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Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods

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Risk-Based Management and Monitoring of Clinical Trials

1. Background

A need for supplementary guidance on the **risk-based management and monitoring of clinical trials** was identified following revision of the AHEC Position Statement on *Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Goods (May 2009)*, which was re-published by NHMRC in November 2016 as *Guidance on Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods*. This guidance brings together advice from regulatory authorities, clinical trial groups and industry organisations on the application of risk-based trial processes and also directs sponsors to relevant guidance so that further information can be obtained.

2. Introduction

All sponsors of clinical trials conducted in Australia have an obligation to ensure that their trials are designed, managed and monitored in a way that ensures participants are protected and the trial data generated are both reliable and robust. This is equally important for commercial¹ and non-commercial² trials, as both types of trial have the potential to significantly impact on the future clinical care of patients.

Over the last decade, there has been international recognition that a more flexible and tailored approach to managing clinical trials should be encouraged, because current practices do not seem to be achieving their desired goals, namely, creating an environment that facilitates, cost effective, high quality clinical trials. *The Integrated Addendum to ICH E6 R1: Guidelines for Good Clinical Practice (ICH E6 R2)* [1] has been amended to embed a risk-based approach to Good Clinical Practice (GCP). This approach is also endorsed by regulatory authorities including the European Medicines Agency [2, 3] and the US Food and Drugs Administration (FDA) [4].

3. Scope

This guidance is relevant to sponsors of commercial and non-commercial trials involving investigational medicinal products (IMPs)³ from early development of unauthorised products to clinical research conducted in the post approval phase. However, **it is written primarily for sponsors of non-commercial trials** to provide advice on how the international guidelines referenced above (particularly the revised requirements relating to risk-based quality management in ICH E6 R2) may be applied in a non-commercial trial setting.

1 A commercial trial is one that is funded and sponsored by a commercial company, where the company designs the protocol and owns the results and intellectual property rights arising from the trial.

2 A non-commercial trial is one where a non-commercial (not-for-profit) organisation retains control of the protocol and is the trial sponsor. Non-commercial trials are usually publically funded (e.g. by government/charities), but may also be funded/supported by a commercial company.

3 The international guidance referenced in this document refers specifically to IMP trials; however many of the principles could be applied to other types of clinical trial.

4. Quality Risk Management

Incorporation of quality management processes into the scientific and operational design of a trial can improve trial quality by helping to address important errors [5]. This process generally requires the input of a multidisciplinary team including clinicians, statisticians as well as experts in trial and data management. Features of a robust design include: a properly generated randomisation schedule, outcome measures that are objective and simple to assess accurately or, when objective outcome measures cannot be used, effective masking of the intervention when assessing outcomes. ICH E6 R2 also recommends that trials '*avoid unnecessary complexity, procedures and data collection*'. The more robust (and less complex) the design, the less dependence there is on trial monitoring to obtain reliable results.

Quality can be defined as the absence of errors that matter [5] and risk-based trial management addresses the question: *What are the critical processes and critical data for this trial and how best can any risks and/or vulnerabilities identified in these areas be mitigated in order to avoid errors that matter?* This question should be considered early in the protocol design stage so that processes to proactively manage those aspects of the trial that are critical to quality can be put in place. The US Clinical Trials Transformation Initiative (CTTI) and TransCelerate Biopharma Inc have produced guidance (based on Quality by Design principles⁴) that provide a useful framework for this process [5, 6].

Methodology recommended for risk-based management of trials [6]

Build Quality By Design into trials

Conduct an early and ongoing risk assessment

Focus on critical processes and critical data

Use risk indicators and thresholds

Adjust monitoring activities based on the issues and risks identified throughout the trial

ICH E6 R2 has also been updated to reflect a systematic approach to quality risk management and now outlines steps for *risk identification, evaluation, control, communication, review and reporting*. As part of the risk control process, ICH E6 R2 recommends that sponsors establish predefined *quality tolerance limits* to identify systematic issues. TransCelerate Biopharma Inc provides useful examples of 'risk indicators' that may be assigned with thresholds (quality tolerance limits) which, once reached, are designed to trigger an action, such as increased data scrutiny or site follow-up [6].

For non-commercial trials, it is important to ensure grant applications or other sources of funding take into account requirements for adequate quality management and monitoring.

