



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



Consultation Paper

Product Vigilance in the Australia New Zealand Therapeutic Products Authority (ANZTPA)

September 2006

HOW TO MAKE A SUBMISSION

You are invited to provide written comment on this consultation paper. Submissions can be sent by post or e-mail and, where possible, should be cross-referenced to specific sections set out in this consultation paper. In addition, we encourage you to provide other comments that may assist in developing the detail of the Authority's pharmacovigilance and device vigilance activities.

Content of submissions

Your submission should include:

- your name and full contact details including: address, telephone number, and if applicable, facsimile and e-mail address;
- the particular issue being addressed;
- relevant evidence and/or examples to support the views expressed; and
- in the case of organisations, the level at which the submission was authorised.

Confidentiality of submissions

If you wish any information contained in a submission to be treated as confidential, please clearly identify the information and outline the reasons you wish it to be treated as confidential.

Address for submissions

Electronic submissions should be e-mailed to: consultation@anztpa.org

Hardcopy submissions should be addressed to either of the addresses below:

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Questions relating to submissions

Any questions relating to submissions should be directed to the Project Officer, by e-mail at: consultation@anztpa.org

Deadline for submissions

The deadline for receipt of submissions is **6 December 2006**.

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PURPOSE OF THIS CONSULTATION PAPER

The purpose of this consultation paper is to collect the views of stakeholders on the proposed pharmacovigilance and device vigilance (hereafter referred to as product vigilance) functions of the Australia New Zealand Therapeutic Products Authority (ANZTPA).

BACKGROUND INFORMATION

Product vigilance includes a range of activities relating specifically to monitoring, assessing, evaluating, and improving the safety of therapeutic products. ANZTPA is committed to developing and operating a comprehensive product vigilance system that is in line with best international practice.

Summary of the proposed regulatory framework for ANZTPA

As proposed in earlier consultation documents, ANZTPA will regulate:

- the import of therapeutic products into Australia and / or New Zealand;
- the export of therapeutic products from Australia and / or New Zealand;
- the supply, manufacture and promotion of therapeutic products in Australia and / or New Zealand; and
- associated activities.

The new scheme is based around a system of licensing, whereby a Product Licence Holder would be the person in Australia or New Zealand with the legal responsibility for a therapeutic product that is imported into, supplied in, or exported from, Australia and/or New Zealand.

Article 1 of the Treaty defines ‘therapeutic product’ for the purposes of ANZTPA. This definition includes the following, all of which will be regulated by the Authority:

- prescription medicines;
- over-the-counter (OTC) medicines (including most sunscreens);
- complementary medicines;
- human blood and blood components;
- cellular and tissue therapies;
- medical devices (including *in vitro* diagnostic devices, sterilants and instrument-grade disinfectants); and
- other products meeting the definition of therapeutic product (or declared in the Rules to be therapeutic products).

A framework comprising Acts in both countries, together with Rules and Orders, will replace the existing Australian *Therapeutic Goods Act 1989* and its Regulations and Orders, and the existing *New Zealand Medicines Act 1981* and its Regulations.

Acts in both countries will contain the broad regulatory matters and obligations that must be contained in primary legislation. Each Act will recognise ANZTPA as the regulator of therapeutic products for that country, and will give effect to the regulatory decisions of ANZTPA made through its Managing Director.

A Ministerial Council, comprising the Australian and New Zealand Ministers of Health, will make a single set of **Rules** (analogous to regulations in the current Australian and New Zealand systems). These Rules will contain much of the detail of the regulatory requirements. The requirements for medicines and medical devices are set out in separate parts of the draft Rules released for consultation in May 2006. The requirements for blood, and for therapies containing cells and tissues, will be published in September/October 2006 and March 2007, respectively.

The Managing Director of ANZTPA will make **Orders** in relation to technical matters such as standards, manufacturing principles and packaging and labelling requirements.

The proposed ANZTPA regulatory scheme is a risk-based system where the regulatory requirements for a product licence are based on the risks posed by the therapeutic product. In addition, other than in a limited set of defined circumstances, all therapeutic products must be issued with a product licence before they can be imported, exported, or supplied in Australia or New Zealand.

