

State of the art clinical trials for medical devices  
Guide to medical device Good Clinical Practices compliance

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# **State of the art clinical trials for medical devices**

A guide to medical device  
Good Clinical Practices compliance

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## **PREFACE**

Internationally the medical device regulations stipulate that clinical evidence is required for all medical devices as part of the evidence-based technical documentation for the licensing of products. The regulations are putting greater emphasis on the need of credible and reliable clinical evidence either obtained through critical analysis of clinical literature or by way of clinical investigation. Manufacturers are obligated to ensure that clinical evidence is an integral part of the marketing authorisation process for medical devices. The need for reliable and credible clinical data is increasingly important in global medical device regulatory compliance<sup>1</sup>.

The regulatory system allow manufacturers to make a choice as how clinical data is provided, i.e., based on critical review of existing historical and published as well as unpublished scientific literature review or from conducting clinical trials or a combination of both. Although clinical evidence is required for all medical devices, for certain specific medical devices, in particular long-term invasive, or implants or novel products without precedent, clinical evidence must come from clinical trials conducted in accordance with relevant Good Clinical Practices (GCP) requirements. Regulators, however, based on review of applications or technical documentation, have come to the conclusion that not all long-term invasive or implantable products have been subject to clinical studies as directed by the law. Manufacturers use clinical evidence from literature review in most situations not only to demonstrate compliance, although limited, with the essential (safety) requirements while simultaneously using it as a justification for not conducting clinical trials<sup>2</sup>. The medical device requirements stipulate that a duly documented justification as to why clinical data is obtained by a specific method (i.e., clinical literature route or clinical investigation) be an integral part of the licensing application. Should clinical data not be obtained from a clinical investigation, then a rationale why this has not been done must be duly documented and justified.

The medical device requirements give legal impetus to having to conduct clinical trials with devices to Good Clinical Practices (GCP). At the closure of the trial, a clinical study or results report must be written in line with the defined medical device guidance documents that are similar to the International Committee for Harmonisation for Pharmaceutical Industry (ICH) requirements for the Clinical Study Report.

Not conducting a clinical trial with a medical device when it is required is no longer an option. The medical device regulations worldwide define when trials are to be conducted and that, when conducted, they must be done in accordance with GCP. GCP no longer applies only to medicinal product trials but to any trial conducted with any healthcare product when the product is used in a medical intervention.

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1 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Public Consultation Text 5 April 2005 : Draft Commission Proposal amending Directive 93/42/EEC

2 M Kenny Clinical data and the need for diligence' RAJ devices. May/June 2005 Vol 13 No 3 pp 1 37-139

As the medical device regulatory environment matures, the issue of obtaining scientifically sound clinical evidence is an increasingly important issue in overall regulatory compliance. Such data provides the medical community with sufficient evidence about the actual use of the product under clinical conditions and helps satisfy stakeholders that the products used in medical intervention are safe, efficacious and perform in accordance with the claims the manufacturer makes for the device.

In this publication, the regulatory and GCP requirements for medical device clinical investigations in the major trading areas (e.g. EU, Australia, Canada, Japan and the US ) is examined in detail. The publication is a road-map on how to meet the compliance when medical device clinical trials are conducted. The publication is divided into the following main sections:

- Part 1 examines the regulatory and GCP requirements for medical devices in key trading markets.
- Parts 2 to 5 lay out the road map on how to conduct medical device trials in compliance with internationally GCP requirements looking at planning, preparing, documenting, conducting and managing the trial from start to finish.



Throughout the publication important information including tips are identified in red boxed text preceded by the symbol.

This practical road-map to the clinical investigation process is a tool for any manufacturer, investigator, researcher, regulatory affairs professional, clinical affairs professional, or monitor involved in clinical investigation and regulatory affairs.

With the regulatory scene in a constant state of flux, the appropriate regulatory and ethics authorities should be consulted prior to setting up a medical device trial in any country.

## TABLE OF CONTENTS

<b>Preface</b> .....	7
<b>List of abbreviations</b> .....	17
<b>PART 1 RULES AND REGULATIONS</b> .....	19
<b>1 The Regulatory Environment</b> .....	21
1.1 Introduction .....	24
1.2 Definitions .....	24
Medical device.....	25
Accessories.....	25
In vitro diagnostics .....	25
Intended use .....	26
Clinical data or evidence.....	28
Substantial equivalence .....	29
Conformity assessment.....	29
Complaint.....	29
Medical device vigilance or adverse event reporting .....	30
1.3 European Regulatory Requirements.....	31
Regulatory characteristics.....	32
Classification.....	32
Essential requirements.....	34
Risk analysis .....	37
Clinical Data or Evidence .....	38
Methods for obtaining clinical data.....	40
Clinical literature route.....	40
Reporting the data.....	43
Equivalence .....	44
Justification .....	45
Summary.....	45
Clinical Investigation .....	45
Clinical Trial Notification .....	46
Clinical Investigation Declaration.....	47
Determining clinical evidence needs.....	48
Other Reasons for Clinical Trials .....	52
1.4 Australia/New Zealand.....	54
Introduction.....	54
Clinical Trial Approval .....	55
Clinical Trial Notification .....	57
Summary .....	58
1.5 Canada .....	59
1.6 Japan .....	61
1.7 United States.....	64
1.8 Summary .....	67

