
Data tag hierarchy

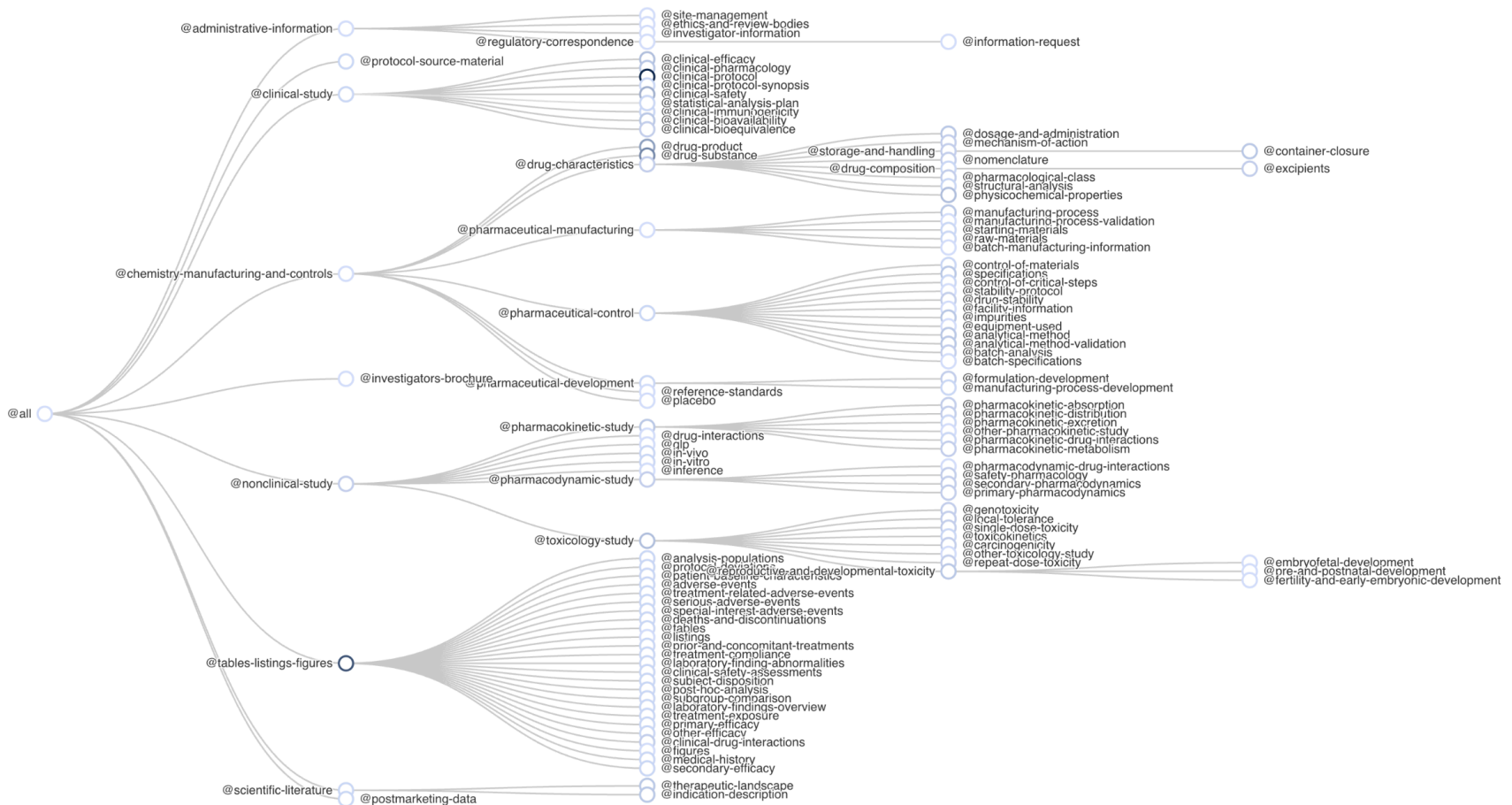
Weave Bio
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To more effectively categorize and use source data for generation, each file in the Data Room now contains data tags. Instead of generating entire sections with many source files, data tags enable content generation of individual parts of a section using only the most appropriate files or source sections as inputs. This offers greater flexibility when using content templates and providing greater control over the type and length of generated content.

