NON-CLINICAL IIS RESEARCH SUPPORT APPLICATION

* Required Information

1. CONTACT GENERAL INFORMATION*			
PRIMARY JANSSEN PHARMACEUTICAL COMPANY CONTACT INFORMATION (IF KNOWN)			
Family/Last Name: **Given/First Name:**		**Phone:**	
Title:		**Janssen Company:**	
Email:		**Fax:**	
SPONSOR-INVESTIGATOR INFORMATION:			
Family/Last Name: **Given/First Name:**			
Institution:			
Address:			
City:			
State:			
Country:		**Postal Code:**	
Phone:		**Fax:**	
Email: (Note: Personal emails will not be accepted.)			
Sub-Investigator(s)/ Coordinating Investigator(s):			

2. BRIEF SYNOPSIS*

Concept Title:	

Background Information on Disease State and Treatment Rationale
(Include supporting preliminary data, experience or correlative science studies integral to the study. Include limitations of existing therapeutic options. For publications/citations, include either National Library of Medicine (NLM/)/ PubMed ID(PMID)/ Digital Object Identifier (DOI), or URL address to permit retrieval of the full text or abstract by reviewers or reference statements and include bibliography.)
Enter text below or include separate document:

ENTER BACKGROUND AND RATIONALE TEXT HERE

ENTER REFERENCES HERE

3. STUDY DESIGN*		
Study Type:*	☐ In vitro ☐ In vivo ☐ Other If "Other", specify:	
For In Vivo Only	**Species:**	
	Total Number of Animals:*	
	Treatment Dose:*	
	Route of Administration:	
Duration of Study (days, months):	Total Study Duration: *Indicate duration for:* Final protocol to Animal Use Committee approval:____ months Animal Use Committee approval to Study Initiation: ____ months Study Initiatiion to Completion of Data Collection: ___ months Completion of Data Collection to Final Study Report :___ months Publication submission timing after final study report:___ months	
Primary Objective(s): (include method of collection and time points to assess outcome)		
Secondary Objective(s):		
Other Objectives:		

4. TREATMENT DETAILS*

Specify below or check here for Not Applicable ☐

Enter Total Treatment Duration: _____

For studies with greater than 4 arms or 4 drugs, please attach protocol synopsis with full details. See protocol synopsis for full details.

a. Treatment Arm 1

Enter Treatment Duration. Indicate days, weeks, months, years, cycles, etc. _____

Sample Size:_____

Drug	Dose	Frequency	Route of Administration *See attachment for options:* Route of Administration List.xls

b. Treatment Arm 2:

Enter Treatment Duration. Indicate days, weeks, months, years, cycles, etc. _____

Sample Size:_____

Drug	Dose	Frequency	Route of Administration

c. Treatment Arm 3:

Enter Treatment Duration. Indicate days, weeks, months, years, cycles, etc. _____

Sample Size:_____

Drug	Dose	Frequency	Route of Administration

d. Treatment Arm 4:
Enter Treatment Duration. Indicate days, weeks, months, years, cycles, etc. _____

Sample Size:_____

Drug	Dose	Frequency	Route of Administration

5. STATISTICAL ANALYSIS

Brief Statistical Rationale:	
Statistical Power Calculations:	
Primary Analysis: (include planned analysis of the primary endpoint)	

6. PUBLICATION/PRESENTATION PLAN

Specify target journals publication will be submitted to:	
Estimated journal submission date:	
Are you planning to present your data at a congress?	☐ Yes ☐ No
Estimated abstract submission date: **(Best case scenario based on feasibility)**	
Target Congress/Conference:	

7. TYPE OF SUPPORT REQUESTED*	
Type of Support:	☐ Drug ☐ Financial ☐ Both Drug and Financial Specify the drug product or active pharmaceutical ingredient(s) (APIs) being requested:
If drug is being requested, will it be used in conjunction with any other drug or propriety model received from another company or third party?	☐ Yes ☐ No ☐ Not Applicable If Yes, please list other drugs that will be used along with treatment doses:
Is this study affiliated with clinical studies? If yes, provide the study number:	

8. FINANCIAL ESTIMATE

Financial considerations will be finalized and mutually agreed upon with the final budget. Please provide high-level projected budget as prompted below.

Please note: **Our Company policy will only allow us to consider financial support for the expenses directly relating to the research related activities for this study. Costs not submitted within this original application will be subject to additional review.**

REQUESTED TOTAL STUDY BUDGET (including Animal Use Committee fees, if appropriate)	AMOUNT	CURRENCY
Total Staff Costs:		
Total Pass Through Costs (e.g., Fees):		
Total Budget:		

Is there additional support being requested or provided from another source? ☐ Yes ☐ No

If "Yes", list source(s) and amount:

SOURCE	AMOUNT	CURRENCY

9. INSTITUTION REQUIREMENTS

Does the Institution require the protocol to be final before contract/budget negotiations begin? ☐ Yes ☐ No ☐ Unknown

Does the Institution require the contract to be executed before the protocol is reviewed/approved by the Animal Use Committee? ☐ Yes ☐ No ☐ Unknown