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)
EMEA	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