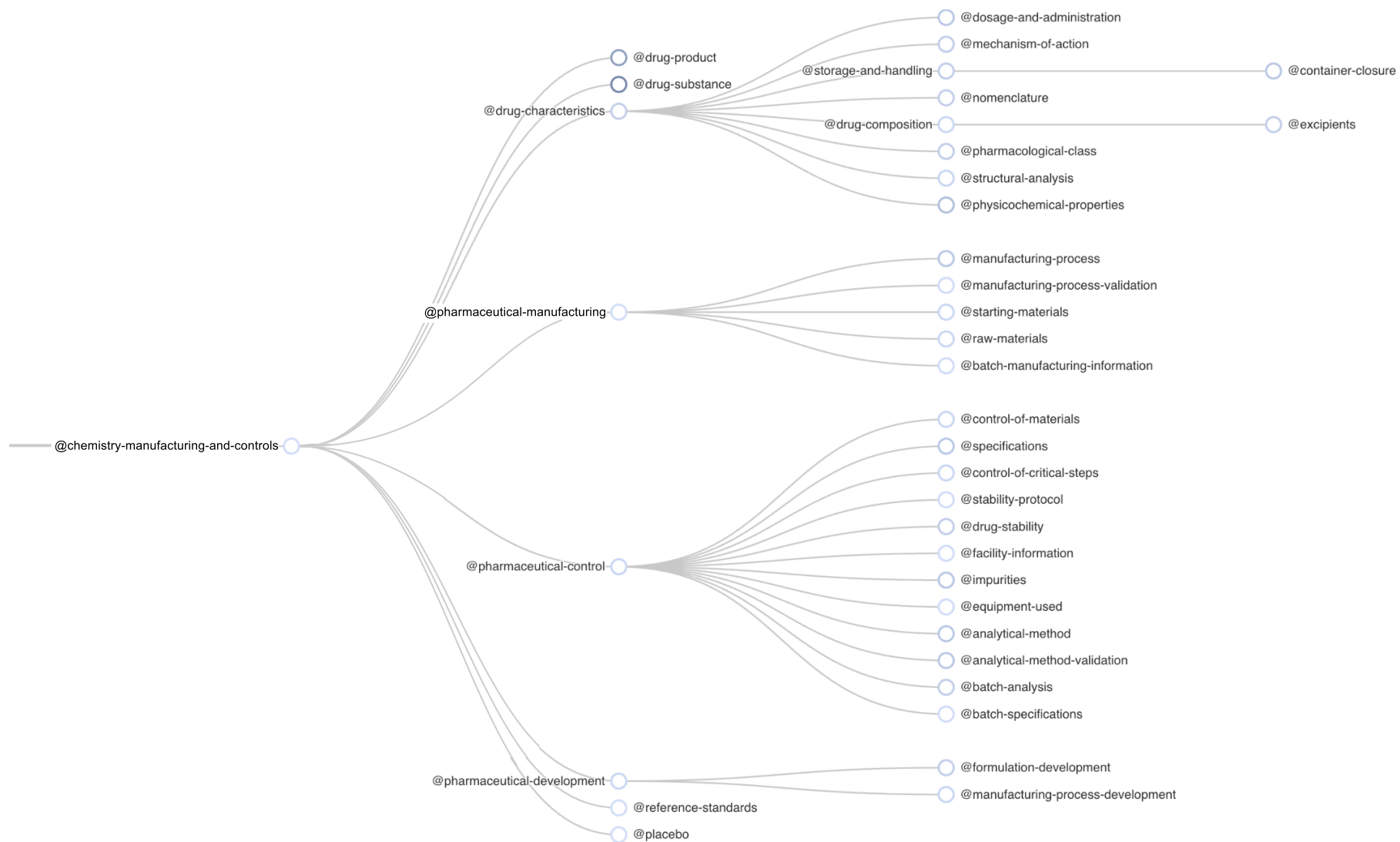
Introduction

Currently, Weave has a core set of approximately 70 data tags that can be used when customizing templates. We do not yet support editing or adding new data tags. These tags are organized in a hierarchy ranging from extremely broad (e.g. @nonclinical-study to very specific (e.g. @excipients) categorization of data.