The draft Rules propose two types of product licence – a *provisional licence*, where data supporting safety and efficacy are limited and the product is required to manage or treat a serious condition for which other treatment options are limited, and a *full product licence*, where the application meets all of the requirements of the Authority. Irrespective of which form of licence is issued, the Authority will place certain requirements on Product Licence Holders to collect and report adverse reactions or adverse events for their products. In addition, the proposed Rules permit the Authority to place other requirements on the product licence holder, including the requirement to prospectively collect data on the safety of their product after it enters the market, either at the time the product licence is issued or if safety issues emerge at any time thereafter.

This document sets out proposals for the administration of a product vigilance scheme within the Authority. It should be read in conjunction with the draft medicines, medical devices, and administration Rules, and other documents released during the consultation process to establish the ANZTPA (including the draft blood Rules when they become available). The existing guidelines for pharmacovigilance and device vigilance in Australia, and the European Union proposals on Risk Management provide additional background information on the strategic direction ANZTPA is proposing for product vigilance. As with other aspects of the proposed draft Rules, the proposals for product vigilance requirements are based upon the risk characteristics of the product.

For the purposes of product vigilance, products are divided into two categories: low-risk and high-risk. The vigilance requirements for each category will be defined in separate guidelines to be released in later consultation phases. The systems and requirements set out below provide high level detail of the proposed ANZTPA product vigilance framework.

Current product vigilance operations

Medsafe and the TGA currently perform a range of product vigilance functions, including collecting and analysing spontaneous reports of adverse events related to medicines, medical devices, blood and tissue products, and blood. Both regulators support expert advisory committees, which review data on the safety of products that are subject to regulation in each country. Both regulators also take regulatory action to update and communicate information on risks for therapeutic products to industry and other stakeholder groups.

Under the joint scheme, all of these services would continue to be performed on behalf of New Zealand and Australia. In addition, the Authority proposes to introduce new requirements for some types of therapeutic products – this includes, pre-licence risk management plans, product vigilance system specifications, and the ability to review Product Licence Holder compliance with the Authority's product vigilance requirements.

These proposals are designed to move the product vigilance system from the current reactive system of passive data collection and reporting, towards the institution of a proactive approach to product vigilance within all parts of a product's lifecycle.

1. PRODUCT VIGILANCE DATA FROM PRODUCT LICENCE HOLDERS

1.1 Medicines and Blood

1.1.1 Pre-Licence Risk Management

It is proposed that all new product licence applications for high-risk therapeutic products must include the submission of a product-specific risk management plan (see Table 1). This should be submitted to ANZTPA in a format specific to each product type – the preferred format for this risk management plan is that described for a European Union Risk Management Plan (EU-RMP). Low-risk therapeutic products would not require the submission of a Risk Management Plan, unless this requirement was placed as a specific condition on the product licence. It is anticipated that this would occur rarely for low-risk products.

Table 1: Proposed Product Vigilance Risk Categorisation

Therapeutic Product Type	High-Risk	Low-Risk
Medicines	Class 2 medicines evaluated by Prescription Medicines stream;	Class 1 medicine; Class 2 medicines evaluated by Non-Prescription or Complementary Medicines stream
Blood	Class 2	Class 1

A risk management system is a set of vigilance activities and interventions designed to identify, characterise, prevent, and minimise risks related to a therapeutic product. Guidance for Product Licence Holders on how to meet the requirements for a Risk Management Plan can be found in the EU *'Guideline on Risk Management Systems for Medicinal Products for Human Use'*, EMEA/CHMP/9628/2005.

ANZTPA and the relevant pre-licensing expert advisory committee for the product concerned (as described in the draft Rules), would evaluate the Risk Management Plan in terms of content and adequacy as part of the licence application procedure.

- Approval of the plan would be required before a product licence could be granted, and ANZTPA would monitor Product Licence Holder compliance with the plan after licensing.
- ANZTPA would have a system in place to monitor the progress of all post-licensing commitments, including Risk Management Plans. In addition, specified outputs would be assessed and evaluated by ANZTPA.

In summary, a Risk Management Plan should contain:

Part I

A Safety Specification: a summary of safety profile of the product

A Product Vigilance Plan: a description of routine product vigilance, additional product vigilance activities & action plans

Part II

An evaluation of the need for risk minimisation activities – and, if required

A Risk Minimisation Plan: description of proposed activities to reduce risks associated with known safety concerns.

