HL7 FHIR Connectathon January 2021
-Track Orientation-

Track: Real World Data Submission to FDA
Vulcan Project

December 17, 2020
3:30 – 4:30 PM ET

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Agenda

- Track Objectives
- Use Case Description
- Use Case Data Flow
- Track Suggested UI
- Data Input / Output
- Q/A

Real World Data (RWD) Submission to FDA
Use Case / Track Objectives

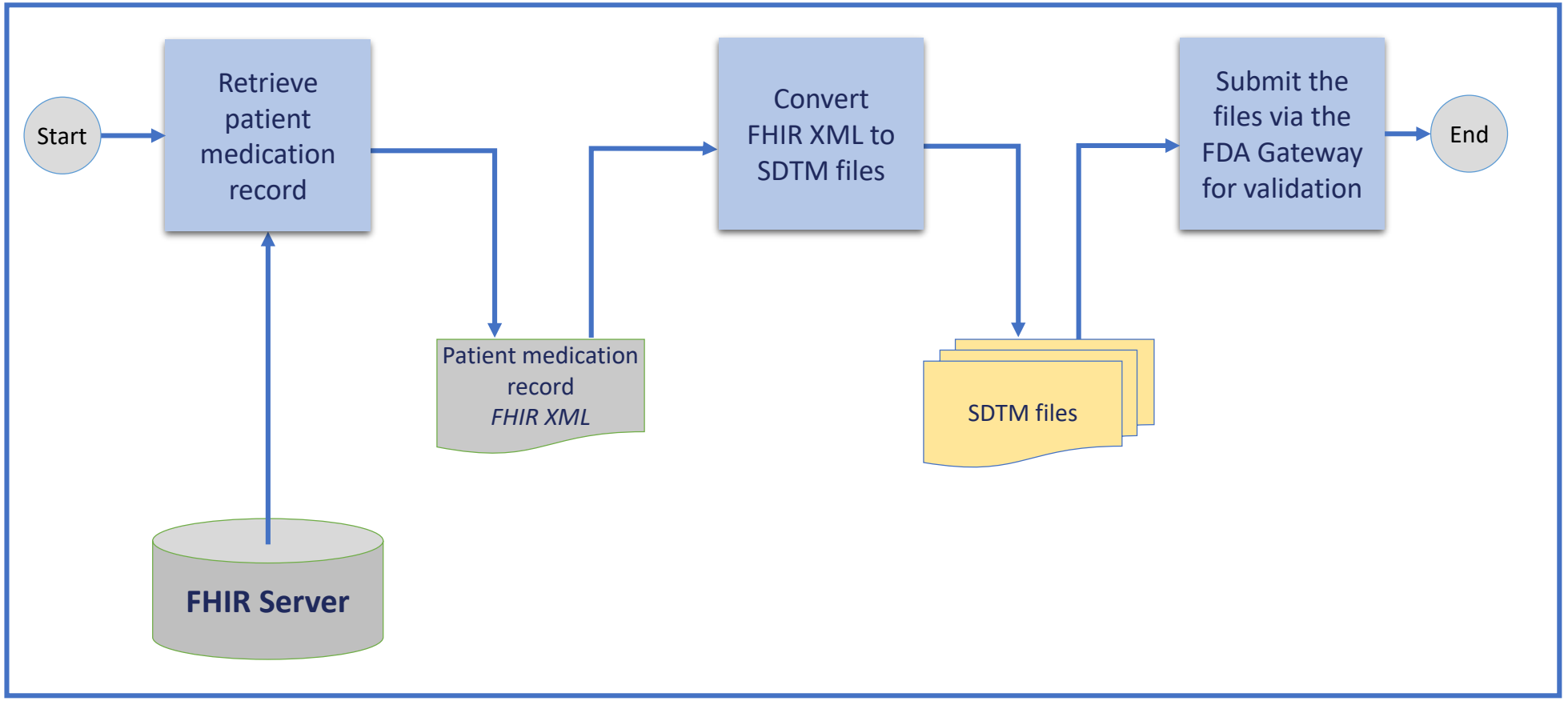
1. Develop HL7 FHIR capabilities to fulfill the study data submission requirements and to use standardized RWD by biopharmaceutical sponsors
2. Generate evidence from Real World Data submitted to the FDA using established guidelines

High Level Track Steps

1. Retrieve patient's medication record from a FHIR EHR server
2. Create the SDTM Concomitant Medication* (CM) and Demographics (DM) domain files**
3. Validate created SDTM file

(*) Concomitant Medications A drug or biological product, other than a study drug, taken by a subject during a clinical trial. The protocol normally defines a specific reporting period in which the subject's use of concomitant medications is documented, e.g., from 60 days prior to signing the informed consent until the last study visit.
(**) This step will use the CDISC FHIR mapping (https://wiki.cdisc.org/display/FHIR2CDISCUG/FHIR-to-CDISC+Mapping+Home).

