

Investigator Initiated Trial Concept Form

Complete as many fields as possible

Submitted by (Name):	
Date Submitted:	dd/mm/yyyy
1. Request Type: (Check all that apply)	<input type="checkbox"/> Drug <input type="checkbox"/> Financial Support
1a. Investigational Mylan Drug & Quantity (If applicable):	Active
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:	
	Country of Primary Site:	
	Additional Countries:	

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8 Estimated Duration of Study	Months:

Personnel

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

10. Mylan Contact: <small>(If applicable)</small>	Name:	
	Country:	
	Phone:	
	Email:	