On completion of its assessment of a pre-licence risk management plan, the Authority may require elements of this plan to be included as specific conditions of the product licence to encourage the safe use of the therapeutic product. In circumstances where ANZTPA has major concerns about a product, it may elect to issue the product with a provisional licence as part of its product vigilance strategy. As is described in the draft Rules, this approach would allow ANZTPA to place specific discriminatory conditions on the licence and review the risk-benefit profile of the product at two and/or four years before making a final decision about the issuing of a full licence for the product.

1.1.2 Post-Licence Risk Management

Risk management is a continuing process throughout the lifecycle of a therapeutic product. As such, ANZTPA may impose conditions on any therapeutic product licence at any time. Such conditions might include:

- Development and submission of a formal Risk Management Plan
- The requirement for a Product Licence Holder to undertake a specific type of product vigilance activity – examples of the types of safety studies or risk minimisation methods that might be used are included in EMEA/CHMP/96268/2005 Annex A and Annex B.

1.1.3 Additional Requirements for High-Risk Therapeutic Products

In addition to the obligations listed above, Product Licence Holders for high-risk therapeutic product categories (see Table 1) would be required to:

- Appoint an individual as the “Designated Person” who has complete oversight of the structure and scope of the Product Vigilance System (see Section 1.3).

Where appropriate, this would include quality control and assurance procedures, standard operating procedures, database operations, compliance data (e.g. in relation to the quality, completeness and timeliness for expedited reporting and submission of PSURs), audit reports and training of personnel in relation to product vigilance. The Designated Person for each Product Licence Holder should be resident in Australia or New Zealand and should have access to appropriate knowledge regarding the practice of medicine in the Australian and New Zealand health systems .

- Maintain awareness of publications by accessing a widely used systematic literature review and reference database no less frequently than every two weeks, or by making formal contractual arrangements with a second party to perform this task. Product Licence Holders would also be expected to ensure that relevant publications in Australia and New Zealand were included in this review.
- Submit specific product vigilance reports as required by the relevant Rule or conditions placed on a Product Licence:
 - For new high-risk medicines, Product Licence Holders would be obliged to supply ANZTPA with Periodic Safety Update Reports (PSURs) – an update of the worldwide safety experience of a therapeutic product – at defined times post-licensing. Each PSUR would be evaluated by ANZTPA.
 - PSURs would be required to be submitted for a period of three years from the date of granting the product licence. PSURs should be submitted every six months and the date of submission should be referenced to the International Birth Date.
 - ANZTPA may require submission of PSURs following changes to existing products e.g., new dosages or new indications for use.
 - ANZTPA would use the data submitted in PSURs towards determining the need for any regulatory action.
 - ANZTPA may require Product Licence Holders of other types of high risk therapeutic products to submit data similar to that required for PSURs for their products as a condition of a Product Licence.

1.2 Medical Devices

1.2.1 Pre-Licence Risk Management

It is proposed that medical devices will be divided into five risk classifications for the purpose of pre-licence Conformity Assessment. Broadly speaking, the risk classification would determine the level of pre-licence assessment the medical device would receive from the ANZTPA before a licence is issued. The risk classifications (in increasing order of risk) will be Class I, Class IIa, Class IIb, Class III and Class AIMD¹.

Medical device manufacturers must apply a risk management framework for every medical device regardless of Class. The medical device risk management system for medical devices would need to comply with the requirements in the relevant parts of ISO/EN 13485, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. ANZTPA would assess the risk management framework periodically by audit, or at any time on demand.

1.2.2 Post-Licence Risk Management

As for medicinal products, ANZTPA would be able to impose conditions on any medical device licence at any time. Such conditions might include:

- Post-licence clinical studies or other specific type of vigilance activity
- Restriction on the supply of the medical device to a particular type of healthcare professional

1.2.3 Additional Requirements for High-Risk and Implantable Medical Devices

Licence holders or manufacturers for Class III, Class AIMD, and implantable Class IIb medical devices would have to provide to the ANZTPA, three consecutive summary reports with vigilance information that had come to the attention of the licence holder or manufacturer during a reporting period. The reporting period for the first report would commence on the date of issue of the licence and would be for a period of at least six months but not more than 18 months, ending on 1 October. For subsequent reports, the reporting period would be 12 months ending on 1 October.

