Sponsor/Sponsor-Investigator (SI) – Study Roles and Responsibilities

Document Version #:

Study Title:	
Protocol No. :	
Version No. :	

Role	Name, Title, and Organization	Signature and Date
Checklist Preparation		
Study Sponsor or SI		

Study Team

Role	Assigned Personnel
Sponsor/SI	
Medical Monitor	
Study Project Management (external)	
CTN Project Management	
CTN Regulatory Affairs	Dana Nohynek
CTN Data Management	

Role	Assigned Personnel
CTN Programming	
CTN Research Assistant	
CTN Communications	
Statistics	
Other (specify)	

Summary of Responsibilities:

[Note to template: There should only be 1 party assigned to an activity/task per line. If the activity/task is shared activity/task should be separated in lower level activities/tasks so that assignment is clear. For any activities/tasks that don't apply, list n/a under Sponsor/SI]

Activities/Tasks	Sponsor/SI	CTN	Comments
Financial Management			
CTN/Sponsor or SI Contract			
Other Contracts			
Budget Management			
Funding			
Pass-through Costs			
Study Start Up			
Protocol Development			
Informed Consent Form(s) Template Development			

Activities/Tasks	Sponsor/SI	CTN	Comments
Regulatory Agenc(ies) Submission(s) and Updates			
Clinical Trial Registration and Updates			
Study Management			
Site Selection			
Main Point of Contact with Sites			
Site Management			
Site Initiation/Training			
Study Drug			
- Supply			
- Labelling			
- Management			
- Release			
Study Supplies			
Study Manual(s) and Materials Development			
Trial Master File			
- Set-up			
- Maintenance			
- Archiving			
Monitoring Plan and Execution			
Serious Adverse Event Reporting			
- Regulatory Agenc(ies)			
- Site investigators / study sites			

Activities/Tasks	Sponsor/SI	CTN	Comments
Protocol Deviation Management			
Communications/Community Awareness			
Vendor Management			
Archiving			
Auditing (if applicable)			
Data Management			
Data Management Plan Preparation			
Case Report Form Development			
Database Set-up			
Randomization System Development			
Data Validation Plan Preparation			
Query Generation and Follow-up			
Statistics			
Randomization and Blinding Design			
Statistical Analysis Plan Preparation			
Data and Safety Monitoring Committee Management			
Interim Analysis			
Final Analysis			
Final Report			
Other (e.g., publications)			