GUIDE

Title: HRB CRCI Checklist for Clinical Trial Costs		
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Quality Approval	Fiona Cregg	**Review date**:07 Sep 19

1. Purpose

The purpose of this Guide document is outline the potential costs associated with running a clinical trial. This document should be used as a guide to investigators when compiling the budget for a clinical trial. The potential cost associated with the sponsor (see Section 2) and the investigator site (see Section 3) are outlined.

2. Checklist for Sponsor Costs

Checklist for Clinical Trial Costs – Sponsor				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
1	Regulatory Approvals	Initial submission	Cost of resource to manage submission Fees. In circumstances where there is no financial support for the conduct of the clinical trial, the investigator may be entitled to a fee waiver. This should be addressed in the application. https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/fin-g0002-guide-to-fees-for-human-products-v20.pdf?sfvrsn=25	
		Amendments		
2	Ethics Approvals	Initial submission	Cost of resource to manage submission Fees	
		Amendments		

Checklist for Clinical Trial Costs – Sponsor				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
3	Insurance	Cost of indemnity for each country taking part in the CT for the entire duration of the recruitment and follow up period Also need insurance to cover the protocol	Irish sites may be eligible for the Clinical Indemnity Scheme (CIS). Contact the State Claims Agency to see if the study would be eligible for the CIS. Please note: CIS only covers HSE employees in HSE designated facilities for negligence and malpractice. The protocol and product need to be insured also. http://stateclaims.ie/about-our-work/clinical-indemnity-scheme/	
4	Investigational Medicinal Product (IMP)	Cost of drug	This is the cost of the drug itself from the distributor Consider how many batches of IMP (to account for expiry dates) may be required	
		Investigational Medicinal Product Dossier (IMPD) and Investigators Brochure (IB)	Development and updating of the Investigational Medicinal Product Dossier (IMPD) and Investigators Brochure (IB)	
		Transport of the drug from the distributor to the IMP manufacturer		

Checklist for Clinical Trial Costs – Sponsor				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
		Placebo manufacture		
		Cost of over encapsulation (if necessary)	If over encapsulation is required. An altered dissolution profile will be required.	
		Packaging & labelling	Could consider relabelling for expiry date extension	
		Stability testing		
		IMP yearly management and storage	This could be by IMP manufacturer or investigator	
		Distribution of IMP		
		Destruction of IMP	IMP can be destroyed by the study sites or transported back to the IMP Manufacturer for destruction	
5	Data Management	CRF/eCRF development and maintenance Validation and User Acceptance Testing Raising Data base queries Database lock	Data Management may be outsourced to a CRO	
		Randomisation system development and maintenance		

Checklist for Clinical Trial Costs – Sponsor				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
		Data manager time		
		Unblinding service	24HR telephone service or web based for unblinding	
6	Trial Master File	Cost of TMF set up and maintenance	Can be a hybrid ISF/TMF if a single centre investigator led study (HPRA have confirmed this)	
		Archiving costs for 25 years	The new CT regulations which are due to become effective in 2018 require Clinical Trial records to be archived for 25 years	
7	Monitoring	Sponsor oversight of the monitoring	Development of risk adapted monitoring plan Ongoing sponsor oversight e.g. review monitoring report	
		Monitoring of study sites	Monitor time, travel costs, accommodation and subsistence Monitor role may be outsourced to a CRO	
8	Auditing	Sponsor site audits	Auditor time, travel costs, accommodation and subsistence.	
9	Training Costs	Training material costs		
		Training infrastructure costs	Investigator meeting For large multi centre studies training might be provided via webinar.	

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10	Pharmacovigilance	Cost of a validated pharmacovigilance system		
		SAE Processing		
		Cost of reporting SUSARs to competent authorities	Eudravigilance training with the EMA or contracted externally.	
		Pharmacovigilance personnel	Processing SAEs, SARs, SUSARs	
11	Staff Costs	Coordinating investigator Time	Involvement in protocol development Medical oversight	
		Clinical Trial Manager/Coordinator	Involvement in protocol development, risk assessment, managing budget, site identification & feasibility, recruitment management, monitoring oversight, essential document development, regulatory & ethics submissions etc	
		Statistician time	Statistical input on protocol design DSMB report preparation Interim and final analysis	

Checklist for Clinical Trial Costs – Sponsor				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
		Quality Regulatory Affairs Manager (QRAM) time	Establishment and maintenance of a quality management system with written SOPs	
		Legal support time	i.e. for contract negotiations, procurement & vendors	
12	Coordination	Teleconference costs		
		Cost of regular study meetings	In cost of venue hire, accommodation, subsistence and travel	
13	Bio-samples	Lab kits		
		Analysis costs		
		Biobanking costs		
		Transport costs for bio-samples	Including the cost of dry ice if applicable	
14	Patient & Public Involvement (PPI) costs	Patient & Public Involvement (PPI) costs	See the following link for studies which need a budget for PPI http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/	
15	Facilities	Office space for Study staff		
		Consumables		

3. Checklist for Investigator Site Costs

Checklist for Clinical Trial Costs – Investigator Site Costs				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
1	Investigator Site File (ISF)	Cost of ISF set up and maintenance		
		Archiving costs for 25 years	The new CT regulations which are due to become effective in 2018 require CT records to be archived for 25 years	
2	Sites Fees	Study set-up, management and close-out fees		
		Local hospital approval(s)	Fee for the local hospital approval (Clinical Trial Agreement (CTA) and Site Specific Assessment Form (SSAF) sign off by hospital legal signatory)	
3	Per Patient Fee	Site staff costs	Principal Investigator time Study Nurses/Research Assistants time	
		Hospital procedures required	All study specific procedures i.e. Blood tests, CT, MRI Scans , ECGs etc	

Checklist for Clinical Trial Costs – Investigator Site Costs				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
		Lab costs for processing of bio-samples		
4	Patient Expenses	Patient expenses	Will the patient's travel expenses be reimbursed?	
5	Pharmacy/IMP Management Fees	Cost of pharmacy file set up and maintenance	Include for sites which are dispensing via a pharmacy	
		Dispensing fees	Include for sites which are dispensing via a pharmacy	
		Pharmacy set up, annual IMP management and close-out fees		
		Cost of acquiring storage cabinets, thermometers, temperature sensors	For sites which are not using a pharmacy to dispense	
6	Translation	Translation fees	If non English speaking countries are included, translation fees will apply to translate and back translate the patient information leaflet, protocol (if applicable) and contracts etc.	
7	Other	Room hire	For both study visits and monitoring visits	
		Equipment	Could include lab kits, phlebotomy consumables, scales, dedicated fridge, BP Monitors etc depending on nature and location of study	

Checklist for Clinical Trial Costs – Investigator Site Costs				
No.	**Category**	**Subcategory**	**Comment**	**Estimated Cost €**
			Equipment for patients to report outcomes e.g. electronic patient diaries	
		Servicing and calibration	May have associated costs	

4. Revision history

Version	Description of Changes
V1.0	Initial Version