COVID-19 Guidance on Clinical Trials

For Sponsors, Researchers, Trial Sites, HRECs, and RGOs

Contents

Version	Date
V1.0	25 Mar 2020
V2.0	09 Sep 2020

PART 1: COVID-19 guidance for clinical trial sponsors, sites and researchers

Clinical trials are essential for the advancement of health and medical research. NSW Health supports continuation and start-up of clinical trials at public health organisations.

Background

The Australian Department of Health has released a guidance document providing general information and advice to institutions conducting or overseeing research, Human Research Ethics Committees (HRECs), researchers and sponsors in the context of the COVID-19 pandemic. www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials

This guidance supplements high level guidance published by the Commonwealth Department of Health, providing further operational detail to minimise the adverse impacts of the COVID-19 pandemic on the delivery of innovative healthcare through clinical trials. As this is a rapidly evolving situation, this guidance may be updated in response to the changing environment.

For queries please contact: clinicaltrialsNSW@health.nsw.gov.au. For the most recent information on COVID-19, please refer to the NSW Health Website.

Key principles

- For urgent clinical trials related to COVID-19 and for existing trials that plan to incorporate COVID-19 elements (e.g. a new sub-study or a COVID-19 treatment arm) every effort should be made to introduce process flexibilities that expedite these trials whilst protecting participants.

- Emphasis is placed on minimising trial burden and disruption to health-related services in NSW whilst also maintaining the safety of trial participants, site, sponsor and vendor staff, and the validity of trials.

- Participants are at the centre of clinical trials and should be kept engaged and informed in relation to clinical trial changes

Note on amendments: During this period, not all amendments need to be reported to the HREC. Amendments will be classified as 'substantial' or 'non-substantial' (see Appendix 2).

Only **substantial amendments** require reporting to the HREC. For example, if a planned modification of a protocol is likely to negatively impact on participants' safety or increase risk to participants, review of the substantial amendments by an HREC (or other approved delegated process) would be required.

Note: *New trials of potential COVID-19 therapeutics must follow current TGA and NHMRC processes including HREC approval and site authorisation.*

Clinical trials currently in start-up or feasibility phase

Sponsors, researchers and sites should consider their planned clinical trials portfolio and allocate according to health system capacity, risk assessment and continuity planning. When planning study start-up it should be noted that some NSW HRECs and Governance Offices may be prioritising COVID-19 studies, so applications for other types of trial may be delayed.

Ongoing trials impacted by the wider COVID-19 response

Researchers, sites and sponsors should work together in conducting risk assessments for the continuation of each study. LHDs are encouraged to develop a business continuity plan with respect to their clinical trials portfolio.

Stakeholders should consider the *risks to participant* in either: (i) continuing a clinical trial or (ii) discontinuing a trial where there are no other treatment options. Where there is an unacceptable risk to participant safety in continuing a clinical trial, sponsors and sites should decide whether to temporarily suspend enrolment, suspend the trial, or discontinue the trial altogether. These decisions will be influenced by many factors including: the nature of the intervention, the ability to conduct appropriate safety monitoring and the nature of the disease under study.

FDA Guidance provides useful information to sponsors on the factors to consider when deciding whether to continue with drug, biological and medical device trials.

Changes to study conduct

Sponsors, sites and researchers should assess the impact of COVID-19 on their current clinical trials portfolio, participants and staff, as related to health system reprioritisation**,** restrictions on movement, and supply chain challenges**.** Critically, this assessment should include consideration for whether a trial can be properly conducted if amendments to trial conduct are implemented. If participants are put at risk because key evaluations cannot be completed or other critical contingency measures cannot be met, then participant withdrawal, trial suspension or termination or enrolment suspension should be considered. Any amendments implemented should be as consistent with the protocol as possible and good documentation practice should be maintained.

The exception is where an immediate action must be taken to protect participants (an **Urgent Safety Measure**) which is then reported to the HREC after the event (see Appendix 2).

Considerations for clinical trial conduct during COVID-19

Sponsor instigated changes

When implementing changes to the Trial Protocol or processes, Sponsors are encouraged to liaise with trial sites and consider the potential burden on trial sites of any changes (e.g. from labour-intensive remote monitoring procedures) and the potential risk to participants.

