Package 'RImmPort'

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Type Package

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Description The RImmPort package simplifies access to ImmPort data for analysis in the R environment. It provides a standards-based interface to the ImmPort study data that is in a proprietary format.

License GPL-3

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`Adverse Events Domain` *Adverse Events Domain*

Description

The Adverse Events data of an ImmPort study is reformated to the CDISC SDTM Adverse Events (AE) domain model, and is a list of 2 data frames containing 1) Adverse Events data AE and 2) any supplemental Adverse Events data SUPP

AE *Adverse Events Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
AESEQ	Sequence Number
AESPID	Sponsor-Defined Identifier
AETERM	Reported Term for the Adverse Event
AEMODIFY	Modified Reported Term
AEBODYSYS	Body System or Organ Class
AELOC	Location of Event
AESEV	Severity/Intensity
AEACN	Action Taken with Study Treatment
AEACNOTH	Other Action Taken
AEREL	Causality
AERELNST	Relationship to Non-Study Treatment
AEOUT	Outcome of Adverse Event
AESTDY	Study Day of Start of Adverse Event
AEENDY	Study Day of End of Adverse Event

APMH *Associated Persons Medical History Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
APID	Associated Persons Identifier
MHSEQ	Sequence Number
RSUBJID	Related Subject
SREL	Subject Relationship
MHTERM	Reported Term for the Medical History
MHCAT	Category for Medical History
MHBODSYS	Body System or Organ Class
MHDTC	Date/Time of History Collection
MHDY	RStudy Day of History Collection

`Associated Persons Medical History Domain`
Associated Persons Medical History Domain

Description

The Associated Persons Medical History data of an ImmPort study is reformated to the CDISC SDTM AAssociated Persons Medical History (APMH) domain model, and is a list of 2 data frames containing 1) Associated Persons Medical History data APMH and 2) any supplemental Associated Persons Medical History data SUPP

`buildNewSqliteDb` *buildNewSqliteDb*

Description

The function `buildSqliteDb` builds a sqlite db of ImmPort study data. It takes in as input the study files in the TSV (Tab) format.

Usage

```
buildNewSqliteDb(data_dir, db_dir)
```

Arguments

`data_dir`	File directory where the study TSV files are stored
`db_dir`	File directory where the sqlite database will be stored

Value

The SQLite database name

Examples

```
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
# set tab_dir to the folder where the zip files are located
tab_dir <- file.path(studies_dir, "Tab")
# set db_dir to the folder where the database file 'ImmPort.sqlite' should be stored
db_dir <- file.path(studies_dir, "Db")
# build a new ImmPort SQLite database with the data in the downloaded zip files
# dbname <- buildNewSqliteDb(tab_dir, db_dir)
```

`Cellular Quantification Domain`

Cellular Quantification Domain

Description

The ImmPort study data generated from assays of types: Flow and ELISPOT are grouped into the Cellular Quantification Domain. The data is reformated to a custom Cellular Quantification domain model in CDISC SDTM standards, and is a list of 2 data frames containing 1) Cellular Quantification data `ZB` and 2) any supplemental Cellular Quantification data `SUPP`

`CM` *Concomitant Medications Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
CMSEQ	Sequence Number
CMTRT	Reported Name of Drug, Med, or Therapy
CMCAT	Category for Medication
CMDOSE	Dose per Administration
CMDOSTXT	Dose Description
CMDOSU	Dose Units
CMDOSFREQ	Dosing Frequency per Interval
CMROUTE	Route of Administration
CMSTDTC	Start Date/Time of Medication
CMENDTC	End Date/Time of Medication
CMSTDY	Study Day of Start of Medication
CMENDY	Study Day of End of Medication

`Concomitant Medications Domain`

Concomitant Medications Domain

Description

The Concomitant Medications data of an ImmPort study is reformated to the CDISC SDTM Concomitant Medications (CM) domain model, and is a list of 2 data frames containing 1) Concomitant Medications data `CM` and 2) any supplemental Concomitant Medications data `SUPP`

