EUCROF
European CRO Federation

Index	Term	Draft Definition	Source
1	Accord européen relatif au transport international des marchandises dangereuses par route (ADR). ADR, short for “Accord Dangereux Routier’’	Association to ensure the safety, security and reliability of shipments on streets. European regulations governing the international transportation of hazardous materials by road. Established as a UN treaty in 1957, the ADR has been regularly updated to align with the evolving rules and regulations within the logistics industry.	
2	Active packaging	Active thermal systems do not use any phase change materials (PCM) such as water/ice or dry ice. These systems use mechanical or electric systems powered by an energy source, combined by thermostatic control to maintain proper product temperatures.	Pharma Logistics IQ
3	Adverse Event (AE)	Any unfavourable or unintended sign, symptom, or disease that occurs in a clinical trial participant during the course of the trial, regardless of whether it is related to the investigational product.	World Health Organization
4	Air Transportation Association (IATA)	Air transportation association is an association of airline traders around the world promoting cooperation in ensuring the safety, the security and the reliability of air services.	
5	Audit	Review of all trial related processes conducted by any sponsor for example pharma companies.	
6	Biological sample	Biological Samples means blood, fluid and/or tissue samples collected from Trial Subjects as may be set forth in the Protocol, and tangible materials directly or indirectly derived from such samples.	Law Insider
7	Biosamples category A (UN 2814)	Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned to UN 2814.	IATA regilation
8	Biosamples category A (UN 2900)	Infectious substances which cause disease only in animals must be assigned to UN 2900.	IATA regulations
9	Biosamples category B (UN 3373)	An infectious substance which does not meet the criteria for inclusion in Category A. The proper shipping name of UN 3373 is Biological substance Category B.	IATA regulations
10	Blinding	The process of concealing from participants, investigators, and/or assessors the identity of the treatment being administered (e.g., active drug vs. placebo) in order to minimize bias and increase the validity of the trial results.	ClinicalTrials.gov

11	Blockchain	It is a continuously growing list of records, called blocks, which are linked and secured using cryptography.' This network usually peer-to-peer managed and follows set rules when validating new data block. The distribution of data is secure and a data transaction is conducted at a minor fee. Data governance rules are enforced to preserve integrity when inputting or retrieving information. After input, data and program modification or removal is usually impossible. These attributes provide all users with a consistent view of the ledger in its latest state.	
12	Calibration	The application of specifically known and accurately measured input to ensure an item will produce specifically known output which is accurately measured or indicated. Calibration includes adjustment or recording of corrections, as appropriate.	IATA regulations
13	CAPA	Corrective action and preventive action (CAPA) is a concept in which product failures are investigated to determine their root cause in an effort to eliminate occurrences of nonconformity (corrective actions) and prevent similar occurrences from happening in the future (preventive actions).	
14	Carriage and insurance paid (CIP)	In CIP, Seller delivers the goods and passes the risk to the buyer upon delivery to the main carrier. Seller arranges and pays for the main carrier (Seller is the shipper) to bring the shipment at agreed place. Seller also arranges for insurance on behalf of buyer to cover buyer's risk. The main difference between CPT and CIP is that the insurance is also paid by the seller. Again, this point was highlighted earlier "arranging for the insurance does not mean that risk is with the party arranging the insurance". Here Seller pays for the insurance, but the risk is not with him. Seller arranges for the insurance to cover buyer's risk. CIP requires seller to arrange for insurance equals to 110% of the cargo value under minimum insurance claim. Buyer must insure himself against any additional risk he thinks need insuring against.	MySea Time Blog
15	Carriage paid to (CPT)	Seller pays for the main carriage to bring the shipment at agreed place. However, the seller passes the risk to the buyer upon delivery to the main carrier. This is the point that we highlighted earlier. "Arranging for the main transport does not mean the risk is with the arranging party". Here even when the seller arranges for the main carrier, risk has already passed to the buyer. Buyer also arranges for the insurance from the point of delivery.	MySea Time Blog