Adding new COVID-19 related elements

If a sponsor wishes to add a sub-study or other component, such as enabling an epidemiological analysis of COVID-19, this should be submitted as a substantial amendment in the usual way. Sponsors and study teams should alert HRECs to make it clear that the amendment relates to COVID-19 so that it may be considered for an expedited review.

Altering participant visit arrangements

To reduce the risk of exposure to COVID-19, sponsors may change participant visit arrangements e.g. using a satellite site outside of the hospital setting, changing site visits to phone calls, postal questionnaires, using remote visits (e.g. using Telehealth), conducting fewer visits, increasing the time between visits, conducting critical tests at a local laboratory/facility.

These changes will generally be considered as non-substantial amendments unless any change potentially increases the risk to participants (e.g. because there are fewer participant checks). These would then need to be reviewed by the HREC as a substantial amendment.

Withdrawing participants: If the safety of a trial participant is at risk because key evaluations or critical mitigation steps cannot be completed, then participant discontinuation should be considered.

Participant withdrawal must be discussed between the Sponsor and the Principal Investigator (PI) with regard to patient care, noting that some interventions must not be abruptly interrupted.

Dispensing, shipping and storage arrangements (drug trials)

Interrupting the provision of study drug may pose a significant risk in some trials. Sponsors must assess the risks relating to supply and consider any shipping and storage arrangements. Interruptions to provision of study drug may occur during the supply chain or if the participant is unable to access the site.

Where previously participants were dispensed trial drug from the site pharmacy for self-administration, alternative arrangements may include:

- dispensing to a nominated person where a trial participant is in self-isolation or practicing social distancing
- dispensing an extended supply of study drug (i.e. beyond protocol-mandated dispensing)
- couriering study drug to a participant's home.

Sponsors, sites and researchers should work in consultation with participants to determine the most appropriate method to enable participants to access study drugs.
If study drug is shipped directly to the participant then, it may be necessary for IP to be shipped from the trial site or via a third-party agent to maintain privacy. Any such arrangements should include a process for obtaining the agreement of the participant to the delivery changes.

For trials where study drug is usually administered in a health care setting (e.g. infusions), consultation with all relevant stakeholders is required to establish whether alternative arrangements, such as drug administered home infusion or at an alternative site by trained non-study personnel, is feasible.

In all cases, sponsors and investigators should communicate with the institution's pharmacy about proposed arrangements, particularly in relation to issues around product stability, temperature monitoring, chain of custody and product accountability. Where possible, such arrangements should be handled prospectively as a substantial amendment but when there is no time to arrange for such a review, the change should be implemented as an urgent safety measure.

Drug Return, Accountability and disposal of investigational drug (IP) or device

NSW Health Pharmacy departments should follow the Clinical Excellence Commission (CEC) document Safe handling of medications during COVID-19 pandemic. Pharmacy departments are reminded that compliance with the Medication Handling in NSW Public Health Facilities Policy Directive is mandatory for sites within NSW Public Health Organisations and that local recommendations should be in accordance.

For drug accountability and public safety, unused IP should always be returned to the trial pharmacy for appropriate disposal. IP returned to pharmacy department from study participants (including suspected or proven COVID-19 participants) may require additional safety precautions to reduce the risk of cross infection. Please follow appropriate guidance regarding PPE for health workers such as that released by the Clinical Excellence Commission..

Pharmacy department may institute a quarantine period for the returned IP and collaborate with the Sponsor to determine the most appropriate way of monitoring of drug returns i.e. drug accountability. All changes should be well documented and communicated.

Potential options for sites to complete drug accountability:

- Sponsor CRA/Monitor conduct onsite visit as per standard study requirement
- Sponsor CRA/ Monitor conduct virtual visit
- Pharmacy department undertakes drug accountability, with an additional witness, without requiring the CRA to conduct the monitoring visit
- Other modality as agreed between the Sponsor and the Pharmacy

After drug accountability has been completed and documented, the disposal of investigational products must comply with the requirements of NSW Health PD2017_026 Clinical and Related Waste Management for Health Service and the institutions standard operating procedures.

