# CDISC CDASH Controlled Terminology, 2022-06-24

Source: NCI EVS Terminology Resources website: http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc

NCI Code	CDISC Submission Value	Codelist Name	/www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cd	Codelist Extensible
C78418	CMDOSFRM	Concomitant Medication Dose Form	A terminology subset of the CDISC SDTM Pharmaceutical Dosage Form codelist created for CDASH Concomitant Medication Dose Form codelist. (NCI)	Yes
C78419	CMDOSFRQ	Concomitant Medication Dosing Frequency per Interval	A terminology subset of the CDISC SDTM Frequency codelist created for CDASH Concomitant Medication Dosing Frequency per Interval codelist. (NCI)	Yes
C78417	CMDOSU	Concomitant Medication Dose Units	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Concomitant Medication Dose Units codelist. (NCI)	Yes
C78420	CMROUTE	Concomitant Medication Route of Administration	A terminology subset of the CDISC SDTM Route codelist created for CDASH Concomitant Medication Route of Administration codelist. (NCI)	Yes
C78421	DAORRESU	Unit of Drug Dispensed or Returned	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Unit of Drug Dispensed or Returned codelist. (NCI)	Yes
C78422	EGORRESU	ECG Original Units	A terminology subset of the CDISC SDTM Unit codelist created for CDASH ECG Original Units codelist. (NCI)	Yes
C128690	ETHNICC	Ethnicity As Collected	A terminology codelist relevant to the ethnicity of an individual as collected on the case report form.	Yes
C78426	EXDOSFRM	Exposure Dose Form	A terminology subset of the CDISC SDTM Pharmaceutical Dosage Form codelist created for CDASH Exposure Dose Form codelist. (NCI)	Yes
C78745	EXDOSFRQ	Exposure Dosing Frequency per Interval	A terminology subset of the CDISC SDTM Frequency codelist created for CDASH Exposure Dosing Frequency per Interval codelist. (NCI)	Yes
C78423	EXDOSU	Units for Exposure	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Units for Exposure codelist. (NCI)	Yes
C78429	EXFLRTU	Unit of Measure for Flow Rate	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Unit of Measure for Flow Rate codelist. (NCI)	Yes
C78427	EXINTPU	Unit for the Duration of Treatment Interruption	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Unit for Duration of Treatment Interruption codelist. (NCI)	Yes
C78430	EXPDOSEU	Units for Planned Exposure	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Units for Planned Exposure codelist. (NCI)	Yes
C78425	EXROUTE	Exposure Route of Administration	A terminology subset of the CDISC SDTM Route codelist created for CDASH Exposure Route of Administration codelist. (NCI)	Yes
C78428	EXVOLTU	Total Volume Administration Unit	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Total Volume Administration Unit codelist. (NCI)	Yes
C181165	MODDLV	Mode of Delivery	A terminology codelist relevant to the mode of delivery of a fetus or neonate.	Yes
C128689	RACEC	Race As Collected	A terminology codelist relevant to the race of an individual as collected on the case report form.	Yes
C181164	SADCRR	Study Agent Dechallenge Reaction Response	A terminology codelist relevant to the resultant reaction due to withdrawing, interrupting, or otherwise altering administration of study treatment.	Yes
C177909	SAERCAT	Serious Adverse Event Report Category	Terminology relevant to the classification of a serious adverse event report.	No
C181163	SARCRR	Study Agent Rechallenge Reaction Response	A terminology codelist relevant to the resultant reaction due to restarting or otherwise returning administration of study treatment to previous level, after a dechallenge event.	Yes
C83004	SUNCF	Substance Use Never/Current/Former Classification	A terminology subset of the CDISC SDTM Never/Current/Former Classification codelist created for CDASH Substance Use Never/Current/Former Classification codelist. (NCI)	Yes
C78431	VSPOS	Vital Signs Position of Subject	A terminology subset of the CDISC SDTM Position codelist created for CDASH Vital Signs Position of Subject codelist. (NCI)	Yes

### **CMDOSFRM (Concomitant Medication Dose Form)**

NCI Code: C78418, Codelist extensible: Yes

C78418	CMDOSFRM			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C42887	AEROSOL	aer	A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system; it is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).	Aerosol Dosage Form
C25158	CAPSULE	сар	A solid pharmaceutical dosage form that contains medicinal agent within either a hard or soft soluble container or shell, usually used for the oral administration of medicine. The shells are made of a suitable form of gelatin or other substance. (NCI)	Capsule Dosage Form
C28944	CREAM		A semisolid emulsion of either the oil-in-water or the water-in-oil type, ordinarily intended for topical use. (NCI)	Cream Dosage Form
C42933	GAS		Any elastic aeriform fluid in which the molecules are separated from one another and have free paths. (NCI)	Gas Dosage Form
C42934	GEL		A semisolid (1) dosage form that contains a gelling agent to provide stiffness to a solution or a colloidal dispersion (2). A gel may contain suspended particles. Note 1: A semisolid is not pourable; it does not flow or conform to its container at room temperature. It does not flow at low shear stress and generally exhibits plastic flow behavior. Note 2: A colloidal dispersion is a system in which particles of colloidal dimension (i.e., typically between 1 nm and 1 micrometer) are distributed uniformly throughout a liquid.	Gel Dosage Form
C42966	OINTMENT	oint	A suspension or emulsion, semisolid (1) dosage form, usually containing less than 20 percent water and volatiles (2) and greater than 50 percent hydrocarbons, waxes, or polyols as the vehicle. This dosage form is generally for external application to the skin or mucous membranes. Note 1: A semisolid is not pourable; it does not flow or conform to its container at room temperature. It does not flow at low shear stress and generally exhibits plastic flow behavior. Note 2: Percent water and volatiles are measured by a loss on drying test in which the sample is heated at 105 degrees C until constant weight is achieved.	Ointment Dosage Form
C42968	РАТСН		A drug delivery system that often contains an adhesive backing that is usually applied to an external site on the body. Its ingredients either passively diffuse from, or are actively transported from, some portion of the patch. Depending upon the patch, the ingredients are either delivered to the outer surface of the body or into the body. A patch is sometimes synonymous with the terms Extended Release Film and System.	Patch Dosage Form
C42972	POWDER		An intimate mixture of dry, finely divided drugs and/or chemicals that may be intended for internal or external use. (NCI)	Powder Dosage Form
C42989	SPRAY		A liquid minutely divided as by a jet of air or steam. (NCI)	Spray Dosage Form
C42993	SUPPOSITORY	supp	A solid body of various weights and shapes, adapted for introduction into the rectal, vaginal, or urethral orifice of the human body; they usually melt, soften, or dissolve at body temperature.	Suppository Dosage Form
C42994	SUSPENSION	Ready to Use Suspension;susp	A liquid dosage form that contains solid particles dispersed in a liquid vehicle. Note: A liquid is pourable; it flows and conforms to its container at room temperature. It displays Newtonian or pseudoplastic flow behavior.	Suspension Dosage Form
C42998	TABLET	tab	A solid dosage form containing medicinal substances with or without suitable diluents. (NCI)	Tablet Dosage Form

