Trial Monitoring Option Checklist

The following tables list some of the ways a trial may be monitored. The checklist is designed for use in conjunction with the Risk Assessment and the Monitoring Procedures document to help researchers develop a monitoring plan.

A. Before the start of patient recruitment

1	**Oversight arrangements**	***Essential / Desirable / Unnecessary / Not Applicable / Alternatives / Comments***
	Trial management group	
	Trial steering committee	
	Independent data monitoring committee	
	Other	
2	**Training and setup**	
	Investigator meeting(s) to review trial and procedures	
	Written assurance from local investigator that setup is complete	
	Site visit to review setup, team understanding of trial procedures etc.	
	Site visit to pharmacy to review setup supplies and procedures	
	Copy of CV of local investigators	
	Other	

B. During the trial

1	**Monitor understanding of/adherence to trial protocol & procedures at sites:**	
	Investigator meeting(s) to review trial protocol and procedures	
	Site visit(s) to review setup, team understanding of trial procedures, check of essential documents etc.	
	Other	
2	**Verification of participant existence**	
	Against clinic records	
	By ONS flagging	
	Other	

3	**Participant consent**	
	Collect signed consent form at coordinating centre	
	Check signed consent form in clinic records	
	Other	

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4	**Participant eligibility**	
	Review eligibility criteria prior to randomisation	
	Check eligibility criteria in clinic records	
	Central review of key investigation results	
	Other	
5	**Trial Supplies**	
	Check drug supply and storage at site	
	Check drug supply by use of drug accountability forms	
	Other	
6	**Trial data**	
	Check case notes for adverse events – accuracy of reports and missing reports	
	Check outcome against clinical records	
	Central review of investigation result	
	Corroborate outcome from routine data (e.g. death/cancer via ONS)	
	Source document verification of other data on CRF	
	Check all relevant source data have been recorded (e.g. concomitant medication, withdrawals)	
	Central data checks – range/consistency	
	Other	

C. At the end of the trial

1	Drug reconciliation by IMP return to coordinating centre or evidence of destruction	
2	Site visit to review drug disposition	
3	Site visit to review archiving of trial documents	
4	Other (*describe)*:	