Specialist Pharmacy Service

N P C T A G
National Pharmacy Clinical Trials Advisory Group

Appendix 2

IMP Risk Assessment

IMP Risk Assessment Form (RAF) for XXXX

The RAF should be reviewed, and amended, if necessary, whenever substantial amendments affecting the IMP are made to the protocol or other key trial documentation.

Study Title (in full):	
Version	
IMP	
IMP class and mode of action	
Date of Completion	xx/xx/xxxx
Completed by	

Review and Revision record

RAF review date	Reason for review	Version of RAF reviewed	Protocol version & date	Outcome of review (revision required /no revision required)	Summary of revisions

Where risks associated with the IMP/intervention are somewhat or markedly higher than the risk of standard care (i.e. Risk Adapted Type B or C trials) details regarding specific risks to body systems and proposed methods for clinical monitoring of such risks should be described below.

Measures and controls where the risk of the intervention is considered to be comparable to standard care (i.e. Risk Adapted Type A) need not be spelled out in detail. However, basic assumptions about routine monitoring and consideration should be summarised as part of the justification provided.

IMP/Intervention	Body system	Potential Toxicities	Mitigation strategies described in the protocol

Outline any other processes that have been put in place to mitigate risks to participant safety

	RISK / HAZARD	Is there a particular risk? Yes/No	**Considerations/Concerns Identified** Provide details of trial-specific considerations/risk concerns	Mitigation Strategies / Adaptations to minimise the hazard: Address all concerns identified Provide details of any risk-adaptations to conventional GCP management strategies employed	Additional monitoring methods required: discuss impact on trial monitoring requirements
1	**SAFETY**				
1.1	Complex dose schedule/ administration regime. Potential risk for dosing errors				
1.2	Contra-indications/cautions in SmPC or IB correlate to protocol (e.g. inclusion/exclusion/withdrawal criteria)				
1.3	Known/anticipated side effects addressed within the protocol				
1.4	May concomitant medications increase the risk? Are drug-drug or drug-food interactions detailed in protocol and PIS?				
1.5	Use of IMP in renal and liver impairment detailed in protocol?				
1.6	Is patient monitoring required during IMP administration?				
1.7	Is patient monitoring required after IMP treatment? Is additional safety monitoring required?				

1.8	Is process for dose escalation, dose reduction, and cessation of IMP detailed in protocol?				
1.9	Does length of treatment with IMP in trial exceed that for current clinical practice?				
1.10	Is an Investigator Brochure required? Is this the current version?				
1.11	Is IMP subject to any safety alerts or require any special measures?				
1.12	Have MHRA drug analysis prints (DAPs) for IMP been reviewed by the research team/CI?				
1.13	Is the CI and the research team experienced with IMP?				
1.14	Has the safety data sheet been reviewed and COSHH concerns addressed?				
1.15	Is Sponsor producing blinding sequence? If not who is? Is this a validated system?				
1.16	Is system for allocation of blinded medication secure and fit for purpose				
1.17	Is unblinding procedure detailed in protocol?				
1.18	Has unblinding process been tested? What was outcome?				

1.19	Are pharmacovigilance systems/procedures detailed in protocol e.g requirements for SAE and SUSAR recording,				
1.20	Are NIMPs/rescue medicines/ challenge agents named in protocol licensed for the indication used?				
1.21	Is rescue medication available in treatment area and/or to take home				
1.22	Will there be a data monitoring committee?				
1.23	Will an annual report be submitted to MHRA?				

2	**IMP MANAGEMENT**				
2.1	Is the supply of IMP from the drug company secure? Is there a contract +/- SLA in place?				
2.2	Is the technical agreement compliant with Sponsor Pharmacy SOPs?				
2.3	Is there a contract in place for clinical trial packaging and labelling activity?				
2.4	Has the manufacturer and clinical trial packaging and labelling facility been audited by Sponsor				

2.5	Will IMP be stored on securely and temperature monitored at central storage location?				
2.6	What are storage instructions for IMP? How will the temperature be controlled and monitored during shipping, storage on site, during transport with patient?				
2.7	Do labels need to include BNF additional labelling requirements?				
2.8	Will additional labelling be required by site? If dosing instructions are not on the IMP label, where is it documented and if held by patient is it sufficient?				
2.9	Is procedure for returned and unused IMP detailed in study documentation?				
2.10	Are compliance calculations required? Whose responsibility is this?				
2.11	Who has responsibility for drug accountability? Does this include shipment receipt, individual dispensing and returns?				
2.12	What is procedure for destruction of returned/expired/unused IMP?				
2.13	Trial oversight. Is frequency for audit of IMP accountability and management set and appropriate in monitoring plan?				

3	**OTHER**				
3.1	Are there any additional treatment costs for drugs?				
3.2	Has continuation of IMP post end of study been considered and clearly communicated to patients?				
3.3	Is it clear to patients that the IMP contains gelatine of animal origin (if this is the case)?				