# CMDOSFRQ (Concomitant Medication Dosing Frequency per Interval)

NCI Code: C78419, Codelist extensible: Yes

C78419	CMDOSFRQ			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C64496	BID	BD;Twice per day	Two times per day, at unspecified times. (NCI)	Twice Daily
C64499	PRN	As needed	As needed. (NCI)	As Needed
C25473	QD	/day;Daily;Per Day	A rate of occurrences within a period of time equal to one day.	Daily
C64530	QID	4 times per day	Four times per day. (NCI)	Four Times Daily
C64498	QM	Every Month;Per Month	Every month. (NCI)	Monthly
C64525	QOD	Every other day;Every Second Day;Every Two Days;Q2D	Every other day. (NCI)	Every Other Day
C64527	TID	3 times per day	Three times per day. (NCI)	Three Times Daily
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

#### **CMDOSU (Concomitant Medication Dose Units)**

NCI Code: C78417, Codelist extensible: Yes

C78417	CMDOSU			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48480	CAPSULE	cap;Capsule Dosing Unit	A dosing measurement based on the capsule unit.(NCI)	Capsule Dosing Unit
C48155	g	Gram	A unit of mass equal to one thousandth (1E-3) of a kilogram, the kilogram being the base unit of mass in the International System of Units (SI).	Gram
C48579	IU	IE;International Unit	The unitage assigned by the WHO (World Health Organization) to International Biological Standards - substances, classed as biological according to the criteria provided by WHO Expert Committee on Biological Standardization, to enable the results of biological and immunological assay procedures to be expressed in the same way throughout the world. The definition of an international unit is generally arbitrary and technical, and has to be officially approved by the International Conference for Unification of Formulae.(NCI)	International Unit
C28253	mg	Milligram	A unit of mass equal to one thousandth (1E-3) of a gram.	Milligram
C28254	mL	cm3;Milliliter	A unit of volume equal to one thousandth (1E-3) of a liter.	Milliliter
C65060	PUFF	Puff Dosing Unit	A means of delivering a defined dose of a therapeutic aerolized solution into either the upper or lower respiratory tract. Metered-dose inhalers or spray pumps are devices that provide a puff dose for delivery into either the oral or the nasal cavity.(NCI)	Puff Dosing Unit
C48542	TABLET	tab;Tablet Dosing Unit	A dosing measurement based on the tablet unit.(NCI)	Tablet Dosing Unit
C48152	ug	mcg;Microgram	A unit of mass equal to one millionth (1E-6) of a gram.	Microgram

#### **CMROUTE (Concomitant Medication Route of Administration)**

NCI Code: C78420, Codelist extensible: Yes

C78420	CMROUTE			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C38250	INTRALESIONAL		Administration within or introduced directly into a localized lesion. (FDA)	Intralesional Route of Administration
C28161	INTRAMUSCULAR		Administration within a muscle. (FDA)	Intramuscular Route of Administration
C38255	INTRAOCULAR		Administration within the eye. (FDA)	Intraocular Route of Administration
C38258	INTRAPERITONEAL		Administration within the peritoneal cavity. (FDA)	Intraperitoneal Route of Administration
C38284	NASAL	Intranasal Route of Administration	Administration to the nose; administered by way of the nose. (FDA)	Nasal Route of Administration
C38288	ORAL	Intraoral Route of Administration;PO	Administration to or by way of the mouth. (FDA)	Oral Route of Administration
C38295	RECTAL		Administration to the rectum. (FDA)	Rectal Route of Administration
C38216	RESPIRATORY (INHALATION)		Administration within the respiratory tract by inhaling orally or nasally for local or systemic effect. (FDA)	Inhalation Route of Administration
C38299	SUBCUTANEOUS	SC;Subdermal Route of Administration	Administration beneath the skin; hypodermic. Synonymous with the term SUBDERMAL. (FDA)	Subcutaneous Route of Administration
C38304	TOPICAL	ТОР	Administration to a particular spot on the outer surface of the body. The E2B term TRANSMAMMARY is a subset of the term TOPICAL. (FDA)	Topical Route of Administration
C38305	TRANSDERMAL		Administration through the dermal layer of the skin to the systemic circulation by diffusion. (FDA)	Transdermal Route of Administration
C38313	VAGINAL		Administration into the vagina. (FDA)	Vaginal Route of Administration