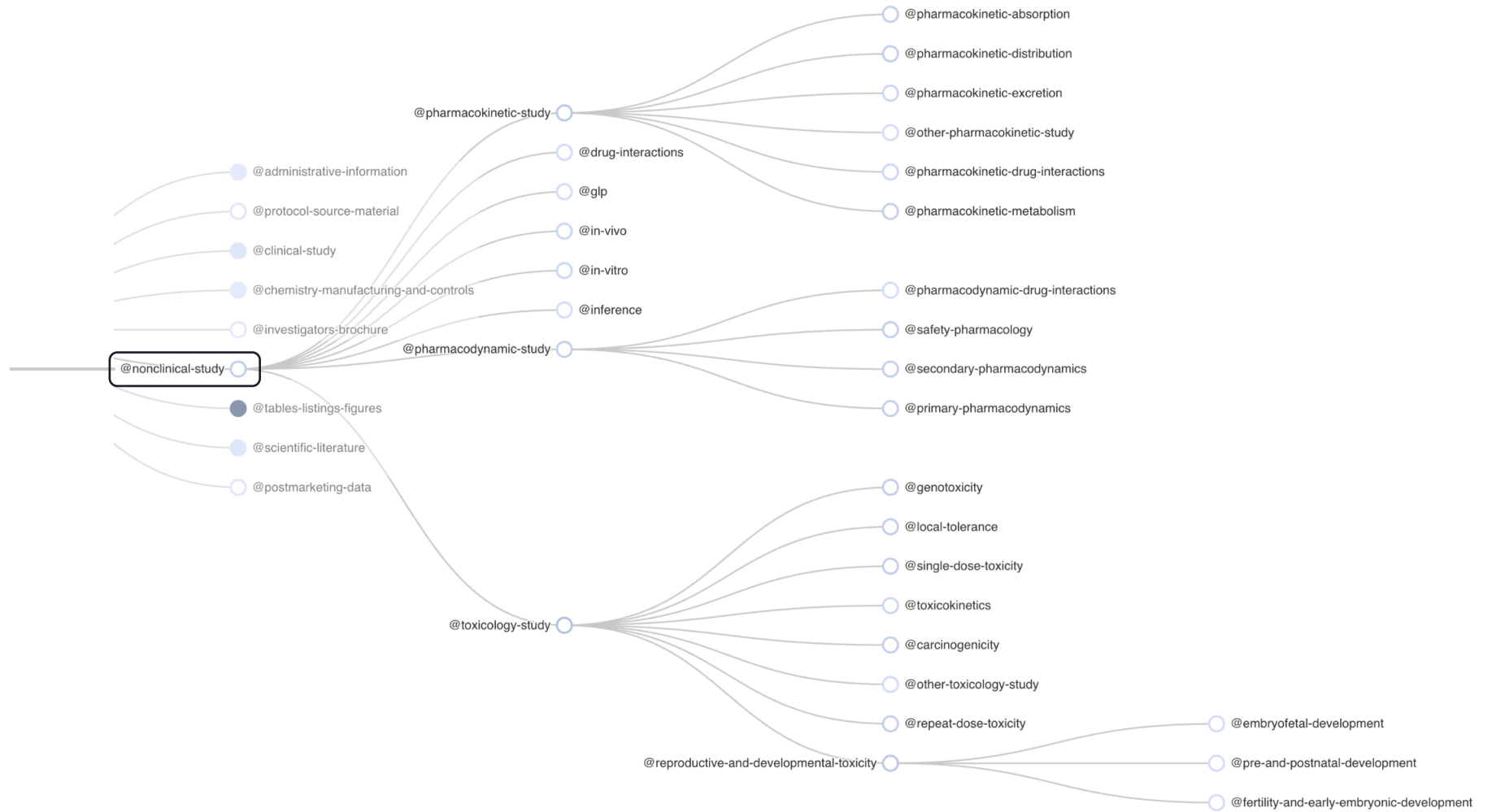
All data tags



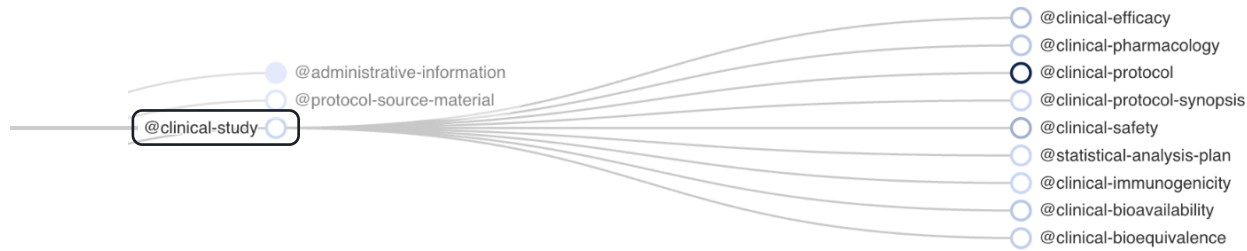
Chemistry manufacturing and controls



Nonclinical study



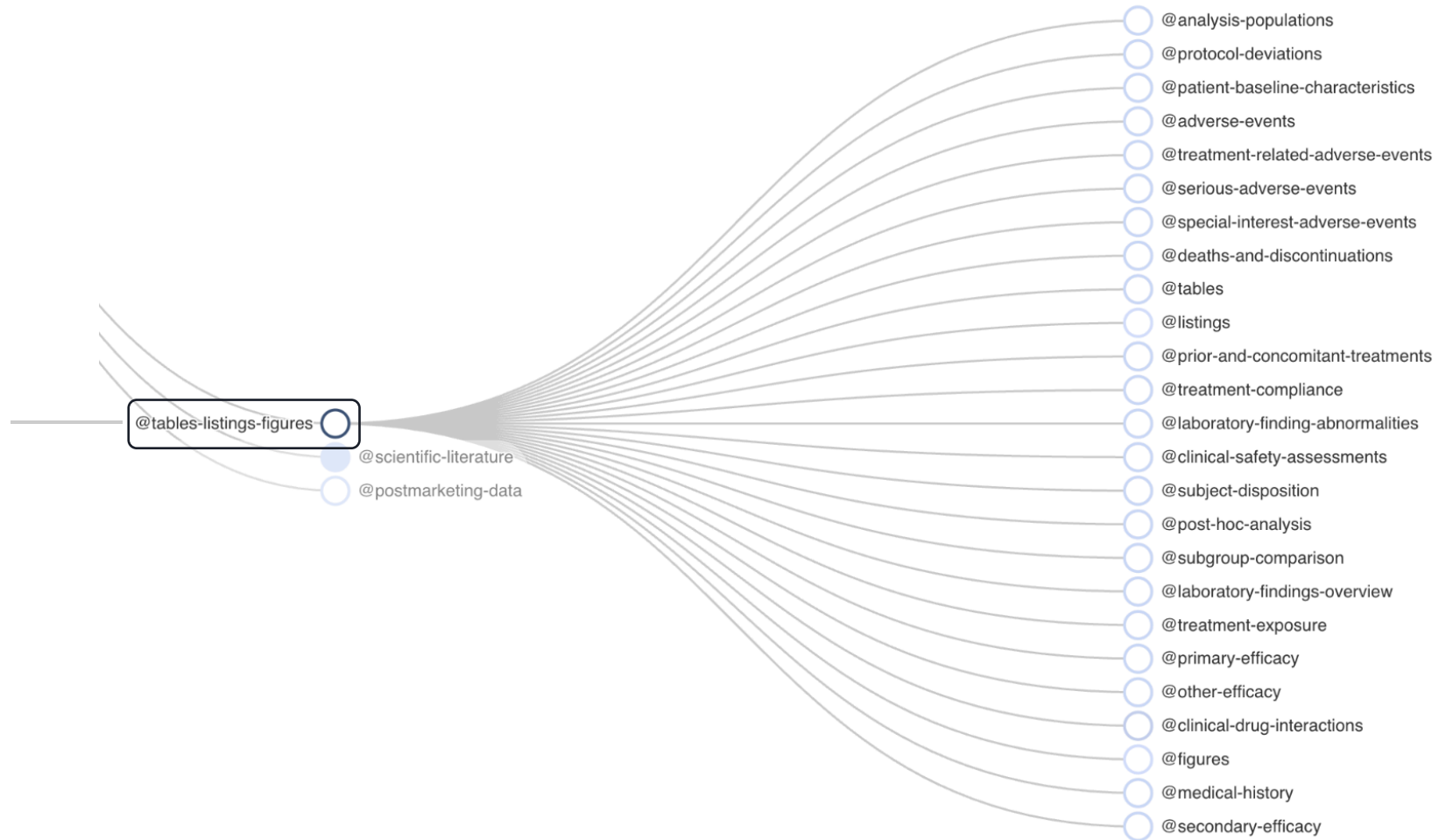
Clinical study



Scientific literature



Tables, listings, and figures



Primary name	Definition	Keywords	Template name	Parent name
Administrative information	General administrative documents relevant to the conduct and oversight of the clinical or regulatory process. Includes materials related to ethics oversight, investigator credentials, site management, and institutional approvals. Keywords: administrative documents, site information, institutional review, regulatory correspondence	administrative documents, site information, institutional review, regulatory correspondence	@administrative-information	@all
Adverse events	Reported adverse events during the study, including frequency and severity. Keywords: adverse events, AE summary, treatment-emergent AEs, safety findings	adverse events, AE summary, treatment-emergent AEs, safety findings	@adverse-events	@tables-listings-figures
All			@all	
Analysis populations	Definitions and counts of populations used for statistical analysis, including ITT and per-protocol. Keywords: analysis sets, intention to treat, per protocol, population definition, exclusions	analysis sets, intention to treat, per protocol, population definition, exclusions	@analysis-populations	@tables-listings-figures
Analytical method	Detailed descriptions of validated procedures specifically for analyzing the identity, strength, purity, potency, and quality of a drug substance or drug product. Keywords: validated method, analytical procedure, CMC testing, characterization technique, quality protocol	validated method, analytical procedure, CMC testing, characterization technique, quality protocol	@analytical-method	@pharmaceutical-control
Analytical method validation	Study performed to demonstrate the suitability of an analytical method for an intended purpose. Keywords: specificity, linearity, accuracy, precision, limit of detection, limit of quantification	specificity, linearity, accuracy, precision, limit of detection, limit of quantification	@analytical-method-validation	@pharmaceutical-control
Batch analysis	Comprehensive assessment of individual production batches, focusing on conformity with CMC specifications. Keywords: batch assessment, production lot testing, CMC compliance, quality evaluation, manufacturing review	batch assessment, production lot testing, CMC compliance, quality evaluation, manufacturing review	@batch-analysis	@pharmaceutical-control
Batch manufacturing information	CMC-specific documentation detailing raw materials, processes, and conditions used in the production of a given batch. Keywords: production details, manufacturing data, raw material usage, batch processing, CMC documentation	production details, manufacturing data, raw material usage, batch processing, CMC documentation	@batch-manufacturing-information	@pharmaceutical-manufacturing
Batch Specifications	Defined CMC criteria establishing the quality attributes for a specific production batch. Keywords: batch quality standards, manufacturing criteria, CMC specifications, production requirements	batch quality standards, manufacturing criteria, CMC specifications, production requirements	@batch-specifications	@pharmaceutical-control
Carcinogenicity	Assessment of whether a substance has the potential to cause cancer. Keywords: cancer risk, carcinogenicity, safety testing, long-term effects	cancer risk, carcinogenicity, safety testing, long-term effects	@carcinogenicity	@toxicology-study
Chemistry Manufacturing and Controls	Activities related to the development, production, and quality control of drug substances and products to ensure consistency, safety, and compliance with regulatory standards. Keywords: CMC, chemistry manufacturing, quality control, drug production, regulatory compliance, process development, consistency, pharmaceutical standards	CMC, chemistry manufacturing, quality control, drug production, regulatory compliance, process development, consistency, pharmaceutical standards	@chemistry-manufacturing-and-controls	@all
Clinical bioavailability	The proportion of a drug that enters the systemic circulation and is available for therapeutic effect after administration. Keywords: bioavailability, drug absorption, systemic circulation, therapeutic effect, pharmacokinetics, drug availability	bioavailability, drug absorption, systemic circulation, therapeutic effect, pharmacokinetics, drug availability	@clinical-bioavailability	@clinical-study
Clinical bioequivalence	A comparison showing that two drug products release their active ingredients into the bloodstream at the same rate and extent under similar conditions. Keywords: bioequivalence, drug comparison, active ingredient, release rate, absorption extent, therapeutic equivalence	bioequivalence, drug comparison, active ingredient, release rate, absorption extent, therapeutic equivalence	@clinical-bioequivalence	@clinical-study
Clinical drug interactions	Observed or potential interactions between the study drug and other drugs or diseases. Keywords: drug-drug interactions, drug-disease interactions, pharmacological interactions	drug-drug interactions, drug-disease interactions, pharmacological interactions	@clinical-drug-interactions	@tables-listings-figures
Clinical efficacy	The ability of a drug or treatment to produce the desired therapeutic effect in a clinical setting. Keywords: clinical efficacy, therapeutic effect, treatment outcomes, effectiveness, medical benefit	clinical efficacy, therapeutic effect, treatment outcomes, effectiveness, medical benefit	@clinical-efficacy	@clinical-study
Clinical immunogenicity	The potential of a drug or therapeutic protein to provoke an immune response in the body. Keywords: immunogenicity, immune response, drug safety, therapeutic proteins, antibody production, adverse effects, pharmacokinetics	immunogenicity, immune response, drug safety, therapeutic proteins, antibody production, adverse effects, pharmacokinetics	@clinical-immunogenicity	@clinical-study
Clinical pharmacology	The study of how drugs interact with the human body, including absorption, distribution, metabolism, and excretion. Keywords: clinical pharmacology, drug interaction, human body, ADME, pharmacokinetics	clinical pharmacology, drug interaction, human body, ADME, pharmacokinetics	@clinical-pharmacology	@clinical-study
Clinical protocol	A detailed plan outlining the objectives, methodology, and conduct of a clinical study. Keywords: clinical protocol, study design, methodology, objectives, clinical research plan	clinical protocol, study design, methodology, objectives, clinical research plan	@clinical-protocol	@clinical-study