Use Case Data Flow



Use Case Description

A prototype application will be developed to accommodate the following:

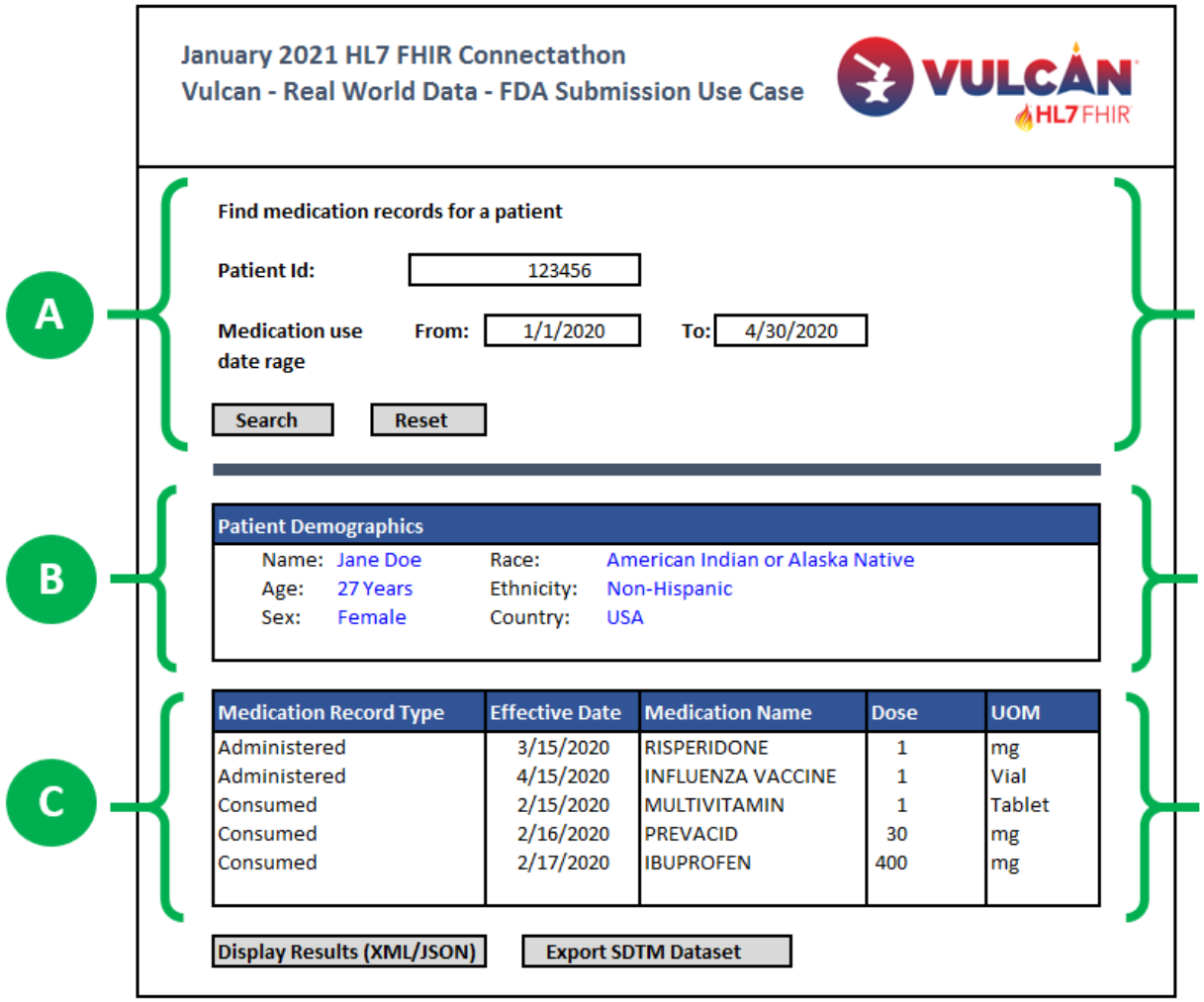
1. Search for a patient in the EHR FHIR server*
2. Retrieve patient's medication record(s)
3. Display medication record(s) on the UI
4. Show the FHIR JSON, or XML, representation of the medication record(s)
5. Convert the FHIR medication record(s) to create the SDTM DM and CM domain files
6. Validate the created SDTM files via the FDA Gateway

