v. May 2014

GCIG Harmonization Committee

Checklist of actions for New Countries [Trial Name]

Country, Participating Group, PI		**Date Activated**	

Action	**Documents sent** **Tick when completed** **Specify date if known (dd-mon-yyyy)**	**Document Received** **Tick when completed** **Specify date if known (dd-mon-yyyy)**	**Document verified and approved** **Tick when completed** **Specify date if known (dd-mon-yyyy)**
GCIG Participating Group Criteria for Joining [Trial name]			
Main Documents for Translation and Back Translation			
Protocol (Back Translation: Specify which sections of the protocol require translating)			
Patient Information Sheet			
Informed Consent			
Clinical Management Guidelines			
Local insurance certificate			
Other documents as applicable			
GCIG Intergroup Agreement			
Clinical Research Forms			
CRFs			
QoL s / PROs versions in local language [list instruments and questionnaires]			
Group Specific Appendix (inc. details of randomisation)			

Regulatory and Ethics Approvals			
Regulatory Approval			
Country Ethics Approval			
Ministry of Health Approval (if necessary)			
Local ethics approval at Site 1:			
Local ethics approval at Site 2:			
Local ethics approval at Site 3:			
REPEAT FOR EACH SITE **Site selection**			
Site 1			
Site 2			
Site 3			
REPEAT FOR EACH SITE **Site accreditation form / Investigator Agreement**			
Site 1			
Site 2			
Site 3			
REPEAT FOR EACH SITE **Site Approval Form**			
Site 1			
Site 2			
Site 3			
Other			

Approver Name and Function		**Signature**	**Date**
SITE 1 Requirements complete (above) Site Activation Confirmation letter sent			
SITE 2 Requirements complete (above) Site Activation Confirmation letter sent			
SITE 3 Requirements complete (above) Site Activation Confirmation letter sent			