes, please specify:	
Secured or Requested (federal, private foundation, and/or institutional/ departmental).	

Publication Plan

Where are you planning to submit for publication? (journals, etc):

Are you planning to present your data at a scientific meeting?

Please list your target date for submission of publication.

Attachments

Investigator(s) curriculum vitae

Preliminary budget