#### DAORRESU (Unit of Drug Dispensed or Returned)

NCI Code: C78421, Codelist extensible: Yes

C78421	DAORRESU			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48474	BAG	Bag Dosing Unit	A dosing measurement based on the bag unit.(NCI)	Bag Dosing Unit
C48477	BOTTLE	Bottle Dosing Unit	A dosing measurement based on the bottle unit.(NCI)	Bottle Dosing Unit
C48478	BOX	Box Dosing Unit	A dosing measurement based on the box unit.(NCI)	Box Dosing Unit
C48480	CAPSULE	cap;Capsule Dosing Unit	A dosing measurement based on the capsule unit.(NCI)	Capsule Dosing Unit
C48484	CONTAINER	Container Dosing Unit	A dosing measurement based on the container unit.(NCI)	Container Dosing Unit
C48490	DISK	Disk Dosing Unit	A dosing measurement based on the disk unit.(NCI)	Disk Dosing Unit
C48520	PACKAGE	Pack Dosing Unit;Package Dosing Unit	A dosing measurement based on the package unit.(NCI)	Package Dosing Unit
C48521	PACKET	Packet Dosing Unit	A dosing measurement based on the packet unit.(NCI)	Packet Dosing Unit
C48524	РАТСН	Patch Dosing Unit	A dosing measurement based on the patch unit.(NCI)	Patch Dosing Unit
C48542	TABLET	tab;Tablet Dosing Unit	A dosing measurement based on the tablet unit.(NCI)	Tablet Dosing Unit
C48549	TUBE	Tube Dosing Unit	A dosing measurement based on the tube unit.(NCI)	Tube Dosing Unit
C48551	VIAL	Vial Dosing Unit	A dosing measurement based on the vial unit.(NCI)	Vial Dosing Unit

### EGORRESU (ECG Original Units)

NCI Code: C78422, Codelist extensible: Yes

C78422	EGORRESU			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49673	beats/min	Beats per Minute;bpm;BPM	The number of heartbeats measured per minute time. (NCI)	Beats per Minute
C41140	ms	Millisecond;ms;msec	A unit of time, which is equal to one thousandth of a second.(NCI)	Millisecond
C42535	S	sec;Second	The base unit of time in the International System of Units (SI) equal to the duration of 9,192,631,770 periods of the specified light radiation corresponding to the transition between the two hyperfine levels of the cesium 133 atom in its ground state at 0 K.	Second

### **ETHNICC (Ethnicity As Collected)**

NCI Code: C128690, Codelist extensible: Yes
C128690 ETHNICC

C128690	ETHNICC			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C158197	ACHANG	AC	A Chinese person from the Achang ethnic group.	Achang Chinese
C17950	ASHKENAZI JEW		A person of Ashkenazi Jewish descent.	Ashkenazi Jew
C158171	BAI	ВА	A Chinese person from the Bai ethnic group.	Bai Chinese
C158193	BLANG	BL	A Chinese person from the Blang ethnic group.	Blang Chinese
C158203	BONAN	BN	A Chinese person from the Bonan ethnic group.	Bonan Chinese
C158169	BUYEI	BY	A Chinese person from the Buyei ethnic group.	Buyei Chinese
C67118	CENTRAL AMERICAN		A person of Central American descent.	Central American
C158172	CHOSEN	CS	A Chinese person from the Chosen ethnic group.	Chosen Chinese
C67115	CUBAN AMERICAN		A person of Cuban and American descent.	Cuban or Cuban American
C107608	CUBAN		A person of Cuban descent.	Cuban
C158176	DAI	DA	A Chinese person from the Dai (including several different Tai-speaking groups historically referred to as Bai-yi) ethnic group.	Dai Chinese
C158191	DAUR	DU	A Chinese person from the Daur ethnic group.	Daur Chinese
C158202	DEANG	DE	A Chinese person from the Deang ethnic group.	Deang Chinese
C158209	DERUNG	DR	A Chinese person from the Derung ethnic group.	Derung Chinese
C158168	DONG	DO	A Chinese person from the Dong ethnic group.	Dong Chinese
C158179	DONGXIANG	DX	A Chinese person from the Dongxiang ethnic group.	Dongxiang Chinese
C158199	EWENKI	EW	A Chinese person from the Ewenki ethnic group.	Ewenki Chinese
C158211	GAOSHAN	GS	A Chinese person from the Gaoshan ethnic group.	Gaoshan Chinese
C158180	GELAO	GL	A Chinese person from the Gelao ethnic group.	Gelao Chinese
C158200	GIN	GI	A Chinese person from the Gin ethnic group.	Gin Chinese
C158158	HAN	HA	A Chinese person from the Han ethnic group (including Chuanqing).	Han Chinese
C158173	HANI	HN	A Chinese person from the Hani (including Sangkong) ethnic group.	Hani Chinese
C158210	HEZHEN	HZ	A Chinese person from the Hezhen ethnic group.	Hezhen Chinese
C17459	HISPANIC OR LATINO		A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. (NCI)	Hispanic or Latino
C158160	HUI	HU	A Chinese person from the Hui (including Utsuls of Hainan, descended from Cham refugees) ethnic group.	Hui Chinese
C158190	JINGPO	JP	A Chinese person from the Jingpo ethnic group.	Jingpo Chinese
C158201	JINO	JN	A Chinese person from the Jino ethnic group.	Jino Chinese
C158175	KAZAK	κz	A Chinese person from the Kazak ethnic group.	Kazak Chinese
C158189	KIRGIZ	KG	A Chinese person from the Kirgiz ethnic group.	Kirgiz Chinese
C158181	LAHU	LH	A Chinese person from the Lahu ethnic group.	Lahu Chinese
C126531	LATIN AMERICAN		A person of Latin American descent.	Latin American
C158212	LHOBA	LB	A Chinese person from the Lhoba ethnic group.	Lhoba Chinese
C158174	LI	Ц	A Chinese person from the Li ethnic group.	Li Chinese
C158178	LISU	LS	A Chinese person from the Lisu ethnic group.	Lisu Chinese
C158161	MAN	МА	A Chinese person from the Man ethnic group.	Man Chinese

