Glossary

Abbreviation	Definition
AMG	German Medicinal Products Act (“Arzneimittelgesetz”)
BLA	Biologic License Application
CBC	Case-by-Case
CBR	Can Be Released
CCI	Commercially Confidential Information
CFR	Code of Federal Regulations
CSR	Clinical Study Report
CTA	Clinical Trial Authorization (application)
CTD	Common Technical Document
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EudraCT	European Clinical Trials Database
FDA	Food and Drug Administration
FDAAA	FDA Amendment Act
FDAMA	FDA Modernization Act
HIPAA	Health Insurance Portability and Accountability Act
HMA	Heads of Medicines Agencies
HRA	(UK) Health Research Authority
ICH	International Council for Harmonisation
ICMJE	International Committee of Medical Journal Editors
INN	International Nonproprietary Name
IPD	Individual Patient Data
MA	Marketing Authorization
MAA	Marketing Authorization Application
MAH	Marketing Authorisation Holder
MRCT	Multi-Regional Clinical Trials
NDA	New Drug Application
NIH	National Institutes of Health
PhRMA	Pharmaceutical Research and Manufacturers of America
PIP	Pediatric Investigation Plan
PPD	Protected Personal Data
PPI	Personal Protected Information
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organization