

# The Site Council

## Solution Worksheet

Problem:	Deficient protocols cause amendments and delays	ID #:	001
Area:	Study design	Version:	002
Authors:	Nicole Stansbury, Norman Goldfarb	Date:	14 MAR 2026
Frequency:	<input type="checkbox"/> Occasionally <input type="checkbox"/> Somewhat Often <input type="checkbox"/> Moderately Often <input type="checkbox"/> Very Often <input type="checkbox"/> Always		
Who suffers:	<input type="checkbox"/> Sponsor <input type="checkbox"/> CRO <input type="checkbox"/> Site		
Cost in time:	A typical protocol amendment of this type takes six weeks to implement, plus the previous unproductive time.		
Cost in money:	A protocol amendment of this type typically incurs the study's running costs during the amendment process, as well as the cost of previously unproductive time.		
<b>Circumstances, Symptoms &amp; Root Causes</b>			
1.	CSR	SCI	The study design process is often behind schedule.
2.	CSR	SCI	Neither the study sponsor's nor the CRO's personnel have the necessary experience.
3.	CSR	SCI	Protocol execution is inherently unpredictable.
4.	CSR	SCI	Study sponsors design protocols without adequate expertise on the practicalities of study conduct.
5.	CSR	SCI	Study sponsors lack access to the necessary expertise.
6.	CSR	SCI	Study sponsors may not know they lack the necessary expertise.
4.	CSR	SCI	Management may overrule those with the necessary expertise.
7.	CSR	SCI	Management may not want to take the time to obtain input from experts.
8.	CSR	SCI	
<b>Metrics &amp; Targets</b>			
1.	Reduce the frequency of avoidable protocol amendments within three years.		
2.	Reduce the time and money lost to avoidable protocol amendments by 50% within three years.		
3.			
<b>Solutions</b>			
1.	SML	Establish a study design process that incorporates the necessary operational expertise.	
2.	SML	Obtain the necessary expertise from a consultant, current site relationships, or a Site Council KPA.	
3.	SML		
4.	SML		
<b>Comments</b>			

Circumstance, **S**ymptom, **R**oot Cause | **S**ponsor, **C**RO, **I**nvestigative Site | **S**hort Term, **M**edium Term, **L**ong Term