Clarivate Cortellis™

Cortellis Regulatory Intelligence

Acronyms and Synonyms List

Cortellis Regulatory Intelligence™ will look by default for terms synonymous to your search terms or for common regulatory abbreviations, except when a wildcard is used in the query. For example, a search for “Pharmacovigilance” will also search for the terms drug safety, vigilance, and surveillance.

This is applicable to the Quick Search and the following Advanced Search fields: Title, Abstract, Comments, Document PDF, and Source. Note: Please do not forget to add double quotes for phrase searches.

Search tips:

“(s)” means that both singular and plurals of a word will be included in search result; Example Clinical trial(s), if you search “clinical trial(s)”, all documents containing “clinical trial” or “clinical trials” will be listed in your search result

“-“ means that both “-“ or empty space between two words will be included in search result; Example, if you search “off-label use”, all documents contain “off label use” or “off-label use” will be listed in your search result

“()” means that both with “()” or without “()” will be included in search result; Example Adverse (drug) reaction report, if you search “Adverse reaction report” (please make sure to add symbols “” to the term), all documents containing “Adverse drug reaction report” or “Adverse reaction report” will be listed in your search result.

0-9

510k	Premarket notification PMN

A

Accelerated assessment	Accelerated Approval
ADME	Absorption, distribution, metabolism, and excretion Absorption, distribution, metabolism, and elimination
ADR	Adverse drug reaction Adverse reaction AR Suspected adverse drug reaction SADR
ADRS	Adverse Drug Reporting System
Advertising	Advertizing Advertisement
Advertising license	Advertizing license
AE	Adverse event Adverse experience Side effect Untoward effect Undesirable effect
AER	Adverse event report
Aerosol	Metered dose inhaler Pressurized metered dose Self-pressurized container
AERS	Adverse event reporting system
AIMD	Active implantable medical device
AIMDD	Active implantable medical devices directive
Alternative medicine	Non-conventional medicine
ANDA	Abbreviated new drug application
ANDS	Abbreviated new drug submission

Animal experimentation	Animal experiment Animal study Animal test Experimental animal Animal trial
API	Active pharmaceutical ingredient Active ingredient Active principle Active raw material Active substance Drug substance Existing active substance Medicinal substance
AQL	Acceptable quality level
ASEAN	Association of Southeast Asian Nations
ASMF	Active substance master file
ATC	Anatomical therapeutic chemical Anatomical therapeutic chemical classification ATC classification
ATMP	Advanced therapy medicinal product somatic cell therapy tissue engineered Product
B	
BIMO	Bioresearch monitoring
Bioavailability	Bioavailability studies
Biocide	Biocidial
Bioequivalence	Biocomparable
Biomarker	Biological marker Surrogate endpoint
Biosimilar	Follow on biologic Similar biological Follow-on protein Similar biotherapeutic Biogeneric(s) Biosimilarity Reproduced medicinal product
BLA	Biologics license application Biologic license application
BPCA	Best Pharmaceuticals for Children Act
Bridge study	Bridging study
Brokering	Broker

C

CADREAC	Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries
CAP	Centrally authorised product
CAPA	Corrective Action Preventive Action
CCDS	Company core data sheet
CE Marking of conformity	CE-mark
CEP	Certificate of suitability to the European pharmacopoeia
CFR	Code of Federal Regulations
CIOMS	Council for international organizations of medical sciences
Clinical trial	Clinical investigation Clinical research Clinical study Medical experiment Clinical investigation Clinical drug trial
Clinical trial endpoint	Clinical endpoint
Clinical trial protocol	CT protocol
Clock stop	Clock-stop
CMC	Chemistry manufacturing and control
COA	Certificate of analysis
COI	Conflict of interest
Combined vaccine	Conjugate vaccine
Compassionate use	Emergency use Expanded access Temporary special license Personal use Unregistered Exceptional use authorization Temporary use authorization Early Access Programs (EAPs) Named patient basis access Named Patient Supply Named Patient Program (NPP) Managed Access Program (MAP) Special Access Scheme Special Access Program Off-label use
Controlled drug	Narcotic
Controlled study	Controlled trial