16	Case Report Form (CRF)	The case report form (CRF) is a printed, optical or electronic document (eCRF) to record all protocol-required information on each subject in a clinical trial.	
17	CE Label	The CE marking (French: Conformité Européenne) certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety.	
18	Cell Therapy	Cell therapy is the transfer of cells into a patient with the goal of improving a disease.	American Society of Gene + Cell Therapy
19	Clinical Research Associate (CRA)	Clinical Research Associate (CRA) will monitor non-interventional trials and clinical trials and check the correctness of data by source data verification.	
20	Clinical Trial	A research study that investigates the safety and efficacy of a medical intervention (such as a drug, device, or procedure) in humans. Clinical trials are conducted to gather evidence on the benefits and risks of medical interventions before they are approved for use in the general population.	National Institutes of Health
21	Clinical Trial Agreement (CTA):	A legal agreement between the sponsor and the clinical site that outlines the terms and conditions of the trial, including the responsibilities of the parties, the financial arrangements, and the intellectual property rights.	National Institutes of Health
22	Clinical Trial Logistics	Clinical Trial Logistics: The planning, coordination, and execution of activities required to support the conduct of a clinical trial, including the management of supplies, equipment, and personnel.	Clinical Trial Logistics
23	Clinical Trials Information System (CTIS)	Central information system for the European Medical Agency to submit clinical trials.	
24	Cold Chain/Temperature controlled packaging (TCP)	Cold chain packaging, also known as temperature-controlled packaging, refers to packaging and distribution methods specifically engineered to keep products at a constant temperature from production through final distribution. While initially established to keep temperature-sensitive goods refrigerated or frozen in transit, temperature-controlled packaging solutions have expanded to encompass packaging that protects room temperature products from extreme external temperatures.	TPC Packing solutions

25	Controlled Room Temperature	A temperature maintained at the usual and customary working environment of 20˚C to 25˚C (68˚F to 77˚F).	National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases/ Office of Regulatory Affair Work Instruction Process for Temperature Excursions
26	Dangerous Goods Regulation (DGR)	IATAs Dangerous Goods Regulation helps you classify mark, pack, label and document dangerous shipments and hazardous materials.	
27	Data logger	Data loggers are electronic devices which automatically monitor and record environmental parameters over time, allowing conditions to be measured, documented, analysed and validated. The data logger contains a sensor to receive the information and a computer chip to store it. Then the information stored in the data logger is transferred to a computer for analysis.	Geminidataloggers
28	Database lock (DBL)	Database lock is a crucial time point in a clinical trial. The process of locking a clinical trial database is an action taken to prevent further changes to maintain the integrity of trial data.	
29	Decentralized Clinical Trials (DCT)	Decentralized clinical trials (DCT) make use of digital technologies and other methods to enable access of patients to clinical research, remote data collection and monitoring, and communication between investigator and participating subjects.	
30	Declaration of Helsinki	Declaration of Helsinki is a set of ethical principles regarding human experimentation developed originally 1964 for the medical community.	
31	Delivered at place (DAP)	DAP means seller delivers when shipment arrives at final destination, ready for unloading from the arriving mode of transport. Seller bears all the costs and risks in bringing the goods to this place: Seller handles export fees, carriage, insurance and destination port charges; Buyer handles import fees and unloading of goods.	MySea Time Blog
32	Delivered at terminal (DAT)	Seller delivers the shipment and passes the risk to the buyer when shipment is put at the disposal of buyer at the terminal of final destination. Seller handles export fees, carriage, insurance, destination port charges and unloading of the goods. The main difference between DAT and DAP is that in DAT, seller handles the final unloading of the goods.	MySea Time Blog

33	Delivered duty paid (DDP)	Delivered duty paid is just the opposite of Ex-works. Seller has the most responsibility. Seller has the responsibility to deliver the goods at buyer's premises, depot or any other place as agreed. It means that from seller's premises to buyer's premises or any other agreed place: The delivery point is buyer's premises or other place agreed; Seller handles the cargo and pays for export as well as import dues and; Seller arranges the transport of the cargo. Which also means that in case of sea transport, seller will be the shipper of the goods; Seller pays for the insurance. As in Ex-works, DDP can also have practical difficulties in cross border assignments. In DDP, seller is responsible to clear the import formalities, but the seller may not have the local knowledge & expertise to clear import formalities.	MySea Time Blog
34	Direct to Patient (DTP)	A Direct-to-Patient model allows for drug therapies to be delivered and administered in the patient's home and/or biological samples to be taken and uplifted from the patient's home.	AmerisourceBergen (World Courier)
35	Dry Ice (UN 1845)	Air Transport Association (IATA) classify dry ice as a "miscellaneous" hazard, Class 9 and assigned to UN 1845. In CT logistics, dry ice is used for transportation of bio samples.	IATA regulations
36	Dry Shipper	Dry shippers are dewars that contain porous material cooled with liquid nitrogen (LN2) but do not have free liquid nitrogen when prepared correctly. They are designed for the safe shipment of specimens at liquid nitrogen temperatures without the risk of spilling liquid nitrogen.	University of Minnesota
37	Ethics Committee (EC)	The duty of the Ethics Committee is to verify the study plan and the required documents, particularly from ethical and legal points of view, and check if the legal requirements are fulfilled.	
38	European Medicines Agency (EMA)	Founded in 1991, the European Medicines Agency (EMA) has worked across the European Union (EU) and globally to protect public and animal health by assessing medicines to rigorous scientific standards and providing partners and stakeholders with independent, science-based information on medicines.	
39	EXW (Ex-Works)	With Ex-works the seller has the least responsibility. Seller has the responsibility to deliver the goods to the buyer at seller's premises, depot or any other agreed places. From there on, all responsibility and risks are with the buyer. It means: The delivery point is seller's premises; buyer pays for the export from seller's premises and import into the destination; buyer arranges for all modes of transport; buyer pays for the insurance. Ex-works is often used while making quoting	MySea Time Blog

