NMA SYMPOSIUM: 14TH MARCH 2017

Experiences with the NMA: the CRO Perspective

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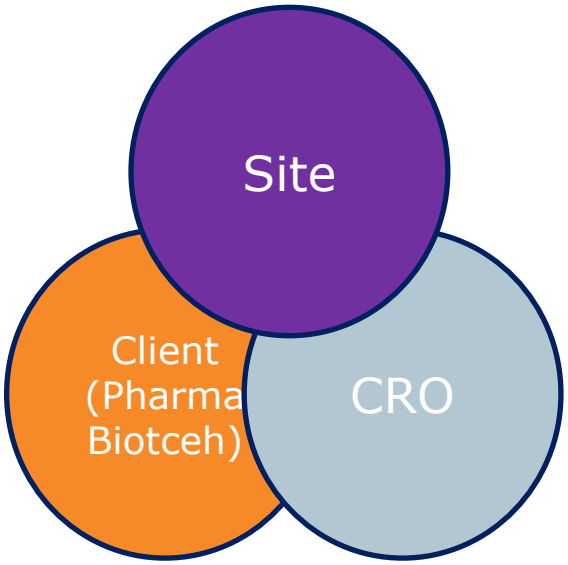
HELPING DELIVER LIFE CHANGING THERAPIES

PPD®

CRO ROLE IN CLINICAL TRIALS



Delivery new therapies to improve Health care for Australians

Start up team

Clinical team

NMA EXPERIENCE…..THE STORY SO FAR

+ 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)
+ Reduced margin of error in core site documents
+ Reduction in overall site activation timelines. However this is widely dependant on local ethics jurisdiction and governance process.
+ Although the implementation of NMA has been generally positive- we still have some challenges to overcome.

CHALLENGES/BARRIERS DURING START UP

- **Consistency amongst local HREC/RGO**

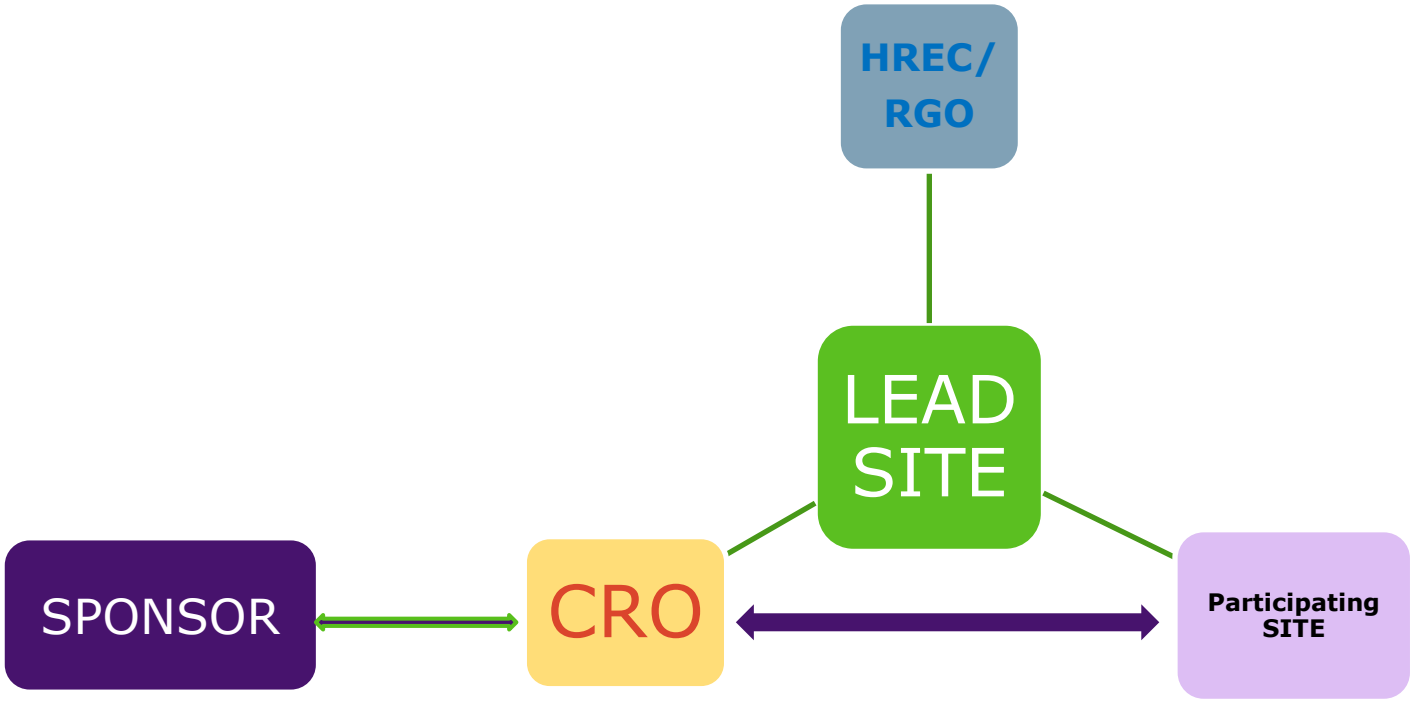
- **Ethics**
  - Identifying Lead sites
  - Monthly Submission deadline
  - Timely receipt of queries
  - Communication
  - Local practises aren't in line with the NMA Guidelines