(*) For the purpose of the connectathon the EHR FHIR server will be a FHIR server loaded with test EHR data. It will be possible to point the prototype to any FHIR server with EHR data that contains MedicationStatement resource records as well as Patient resource records.
Note: Steps above may vary.

FHIR Resources

- The prototype will use the following FHIR resources:
  - Patient
  - Medication
  - MedicationStatement *-renamed to MedicationUsage in R5*
- The prototype maybe modified to evaluate data in all medication-related resources that exist for the patient such as:
  - MedicationAdministration
  - MedicationDispense
  - MedicationKnowledge
  - MedicationRequest

Track Suggested UI



1. The user enters a patient number in block A and clicks [Search]
2. The system will retrieve the patient from the FHIR EHR server and display basic patient demographics information in block B, and the patient's medications record in block C.
3. The user can click [Display Results (XML/JSON)] to display the XML or JSON FHIR representation of the medications record
4. The user can click [Export SDTM Dataset] and the system creates the DM (Demographics) and CM (Concomitant Medication) CDISC SDTM domain files to store on the user's local machine.

Note: Other CDISC SDTM files necessary for the submission will be manually created, i.e. TS (Trial Summary), TE (Trial Elements), TA (Trial Arms), and define.xml. Since the server will have EHR clinical data, and no clinical trial data, the clinical trial related variable values used in these SDTM domain files will be synthetic and constant for any patient used in the prototype.

Sample Input MedicationStatement Resource

MedicationStatement-sample-input.txt


```
{
  "resourceType": "Bundle",
  "id": "abcb9b01-79aa-438c-8cc8-5107245f42f5",
  "meta": {
    "lastUpdated": "2020-12-15T22:08:44.462+00:00"
  },
  "type": "searchset",
  "total": 4,
  "link": [ {
    "relation": "self",
    "url": "http://hapi.fhir.org/baseR4/MedicationStatement/?patient=ab2e57e2-83ab-43c3-a56e-1e3c289c37e2"
  } ],
  "entry": [ {
    "fullUrl": "http://hapi.fhir.org/baseR4/MedicationStatement/11d7c21f-88e9-48d0-8b4b-222fcefaa944",
    "resource": {
      "resourceType": "MedicationStatement",
      "id": "11d7c21f-88e9-48d0-8b4b-222fcefaa944",
      "meta": {
        "versionId": "1",
        "lastUpdated": "2020-03-24T22:08:45.135+00:00",
        "source": "#bzQAuiKOwnJKAfSv",
        "profile": [ "http://hl7.org/fhir/us/core/StructureDefinition/us-core-medicationstatement" ],
        "tag": [ {
          "system": "https://smarthealthit.org/tags",
          "code": "Covid19 synthetic population from Synthea"
        } ]
      },
      "status": "active",
      "medicationReference": {
        "reference": "Medication/d1cfb6be-f508-4a59-a6d8-2b8cbbf6dc3e"
      },
      "subject": {
        "reference": "Patient/ab2e57e2-83ab-43c3-a56e-1e3c289c37e2"
      },
      "context": {
        "reference": "Encounter/251a0b4b-4fe6-4f6b-aabc-233b245b0274"
      },
      "effectiveDateTime": "1969-06-06T12:38:17-05:00",
      "dateAsserted": "1969-06-06T12:38:17-05:00",
      "derivedFrom": [ {
        "reference": "MedicationRequest/78e5598c-0ff2-4622-b83b-c0cc4400f3ac"
      } ],
      "reasonCode": [ {
```

Sample Output
SDTM CM Domain File (CSV)