The reports must contain details and summary information regarding all reports of complaints, problems, incidents or adverse events regardless of how minor they may be. The reports must also contain information about what action has been taken to minimise or eliminate the problems encountered during the reporting period.

¹ AIMD = Active Implantable Medical Device

During the initial reporting period, and for as long as the product is licensed, the licence holder or manufacturer must report serious events to the ANZTPA within set timeframes, as specified in Section 1.3 below. These reports should also be included in the yearly summary report.

This reporting requirement has been established in the proposed Rules so that an early understanding of medical device performance and safety can be gained, and to ensure that the licence holder's or manufacturer's system to deal with problems is working effectively.

1.3 Licence Holder Product Vigilance Requirements for All Therapeutic Products

It is proposed that ANZTPA will require each Product Licence Holder (or the manufacturer in the case of medical devices) to have an appropriate system of product vigilance in place to assure Licence Holder responsibility and liability for its products on the market and to ensure that appropriate action can be taken when necessary.

ANZTPA may ensure that the Product Licence Holder is compliant with their product vigilance obligations by means of inspection and would have the authority to take action against the Product Licence Holder should it fail to meet its obligations.

Included as part of a Product Vigilance System, all Product Licence Holders would be obligated to:

- Maintain records of all reported suspected adverse reactions (or adverse events in the case of medical devices) associated with the use of their product occurring in Australia or New Zealand.
 - Such reports include those obtained from spontaneous reporting by healthcare practitioners and consumers, published reports, and post-market study reports. Product Licence Holders are obligated to follow-up all complaints, reports of problems, incidents, or suspected adverse reactions or events associated with the use of their products to obtain comprehensive information, if available.
- Promptly inform ANZTPA of all serious suspected adverse reaction reports (or adverse event reports in the case of medical devices) occurring in Australia or New Zealand within the timeframe specified by ANZTPA.
 - For medicines and blood, this would be no later than 15 calendar days of initial receipt or discovery.
 - For medical devices, this is likely to be no later than 48 hours for serious public health threats; no later than 10 days for events involving serious injury or death; and no later than 30 days for events that could have led but did not lead to serious injury or death.

- Indicate what action the Licence Holder proposes in relation to the conditions of the product licence (including, when available, the approved Product Information and the Consumer Medicine Information), in situations where adverse reaction or adverse event reports impact on the safety profile of a product.
- Inform ANZTPA that another regulator has indicated intention to act (or has acted) to withdraw or suspend a therapeutic product that the Licence Holder holds a product licence for in Australia or New Zealand. This must be communicated to ANZTPA within 72 hours of the Product Licence Holder becoming aware of the action.
- Ensure all information that ANZTPA has defined as relevant to the risk-benefit balance of a therapeutic product is reported to the Agency fully and promptly – this includes advising of safety-related regulatory action carried out in Europe, the United States, or Canada.
- Respond fully to requests from ANZTPA for additional information necessary for evaluation of the benefits and risks of a therapeutic product, including but not limited to the provision of information about the volume of sales of the therapeutic product concerned.
- Where Product Information and Consumer Medicine Information is required, Licence Holders must ensure the currency of these documents is maintained with regard to safety information

2. MANAGEMENT OF A SPONTANEOUS REPORTING PROGRAMME

ANZTPA would have systems in place for the collection of information from Product Licence Holders, healthcare professionals, and consumers on suspected adverse reactions to medicines and biological products, and suspected adverse events with medical devices. These reports would be scanned into ANZTPA adverse reactions databases for validation, assessment, and analysis.

2.1 Collection of Reports

The joint scheme would promote the use of standard forms for reporting adverse reactions and would receive reports by freepost, facsimile, e-mail, and via an Internet-based system.

Medicines and Blood

ANZTPA would primarily seek reports about suspected adverse reactions that are unexpected (e.g., the nature or severity is not consistent with what is in the Product

Information and in the Consumer Medicine Information that may come with a product), or serious (e.g., side effects that have caused problems serious enough to interfere with everyday activities). The major purpose of the system would be to provide early warning that a product may be associated with an unknown adverse effect, or that a known adverse effect may be quantitatively or qualitatively different that is thought.

