Royal Children's Hospital-Melbourne Information Session

The Role of the Lead Site: a CRO Perspective

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HELPING DELIVER LIFE CHANGING THERAPIES

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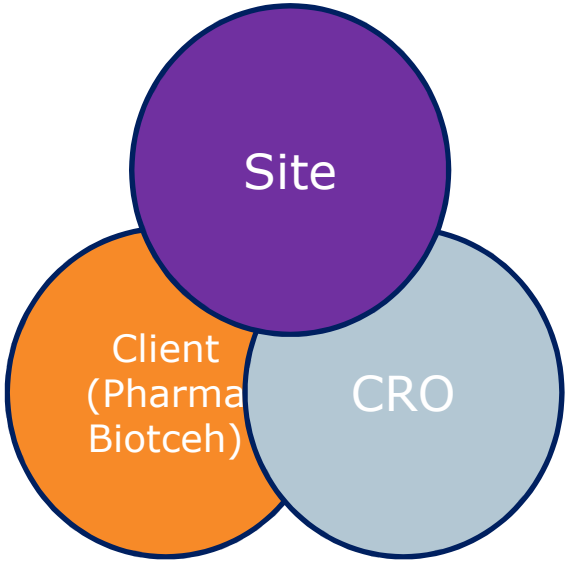
THE ROLE OF THE CRO IN NMA CLINICAL TRIALS



Delivery new therapies to improve Health care for Australians

Start up team

Clinical team

NMA SUBMISSIONS…..THE GOOD VS THE BAD

THE GOOD

- Overall POSITIVE experience.
- Reduction in the duplication of submissions.
- Establishment of consistency of core study/site documents such as ICFs; Patient Materials (Cards, Diaries); NEAF (Online Forms)
- As of 31 AUG 17- WA is now included on NMA submissions. Conditions and additional documents required to include them.

THE BAD

- Inconsistency amongst local Ethics committees and RGOs
- Identifying Proactive and Efficient Lead site
- Timely receipt of ethics queries and consequent resubmission
- Communication between lead site/CRO/Participating sites

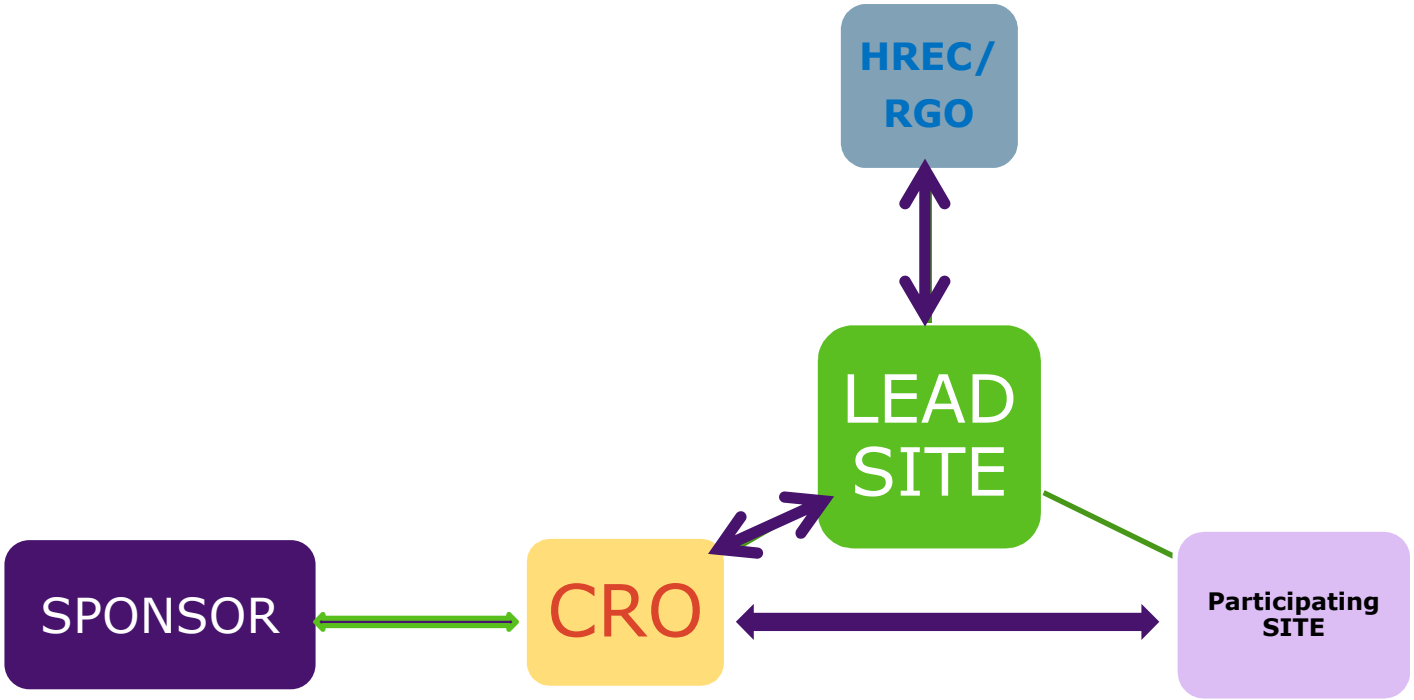
PARTNERSHIP WITH THE LEAD SITE-
Sponsor expectations