C128690	ETHNICC			
	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C158194 I	MAONAN	MN	A Chinese person from the Maonan (including the Then) ethnic group.	Maonan Chinese
C67114 I	MEXICAN AMERICAN		A person of Mexican and American descent.	Mexican American
C67113	MEXICAN		A person of Mexican descent.	Mexican
C158163 I	MIAO	MH	A Chinese person from the Miao (Including Hmong) ethnic group.	Miao Chinese
C158207	MONBA	MB	A Chinese person from the Monba ethnic group.	Monba Chinese
C158167	MONGOL	MG	A Chinese person from the Mongol ethnic group.	Mongol Chinese
C158187 I	MULAO	ML	A Chinese person from the Mulao (including the Qago) ethnic group.	Mulao Chinese
C158184 I	NAXI	NX	A Chinese person from the Naxi (including Mosuo) ethnic group.	Naxi Chinese
	NOT HISPANIC OR LATINO		A person not of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. An arbitrary ethnic classification. (NCI)	Not Hispanic or Latino
C43234 I	NOT REPORTED	Not reported	Not provided or available.	Not Reported
C158198	NU	NU	A Chinese person from the Nu ethnic group.	Nu Chinese
C158208	OROQEN	OR	A Chinese person from the Orogen ethnic group.	Oroqen Chinese
C67112	PUERTO RICAN		A person of Puerto Rican descent.	Puerto Rican
C158196	PUMI	РМ	A Chinese person from the Pumi ethnic group.	Pumi Chinese
C158185	QIANG	QI	A Chinese person from the Qiang ethnic group.	Qiang Chinese
C158204	RUSS	RS	A Chinese person from the Russ ethnic group.	Russ Chinese
C158192	SALAR	SL	A Chinese person from the Salar ethnic group.	Salar Chinese
C103283	SEPHARDIC JEW		A person of Sephardic Jewish descent.	Sephardic Jew
C158177 9	SHE	SH	A Chinese person from the She ethnic group.	She Chinese
C126532	SOUTH AMERICAN		A person of South American descent.	South American
C67120 S	SPANISH		A person from Spain or of Spanish descent.	Spanish
C158183	SUI	SU	A Chinese person from the Sui ethnic group.	Sui Chinese
C158195	ТАЈІК	ТА	A Chinese person from the Tajik ethnic group.	Tajik Chinese
C158213	TATAR	тт	A Chinese person from the Tatar ethnic group.	Tatar Chinese
C158186	TU	TU	A Chinese person from the Tu ethnic group.	Tu Chinese
C158165	TUJIA	τJ	A Chinese person from the Tujia ethnic group.	Tujia Chinese
C17998 U	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C158162 (	UYGUR	UG	A Chinese person from the Uygur ethnic group.	Uygur Chinese
C158206 U	UZBEK	UZ	A Chinese person from the Uzbek ethnic group.	Uzbek Chinese
C158182	VA	VA	A Chinese person from the Va ethnic group.	Va Chinese
C158188	XIBE	ХВ	A Chinese person from the Xibe ethnic group.	Xibe Chinese
C158170	YAO	YA	A Chinese person from the Yao ethnic group.	Yao Chinese
C158164	YI	YI	A Chinese person from the Yi ethnic group.	Yi Chinese
C158205	YUGUR	YG	A Chinese person from the Yugur ethnic group.	Yugur Chinese
C158166	ZANG	ZA	A Chinese person from the Zang (including Amdowa, Khampa and some Pumi speakers) ethnic group.	Zang Chinese
C158159	ZHUANG	ZH	A Chinese person from the Zhuang ethnic group.	Zhuang Chinese

#### **EXDOSFRM (Exposure Dose Form)**

NCI Code: C78426, Codelist extensible: Yes

C78426 EXDOSFRM

C78426	EXDOSFRM			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C42887	AEROSOL	aer	A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system; it is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).	Aerosol Dosage Form
C25158	CAPSULE	сар	A solid pharmaceutical dosage form that contains medicinal agent within either a hard or soft soluble container or shell, usually used for the oral administration of medicine. The shells are made of a suitable form of gelatin or other substance. (NCI)	Capsule Dosage Form
C28944	CREAM		A semisolid emulsion of either the oil-in-water or the water-in-oil type, ordinarily intended for topical use. (NCI)	Cream Dosage Form
C42933	GAS		Any elastic aeriform fluid in which the molecules are separated from one another and have free paths. (NCI)	Gas Dosage Form
C42934	GEL		A semisolid (1) dosage form that contains a gelling agent to provide stiffness to a solution or a colloidal dispersion (2). A gel may contain suspended particles. Note 1: A semisolid is not pourable; it does not flow or conform to its container at room temperature. It does not flow at low shear stress and generally exhibits plastic flow behavior. Note 2: A colloidal dispersion is a system in which particles of colloidal dimension (i.e., typically between 1 nm and 1 micrometer) are distributed uniformly throughout a liquid.	Gel Dosage Form
C42966	OINTMENT	oint	A suspension or emulsion, semisolid (1) dosage form, usually containing less than 20 percent water and volatiles (2) and greater than 50 percent hydrocarbons, waxes, or polyols as the vehicle. This dosage form is generally for external application to the skin or mucous membranes. Note 1: A semisolid is not pourable; it does not flow or conform to its container at room temperature. It does not flow at low shear stress and generally exhibits plastic flow behavior. Note 2: Percent water and volatiles are measured by a loss on drying test in which the sample is heated at 105 degrees C until constant weight is achieved.	Ointment Dosage Form
C42968	РАТСН		A drug delivery system that often contains an adhesive backing that is usually applied to an external site on the body. Its ingredients either passively diffuse from, or are actively transported from, some portion of the patch. Depending upon the patch, the ingredients are either delivered to the outer surface of the body or into the body. A patch is sometimes synonymous with the terms Extended Release Film and System.	Patch Dosage Form
C42972	POWDER		An intimate mixture of dry, finely divided drugs and/or chemicals that may be intended for internal or external use. (NCI)	Powder Dosage Form
C42989	SPRAY		A liquid minutely divided as by a jet of air or steam. (NCI)	Spray Dosage Form
C42993	SUPPOSITORY	supp	A solid body of various weights and shapes, adapted for introduction into the rectal, vaginal, or urethral orifice of the human body; they usually melt, soften, or dissolve at body temperature.	Suppository Dosage Form
C42994	SUSPENSION	Ready to Use Suspension;susp	A liquid dosage form that contains solid particles dispersed in a liquid vehicle. Note: A liquid is pourable; it flows and conforms to its container at room temperature. It displays Newtonian or pseudoplastic flow behavior.	Suspension Dosage Form
C42998	TABLET	tab	A solid dosage form containing medicinal substances with or without suitable diluents. (NCI)	Tablet Dosage Form