SDTM CM Sample Output

STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCAT	CMINDC	CMCLAS	CMCLASCD	CMDOSTX	CMDOSU	CMDOSFR	CMROUTE	CMSTDTC	CMENDTC	CMSTDY	CMENDY	CMENRF
CDISC01	CM	CDISC01.1	1	PROCARDIA XL		NIFEDIPINE	CONCOMITANT MEDICATI	HYPERTEN	CALCIUM	C08	60	mg	Q24H	ORAL	1986		-5963		AFTER
CDISC01	CM	CDISC01.1	2	GLYBURIDE		GLIBENCLAMIDE	CONCOMITANT MEDICATI	DIABETES	DRUGS US	A10	5	mg	BID	ORAL	1987		-5598		AFTER
CDISC01	CM	CDISC01.1	3	ACCUPRIL		QUINAPRIL HYDROCHLORID	CONCOMITANT MEDICATI	HYPERTEN	AGENTS A	C09	20	mg	Q24H	ORAL	1995		-2676		AFTER
CDISC01	CM	CDISC01.1	4	CALCIUM		CALCIUM	CONCOMITANT MEDICATI	SUPPLEME	MINERAL	A12	600	mg	Q24H	ORAL	1995		-2676		AFTER
CDISC01	CM	CDISC01.1	5	GLUCOPHAGE		METFORMIN HYDROCHLORI	CONCOMITANT MEDICATI	DIABETES	DRUGS US	A10	1000	mg	Q24H	ORAL	1995		-2676		AFTER
CDISC01	CM	CDISC01.1	6	GLUCOPHAGE		METFORMIN HYDROCHLORI	CONCOMITANT MEDICATI	DIABETES	DRUGS US	A10	500	mg	Q24H	ORAL	1995		-2676		AFTER
CDISC01	CM	CDISC01.1	7	MAGNESIUM		MAGNESIUM	CONCOMITANT MEDICATI	SUPPLEME	MINERAL	A12	400	mg	Q24H	ORAL	1995		-2676		AFTER
CDISC01	CM	CDISC01.1	8	MULTIVITAMIN		MULTIVITAMINS	CONCOMITANT MEDICATI	SUPPLEME	VITAMINS	A11	1	TABLET	Q24H	ORAL	1995		-2676		AFTER
CDISC01	CM	CDISC01.1	9	PREVACID		LANSOPRAZOLE	CONCOMITANT MEDICATI	INDIGESTI	DRUGS FO	A02	30	mg	Q24H	ORAL	1998		-1580		AFTER
CDISC01	CM	CDISC01.1	10	ASPIRIN		ACETYLSALICYLIC ACID	CONCOMITANT MEDICATI	PREVENTA	ANALGESI	N02	81	mg	Q24H	ORAL	2000-10		-910		AFTER
CDISC01	CM	CDISC01.1	11	LEVOXYL		LEVOTHYROXINE SODIUM	CONCOMITANT MEDICATI	HYPOTHYF	THYROID T	H03	50	mg	Q24H	ORAL	2002		-119		AFTER
CDISC01	CM	CDISC01.1	1	LANSOPRAZOLE		LANSOPRAZOLE	CONCOMITANT MEDICATI	REFLUX	DRUGS FO	A02	30	mg	Q24H	ORAL	12/31/2003	2/6/2004	78	115	
CDISC01	CM	CDISC01.1	2	MIDAZOLAM		MIDAZOLAM	CONCOMITANT MEDICATI	HAVING U	PSYCHOLE	N05	1	mg	ONCE	INTRAVEN	2/5/2004	2/5/2004	114	114	
CDISC01	CM	CDISC01.1	3	COMPAZINE		PROCHLORPERAZINE EDISYL	CONCOMITANT MEDICATI	VOMITING	ANTIEMET	A04	10	mg	PRN	ORAL	2/6/2004	2/8/2004	115	117	
CDISC01	CM	CDISC01.1	4	PANTOPRAZOLE-SOI	PANTOPRAZOLE SODIUM	PANTOPRAZOLE SODIUM	CONCOMITANT MEDICATI	REFLUX	DRUGS FO	A02	40	mg	Q24H	ORAL	2/9/2004		118		AFTER
CDISC01	CM	CDISC01.2	1	LEVOTHYROXINE-SO	LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM	CONCOMITANT MEDICATI	THYROID I	THYROID T	H03	0.125	mg	Q24H	ORAL	1960		-15613		AFTER
CDISC01	CM	CDISC01.2	2	CENTRUM		CENTRUM	CONCOMITANT MEDICATI	NUTRITIO	VITAMINS	A11	1	TABLET	Q24H	ORAL	2001		-638		AFTER
CDISC01	CM	CDISC01.2	3	GARLIC		GARLIC	CONCOMITANT MEDICATI	NUTRITIO	ALL OTHEF	V03	1	TABLET	Q24H	ORAL	2001		-638		AFTER