		initial prices for sale contracts. In practice, this incoterm can have practical difficulties specially in cross border assignments. These difficulties may include buyer's inability to arrange for export formalities.	
40	FDA product code	The name and the product code identify the generic category of a device for the FDA. The Product Code assigned to a device is based upon medical device product classification.	
41	Food and Drug Administration (FDA)	Founded in 1906 the Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and by ensuring the safety of food supply, cosmetics, and products that emit radiation.	FDA Gov
42	Free Carrier (FCA)	Free carrier means the delivery point is carrier or other person nominated by the buyer at the seller's premises or other agreed place. If the agreed place is seller's premises, delivery takes place when the goods load on the truck. If the agreed place is not seller's premises then the delivery takes place when truck arrives at this place and is ready for unloading. In Free carrier (FCA): The delivery point is seller's premises or any other place agreed; buyer pays for the export from seller's premises and import into the destination; buyer arranges for all modes of transport. In FCA incoterm, the agreed place has implications on the loading of the carrier. If the agreed place is seller's premises then seller handles the loading. If the agreed place is other than seller's premises, then seller has delivered the goods once the carrier arrives at the agreed place. "FCA seller's premises" might look similar to Ex-works but there is one main difference. In FCA, seller has the obligation to load the goods on the carrier.	MySea Time Blog
43	Gene Therapy	Gene therapy is the introduction, removal, or change in the content of a person's genetic code with the goal of treating or curing a disease.	American Society of Gene + Cell Therapy
44	Good Clinical Practice (GCP)	A set of ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials that involve the participation of human subjects. GCP ensures that the rights, safety, and well-being of trial participants are protected, and that the trial data are accurate, reliable, and verifiable.	International Conference on Harmonisation
45	Good Distribution Practice (GDP)	is a set of guidelines and regulations that ensure the quality and integrity of pharmaceutical products throughout the distribution chain, from the manufacturer to the end user.	Paraphrased from World Health Organization. (2014). Good distribution practices for pharmaceutical products.

46	ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines.	
47	Incoterms	A cargo may move several days before it arrives at its destination. Even though shipping is safer these days, many cargoes still do not reach their destination or reach in bad shape. And when that happens, one should know who had the title of the goods lost. For that reason, It is important for buyer and seller to pre-define the responsibilities and obligations for transport of the goods. INCOTERMS are all the possible ways of distributing responsibilities and obligations between two parties.	MySea Time Blog
48	Informed consent	Informed consent is used by researchers to explain the clinical trial to potential volunteers. Its purpose is to protect the participant. It is used when somebody who is interested in participating first asks about the study and it continues throughout the study, until the study ends. The research team will review the details of the trial with the potential participant and will answer any questions. This information is also written in a document, known as the informed consent form, which is designed to be clear and easy to understand. If a person decides to enrol in a clinical trial, they will sign the informed consent form to acknowledge that they understand the details of the trial and consent to participating. The informed consent form is not a contract, and the participant can withdraw from the trial at any time, and for any reason.	Novartis Glossary
49	Inspection	Review of all trial related processes conducted by a regular authority.	
50	Insurance costs	Incoterms outlines who bears the insurance costs. Arranging for the insurance does not mean that risk is with the party arranging the insurance. In few of the INCOTERMS, seller arranges for insurance to cover buyer's risk. In these cases, seller is only required to cover minimum risk as defined in the minimum risk clause in respective incoterm. Buyer must take more insurance to cover any extra risk that he wishes to insure against.	MySea Time Blog
51	International Health Regulations (IHR)	IHR provide an overarching legal framework that defines countries rights and obligations in handling public health events and emergencies that have the potential to cross borders.	