+ Critically important to the integrity and success of any clinical trial
+ CRO partner with the Sponsor to identify lead site.
+ During feasibility and PSV critical intel is collected from the sites
+ Key Identifiers of a lead site:
  - Communication
  - Productivity and Motivation
  - Organisation
  - Resource
  - HREC Considerations

ROLES AND RESPONSIBILITIES OF THE LEAD SITE

PPD	SITE
Providing study documents (Protocol, Draft NMA Master ICF, IB, Patient Material etc), HREA/Online Forms (partially completed), VSM, WA Specific Forms.	Clear understanding of local Ethics/RGO requirements- is there anything unique?! Inform PPD of special requirements early.
Collecting Signature pages from participating sites	Customising and reviewing NMA Master ICF. PPD will provide draft version.
Collecting study documents from participating sites for ethics submission	Reviewing HREA/Online Forms and adding site specific details. Collecting local site signatures.
Ethics queries- answer and prepare cover letter	Submitting documents to ethics by agreed deadline
Communication with participating sites re: HREC submission, updates and approval	Sending participating sites SSA Form once ethics submission is completed.
Send ALL HREC approved documents to participating sites	Communicating with CRO in timely manner (email): HREC queries, HREC Approval, Site Delays, Resourcing Issues, Staff leave
Collate and QC EDs- send to Sponsor for review and approval	
Inform site when open to recruitment	

CLEAR COMMUNICATION PROCESSES



+ Delays are inevitable- it's how we communicate, process and work through them as a team that makes the difference!

SITE SPECIFIC BUDGETS- WHO IS RESPONSIBLE

+ Budget template used to negotiate budget requirements for each site separately. Each participating site is solely responsible for their own budget negotiations

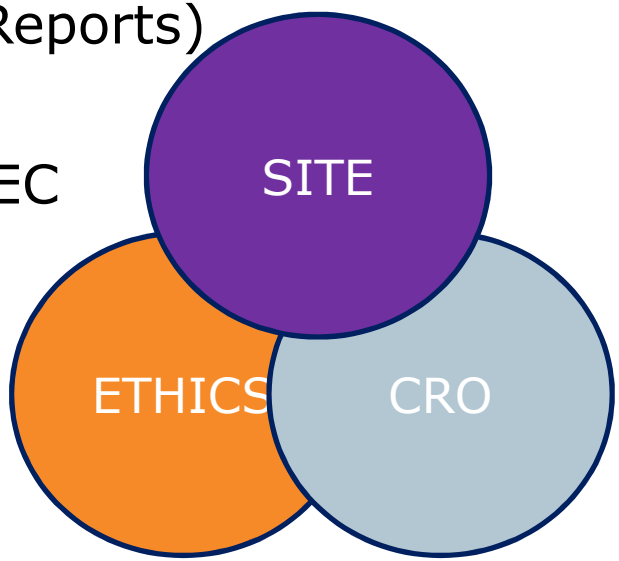
+ Lead site is not responsible for any aspect of budget requirements at a participating site.

