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RE TGA GCP Inspections Program Consultation Paper

Thank you for the opportunity to comment on the TGA's proposed Good Clinical Practice (GCP) Inspections Program as outlined in the consultation paper version 1.0, December 2018.

The feedback below has been coordinated by the Research Portfolio of the University of Sydney (the University) though consultation with clinical trial researchers and our internal Research Integrity, Human Ethics and Clinical Trial Risk & Governance teams.

What are your thoughts on a pilot GCP inspection program and proposed establishment of a routine program following the pilot?

The university recognises GCP inspection programs are already implemented in many jurisdictions. The University agree this is an appropriate step for Australia.

The University notes the statement *"Inspections will be initially restricted to investigator sites of clinical trials involving pharmaceuticals*" and seek clarification on likely expansion e.g. at the completion of the pilot, will the TGA expand to inspect

- sites participating in clinical trials involving
    - biologicals & medical devices
    - non-drug / non-device trials , and
- clinical trial sponsors

Would you consider volunteering to be a clinical trial site inspected under the pilot program?

No University clinical trial sites have volunteered to participate in the pilot. We understand TGA inspectors will attend as observers at a forthcoming EMEA inspection of a University site (commercial sponsor) and are interested to know if this will be considered one of the TGA pilot inspections.

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Would the release of inspection findings to the approving HREC and/or Authorising Institution on be an appropriate mechanism for managing issues relating to the conduct of the trial or integrity?

The NHMRC "Reporting of Serious Breaches of GCP or the protocol for Trials Involving Therapeutic Goods", 2018 requires all serious GCP breaches occurring at a site to be reported. Accordingly, the University agrees any serious breach identified by the TGA inspection program should be reported within the required time frames.

The University feels it is slightly more complex with all other findings. Clinical trial sponsors, approving Instructions & responsible HRECs should be informed of all findings. However, there is the need for assessors to be able to appropriately contextualise reports received. Accordingly, we propose

- the results be shared, but they should also include Corrective and Preventative Actions (CAPAs) proposed and agreed to by the site to address findings.

- As part of the pilot the TGA, share with the responsible HREC, sponsors and approving Institutions de-identified high-level cumulative results of all inspections from the pilot program. This would assist reviewing authorities to contextualise the findings for sites under their responsibility.

What impact, if any, would a domestic GCP inspections program have on Australia's competitiveness as a place to conduct clinical trials?

Although the consultation paper states …*(an Inspection programme)…. will address the potential risk of a decline in international recognition of Australian clinical trial data quality and integrity* The University has some concerns that in the short term there is a risk of decreasing Australian competitiveness particularly in the areas of financial and reputational (quality) considerations.

<u>Financial Implication</u>

Australia has a reputation as a comparatively expensive location to conduct clinical trials. For commercial sponsors this is partially mitigated by the Federal Government's R&D Tax incentive Scheme. The R&D tax incentive scheme does not generally support academic researchers who have expressed concerns regarding the potential to further erode the thin margins they work with for grant-funded research

As with most areas of work, there are likely to be varying interpretations and/or understanding of the requirements of the inspection. Although the pilot will be at no charge, researcher and sponsor time will be required to prepare for and participate in the inspections.

The University also notes the suggestion in the Consultation paper that after completion of the pilot the TGA is may introduce a fee for service model to cover its Inspection costs. Although aligned with the UK model, the UK model,

as noted in the consultation paper, is unique in charging fees for inspections compared to other regulatory authorities.

Quality reputation

Early inspections are likely to uncover many issues that will inevitably reduce as researchers become more aware of the practical implications of GCP expectations.

Further considerations

The University agrees that in the long-term an effective inspection program will improve quality and assist researcher education in practical implications of GCP expectations.

In order to realise these goals in a timely manner, the University suggests an inspection program should be accompanied by an equal investment in educational & researcher support initiatives e.g. information on the TGA website that provides

- GCP training materials, including quiz and certification facilities. Training specifically targeted to each of the three 3 pillars of GCP (researchers, sponsors, ethics and governance staff)
- Provision of standard tools and template on the TGA website that support researcher compliance
- After an initial period (duration to be determined), the TGA publish annual high-level summary results of their inspection findings. Similar to the publications of the UK MHRA.

We trust this feedback is helpful and appreciate, support and agree with the TGA's focus on facilitating conduct of high-quality clinical trials across Australia.

Yours sincerely,

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