Primary name	Definition	Keywords	Template name	Parent name
Clinical protocol synopsis	A concise summary of the clinical protocol, highlighting the study objectives, design, population, treatment plan, and key assessments. Keywords: clinical protocol synopsis, trial design summary, synopsis document	clinical protocol synopsis, trial design summary, synopsis document	@clinical-protocol-synopsis	@clinical-study
Clinical safety	Assessment of the adverse effects and risks associated with a drug or treatment in a clinical setting. Keywords: clinical safety, adverse effects, risk assessment, treatment safety, patient outcomes	clinical safety, adverse effects, risk assessment, treatment safety, patient outcomes	@clinical-safety	@clinical-study
Clinical safety assessments	Vital signs, ECGs, and physical exam findings to evaluate safety. Keywords: clinical safety, vital signs, electrocardiogram, physical examination, clinical observations	clinical safety, vital signs, electrocardiogram, physical examination, clinical observations	@clinical-safety-assessments	@tables-listings-figures
Clinical study	Research involving human participants to evaluate the safety, efficacy, or outcomes of a medical intervention. Keywords: clinical research, human participants, medical intervention, safety, efficacy	clinical research, human participants, medical intervention, safety, efficacy	@clinical-study	@all
Container closure	Specifications, tests, certificates, and analysis of materials or components used in the storage, packaging, or protection of drug substances or products. This includes information on physical characteristics, material composition, compliance with standards, and quality control of packaging materials like bags, bottles, caps, or seals. Keywords: container, bag, bottle, cap, sealing, material analysis, contamination prevention, protective packaging, physical dimensions	container, bag, bottle, cap, sealing, material analysis, contamination prevention, protective packaging, physical dimensions	@container-closure	@storage-and-handling
Control of critical steps	Key manufacturing operations within CMC that directly affect the quality, efficacy, or safety of the final product. Keywords: essential CMC operations, quality-critical steps, safety-impact processes, manufacturing checkpoints	essential CMC operations, quality-critical steps, safety-impact processes, manufacturing checkpoints	@control-of-critical-steps	@pharmaceutical-control
Control of materials	Procedures and measures to ensure the quality and integrity of materials used in CMC processes. Keywords: material control, quality assurance, CMC integrity, process measures	material control, quality assurance, CMC integrity, process measures	@control-of-materials	@pharmaceutical-control
Deaths and discontinuations	Deaths and study discontinuations due to adverse events or other reasons. Keywords: mortality, death, SAE, discontinuation, AE-related withdrawal	mortality, death, SAE, discontinuation, AE-related withdrawal	@deaths-and-discontinuations	@tables-listings-figures
Dosage and administration	Information on the amount, frequency, and method of administering a drug. Includes information on reconstitution diluents or dosage devices. Keywords: dosage, administration, administration method, frequency, dosage form, reconstitution diluent, dosage devices	dosage, administration, administration method, frequency, dosage form, reconstitution diluent, dosage devices	@dosage-and-administration	@drug-characteristics
Drug characteristics	Information describing the fundamental properties of a drug, including its mechanism of action, structure, chemical composition, pharmacological classification, and standardized nomenclature. Keywords: mechanism of action, drug composition, pharmacological class, nomenclature, drug identity, drug properties, therapeutic classification, chemical attributes	mechanism of action, drug composition, pharmacological class, nomenclature, drug identity, drug properties, therapeutic classification, chemical attributes	@drug-characteristics	@chemistry-manufacturing-and-controls
Drug composition	Description of the quantities of each ingredient in a drug product, including the active ingredient and any excipients. Keywords: drug composition, formulation, active ingredients, excipients, API, drug properties, pharmaceutical formulation	drug composition, formulation, active ingredients, excipients, API, drug properties, pharmaceutical formulation	@drug-composition	@drug-characteristics
Drug interactions	A description of how a drug affects or is affected by other drugs, substances, or conditions. Keywords: drug interactions, interaction effects, drug compatibility, labeling, food-drug interactions, drug-drug interactions	drug interactions, interaction effects, drug compatibility, labeling, food-drug interactions, drug-drug interactions	@drug-interactions	@nonclinical-study
Drug product	The finalized, packaged formulation intended for therapeutic use, containing both active and inactive components as per CMC standards. Keywords: finished product, CMC formulation, packaged dosage, therapeutic formulation, API-containing medication	finished product, CMC formulation, packaged dosage, therapeutic formulation, API-containing medication	@drug-product	@chemistry-manufacturing-and-controls
Drug stability	Detailed assessments of the behavior of drugs under stress conditions such as temperature fluctuations, humidity, or prolonged storage, aiming to establish degradation pathways, expiration dates, and optimal storage conditions. Keywords: stability testing, drug degradation, storage stability	stability testing, drug degradation, storage stability	@drug-stability	@pharmaceutical-control
Drug substance	The purified active pharmaceutical ingredient (API) synthesized or extracted as part of the CMC process. Keywords: CMC API, active compound, therapeutic ingredient, drug base substance	CMC API, active compound, therapeutic ingredient, drug base substance	@drug-substance	@chemistry-manufacturing-and-controls
Embryofetal development	Assessment of drug-induced effects during the embryonic and fetal development phases. Keywords: teratogenicity, fetal development, malformations, embryo toxicity	teratogenicity, fetal development, malformations, embryo toxicity	@embryofetal-development	@reproductive-and-developmental-toxicity
Equipment Used	Details about the machinery and tools utilized in CMC processes, including their specifications and maintenance. Keywords: machinery, equipment, tools, CMC processes, specifications, maintenance	machinery, equipment, tools, CMC processes, specifications, maintenance	@equipment-used	@pharmaceutical-control