+ Each site has Local Institutional requirements around who negotiates the budget, site costs, reviews and sign off process.

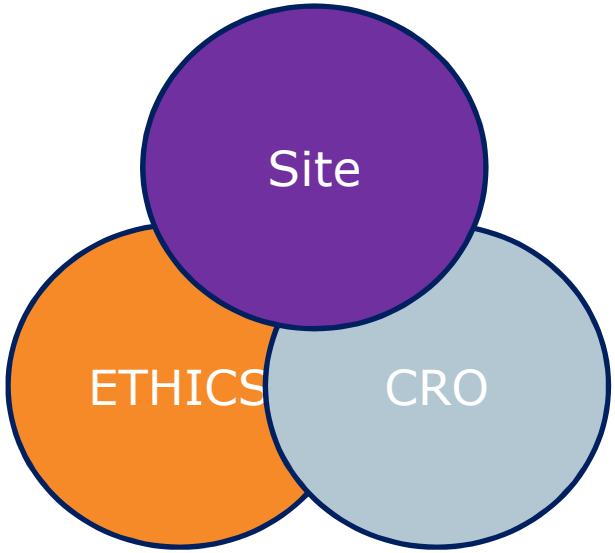
+ **Budgets are always rate limiting step in start up- so please start them early!**

CASE STUDY- WHEN LEAD SITE WORKS WELL

+ Lead Site has Capacity and Resource
+ Motivated and Organised Lead Site
+ Dedicated staff for Ethics/RGO
+ Documents are provided to the lead site early by CRO
+ Documents are secured early from lead site AND participating sites (ie CVS, GCP, Radiation Safety Reports)
+ Clear Communication Pathway
+ Budget Negotiations in Parallel to HREC
+ Q-A in 3 months for a public site



CASE STUDY- WHEN LEAD SITE HAS NOT WORKED WELL



- Lack of communication from lead site- no confirmation of receiving submission documents, submission plan, study submission.
- Delays from site in receiving communication/queries from HREC (+30days).
- Delays with re-submitting queries
- ED collection- delays with site obtaining signatures.
- Delays patients at the participating sites access to new drug therapy.

POTENTIAL IMPROVEMENTS

Lead Site:

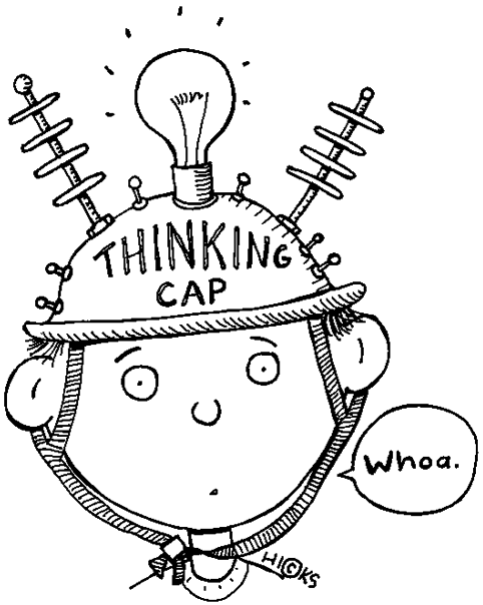
+ Improved Communication between lead site/CRO/participating sites
+ CRO Inclusion on all communication to HREC and RGO
+ Dedicated Ethics/governance liaison to support the studies

CRO/Sponsor

+ Improved Communication between lead site/CRO/participating sites
+ Better outline of study requirements and activation timelines provided to lead site. (ie- SIV in late Nov and open for recruitment before Christmas).
+ Clear understanding of all requirements for opening their site to recruitment and requirements for them as lead. (ie trainings, QC of all study documents-PPD RCR).

THOUGHTS FOR THE FUTURE……

- Work towards "selling Australia" as an attractive and competitive global first choice for Clinical Trials
- Improve sustainability to bring new business to the region as we become faster, more reliable and more competitive.
- Greater access to wider range of new treatment therapies for Australian patients.
- Increase patient enrolment numbers through shorter start up timelines; more patients access to new, innovate and life changing treatments.



QUESTIONS