CDISC01	CM	CDISC01.2	4	GINKO BILOBA		GINKGO BILOBA	CONCOMITANT MEDICATI	NUTRITIO	ALL OTHEF	V03	1	TABLET	Q24H	ORAL	2001		-638		AFTER
CDISC01	CM	CDISC01.2	5	OSCAL		CALCIUM CARBONATE	CONCOMITANT MEDICATI	NUTRITIO	MINERAL	A12	1	TABLET	Q24H	ORAL	2001		-638		AFTER
CDISC01	CM	CDISC01.2	6	VITAMIN "E"	VITAMIN E	TOCOPHEROL	CONCOMITANT MEDICATI	NUTRITIO	VITAMINS	A11	400	IU	Q24H	ORAL	2001		-638		AFTER
CDISC01	CM	CDISC01.2	7	DONEPEZIL-HYDROC	DONEPEZIL HYDROCHLOI	DONEPEZIL HYDROCHLORID	PSYCHOTROPHIC DRUG TRI	ALZHEIME	PSYCHOAI	N06	5	mg	Q24H	ORAL	9/1/2001	9/15/2001	-759	-745	
CDISC01	CM	CDISC01.2	8	RIVASTIGMINE TARTRATE		RIVASTIGMINE TARTRATE	PSYCHOTROPHIC DRUG TRI	ALZHEIME	PSYCHOAI	N06	2.5	mg	BID	ORAL	9/16/2001	9/22/2001	-744	-738	
CDISC01	CM	CDISC01.2	9	RISPERIDONE		RISPERIDONE	PSYCHOTROPHIC DRUG TRI	INSOMNIA	PSYCHOLE	N05	1	mg	BID	ORAL	2003-06	2003-06	-92	-92	
CDISC01	CM	CDISC01.2	10	TRAZODONE-HYDRO	TRAZODONE HYDROCHLO	TRAZODONE HYDROCHLORI	PSYCHOTROPHIC DRUG TRI	INSOMNIA	PSYCHOAI	N06	25	mg	Q24H	ORAL	2003-06	8/26/2003	-92	-35	
CDISC01	CM	CDISC01.2	11	ZOLPIDEM TARTRATE		ZOLPIDEM TARTRATE	CONCOMITANT MEDICATI	INSOMNIA	PSYCHOLE	N05	2.5	mg	Q24H	ORAL	10/16/2003	10/17/2003	17	18	
CDISC01	CM	CDISC01.2	12	ZOLPIDEM TARTRATE		ZOLPIDEM TARTRATE	CONCOMITANT MEDICATI	INSOMNIA	PSYCHOLE	N05	5	mg	Q24H	ORAL	10/19/2003	10/19/2003	20	20	
CDISC01	CM	CDISC01.2	13	INFLUENZA VACCINE		INFLUENZA VACCINE	CONCOMITANT MEDICATI	INFLUENZ	VACCINES	J07	1	VIAL	ONCE	SUBCUTAI	11/7/2003	11/7/2003	39	39	
CDISC01	CM	CDISC01.2	14	ALKA SELTZER PLUS		ALKA-SELTZER PLUS	CONCOMITANT MEDICATI	COLD PRO	COUGH AI	R05	2	TABLET	Q24H	ORAL	11/11/2003	11/11/2003	43	43	
CDISC01	CM	CDISC01.2	1	DONEPEZIL-HYDROC	DONEPEZIL HYDROCHLOI	DONEPEZIL HYDROCHLORID	CONCOMITANT MEDICATI	ALZHEIME	PSYCHOAI	N06	10	mg	Q24H	ORAL	2001-12	9/4/2003	-648	-36	
CDISC01	CM	CDISC01.2	2	DONEPEZIL-HYDROC	DONEPEZIL HYDROCHLOI	DONEPEZIL	PSYCHOTROPHIC DRUG TRI	ALZHEIME	PSYCHOAI	N06	10	mg	Q24H	ORAL	2001-12	9/4/2003	-648	-36	
CDISC01	CM	CDISC01.2	3	MULTIVITAMIN		MULTIVITAMINS	CONCOMITANT MEDICATI	NUTRITIO	VITAMINS	A11	1	TABLET	Q24H	ORAL	2003-06		-102		AFTER
CDISC01	CM	CDISC01.2	4	INFLUENZA VACCINE		INFLUENZA VACCINE	CONCOMITANT MEDICATI	INFLUENZ	VACCINES	J07	1	VIAL	ONCE	SUBCUTAI	11/15/2003	11/15/2003	37	37	
CDISC01	CM	CDISC01.2	1	DONEPEZIL-HYDROC	DONEPEZIL HYDROCHLOI	DONEPEZIL	CONCOMITANT MEDICATI	ALZHEIME	PSYCHOAI	N06	UNK	mg	Q24H	ORAL	2001	9/14/2003			
CDISC01	CM	CDISC01.2	2	CALCIUM		CALCIUM	CONCOMITANT MEDICATI	NUTRITIO	MINERAL	A12	1	TABLET	Q24H	ORAL	2002				AFTER
CDISC01	CM	CDISC01.2	3	IBUPROFEN		IBUPROFEN	CONCOMITANT MEDICATI	BACK PAI	ANTIINFLA	M01	400	mg	PRN	ORAL	2002				AFTER