5. Risk Assessment

Risk assessment is the process of identifying the potential hazards associated with a clinical trial⁵ and evaluating the likelihood of those hazards occurring and resulting in harm to participants or the validity of trial data.

⁴ Quality by Design is a systematic approach to development that begins with predefined objectives and emphasises product and process understanding and process control, based on sound science and quality risk management.

⁵ In addition to the trial-related risks described here, system level risks should be identified as part of the overall risk assessment, for example, those risk associated with computerised systems, standard operating procedures and personnel.

The risks of a clinical trial depend on a number of factors but can be broadly categorised as:

- the risks of the investigational medicinal product (IMP)
- the risks associated with trial conduct, design and methods.

a) Risks related to the Investigational Medicinal Product (IMP)

For each clinical trial, the risks related to the IMP should be categorised in relation to how much is known about the medicinal product being investigated. Potential risk should be assessed relative to standard of care for the relevant clinical condition and the level of clinical experience with the intervention, rather than the participant's underlying illness or the recognised adverse effects of the intervention.

International initiatives⁶ have recommended that sponsors assign an overall IMP risk category to each trial so that this information may be used 1) by sponsors to inform their trial management plans and 2) by regulators and other approval bodies to implement proportionate review, approval and authorisation processes.

Table 1 illustrates how risks may be benchmarked against standard of care.⁷ This approach, as an alternative to adopting a strict risk categorisation corresponding to trial phase, takes into account the off-label use of established therapies where risks may be comparable to standard of care.

Table 1: Risk Category for the Trial (Type A, B or C)

Type of Clinical Trial	Risk Category
1) Trials involving a drug entered onto the Australian Register of Therapeutic Goods (ARTG) if: <ul style="list-style-type: none"> • The use of the drug is within the conditions of its marketing approval, or • The trials involve off-label use of a registered drug, if this off-label use is established practice and supported by sufficient published evidence and/or guidelines (for example in paediatrics or oncology). 	TYPE A Risk comparable to standard medical care
2) Trials involving a drug entered onto the ARTG if: <ul style="list-style-type: none"> • Such products are used for a new indication (different patient population/disease group), or • Substantial dosage modifications are made, or • Drugs are used in combinations for which interactions are suspected. 3) Trials involving a drug NOT entered onto the ARTG if: <ul style="list-style-type: none"> • The active substance is part of a drug that is entered onto the ARTG. <i>Note: A 'TYPE A' grading may be justified if there is extensive use/clinical experience with the product and no reason to suspect a different safety profile in the trial population.</i>	TYPE B Risk associated with modified use of an existing product
4) Trials involving a drug not entered onto the ARTG <i>Note: A grading other than 'TYPE C' may be justified for drugs not on the ARTG but which have been approved in other jurisdictions and for which there is extensive clinical data.</i>	TYPE C Risk associated with use of an unlicensed product

⁶ Including OECD Recommendation on the Governance of Clinical Trials and ADAMON: Risk analysis in clinical trials regarding the required amount of on-site Monitoring.

⁷ Global trials, may be less amenable to such categorisation as the marketing status of IMPs may differ between countries participating in the trial. However, the general principles described could still be considered.

b) Risks related to trial conduct, design and methods

The stratified approach described above (i.e. the categorisation of risk that is based upon the marketing authorisation status of the investigational medicinal product) is not sufficient on its own as a risk assessment, and a trial specific approach is required to identify the additional risks associated with trial conduct, design and methods which include risks to participants' rights and the reliability of results. These risks would be dependent upon, for example, the protocol complexity, patient population (e.g. patients who are undergoing emergency care, who have impaired mental capacity, or who are children), therapeutic indication and nature of endpoints, clinical trial setting, and complexity of trial procedures or measurements.

6. Areas where risk-based approaches can be applied

a) Selective safety data collection

As a general rule, all clinical trial adverse events should be collected and reported unless there is justification in a risk assessment not to do so. In the early stages of IMP development this is standard practice; however, in the later stages of development, both FDA guidance [7] and a document from the European Expert Working Group Guidance [3] describe selective safety data reporting based on a risk assessment:

When registered IMPs are used within their marketing approval

The risk assessment should consider whether a reduced or targeted safety data collection may be appropriate if supported by data from use and if the number of participants exposed is sufficient to adequately characterise the medicinal product's safety profile. The risk assessment should also consider whether the occurrence of common, non-serious adverse events has been generally similar across multiple trials so that it is reasonable to conclude that their occurrence in the population to be studied will be similar to rates observed in previously conducted trials.

