Guidance Document:

Table 1.3 Key project/trial management considerations

Project/trial management		
Before	**During**	**End/After**
Communication		
Project team set up	Project meetings and telephone/video conferences	Trial debrief
Project plan/milestones	Progress/status reports	
Communication plan	Dissemination of key information/minutes etc.	
	Changes to trial team	
Documentation		
Prepare trial master file	Maintain trial master file	Complete and archive trial master file
Risk assessment	Review/update/circulate risk assessment	Clinical study report
Key trial documents (for example, protocol, investigator's brochure, subject information sheet/consent forms, accountability records etc.)	Review/update/circulate key trial documents, trial plans, written procedures etc.	
Regulatory green light check	Amendments (including substantiality decision and implementation)	
Trial manuals/plans (for example, pharmacy, laboratory manuals etc.)	Document and circulate any actions and decisions	
Written procedures		
Regulatory/ethical correspondence		
Competent authority authorisation	Substantial amendments	End of trial notification
Favourable research ethics committee opinion	Research ethics committee annual progress reports	Clinical trial summary report submission
	Serious breaches	
	Urgent safety measures	
	Development safety update reports	

Table 1.3 *continued*

Project/trial management		
Before	**During**	**End/After**
	Vendors	
Vendor selection	Oversight	Vendor performance assessment
Contracts and insurance	Review of contracts	
Provision of required documentation	Ensure obligations of all parties being met	
Training	Status updates	
	Visits/audits	
	Management and escalation of issues	
Investigational medicinal product		
Manufacture, packaging and labelling	Ongoing supply	Complete accountability
Qualified person certification	Ongoing accountability	Return/destruction
Randomisation and blinding	Maintenance of blinding	
Release and distribution	Temperature excursions	
Investigational medicinal product dossier/summary of product characteristics	Shelf-life changes	
Investigator site		
Monitoring plan	Routine on-site/central monitoring	Notification of end of recruitment
Monitors assigned	Recruitment updates	Close out
Site selection	Issue identification and escalation	Complete and archive Investigator site file
Initiation and training	Collection of case report form data	
	Data query answering	
	Additional investigator sites initiation and training	
Pharmacovigilance		
Safety plan	Adverse event collection, assessment and reporting	Final reconciliation of safety and clinical databases
	Ongoing safety updates	
	Safety signal detection	

Table 1.3 *continued*

Project/trial management		
Before	**During**	**End/After**
	Pharmacovigilance	
	Data monitoring committee/data safety monitoring board	
	Development safety update reports (DSUR) preparation	
	Reconciliation of safety and clinical databases	
	Data management and analysis	
Case report form design and preparation	Data Entry	Final electronic data transfer
Define major non-compliances	Protocol non-compliance collection and circulation	Protocol non-compliance review for analysis
Database build	Data queries	Final analysis (for example, statistical and pharmacokinetic etc.)
Computer systems validation and validation of application builds	Electronic data transfer	
Data management plan	Interim analyses (including dose escalation)	
Statistical analysis plan		

Version 17 May 2012

The above table was kindly provided by the Medicines and Healthcare Products Regulatory Agency and appropriate permission granted for use by the Research and Development Department, Papworth Hospital NHS Foundation Trust. The table can be found within the Good Clinical Practice Guide (page 42-44) published 2012.