#### EXDOSFRQ (Exposure Dosing Frequency per Interval)

NCI Code: C78745, Codelist extensible: Yes

C78745	EXDOSFRQ			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C64496	BID	BD;Twice per day	Two times per day, at unspecified times. (NCI)	Twice Daily
C64499	PRN	As needed	As needed. (NCI)	As Needed
C25473	QD	/day;Daily;Per Day	A rate of occurrences within a period of time equal to one day.	Daily
C64530	QID	4 times per day	Four times per day. (NCI)	Four Times Daily
C64498	QM	Every Month;Per Month	Every month. (NCI)	Monthly
C64525	QOD	Every other day;Every Second Day;Every Two Days;Q2D	Every other day. (NCI)	Every Other Day
C64527	TID	3 times per day	Three times per day. (NCI)	Three Times Daily
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

#### **EXDOSU (Units for Exposure)**

#### NCI Code: C78423, Codelist extensible: Yes

C78423	EXDOSU			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48480	CAPSULE	cap;Capsule Dosing Unit	A dosing measurement based on the capsule unit.(NCI)	Capsule Dosing Unit
C48155	g	Gram	A unit of mass equal to one thousandth (1E-3) of a kilogram, the kilogram being the base unit of mass in the International System of Units (SI).	Gram
C28253	mg	Milligram	A unit of mass equal to one thousandth (1E-3) of a gram.	Milligram
C28254	mL	cm3;Milliliter	A unit of volume equal to one thousandth (1E-3) of a liter.	Milliliter
C65060	PUFF	Puff Dosing Unit	A means of delivering a defined dose of a therapeutic aerolized solution into either the upper or lower respiratory tract. Metered-dose inhalers or spray pumps are devices that provide a puff dose for delivery into either the oral or the nasal cavity.(NCI)	Puff Dosing Unit
C48542	TABLET	tab;Tablet Dosing Unit	A dosing measurement based on the tablet unit.(NCI)	Tablet Dosing Unit
C48152	ug	mcg;Microgram	A unit of mass equal to one millionth (1E-6) of a gram.	Microgram

#### EXFLRTU (Unit of Measure for Flow Rate)

NCI Code: C78429, Codelist extensible: Yes

C78429	EXFLRTU			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C64777	mL/min		A unit of flow rate equal to one milliliter per minute.	Milliliter per Minute
C67420	mmol/day	mmol/24h	A unit of substance flow rate equal to one millimole per day.	Millimole per 24 Hours
C71205	ug/day	mcg/day	A unit of mass flow rate equal to one microgram per day.	Microgram per Day
C71211	ug/min	mcg/min	A unit of mass flow rate equal to one microgram per minute.	Microgram per Minute
C67406	umol/day	mcmol/day	A unit of substance flow rate equal to one micromole per day.	Micromole per 24 Hours

#### **EXINTPU (Unit for the Duration of Treatment Interruption)**

NCI Code: C78427, Codelist extensible: Yes

C78427	EXINTPU				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C25529	HOURS	h;Hours;hr	A unit of measurement of time equal to 60 minutes.	Hour	
C48154	min	Minute	A unit of measurement of time equal to 60 seconds.	Minute	
C42535	S	sec;Second	The base unit of time in the International System of Units (SI) equal to the duration of 9,192,631,770 periods of the specified light radiation corresponding to the transition between the two hyperfine levels of the cesium 133 atom in its ground state at 0 K.	Second	

#### **EXPDOSEU (Units for Planned Exposure)**

NCI Code: C78430, Codelist extensible: Yes

C78430	EXPDOSEU			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48480	CAPSULE	cap;Capsule Dosing Unit	A dosing measurement based on the capsule unit.(NCI)	Capsule Dosing Unit
C48155	g	Gram	A unit of mass equal to one thousandth (1E-3) of a kilogram, the kilogram being the base unit of mass in the International System of Units (SI).	Gram
C28253	mg	Milligram	A unit of mass equal to one thousandth (1E-3) of a gram.	Milligram
C28254	mL	cm3;Milliliter	A unit of volume equal to one thousandth (1E-3) of a liter.	Milliliter
C65060	PUFF	Puff Dosing Unit	A means of delivering a defined dose of a therapeutic aerolized solution into either the upper or lower respiratory tract. Metered-dose inhalers or spray pumps are devices that provide a puff dose for delivery into either the oral or the nasal cavity.(NCI)	Puff Dosing Unit
C48542	TABLET	tab;Tablet Dosing Unit	A dosing measurement based on the tablet unit.(NCI)	Tablet Dosing Unit
C48152	ug	mcg;Microgram	A unit of mass equal to one millionth (1E-6) of a gram.	Microgram