Making changes to monitoring arrangements

Sponsors are encouraged to review the frequency of monitoring prior to considering risk-based approaches and remote monitoring. Alternative arrangements to site visits must minimise the burden on trial site staff from any remote monitoring arrangements and videoconference contacts. Any alternative monitoring arrangements must still maintain patient confidentiality protocols already in place.

Managing protocol/GCP deviations and serious breaches

Sites may need to make rapid changes to manage clinical situations. Sites and sponsors should document all specific protocol deviations necessitated by the impact of the current COVID-19 pandemic and the reason for the deviation. Further information can be found at Appendix 2.

Closing, temporarily suspending a trial, or temporarily suspending enrolment

Central to any decision should be ensuring that the safety of clinical trial participants can be maintained. For a multi-centre trial, sites may reach differing conclusions about whether to proceed due to local public health risk assessments and/or workforce pressures placed on frontline services. In this scenario, the Coordinating PI should discuss with the sponsor whether to temporarily suspend the trial or trial enrolment at one or several sites. Simply suspending enrolment does not need to be reported as a temporary halt, although sites and sponsors should maintain a record of such decisions:

- Where a study that involves a therapeutic good (drug, device, or biological) is temporarily halted, sponsors should inform the HREC. HREC acknowledgement is not required prior to implementing a suspension.
- Where a study that does not involve a therapeutic good is temporarily halted, this may be made as a non-substantial amendment. It may be implemented at the site through communication with the study team.

Closing a study is a serious consideration, as the successful completion of a study is an important ethical endpoint. A study should only be closed if there is no practical way of allowing it to achieve its primary outcomes in the COVID-19 world.

Site-instigated changes due to increased clinical requirements or staff availability issues

Sites may need to make rapid changes to manage front line services. The priority should be the safety of participants and staff involved in clinical trials.

The availability of the PI should be considered in terms of current healthcare reprioritisation and the PI's primary responsibility for the trial under ICH-GCP. Availability of clinician investigators and research nurses may be impacted if resources are diverted to essential services. Sites should work with sponsors to plan for this occurrence and, wherever feasible, come to an arrangement so trials can continue without posing an unacceptable risk to participants, trial data or trial staff. For example, if the study must be temporarily halted or closed at the site, it may be possible to transfer patients to a nearby site or exceptionally, for the sponsor to open a new site (the TGA has issued guidance on its interpretation of new trial site additions, reproduced at Appendix 3). In such situations, the impact on participants should be considered and arrangements made to manage logistics, for example additional transport.

Note: Disruptions to clinical studies may have implications for contractual obligations, particularly for commercial research. Sites conducting their trial under the Clinical Trial Research Agreements (CTRAs) are reminded that termination provisions are contained in the Force Majeure clause of the agreements. Sites needing to invoke a force majeure provision are reminded that they must follow the process described in the clause.

Studies where the PI is taken off the trial:
Any existing arrangements covering a PI's absence should be followed. HRECs may review and amend their own arrangements. Where no such arrangements are in place, NSW Health guidance is that:

- if the PI's absence will be greater than one month the HREC should be notified.
- if the PI is absent for greater than three months, alternative arrangements should be put in place.

PART 2: COVID-19: Clinical trial principles and guidance for HRECs, RGOs and Researchers

Partly adapted from UK NHS HRA COVID-19: Guidance for Sponsors, Sites and Researchers with additional feedback from NSW Ethics and Governance Offices on current best practice actions being taken.

Research Office Prioritisation of COVID-19 Research

Since the first wave of COVID-19 in NSW and the request for prioritisation contained in the first release of this Guidance (April 2020), evidence has shown that NSW Public Health Organisation (PHO) Research Offices have clearly focussed on fast-tracking COVID-related research projects and amendments.

This prioritisation has been essential as, to date, time has been of the essence in getting studies into the field that can directly examine the COVID phenomenon, both from a health services research perspective, as well as finding a potential COVID diagnostic, preventative or treatment.

Development of innovative practice and sustainability

OHMR commends all Research Office staff for their extraordinary efforts during this time in finding innovative ways to work with their research communities to reduce study start-up times. OHMR further encourages the identification of which of those innovations can be embedded into business as usual.

Practices such as the scheduling of additional HREC meetings, creation of separate COVID working groups, out of session reviews and proactive pre-approval processes appear to have contributed to rapid review times. However, Research Offices must also look to the COVID-related practices they have introduced and determine how sustainable they are in the short-, medium- and long-terms.