When IMPs are used differently from the conditions of their marketing approval or in the later stages of premarket development

The need for recording IMP and anticipated disease or population related adverse events in the Case Report Form (CRF) may be waived and, hence, reporting to the sponsor may not be necessary if it is reasonable to conclude that the occurrence of common, non-serious adverse events in the population to be studied will be similar to rates observed in previously conducted trials. The sponsor should clearly describe and justify any selective safety reporting processes in the protocol and/or ethics application.

Where IMPs are used differently from the conditions of their marketing approval, the risk assessment should consider whether the clinical trial under evaluation includes a new indication, a new population (e.g. in terms of age, gender or other patient characteristics), a new combination therapy, a different concomitant medication, a different dose or dosage regime or a different route of administration compared to the conditions of use in the Australian Product Information that may lead to new or more severe or frequent adverse reactions or new drug-drug interactions.

When IMPs are in the earlier stages of premarket development

As noted above, comprehensive safety data, including essentially all adverse events, are collected in the early stages of IMP development in order to adequately characterise an IMP's safety profile.

In addition to the selective reporting of adverse events, the following risk-based approaches are outlined in FDA guidance [7]:

- **Routine laboratory monitoring:** If existing data satisfactorily characterise the safety profile, there may be less (or no) requirement for routine monitoring (e.g., less-frequent liver function testing if the safety profile data has diminished concerns about hepatotoxicity).
- **Information on concomitant medications:** If existing data satisfactorily characterise all anticipated drug-drug interactions and metabolic pathways, additional detailed information on concomitant medications (e.g., dose, dosing schedule, start and stop dates) may be of limited use, particularly for IMPs used only short term.
- **Patient history and physical exams:** If existing data satisfactorily characterise safety profile, there may be less need for detailed histories; or there may be fewer physical examinations for participants.

b) Non-expedited reporting of certain serious adverse events

Within the protocol, it is possible for sponsors to define serious adverse events (SAEs) that do not require immediate reporting by the investigator to the sponsor despite meeting the definition of a SAE.⁸ Examples include:

- Trial endpoints that will be captured and monitored by the trial's Data and Safety Monitoring Board (e.g. death in a stroke trial).
- Events that are common in the patient population as a consequence of their age, medical condition or other circumstances (e.g. hospice admission following disease progression in an oncology trial).
- Well characterised adverse reactions (e.g. a typical occurrence of neutropenic sepsis in a chemotherapy trial).
- Pre-planned events (e.g. elective surgeries).
- Prolongation of hospitalisation without an associated adverse event (e.g. delayed discharge while arrangements for social care are made).

The protocol should describe how non-expedited serious adverse events will be collected and monitored (e.g. through collection in the trial's case report form).

c) Trial monitoring

The purpose of trial monitoring is to oversee the progress of a trial to protect the rights and well-being of trial participants and to give reassurance that the trial protocol and procedures are being followed, that legal/governance requirements are being complied with, and that the critical data collected are reliable.

The trial risk assessment should be used to determine the intensity, focus and type of monitoring undertaken. **Table 2** illustrates a number of different approaches and techniques that are used for trial monitoring, which can be categorised into two main types:

⁸ Section 4.11.1 of ICH GCP requires SAEs to be reported immediately '*except for those SAEs that the protocol identifies as not needing immediate reporting*'.

- **Central monitoring** involves the review of centralised data, for example, by trial oversight committees or data management personnel. This may include the central review of data from sites (e.g. a review of the completeness of the Case Report Form) or for large or multicentre trials, the use of **statistical monitoring**; where patterns of accumulating data are examined using statistical approaches or modelling across the trial. The term **remote monitoring** describes monitoring activities that were previously conducted at the trial site by the trial monitor, but can now be conducted off-site (e.g. the review of documents sent by e-mail or the remote training of site staff).
- **On-site monitoring** involves visits to the site to perform checks that include verification that trial documents and source data exist. It also involves an assessment of the site’s understanding of, and compliance with the protocol and trial procedures. In general, on-site monitoring can provide sponsor staff with a sense of the quality of the overall conduct of the trial at the site.