SDTM DM Domain Variable Definitions (1 of 2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. See Assumption 9 for additional detail on when RFSTDTC may be null.	Exp
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	Record Qualifier	Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects.	Exp
RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date/time of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.	Exp
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date/time of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).	Exp

Source: CDISC's Study Data Tabulation Model Implementation Guide - Human Clinical Trials - Version 3.3

SDTM DM Domain Variable Definitions (2 of 2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
RFPENDTC	Date/Time of End of Participation	Char	ISO 8601	Record Qualifier	Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, or death date.	Exp
DTHDTC	Date/Time of Death	Char	ISO 8601	Record Qualifier	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.	Exp
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indicates the subject died. Should be "Y" or null. Should be populated even when the death date is unknown.	Exp
SITEID	Study Site Identifier	Char	*	Record Qualifier	Unique identifier for a site within a study.	Req
INVID	Investigator Identifier	Char		Record Qualifier	An identifier to describe the Investigator for the study. May be used in addition to SITEID. Not needed if SITEID is equivalent to INVID.	Perm
INVNAM	Investigator Name	Char		Synonym Qualifier	Name of the investigator for a site.	Perm
BRTHDTC	Date/Time of Birth	Char	ISO 8601	Record Qualifier	Date/time of birth of the subject.	Perm
AGE	Age	Num		Record Qualifier	Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).	Exp
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with AGE.	Exp
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject.	Req
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, October, 2016) for guidance regarding the collection of race (https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf) See Assumption below regarding RACE.	Exp
ETHNIC	Ethnicity	Char	(ETHNIC)	Record Qualifier	The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, October, 2016) for guidance regarding the collection of ethnicity (https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf).	Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARMCD is limited to 20 characters. It is not subject to the character restrictions that apply to TESTCD.The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20. If the subject was not assigned to an Arm, ARMCD is null and ARMNRS is populated. With the exception of studies which use multi-stage Arm assignments, must be a value of ARMCD in the Trial Arms Dataset.	Exp
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name of the Arm to which the subject was assigned. If the subject was not assigned to an Arm, ARM is null and ARMNRS is populated. With the exception of studies which use multi-stage Arm assignments, must be a value of ARM in the Trial Arms Dataset.	Exp
ACTARMCD	Actual Arm Code	Char	*	Record Qualifier	Code of actual Arm. ACTARMCD is limited to 20 characters. It is not subject to the character restrictions that apply to TESTCD. The maximum length of ACTARMCD is longer than for other short variables to accommodate the kind of values that are likely to be needed for crossover trials. With the exception of studies which use multi-stage Arm assignments, must be a value of ARMCD in the Trial Arms Dataset. If the subject was not assigned to an Arm or followed a course not described by any planned Arm, ACTARMCD is null and ARMNRS is populated.	Exp
ACTARM	Description of Actual Arm	Char	*	Synonym Qualifier	Description of actual Arm. With the exception of studies which use multi-stage Arm assignments, must be a value of ARM in the Trial Arms Dataset. If the subject was not assigned to an Arm or followed a course not described by any planned Arm, ACTARM is null and ARMNRS is populated.	Exp
ARMNRS	Reason Arm and/or Actual Arm is Null	Char	*	Record Qualifier	A coded reason that Arm variables (ARM and ARMCD) and/or actual Arm variables (ACTARM and ACTARMCD) are null. Examples: "SCREEN FAILURE", "NOT ASSIGNED", "ASSIGNED, NOT TREATED", "UNPLANNED TREATMENT". It is assumed that if the Arm and actual Arm variables are null, the same reason applies to both Arm and actual Arm.	Exp
ACTARMUD	Description of Unplanned Actual Arm	Char		Record Qualifier	A description of actual treatment for a subject who did not receive treatment described in one of the planned trial Arms.	Exp
COUNTRY	Country	Char	ISO 3166-1 Alpha-3	Record Qualifier	Country of the investigational site in which the subject participated in the trial.	Req
DMDTC	Date/Time of Collection	Char	ISO 8601	Timing	Date/time of demographic data collection.	Perm
DMDY	Study Day of Collection	Num		Timing	Study day of collection measured as integer days.	Perm

