

Appendix 2 List of Abbreviations

ACK	Acknowledgement
ADME	Absorption Distribution Metabolism Excretion
ADR	Adverse Drug Reaction
AE	Adverse Event
AMD	Amendment
C(P)U	Clinical (Phase I, Pharmacology) Unit
CA	Competent Authority (regulatory body charged with monitoring compliance with European Union member state national statutes and regulations)
CDA	Confidentiality Agreement
CDISC	Clinical Data Interchange Standards Consortium
CFR	Code of Federal Regulations
CIOMS	Council for International Organization of Medical Science
CO	Clinical Operations, also ClinOps
COV	Close-Out Visit
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract (or Clinical) Research Organization
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Administrator/but also Clinical Trial Application (European form)
CTD	Clinical Trial Directive / but also Common Technical Document
CTMS	Clinical Trial Management System
CTR	Clinical Trial Report
CV	Curriculum Vitae
D/D	Drug/Device
DB	Data Base
DCF	Data Clarification Form
DEV	Deviation
DM	Data Management
DMC	Data Monitoring Committee
DRA	Drug Regulatory Authority (US Term)
DSMB	Data Safety Monitoring Board
EC	Ethics Committee
EDC	Electronic Data Capture
EEA	European Economic Area
EFGCP	European Forum for Good Clinical Practice

EFPIA	European Federation of Pharmaceutical Industries and Associations, and one of the six ICH parties
EFTA	European Free Trade Association and one of the ICH Observers
EIR	Establishment Inspection Report (FDA Inspection Report)
EMA	European Medicines Evaluation Agency
ESTRI	Electronic Standards for the Transfer of Regulatory Information and Data
EU	European Union
EU MS	European Member State
EudraCT	European Union Drug Regulation Authorities Clinical Trials
EV	EudraVigilance
EV CTM	EudraVigilance Clinical Trial Module
EV PM	EudraVigilance Post-marketing Module
FD&C Act	Food, Drug and Cosmetics Act
FDA	Food and Drug Administration
FTC	Final Trial Close-out
FU	Follow Up
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GP	General Practitioner
I(M)P	Investigational (Medical) Product
IATA	International Air Transport Association
IB	Investigators' Brochure
IC	Informed Consent
ICF	Informed Consent Form
ICH	International Conference on Harmonization
ICSR	Individual Case Safety Report
IEC	Independent Ethics Committee
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations; provides the ICH Secretariat.
IFQ	Investigator Feedback Questionnaire
IGPA	International Generic Pharmaceutical Alliance and one of the ICH Interested Parties
IMDG	International Maritime Dangerous Goods Code
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
IND	Investigational New Drug application (FDA)
INV	Investigator
IRB	Institutional Review Board
IS	Information Sheet
ISF	Investigator Study File

ISO	International Standards Organization
IT	Information Technology
IVRS	Interactive Voice Response System
JPMA	Japan Pharmaceutical Manufacturers Association, and one of the six ICH parties
LEC	Leading Ethics Committee
LOC	Local
LPM	Lead Project Manager
MA	Marketing Authorization
MD	Medical Doctor
MedDRA	Medical Dictionary for Regulatory Activities
MHLW	Ministry of Health, Labor and Welfare Japan
MS	Member State
NAI	No Action Indicated (most favorable FDA post-inspection classification)
NAP	Not Applicable
NCCT	Non Commercial Clinical Trial
NCR	No Carbon [paper] Required
NDA	New Drug Application
NIMP	Non-Investigational Medicinal Product
NTF	Note To File
OAI	Official Action Indicated (serious FDA post-inspection classification)
ODM	Operational Data Model
PANDRH	Pan American Network on Drug Regulatory Harmonization, and one of the Regional Harmonization Initiatives (RHIs).
PD	PharmacoDynamics
PhRMA	Pharmaceutical Research and Manufacturers of America, and one of the six ICH parties
PI	Principal Investigator
PIP	Pediatric Investigation Plan
PK	PharmacoKinetics
PM	Project Manager
PMDA	Pharmaceuticals and Medical Devices Agency (Japan).
PMS	Post Marketing Surveillance
PPI	Patient Package Insert
PSUR	Periodic Safety Update Report
PTV	Pre-Trial Study Visit
PUMA	Pediatric Use Marketing Authorisation (& Label)
PV	PharmacoVigilance
QA	Quality Assurance
QC	Quality Control/ (Check)
QM	Quality Management
QP	Qualified Person

R&D	Research & Development
RA	Regulatory Affairs
RID	Regulations concerning International Carriage of Dangerous Goods by Rail
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SAS	Statistical Analysis System
SC	Study Coordinator
SDMB	Safety Data Monitoring Board
SDTM	Submission Data Tabulation Model
SDV	Source Data Verification
SIV	Site Initiation Visit
SmPC	Summary of Product Characteristics
SMV	Site Monitoring Visit
SOP	Standard Operating Procedure
SSC	Study Site Coordinator
SUSAR	Suspected Unexpected Serious Adverse Reaction
TC	Telephone Conference
TIV	Trial Initiation Visit
TMF	Trial Master File
TMV	Trial Monitoring Visit
UN	United Nations
V#	Visit Number
VAI	Voluntary Action Indicated (FDA post-inspection classification)
WHO	World Health Organization, and one of the ICH Observers
WMA	World Medical Association
WSMI	World Self-Medication Industry, and one of the ICH Interested Parties
XML	Extensible Mark-up Language

