

Country Feasibility Questionnaire



Protocol ID	TRIDENT	Country	
Person Completing Questionnaire			
Signature		Date	
Institution		Role	

Question		Response
1	Stroke Care	
1.1	The study population for this study are patients with a history of intracerebral haemorrhage up to 6 months prior. Is this population accessible through your institution, or through referral mechanisms?	
1.2	Please briefly describe the usual patient pathway for care of intracerebral haemorrhage in your country, i.e. referral systems, usual care giver and hospital setting where this is given, with a focus on intracerebral haemorrhage.	
1.3	Please describe the usual standard of care for patients following intracerebral haemorrhage in your country (e.g. blood pressure-lowering medications, rehabilitation). Please indicate any concerns regarding standard of care in your country.	
2	Protocol	
2.1	Do you think there are any inclusion criteria in this synopsis/ protocol that may impact the study conduct in your country? (e.g. use of polypill, pregnancy testing of women of child-bearing potential, more specifically, questions pertaining to this exclusion)	
2.2	Are the tests/assessments to be conducted in this study part of usual practice / able to be conducted in your country? (e.g. smRS, MoCA, BMET, EQ-5D)	





3	Investigational Medicinal Product (IMP)	
3.1	This is a placebo-controlled study; will that be an issue in your country?	
3.2	Are telmisartan 20mg, amlodipine 2.5mg and indapamide 1.25mg marketed in your country?	
3.3	Do you have access to a country regulatory expert who can approve the IMP labels for your country?	
4	Ethics, Regulatory & IMP Importation	
4.1	Do you consider the trial needs regulatory approval in your country?	
	If yes, how long will this take?	
	Any other comments?	
4.2	Are there any specific regulatory requirements that should be taken into account in order to obtain study approval?	
	What are the costs involved?	
4.3	Do you anticipate any Regulatory Body or IRB/EC issues with this protocol in your country?	
4.4	Do you anticipate any issues with importing IMP into the country?	
	What are the costs involved e.g. customs, taxes?	
	What are the timelines for importation procedures?	





4.5	What are the trial insurance requirements for your country?	
5	Participant & Enrolment Feasibility	
5.1	How many sites do you think could potentially participate from your country?	
5.1	How many patients do you think each site could contribute?	
5.3	How long does the recruitment period need to be?	
5.4	Are you aware of any current or planned competitive trials that may impact the running of this study in this country?	
5.5	Do you anticipate any challenges associated with enrolling the required subjects in your country?	
5.6	Please provide recommendations that might help study enrolment in your country.	
6	Networks	
6.1	How are you connected to the other specialists in the region – e.g. through societies, professional forums etc. What are the main meeting opportunities through these societies in the region where most clinicians treating these patients would go?	





6.2	Are there any other key investigators in your country with a specific interest in intracerebral haemorrhage and/or treatment of stroke with blood pressure- lowering medications that you recommend we speak to?	
6.3	Are you able to recommend or comment on potential sites for the study?	