SDTM CM Domain Variable Definitions (1 of 3)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
CMSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of subject records within a domain. May be any valid number.	Req
CMGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
CMSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Example: a number pre-printed on the CRF as an explicit line identifier or record identifier defined in the sponsor's operational database. Example: line number on a concomitant medication page.	Perm
CMTRT	Reported Name of Drug, Med, or Therapy	Char		Topic	Verbatim medication name that is either pre-printed or collected on a CRF.	Req
CMMODIFY	Modified Reported Name	Char		Synonym Qualifier	If CMTRT is modified to facilitate coding, then CMMODIFY will contain the modified text.	Perm
CMDECOD	Standardized Medication Name	Char		Synonym Qualifier	Standardized or dictionary-derived text description of CMTRT or CMMODIFY. Equivalent to the generic drug name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the Define-XML document. If an intervention term does not have a decode value in the dictionary, then CMDECOD will be left blank.	Perm
CMCAT	Category for Medication	Char		Grouping Qualifier	Used to define a category of medications/treatment. Examples: "PRIOR", "CONCOMITANT", "ANTI-CANCER MEDICATION", or "GENERAL CONMED".	Perm
CMSCAT	Subcategory for Medication	Char		Grouping Qualifier	A further categorization of medications/treatment. Examples: "CHEMOTHERAPY", "HORMONAL THERAPY", "ALTERNATIVE THERAPY".	Perm
CMPRESP	CM Pre-specified	Char	(NY)	Variable Qualifier	Used to indicate whether ("Y"/null) information about the use of a specific medication was solicited on the CRF.	Perm
CMOCCUR	CM Occurrence	Char	(NY)	Record Qualifier	When the use of a specific medication is solicited. CMOCCUR is used to indicate whether or not ("Y"/"N") use of the medication occurred. Values are null for medications not specifically solicited.	Perm
CMSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of "NOT DONE".	Perm
CMREASND	Reason Medication Not Collected	Char		Record Qualifier	Reason not done. Used in conjunction with CMSTAT when value is "NOT DONE".	Perm
CMINDC	Indication	Char		Record Qualifier	Denotes why a medication was taken or administered. Examples: "NAUSEA", "HYPERTENSION".	Perm
CMCLAS	Medication Class	Char		Variable Qualifier	Drug class. May be obtained from coding. When coding to a single class, populate with class value. If	Perm

Source: CDISC's Study Data Tabulation Model Implementation Guide - Human Clinical Trials - Version 3.3

