



Improving the Environment for Medical Device
Clinical Research

Stakeholder Workshop

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MORE CONTROL. LESS RISK.

12th October 2009



What I Want, What I Need.

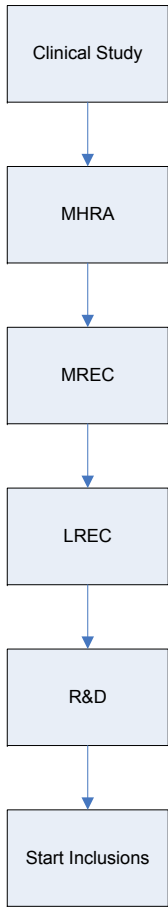
- TIME
- COST



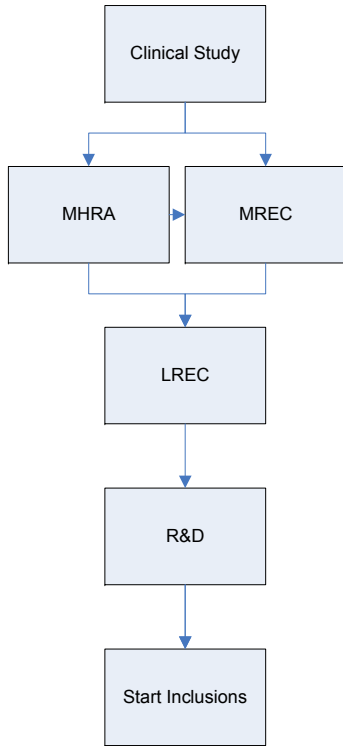


A Brief History of 'the Application'

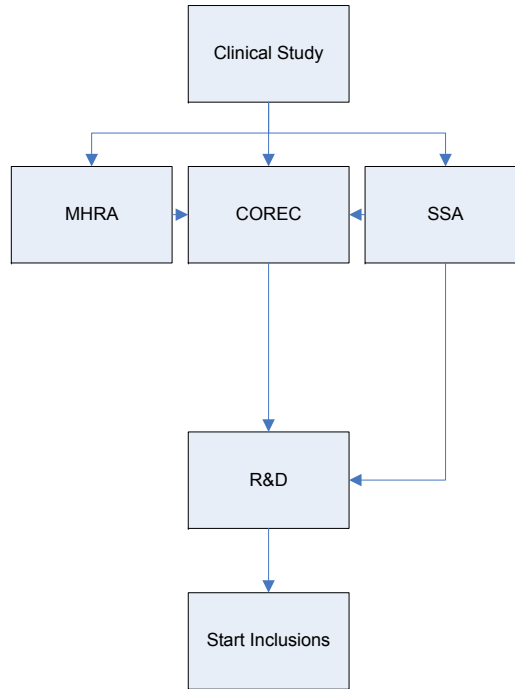
1995



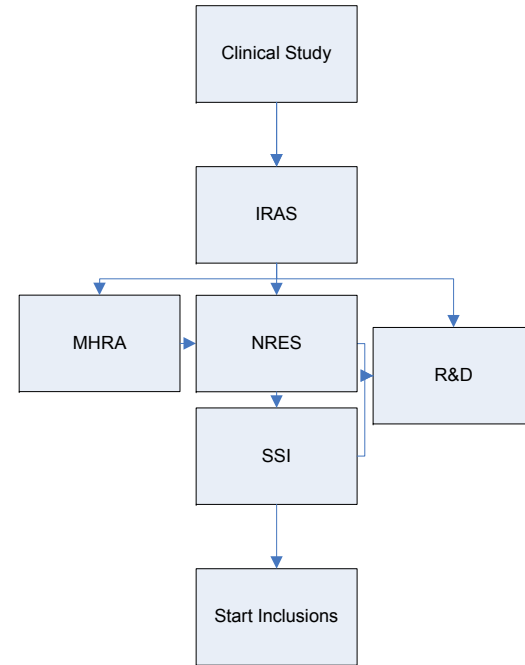
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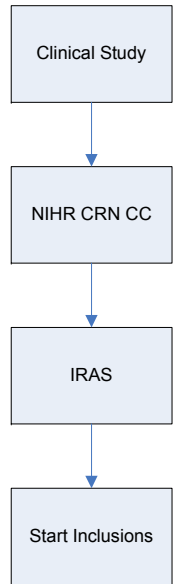
2004 (CTA)



2008 (CIA)



Today



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NIHR CRN CC Time

- 6 week adoption period
- 35 days (non CE Mark)
- To be proven



Ethical Time

- What happens if you fail:
 - Re-submit.
 - Can not do so with same CIP and/or justification.
 - Bias.
- Education:
 - Leads to delays.
- Delays due to committees raising questions that are outside the bounds of their remit.
- Appeal:
 - What appeal.
- Representation:
 - What representation.