Primary name	Definition	Keywords	Template name	Parent name
Ethics and review bodies	Documents related to Institutional Review Boards (IRBs), Independent Ethics Committees (IECs), or other oversight entities that evaluate and approve clinical study protocols. Keywords: IRB, IEC, ethics approval, review board, ethics committee documentation	IRB, IEC, ethics approval, review board, ethics committee documentation	@ethics-and-review-bodies	@administrative-information
Excipients	Non-active materials included in drug products to enhance stability, delivery, or usability as per CMC guidelines. Keywords: inactive carriers, formulation agents, stabilizers, delivery aids, excipient materials	inactive carriers, formulation agents, stabilizers, delivery aids, excipient materials	@excipients	@drug-composition
Facility Information	Specific details regarding the infrastructure, equipment, and compliance of CMC manufacturing sites. Keywords: manufacturing site details, CMC facility data, operational infrastructure, compliance location	manufacturing site details, CMC facility data, operational infrastructure, compliance location	@facility-information	@pharmaceutical-control
Fertility and early embryonic development	Study focusing on the potential effects of a drug on fertility and early stages of embryonic development. Keywords: fertility, implantation, pre-implantation loss, early embryonic development	fertility, implantation, pre-implantation loss, early embryonic development	@fertility-and-early-embryonic-development	@reproductive-and-developmental-toxicity
Figures	Graphical representations of clinical study data such as line graphs, bar charts, or Kaplan-Meier curves. Keywords: clinical figures, plots, data visualization, efficacy figures, safety figures	clinical figures, plots, data visualization, efficacy figures, safety figures	@figures	@tables-listings-figures
Formulation development	The process of designing and optimizing the composition of a drug product, including active and inactive ingredients, to ensure stability, efficacy, and manufacturability under CMC standards. Keywords: formulation development, drug design, CMC optimization, stability, efficacy, composition, manufacturability	formulation development, drug design, CMC optimization, stability, efficacy, composition, manufacturability	@formulation-development	@pharmaceutical-development
Genotoxicity	Study of a drug's potential to damage genetic material, including DNA and chromosomes. Keywords: genetic damage, genotoxicity, DNA effects, safety testing	genetic damage, genotoxicity, DNA effects, safety testing	@genotoxicity	@toxicology-study
GLP	Good Laboratory Practice (GLP) guidelines ensuring the quality, consistency, and integrity of nonclinical studies. Keywords: GLP, good laboratory practice	GLP, good laboratory practice	@glp	@nonclinical-study
Impurities	Substances unintentionally present in raw materials or products, identified and quantified during CMC analysis. Keywords: unintended compounds, CMC contaminants, byproducts, degradation substances, process residues	unintended compounds, CMC contaminants, byproducts, degradation substances, process residues	@impurities	@pharmaceutical-control
In vitro	Studies conducted outside of a living organism, typically using cells, tissues, or biochemical assays to examine drug effects or mechanisms in a controlled environment. Keywords: cell culture, cell line, isolated tissue, in vitro model	cell culture, cell line, isolated tissue, in vitro model	@in-vitro	@nonclinical-study
In vivo	Studies conducted within living organisms, typically animals, to evaluate the safety, efficacy, pharmacokinetics, or pharmacodynamics of a compound. Keywords: animal study, whole organism, live model, in vivo model	animal study, whole organism, live model, in vivo model	@in-vivo	@nonclinical-study
Indication description	Description of the medical condition or disease that the proposed drug is intended to treat or prevent. Keywords: indication description, target indication, medical condition, disease treatment, therapeutic target	indication description, target indication, medical condition, disease treatment, therapeutic target	@indication-description	@scientific-literature
Inference	Data or conclusions derived from modeling, simulation, or extrapolation rather than direct experimental measurement. Keywords: modeling and simulation, PBPK, QSAR, computational prediction, differential equation	modeling and simulation, PBPK, QSAR, computational prediction, differential equation	@inference	@nonclinical-study
Information request	Formal communications with regulatory authorities comprising questions and answers about the application or the data therein. Keywords: health authority questions, HAQ, FDA questions, EMA questions	health authority questions, HAQ, FDA questions, EMA questions	@information-request	@regulatory-correspondence
Investigator information	Documentation pertaining to the contact information, qualifications and credentials of study investigators. Includes curriculum vitae (CVs), medical licenses, addresses, and related professional records. Keywords: investigator CV, investigator qualifications, site personnel, clinical staff background	investigator CV, investigator qualifications, site personnel, clinical staff background	@investigator-information	@administrative-information
Investigator's brochure	A comprehensive document provided to clinical investigators that includes clinical and nonclinical data on the investigational product relevant to the study. Keywords: investigator brochure, IB, investigational product summary	investigator brochure, IB, investigational product summary	@investigators-brochure	@all
Laboratory finding abnormalities	Clinically significant or abnormal lab results identified during the study. Keywords: lab abnormalities, abnormal values, lab outliers, clinically meaningful labs	lab abnormalities, abnormal values, lab outliers, clinically meaningful labs	@laboratory-finding-abnormalities	@tables-listings-figures
Laboratory findings overview	Changes in laboratory test results over time for the study population. Keywords: lab trends, laboratory results, clinical labs, time-course analysis	lab trends, laboratory results, clinical labs, time-course analysis	@laboratory-findings-overview	@tables-listings-figures
Listings	Detailed participant-level data presented in tabular form, used to verify and support summary tables. Keywords: patient listings, raw data listings, clinical trial listings, subject-level data	patient listings, raw data listings, clinical trial listings, subject-level data	@listings	@tables-listings-figures