The term *risk-based monitoring* may be used to denote the reduced (but essentially fixed) monitoring of a trial that is deemed lower risk, but more and more, risk-based monitoring is being used to describe ‘adaptive’ or ‘triggered’ monitoring methods that focus monitoring activities on those sites that appear to need it most. In their paper, *Tudur et al* [8], illustrate how monitoring activities may be planned and conducted in a multicentre non-commercial trial and how increasingly, central monitoring activities are being used to complement, reduce or replace on-site monitoring, particularly the focus on source data verification.

Table 2: Commonly Used Monitoring Procedures

Types of Monitoring	Examples
Central monitoring including remote monitoring and statistical monitoring [9]	<ul style="list-style-type: none"> • Oversight of trial by groups or committees • Eligibility checks prior to randomisation (e.g. de-identified histology report faxed to coordinating centre) • Checks for unusual data patterns or trends (digit preference, rounding, or unusual frequency distribution – e.g. mean, variance, skewness) • Rates of recruitment, withdrawals and losses to follow-up by site • Checks for missing or invalid data on the CRF (e.g. range, plausibility and consistency checks) • Checks to confirm that dose adjustments, investigation and management of events are consistent with the protocol • Calendar checks • Assessment of adverse event reporting rates compared between sites • Assessment of CRFs (e.g. review for logical consistency, late or poor CRF completion, checks to confirm CRFs have been completed by authorised personnel) • External verification (with participant consent) of events/endpoints (e.g. birth, disease and death registries) • Resolving trial-related issues by telephone/e-mail • Ongoing motivation meetings conducted by video/teleconference • Web-enabled training

Types of Monitoring	Examples
On-site monitoring visits	<ul style="list-style-type: none"> • Ongoing training/motivation • Checks for understanding and adherence to trial protocol, GCP and regulatory requirements • Review of trial procedures (e.g. informed consent and safety reporting procedures, data capture, CRF completion) • Source data review to check quality and completeness of the source data • Targeted source data verification (SDV) focussing on critical data elements such as key eligibility and endpoint data • Verification that resources and facilities remain adequate • Verification of appropriate oversight and documented delegation by the principal investigator

Table 3 provides principles for investigators and sponsors to consider when determining the intensity, type and focus of trial monitoring. There are many different approaches to quality control in a clinical trial, and the most appropriate modalities will depend on the number of sites and logistical issues as well as the risk.

Table 3: Overall Risk Category to Determine the Intensity, Type and Focus of Monitoring

Risk associated with the trial intervention (IMP)		
Type A	Type B	Type C
<p>Low intensity</p> <p>Central monitoring of key data, protocol adherence and data quality. Site visits not planned but may be triggered by concerns identified from central monitoring that cannot be addressed by other means.</p>	<p>Moderate intensity</p> <p>Central monitoring of key data, protocol adherence and data quality. Targeted site visits may be planned with frequency guided by central monitoring outputs.</p>	<p>Higher intensity</p> <p>Likely to require more intense monitoring involving both central and on-site activities in order to have confidence in the completeness and reliability of data, particularly safety data.</p>

Additional monitoring to mitigate risks associated with other factors

If the risk assessment has identified specific vulnerabilities associated with the factors other than the IMP, (e.g. the design, methods or conduct of the trial), add appropriate monitoring to address these issues.

Examples* include:

- Additional monitoring visits to provide extra support and training to new or inexperienced site staff.
- Additional monitoring checks/visits when the sensitivity of sample analysis is highly dependent on how the samples are taken, processed, stored and transported, (i.e. in order to provide assurance that sample integrity has been maintained).
- Additional monitoring checks/visits to verify that any equipment used to make primary end-point assessments or to calculate doses or dose adjustments is suitable for use and being used correctly.
- Additional monitoring checks/visits to confirm understanding and adherence with the protocol when trial procedures or requirements are particularly complex.

*Examples from the MHRA Inspectorate

Monitoring Plan

The sponsor's approach to monitoring should be documented and ICH E6 R2 recommends that sponsors develop a plan that describes their monitoring strategy, the monitoring responsibilities of all the parties involved, the various monitoring methods to be used, and the rationale for their use.