Ethical Case Study

- Panoramic: passed in 18 European Countries
- Passed in Ireland.
- Why did it fail in the UK.
- Opinion.
- Resolution:
 - None,



R&D Time

- AnalyST: Service Evaluation:
 - Royal Brompton; 96 days and counting.
 - John Radcliffe; 16 days.

- Promote: Rnd Trial:
 - Thommies; 82 days.
 - Bart's; 14 days.

- A(f)MAZE: Rnd Trial:
 - Southampton: 102 days and counting
 - Derriford: 27 days.



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R&D Cost: Case Study

- European costing for new technology NTA: Germany, Italy, France and Netherlands approved and agreed.

Visit	Enrolment CRF	Implantation CRF	Post-Implant CRF	M1 Follow-Up CRF	Re intervention CRF	Out Of Service CRF	Death CRF	Deviation CRF	Adverse Event CRF	Termination CRF	Fees in euros
Inclusion	X						*	*	*		50 euros
Implantation		X			*	*	*	*	*		50 euros
Post-Implant			X			*	*	*	*		100 euros
1 Month Follow Up				X		*	*	*	*		150 euros
Total											350 euros

- Total cost: 1750Euros (£1500)





R&D Cost: Case Study

- A NHS R&D Office costings:

Study Budget			
Fixed Costs		Total	
R&D Set-up Fee	Due on execution of contract and non refundable		£5,000
Archive & Storage	Due on completion of study		£300
Per Subject Costs			
		Max per Subject	For 5 Subjects
Subject Access Fee (per enrolled subject)		£108	£540
Per Subject Fee	<i>As detailed below</i>	£550	£2,750
TOTAL CONTRACT VALUE (5 Subjects)			£8,590



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R&D Cost: Case Study

- **Taken from European SJM Legal correspondence:-**
 - Which activity they consider as over and above routine care and how much they have charged for this
 - How long they have allocated for each visit in Staff time (as Ali has stated that she worked out with the research team)
 - What the hourly rate they use for Doctor and nurse time
 - How the “subject access fee” is calculated and what it relates to as this is a new charge.
 - The R&D setup fee is not being negotiated and we don’t want to include it in the subject fees (as this will make the problem we have bigger.)
 - We just need to know how they arrived at the per patient figures and I can’t see how that is difficult if they have already done these calculations themselves?
 - **You have to justify this cost. We could be vulnerable to Eucomed as they are so high compared to other countries that this could be perceived as an inducement.**



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R&D Issues

- Accountability.
- What is standard of care?
- Costing Template?



The Costing Template

Study	NIHR staff costs:- pre capacity / overhead adjustment	SJM staff costs:- pre capacity / overhead adjustment	NIHR Investigation costs	SJM Test costs	NIHR calculated Fee per Pt	SJM calculated Fee per Pt
BioPace	£1006.19	£584.60	£839.97	£793.03	£2919.73	£2062.37
EVITA	£473.91	£260.98	£49.94	£49.94	£960.35	£555.78
FREEDOM	£539.10	£329.30	N/A	N/A	£1024.29	£625.66
OPTIMISE	£470.30	£303.45	£590.80	£590.80	£1602.53	£1285.52





The Costing Template

- Why?
- Centre Uplift.
- PbR MFF 0 – 25%
- Capacity Building – What is this
- Overheads – where does this come from
- SIMPLIFICATION





Finally / Summary

- We are a millions miles away from where we were.
- We need accountability at all levels.
- Time is getting into the realms needed to compete at a European level.
- Cost still has some distance to go, but, it's going in the right direction.
- Overall – I am actually very happy with the direction we are taking.



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Grey Areas

- Academic Studies
- Consultant Authority
- Audit, LMR and Product Evaluation
- Hospital Manufactured Device

