

Name & contact information	Principal Investigator		Alternate Contact
Institution Name & address			
Institution Type – SELECT ONE	<input type="checkbox"/> Academic Medical Center / University	<input type="checkbox"/> Charitable / Non-profit Organization	<input type="checkbox"/> Clinic
	<input type="checkbox"/> Government Agency	<input type="checkbox"/> Hospital	<input type="checkbox"/> Other
Study Title			
Therapeutic Area	<input type="checkbox"/> Oncology <input type="checkbox"/> Rare Genetic Disease <input type="checkbox"/> Other, specify:		
Disease			
Scientific Basis/Rationale			
Study Classification (ie, endpoint) – SELECT ONE	<input type="checkbox"/> Case Reports	<input type="checkbox"/> Dose Finding	<input type="checkbox"/> Drug-drug Interaction
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Epidemiology	<input type="checkbox"/> Meta-analysis
	<input type="checkbox"/> Natural History	<input type="checkbox"/> Healthy Volunteer	<input type="checkbox"/> Observational
	<input type="checkbox"/> Pharmacoeconomic	<input type="checkbox"/> Pharmacokinetic	<input type="checkbox"/> PK/PD
	<input type="checkbox"/> Preclinical	<input type="checkbox"/> Quality of Life	<input type="checkbox"/> Registry
	<input type="checkbox"/> Safety & Tolerability	<input type="checkbox"/> Safety/Efficacy	<input type="checkbox"/> Screening
	<input type="checkbox"/> Translational / Biomarker		
Study Objective(s)			
Inclusion Criteria			
Exclusion Criteria			

<b>Primary and secondary endpoints</b>	
<b>Treatment Regimen, Dosing, and Schedule</b>	
<b>Study Phase</b>	<input type="checkbox"/> Phase I <input type="checkbox"/> Phase I/II <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Other, specify: _____
<b>Number of Sites</b>	Enter number or range: _____
<b>Statistical analysis plan / Sample Size Justification</b>	
<b>Agios contact (if any)</b>	

<b>STUDY DESIGN DETAILS (Optional but preferred)</b>	
<b>Study Type</b>	<input type="checkbox"/> Interventional <input type="checkbox"/> Observational
<b>Interventional studies only: Intervention Model</b>	<input type="checkbox"/> Single Group <input type="checkbox"/> Parallel <input type="checkbox"/> Cross-over <input type="checkbox"/> Factorial
<b>Interventional studies only: Allocation</b>	<input type="checkbox"/> N/A (single arm) <input type="checkbox"/> Non-randomized <input type="checkbox"/> Randomized
<b>Interventional studies only: Masking</b>	<input type="checkbox"/> Open label <input type="checkbox"/> Single blind, specify blind: _____ <input type="checkbox"/> Double blind
<b>Observational studies only: Observational Design</b>	<input type="checkbox"/> Cohort <input type="checkbox"/> Case-control <input type="checkbox"/> Case only <input type="checkbox"/> Case-crossover <input type="checkbox"/> Ecologic or community study <input type="checkbox"/> Family-based <input type="checkbox"/> Other, specify: _____
<b>Observational studies only: Time Perspective</b>	<input type="checkbox"/> Prospective <input type="checkbox"/> Retrospective <input type="checkbox"/> Cross-sectional <input type="checkbox"/> Other, specify: _____

<b>STUDY ENROLLMENT</b>	
<b>Total # of Patients to be enrolled</b>	
<b># of Patients to be treated</b>	
<b># of Patients to complete treatment</b>	
<b># of months to enroll all patients</b> (First Patient In to Last Patient In)	
<b># of months for 1 patient to complete the study</b> (First Visit to Last Visit for 1 patient)	
<b>Planned First Patient In (FPI) Date</b>	



# Investigator Sponsored Trial (IST) Concept Worksheet

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Are you involved in a competing study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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REGULATORY INFORMATION	
Does this require Regulatory Approval (e.g. IND or equivalent?)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Do you plan to cross reference an Agios IND?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Is the study already in progress?	<input type="checkbox"/> No <input type="checkbox"/> Yes, provide additional information: _____

STUDY SUPPORT	
Type of support	<input type="checkbox"/> Funding <input type="checkbox"/> Product <input type="checkbox"/> Funding and Product
Agios Products Requested	<input type="checkbox"/> AG-120 <input type="checkbox"/> AG-348
Will you be using multiple products?	<input type="checkbox"/> No <input type="checkbox"/> Yes, specify other products: _____
Are you authorized to destroy investigational drug locally?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Will you request support from other entities?	<input type="checkbox"/> No <input type="checkbox"/> Yes, specify: _____
Total Budget (please attach budget)	_____ Specify currency: _____
Overhead %	_____
Funds Requested from Agios	_____ Specify currency: _____

Additional Comments:
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**This worksheet is to facilitate your concept proposal entry into Vision Tracker  
Please refer to the IST guideline document**