Research Offices are encouraged to calibrate COVID practices to ensure consistent practice over the long term. For example, if extra meetings are being conducted, assess how frequently these are required, and adjust accordingly. Current infection rate trends (early August 2020) suggest that public health orders may still be in place for some time to come.

Non-COVID research and a pivot back to processing all research using current practice

Non-COVID research still accounts for about 90% of all new projects being reviewed through Research Offices and much of this has understandably taken a back seat to the priority of COVID-related research.

However, these studies are also important for providing the evidence required for introducing new therapies or changes in clinical practice, and it is essential that they continue to be approved and authorised wherever public health policy and technical innovation allows the research to be conducted.

PHOs and their Research Offices should continue to make themselves aware of the public health orders issued and the developing trends in the COVID infection rate. Offices should plan to pivot back to a balanced portfolio of COVID and non-COVID research approval/authorisation as this becomes practicable and sustainable.

Communication from and to Research Offices

Overwhelmingly, Research Offices report that early and frequent communication at all levels and between all parties has led to an ability to fast-track most of the applicable research projects they receive.

Research Offices should develop draft guidance (many have already) on the communication practices they encourage with their research communities, with a view to implementing these in their ongoing practice post-COVID. The guidance should address preferred contact methods and times of availability of Research Office staff for researcher enquiries.

Researchers

Researchers are encouraged to proactively contact their Research Offices at the first available opportunity following protocol development or receipt of a study and establish what the local requirements are. Practice has been reported to show that this is a simple and effective step to getting research up and running quickly.

- Researchers must ensure, to the greatest extent possible, that their submission is complete and accurate.
- Researchers should inform the Research Office of their anticipated submission date to facilitate planning within Research Office.
- Researchers should include final versions of their Protocol, IB and PICF in their application to expedite the review process.

Human Research Ethics Committee (HREC)

General points for meetings and general practice

Many HRECs report that videoconferencing platforms have contributed to enhanced meeting practice during COVID. HRECs are encouraged to adopt such technologies to meet remotely as circumstances determine. NHMRC has released a supporting statement to HRECs (at Appendix 1).

- HRECs should review and modify their Terms of Reference and/or SOPs to support the mechanisms required to deal with the COVID-19 situation.
- HRECs should develop methods to allow all self-isolating members to continue to actively participate in meetings as well as pre- and post-meeting processes.
- HRECs may wish to revaluate what matters may be dealt with by an executive committee of the HREC and whether changes to the HREC's terms of reference are required.
- HRECs should accept, and encourage study teams to use, electronic transfers of documents over paper documents where possible and the use of digital/electronic signatures (where available) over "wet-ink" signatures. [See below for further guidance on e-signatures.]
- HRECs who need to source expertise not available internally may develop arrangements with other HRECs; noting that health system reprioritisation means that experts will have limited capacity.

New studies relating to COVID-19

- HRECs should encourage trial teams (esp. those in COVID-relevant areas such as respiratory medicine, virology, etc) to contact their office as soon as a protocol has been developed and/or should proactively liaise with their research community to horizon-scan projects that are being developed in order to minimise duplication and maximise efficiency of trial review and start-up.

- HRECs must develop mechanisms to identify and provide rapid preliminary assessment and feedback on new COVID-19 protocols, prior to HREC submission.
- HRECs should work with their health service managers to actively determine the priority of triage studies to prioritise COVID-19 studies.
- Whenever feasible, HRECs should utilise extraordinary meetings, convened at short notice, to conduct expedited reviews.
- HRECs may consider inviting the trial investigator to remotely attend HREC meetings at an allotted time to enable the investigator to provide clarification in respect to any ethical issues that the committee raises in order to potentially resolve these in real time.

