

Investigator Initiated Trial Concept Form

Complete as many fields as possible

Submitted by (Name):	
Date Submitted:	
1. Request Type: (Check all that apply)	<input type="checkbox"/> Drug <input type="checkbox"/> Financial Support <input type="checkbox"/> Placebo * Please note Mylan may not manufacture placebo and this could require additional funding.
1a. Investigational Mylan Drug & Quantity (If applicable):	Active Placebo
1b. Total Funding Request (If applicable) Attach financial breakout:	\$
1c. Related/Other IITs with Mylan (if applicable)	
2. Protocol Title:	

Trial Objective

3. Trial Background/ Rationale: Provide brief study synopsis. Provide justification why this study has scientific merit.	
4. Study Objective(s) and Hypothesis: State the primary and secondary objectives and hypotheses.	

Study Design

5. Study Type	<input type="checkbox"/> Pre-Clinical/ Animal <input type="checkbox"/> Clinical (I-IV)	Non-clinical: <input type="checkbox"/> Registry <input type="checkbox"/> Epidemiology <input type="checkbox"/> HEOR <input type="checkbox"/> In vitro
6. Target Subject Demographics (Do not include any patient specific information):	Age:	
	Gender:	
	Target Disease/Population:	
7 Research Setting:	Single-site or Multi-site:	

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	Country of Primary Site: Additional Countries:
8 Estimated Duration of Study	Months:

Personnel

9. Principal Investigator Information: ATTACH CURRICULUM VITAE	Name:		
	Title:		
	Institution:		
	Address:		
	City:		
	State/Province:		Post/Zip Code:
	Country:		
	Phone:		
	Fax:		
	E-mail:		

10. Mylan Contact: (If applicable)	Name:		
	Country:		
	Phone:		
	Email:		