#### **EXROUTE (Exposure Route of Administration)**

NCI Code: C78425, Codelist extensible: Yes

C78425	EXROUTE			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C38250	INTRALESIONAL		Administration within or introduced directly into a localized lesion. (FDA)	Intralesional Route of Administration
C28161	INTRAMUSCULAR		Administration within a muscle. (FDA)	Intramuscular Route of Administration
C38255	INTRAOCULAR		Administration within the eye. (FDA)	Intraocular Route of Administration
C38258	INTRAPERITONEAL		Administration within the peritoneal cavity. (FDA)	Intraperitoneal Route of Administration
C38284	NASAL	Intranasal Route of Administration	Administration to the nose; administered by way of the nose. (FDA)	Nasal Route of Administration
C38288	ORAL	Intraoral Route of Administration;PO	Administration to or by way of the mouth. (FDA)	Oral Route of Administration
C38295	RECTAL		Administration to the rectum. (FDA)	Rectal Route of Administration
C38216	RESPIRATORY (INHALATION)		Administration within the respiratory tract by inhaling orally or nasally for local or systemic effect. (FDA)	Inhalation Route of Administration
C38299	SUBCUTANEOUS	SC;Subdermal Route of Administration	Administration beneath the skin; hypodermic. Synonymous with the term SUBDERMAL. (FDA)	Subcutaneous Route of Administration
C38304	TOPICAL	ТОР	Administration to a particular spot on the outer surface of the body. The E2B term TRANSMAMMARY is a subset of the term TOPICAL. (FDA)	Topical Route of Administration
C38305	TRANSDERMAL		Administration through the dermal layer of the skin to the systemic circulation by diffusion. (FDA)	Transdermal Route of Administration
C38313	VAGINAL		Administration into the vagina. (FDA)	Vaginal Route of Administration

# EXVOLTU (Total Volume Administration Unit)

NCI Code: C78428, Codelist extensible: Yes

C78428	EXVOLTU				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C28253	mg	Milligram	A unit of mass equal to one thousandth (1E-3) of a gram.	Milligram	
C28254	mL	cm3;Milliliter	A unit of volume equal to one thousandth (1E-3) of a liter.	Milliliter	
C48152	ug	mcg;Microgram	A unit of mass equal to one millionth (1E-6) of a gram.	Microgram	

#### **MODDLV (Mode of Delivery)**

NCI Code: C181165, Codelist extensible: Yes

C181165	MODDLV			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C114136	BREECH EXTRACTION		The delivery of a breech-presenting fetus, which is manually pulled through the birth canal.	Breech Extraction
C46088	CESAREAN SECTION		Surgical delivery of one or more intrauterine fetuses though an abdominal incision.	Cesarean Section
C114143	DELIVERY BY DESTRUCTIVE OPERATION		Extraction of a fetus through the cervix using destructive surgical techniques.	Delivery by Destructive Operation
C81301	VAGINAL ASSISTED DELIVERY	Operative Vaginal Delivery	Birth of the fetus through the vagina with the application of vacuum or forceps or any other instrument.	Vaginal Assisted Delivery
C81302	VAGINAL BIRTH AFTER CESAREAN DELIVERY		A vaginal birth in a woman with one or more previous cesarean births. (reVITALize)	Vaginal Birth after Cesarean Delivery
C81303	VAGINAL DELIVERY		Birth of the fetus through the vagina.	Vaginal Delivery

### **RACEC (Race As Collected)**

#### NCI Code: C128689, Codelist extensible: Yes

C128689 RACEC

C128689	RACEC			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C154875	ABORIGINAL AUSTRALIAN		The native people of Australia.	Aboriginal Australian
C128937	AFRICAN AMERICAN		A person having origins in the original peoples of sub- Saharan Africa and the United States.	African American
C41226	AFRICAN CARIBBEAN		A person having origins in the original peoples of sub- Saharan Africa and the Caribbean.	African Caribbean
C42331	AFRICAN		A person having origins in any of the original peoples of sub-Saharan Africa.	African
C18237	ALASKA NATIVE		The native people of Alaska.	Alaska Native
C41259	AMERICAN INDIAN OR ALASKA NATIVE		A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. (FDA)	American Indian or Alaska Native
C43877	AMERICAN INDIAN		The native people of North America.	American Indian
C43876	ARAB		A person having origins in any of the original peoples of the Arabian peninsula and surrounding territories in the Middle East and northern Africa.	Arab
C16310	ASIAN AMERICAN		A person having origins in the original peoples of Asia and the United States.	Asian American
C41262	ASIAN INDIAN		A person having origins in any of the original peoples of the Indian subcontinent.	Asian Indian
C41260	ASIAN		A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (FDA)	Asian
C67271	BAHAMIAN		A person having origins in any of the original peoples of the Bahamas.	Bahamian
C43671	BANGLADESHI		A person having origins in any of the original peoples of Bangladesh.	Bangladeshi
C43823	BARBADIAN		A person having origins in any of the original peoples of Barbados.	Barbadian
C43673	BHUTANESE		A person having origins in any of the original peoples of Bhutan.	Bhutanese
C128991	BLACK CENTRAL AMERICAN		A person having origins in the original peoples of sub- Saharan Africa and Central America.	Black Central American
C16352	BLACK OR AFRICAN AMERICAN		A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." (FDA)	Black or African American
C128992	BLACK SOUTH AMERICAN		A person having origins in the original peoples of sub- Saharan Africa and South America.	Black South American
C128938	BLACK		A person having origins in the original peoples of sub- Saharan Africa or the Caribbean.	Black
C43830	BOTSWANAN		A person having origins in any of the original peoples of Botswana.	Botswanan
C43674	BURMESE		A person having origins in any of the original peoples of Myanmar (formerly Burma).	Burmese
C43399	CAMBODIAN		A person having origins in any of the original peoples of Cambodia (formerly Kampuchea).	Cambodian
C77810	CARIBBEAN INDIAN		The native people of the Caribbean.	Caribbean Indian
C44950	CENTRAL AMERICAN INDIAN		The native people of Central America.	Central American Indian
C126534	CENTRAL ASIAN		A person having origins in any of the original peoples of Central Asia.	Central Asian