Conduct of the trial.....	67
Labelling language requirements.....	68
Adverse event reporting.....	68
Regulatory approval of the trial.....	69
Investigational products.....	69
<b>2 The GCP Environment.....</b>	<b>71</b>
2.1 Introduction.....	71
2.2 GCP Principles.....	72
2.3 Responsibilities and Players.....	74
Sponsor.....	74
Investigators.....	75
Monitor.....	75
Auditor.....	75
Ethics Committee.....	78
Trial Subjects.....	79
2.4 European rules.....	81
Data Protection.....	84
2.5 Australian/New Zealand rules.....	86
2.6 Canadian rules.....	88
2.7 Japanese rules.....	89
2.8 United States rules.....	91
2.9 Summary of the GCP Requirements.....	93
Documentation.....	94
Informed consent/ Patient information.....	95
Investigator's Contract.....	96
Record keeping.....	96
Insurance.....	96
Adverse event reporting.....	96
Ethics Committee.....	97
2.10 Conclusion.....	97
<b>PART 2 PLANNING PHASE.....</b>	<b>99</b>
<b>1 Clinical Investigation.....</b>	<b>101</b>
1.1 Proposal.....	101
1.2 Strategy.....	101
1.3 Project Characteristics.....	102
1.4 Project Team.....	103
1.5 Study name.....	105
1.6 Study Design.....	106
Design features.....	107
Longitudinal and cross-sectional studies.....	107
Randomisation.....	107
Comparative (controlled) trials.....	108
Placebo studies.....	108

Parallel group design .....	108
Conclusion .....	108
1.7 Project Plan .....	109
<b>PART 3 PREPARATION PHASE</b> .....	<b>111</b>
<b>1 Quality Assurance procedures</b> .....	<b>113</b>
1.1 Introduction .....	113
1.2 Tips for quality assurance documentation .....	114
1.3 Quality System Related Documents .....	115
General SOPs .....	116
Project related procedures .....	122
Specific Clinical Trial Procedures .....	123
<b>2 The clinical trial documents</b> .....	<b>129</b>
2.1 Investigator's brochure (IB) .....	129
Format .....	131
2.2 Clinical investigation plan (CIP) or protocol .....	133
Contents .....	134
Format/Layout .....	135
2.3 Case report forms (CRF's) .....	138
Types of data .....	139
Format .....	139
Tips on creating case report forms .....	140
2.4 Informed consent (IC) .....	141
Content .....	141
Local nuances .....	143
Information for subject .....	144
Sample informed consent/patient information .....	144
2.5 Clinical Study report (CSR) .....	144
Format/layout .....	145
2.6 Contracts between the parties .....	146
Investigator Agreement .....	146
Other Agreements .....	148
2.7 Other documents .....	148
Subject Screening record .....	148
Subject Identification Code List: .....	149
Subject Enrolment Record .....	149
Initials/signatures List .....	149
<b>3 Medical Device Vigilance</b> .....	<b>151</b>
3.1 Introduction .....	151
3.2 Handling adverse events .....	155
3.3 The process .....	155
Setting up the system .....	155
Initial information and screening .....	155

Screening.....	157
Initial Reporting.....	158
Investigate.....	158
Retrieve the product/technical assessment.....	160
Analyse the findings.....	160
Determine correction actions.....	161
Follow-up.....	162
Final reporting to the authorities.....	162
Closure.....	163
3.4 Who is to report what when and how .....	163
3.5 The time-limits for reporting .....	165
<b>4 Post-market surveillance &amp; clinical follow-up.....</b>	<b>167</b>
<b>5 Labelling .....</b>	<b>169</b>
5.1 Labelling requirements.....	169
5.2 Labelling tips.....	172
<b>6 Insurance Coverage .....</b>	<b>173</b>
6.1 Introduction .....	173
6.2 Types of Insurance.....	173
Liability/Compensation.....	174
Risk.....	174
6.3 Factors related to insurance.....	175
6.4 Summary .....	176
<b>7 Preparing for Effective Monitoring.....</b>	<b>177</b>
7.1 Introduction .....	177
7.2 Responsibilities .....	177
7.3 Monitoring Strategy .....	178
<b>8 Site selection and Qualification.....</b>	<b>183</b>
8.1 Introduction .....	183
8.2 Selection and Qualification Visit .....	183
<b>9 Informed consent process .....</b>	<b>187</b>
9.1 Introduction .....	187
9.2 Witnessed informed consent .....	187
9.3 Vulnerable trial subjects and informed consent.....	188
9.4 Missing/Forgotten informed consent.....	188
<b>10 Ethics committee’s opinions/approvals.....</b>	<b>189</b>
<b>11 Regulatory Notification/Authorisation.....</b>	<b>191</b>
11.2 Introduction .....	191
11.3 Notification.....	192