`Demographics Domain` *Demographics Domain*

Description

The Demographics data of an ImmPort study is reformated to the CDISC SDTM Demographics (DM) domain model, and is a list of 2 data frames containing 1) Demographics data `DM` and 2) any supplemental Demographics data `SUPP`

`DM` *Demographics Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
AGE	Age
AGEU	Age Units
SEX	Sex
RACE	Race (only for human data)
ETHNIC	Ethnicity (only for human data)
SPECIES	Species (only for non-human data)
STRAIN	Strain/Substrain (only for non-human data)
SBSTRAIN	Strain/Substrain Details (only for non-human data)
ARMCD	Planned Arm Code
ARM	Description of Planned Arm

`DV` *Protocol Deviations Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
DVSEQ	Sequence Number
DVTERM	Protocol Deviation Term

`Events-class` *Events class*

Description

Events class

Fields

`ae_l` Adverse Events data AE and supplemental Adverse Events data SUPP

`dv_l` Protocol Deviations data DV and supplemental Protocol Deviations data SUPPDV

`mh_l` Medical History data MH and supplemental Medical History data SUPPMH

`apmh_l` Associated Persons Medical History data APMH and supplemental Associated Persons Medical History data SUPP

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
sdy139 <- getStudy("SDY139")
ae_df <- sdy139$events$ae_l$ae_df
```

EX *Exposure Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
EXSEQ	Sequence Number
EXTRT	Name of Treatment
EXCAT	Category of Treatment
EXDOSE	Dose
EXDOSTXT	Dose Description
EXDOSU	Dose Units
EXDOSFRQ	Dosing Frequency per Interval
EXROUTE	Route of Administration
EXSTDTC	Start Date/Time of Treatment
EXENDTC	End Date/Time of Treatment
EXSTDY	Study Day of Start of Treatment
EXENDY	Study Day of End of Treatment

Exposure Domain *Exposure Domain*

Description

The Exposure data of an ImmPort study is reformated to the CDISC SDTM Exposure (EX) domain model, and is a list of 2 data frames containing 1) Exposure data EX and 2) any supplemental Exposure data SUPP

FA *Findings About Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
FASEQ	Sequence Number
FATEST	Findings About Test Name
FAOBJ	Object of the Observation
FACAT	Category for Findings About
FAORRES	Results or Findings in Original Units
FAORRESU	Original Units
FALOC	Location of the Finding About
VISITNUM	Visit Number
VISIT	Visit Name
FADY	Study Day of Collection

Findings About Domain *Findings About Domain*

Description

The Findings About data of an ImmPort study is reformated to the CDISC SDTM Findings About (FA) domain model, and is a list of 2 data frames containing 1) Findings About data FA and 2) any supplemental Findings About data SUPPFA

Findings-class *Findings class*

Description

Findings class

Fields

- `lb_l` Laboratory Test Results data LB and supplemental Laboratory Test Results data SUPPLB
- `pe_l` Physical Examination data PE and supplemental Physical Examination data SUPPPE
- `vs_l` Vital Signs data VS and supplemental Vital Signs data SUPPVS
- `qs_l` Questionnaires data QS and supplemental Questionnaires data SUPP
- `fa_l` Findings About data FA and supplemental Findings About data SUPPFA
- `sr_l` Skin Response data SR and supplemental Skin Response data SUPP
- `pf_l` Genetics Findings data PF and supplemental Genetics Findings data SUPPPF
- `za_l` Protein Quantification data ZA and supplemental Protein Quantification data SUPPZA
- `zb_l` Cellular Quantification data ZB and supplemental Cellular Quantification data SUPP
- `zc_l` Nucleic Acid Quantification data ZC and supplemental Nucleic Acid Quantification data SUPP
- `zd_l` Titer Assay Results data ZD and supplemental Titer Assay Results data SUPP

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
sdy139 <- getStudy("SDY139")
zb_df <- sdy139$findings$zb_l$zb_df
```

