Australian Clinical Trials Alliance

ACTA Submission on the Structural Review of NHMRC's Grant Program

Response to the Public Consultation Paper

August 2016

Structural Review of NHMRC's Grant Program

Public Consultation, August 2016

The Australian Clinical Trials Alliance (ACTA) is a coalition of more than 60 Clinical Trials Networks, Clinical Trials Coordinating Centres and Clinical Quality Registries in Australia. Collectively, **ACTA's membership represents more than 10,000 practicing clinician researchers and clinical research professionals.**

As previously identified in a report commissioned by the NHMRC, **over the last decade these groups have completed or initiated more than 1,000 studies involving more than 1 million participants– the vast majority of which were phase III clinical trials.**[1]

Over 100 of these were high-impact clinical trials reported to have directly impacted clinical practice –both in Australia and Internationally. As such, ACTA is uniquely placed to provide a whole-of-sector view on the potential impacts of an NHMRC restructure on clinical trials undertaken in Australia.

ACTA welcomes the opportunity to provide comments on the consultation paper and the three models proposed as potential frameworks to guide a major restructure of NHMRC funding.

General Comments:

- **ACTA strongly supports the principal aims of and the need for the Review to *optimise* the significant public investment in health and medical research to achieve the best possible health outcomes.**
- We recognise that the "status quo" is unsustainable.
- **We welcome recognition of the importance of National networks** in delivering high-impact research. We strongly recommend that throughout the review process the NHMRC gives **close consideration to the inherent differences in how highly successful collaborations of clinician researchers are best built and sustained, compared to other fields of research.**
- We note that the need for "comprehensive transition arrangements" has been acknowledged in the discussion document. We presume that a phased approach, over several years, that allows for smooth transition for CIs that currently hold multiple project grants will occur. We suggest that the **timing of implementation of new arrangements should remain flexible, being implemented when, and only when, a successful transition can be achieved.** This may involve a delay of one or two years to ensure that the transition occurs smoothly.
- **We have provided only brief, high-level comments** on the proposed models as it is difficult to make a meaningful assessment of their likely impact on Australia's clinical research outputs without much greater detail and clarity around a number of key issues.
- We trust that it is the NHMRC's intention to continue to work closely with the sector throughout the review process**. ACTA welcomes the opportunity to provide further input and advice on the development of a revised model** that will protect and strengthen our capacity to generate evidence that directly impacts health outcomes for Australians through high-impact clinical trials and related research.

[1] http://www.clinicaltrialsalliance.org.au/wp-content/uploads/2015/12/ACTA_Networks_Report_2004-14_online.pdf

Comments on Alternative Model 1

How effectively would the model optimise NHMRC's public investment in health and medical research by meeting the aims of this Review, including the major objectives of NHMRC's grant program found on page 12 of the consultation paper?

Overarching general comments are provided in Q4 [*reproduced above*] and should be considered alongside each of the comments made. ACTA also endorses the submission made by the ACTA Statistics in Trials Interest Group (ACTA STInG) that specifically addresses the impact of the models on critical biostatistical capacity to support high-impact clinical trials in Australia.

In relation to Model 1, we believe this model has a number of potentially positive aspects that could support the achievement of NHMRC objectives:

- **The streamlining and simplification of the Model is welcomed.** However, we caution that **if implemented as currently proposed, this model could wipe out some of the strategic achievements that have previously been enabled through the existing structure.**

  For example, **Practitioner Fellowships** are not mentioned and **are crucial in providing protected time for clinician researchers**. This is a highly productive segment of the health and medical research workforce and **provides the critical interface that embeds clinical research into practice.**

- **We welcome recognition of the specific needs of large-scale clinical trials, a key aspect of research that it is important for the NHMRC to continue to fund going forward**. However, details of the revised approach will be needed to determine its relative impact. For example**, grants longer than 5 years are critical to support some of the most impactful phase 3 clinical trials.**

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?)

- **Team Grants could be well suited to supporting high-performing networks of clinical trialists and allowing them to build a program of research answering key clinical questions.** The flexibility of use of Team Grants is also welcomed, as it would allow groups to develop capacity among early and mid-career researchers.

- **Team Grants would need to be relatively large to achieve their goals, and would need to correspond to funding currently provided to individual trials.**

- The focus on track record by Team Grants is welcomed, and will help to support innovation from our best performing researchers. However, it is **vital that pathways exist to ensure early- and mid-career investigators can acquire their own track record, independent of the senior investigators on a Team Grant.**

Can you identify negative consequences for Australia's health and medical research system if the model was introduced and how might these be mitigated?

- **The limit on grants per CI will likely discourage key participants** from being involved in grant submissions and this will have a major negative impact on the whether proposals have the skillset to provide confidence about feasibility, with downstream impacts on the reliability of assessment.

- **Other individuals with key methadologic (as distinct from content area) skillsets relevant to clinical trials and health services/systems research, such as biostatisticians, clinical trial methodologists and health economists, are at risk of being disadvantaged.** Such individuals typically provide support to a range of projects and the proposed approach will limit the number of projects from which appropriate recognition (as a CI) can be achieved or cause projects to be proposed, and proceed, without this expertise (or being able to demonstrate the presence of the expertise). The submission made by the ACTA Statistics in Trials Group (STInG) addresses this issue in more detail.