11.4 Authorisation Application.....	193
<b>12 Record keeping.....</b>	<b>195</b>
12.1 Introduction .....	195
12.2 Filing and Archiving .....	196
<b>13 Training.....</b>	<b>199</b>
13.1 Introduction .....	199
13.2 Monitor Training.....	199
13.3 Preparing the clinic.....	201
<b>PART 4 CONDUCTING THE TRIAL.....</b>	<b>205</b>
<b>1 On-site/Periodic Monitoring.....</b>	<b>207</b>
1.1 Introduction .....	207
1.2 In-process data control.....	207
1.3 On-site monitoring .....	209
1.4 Monitoring Report.....	210
1.5 Tips for good monitoring .....	211
<b>2 Auditing.....</b>	<b>213</b>
2.1 Introduction .....	213
2.2 Key Auditing Elements.....	213
<b>3 Handling Fraud or Suspect Data.....</b>	<b>215</b>
3.1 Introduction .....	215
3.2 Detection .....	216
Direct proof.....	216
Indirect proof.....	216
Presumed proof.....	217
3.3 Prevention .....	217
3.4 Steps in case of suspected fraud.....	218
<b>PART 5 DATA MANAGEMENT AND CLOSURE.....</b>	<b>221</b>
<b>1 Data Handling.....</b>	<b>223</b>
1.1 Introduction .....	223
1.2 Data monitoring committee.....	223
1.3 System Validation.....	223
1.4 Data Management/Data Entry.....	224
1.5 Data Analysis .....	225
<b>2 Study Closure.....</b>	<b>229</b>
<b>3 Reporting of the study's results.....</b>	<b>231</b>
<b>PART 6 CONCLUSIONS.....</b>	<b>233</b>

**PART 7 APPENDICES** ..... 239

**Appendix 1: National GCP Overview Requirements** ..... 240

**Appendix 2: Basis for developing a compliant case report form** ..... 245

**Appendix 3: Sample layout for an internationally acceptable informed consent** .... 251

**Appendix 4: Dictionary of key terms**..... 259

## **TABLE OF TABLES AND FIGURES**

Table 1	Summary of major essential requirements	35
Table 2	Canadian clinical trial requirements under the Medical Device Act	59
Table 3	Significant versus Non-Significant risk devices	65
Table 4	Contents of the application for SR IDE to the FDA	66
Table 5	Responsibilities of the key parties under gcp	76
Table 6	Ethics Committees/IRB's responsibilities	79
Table 7	Rights of the Subjects	80
Table 8	Overview of CTD (ICH) requirements as transposed into national biomedical laws	83
Table 9	The Roles and responsibilities of the parties under Australian GCP	87
Table 10	Summary of the United States GCP as found in the IDE requirements	91
Table 11	Classification of clinical trial designs	107
Table 12	General quality system SOPs	116
Table 13	Project related criteria	122
Table 14	Specific clinical trials SOPs	124
Table 15	Layout for the Investigator's Brochure	131
Table 16	Layout for the clinical investigational plan	136
Table 17	Tips on creating compliant and easy to use case report forms	140
Table 18	Contents of the investigator contract	147
Table 19	Reporting sequence	165
Table 20	Reporting times per country	166
Table 21	Generic labelling requirements for medical devices	170
Table 22	Specific and general monitor responsibilities	177
Table 23	Clinical trial record keeping	195
Table 24	Clinical files to be retained	197
Table 25	Samples of source documents	208
Table 26	Periodic monitoring visit checklist	208
Table 27	Steps which can be taken when fraud is suspected	219
Figure 1	Sample clinical trial declaration	47
Figure 2	Planning Flowchart	100
Figure 3	Preparation Flowchart	112
Figure 4	Flowchart for adverse events with medical devices	153
Figure 5	Flowchart for clinical trial related adverse events	154
Figure 6	Flowchart of the conduct of the trial	206
Figure 7	Flowchart for data handling and trial closure	222
Figure 8	Flowchart overview for conducting medical device trials	234