A guide to pre-approval regulatory documents

Raquel Billiones

Clinipace Worldwide, Volketswil (Zurich), Switzerland

Correspondence to:

Raquel Billiones
Clinipace Worldwide
(Volketswil) Zurich
Switzerland
rbilliones@clinipace.com

The following table provides a list of the most common pre-approval regulatory documents for drugs with their associated guidelines and regulations. The clinical study report (p86), clinical study protocol (p93), investigator's brochure (p96), and common technical document (and components; p101) are dealt with in detail elsewhere in this issue.

Document	Commonly used abbreviation	Associated guidelines and regulations and other sources of information
Case report form	CRF	Good clinical data management practices, version 3 (September 2003), Society for Clinical Data Management
Clinical development plan	CDP	–
Clinical overview	CO	ICH M4E
Clinical study protocol	CSP	ICH E6; ICH E8; ICH E9
Clinical study protocol amendment	CSP amendment	ICH E6; ICH E8
Clinical study report, full or abbreviated	CSR	ICH E3; ICH E9; FDA GfI submission of abbreviated reports and synopses in support of marketing applications
Clinical trial application (EU)	CTA	EudraLex – Volume 10 Clinical trials guidelines; Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments, and declaration of the end of the trial (August 2003)
Common technical document	CTD	ICH M2, ICH M4, ICH M8
Data management plan	DMP	Good clinical data management practices, version 3 (September 2003), Society for Clinical Data Management
Developmental periodic safety update report	DSUR	ICH E2F; see also PBRER
Electronic case report form	eCRF	See CRF; 21 CFR Part 11
Electronic common technical document	eCTD	ICH M2, ICH M4, ICH M8
Informed consent form	ICF	ICH E6, HIPAA
Integrated summary of effectiveness (US)	ISE	FDA GfI Integrated summary of effectiveness; FDA GfI Integrated summaries of effectiveness and safety: location within the common technical document
Integrated summary of safety (US)	ISS	FDA GfI Integrated summaries of effectiveness and safety: location within the common technical document
Investigational medicinal product dossier, full or abbreviated (EU)	IMPD	Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments, and declaration of the end of the trial (March 2010); http://www.imp-dossier.eu/imdp_guidance/
Investigational new drug annual report (US)	INDR	FDA information on IND application reporting
Investigational new drug application (US)	INDA	FDA information on IND application
Investigator's brochure	IB	ICH E6
Investigator's brochure update	IB Update	ICH E6

Continued

DOI: 10.1179/2047480614Z.000000000206

Continued

Document	Commonly used abbreviation	Associated guidelines and regulations and other sources of information
Marketing authorisation application (EU)	MAA	EMA guidance on applying for EU marketing authorisation medicinal products for human use; EudraLex – Volume 2 – Pharmaceutical Legislation Notice to applicants and regulatory guidelines for medicinal products for human use
New drug application, full or abbreviated (US)	NDA, ANDA	FDA information on NDA and ANDA
Orphan drug application	ODA	Common EMA/FDA application for orphan medicinal product designation; EMA regulatory and procedural guidance
Paediatric study plan (US)	PSP	ICH E11; FDA GfI PSP: Content of and process for submitting initial paediatric study plans and amended paediatric study plans
Paediatric investigation plan (EU)	PIP	ICH E11; EMA information on standard PIP, waivers, and modifications
Patient or subject narratives	–	ICH E2 series; ICH E3
Periodic benefit risk assessment report	PBRER	ICH E2C (R2)
Risk assessment plan	RAP	EMA information on RAP for marketing authorisation holders
Safety management plan	SMP	ICH E2 series
Statistical analysis plan	SAP	ICH E9; ICH E3
Summary of clinical pharmacology	SCP	ICH M4E
Summary of clinical efficacy	SCE	ICH M4E
Summary of clinical safety	SCS	ICH M4E

Abbreviations: CFR, Code of Federal Regulations; EMA, European Medicines Agency; EU, European Union; GfI, Guidance for Industry; FDA, Food and Drug Administration; HIPAA, Health Insurance Portability and Accountability Act; ICH, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; US, United States.