The existing Australian and New Zealand systems for reporting adverse reactions to medicines are of comparatively high quality internationally, and provide an established means of detecting certain types of safety signals. It is therefore proposed that:

- reporting of serious adverse reactions will continue to be mandatory for Product Licence Holders
- reporting of suspected adverse reactions will continue to be voluntary for healthcare professionals and consumers
- Product Licence Holders must inform ANZTPA of all serious suspected adverse reaction reports occurring in Australia or New Zealand according to criteria laid down in Orders – i.e., within 15 calendar days of initial receipt or discovery

Medical Devices

ANZTPA would seek reports of all serious adverse events – i.e., events that have led to a death, or led to a serious injury to a patient, user, or other person – suspected to be associated with a medical device. It is likely that the current Australian Therapeutic Goods Administration Medical Devices Post-marketing Activities Guidelines will be adopted – as such,

- reporting of events meeting the following three criteria would be mandatory for Product Licence Holders
 - i) an event has occurred
 - ii) the Product Licence Holder's medical device is associated with the event
 - iii) the event led to death or serious injury, or might lead to death or serious injury if it were to occur again
- reporting of adverse events would be voluntary for users of medical devices e.g., nurses, doctors, surgeons, biomedical engineers and patients

2.2 Storage, Validation, and Assessment of Reports

Upon receipt, adverse reaction and adverse event reports would be scanned into secure ANZTPA databases. At all times, both electronic and paper-based reports would be handled with respect for confidentiality in accordance with Australian and New Zealand legislation.

- Each report would be validated (e.g., to ensure necessary information required is included; to identify duplicate reports) according to common and internationally accepted standard operating procedures.
- As appropriate, reports would be coded and entered into the database using the Medical Dictionary for Regulatory Activities (MedDRA) terminology or the collective/preferred terms of the Global Medical Device Nomenclature System.
- Each report would undergo causality assessment (e.g., the likelihood that the reaction was caused by the therapeutic product under suspicion), assessment of seriousness, and assessment of expectedness using appropriate classification criteria. In the case of medicines, these criteria would be consistent with those of the World Health Organization.
- Where required, the report would be followed-up to obtain additional information.
- It is proposed that scanning into a database, validation, and professional assessment of the report should occur within five working days of its receipt, with the full report entered into a database within 10 working days of receipt.
- Databases of spontaneous reports would be proactively analysed for signals of potential safety issues. Tools (e.g., data-mining software) would be available to routinely interrogate data for such signals. An identifier for country of origin of a report (i.e Australia or New Zealand) would allow analysis on a country specific basis.

3. EXPERT ADVISORY COMMITTEES

ANZTPA will administer, provide data to, and seek advice from expert advisory committees. As described in the draft Administration Rule, these committees will be:

- Expert Advisory Committee on Prescription Medicines
- Expert Advisory Committee on Over-the-Counter (OTC) Medicines
- Expert Advisory Committee on Complementary Medicines
- Expert Advisory Committee on Adverse Reactions to Medicines
- Expert Advisory Committee on Medical Devices

The proposed composition and terms of reference for each committee are set out in the draft Administration Rules released for consultation in May 2006. The terms of reference include the ability to invite experts to attend meetings if required, meet out-of-session physically or by video or teleconference, and to create sub-committees, if required.

A further committee, the Expert Advisory Committee on Biologicals, is also proposed. The suggested composition and terms of reference for this committee will be set out in the draft Blood Rules to be released for consultation in September/October 2006.

The committees would include expertise from a number of specialties, including the practice of medicine in each country. The Ministerial Council would appoint committee members as experts, not representatives of their specialty or of the country in which they are employed. Each expert committee would have the expertise necessary to assess the degree of risk posed by a therapeutic product and would be able to determine country-specific regulatory responses to protect the safety of consumers.

One of the primary roles of each committee would be to provide advice to the Managing Director of ANZTPA on the safety, quality and efficacy or performance of therapeutic products. In providing advice to the Managing Director, the committees would consider available data, identify whether the safety issue raised any country-specific problems, then make recommendations on appropriate action, including any country-specific action.