SDTM CM Domain Variable Definitions (2 of 3)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
					using a dictionary and coding to multiple classes, then follow Section 4.2.8.3, Multiple Values for a Non-Result Qualifier Variable, or omit CMCLAS.	
CMCLASCD	Medication Class Code	Char		Variable Qualifier	Class code corresponding to CMCLAS. Drug class. May be obtained from coding. When coding to a single class, populate with class code. If using a dictionary and coding to multiple classes, then follow Section 4.2.8.3, Multiple Values for a Non-Result Qualifier Variable, or omit CMCLASCD.	Perm
CMDOSE	Dose per Administration	Num		Record Qualifier	Amount of CMTRT given. Not populated when CMDOSTXT is populated.	Perm
CMDOSTXT	Dose Description	Char		Record Qualifier	Dosing amounts or a range of dosing information collected in text form. Units may be stored in CMDOSU. Examples: "200-400", "15-20". Not populated when CMDOSE is populated.	Perm
CMDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for CMDOSE, CMDOSTOT, or CMDOSTXT. Examples: "ng", "mg", or "mg/kg".	Perm
CMDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for CMTRT. Examples: "TABLET", "LOTION".	Perm
CMDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of CMDOSE within a specific time period. Examples: "BID" (twice daily), "Q12H" (every 12 hours).	Perm
CMDOSTOT	Total Daily Dose	Num		Record Qualifier	Total daily dose of CMTRT using the units in CMDOSU. Used when dosing is collected as Total Daily Dose. Total dose over a period other than day could be recorded in a separate Supplemental Qualifier variable.	Perm
CMDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the (intended) schedule or regimen for the Intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".	Perm
CMROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".	Perm
CMADJ	Reason for Dose Adjustment	Char		Record Qualifier	Describes reason or explanation of why a dose is adjusted. Examples: "ADVERSE EVENT", "INSUFFICIENT RESPONSE", "NON-MEDICAL REASON".	Perm
CMRSDISC	Reason the Intervention Was Discontinued	Char		Record Qualifier	When dosing of a treatment is recorded over multiple successive records, this variable is applicable only for the (chronologically) last record for the treatment.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the Element within the Arm for the Element in which the medication administration started. Null for medications that started before study participation.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the medication administration. Null for medications that started before study participation.	Perm
CMSTDTC	Start Date/Time of Medication	Char	ISO 8601	Timing	Start date/time of the medication administration represented in ISO 8601 character format.	Perm
CMENDTC	End Date/Time of Medication	Char	ISO 8601	Timing	End date/time of the medication administration represented in ISO 8601 character format.	Perm
CMSTDY	Study Day of Start of Medication	Num		Timing	Study day of start of medication relative to the sponsor-defined RFSTDTC.	Perm
CMENDY	Study Day of End of Medication	Num		Timing	Study day of end of medication relative to the sponsor-defined RFSTDTC.	Perm
CMDUR	Duration	Char	ISO 8601	Timing	Collected duration for a treatment episode. Used only if collected on the CRF and not derived from start and end date/times.	Perm
CMSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the medication relative to sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time	Perm

SDTM CM Domain Variable Definitions (3 of 3)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
					defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR" was collected, this information may be translated into CMSTRF. Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.	
CMENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the medication relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING, or "CONTINUING" was collected, this information may be translated into CMENRF. Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.	Perm
CMSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the medication as being before or after the sponsor-defined reference time point defined by variable CMSTTPT. Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.	Perm
CMSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by CMSTRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
CMENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the medication as being before or after the sponsor-defined reference time point defined by variable CMENTPT. Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.	Perm
CMENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by CMENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

References

- Vulcan – HL7 FHIR
  http://www.hl7.org/vulcan/
- CDISC SDTM Implementation Guide v3.3 *(CDISC login required)*
  https://www.cdisc.org/system/files/members/standard/foundational/SDTMIG_v3.3_FINAL.pdf
- SDTM Validation Tool – Pinnacle 21
  https://www.pinnacle21.com/
- CDISC FHIR Mappings
  https://wiki.cdisc.org/display/FHIR2CDISCUG/FHIR-to-CDISC+Mapping+Home

- Connectathon Track Page
  https://confluence.hl7.org/display/FHIR/2021-01+Vulcan+-+Real+World+Data+%28RWD%29+Submission+to+FDA
- CDISC – FHIR to CDISC Mapping FHIR IG – targeted for January 2021 ballot cycle
  http://www.hl7.org/ctl.cfm?action=ballots.participantdetailbydocument&ballot_voter_id=15863&ballot_id=1951&ballot_cycle_id=554

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Questions / Comments?