Existing studies requiring amendment:

- HRECs should familiarise themselves with the information at Appendix 2 in relation to substantial and non-substantial amendments. They should also be familiar with the distinction between amendments and urgent safety measures.
- HRECs should communicate with their research communities to encourage the sponsors they are working with to prioritise those amendments that are critical to patient safety.
- HRECs must develop a triage/processing system to fast-track amendments to existing studies where ongoing conduct is urgently affected by COVID-19.
- HRECs should publicly communicate that they are using a triage and processing system in order to set expectations on turnaround time for those amendments not urgently affected by COVID-19.
- HRECs may choose to use a 'virtual' full HREC meeting to process amendments or may develop criteria to delegate the responsibility for reviewing such amendments - e.g. to the HREC executive committee.
- HRECs should recognise that their responsibilities remain unchanged in ensuring that investigators provide appropriately detailed information to participants to enable their informed consent to patient-relevant amendments.

Research Governance Officers (RGOs)

Communications

In line with the principles on communication above, institutions should develop communications to clarify to their research communities whether any studies are to be prioritised, and if so, the type and nature of those.

Research Offices should endeavour to:

- Communicate widely with their research-active departments asking them to approach the RGO/Research Office as soon as they have a protocol and PICF.
- Examine their active research portfolio and triage studies to prioritise urgent COVID-19 studies; but also ensure that non-COVID trials that can be conducted safely (especially those that provide a treatment option) are also able to do.
- For COVID-19 studies, perform an initial, fast-track 'pre-review' of the trial.
- Facilitate access to additional support the research team may need to expedite their application.
- For locally sponsored trials, fast-track the governance review in parallel with the research team completing the HREA, working closely with RGOs from other sites if required. For local investigator-led, multicentre trials, lead RGOs are encouraged to seek advice from, and liaise with, other research office(s) to address operational issues early in the critical path.

- For externally sponsored trials, conduct a fast-track review as soon as the application is received.

Digital / Electronic Signatures

- Research Offices should encourage the use and acceptance of digital/electronic signatures, where practicable, in place of 'wet ink' signatures, especially as a COVID-safe measure.
- There are no policy restrictions on NSW Health entities using digital/electronic signatures to execute clinical trial documents.
- OHMR has representation on a CT:IQ Working Party that is developing national guidance on digital/electronic signatures. When this is released, OHMR will circulate it amongst stakeholders.

Ongoing studies

- For ongoing studies, wherever possible, work with the reviewing HREC (whether they are based at the same institution or another Certified HREC) to expedite review of proposed amendments.
- Work with investigators of ongoing studies to phase in a return to study conduct, in line with public health advice, as that becomes possible and practicable.

Sources consulted:

- UK NHS HRA COVID-19: Guidance for Sponsors, Sites and Researchers
- Bellberry Ltd – Clinical trials and COVID-19 https://bellberry.com.au/?cat=-1
- TGA - TGA Clinical Trials Processes
- FDA: Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic
- MHRA Guidance: Managing Clinical Trials during COVID-19
- EU: Guidance on the management of clinical trials during COVID-19 pandemic

Appendix 1:

From: HREC.admin <HREC.admin@nhmrc.gov.au>
Sent: Monday, 16 March 2020 4:32 PM
Subject: HREC meetings by video or phone conference [SEC=OFFICIAL]

Dear HREC Chairs and administration officers

We have had a few queries about the suitability of holding ethics committee meetings by means other than face-to-face (i.e. video or phone conferencing).

While the National Statement on Ethical Conduct in Human Research doesn't address this matter specifically, we would like to assure you that meetings by video or phone are fine (so long as they meet the requirements of 5.2.30) and are encouraged at this time. We would also like to assure you that as per paragraphs 5.2.31 and 5.2.32, the views of and opinions of those in the minimum membership categories need to be provided. While this is ideally at a meeting, if this is not possible, then the views of those absent should be received and considered before a decision is reached.

We would like to take this opportunity to thank you for your valuable work and contribution to progressing the research effort in Australia, particularly with the challenges around us at this present moment.

Please email HREC.admin@nhmrc.gov.au if you have any further queries.

Kind regards

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Australian Government
National Health and Medical Research Council

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Appendix 2:

Mechanisms used to make changes to trials

1. Substantial and non-substantial amendments

Amendments can be substantial or non-substantial. A ***substantial amendment*** can be defined as an amendment that is likely to affect to a significant degree:

(a) the safety or physical or mental integrity of trial participants
(b) the scientific value of the trial
(c) the conduct or management of the trial, or
(d) the quality or safety of any therapeutic good used in the trial.

