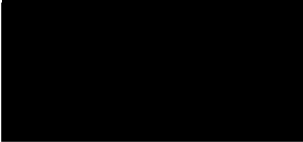




12 April 2019



Dear [REDACTED]

Re: OIA request – DHB-hosted clinical drug trials

Thank you for your Official Information Act request received 9 April 2019 seeking the following of Waitemata District Health Board (DHB):

The number of clinical drug trials your DHB hosted in the 2017/2018 financial year and ongoing trials in 2019.

Could figures please be broken-down by:

- *The number of sponsored clinical trials involving devices and pharmaceuticals.*
- *Phase 1 first-man-in clinical trials and phase 2a/b safety and efficacy trials, phase 3 broader efficacy trials and phase 4 post-marketing surveillance. And whether these trials are investigator-initiated or industry-sponsored commercially contracted trials.*
- *Investigator-initiated studies of non-therapeutic interventions, e.g. new diagnostics or new applications of existing diagnostics.*
- *Investigator-initiated observational studies including epidemiologic studies.*

Can you please also provide the aggregate income figure your DHB obtained from trials conducted in the 2017/2018 financial year.

It is important to note that health and medical research is recognised worldwide as being integral to quality healthcare systems. Waitemata DHB has a number of research groups that produce high-quality research informing local clinical practice.

As well, collaborative relationships with other research groups, tertiary partners (regional, national and international) and the community are encouraged. Research has ensured that our clinicians are informed of latest developments within their fields and, in turn, this has directly benefited our patients.

In response to your specific questions, we can advise that in the 2017/2018 financial year, there were 73 industry-sponsored clinical trials hosted by Waitemata DHB and recorded as ongoing.

By phase:

Phase 4 - five

Phase 3 - 51

Phase 2 - five (listed as 1= Phase 2a; 1= Phase 2b; 3= Phase 2)

Phase 1 - two

Device - 10

From this 73, there were 27 industry-sponsored clinical trials that received locality approval in the period 2017/2018.

Locality Approval 2017/2018:

Phase 4 - one

Phase 3 - 21

Phase 2 - four (listed as 1= Phase 2a; 1=Phase 2b; 2= Phase 2)

Phase 1 – zero

Device - two

The net direct income figure from these trials conducted in the 2017/2018 financial year was \$1,137,744.

These funds are deposited and held in trust by the Three Harbours Health Foundation and able to be accessed by the researchers to use for creating capacity for further research and payment of expenses for research nurses and any costs directly attributable to conducting clinical trials, including clinical supplies, consumables and additional diagnostic costs of laboratories and radiology.

In the 2017/2018 financial year, there were 62 non-industry-funded investigator-initiated clinical trials hosted by Waitemata DHB and recorded as ongoing.

In the same period, there were 124 investigator-initiated observational studies hosted by Waitemata DHB and recorded as ongoing.

This group includes interventional research requiring Health and Disability Ethics Committee (HDEC) review and approval and the research activity may include medication, device and other interventions, such as computer applications, cognitive therapies and pathways of care.

A small portion will have received funding that is included in the amount referred to above (for example, grant funds from the Health Research Council or similar funding organisation).

Other research may have been conducted in collaboration with an external researcher (eg university/other DHB, collaborative research groups) and - while hosted by the DHB and involving participants who may have been patients and/or staff - the conduct of the research and the costs associated with the conduct will have been met in large part by the external researcher.

I trust that this information meets your requirements. Waitemata DHB, like other agencies across the state sector, supports the open disclosure of information to assist the public's understanding of how we are delivering publicly-funded healthcare.

This includes the proactive publication of anonymised Official Information Act responses on our website from 10 working days after they have been released.

If you feel that there are good reasons why your response should not be made publicly available, we will be happy to consider this.

Yours sincerely



Robert Paine
Chief Financial Officer & Head of Corporate Services
Waitemata District Health Board