The Royal Marsden Hospital NHS Foundation Trust, Gastrointestinal Trials Unit

Watch and Wait: Site feasibility checklist

1. Site and staff details

Site principal investigator:	
Site name:	
Site address:	
Name of Site study coordinator (responsible for obtaining local study approval and ongoing study administration):	
Designation:	
Telephone No.	
Fax No.	
Email address:	
Address:	
Site R&D Contact Name:	
Designation:	
Telephone No.	
Fax No.	
Email address:	
Address:	

- Has the site participated in clinical trials in rectal cancer?
  Yes/No
  -If yes, please give study names:

- Have staff participated in studies in this tumour type previously? Yes/No
  -If so, approximately how many? _____

- Are investigators and research staff at the site familiar with conduct of clinical trials according to the principles of good clinical practice and United Kingdom law (SI 1031 of 2004, as amended by SI 1928 of 2006)?
  Yes/No

- Do all investigators and research staff at the site who will be involved with the study have current GCP training, or are any staff without current GCP training booked to attend a GCP course?
  Yes/No

- Will a dedicated research nurse be assigned to this study? Yes/No
  -If yes, please provide name(s):

- Can a site log be maintained? Yes/No

- Who will take patient consent?

Name	Position

- Who will perform the study-related patient checks as detailed in the schedule of events? i.e. patient review, toxicity review and biochemical parameters?

Name	Position

- Who will organise the investigational studies (MRI, PET-CT and flexible sigmoidoscopy?

- Who will organise the preparation of images to come to the Royal Marsden for central review at the Royal Marsden?

Name	Position

- Who will coordinate patient care on receipt of central imaging review?

Name	Position

2. Patients and eligibility

- How many trials targeting the same patient population which may potentially compete with this trial are there running at this site, either at present or in the foreseeable future? _____

- Considering the study eligibility criteria, any competing trials and patient numbers, how many patients will this site enrol:

  - Per month: _____

  - In total for the duration of the trial (24 months): _____

- Who is responsible for confirming that patient eligibility is accurate?

Name	Position

3. Study procedures

- **Study-related investigations including staging and assessment of tumour response:** Are the following investigations, required by the trial, available at this site to the standard required by the study protocol?

  - CT thorax/abdomen/pelvis Yes/No
  - Pelvic MRI Yes/No
  - PET-CT Yes/No
  - Flexible Sigmoidoscopy Yes/No

- Can these be performed at the frequency requested in the schedule of events? Yes/No
- Who will assess tumour responses?

Name	Position	Are they experienced and familiar with RECIST?

- **Histopathology:**

  - Is there a named pathologist to be involved with this study? Yes/No
    -If yes, please name:

    _____

  -Can CRFs be filled in by the histopathologist if required? Yes/No

- **Collection /Storage of Human Tissue:**

  - Does the site have experience in collection/storage of human tissue for translational components of trials? Yes/No
  - Is there a -20 0C freezer? Yes/No
  - If yes who is responsible for maintaining it?

    _____

4. Data return:

- Please confirm that the site has adequate staff resources to ensure timely completion of case report forms, and prompt return of data and responses to data queries: Yes/No

- Who will complete and send in the CRFs?

  _____

- Is there a fax machine? Yes/No
  -who maintains it?

  _____

- Who will sign off Serious Adverse Event Forms?

Name	Position

- Please confirm that site research staff will be able to assist with monitoring procedures required by the study Sponsor: Yes/No

- Can all case report forms be sent at the end of the study back to the Sponsor for archiving? Yes/No

5. Standard operating procedures (SOPs): Please indicate if the site has SOPs or Guidance notes for the following:

- Obtaining local regulatory and ethical approval: Yes/No
- Maintenance of study site file and study documentation: Yes/No
- Informed consent for participation in clinical trials: Yes/No

Can copies of these SOPs be provided to the Sponsor of this study? Yes/No

I confirm that as Principal Investigator, I have reviewed the study protocol and that I agree with the responses to the above questions:

Signature of PI: _____

Name of PI: _____Date: _____