

Trials and Tribulations

overcoming challenges in Investigator–led Studies

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Where we were... (2000s)

Hungry

(lack of
funding)

**Feeling
isolated**

(fewer support
channels)



**No
family**

(no team or
infrastructure)

A researcher was born!



Bristol Bladder

- Protracted set up of study
- Lack of dedicated support – Governance, Stats, Database
- Data Management – woeful data
- Timelines – undefined
- CRIC collaboration
- NBT collaboration



Moment of realisation

Slow
deliverables

Governance
improvements
required



Inconsistent
recruitment



CNCEPT - Concept

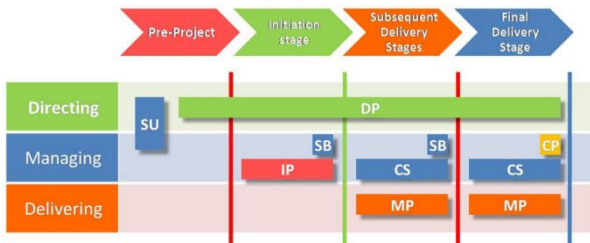
- Improved infrastructure (dedicated staff)
- Improvements in CRF design
- Database produced
- Thorough Trial Master File in situ
- Multi-centre (12 sites)
- ICR collaboration
- Engaging CRNs



Principal Investigators vying for competitive recruitment



The ACE Study



- Prospective
- Multi-faceted R&I support (dev, gov and legal)
- Thorough feasibility
- eCRF design (streamlining human resource)
- Planning – committees







A research cygnet being supported by R&I



Initiating a study






Area	Challenges faced	Suggested solution
<p>Funding</p> 	<p>Lack of funding to sustain an ILS team (vs hosted study teams)</p>	<p>Look for funding calls:</p> <p>Investigator Initiated Study calls (bread and butter)</p> <p>Lead onto larger NIHR/CRUK grants</p> <p>Charitable funding</p>
<p>Infrastructure</p> 	<p>Lack of in house statistical resource for non NIHR grants</p> <p>Lack of Database Programmer</p>	<p>Collaborate locally with local universities (e.g. UWE or seek nationwide)</p> <p>Software as a Service (SaaS) regulatory compliant databases within the team</p>
<p>Committees</p> 	<p>Seeking appropriate personnel to be on the committees</p> <p>Quorate meetings</p>	<p>Various contacts</p> <p>Ensure a charter is agreed by all members</p>
	<p>Appropriate patient reps</p>	<p>Seek local patient support groups such as 'Bosom Buddies' and Prospect</p>



Initiating a study



Area	Challenge	Suggested solutions
<p>Set up timelines</p> 	<p>Delays in opening sites</p> 	<p>Set out your expectations at the start</p> <p>Site selection based on timelines (accountable)</p> <p>Value of calling set-up staff</p> <p>Set up sites all at once</p>
<p>Site feasibility</p> <p><i>Tall stories lead to short falls</i></p> 	<p>Conservative numbers from sites – penalties for under recruiting</p> <p>Overly optimistic Investigators</p>	<p>Encourage realistic numbers</p> <p>Encourage evidence based prevalence data</p>



Motivating sites



Area	Challenge	Suggested solutions
Recruitment	Poorly recruiting sites	Identifying barriers to recruitment early Using Edge for KPIs on screening activity CI correspondence Utilise the CRNS
Patient retention	Fast changing landscape in oncology New regimens available prior to PFS Deferred in the treatment pathway	?!?! Recruit quickly – more sites More resource upfront, but duration of study decreased



Where we are going....(2018 and beyond...)

- NIHR grant submission (following Bristol Bladder publication)
- Mixed portfolio of NIHR badged commercial backbone of IISs and progressing to NIHR studies
- Emerging researchers (including research fellows) mentored by Dr Bahl
- Investigator led component of our Research Strategy



Conclusion

- Significant small improvements over the last decade – overall a substantial bird migration pattern!
- Systematic support from R&I imperative
- Value of the team, appropriate leadership and lots of collaborators



- Patience
- Perseverance
- A sense of humour...

A Chief Investigators flapping feet, unbeknown to many