Feasibility and risk assessment for clinical trials

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Feasibility and Risk Assessment for Clinical Trials

Protocol Name / Number:

Protocol Version:

Date Protocol Received:

REVIEW RECORD

Risk Assessment Completion or Review Date	**Completed by**	**Initial Completion or Reason for Review***	**Protocol version & date**	**Outcome of Review** (Revision required/ no revision required)	**Summary of Revisions**

*Amendments: Protocol or patient information sheet. Any other changes that may alter risk, e.g. significant change in SPC/IB, serious breach, following DMC/interim analysis

IRAS #:		**R&I Ref #:**	
Sponsor		**Monitoring company**	
Principal Investigator Co-Investigator *(if cross-site)*		**Sponsor contact Set-up**	
Trial manager/Trial coordinator		**Location** *Indicate as appropriate*	
Research nurse		**Clinical pharmacist covering the specialist area (incl. Aseptics)** **Date protocol sent**	

PART A - Feasibility Assessment

CTIMP ☐ ATIMP ☐ Early Phase ☐	Non-CTIMP ☐ Clinical investigation or other study of a medical device ☐ Combined trial of an investigational medicinal product and an investigational medical device ☐
Indication /Disease State	
Phase of Study	
Duration of trial for patients (screening period +treatment period + follow up)	
Estimated number of patients	
Recruitment period	

Category / Activity	Can we support (yes / no / NA)	If no, give details / possible actions to be able to support	Outcome
Storage requirements			
Working hours / Out of hours / Urgent dispensing?			
Excess treatment costs?			
Multi-site / One site (consider this for shipments/IXRS)			
Preparation facilities requirements			
Preparation method/process			
Any other issues *e.g. does the trial deviate from MFT policies or procedures.* *Is standard care arm in line with local practice?* *Homecare?* *Funding?*			

APPROVALS	
Date R-Peak task for pharmacy feasibility completed	
Actions to be taken to provide support	
If unable to approve/support trial state reason	

_____ _____ _____

Approved by Printed name Date

PART B – Risk Assessment

Study Population *Indicate as appropriate*	**Adults - Paediatrics**
Trust committee approvals required ☐ Anti-microbial ☐ Early phase ☐ MMC ☐ Genetic Modification Safety Committee ☐ SAGO ☐ NMP ☐ Homecare ☐ Other ☐ Not required	Details *Issues raised* *Date forwarded to relevant committee* Date approval received
Type of trial *(Blinded, open label, etc.)*	
Project type *(commercial , non-commercial, Investigator initiated)*	

INVESTIGATIONAL MEDICINAL PRODUCT(S) ☐ NA

IMP *Name, Strength, Formulation*	**Route**	**Classification**[1]	**Licensed** (Yes/No)	**Licensed for indication** (Yes/No)	**Supplied by**[2]

1) Controlled drug, Cytotoxic, Monoclonal antibody, GMM etc 2) Sponsor, Hospital Stock

NON-INVESTIGATIONAL MEDICINAL PRODUCT(S) ☐ NA

NIMP *Name, Strength, Formulation*	**Route**	**Classification**[1]	**Licensed** (Yes/No)	**Licensed for indication** (Yes/No)	**Supplied by**[2]

1) Controlled drug, Cytotoxic, Monoclonal antibody, GMM etc 2) Sponsor, Hospital Stock

RESCUE MEDICATION ☐ NA

Medication *Name, Strength, Formulation*	**Dose**	**Classification**[1]	**Supplied by**[2]

1) Controlled drug, Cytotoxic, Monoclonal antibody, GMM etc 2) Sponsor, Hospital Stock

ANCILLARIES' ☐ NA

Ancillaries	**Suitable for use locally?**	**Supplied by Sponsor?**	**Storage location?**

Category / Activity	Information *include source document where applicable*	Risk identified (No / Yes / NA)	If yes, list specific concerns	If yes, can the risks be minimised, supporting information
TREATMENT – *Pharmacist to complete*				
Dosing / dose schedule / administration regimen			*Dose capping, Actual or ideal body weight, BSA calculation*	
Potential risk for dosing errors				
Contra indications / cautions in SmPC or IB correlate to protocol (e.g. inclusion/ exclusion/ withdrawal criteria)			*Trial monitoring less than standard of care?*	
Side effects - For each IMP				
May concomitant medications increase the risk? Drug-drug interactions? (protocol / PIS)				
Drug-food interactions? (protocol / PIS)				
Use of IMP in renal impairment?				
Use of IMP in liver impairment?				
Dose escalation required during trial				
Dose reduction required during trial				
Dose Tapering				
End of trial arrangement (protocol / PIS)				
RANDOMISATION				
Randomisation process	*who creates the randomisation schedule, IWRS system, When randomisation list can be released for trust sponsored*			
SUPPLY				
IMP			*specific brand,*	

