Royal Children’s Hospital-Melbourne Information Session

The Role of the Lead Site: a CRO Perspective

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THE ROLE OF THE CRO IN NMA CLINICAL TRIALS

Client (Pharma Biotceh)  CRO  Site

Delivery new therapies to improve Health care for Australians

Start up team
Clinical team
**NMA SUBMISSIONS.....THE GOOD VS THE BAD**

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<th>THE GOOD</th>
<th>THE BAD</th>
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<td>• Overall POSITIVE experience.</td>
<td>• Inconsistency amongst local Ethics committees and RGOs</td>
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<td>• Reduction in the duplication of submissions.</td>
<td>• Identifying Proactive and Efficient Lead site</td>
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<td>• Establishment of consistency of core study/site documents such as ICFs; Patient Materials (Cards, Diaries); NEAF (Online Forms)</td>
<td>• Timely receipt of ethics queries and consequent resubmission</td>
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<td>• As of 31 AUG 17- WA is now included on NMA submissions. Conditions and additional documents required to include them.</td>
<td>• Communication between lead site/CRO/Participating sites</td>
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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

<table>
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<th>PPD</th>
<th>SITE</th>
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<td>Providing study documents (Protocol, Draft NMA Master ICF, IB, Patient Material etc), HREA/Online Forms (partially completed), VSM, WA Specific Forms.</td>
<td>Clear understanding of local Ethics/RGO requirements- is there anything unique?! Inform PPD of special requirements early.</td>
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<td>Collecting Signature pages from participating sites</td>
<td>Customising and reviewing NMA Master ICF. PPD will provide draft version.</td>
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<td>Collecting study documents from participating sites for ethics submission</td>
<td>Reviewing HREA/Online Forms and adding site specific details. Collecting local site signatures.</td>
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<td>Ethics queries- answer and prepare cover letter</td>
<td>Submitting documents to ethics by agreed deadline</td>
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<td>Communication with participating sites re: HREC submission, updates and approval</td>
<td>Sending participating sites SSA Form once ethics submission is completed.</td>
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<td>Send ALL HREC approved documents to participating sites</td>
<td>Communicating with CRO in timely manner (email): HREC queries, HREC Approval, Site Delays, Resourcing Issues, Staff leave</td>
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<td>Collate and QC EDs- send to Sponsor for review and approval</td>
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<td>Inform site when open to recruitment</td>
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+ 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 (+30 days).
- 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
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