



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

**Document Version #:**

<b>Study Title:</b>	
<b>Protocol No. :</b>	
<b>Version No. :</b>	

<b>Role</b>	<b>Name, Title, and Organization</b>	<b>Signature and Date</b>
Checklist Preparation		
Study Sponsor or SI		

### Study Team

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

Document Version No.: [insert]  
Study Protocol No: [insert]



Role	Assigned Personnel
CTN Programming	
CTN Research Assistant	
CTN Communications	
Statistics	
<b>Other (specify)</b>	

**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
<b>Financial Management</b>			
CTN/Sponsor or SI Contract			
Other Contracts			
Budget Management			
Funding			
Pass-through Costs			
<b>Study Start Up</b>			
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			
<b>Study Management</b>			
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)			
<b>Data Management</b>			
Data Management Plan Preparation			
Case Report Form Development			
Database Set-up			
Randomization System Development			
Data Validation Plan Preparation			
Query Generation and Follow-up			
<b>Statistics</b>			
Randomization and Blinding Design			
Statistical Analysis Plan Preparation			
Data and Safety Monitoring Committee Management			
Interim Analysis			
Final Analysis			
Final Report			
<b>Other (e.g., publications)</b>			