

Site Feasibility Capacity Study

Date Questionnaire was completed:	(dd/mm/yyyy)	Name of person completing questionnaire	
		Role of person	
Site Name			
Department			

Principal Investigator's			
Principal Investigator's Title			
Principal Investigator Name			
Principal Investigator's Contact Details	Postal Address: _____		Email: _____

	Phone: _____		
	Fax: _____		
Does the Principal Investigator have previous experience conducting any clinical trials?	☐ Yes ☐ No		
How many trials is the Principal Investigator presently involved?			
Does the Principal Investigator have a current GCP Certificate	☐ Yes, please indicate month and year of expiration /		
	☐ No		

Is the Principal Investigator the main contact during set up	☐ Yes										
	☐ No, please indicate details										
	<table border="1"> <tr> <td>Title</td> <td></td> </tr> <tr> <td>Name</td> <td></td> </tr> <tr> <td>Address</td> <td></td> </tr> <tr> <td>Telephone</td> <td></td> </tr> <tr> <td>e-mail address</td> <td></td> </tr> </table>	Title		Name		Address		Telephone		e-mail address	
	Title										
	Name										
	Address										
Telephone											
e-mail address											

Study Personnel/ GCP

Is current staffing adequate to conduct the trial (at least 2 fully trained staff with 1 year minimum experience)?	☐ Yes ☐ No												
Indicate the number of staff that will be assigned to this study	<table border="1"> <tr> <td></td> <td></td> </tr> </table>												
Can the site accommodate 1 day per week dedicated to study related activities?	☐ Yes ☐ No												
Can the site assign 1 clinical staff member 1 day per week dedicated to study related activities?	☐ Yes ☐ No												
Indicate all job titles of staff that will be working on this protocol (tick ✓ all that applies)	<table> <tr> <td>☐ SpR</td> <td>☐ Nurse - Research</td> </tr> <tr> <td>☐ Nurse - Colorectal</td> <td>☐ Consultant</td> </tr> <tr> <td>☐ Administrator</td> <td>☐ Medical Student</td> </tr> <tr> <td>☐ Consultant Specialist Nurse</td> <td>☐ Physiotherapist</td> </tr> <tr> <td>☐ Radiographer</td> <td>☐ Healthcare Assistant</td> </tr> <tr> <td>☐ Scientist</td> <td>☐ Research Fellow</td> </tr> </table>	☐ SpR	☐ Nurse - Research	☐ Nurse - Colorectal	☐ Consultant	☐ Administrator	☐ Medical Student	☐ Consultant Specialist Nurse	☐ Physiotherapist	☐ Radiographer	☐ Healthcare Assistant	☐ Scientist	☐ Research Fellow
☐ SpR	☐ Nurse - Research												
☐ Nurse - Colorectal	☐ Consultant												
☐ Administrator	☐ Medical Student												
☐ Consultant Specialist Nurse	☐ Physiotherapist												
☐ Radiographer	☐ Healthcare Assistant												
☐ Scientist	☐ Research Fellow												

Study Personnel/ GCP

Please indicate the number of staff that require GCP Training	
Is there resource available to ensure GCP training is maintained for all site staff for the 5 year programme duration?	☐ Yes ☐ No, if no what is being done about this?
Indicate the total FTE that will be assigned to this protocol each week	.

Recruitment and Enrolment

Are there any competing trials ongoing?	☐ Yes ☐ No
Indicate the number of competing Trials	In/Total
Having reviewed the protocol; Is there sufficient number of eligible participants for this trial?	☐ Yes ☐ No
Estimated recruitment target per month	Per/Month
Do you have a recruitment plan?	☐ Yes ☐ NO
Indicate your realistic Total enrolment target	
In months, indicate the time needed to meet this recruitment target (<i>total patients</i>)	

Recruitment and Enrolment

Please indicate preferred method (s) for screening and recruiting participants for this protocol <i>Tick (✓) all that applies</i>	☐ Database ☐ Referrals – Primary Care ☐ Referrals – Secondary ☐ Referrals – Tertiary ☐ Routine Clinic List ☐ Trust Website ☐ Social Media (Facebook, twitter) ☐ Trial website ☐ Patient Support Group ☐ Clinic Advertisement Poster/Pamphlet ☐ Advertisement Newspaper advert ☐ Patient Partnership Group ☐ Local Newspaper
Does your clinical area have patient information monitors	☐ Yes ☐ No
If your clinical area has patient information monitors, can advertisement space be purchased/allocated	☐ No do not have monitor ☐ Yes, but advertisement space cannot be purchased ☐ Yes, advertisement space can be purchased, indicate contact details of vendor:
Can posters/pamphlets be placed in the clinical area?	☐ Yes ☐ No
Does the Consent Form, Patient Information Sheet and Adverts need to be produced in other languages?	☐ Yes, if yes, indicate language/s? ☐ No
Indicate any potential barrier (s) to meeting recruitment targets	

Inquires/Concerns (If additional space is needed, please use the further comment box at the end of this form)