`Genetics Findings Domain`

Genetics Findings Domain

Description

The ImmPort study data generated from assays of types: HLA Typing and Array are grouped into the Genetics Findings Domain. The data is reformated to a PharmacoGenomics and Genetics Findings (PF) model in CDISC SDTM standards, and is a list of 2 data frames containing 1) Genetics Findings data PF and 2) any supplemental Genetics Findings data SUPP

getAssayDataOfStudies *Get specific assay data of one or more studies from the ImmPort database*

Description

Get specific assay data of one or more studies from the ImmPort database

Usage

```
getAssayDataOfStudies(study_ids, assay_type)
```

Arguments

study_ids	List of study indentifiers
assay_type	Assay Type

Value

a list of 1) domain data of specicifc assay technology and 2) any supplemental domain data of the studies

Author(s)

Ravi Shankar

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
elispot_l <- getAssayDataOfStudies("SDY139", "ELISPOT")
if (length(elispot_l) > 0)
  names(elispot_l)
head(elispot_l$zb_df)
```

getDomainCode *Get code of a specific domain*

Description

The function getListOfDomains returns the code of a specific domain

Usage

```
getDomainCode(domain)
```

Arguments

domain	Name of a specific domain

Value

A list of of all domain names and codes

Examples

```
domain <- "Demographics"
code <- getDomainCode(domain)
```

getDomainDataOfStudies *Get specific domain data of one or more studies from the ImmPort database*

Description

Get specific domain data of one or more studies from the ImmPort database

Usage

```
getDomainDataOfStudies(domain, study_ids)
```

Arguments

domain	Name of a specific domain
study_ids	List of study indentifiers

Value

a list of 1) domain data and 2) supplemental domain data of the studies

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
dm_df <- getDomainDataOfStudies("Demographics", "SDY139")
```

`getListOfAssayTypes` *Get a list of Assay Types*

Description

The function `getListOfAssayTypes` returns a list of assay types that ImmPort studies have employed in their experimetal assays

Usage

```
getListOfAssayTypes()
```

Value

A list of assay types

Examples

```
at_l <- getListOfAssayTypes()
```

`getListOfDomains` *Get names of all domains and their codes*

Description

The function `getListOfDomains` returns a list of all domain names and codes

Usage

```
getListOfDomains()
```

Value

A list of of all domain names and codes

Examples

```
domains_df <- getListOfDomains()
```

getListOfStudies *Get a list of all studies*

Description

Get a list of all studies

Usage

```
getListOfStudies()
```

Value

List of study indentifiers

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
study_ids <- getListOfStudies()
```

getStudiesWithSpecificAssayData *Get a list of studies that have specific assay type data*

Description

Get a list of studies that have specific assay type data

Usage

```
getStudiesWithSpecificAssayData(assay_type, all_study_ids = c("ALL"))
```

Arguments

assay_type	Assay Type
all_study_ids	List of study indentifiers to search on

Value

List of study indentifiers

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
study_ids <- getStudiesWithSpecificAssayData("ELISPOT")
```

---

getStudiesWithSpecificDomainData

Get a list of studies that have specific domain data

Description

Get a list of studies that have specific domain data

Usage

```
getStudiesWithSpecificDomainData(domain, all_study_ids = c("ALL"))
```

Arguments

domain	Name of a specific domain
all_study_ids	List of study indentifiers to search on

Value

List of study indentifiers

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
study_ids <- getStudiesWithSpecificDomainData("Demographics")
```

getStudy *Get all data of a specific study from the ImmPort data source*

Description

The function getStudy queries the ImmPort data source for data of a specific study in all domains. The data is then structured into Study as classes, domains, variables and values.

Usage

```
getStudy(study_id)
```

Arguments

study_id	Identifier of a specific study

Value

A study data object where in all data are structured as classes, domains, variables and values (in CDISC format)

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
sdy139 <- getStudy("SDY139")
```