C128689	RACEC			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C43403	CHAMORRO		The native people of the Mariana Islands, including the United States territories of Guam and the Commonwealth of the Northern Mariana Islands in Micronesia.	Chamorran
C43391	CHINESE		A person having origins in any of the original peoples of China.	Chinese
C43824	DOMINICA ISLANDER		A person having origins in any of the original peoples of Dominica.	Dominica Islander
C67117	DOMINICAN		A person having origins in any of the original peoples of the Dominican Republic.	Dominican
C161419	EAST ASIAN		A person having origins in any of the original peoples of East Asia.	East Asian
C77819	EASTERN EUROPEAN		A person having origins in any of the original peoples of Eastern Europe.	Eastern European
C43831	ETHIOPIAN		A person having origins in any of the original peoples of Ethiopia.	Ethiopian
C43851	EUROPEAN		A person having origins in any of the original peoples of Europe.	European
C43393	FILIPINO		A person having origins in any of the original peoples of the Philippines.	Filipino
C44265	GREENLAND INUIT		The native people of Greenland.	Greenland Eskimo
C43837	GUAMANIAN OR CHAMORRO		A person having origins in the original peoples of the United States territories of Guam and the Commonwealth of the Northern Mariana Islands in Micronesia.	Guamanian or Chamorro
C43404	GUAMANIAN		A person having origins in any of the original peoples of Guam.	Guamanian
C43825	HAITIAN		A person having origins in any of the original peoples of Haiti.	Haitian
C43398	HMONG		The native people originating in China around the Yellow River or Hoang Ho.	Hmong
C43715	INDONESIAN		A person having origins in any of the original peoples of Indonesia.	Indonesian
C44268	INUPIAT INUIT		The native people inhabiting the territory spanning the Norton Sound on the Bering Sea to the Canadian border.	Inupiat Eskimo
C43718	IWO JIMAN		A person having origins in any of the original peoples of Iwo Jima.	Iwo Jiman
C43826	JAMAICAN		A person having origins in any of the original peoples of Jamaica.	Jamaican
C43392	JAPANESE		A person having origins in any of the original peoples of Japan.	Japanese
C154874	KHOISAN		The native people of the Western Cape in southern Africa.	Khoisan
C43395	KOREAN		A person having origins in any of the original peoples of North and South Korea.	Korean
C43397	LAOTIAN		A person having origins in any of the original peoples of Laos.	Laotian
C126531	LATIN AMERICAN		A person of Latin American descent.	Latin American
C43832	LIBERIAN		A person having origins in any of the original peoples of Liberia.	Liberian
C43722	MALAGASY		A person having origins in any of the original peoples of Madagascar.	Malagasy
C43716	MALAYSIAN		A person having origins in any of the original peoples of Malaysia.	Malaysian
C43719	MALDIVIAN		A person having origins in any of the original peoples of the Maldives.	Maldivian
C158274	MAORI		The native people of New Zealand.	Maori

C128689	RACEC			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C77811	MEDITERRANEAN		A person having origins in any of the original peoples of the countries surrounding the Mediterranean sea.	Mediterranean
C43409	MELANESIAN		A person having origins in any of the original peoples of Melanesia.	Melanesian
C43402	MICRONESIAN		A person having origins in any of the original peoples of Micronesia.	Micronesian
C77820	MIDDLE EASTERN		A person having origins in any of the original peoples of the Middle East.	Middle Eastern
C43864	MONGOLIAN		A person having origins in any of the original peoples of Mongolia.	Mongolian
C43833	NAMIBIAN		A person having origins in any of the original peoples of Namibia.	Namibian
C41219	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER		Denotes a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. The term covers particularly people who identify themselves as part-Hawaiian, Native Hawaiian, Guamanian or Chamorro, Carolinian, Samoan, Chuu. (FDA)	Native Hawaiian or Other Pacific Islander
C43394	NATIVE HAWAIIAN		A person having origins in any of the original peoples of Hawaii. (NCI)	Native Hawaiian
C43720	NEPALESE		A person having origins in any of the original peoples of Nepal.	Nepalese
C43834	NIGERIAN		A person having origins in any of the original peoples of Nigeria.	Nigerian
C77813	NORTH AFRICAN		A person having origins in any of the original peoples of North Africa.	North Coast of Africa
C77814	NORTHERN EUROPEAN		A person having origins in any of the original peoples of Northern Europe.	Northern European
C43234	NOT REPORTED	Not reported	Not provided or available.	Not Reported
C43717	OKINAWAN		A person having origins in any of the original peoples of Okinawa.	Okinawan
C107602	OTHER PACIFIC ISLANDER		A person having origins in the original peoples of the Pacific Islands, but not Guam, Hawaii, the Mariana Islands or Samoa. (NCI)	Other Pacific Islander
C43427	PAKISTANI		A person having origins in any of the original peoples of Pakistan.	Pakistani
C43405	POLYNESIAN		A person having origins in any of the original peoples of Polynesia.	Polynesian
C43860	RUSSIAN		A person having origins in any of the original peoples of Russia.	Russian
C43407	SAMOAN		A person having origins in any of the original peoples of Samoa. (NCI)	Samoan
C44269	SIBERIAN ESKIMO		The native Yupik people inhabiting the coast of the Chukchi Peninsula in the far northeast of the Russian Federation and on St. Lawrence Island in Alaska.	Siberian Eskimo
C43721	SINGAPOREAN		A person having origins in any of the original peoples of Singapore.	Singaporean
C44953	SOUTH AMERICAN INDIAN		The native people of South America.	South American Indian
C41263	SOUTH ASIAN		A person having origins in any of the original peoples of the South Asia.	South Asian
C126533	SOUTHEAST ASIAN		A person having origins in any of the original peoples of Southeast Asia.	Southeast Asian
C156583	SOUTHERN AFRICAN COLOURED		A person of mixed race, whose ancestry is from one or more of the naturalized racial groups of Southern Africa (typically Western European, South Asian, or Southeastern Asian) and one or more of the indigenous Southern African peoples.	Southern African Coloured

