The ROYAL MARSDEN
NHS Foundation Trust

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# Site files

Investigator brochure

Protocol Amendments

Patient Information Sheets & Consent Forms

Team Contact details

Financial Disclosures

Ethical Approval

Clinical Trial Agreements (Financial & Indemnity)

Regulatory Approval

Signature Log

Site Staff CV’s

- Laboratory Normal Ranges
- Pharmacy Information
- Trial initiation monitoring report
- Signed PIS/Consent forms
- Serious Adverse Events
- Correspondence
- Case Report Form
- Subject screening log/Enrolment
- Pharmacy Information
- Completed subject identification
- ARSAC licence

# Examples of Trial Master File

Microsoft Office
Word 2007 Document

Microsoft Word
Document

# How will you implement the Protocol

- Background of IMP
- Consider known side effects ( later phases trials)
- Pre-Clinical data ( early phase)
- Mechanism of IMP
- Clinical Trial Management Group (local)

# Drug administration

- Starting dose
- Dosing administration guidelines
- Oral (Fed/Fasted,diaries,drug compliance….)

intravenous ( light sensitive, filter, expiry time of drug…..)

# Inclusion and Exclusion Criteria

- Specific mutation
- Previous lines of treatment
- Tumour specific
- Biopsies (fresh or archival)

# Schedule of Assessments

- How Feasible are the assessment
- How will you manage assessments
- What it means for the patients
- Timelines (recruitment,awating patient review start next cohort)
- Additional costs

# Quality Control

- Training for all staff ( CTO, DM, Lab manager,DRs…)
- Who is responsible for creating care plan/work book
- Cross checking to ensure all protocol data are captured.
- Delegation logs
- SOP

# Trial Folder With Sections

- Labelling A4 Folder
- Blood Request forms
- Patient contact details
- Nurses Guide
- Care Plan
- Drug Compliance
- Physical Exam Forms
- ECGs
- Trial Specific Tests ( echo, lung function)
- Eligibility & Registration Forms
- Consent forms

# Management of side effects

- Specific algorithm for treatment e.g.
- Rash
- Hyperglycaemia
- Hypertension

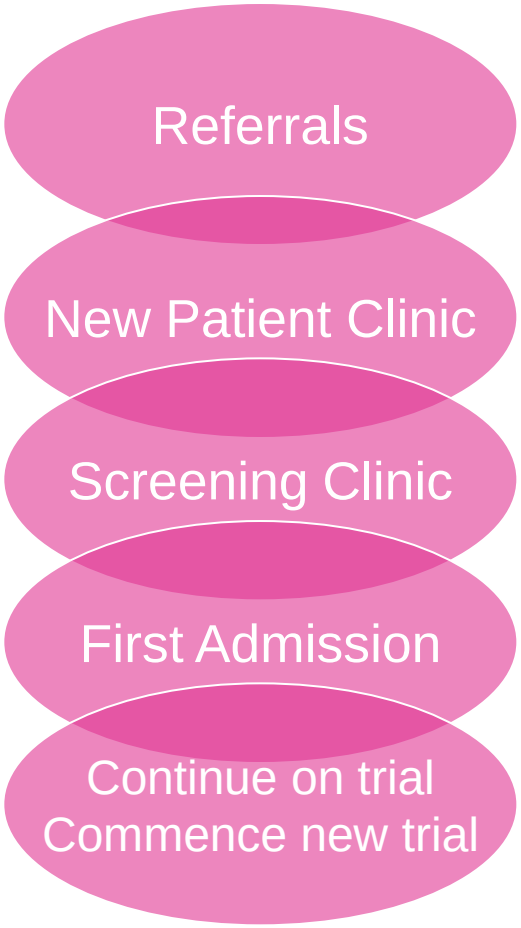
Contact

In/out of hours ( on call)

Help files

# Questions

# Screening & Recruitment




- New referrals all seen by a consultant
- The concept of Phase I trials are discussed and a history and general assessment taken (eligibility?)
- Patients are allocated to a trial
- Nurse led screening clinic
- Admitted to the ward for cycle 1 of treatment and intensive PK collection
- Follow up clinic
- New Trial

# Patient Recruitment

Feasibility of studies

Population

Site selection

Relationships within other tumour groups / other sites/ pharma companies

- Reputation (P.I ; site; data )
- Resources
- Monitoring
- Patient retention
- Site support
- Local & national metrics

# Screening

- Patient Information sheet ( PPI involvement)
- Risks/benefits ( trial)
- Windows of opportunity patients with advanced disease ( early phase trials)
- Target population

# Assessing patients


Adobe Acrobat Document

Microsoft Word Document

- Questions

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