Clinical Investigator-Initiated Study (IIS) Research Support Application

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):			

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2. BRIEF SYNOPSIS*	
Concept Title:	

Background Information on Disease State and Treatment Rationale
(Include supporting preliminary data, either multi-center 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

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3. STUDY DESIGN*		
Study Type:*	☐ Interventional ☐ Non-Interventional/Observational (if selected, choose subtype below): ☐ Epidemiology ☐ Outcomes Research ☐ Registry ☐ Retrospective Data Review ☐ Human Biological Sample (if selected, please specify type below):	
Study Design: (check all that apply)	☐ Longitudinal ☐ Cross Sectional ☐ Single-Blind ☐ Double-Blind ☐ Open Label ☐ Placebo Control ☐ Active Control ☐ Dose Comparison ☐ Uncontrolled ☐ Historic Control ☐ Single Arm ☐ Parallel ☐ Cross Over ☐ Factorial ☐ Other, please specify:	
Randomization:	☐ Randomized ☐Non-Randomized ☐Not-Applicable	
Primary Goals: (select all necessary)	☐ Efficacy (measurement of the capacity of beneficial change) ☐ Effectiveness (how well a treatment works in practice) ☐ Pharmacokinetics	☐ Pharmacodynamics ☐ Outcomes Research ☐ Pharmacogenomics ☐ Quality of Life ☐ Other, specify:

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3. STUDY DESIGN*	
Duration of Study:*	Total Study Duration: *Indicate duration for:* Final protocol to an Independent Ethics Committee (IEC)/Institutional Review Board (IRB)/Health Authority (HA) approval:____ months IEC/IRB/HA approval to First Patient, First Visit: ____ months First Patient, First Visit to Last Patient, First Visit: ___ months Treatment period:___ months Long term follow up period:___months Is an interim analysis planned, if yes, list and specify timing(s): Final study report timing after Last Patient, Last Visit:___ months Publication submission timing after final study report:___ months ☐ Check here if durations are not applicable (e.g., study is non-interventional where durations do not apply).
Primary Endpoint(s):* (include method of collection and time points to assess outcome)	
Secondary Endpoint(s):*	
Other Endpoints:	

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4. STUDY POPULATION*		
Diagnosis or Disease being Studied: View list choices in attached document.  Diagnosis or Disease.xlsx	If "Other", specify:	
Primary Study Population:* (select all necessary)	☐ Pediatric ☐ Adult ☐ Geriatric ☐ Other, specify:	
Age in Years:*	Minimum:	
	Maximum:	
Sex:* (select all necessary)	☐ Male ☐ Female ☐ Other, specify:	
Key Inclusion Criteria:*		
Key Exclusion Criteria:*		
Total Sample Size:*		

5. 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

6. NON-INTERVENTIONAL STUDIES

If this is a non-interventional study, provide additional design details below:

7. STATISTICAL ANALYSIS*

Brief Statistical Rationale:	**Error! Reference source not found.**

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7. STATISTICAL ANALYSIS*	
Statistical Power Calculations:*	
Primary Analysis: (include planned analysis of the primary endpoint)	

8. MULTI-CENTER*	
Is this a multi-center/multi-country study:*	☐ Yes ☐ No **If "Yes", provide rationale and site details below.**

Enter Multi-Center Rationale:
Provide the number of sites and the countries in which they are located (list number of sites per country if multiple sites in a single country):
Will there be involvement by a Cooperative group? ☐ Yes ☐ No **If Yes, provide details:**

9. PUBLICATION/PRESENTATION PLAN*	
Specify target journals a manuscript will be submitted to:	
Estimated journal submission date (MM/YYYY):	
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:	

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10. TYPE OF SUPPORT REQUESTED*

Type of Support: ***Note: Provision of placebo is not permitted.***	☐ Drug ☐ Financial ☐ Both Drug and Financial Specify drug(s) and formulation being requested:

11. 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 IEC/IRB fees, sample analysis/assay costs (e.g., PK, PD, biomarkers), if appropriate)**	**AMOUNT**	**CURRENCY**
Cost Per Subject (inclusive of long term follow up):		
Total Staff Costs (time spent on study not treating subjects):		
Total Pass Through Costs (e.g., IEC/IRB 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**

12. 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 IEC/IRB reviewed/approved? ☐ Yes ☐ No ☐ Unknown