Primary name	Definition	Keywords	Template name	Parent name
Local tolerance	Evaluation of a drug's local effects at the site of application or administration. Keywords: local effects, tolerance testing, site-specific safety, local reaction	local effects, tolerance testing, site-specific safety, local reaction	@local-tolerance	@toxicology-study
Manufacturing process	The sequence of operations, controls, and validations involved in producing a drug substance or product, as documented in CMC to ensure quality and consistency. Keywords: manufacturing process, production steps, CMC operations, quality assurance, process validation, drug production	manufacturing process, production steps, CMC operations, quality assurance, process validation, drug production	@manufacturing-process	@pharmaceutical-manufacturing
Manufacturing process development	Changes in the processes for the production of drug substances and products in CMC. Keywords: process development, optimization, CMC manufacturing, drug production design	process development, optimization, CMC manufacturing, drug production design	@manufacturing-process-development	@pharmaceutical-development
Manufacturing process validation	Demonstration that a manufacturing process consistently produces products meeting predetermined CMC specifications. Keywords: process validation, CMC compliance, manufacturing consistency, product quality	process validation, CMC compliance, manufacturing consistency, product quality	@manufacturing-process-validation	@pharmaceutical-manufacturing
Mechanism of action	Description of how the drug works, including how it binds or interacts with the intended target. Keywords: mechanism of action, MOA, binding, receptor, affinity	mechanism of action, MOA, binding, receptor, affinity	@mechanism-of-action	@drug-characteristics
Medical history	Summary of pre-existing conditions and relevant past illnesses of participants. Keywords: medical history, past illnesses, comorbidities, pre-existing conditions	medical history, past illnesses, comorbidities, pre-existing conditions	@medical-history	@tables-listings-figures
Nomenclature	Standardized naming conventions for drug substances and products in the context of CMC documentation. Keywords: drug naming, nomenclature, standardized terms, CMC documentation, naming conventions	drug naming, nomenclature, standardized terms, CMC documentation, naming conventions	@nomenclature	@drug-characteristics
Nonclinical study	Preclinical research conducted to assess the safety and efficacy of a drug before human trials. Keywords: nonclinical research, preclinical study, drug safety, efficacy assessment, animal studies, in vitro study	nonclinical research, preclinical study, drug safety, efficacy assessment, animal studies, in vitro study	@nonclinical-study	@all
Other efficacy	Exploratory, non-primary, or tertiary endpoints including non-predefined analyses. Keywords: other efficacy endpoints, exploratory analysis, tertiary outcomes	other efficacy endpoints, exploratory analysis, tertiary outcomes	@other-efficacy	@tables-listings-figures
Other pharmacokinetic study	Pharmacokinetic studies that do not strictly fit into absorption, distribution, metabolism, or excretion categories. It includes exploratory or supplementary pharmacokinetic analyses that provide additional insights but are not directly related to ADME processes. Keywords: other pharmacokinetic study	other pharmacokinetic study	@other-pharmacokinetic-study	@pharmacokinetic-study
Other toxicology study	A report covering additional toxicity studies not classified under: single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity, local tolerance, or reproductive toxicity. Keywords: specialized toxicity, immunotoxicity, organ-specific effects	specialized toxicity, immunotoxicity, organ-specific effects	@other-toxicology-study	@toxicology-study
Patient baseline characteristics	Demographic and baseline medical information of study participants. Keywords: demographics, baseline characteristics, age, sex, BMI, disease stage	demographics, baseline characteristics, age, sex, BMI, disease stage	@patient-baseline-characteristics	@tables-listings-figures
Pharmaceutical control	The systems and measures implemented to monitor, regulate, and ensure the quality, safety, and efficacy of drug substances and products throughout the manufacturing and distribution processes. Keywords: drug control, quality assurance, regulatory oversight, safety monitoring, compliance, product standards, manufacturing regulation	drug control, quality assurance, regulatory oversight, safety monitoring, compliance, product standards, manufacturing regulation	@pharmaceutical-control	@chemistry-manufacturing-and-controls
Pharmaceutical development	The process of refining and optimizing the formulation, manufacturing methods, materials and quality attributes of a drug substance or product to improve its safety, efficacy, stability, and scalability for production, in alignment with regulatory standards. Keywords: formulation development, manufacturing process development	formulation development, manufacturing process development	@pharmaceutical-development	@chemistry-manufacturing-and-controls
Pharmaceutical manufacturing	The process of producing drug substances and drug products, involving raw material sourcing, formulation, quality control, and compliance with regulatory standards to ensure safety and efficacy. Keywords: drug manufacturing, production process, formulation, quality control, raw materials, regulatory compliance, drug production	drug manufacturing, production process, formulation, quality control, raw materials, regulatory compliance, drug production	@pharmaceutical-manufacturing	@chemistry-manufacturing-and-controls
Pharmacodynamic drug interactions	Interactions between drugs that alter their pharmacological effects, including synergistic or antagonistic actions. Keywords: drug interactions, pharmacodynamics, synergistic effects, antagonistic effects, combined effects	drug interactions, pharmacodynamics, synergistic effects, antagonistic effects, combined effects	@pharmacodynamic-drug-interactions	@pharmacodynamic-study
Pharmacodynamic study	Research analyzing the biological effects and mechanisms of action of a drug. Keywords: pharmacodynamics, drug effects, mechanisms of action, biological impact	pharmacodynamics, drug effects, mechanisms of action, biological impact	@pharmacodynamic-study	@nonclinical-study