Although a risk based monitoring plan will often build in flexibility for monitoring activities, ICH E6 R2 requires sponsors to periodically review their risk control measures to ascertain whether the quality management activities that have been implemented remain effective and relevant. The results of monitoring may direct changes to the monitoring plan/strategy; either moderation (downgrading of activities) or escalation of activities.

d) Traceability and accountability of Investigational Medicinal Products

IMP (drug) accountability refers to maintaining documentation that ensures traceability of the IMP used in a clinical trial. The level of IMP accountability should correspond to what is necessary for the scientific validity of the trial outcome or the safety to the trial participants and, as such, any risk adaptations proposed should take into account the impact of not performing drug accountability.

The level of accountability needed may vary depending on several factors, such as whether the IMP has marketing approval, the trial design (e.g. blinding or the complexity of the dosing regimen) who is administering the IMP, the toxicity of the IMP and its supply chain. A higher intensity of monitoring would be appropriate when compliance or storage of the IMP is critical to the endpoints of the trial. The risk assessment and mitigation plan should include justifications for the documentation used to reconstruct IMP traceability and the doses administered.

In some trials, IMPs may be sourced from normal stock from a community or hospital pharmacy and normal prescribing practice and documentation would apply.⁹ For such trials, it may be possible to maintain simplified accountability records. For example, the batch number of the product dispensed may be captured on a trial specific or standard prescription form¹⁰ and filed in a trial folder to permit retrospective verification. It should be noted that even for Type A trials, where IMPs require a manufacturing activity (e.g. over-encapsulation in order to blind the trial), full chain of custody from manufacture to destruction would apply.

In cases where the IMP is provided to sites e.g. by the trial sponsor, accountability records of bulk receipt and destruction/return would be required, as well as records that enable the reconciliation of bulk supply against individual participant use.

For Type C trials, documentary evidence of a full chain of custody of IMP from supply to destruction, from which both the quantities and quality of the trial product used can be determined, will be required.

IMP labelling

For CTX/CTN trials involving medicinal products, Annex 13 of the *PIC/S Guide to Good Manufacturing Practice* - 15 January 2009, PE 009 outlines the Good Manufacturing Practice requirements. Trial-specific labelling in accordance with Articles 26-30 of Annex 13 is generally required unless the absence of information can be justified.

⁹ Provided that sample size is acceptable to account for the variability in drug compliance. Alternatively, if sample size is small, participants may be asked to complete a diary card or return the remainder of the prescription.

¹⁰ Which may include a sticker indicating the prescription is for a clinical trial.

In the case of pragmatic or real-world trials, where provision of IMP may be hampered by complex record-keeping requirements (for example where medication is supplied through routine prescribing practices involving community pharmacies), sponsors/coordinating principal investigators should consider the extent of the information necessary for them to confirm the results and end-points of their trial, and devise relevant mechanisms on a case-by-case basis.

IMP storage

Shipment and storage of IMP is a critical part of any clinical trial, and sponsors and sites should be able to demonstrate that the integrity of all IMPs has been maintained both during transit to site and during storage at site.

As part of the risk assessment, risk factors such as the stability of the active ingredient should be used to determine the extent of temperature monitoring, moisture, or light protection. Generally, the more sensitive the product to deviation from the determined storage conditions, the closer the scrutiny to compliance should be. For example, where small deviations can result in marked negative impact upon the quality or activity of the product, daily measurements of the temperature (typically using a minimum/maximum thermometer or continuous monitoring) would be a minimum expectation.

For Type A and Type B trials, storage requirements for the IMP are likely to be well known and storage in accordance with normal clinical practice will be appropriate. In particular, where a marketed product is licensed with no special storage requirements, 24-hour temperature monitoring for its use within a clinical trial, would be excessive if such arrangements were not employed for standard clinical use.¹¹

Handling of temperature excursions

For Type A and Type B trials with extensive supporting stability data, it may be possible to decide what limits are appropriate for IMP storage deviations (e.g. small, transient temperature changes of little significance to the trial outcome may not need to be recorded or result in further action).

For Type C trials, the extent of available stability data should support any proposed plans for the handling of temperature deviations/excursions.

¹¹ However, trial sites must follow the requirements detailed in the protocol or confirmed by the trial sponsor.

Acknowledgement and References

This guidance contains sections adapted from the MRC/DH/MHRA joint project: *Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products* and Clinical Trial Toolkit: *Workstream Document C) Monitoring Procedures* (with kind permission from the MHRA Clinical Trials Unit).

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