

Notes on Good Practice for Research Organisations in the Management of a Portfolio of Trials 1: Introduction and summary of primary risks to a research active organisation.

1. INTRODUCTION

1.1 Purpose of Work

The main purpose of the Joint Project is to provide guidance in the interpretation of the Medicines for Human Use (Clinical Trials) UK Regulations 2004, for researchers and research managers, by documenting and sharing good practice, to ensure that high quality research is enabled and supported, and not unnecessarily hindered or burdened.

In line with the other Joint Project Workstreams, these notes on good practice for organisations relates primarily to publicly funded clinical trials of medicinal products.

It is intended, however, that the principles of good clinical practice referred to throughout will apply to other clinical trials.

To complement the Joint Project Workstream 4, which examines the management of individual trials of different types, this document of good practice is concerned with an organisation which is responsible for a portfolio of trials.

These organisations will include some funders of research but are likely to be primarily Universities or NHS Trusts.

The overall message from the work conducted so far is that the risks associated with research are not increased as a result of the new UK regulations and that the benefits to patients, health and research organisations, and society, of conducting and encouraging high quality clinical research, far outweigh the risks, i.e. the probability of the hazards of research causing harm.

A system for quality assurance, which supports the highest standards of good practice and which is well understood and communicated, will reduce the risks of clinical research to both research participants and the organisation.

1.2 Aims

In support of good quality clinical research and in an effort to reduce the potential risk to research itself, which could arise from inappropriate interpretation of regulation, these notes aim to:

- promote the understanding of the hazards arising from research and their effective management, thus reducing the potential risks involved in conducting clinical research
- provide practical advice on a risk-based approach to managing a portfolio of publicly funded trials, with examples of good practice and views of the group members.

It refers to current knowledge and support available, with source documents/references and provides advice on how organisations can minimise risk via existing and developing quality risk management systems, with exemplars of good practice.

It is recognised that different organisations are likely to have different types of trial in their portfolios – ranging from laboratory to clinically based trials in both primary and secondary care.

There may be early phase trials designed to establish safety and efficacy and later phase trials designed to elicit effectiveness.

For a more detailed exposition of the different types of trials and a risk-based approach to their management, please refer to the [Trial Management Systems documentation](#).

1.3 Membership of Group

This working group was formed in February 2004 with individuals from the funder, university and NHS sectors – please refer to *Appendix 1* for full details.

1.4 Scope of Project

The approach we have taken to the project is to examine what an organisation with some form of responsibility for a portfolio of clinical trials will need to consider, both in response to the new UK regulations for Clinical Trials, and more generally in adopting Good Clinical Practice in the management of research.

These notes are intended to be relevant to the spectrum of organisational responsibility – sponsor, co-sponsor, employing organisation, host organisation and collaborating organisation.

We have not at this stage attempted to go further and spell out, for each type of organisation, the different levels of quality management/good practice which may best match these different roles.

We acknowledge that more work is needed, in particular, on the management of trials across organisational boundaries - this may be developed in future work.

This has entailed firstly, considering the *potential* risks to an organisation, by looking at the hazards associated with a portfolio of trials.

The starting point for the organisation is to be clear about the mix of different trials in their current portfolio and to refer to the guidance from Workstream 4, which considers the type of trial specific monitoring and auditing procedures which the organisation needs to put in place.

Beyond this, however, there are considerations around the research strategy, structures and systems of management in the organisation and it is these areas that these notes will attempt to address.

2. SUMMARY OF PRIMARY RISKS TO A RESEARCH ACTIVE ORGANISATION

An organisation's research activity and reputation are improved when it understands the potential hazards of being research active and acts to manage and therefore to minimise the risks.

Hazard: Anything that could cause harm

Risk: The probability that harm will be caused by the hazard

The main risks to a research active organisation are in the following categories:

- Risks to research being undertaken - the first risk for a research active organisation to avoid is a decline in clinical research. The regulatory framework for research could be seen as a burden, which may discourage activity, or it could be seen as a challenge to the organisation to ensure that its research active professionals are given the support they need to continue with their activity. Through the work undertaken by the *Research for Patient Benefit Working Party*, led by the DH, it is recognised that support is required if the downturn in clinical research in the UK is to be reversed. The final report from this Working Party is available and considers what actions need to be taken to encourage and promote clinical research.
- Risks to the reputation of the organisation, which may arise from harm to patients, inadequate communications with patients, harm to the wider population, failure to comply with legal and governance frameworks – all potentially leading to a decline in clinical research through consequent inability to obtain grant funding, or to obtain acceptance as a sponsor or co-sponsor for research.
- Risks to conducting/completing the research arising from researchers' lack of experience, inadequate training and support, lack of project management capability or lack of attention to the design or feasibility of the individual projects.
- Risks to dissemination of research, which will include lack of resources available to ensure publication or an inappropriate agreement with the funder of the research.
- Risks to the researcher – career and reputation; hazards include service pressures on time available for research, inadequate patient recruitment, non-completion of research, and damage to reputation arising from misconduct

3. SOURCE DOCUMENTS

[Trial Management and Monitoring Guidance – MRC/DH Joint Project on Clinical Trials](#)

[The Medicines for Human Use \(Clinical Trials\)](#)

[Description of the Medicines for Human Use \(Clinical Trials\) Regulations 2004](#)

[EU Clinical Trials Directive: Sponsorship responsibilities in publicly funded trials](#)

[Responsibilities, liabilities and risk management in clinical trials of medicines – DH/Universities UK Joint Statement](#)

[Research for Patient Benefit Working Party: Final Report](#)

[MRC-EU Clinical Trials Directive Policy Statement](#)

[MRC Guidelines for Good Clinical Practice in Clinical Trials](#) *[to be amended in 2004 so that it refers to the EUCTD and UK Regulations]*

Department of Health. The Research Governance Framework for Health and Social Care. Draft 2nd Edition, HM Stationery Office, London, 2003. *[2nd Edition to be revised so that it and the EUCTD are consistent]*

Research Governance in Health and Social Care – NHS Permission for R&D Involving Patients

NHS Research Governance Controls Assurance Indicators

[NHS R&D Forum Guidance via Working Groups, Website and Workshops](#)

APPENDIX 1

Membership of Working Group

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