

2017													2018	
	January	February	March	April	May	June	July	August	September	October	November	December	January	
Study Milestones			Database Freeze		Key Stats Available			Clinical Trial Report Available						
Trial Master File		TMF Cross functional Quality Review						TMF QA Quality AUDIT	Audit findings resolution					
Mock Inspection	GMP audits & data integrity assessment of Manufacturing Sites					GMP Mock inspections of Manufacturing Sites		GCP Mock Inspection Training		GCP Mock Inspection				
NDA/BLA Submission Planning											NDA/BLA FDA Submission			
Inspection Planning							Sponsor's Clinical Site QA Audits				FDA Site Inspections (+30d post submission)	FDA Inspection		
Ongoing Cross Functional Inspection Readiness Preparation	<p>Inspection Readiness is a continuous process from DAY 1</p> <p>*there should be NO FIRE DRILLS needed</p> <p>*maintain 100% compliance with the SOPs</p> <p>*every company should have relevant SOP/working instructions for the IR</p> 													