COO	Certificate of origin Country of origin
COS	Certificate of suitability
COVID	COVID-19 Covid 19 SARS-CoV-2 2019-Ncov Coronavirus
CP	Centralized procedure Centralised procedure
CPP	Certificate of pharmaceutical product Certificate of medicinal product CoPP CMP
CRF	Case report form
CRO	Contract research organization Clinical research organization Site management organization SMO
CTA	Clinical trial application Investigational new drug application INDA Clinical Trial Notification Clinical Trial Exemption CTN CTX
CTD	Common technical document
CTIL	Clinical Trial Import License
CTR	Clinical Trials Register Clinical Trials Registry
Customs clearance	Customs check
CV	Curriculum vitae

D

DCP	Decentralized procedure Decentralised procedure
DDPS	Detailed description of pharmacovigilance system
DESI	Drug Efficacy Study Implementation
DH	Digital health
DHR	device history record

DIBD	Development International Birth date
DMF	Drug master file European drug master file EDMF
DMR	Device master record
DOI	Declaration of interest
Dosage regimen	Dosing schedule Posology
Dossier validation	Dossier clearance
DRLM	Device registration and listing module
Drug abuse	Drug over use Drug addiction Drug dependence
DSUR	Development safety update report Annual safety report ASR

E

EAPs	Early Access Programs Compassionate use Emergency use Expanded access Temporary special license Personal use Unregistered Exceptional use authorization Temporary use authorization Named patient basis access Named Patient Supply Named Patient Program (NPP) Managed Access Program (MAP) Special Access Scheme Special Access Program Off-label use
eCTD	Electronic technical document
EDMS	Electronic document management system
EHR	Electronic health record
EIR	Establishment inspection report
Electronic submission	Esubmission E-submission Online submission Pre-IDE submission

EMR	Electronic medical record
EPAR	European public assessment report
ERA	Environmental risk assessment
ERB	Ethics Review Board Ethical review board
EudraCT	European clinical trials database
EudraNet	European Drug Regulatory Network
EURD	European Union Reference Date Union Reference Date
EWG	Expert working group
excipient	Inactive ingredient Additive Inactive raw material Non-medicinal ingredient Added substance
Export license	Export licence

F

Falsified medicine	Counterfeit medicine
FDC	Fixed dose combination
Fee	Charges
Finished product	Drug product
FLP	Final printed label Labelling
FOI	Freedom of information
FOIA	Freedom of Information Act
FSC	Free sale certificate
FSCA	Field safety corrective action
FUM	Follow up measure Follow-up measure
FUMSO	Follow-Up Measure/Safety Obligation

G

galenic	Pharmaceutical dosage form

GCP	Good clinical practice
GDP	Good distribution practice
Generic	Copy drug Similar product Interchangeable product Me-too drug Bioequivalent
Generic substitution	Interchangeability
Genetic toxicology	Genotoxicity
Genetically engineered animal	Transgenic animal
Geriatric	Elderly Older people
GGP	Good guidance practice
GLN	Global location number
Global clinical trial	International clinical trial Multi-regional clinical trial
GLP	Good laboratory practice Good clinical laboratory practice GCLP
GMDN	Good medical device nomenclature
GMO	Genetically modified organism
GMP	Good manufacturing practice Current good manufacturing practice cGMP
GPhP	Good pharmacovigilance practice Good reporting practices
GPhVP	Good pharmacovigilance practice Good vigilance practice GVP
GPSP	Good post-marketing study practice
GRP	Good review practice
GSP	Good scientific practice
GTIN	Global Trade Item Number
GTP	Good tissue practice Current good tissue practice cGTP

H

HCP	Healthcare professional Health care professional Physician Medical doctor
HDE	Humanitarian device exemption Humanitarian use exemption
HTA	Health technology assessment
HUD	Humanitarian use device
Hybrid applications	Hybrid medicine
I	
ICF	Informed consent form Informed consent IC
ICH	International conference on harmonization International conference on harmonisation
ICSR	Individual Case Safety Report Adverse drug reaction report Adverse reaction report Case safety report
IDE	Investigational device exemption
IFU	Instruction(s) for use
IMPD	Investigational medicinal product dossier
Import	Importation
Import license	Import licence
IND	Investigational new drug Investigational product Investigational medicinal product IMP
INN	International non-proprietary name Recommended international non-proprietary name rINN
Insurance	Compensation
International cooperation	Memorandum of agreement Memorandum of understanding Mutual recognition agreement MOU MRA
Investigational new drug annual report	IND annual report
IRB	Institutional Review Board
ISE	Integrated summary of efficiency

ISR	Individual Safety Report
ISRTN	International Standard Randomised Controlled Trial Number
ISS	Integrated Summary of Safety
IVD	In vitro diagnostics
IVDD	In vitro diagnostic devices
IVMD	In vitro medical device IVDs
L	
LOA	letter of authorization letter of authorisation letter of acceptance
Long term trial	Long term study Long term treatment Long term testing
M	
MAA	Marketing Authorization Application
MAH	Marketing Authorization Holder
MAP	Managed Access Program Named Patient Program (NPP) Early Access Programs (EAPs) Compassionate use Emergency use Expanded access Temporary special license Personal use Unregistered Exceptional use authorization Temporary use authorization Named patient basis access Named Patient Supply Special Access Scheme Special Access Program Off-label use
Manufacturing license	Manufacturing licence
Manufacturing site	Manufacturing plant
MAPP	Manual of Policy and Procedures
MAUDE	Manufacturer and user device experience Manufacturer and user facility device experience
MDCG	Medical Device Coordination Group
MDV	Medical device vigilance
MedDRA	Medical Dictionary for Regulatory Activities

	MEDRA
MEDWATCH	FDA Safety Information and Adverse Event Reporting Program
MERCOSUL	Mercado comun del sur Mercado comum do sul MERCOSUR
mRCT	Meta Register of Controlled Trials
MRP	Mutual recognition procedure
MSDS	Material safety data sheet
N	
NCA	National Competent Authority Health authority Local agency Local authority Medicines agency Ministry of Health National agency National authority National health authority Regulatory agency Regulatory authority MOH
NCE	New chemical entity
NDA	New drug application New drug authorization
NDS	New drug submission
NeeS	Non-eCTD electronic submission
NIMPs	Non-investigational product(s)
NIS	Non-interventional studies Uncontrolled study Non controlled study Non controlled trial Uncontrolled trial
NME	New molecular entity
NPP	Named Patient Program Early Access Programs (EAPs) Compassionate use Emergency use Expanded access Temporary special license Personal use Unregistered Exceptional use authorization Temporary use authorization Named patient basis access Named Patient Supply Managed Access Program (MAP) Special Access Scheme Special Access Program

	Off-label use
Non interventional clinical trial	Non-interventional study
Notified body	Notified bodies
NTA	Notice to applicants
O	
Off label use	Off-label use Unapproved drug use

	Unapproved use
OMAR	Orphan maintenance assessment report
On-site inspection	Self inspection
Orphan disease	Rare disease
Orphan drug	Orphan product Orphan medicinal product
OTC	Over the counter Over-the-counter
P	
Package leaflet	Patient information Patient package insert Patient information sheet Product information leaflet Package insert Package leaflet pack insert PIS PIL
Packaging	Patient pack
PAES	Post authorisation efficacy study Post authorisation effectiveness study Post-approval effectiveness study Post-approval efficacy study
PAM	Post authorization measure Post authorisation measure
PAR	Public Assessment Report
Parallel import	Parallel information Parallel trade
PASS	Post authorisation safety studies Post authorization safety study Post-approval safety study
Patient selection	Subject selection
PBRER	Periodic Benefit-Risk Evaluation Report Periodic safety update report PSUR
PDR	Physician's Desk Reference

Pediatrics	Pediatric Paediatric Paediatrics Pediatric study plan Child Infants Neonate Newborn Adolescent Teenager
Pharmacoeconomic study	Pharmaco economic study
PhV	Pharmacovigilance Post-marketing surveillance PhVig
PIC(s)/PICS	Pharmaceutical inspection convention and Pharmaceutical inspection co-operation scheme
Pilot trial	Pilot study Pivotal trial
PIM	Product Information Management system
PIP	Paediatric(s) investigation plan Pediatric investigation plan Pediatric study plan
PIS	Patient information sheet
PLM	Product lifecycle management
PMA	Premarket approval Pre-market approval Premarket application Pre-market application
PMF	Plasma master file
PMOA	Primary mode of action
PMR	Post marketing requirement Postmarketing commitment Postmarketing study requirement Post-marketing study commitment
POM	Prescription only medicine Prescription-only medicine Prescription-only medicinal product Prescription only medicinal product
Post-market surveillance	Post-market surveillance plan Post-market surveillance report Post-market performance follow-up Post-market clinical follow-up PMPF PMCF
Pre-cert	Software precertification
PREA	Pediatric Research Equity Act of 2003

Premarketing	Pre marketing Pre-marketing
PRIME	Priority medicines
Priority review	Accelerated review
Promotional sample	Free medical sample Free sample Promotional information
Proprietary name	Brand name Trade name Tradename
PSMF	Pharmacovigilance system master file
PSUR	Periodic safety update report Periodic Summary Reporting
PUMA	Paediatric use marketing authorisation
Q	
Q&A	Question and answer
QBD	Quality by design
QMS	Quality management system
QP	Qualified person Qualified person for pharmacovigilance QPPV
QRD	Quality review of document
QRM	Quality risk management
R	
Reference medicinal product	Reference product Reference medicine comparator
Referral	Arbitration Appeal
Reimbursement rate	tariff
Renewal	Re-evaluation Reevaluation

RMP	Risk management plan Risk evaluation and mitigation strategy REMS Safety concern Safety risk Routine pharmacovigilance activity Additional pharmacovigilance activity Risk assessment Risk minimisation measure Risk minimization plan Risk minimisation activity RMA Risk minimization action plan RiskMAP
RMS	Reference member state
RWD	Real-world evidence Real-world data Real-world studies Natural history study External control Historical data Pragmatic study Cohort study
RWE	Real-world evidence Real-world data Real-world studies Natural history study External control Historical data Pragmatic study Cohort study
Rx	Prescription drug Prescription medicine Prescription medication

S

SAE	Serious adverse event
Safety surveillance	Pre-marketing surveillance
SAMD/SaMD	Software as a medical device Standalone software
SAR	Serious adverse reaction
SBA	Summary basis of approval
sBLA	Supplemental biologics license application Biological license application supplement
Scientific advice	Scientific consultation
SDS	Safety data sheet
Single dose	Mono dose

Slow release	Prolonged release Delayed release
SME	Small and medium-sized enterprise
SmPC	Summary of product characteristics Information for Healthcare professionals Summary of product information
sNDA	Supplemental new drug application
SOPP	Standard operating policy and procedure
SPC	Supplementary protection certificate
SPL	Structured product labeling
SRD	Significant risk device
STCD	Sterile connecting device
STD	Standard technical document
SUD	Single use device
Sunset clause	Sunset provision
SUSAR	Suspected unexpected serious adverse reaction

T

Tax	Taxes
TDD	Telecommunications device for the deaf
Transfer of authority	Change of ownership Transfer of MA
TRIPS	Trade related aspects of intellectual property rights
TSE	Transmissible spongiform encephalopathy

U

UADE	Unanticipated adverse device event
UDI	Unique device identification Unique device identifier
UMDNS	Universal medical device nomenclature system
USR	Urgent safety restriction Recall

V

VAERS	Vaccine Adverse Event Reporting System Post marketing change
Variation	Change control Changes being effected Postmarketing change Post-marketing change Post-market change Postapproval change Post approval change Post-approval change Post-market modification
VHP	Voluntary Harmonization Procedure NAN

W

WEU	Well-established use
WIPO	World Intellectual Property Organization
Withdrawal	Suspension

About Cortellis™

Cortellis gives life to science by unlocking the hidden insights in data. As an industry-leading solution, Cortellis curates broad and deep sources of intelligence to enable precise, actionable answers to specific questions across the R&D lifecycle — from discovery and clinical development through regulatory submission and commercialization. By supporting data-driven decisions, Cortellis helps pharmaceutical companies, biotech and medical device/diagnostic firms accelerate innovation.

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