52	Internet of Things (IoT)	IoT devices can provide real-time monitoring of temperature and environmental conditions, enabling proactive interventions to prevent temperature excursions and ensure product quality.	
53	Investigational Product (IP):	Any drug, biological product, or medical device that is being studied in a clinical trial.	Food and Drug Administration
54	Investigator	Investigators are responsible for the conduct of a clinical trial at the trail site.	
55	Investigator brochure (IB)	Comprehensive document summarizing the body of information about an investigational product (IP or study drug) obtained during a clinical trial.	
56	IVDR	In Vitro Diagnostic Medical Device Regulation started in May 2022 in all EU countries and replaced the 98/79/EG (IVDD).	
57	Laboratory kits	Provision of laboratory kits direct to the investigational site. Depending on the country the Kit components must be CE labelled or marked with the FDA product codes.	
58	Logistics	The process of planning, implementing, and controlling the movement of goods, information, and resources from the point of origin to the point of consumption.	
59	Medical device	A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.	WHO
60	Medication number	A unique number on the label of each investigational drug package that is used in a trial to dispense and track medication. The number is used to make sure the drug is supplied in the right quantities to different research centres.	Novartis Glossary
61	MSDS (Material Safety Data Sheet)	An MSDS (Material Safety Data Sheet) is a document containing information about the potential hazards of a product, and how to safely handle it. An MSDS is required for all potentially dangerous products and all lithium battery shipments (whether dangerous or not). An MSDS may also be required for potentially dangerous products, like liquids, creams, and powders, just to prove that they aren't dangerous. Carriers may also request an MSDS for dry or alkaline batteries, to certify they are not lithium based.	IATA regulations

62	Notify Party	Notify party is the party to whom the carrier is supposed to notify regarding the arrival ETA's of the vessel. Notify party is then responsible for arranging the arrival formalities of the vessel. By now you must have guessed it rightly that notify party could be agent, receiver of the cargo or any other person/entity who has the interest in the arrival of the cargo.	MySea Time Blog
63	OBC (onboard-carrier service)	moves small packages and documents on scheduled passenger flights - 24/7, 365 days a year. It is one of the fastest modes of cargo transportation and is also known as 'hand-carry'.	MySea Time Blog
64	Passive packaging	Passive thermal systems commonly use phase change materials (PCM) such as water/ice or dry ice. These shipping systems are the most basic and cost effective.	Pharma Logistics IQ
65	Pharmacokinetic / Pharmacodynamic	PK/PD analysis is an alternative to conventional dose –effect analyses and its relates drug effects to a measure of drug concentration in a body compartment (e.g. venous blood) rather than a drug dose.	
66	Point of delivery	Incoterms defines the point of delivery of the goods by seller to buyer. The meaning of delivery here is "transfer of risk and responsibility". So, the INCOTERMS defines the point of change of hands (passing of risk) from seller to buyer.	MySea Time Blog
67	Protocol	A detailed plan for conducting a clinical trial, including the study design, objectives, methods, statistical analyses, and ethical considerations. The protocol serves as a blueprint for the trial and is reviewed and approved by regulatory authorities and ethics committees.	National Institutes of Health
68	Quarantine	Effective restriction of the availability product for use until released.	National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases/ Office of Regulatory Affair Work Instruction Process for Temperature Excursions
69	Randomization	The process of assigning participants in a clinical trial to different treatment groups (e.g., treatment vs. placebo) in a random manner to minimize bias and ensure that the groups are similar in terms of baseline characteristics.	ClinicalTrials.gov
70	Recipient / receiver	Consignee is the person to whom the carrier (Ship) is supposed to deliver the goods. In most cases the consignee is the Buyer of the goods but not always. Consignee could be the agent nominated by the buyer.	MySea Time Blog

71	Shipper / consignor	Many believe “Shipper” is the supplier or owner of the goods being supplied. It is true but not always. The business directory defines shipper as the party responsible for the shipment. When a buyer of goods enters into a contract with seller of the goods through sale contract, apart from other things they also decide who would arrange for the transport. In the multi-modal transport, they may decide which leg of transport is under whom.	MySea Time Blog
72	Standard Operation Procedures (SOPs)	Standard Operation Procedure (SOPs) are standardized written procedures with detailed instructions to record routine operations, processes and procedures followed within the organization.	
73	Temperature excursion	An excursion event in which a TTSPP is exposed to temperatures outside. the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.	WHO
74	Temperature-controlled	Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise predefined limits.	WHO
75	Timelines	Defined in each clinical trial protocol: FPFV: First patient first visit LPFV: Last patient first visit LPLV: Last patient last visit	
76	Transportation Costs	Incoterms defines which party pays for the transportation cost. There may be more than one means of transportation and INCOTERMS defines who pays for which leg of the transportation.	MySea Time Blog
77	Trial Master File (TMF)	A Trial Master File (TMF) is a compilation of documents that prove that the clinical trial has been conducted following the regulatory requirements. The TMF plays a crucial role in ensuring that the trial has been managed successfully by the investigator, the sponsor and all other service provider.	
78	Ultimate consignee	The ultimate consignee is the intended recipient of the imported merchandise sold by the shipper. In many cases the consignee is the same party as the ultimate consignee.	MySea Time Blog

79	Validation	Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting predetermined acceptance criteria.	Definition from PDA Technical Report No. 39, 2007.
80	World Health Organisation (WHO)	Founded in 1948, WHO is the United Nations agency that connect nations, partners and people to promote health, keep the world safe and serve the vulnerable.	