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C128689	RACEC			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C43672	SRI LANKAN		A person having origins in any of the original peoples of Sri Lanka.	Sri Lankan
C43675	TAIWANESE		A person having origins in any of the original peoples of Taiwan.	Taiwanese
C43400	THAI		A person having origins in any of the original peoples of Thailand.	Thai
C43827	TOBAGOAN		A person having origins in any of the original peoples of Tobago.	Tobagoan
C43828	TRINIDADIAN		A person having origins in any of the original peoples of Trinidad.	Trinidadian
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C43396	VIETNAMESE		A person having origins in any of the original peoples of Viet Nam.	Vietnamese
C153343	WEST ASIAN		A person having origins in any of the original peoples of Western Asia.	Western Asian
C43829	WEST INDIAN		A person having origins in any of the original peoples of the West Indies.	West Indian
C77817	WESTERN EUROPEAN		A person having origins in any of the original peoples of Western Europe.	Western European
C77816	WHITE CARIBBEAN		A person having origins in the original peoples of Europe, the Middle East, or North Africa, and the Caribbean.	White Caribbean
C128993	WHITE CENTRAL AMERICAN		A person having origins in the original peoples of Europe, the Middle East, or North Africa, and Central America.	White Central American
C128994	WHITE SOUTH AMERICAN		A person having origins in the original peoples of Europe, the Middle East, or North Africa, and South America.	White South American
C41261	WHITE		Denotes a person with European, Middle Eastern, or North African ancestral origin who identifies, or is identified, as White. (FDA)	White
C44270	YUPIK ESKIMO		The native people inhabiting western, southwestern, and southcentral Alaska and the Russian Far East.	Yupik Eskimo
C43835	ZAIREAN		A person having origins in any of the original peoples of Zaire.	Zairean

#### SADCRR (Study Agent Dechallenge Reaction Response)

NCI Code: C181164, Codelist extensible: Yes

C181164	SADCRR			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C181222	NEGATIVE DECHALLENGE		Continued presence of an adverse event after decrease or change in dose, or withdrawal of the product/drug.	Negative Dechallenge Response
C181224	NOT APPLICABLE DECHALLENGE		The outcome of decreasing the dose or discontinuation of the product/drug is not relevant in the current context.	Not Applicable Dechallenge Response
C181223	POSITIVE DECHALLENGE		Partial or complete abatement of an adverse event after decrease or change in dose, or withdrawal of the product/drug.	Positive Dechallenge Response
C181225	UNKNOWN DECHALLENGE		No information regarding the outcome of decreasing the dose or discontinuation of the product/drug.	Unknown Dechallenge Response

#### SAERCAT (Serious Adverse Event Report Category)

NCI Code: C177909, Codelist extensible: No

C177909	SAERCAT			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C41200	AMENDMENT	Amended	Action(s) undertaken to modify by means of correction, addition, subtraction, or replacement.	Amendment
C178052	NULLIFICATION	Nullified	Action(s) undertaken to void, negate, or invalidate.	Nullification
C25604	ORIGINAL		Preceding all others in time or being as first made or performed.	Original

# SARCRR (Study Agent Rechallenge Reaction Response)

NCI Code: C181163, Codelist extensible: Yes

C181163	C181163 SARCRR							
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term				
C181226	NEGATIVE RECHALLENGE		Failure of the product/drug, when reintroduced, to produce signs or symptoms similar to those observed when the product/drug was previously used.	Negative Rechallenge Response				
C181228	NOT APPLICABLE RECHALLENGE		The outcome of reintroduction of product/drug is not relevant in the current context.	Not Applicable Rechallenge Response				
C181227	POSITIVE RECHALLENGE		Recurrence of similar or new signs and symptoms upon reintroduction of the product/drug.	Positive Rechallenge Response				
C181229	UKNOWN RECHALLENGE		No information regarding the outcome of reintroduction of product/drug.	Unknown Rechallenge Response				

#### SUNCF (Substance Use Never/Current/Former Classification)

NCI Code: C83004, Codelist extensible: Yes

C83004	SUNCF					
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term		
C25471	CURRENT		Occurring in or belonging to the present time. (NCI)	Current		
C25627	FORMER	Previous	Occurring prior to something else. (NCI)	Previous		
C70543	NEVER		Not ever; at no time in the past.	Never		

### VSPOS (Vital Signs Position of Subject)

NCI Code: C78431, Codelist extensible: Yes

C78431	VSPOS					
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term		
C62122	SITTING	Sitting	The state or act of one who sits; the posture of one who occupies a seat. (NCI)	Sitting		
C62166	STANDING	Orthostatic;Standing	The act of assuming or maintaining an erect upright position. (NCI)	Standing		
C62167	SUPINE	Supine	A posterior recumbent body position whereby the person lies on its back and faces upward. (NCI)	Supine Position		