

Scientific Review and Monitoring Committee
Low Accrual Corrective Action Plan

Protocol ID:

Study Title:

PI:

Total Accrual:

Review Period: to

Period Accrual:

LAG: AAG:

CRO Feasibility Review

PATIENT POPULATION & ENROLLMENT		COMMENTS
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the disease population for your trial considered a rare disease? <i>(A rare cancer as one with an incidence of ≤ 3 newly diagnosed persons out of a population of 100,000 persons per year ($\leq 3/100,000$ per year).)</i>	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this considered a targeted therapy trial? <i>NCI definition can be referenced here:</i> http://www.cancer.gov/cancertopics/factsheet/Therapy/targeted	
CY <input type="checkbox"/> FY <input type="checkbox"/>	How many patients with this diagnosis were seen at UF during the last CY or FY? <i>Please attach a copy of the data source with this form.</i>	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Are the accrual goals reasonable compared to the number of patients with this diagnosis seen at UF? <i>In general, we should have evidence that UF sees 3X the AAG for non-rare disease studies and at least 2X the AAG for rare disease studies.</i>	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Are there any targeted recruitment strategies to consider? <i>If yes, please comment. This could include IT solutions, education, patient directed advertising, etc.</i>	

Additional Comments

Signature of Feasibility Reviewer

PI/DSG Corrective Action Plan

What is the root cause for the low accrual?

Please describe the screening efforts to date

Please describe your strategy for increasing accrual

Please describe how (by whom and how often) accruals will be monitored if a probationary extension is granted by SRMC

Signature of PI:

Signature of DSG Leader: