

BSG IBD clinical research group meeting

Clinical research – how to get it done: funding



James Lindsay

Professor of Inflammatory Bowel Disease

Barts and The London School of Medicine

Queen Mary University of London

Consultant Gastroenterologist, Barts Health NHS Trust



BSG IBD Clinical Research Group Investigators' Meeting 2024

Why me?



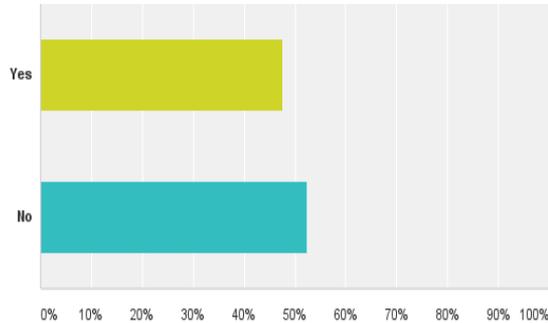
- 0.5WTE academic & NHS contracts
 - No NHS clinical research time
- Started clinical trials in 2006 using Barts Health CRC
 - Originally 50% overheads came to PI: funded research fellows to do trial visits
 - 2011: Trust “repatriates” overheads – I work solo
 - 2014: told by trust that I was underperforming my research target?
 - Academic appraisal asked why I was bothering with clinical trial research
- Needed a radical rethink of strategy...
 - 2014 CLRN funded research nurse for investigator led trials
 - 2017 NIHR seed funding for 1PA research time each for 2 consultant colleagues
 - Expanded commercial and investigator led research team with budget oversight
 - Set up bespoke Gastroenterology Clinical Trials Unit separate from Trust
 - Appointed clinical trials fellow
 - Now have 6 research nurses across our commercial and non-commercial trials

The most frustrating aspect of clinical research is still the finance...

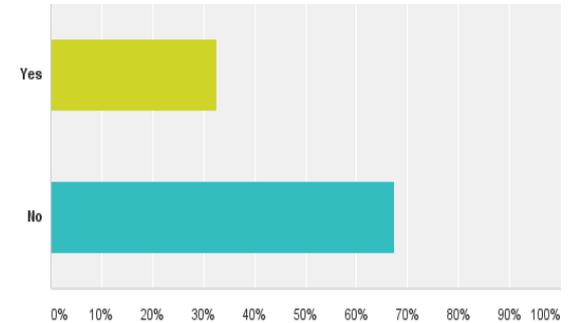
2016 BSG IBD CRG survey of clinical research investigators

I am not alone...

Are you confident in your understanding of the contracting / costing of clinical trials?



Do you review the costing template, announcement and distribution allocation?



- what are you not confident about?
 - Finance....
 - Are costs set in stone or are they that start of a negotiation
 - for NIHR portfolio studies: costs are shrouded in mystery
 - How do you know what is a research cost, direct clinical care, supporting service costs
 - How do they calculate the overheads
 - Where does the money go... / Who gets the money.... / I don't!
 - Its all done by R&D and not sure whether I can influence this
 - ***Its pretty opaque...***

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How to get it done: funding

- What has changed recently?
- Understanding the different costs and how they are allocated
- The importance of oversight and what to focus on

What is new in the funding of commercial clinical trials

National Contract Value Review April 2022

- **UK wide underpinned by National Standard Contract and Directive on Commercial clinical trials**
 - England: NIHR, HRA, DHSC
 - Aligned in the devolved nations
 - Stage 1 April 2022: 200 studies with average of 29 days for study resource review
 - Reduced time from submission of costing to fist recruit by 45% (from 213 days to 118 days)

- **Stage 2: from October 2023**
 - Sponsor / CRO must use integrated costing tool and submit before IRAS submission
 - Single study resource review (by CI site) and ICT generates site specific price (not phase I/IIa)
 - Site specific multipliers are being revised (Market forces 1.03-1.2; Overheads 1.7; Capacity 1.2)
 - NO local negotiation around costs: CI review is important... but many costs are fixed

What is new in the funding of commercial clinical trials

The chief investigator negotiates the budget: tips to consider

- Always review the costing template with the protocol
- Highlight issues with process and identify additional costs as the timings are fixed...
- Ensure procedures are correctly listed

521	45305	Proctosigmoidoscopy, rigid; with biopsy, single or multiple	Interventional Diagnostics	Intervention includes Investigation (where applicable)	£	1,142	£	1,534
522	45330	Sigmoidoscopy, flexible; diagnostic, with or without collection of specimen(s) by brushing or washing	Interventional Diagnostics	Investigation	£	196	£	264
523	45331	Sigmoidoscopy, flexible; diagnostic, with biopsy; single or multiple	Interventional Diagnostics	Investigation	£	151	£	203
524	45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	Interventional Diagnostics	Investigation	£	151	£	203
525	45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	Interventional Diagnostics	Investigation	£	1,189	£	1,598
526	45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	Interventional Diagnostics	Investigation	£	1,685	£	2,264
527	45380	Colonoscopy, flexible; with biopsy, single or multiple	Interventional Diagnostics	Intervention includes Investigation (where applicable)	£	1,142	£	1,534
528	45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed); moderate sedation	Interventional Diagnostics	Investigation	£	1,685	£	2,264
529	45390	Colonoscopy, flexible; with endoscopic mucosal resection	Interventional Diagnostics	Investigation	£	196	£	264

What is new in the funding of commercial clinical trials

The chief investigator negotiates the budget: tips to consider

- Always review the costing template with the protocol
- Highlight issues with process / procedure times
- Ensure procedures are correctly listed
- Look at set up costs: listed separately
 - R&D set up / CRC set up
 - Pharmacy set up
 - Archiving etc for end of study
- Add in PI time for reviewing SAEs from trial program (1-2 hours / week)
- Time for re-consent / training / monitoring visits
- ALWAYS negotiate CI fees
- Look at overheads
- This is on top of capacity building supplement

Clinical research: how to get the funding sorted

Costing an investigator led trial

- Most CTIMPs will require bringing a Clinical Trials Unit on board
 - Largest expense for the trial so make sure you know what you are paying for...
 - Establish roles and responsibilities at outset - particularly interaction with research finance
- Never under cost a study
 - Research time for you and co-applicants
 - Admin support: costs for TSC / DMEC
 - Study set up costs
 - Consider all aspects of patient journey through the trial: SoECAT
 - Patient expenses / shipping costs / costs associated with conference presentation & publication
 - Close down of study / archiving for sites

Clinical research: how to get the funding sorted

Costing an investigator led trial

Costs for NHS clinical research are detailed on a schedule of events cost attribution template (SoECAT)

- All trials that are eligible for the CLRN portfolio and want to access service support costs
- Research requires HRA approval
- NHS resources will be used even if there are no excess treatment costs
- Early discussion with LCRN “AcoRD specialist”
- Create account on Central Portfolio Management System (CPMS)

Research: costs that are required as part of research delivery and do not form part of clinical care

NHS treatment: costs that would be required to deliver the intervention in routine NHS care. Costs in excess of current standard of care are the **Excess treatment costs**.

NHS service support: clinical care costs that would not be required if delivering intervention outside a clinical trial

How can I make the research budget work for me?

Tips to consider when discussing with R&D

- **Insist on looking at local distribution sheet**
 - Is the money being directed correctly
 - Does it go to trust / your department / you
 - Does your manager know?
 - Keep a track of the money that comes to your dept
 - You can negotiate research Pas / Clinical fellow / Nurse etc
- **Where do the overheads go**
 - Normally split between R&D / NHS Trust / PI
 - Use CLRN guidelines – at least 20% should go to investigator
- **What is the process for tracking finance and issuing invoices**
 - CRO raises purchase order and your research dept sends invoice
 - How is the money divided?

How can I make the research budget work for me?

Tips to consider when discussing with R&D

Joint Research Management Office Announcement Copy				STAFF (Option 1)							
				Department	A/C Code	Unit Cost (per hour)	Year 1	Year 2	TOTAL		
Investigator :	Dr James Lindsay			CAG	634300	£73.94	£628.50	£628.50	£1,257.00		
CAG:	ECAM			26IW44	634310	£31.44	£1,079.50	£1,079.50	£2,159.00		
REDA:	11262			26IW44	634230	£14.58	£0.00	£0.00	£0.00		
Budget Code:	12RM70										
Title :	A Phase 2, Randomized										
Date:	14 November 2016										
PI ACCOUNT- 12IX06											
				R&D		Services		CAG		PI	
				£4,781		£10,052		£4,403		£4,885	
				20%		42%		18%		20%	
										£3,416.00	
										£6,313.00	
										£582.00	
										£848.96	
										£242.56	
										£624.59	
										£485.12	
										£1,455.36	
										£1,697.92	
										£786.00	
										£3,146.00	
										£3,932.00	

Service Cost	Department	Code	Expendi
Full Blood Count (FBC/CBC)	Haematology	631700	
Biochemistry Profile - Full	Biochemistry	632000	£ 279 £
Urine pregnancy, chorionic gonadotropin (hCG) (BetahCG); qualitative	Microbiology	631600	£ 107 £
0	0	0	£ - £
0	0	0	£ - £

Service Cost	Department	Code	Expendi
Chief Investigator fee		26IW44 630600	£727.68 £727.68
Clinical Research Facility set-up fee (only chargeable when specialist CRF is required for trial conduct or Sponsor has chosen to use facilities for potential study benefits)		JEE300 630300	£848.96 £848.96
Overhead			
PI		26IW44 630600	£393.00 £393.00
Corporate Overheads		CAG 630450	£1,573.00 £1,573.00
R&D Overheads		JDQ300 630400	£1,966.00 £1,966.00

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How to get it done: funding

- Introduction of National Value Contract Review for commercial trials
- Definitions of costs are relevant from investigator led research
 - Research costs
 - NHS routine clinical care
 - NHS service support costs
- You need to have oversight over distribution of research income