National Mutual Acceptance (NMA) Symposium

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NMA – National Mutual Acceptance Scheme

- National Mutual Acceptance (NMA) is the system of single scientific and ethical review of multi-centre human research projects across Australian jurisdictions (public health organisations only).
- Australian Capital Territory, New South Wales, Queensland, Victoria and South Australia are current participants in NMA, and other jurisdictions may join in the future.
- The system has been in operation for review of multi-centre clinical trials since 1 November 2013;
- It was agreed to expand the system to include all human research commencing 14 December 2015.

Aim

Aim

(a) Enable Public H… jurisdict… entific review of human …

Under the Na… greement a multi-centre hum… viewed for ethical and scientific merit on… ere will be exceptions to some areas of research … will apply in each jurisdiction.

Achieved

Overall NMA

- Overall our experience has been positive
- Reduced duplication
- NMA scheme is most efficient when we can obtain approval for most if not all sites with one submission
- Site assessment process (RGO) is improving but still room for improvement

What can we improve to make it even better?

1. Lead Site Coordinating Role
2. True parallel submissions for the HREC and RGO
3. Administrative items

1. Lead Coordinating Site Role

- Lead role is essential to the success of NMA
- Proactively advertise if you are willing to be a lead site
- What can we all do to make the lead site role more appealing to take on?
- It is essential the lead site has resources and capacity and is very clear on the requirements of a lead site

How can we help?

- Can the sponsor take on more responsibility of the role given new world of NMA?

1. Lead Coordinating Site Role

Examples

- Sponsor needs clear guidance if the Lead ethics approves a study, and then receives further comments from other ethics or governance office as it ultimately delays study start-up.
- Guidance for how Lead sites should share HREC communications (approval letters, etc.) with the non-lead, participating sites.
  - Example 1: the sponsor is expected to be the go-between for the lead site and non-lead sites
  - Example 2: Lead site communicates directly with non lead sites in a timely manner and even follow-up with participating sites directly for site-specific information for e.g.. when the annual report is due.

1. Lead Coordinating Site Role

Examples:

- Lead sites do not always accept all of the clauses in the PICF.
  - Pregnancy and contraceptive wording

- This requires the sponsor to prepare another submission to ethics to gain approval

- Be upfront if there are clauses you cannot approve

2. True parallel submissions for the HREC and RGO – how can we do this?

Proactively Identify solutions:

2. 1 Consider if it would be more effective and efficient if the Sponsor submitted directly to the HREC and the RGO, after the appropriate parties have reviewed the information and signed it off.

2.2 The RGO approval letter could simply state "This study cannot proceed unless HREC approval has been obtained" (the same as the HREC approval letter states).

2. True parallel submissions for the HREC and RGO

Example:

2.3 Signing of the contract

- Implement a process to have the contract signed as soon as governance has been approved to prevent study start-up delays.

- If two people could sign the contract (delegate in each others absence) it would prevent delays.

2. True parallel submissions for the HREC and RGO

Example:

2.4 The sponsor is consistently advised non-lead sites are unable to submit their SSA application until HREC approval is obtained and final version of the Master ICF is available.

2.5 Administrative errors in approval documentation, move to electronic system – typed in once, naming conventions

2. True parallel submissions for the HREC and RGO

Clarification needed;

Help the sponsor understand why;

- Some RGOs require HREC-approved documents to be submitted to them and be listed on their RGO approval.
- The RGO taking on the burden of reviewing and approving documents that the HREC has already approved.

3. Administrative Issues – Quick wins?

3.2 We cant de-prioritise the approval of amendments

- This directly impacts the Phase (I/II) recruitment as the amendments are used for opening and closing cohorts

3.3 Role out of New NHMRC "Safety monitoring and reporting in clinical trials involving therapeutic goods".

3. Administrative Issues – Quick wins

Monitors obtaining access to records

3.3 Consistent Policies across states or hospitals

- Some hospitals now requesting each CRA to sign separate confidentiality agreement
- provide police check
- and CV

Consequence

- Delay in study start up while access is negotiated and internal legal review required for additional documents.

Important points to note on confidentiality

- CTRA addresses access to records
- Informed consent addresses access to records
- Employment contracts contain confidentiality clauses

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