Appendix 3 Index

A

Accessory 87
accountability form 90
accreditation 71
acknowledgement of receipt 90
action list 108
action lists 62
Active implantable medical device 87
Adverse Drug Reaction (ADR) 103
Adverse Event (AE) 101
advertisement 70, 100
Agreement 70
airway bills 90
animal research 13
Annual Safety Report 129
arms 17
Assessment of Efficacy 45
Assessment of Safety 45
audit/inspection 115
auditor 49
Auditors 114

B

baseline evaluations 16
blinding 17

C

Carcinogenicity 13
Case Report Form 49
certificate of analysis 90
certificate of destruction 93
Certificate(s) of Analysis 71
certified copies 84
CIOMS form 106
clinical operations 46
clinical research 15
clinical study report 129, 130
close-out visit 113
Code of Federal Regulations (CFR) Title 21 14
cold call 56
commercial trials 17
Committee (IEC) 70
communication reports 127
Competent Authorities 22
competent authority 68
computer environment 13
confidentiality agreement (CDA) 57
confirmation of your appointment 62
Contract Research Organizations (CROs) 20
control group 15
correction 132
correspondence 62
Council for the International Organization of Medical Sciences (CIOMS) 24
cross-over design 17
Curriculum Vitae (CV) 66

D

Data managers 20
data protection 48
Declaration of Helsinki 14
delegation of duties 78

design 15
deviations 107
Directive 1995/46/EC 29
Directive 2001/20/EC 29
Directive 2001/83/EC 29
Directive 2005/28/EC 29
directives 29
double-blind 17
drug accountability 83
Drug Regulatory Authorities (DRA) 22

E

e-mail 127
enrollment 16
Essential documents 132
ethics committees 66
EU Clinical Trial Directive 29
EU GCP Directive 29
European directive 2001/20/EC & 2005/28/EC 14
experience 65

F

factorial design 17
FDA 24
FDA Form 1572 69
FDA Form 3455 69
Filing 93
final study report 115
Financial Disclosure Form 114
follow-up letter 68

G

galenic formulation 13
Good Laboratory Practice 13
Good Manufacturing Practice 88
green light documents 68
guidances 29

I

ICH-GCP (Good Clinical Practice) 24
ICH-Good Clinical Practice 14
IMP accountability 89
Import and export 87
inclusion and exclusion criteria 22
individual usernames 85
informed consent form (ICF) 47
initiation visit 75
inspectors 114
Institutional Review Board (IRB) 70
Insurance 70
Interventional trials 18
investigational center/site/private 67
Investigational medicinal Product 86
Investigational Medicinal Products 11
investigator 19
Investigator Brochure (IB) 51
investigator site file 62
In vitro diagnostic devices (IVD) 87
in vitro research 13
in vivo 13

L

labeling 91
Label(s) 71
laboratory 66
Line listings 128
logistics 67

M

marketing authorization 22
Master Randomisation List 71
Medical device 86
medical doctor 55
medical writer 20
molecules 13
monitor 12
monitoring plan 61
monitoring report 40
monitoring visit 49
monitoring visit log 83
Monitoring Visit Report 107
Monitoring visits 83
Monitors 37

N

non-commercial trials 17
Non-interventional trials 18
non-substantial amendments 46
Normal Value(s)/range(s) 71
Nuremberg trial 24

O

open label trial 17

P

parallel design 17
passwords 85
patient population 66
patient populations 22
patients 19
patient working files 39
pharmacodynamics 13
pharmacokinetics 13
pharmacy 66
Pharmacy File 89
Phase I 21
phase II 21
Phase III 22
phase IV 22
Policy 45
post-treatment follow-up phase 16
pre-clinical studies 14
pre-study visit 67
project manager 19
protocol 15, 45
protocol synopsis 67
Publication 45

Q

Qualified Persons 88
Quality assurance 119
Quality Assurance 45
Quality control 119
Quality Control 45

R

radiology 66
Recruitment 95
Regulation 2006/1901/EC 29
regulations 29
relationship 41
report 68
research period 12
research subjects 19
responsibilities 67
run-in 16

S

SAE report 104
safety 101
Safety reporting 128
screening phase 16
Serious Adverse Event (SAE) 104
single blind 17
site inventory & patient accountability 91
site management 94
Source Data 45
source data verification 83
Source document 84
Source documents 52
sponsor 19
Standard Operating Procedures 122
statisticians 20
Statistics 45
Storage conditions 92
study flowchart 67
study nurses 76
sub-investigators 76
subject compensation 71
substantial amendments 46
SUSAR 105

T

temperature control 92
Title 21 30
Title 45 of the Code of Federal Regulations (CFR) 30
toxicity 13
tracker 39
Tracking of Imp 89
tracking sheet 39
training certificate 75
treatment phase 16
treatments 13
Trial Design 45
trial master file 62
Trial Objectives 45

V

violations 107
volunteers 21

W

wash-out 16
World Health Organization 24
World Medical Association 24