Study set-up

Budget & Contracts

Set up project code
Staff planner and budget meeting
Submit protocol to contract/finance teams
Radiology Approval
Complete NHS Trials Request Questionnaire
Local NHS approval if required

Protocol

Draft protocol
Develop protocol
Finalise protocol
Create lay summary

Staff allocation

Notify of study set up:
- Lab/team
- IT
- Admin department

Identify:
- Lead Research Nurse
- Laboratory Lead
- Clinical Trial Support Office
- Other key staff (including statistician, QA Manager, Data Manager)

Meetings:
- Study team start up meeting
- Schedule regular re-occurring study team meetings
- Investigator's meeting (IM) if applicable

STUDY DOCUMENTS & PLANS

Public and Patient Involvement (PPI) group review
Create list of all required study documents
Draft, review then finalise documents requiring approval
Submit documents for regulatory approval
Draft, review then finalise non-approved documents
Localise approved documents
Statistical Analysis Plan (SAP)
Lab Analysis Plan (LAP)
Data Management Plan (DMP)

Clinical Study Plan (CSP)

QA PLANNING

Risk assessment meeting
Finalise risk assessment
Monitoring Plan
SOP review/identification of new SOPs
Create Green Light Form (GLF)

IT PLANNING & DEVELOPMENT

Electronic case report form (eCRF) and eDiary:

- Identify data fields required
- Approve dataset
- Build
- Test and validate
- Access
- Create eCRF back up

Build and test Access database
Create and test website/booking form

MEDICATION/CHALLENGE PLANNING

Medication supply and ordering
Medication cupboard space
Medication labelling
Unblinded team
Challenge preparation/arrangements
Challenge protocol

RECRUITMENT PLANNING

Recruitment planning meeting
Plan study advertising methods
Create recruitment strategy

REGULATORY & OTHER SUBMISSIONS

Sponsor:

- Draft Integrated Research Application System (IRAS) form
- Funding letter

Submit submission package for Sponsor review
Following Sponsor Review Meeting, address comments.
Re-submit and repeat review until all comments resolved
Finalise submission package
Lock IRAS form and obtain signatures

Insurance:

Division of Responsibilities (Sponsor & CI)
Non-NHS Site Specific Information (SSI) form if required

Department for Environment, Food & Rural Affairs (DEFRA) (if applicable):

DEFRA application
DEFRA acknowledgment and validation
Arrange newspaper advert for newspaper
Contact the Sponsor's Press Office ahead of the advert being printed
DEFRA approval

Research Ethics Committee (REC):

REC submission
REC validation
Submit Non-NHS Site Specific Information (SSI)
REC Meeting/Proportionate Review
Provisional approval
Reply to conditions if required
REC approval

Local GMO approvals (if applicable):

Facility Committee Approval
NHS GMO Approval

Health Research Authority (HRA):

HRA submission
Provisional approval
Reply to conditions
HRA approval

R&D:

Local R&D submission
Other sites R&D submission
Complete submission package (HRA approval letter)
R&D approval

Other Submissions:

Clinical studies database registration
Mailout company agreements

STUDY SPECIFIC TRAINING

Create delegation log
Training matrix
Training tasks issued & completed

Telephone screening training
Consent training
eCRF training
eDiary training
Clinical visit training
Recruitment response training
Admin training
Site Initiation Visit (SIV)/Site Investigator Meeting (SIM)
Sign off delegation log

STUDY PREPARATIONS

Identify any study specific lab supply requirements
Identify any study specific clinical supply requirements
Allocate study drawer/cupboard (blinded/unblinded)
Create and populate Trial Master File (TMF)/Investigative Site File (ISF)
Create study folders
Screening/Participant ID numbers
Print/order paperwork
Create Clinical Research Facility (CRF) packs
Create screening packs
Sample labels
Reimbursements
Tracking spreadsheets
Payment request forms
Raise blanket Purchase Order numbers
Clinical supplies ordered
Lab supplies ordered

GREEN LIGHT CHECK

Sign green light form
Update website to 'Recruitment Open'