- **Governance**
  - Communication
  - Timely reviews of submission packages (10-12 weeks for approval at some sites)
  - Additional administrative burden- review of HREC approved documents

PARTNERSHIP WITH THE LEAD SITE

- Critically important to the integrity and success of any clinical trial
- CRO partner with the client 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

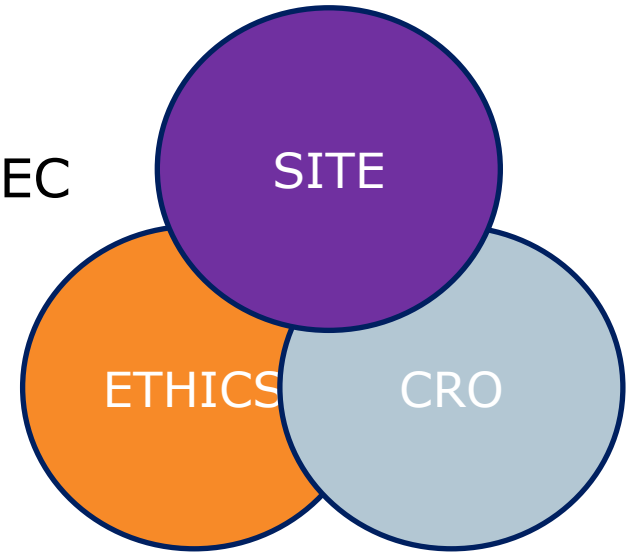
CLEAR COMMUNICATION PROCESSES



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

CASE STUDY- WHEN NMA WORKS WELL

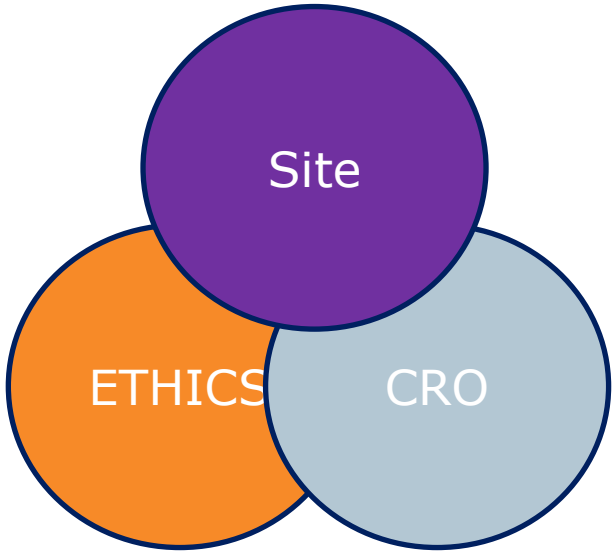
+ Lead Site has Capacity and Resource
+ Documents are secured early from lead site AND participating sites
+ Documents are provided to the site early by CRO
+ Dedicated staff for Ethics Process
+ Motivated and Organised Lead Site
+ Clear Communication Pathway
+ Budget Negotiations in Parallel to HREC



BELLBERRY

+ Strong "selling" point for Australia- Identification of private sites that can utilise Bellberry
+ Consistent and timely reviews
+ Clear SOPs available for ICF customisation and approval process.
+ Weekly submission deadlines (guaranteed review 2 weeks later): no risk of HREC meeting being full
+ Weekly meetings
+ Fast approval timelines:
  - Approx. 20 days for a Bb review (submission to final Approval)
  - 16 days for a Phase 1 Bb review.