Wherever feasible, all substantial amendments should be prospectively approved by the HREC (unless they meet the definition of an **urgent safety measure -** see below).

Non-substantial amendments are amendments that do not meet the definition of a substantial amendment. These will not require real-time HREC review. A summary of all non-substantial amendments should instead, be provided either, when the next substantial amendment is submitted or in the next progress report provided to the HREC.

Box 1: Examples of non-substantial amendments (adapted from the UK HRA website):

- The addition of COVID screening procedures mandated by the health system
- Minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications
- Changes to monitoring arrangements, unless those changes have the potential to increase the risk to participants (e.g. in-person visits are necessary to fully assure the safety of trial participants).
- Updates of the investigator's brochure (unless there is a change to the risk/benefit assessment for the trial)
- Changes to the investigator's research team
- Changes to the research team at trial sites (other than appointment of a new principal investigator)
- Changes in funding arrangements
- Changes in the documentation used by the research team for recording study data
- Changes in the logistical arrangements for storing or transporting samples
- Inclusion of new sites and investigators in studies
- Extension of the study beyond the period specified in the ethics application.

2. Urgent safety measures

An urgent safety measure is defined in the NHMRC's Safety Monitoring and Reporting of Clinical Trials Guidance as: *A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.*

This type of significant safety issue can be instigated by either the investigator or sponsor.

3. Protocol Deviations and Serious Breaches

At this time, there are significantly greater reports of unavoidable protocol and standard operating procedure deviations due to missed visits, interruption in the supply of investigational product, staff absence and COVID-19 control measures. Wet-ink signatures are also difficult to obtain if staff are not in the office and alternative mechanisms are being put in place.

Sites and sponsors should continue to ensure that all deviations are well documented to enable appropriate evaluation of their impact on the trial. For example, prior to database lock, the statistical analysis plan should clarify how protocol deviations related to COVID-19 will be handled for the prespecified analyses.

Note: A deviation of the protocol or GCP will constitute a Serious Breach (NHMRC Guidance on the Reporting of Serious Breaches of GCP or the Protocol) if it impacts to a significant degree, the safety and rights of participants and/or the reliability of data.

However, protocol/GCP deviations in relation to Coronavirus will not normally constitute a serious breach as they are sensible modifications to safely manage trial patients in the current environment.

Individual protocol/GCP deviations should be assessed individually and collectively by the sponsor. Any serious breach that arises from this assessment is reported to the HREC. **All other protocol deviations do not need to be reported to the HREC (in line with NHMRC Guidance).**

The HREC should be periodically updated on the impact of COVID-19 on the trial. This can be achieved by ensuring the next HREC progress report includes information on:

- number of patients impacted
- changes to medication dispensing
- dose interruptions
- changes to visit schedule and visit activities
- use of external services (e.g. pathology, imaging, visit sites)
- missing data.

For trials conducted under a Clinical Trial Notification, the TGA website describes flexibilities in response to COVID-19 on informing the TGA of certain amendments.

Appendix 3

TGA response to coronavirus (COVID-19)

As part of the Department of Health, the Therapeutic Goods Administration (TGA) is providing active support for monitoring a number of issues relating to therapeutic goods including medicines and medical devices in response to the novel coronavirus (COVID-19).

Information about access to medication
https://www.tga.gov.au/media-release/tga-response-coronavirus-covid-19

Information about clinical trial processes
https://www.tga.gov.au/clinical-trial-processes

TGA Requirements for new trial site additions

From:
Sent: Friday, 3 April 2020 2:19 PM
To:
Subject: RE: CTPRG Teleconference - midday 2 April [SEC=OFFICIAL]

Hi all,

To clarify regarding TGA requirements for new trial site additions;
Addition of new trial sites, as determined by the HREC, will need to be notified to the TGA as a variation.
A change to site address due to COVID-19 would not incur a fee nor require notification so long as both the sponsor and HREC are in agreeance that it is a change to previously notified site only and not an addition of a new site.
Ultimately, it is up to the HREC and the trial sponsor to determine whether a new address is considered to be a new site requiring variation submission.

Kind regards,

Experimental Products Section

Medicines Regulation Division | Health Products Regulation Group
Pharmacovigilance and Special Access Branch
Australian Government Department of Health

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