Primary name	Definition	Keywords	Template name	Parent name
Pharmacokinetic absorption	The process by which a drug is absorbed into the bloodstream. Keywords: bioavailability, rate of absorption, absorption kinetics, systemic circulation, plasma concentration, time to maximum concentration (Tmax), area under the curve (AUC), administration site	bioavailability, rate of absorption, absorption kinetics, systemic circulation, plasma concentration, time to maximum concentration (Tmax), area under the curve (AUC), administration site	@pharmacokinetic-absorption	@pharmacokinetic-study
Pharmacokinetic distribution	The process by which a drug is distributed throughout the body's tissues, particularly the site of action of the drug. Keywords: tissue distribution, biodistribution	tissue distribution, biodistribution	@pharmacokinetic-distribution	@pharmacokinetic-study
Pharmacokinetic drug interactions	Study of interactions between two different substances that affect the absorption, distribution, metabolism, or excretion of a drug. Keywords: interaction studies, synergistic effects, inhibitory effects, combined pharmacokinetics, drug-drug interaction	interaction studies, synergistic effects, inhibitory effects, combined pharmacokinetics, drug-drug interaction	@pharmacokinetic-drug-interactions	@pharmacokinetic-study
Pharmacokinetic excretion	The process by which a drug and its metabolites are eliminated from the body. Keywords: elimination, renal clearance, excretory pathways	elimination, renal clearance, excretory pathways	@pharmacokinetic-excretion	@pharmacokinetic-study
Pharmacokinetic metabolism	The process by which a drug is metabolized. Includes studies on metabolic pathways, stability, and transformation of the drug within the body. Keywords: metabolic profiling, biotransformation, enzyme interactions	metabolic profiling, biotransformation, enzyme interactions	@pharmacokinetic-metabolism	@pharmacokinetic-study
Pharmacokinetic study	Research focused on the absorption, distribution, metabolism, and excretion (ADME) of a drug. Keywords: pharmacokinetics, ADME, drug study, bioavailability	pharmacokinetics, ADME, drug study, bioavailability	@pharmacokinetic-study	@nonclinical-study
Pharmacological class	The category of drugs that share similar chemical structures, mechanisms of action, or therapeutic effects. Keywords: pharmacological class, drug category, mechanism of action, chemical structure	pharmacological class, drug category, mechanism of action, chemical structure	@pharmacological-class	@drug-characteristics
Physicochemical properties	Physical and chemical attributes of substances or products relevant to their performance and stability in CMC. Keywords: physical properties, chemical properties, stability, CMC attributes, performance metrics	physical properties, chemical properties, stability, CMC attributes, performance metrics	@physicochemical-properties	@drug-characteristics
Placebo	A substance that has no therapeutic effect, used as a control in testing new drugs. Keywords: placebo, control treatment, inactive substance	placebo, control treatment, inactive substance	@placebo	@chemistry-manufacturing-and-controls
Post-hoc analysis	Analyses conducted after unblinding that were not pre-specified in the protocol. Keywords: post-hoc, exploratory analysis, unplanned analysis, retrospective insights	post-hoc, exploratory analysis, unplanned analysis, retrospective insights	@post-hoc-analysis	@tables-listings-figures
Postmarketing data	Information collected about a drug's safety, efficacy, and usage after it has been approved and made available to the public. Keywords: postmarketing surveillance, real-world data, pharmacovigilance, long-term effects, drug usage trends	postmarketing surveillance, real-world data, pharmacovigilance, long-term effects, drug usage trends	@postmarketing-data	@all
Pre- and postnatal development	Evaluation of potential drug effects on offspring from late pregnancy through weaning. Keywords: lactation, developmental milestones, growth, postnatal development	lactation, developmental milestones, growth, postnatal development	@pre-and-postnatal-development	@reproductive-and-developmental-toxicity
Primary efficacy	Outcomes for the primary objective of the clinical study. Keywords: primary endpoint, efficacy results, main outcome, treatment effect	primary endpoint, efficacy results, main outcome, treatment effect	@primary-efficacy	@tables-listings-figures
Primary pharmacodynamics	Studies of drug effects on the main therapeutic target, or studies on immunogenic response to the drug or delivery system. Keywords: therapeutic effects, pharmacodynamics, target systems, drug action, drug target, binding studies	therapeutic effects, pharmacodynamics, target systems, drug action, drug target, binding studies	@primary-pharmacodynamics	@pharmacodynamic-study
Prior and concomitant treatments	Treatments taken before or during the clinical study. Keywords: prior medication, concomitant medication, drug history, treatment summary	prior medication, concomitant medication, drug history, treatment summary	@prior-and-concomitant-treatments	@tables-listings-figures
Protocol deviations	Deviations from the planned study protocol, classified by type, reason, and site. Keywords: protocol deviations, non-compliance, study violations, deviation summary	protocol deviations, non-compliance, study violations, deviation summary	@protocol-deviations	@tables-listings-figures
Protocol source material	A grouping tag indicating the document is related to core protocol source materials.		@protocol-source-material	@all
Raw Materials	Unprocessed or minimally processed substances used in pharmaceutical manufacturing, including solvents, reagents, and excipients. Raw materials do not necessarily undergo chemical transformation but are essential in the formulation or synthesis of pharmaceutical products. Keywords: excipients, solvents, reagents, base materials, inactive ingredients	excipients, solvents, reagents, base materials, inactive ingredients	@raw-materials	@pharmaceutical-manufacturing
Reference standards	Documentation of materials or substances used as benchmarks for ensuring the precision, consistency, and reproducibility of analytical or quality control tests, such as Certificates of Analysis for substances employed to validate assay methods, confirm molecular structure, or establish test sensitivity. Keywords: reference materials, standards, benchmarks, test reproducibility	reference materials, standards, benchmarks, test reproducibility	@reference-standards	@chemistry-manufacturing-and-controls