CASE STUDY- WHEN NMA HAS NOT WORKED WELL



- Inconsistency: HREC not providing initial lead site approval for the study until CTRA was finalised.
- Delays from site in receiving communication/queries from HREC (+30days).
- Excessive rounds of queries (4)
- 5 months for lead site HREC approval
- Delays patients at the participating sites access to new drug therapy.

POTENTIAL IMPROVEMENTS

Ethics

+ Improved Communication- Can CRO work directly with HREC
+ CRO Inclusion on all communication to HREC
+ More Regular Meetings- Bi monthly?

Governance

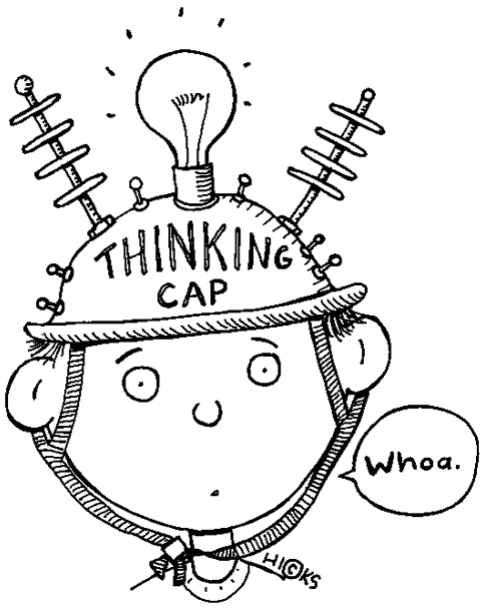
+ Improved Communication- Can CRO work directly with RGO
+ Inclusion of CRO on communication: faster resolution of queries.
+ Review of CTRA/Indemnities only: diminish the burden of additional administrative reviews of already approve HREC documents.

CONTINUING CHALLENGES……..

- NO LEAD SITE- how to over come this?
- Generally still require Multiple Submissions per study: Bellberry, TAS, WA are not included on NMA. Can we move towards including these regions/committees on the NMA?
- How can we fully implement the concept of parallel submissions? This is the key “rate limiting” step for site activation in Australia.

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.
- Implications on recruitment and clinical monitoring
- Increase patient enrolment numbers; more patients access to new, innovate and life changing treatments.



KEEP THE SUCCESS COMING….

The Success Of Teamwork

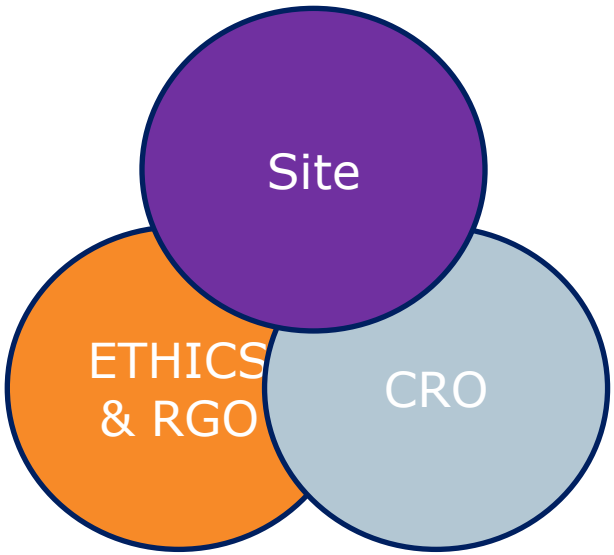
Coming together is a beginning.

Keeping together is progress.

Working together is success.

~ Henry Ford ~

The Team



QUESTIONS