Does the research team have ethical concerns	☐ None ☐ Please indicate concern
Does the research team have safety concern	☐ None ☐ Please indicate concern
Are the procedures documented in the protocol consistent with the site's standards of care?	☐ Yes ☐ No, please list procedure and indicate the difference

Facilities and Equipment:

Does your site have secured storage for study records?	☐ Yes ☐ No ☐ Not yet – expected date:
Are archiving facilities available to the site	☐ Yes ☐ No ☐ Not yet, expected date:
Does the site have the capability to perform abdominal x-ray at a 3 day interval?	☐ Yes ☐ No ☐ Not yet, expected date:
Does the site have the capability to perform abdominal x-ray at a 5 day interval?	☐ Yes ☐ No ☐ Not yet, expected date:
Does your site have the capability to schedule and perform anorectal physiology investigation within a 5 week window?	☐ Yes ☐ No ☐ Not yet, expected date:

Study Related Equipment (Tick (v) all that apply)

Does your site have the following equipment and capability? <i>(tick v all that applies)</i>	☐ Copy Machine ☐ Examination Room ☐ Examining Couch ☐ Electrical ☐ Stationary ☐ K-Y Gel ☐ Sandhill HRM catheter (including balloons, software, calibration kit, isolation transformer) ☐ Porridge + Water + Barium	☐ Fax Machine ☐ Scanner ☐ 17 inch laptop ☐ 60 cc syringe ☐ Water Supply ☐ Urine Pregnancy Dipstick ☐ Local lab for Serum Pregnancy testing ☐ Multiple shape Transit Markers ☐ Medium 3 Shelve Trolley ☐ Portable Commode, maximum weight = _____
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Study Related Equipment (Tick (v) all that apply)

	☐ Glycerine Suppositories – unit stock item ☐ Lever Files A-4 (6) ☐ 3 way IV taps ☐ Internet Access ☐ Radio-opaque markers (3 types) ☐ Ballooned Cather ☐ Manufactured Device ☐ Site created device ☐ Latex Free HRM catheter balloons ☐ Surgical Tape ☐ Mepore Tape ☐ Surgical Mask ☐ Latex Gloves	☐ Yoga Blocks /wooden blocks Indicate Dimensions : _____ ☐ Telephone extension ☐ Secure Cabinet ☐ Fluoroscopic Proctogram ☐ Disposable proctoscope ☐ Radiolucent commode ☐ X-ray Department IR(ME)R certificate ☐ Infection Prevention and control protocol for cleaning invasive catheter with lumens ☐ Sluices ☐ Eye guards ☐ Non- Latex Gloves ☐ Answering Machine or Answer phone
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Electronic Data Reporting

Does the trial staff have experience with electronic data management systems? E.g. OpenClinica	☐ Yes ☐ No ☐ Unsure
Does your site have internet access?	☐ Yes ☐ No, IT security can grant access ☐ No, there is no internet access facilities
Indicate the computer Web Browser that is available on the local computers (tick v all that applies)	☐ Do not have a local computer ☐ Unknown ☐ Internet Explorer 8 ☐ Chrome ☐ Internet Explorer 7 ☐ Firefox versions greater than 3.5. ☐ Need to contact IT to have Internet Explorer or Firefox install
Does the site have the capability to upload documentation to centralised website?	☐ Yes ☐ NO ☐ Not sure
Does the site have sufficient resource to collect data, conduct	☐ Yes

Electronic Data Reporting	
data entry and resolve data queries?	☐ No ☐ Not yet ☐ Comments:
What is the preferred method of data management?	☐ Routine Data to Paper CRF with centralised data entry ☐ Routine data to Electronic eCRF with data entry at site. ☐ Electronic patient diary and questionnaires ☐ Paper patient diaries and questionnaires ☐ Other – describe e.g. mix capturing of data

Monitoring/Audit:	
Is the site willing to allow the PCTU QA manager and/or trial monitor access to all medical records (paper or electronic) and source documents to ensure compliance with good clinical practice and adherence to the protocol?	☐ Yes, ☐ No ☐ Access to electronic records not available ☐ Access to electronic records needs to be authorized and set up ☐ Access to electronic and paper data needs to be authorized and set up
Is the site happy to undertake central monitoring	☐ Yes ☐ No
Does the site have facilities where monitoring visits can be conducted?	☐ Yes ☐ No
Is the site staff willing to maintain site file, Study logs and study documentation?	☐ Yes ☐ No ☐ Staff not yet identified
Site staff willing to return copies of essential documents to central team as required?	☐ Yes ☐ No ☐ Staff not yet identified

Local Contacts			
Provide the details of R&D link person	Title		
	Name		
	Address		
	Telephone		
	e-mail address		
Provide the details GI Physiology Radiographer – X-ray	Title		
	Name		
	Address		
	Telephone		
	e-mail address		
Provide the details GI Physiology Radiographer - ARP	Title		
	Name		
	Address		
	Telephone		
	e-mail address		

Any Further Comments?