Primary name	Definition	Keywords	Template name	Parent name
Regulatory correspondence	Formal communications with regulatory authorities regarding the application, clinical trials, or product development. Includes meeting minutes, information requests, and responses. Keywords: regulatory letters, health authority communication, FDA correspondence, EMA communication, meeting minutes	regulatory letters, health authority communication, FDA correspondence, EMA communication, meeting minutes	@regulatory-correspondence	@administrative-information
Repeat dose toxicity	Assessment of toxic effects from repeated exposure to a drug over time in animal models. Keywords: repeat dose, toxicity testing, chronic exposure, safety assessment	repeat dose, toxicity testing, chronic exposure, safety assessment	@repeat-dose-toxicity	@toxicology-study
Reproductive and developmental toxicity	Study of the adverse effects of a drug on reproduction and development in animal models. Keywords: reproductive toxicity, developmental toxicity, adverse effects	reproductive toxicity, developmental toxicity, adverse effects	@reproductive-and-developmental-toxicity	@toxicology-study
Safety pharmacology	The study of the potential undesirable pharmacodynamic effects of a drug on physiological functions. Keywords: safety assessment, pharmacology, undesirable effects, physiological impact, telemetry, vital functions	safety assessment, pharmacology, undesirable effects, physiological impact, telemetry, vital functions	@safety-pharmacology	@pharmacodynamic-study
Scientific literature	Published research article, review, or paper relevant to the drug or therapeutic area. Keywords: academic publications, research articles, literature references, peer-reviewed publication	academic publications, research articles, literature references, peer-reviewed publication	@scientific-literature	@all
Secondary efficacy	Outcomes for secondary objectives supporting the primary endpoint. Keywords: secondary endpoint, additional outcomes, secondary efficacy	secondary endpoint, additional outcomes, secondary efficacy	@secondary-efficacy	@tables-listings-figures
Secondary pharmacodynamics	The study of additional pharmacological effects beyond the primary target, including off-target binding, binding selectivity, and downstream effects. Keywords: secondary effects, pharmacodynamics, non-therapeutic outcomes, drug evaluation, off-target effects, off-target binding, selectivity	secondary effects, pharmacodynamics, non-therapeutic outcomes, drug evaluation, off-target effects, off-target binding, selectivity	@secondary-pharmacodynamics	@pharmacodynamic-study
Serious adverse events	Reported serious adverse events during the study, including frequency and severity. Keywords: serious adverse events, SAE summary, treatment-emergent SAEs, safety findings	serious adverse events, SAE summary, treatment-emergent SAEs, safety findings	@serious-adverse-events	@tables-listings-figures
Single dose toxicity	Evaluation of the toxic effects of a single dose of a drug or chemical. Keywords: toxicity evaluation, single dose, acute toxicity, adverse effects	toxicity evaluation, single dose, acute toxicity, adverse effects	@single-dose-toxicity	@toxicology-study
Site management	Documentation related to the operational aspects of clinical trial sites, including site initiation, training, communication logs, and delegation of duties. Keywords: site initiation, site log, delegation of authority, training record, site contact	site initiation, site log, delegation of authority, training record, site contact	@site-management	@administrative-information
Special interest adverse events	AEs identified as being of special interest due to specific safety concerns. Keywords: AESI, special interest events, protocol-defined AEs, safety signal	AESI, special interest events, protocol-defined AEs, safety signal	@special-interest-adverse-events	@tables-listings-figures
Specifications	Documented quality benchmarks specific to CMC to ensure consistency and compliance across materials and products. Keywords: quality benchmarks, CMC standards, product criteria, compliance limits, documented requirements	quality benchmarks, CMC standards, product criteria, compliance limits, documented requirements	@specifications	@pharmaceutical-control
Stability protocol	A predefined plan outlining the methodology and conditions for assessing the stability of a drug substance or drug product over time. Includes storage conditions, time points, and parameters measured. Keywords: stability study plan, ICH stability, storage conditions, time-point testing, stability testing design	stability study plan, ICH stability, storage conditions, time-point testing, stability testing design	@stability-protocol	@pharmaceutical-control
Starting Materials	Key substances or intermediates that are used in the synthesis of the active pharmaceutical ingredient (API) or other critical manufacturing steps. Starting materials undergo chemical transformation during processing. Keywords: API precursors, synthesis intermediates, chemical starting compounds, processed raw materials	API precursors, synthesis intermediates, chemical starting compounds, processed raw materials	@starting-materials	@pharmaceutical-manufacturing
Statistical Analysis Plan	A document that details the statistical methods and analyses to be performed in a clinical study. Keywords: clinical trial statistical analysis, clinical trial methodology, clinical trial statistical plan	clinical trial statistical analysis, clinical trial methodology, clinical trial statistical plan	@statistical-analysis-plan	@clinical-study
Storage and handling	Guidelines for the proper handling, storage conditions, and precautions to maintain the stability and integrity of a drug as part of CMC requirements. Keywords: handling, storage, stability, storage conditions, drug integrity, precautions	handling, storage, stability, storage conditions, drug integrity, precautions	@storage-and-handling	@drug-characteristics
Structural Analysis	Examination of the molecular or structural characteristics of a drug substance or product. Keywords: structural analysis, molecular characteristics, CMC examination, drug structure	structural analysis, molecular characteristics, CMC examination, drug structure	@structural-analysis	@drug-characteristics
Subgroup comparison	Comparisons of treatment effects within participant subgroups. Keywords: subgroup analysis, stratified results, demographic comparisons, treatment heterogeneity	subgroup analysis, stratified results, demographic comparisons, treatment heterogeneity	@subgroup-comparison	@tables-listings-figures
Subject disposition	Summary of participant enrollment, completion, and discontinuation across the study phases. Keywords: disposition, enrollment summary, participant flow, completion status, withdrawal reasons	disposition, enrollment summary, participant flow, completion status, withdrawal reasons	@subject-disposition	@tables-listings-figures

Primary name	Definition	Keywords	Template name	Parent name
Tables	Tabular presentations of clinical study data, typically summarizing outcomes, characteristics, or safety findings. Keywords: summary tables, TLFs, clinical data tables, analysis tables	summary tables, TLFs, clinical data tables, analysis tables	@tables	@tables-listings-figures
Tables, Listings, Figures	Presentation of clinical study data through tables, listings, and graphical representations, typically in files comprised only of tables, listings, and/or figures. Keywords: TLF, clinical trial tabular data, clinical data visualization, clinical trial statistical results	TLF, clinical trial tabular data, clinical data visualization, clinical trial statistical results	@tables-listings-figures	@all
Therapeutic landscape	Overview of the available therapeutic options, strategies and unmet medical needs for a given disease or condition. Keywords: therapeutic landscape, treatment options, disease context, medical strategies, unmet needs, drug development, therapeutic area	therapeutic landscape, treatment options, disease context, medical strategies, unmet needs, drug development, therapeutic area	@therapeutic-landscape	@scientific-literature
Toxicokinetics	The quantitative study of how a test substance is absorbed, distributed, metabolized, and excreted in laboratory species, specifically for the assessment of systemic exposure and potential toxicity. Keywords: toxicokinetics, toxicokinetic analysis, toxicokinetic study	toxicokinetics, toxicokinetic analysis, toxicokinetic study	@toxicokinetics	@toxicology-study
Toxicology study	Comprehensive analysis of a drug's potential toxic effects on biological systems. Keywords: toxicology, safety testing, adverse effects, toxicity evaluation	toxicology, safety testing, adverse effects, toxicity evaluation	@toxicology-study	@nonclinical-study
Treatment compliance	Assessment of participants' adherence to the assigned treatment regimen. Keywords: compliance, adherence, dosing accuracy, missed doses, protocol adherence	compliance, adherence, dosing accuracy, missed doses, protocol adherence	@treatment-compliance	@tables-listings-figures
Treatment exposure	Extent and duration of exposure to the investigational treatment. Keywords: treatment duration, drug exposure, dosage received, exposure summary	treatment duration, drug exposure, dosage received, exposure summary	@treatment-exposure	@tables-listings-figures
Treatment-related adverse events	Reported treatment-related adverse events during the study, including frequency and severity. Keywords: treatment-related adverse events, TRAE summary, treatment-emergent TRAEs, safety findings	treatment-related adverse events, TRAE summary, treatment-emergent TRAEs, safety findings	@treatment-related-adverse-events	@tables-listings-figures