- **The cap on the number of grants risks significant adverse impact on the conduct of high-impact multicentre clinical trials, particularly those conducted through collaborative clinical trials networks (Networks).**

  These Networks regularly conduct work that changes global clinical practice and is consistently amongst the work funded by the NHRMC that has the highest impact. In many ways, Australia is a world leader in the conduct of large-scale multicentre collaborative trials and this is because the existing system has facilitated effective collaboration. **Collaboration that includes practicing clinicians within and between disciplines is critical to the effectiveness of the trials conducted by these Networks.**

  A cap on the number of grants is antithetical to this collaboration. A cap ignores the crucial 'team' nature of large-scale clinical trials in which multiple individual CIs each make major contributions to multiple trials**. This restriction should be reviewed and modified to avoid a negative impact on high-value clinical trials that are translated directly into better health outcomes and healthcare system productivity.**

- The lack of a lead CI raises questions about how accountability will be handled.

- **The lack of a clear career path within People Grants for our best performing clinician researchers beyond early career fellowships will act as a disincentive to a research career for many of these individuals and reduce our capacity into the future.** This will be accentuated by the potential risk to large numbers of researchers if a team grant is not awarded in any particular year. This would seem at odds with the stated commitment that "Fellowships will continue to cover the range of career stages, as they do now."

Could the Model be adjusted to optimise its impact? If so, how?

A modified version of model 1 could be a strong option going forward that could improve the value obtained from NHMRC funding.

Some suggested adjustments include:

- **Provide greater clarity as to the capacity of Team Grants to fund the proposed work.** This should be done in separate consultation with different types of researchers to ensure their needs are met, including clinical trialists and related research areas**. The quanta associated with successful Team Grants must be sufficient to complete the project (i.e. have a project-specific budget) and not be linked directly to track record (as per the current Program Grant scheme).**
- **A single lead investigator should be reinstituted to facilitate accountability and leadership,** while the other investigators could all be equally considered.
- **Options to limit the number of applications without placing a crude cap on the number of grants** include that it applies to lead investigators only, that it is linked to demonstrating the essential nature of the collaboration, or that the cap should be one more grant than is held currently.
- Some key groups of investigators require specific consideration. **There is a major issue for researchers who bring specific methadologic expertise that can be, and is currently, spread across multiple projects if they are restricted from being CIs on multiple projects.** Where an individual brings key methadologic expertise that can be spread effectively over multiple projects the leadership role (as a CI) of these individuals must be capable of being recognised. Perhaps, distinguishing 'content expertise' CIs from 'methadologic expertise' CIs, particularly with respect to a cap on grants should be considered.
- People Grants should support the full spectrum of research fellowships to provide a career path for our best researchers. **Effective pathways to support research time for senior clinical leaders is essential if the advantages of the Practitioner Fellowship scheme are to be retained.** In addition, consideration should be given to providing some sort of bridging support to Team Grant members who miss out on funding in one particular year.

Comments on Alternative Model 2

How effectively would the model optimise NHMRC's public investment in health and medical research by meeting the aims of this Review, including the major objectives of NHMRC's grant program found on page 12 of the consultation paper?

Model 2 has the advantage of even greater simplicity in some ways than model 1. It also rewards individual high-performing researchers, and encourages collaboration rather than mandating it. **However, clinical trials are always conducted by teams in which many individuals make a major contribution. This model does not fit the way clinical trials are conceived, designed and conducted.**

The collaboration bonus would need to be substantial to be effective, raising questions about how it is superior to a team grant as per Model 1. While many of the comments made in regards to Model 1 are also relevant to Model 2, **we suggest that this model could be less likely to achieve the goals of the NHMRC than Model 1.**

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?)

Many of the advantages of Model 2 are similar to Model 1: the simplicity, rewarding of top-performing researchers, and recognition of the value of collaboration. However, the **optional nature of the collaborative bonus would be less well suited to groups undertaking clinical trials and related research.**

- **The funding packages are also less likely to be large enough to support high quality clinical research due to its collaborative nature.** Team Grants are therefore preferred.
- **The flexibility of funding CIs from the grant or from fellowships is a strength.** However, we suggest that Non-NHMRC fellowships (eg Heart Foundation) should also be explicitly recognised.
- **The multiple streams involved in the grants could be an advantage, as they allow consideration of issues specific to different types of research.** For example, this would need to take into account the inherent differences in career structure and support needs for clinician researchers versus career researchers. **This would need to be carefully managed, and normalised in some way, to ensure equity and balance across the different streams.**
- **We suggest that the definition, value and criteria used for the collaborative bonus are crucial to this approach and are likely to prove challenging to achieve.**

Comments on Alternative Model 3

How effectively would the Model optimise NHMRC's public investment in health and medical research by meeting the aims of this Review, including the major objectives of NHMRC's grant program found on page 12 of the consultation paper?

Model 3 was the least clear of the models proposed, making it very difficult to provide meaningful comment.

The separate streams have advantages as described for the other models, however the requirement **for co-funding only for implementation research would be a clear disincentive** and thus unfairly inhibit work in health care delivery research. Furthermore, the lack of fellowships is a disadvantage.

ACTA does not support this model.

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