

## PROTOCOL SYNOPSIS TEMPLATE

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TITLE	
STUDY DESIGN	
INDICATION/TARGET POPULATION	
INVESTIGATIONAL PRODUCT(S)	
RATIONALE	
OBJECTIVES	Primary objective

	Secondary objectives
	Exploratory objectives
NUMBER OF SITES	
NUMBER OF PATIENTS	
DURATION OF STUDY AND FOLLOW-UP PERIOD	
STUDY OVERVIEW	
INCLUSION CRITERIA	

CONFIDENTIAL

EXCLUSION CRITERIA	
ENDPOINTS	
SAFETY CONSIDERATIONS	
STATISTICAL CONSIDERATIONS	

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