Broadly, the Expert Advisory Committees on Medical Devices and Biologicals would provide pre- and post-licensing advice for these products. The Expert Advisory Committees on Prescription, OTC, and Complementary Medicines would provide pre-licensing advice on their respective product classes. The Expert Advisory Committee on Adverse Reactions to Medicines would provide advice relating to the post-licensing safety of all medicines.

Expert Advisory Committees advising the Managing Director on the safety of therapeutic products would consider:

- Risk-benefit assessment of therapeutic products;
- Risk management advice for therapeutic products;
- Other matters related to product vigilance.

Activities the Expert Advisory Committees might carry out in performing this function include:

- Reviewing analyses of adverse reaction or adverse event reports prepared by ANZTPA, e.g.,
 - Reports of serious reactions, including deaths;
 - Key risks identified by systematic and semi-systematic data analysis

- Reviewing specific product vigilance issues identified from:
 - Published literature;
 - Adverse reaction or adverse event reports;
 - Targeted product vigilance activities;
 - Other regulators;
- Advising ANZTPA on the need for formal risk-benefit assessments and reviewing reports of these assessments

4. FORMAL RISK-BENEFIT ASSESSMENTS

Where ANZTPA is concerned about a particular safety issue, it may perform a formal risk-benefit assessment (FRBA). The need to conduct a FRBA would be dependant on the type of safety issue identified, the product under review, and the medical condition the product is used to treat. Where it is identified that a FRBA is required, ANZTPA may create a multidisciplinary project team to conduct the assessment, consisting of the most appropriate ANZTPA staff and would consult with external experts and the relevant expert advisory committee, as appropriate. The involvement of representative stakeholder groups, including patient groups, in the FRBA process is supported.

5. INTERNATIONAL LIAISON

ANZTPA will liaise and share data with international regulators and the World Health Organisation on matters relating to product vigilance. This will enable ANZTPA to contribute to the global safety of therapeutic products, assist with timely responses to emerging safety issues, and provide opportunities for collaboration on safety issues. It will also provide an external reference for the best regulatory practice of risk assessment and risk management.

6. RISK COMMUNICATION

Risk communication is a significant component of risk management and a key regulatory tool. A range of communication strategies will be used by ANZTPA in its communications with stakeholders.

Pre-testing of particular communication material would be considered to ensure comprehension and acceptance of the communication method and contents. Testing methods may include readability testing, focus groups or surveys.

Additionally, ANZTPA would seek information from various stakeholders, e.g., safety data from Product Licence Holders; follow-up information related to adverse reaction reports from health professionals; opinion from external experts; and consultation with consumer groups.

ANZTPA is committed to engaging in transparent communication with all stakeholders.

7. PRODUCT VIGILANCE-RELATED RESEARCH ACTIVITIES

It is proposed that ANZTPA will have the capacity to request, commission or perform a number of research activities to identify and quantify safety issues related to therapeutic products. In particular, ANZTPA recognises that pharmacoepidemiology has considerable importance as a tool for the evaluation of the safety of therapeutic products. As such, it is proposed that the ANZTPA should include the ability to conduct and/or commission epidemiological research, such as data linkage and other studies, as part of its product vigilance toolbox.

8. ASSESSING THE IMPACT OF PRODUCT VIGILANCE ACTIVITIES

Monitoring the impact of risk management activities and interventions is a critical part of the risk management continuum. It is proposed that ANZTPA will explore methodologies for conducting product vigilance impact assessments.

It is proposed that impact assessments undertaken by ANZTPA should encompass all therapeutic products and should include assessment of the communication outputs of ANZTPA.

9. AVAILABILITY OF PRODUCT VIGILANCE INFORMATION

ANZTPA will promote the values of openness, integrity and transparency in carrying out its product vigilance functions. To this end, product vigilance information would be made publicly available through a number of means. These may include but would not be limited to:

- minutes of Expert Advisory Committee meetings
- a publicly accessible adverse reaction/event database
- reports of risk-benefit analyses conducted by ANZTPA
- website publication of product vigilance regulatory actions taken by ANZTPA
- website links to Product Information and Consumer Medicine Information

10. QUALITY ASSURANCE WITHIN ANZTPA

A culture of monitoring performance and continuous quality improvement will be advocated within ANZTPA. As such, quality control and quality assurance procedures will be implemented with the view to constantly improving product vigilance-related performance and outcomes.