			formulation, cost reimbursed	
NIMP			*SoC? specific brand, formulation, cost reimbursed*	
ORDERING				
Ordering process / Resupply			*IWRS system or Sponsor controlled, reorder levels, time lag between ordering and delivering, order forms*	
SHIPMENTS				
First delivery	*After first screening / green light*			
Size of shipment			*space required for storage*	
QP release	*Included with shipment? File note provided?*			
Shipment acknowledgement				
Temperature monitoring device				
Shelf life/expiry			*Frequency of shipments? After reconstitution?*	
ACCOUNTABILITY				
Master Accountability logs	*Site or sponsor providing?*			
Patient Specific accountability logs	*Site or sponsor providing?*			
Other type of accountability logs				
IWRS accountability				
Accountability of NIMP				
PACKAGING				
State packaging details	*primary and secondary packaging*		*Click-lock / complex blister*	
Dimensions				
LABELLING				
IMP labelled by the Sponsor			*tear off label*	
Is labelling compliant with trial regulations (Annex 13)?			*Missing information, compliant with trust policy*	
Additional labelling by site			*directions required?, Sponsor approval required? Storage requirements, expiry date, cytotoxic, stability after opening*	
STORAGE				
Storage location			*in pharmacy, CD room, ward, fridge, freezer, stem*	

			cell lab	
Storage conditions on product label	*(permitted excursion)*			
Storage of IMP outside pharmacy	*Complete an assessment on the ward , audit stem cell lab*		*Ward, stem cell lab? Procedure in place? By patient?*	
Temperature excursion reporting procedure	*(form)*			
DISPENSING				
Prescription	*who is designing the prescription, e-prescribing system) NMPS? Sponsor approved? Trained? formulary?*		*Sponsor approval required, e-prescribing system, dose rounding*	
Clinical check required?				
Confirm subject identifier			*To correspond to IMP label identifier*	
Number of dispensing	*how many items to be dispensed every visit*		*Is prescription required early i.e. lots of PKs?*	
Ancillaries to be supply	*specific requirements, sponsor supplying?*		*Hospital stock*	
Transport arrangements	*to ward/department/ between sites/to patient*		*Courier? Documentation?*	
Temperature monitoring *For transport from pharmacy*	*Sponsor providing thermometer, bags, packaging?*			
ADMINISTRATION				
IMP administration	*If new medicine injectable Complete NPSA Injectable Medicines Risk Assessment Tool*		*Who is going to administer? Which foods we can mix with*	
Patient instruction for administration	*Diary?*		*Standard practice?*	
Specific ancillaries			*CE marked? Flushes? Filters?*	
BLINDING				
Pharmacy involvement?				
Code break Procedure				
IWRS				
IWRS access			*Requirement to be on delegation logs Number of accounts*	
RETURNS				
Procedure for returns	*(compliance calculations, used and/or unused returns, packaging only)*		*Sharps? Contaminated?*	
DESTRUCTION & HANDLING				

Procedure for destruction	*(Expired stock, returns from patients)*			
Return to Sponsor procedure	*(Expired stock, returns from patients)*			
Waste pathway	*(Containment level)*	*GMM? Cytotoxic/static?*	*(check trust policy, identify clearly which bin to use)*	
RECONSTITUTION / DILUTION OR (ASEPTIC) PREPARATION				
Preparation facilities	?Complete the "CLINICAL TRIAL INFORMATION CHECKLIST"		*isolator or laminar airflow cabinet, cytotoxic*	
Aseptic preparation to be completed in a clinical area			*Experienced nurses, GMP level 1, MABs, non-cytotoxic preparation*	
Method for reconstitution /dilution	*Sponsor provided worksheet? diluent, volume, container, infusion volume*		*Concerns with provided worksheet or suggested method? Number of vials? Compatibility of materials? Open or closed system?*	
Ancillaries for reconstitution			*EU licensed? Validation required?*	
Concentration of preparation				
Special precautions during reconstitution			*use of filters, protection from light*	
Outsourced products			*MAIMP holder required*	
HAZARD				
Safety / COSHH	*Specific requirements for spillages or handling*		*Spillages, PPE*	
Cytotoxic Product				
Material Safety Data sheet				
GMO *see EPSC application form*	*Containment level*		*Spillage kit to accompany the IMP*	
FINANCE				
Invoice				
Reimbursement of hospital stocks	*Mechanism to control reimbursed*		*how to manage the stock on e-system*	

RISK & ACTIONS	
Risk identified	**Actions to be taken to reduce identified risks**

Approved by	Printed name	Date