Interventions-class *Interventions class*

Description

Interventions class

Fields

cm_l	Concomitant Medications data CM and supplemental Concomitant Medications data SUPP
ex_l	Exposure data EX and supplemental Exposure data SUPP
su_l	Substance Use data SU and supplemental Substance Use data SUPP

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
sdy139 <- getStudy("SDY139")
cm_df <- sdy139$interventions$cm_l$cm_df
```

Laboratory Test Results Domain

Laboratory Test Results Domain

Description

The Laboratory Test Results data of an ImmPort study is reformated to the CDISC SDTM Laboratory Test Results (LB) domain model, and is a list of 2 data frames containing 1) Laboratory Test Results data LB and 2) any supplemental Laboratory Test Results data SUPPLB

LB *Laboratory Test Results Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
LBSEQ	Sequence Number
LBTEST	Lab Test or Examination Name
LBCAT	Category for Lab Test
LBORRES	Result or Finding in Original Units
LBORRESU	Original Units
LBSPEC	Specimen Type
LBREFID	Specimen Identifier
VISITNUM	Visit Number
VISIT	Visit Name
LBELTM	Planned Elapsed Time from Time Point Ref
LBTPTREF	Time Point Reference

loadSerializedStudyData

Load the Serialized Data of a Study

Description

Load the serialzed data (.rds) file of a specific domain of a study study from the directory where the file is located

Usage

```
loadSerializedStudyData(data_dir, study_id, domain)
```

Arguments

data_dir	Path to a file folder where the .rds study files reside
study_id	Study indentifier
domain	Domain of interest

Value

A study data object where in all data are structured as classes, domains, variables and values (in CDISC format)

Examples

```
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
# the folder where the .rds files will be stored
rds_dir <- file.path(studies_dir, "Rds")
# load the serialized data of study `SDY208`
loadSerializedStudyData(rds_dir, 'SDY208', "Demographics")
```

Medical History Domain

Medical History Domain

Description

The Medical History data of an ImmPort study is reformated to the CDISC SDTM Medical History (MH) domain model, and is a list of 2 data frames containing 1) Medical History data MH and 2) any supplemental Medical History data SUPPMH

mergeDomainAndSupplemental

Merge the Domain dataframe and Supplemental dataframe (long form)

Description

The Domain data list comprises of the the Domain datafrome that is in wide form, and any Supplemental dataframe that is in long form. The function `mergeDomainAndSupplemental` transposes the Supplemental dataframe into a wide form, and merges it with the Domain dataframe.

Usage

```
mergeDomainAndSupplemental(data_list)
```

Arguments

`data_list`	A list of 1) Domain dataframe and 2) any Supplemental dataframe

Value

The merged dataframe

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
l <- getDomainDataOfStudies("Cellular Quantification", "SDY208")
df <- mergeDomainAndSupplemental(l)
```

MH

Medical History Domain Variables

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
MHSEQ	Sequence Number
MHTERM	Reported Term for the Medical History

MHCAT	Category for Medical History
MHBODSYS	Body System or Organ Class
MHDY	Study Day of History Collection

`Nucleic Acid Quantification Domain`
Nucleic Acid Quantification Domain

Description

The ImmPort study data generated from assays of types: PCR are grouped into the Nucleic Acid Quantification Domain. The data is reformated to a custom Nucleic Acid Quantification domain model in CDISC SDTM standards, and is a list of 2 data frames containing 1) Nucleic Acid Quantification data ZC and 2) any supplemental Nucleic Acid Quantification data SUPP

`PE` *Physical Examination Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
PESEQ	Sequence Number
PETEST	Body System Examined
PECAT	Category for Examination
PEBODSYS	Body System or Organ Class
PEORRES	Verbatim Examination Finding
PEORRESU	Original Units
PELOC	Location of Physical Exam Finding
VISITNUM	Visit Number
VISIT	Visit Name
PEDY	Study Day of Examination

PF *Genetics Findings Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
PFSEQ	Sequence Number
PFGRPID	Group Identifier
PFTEST	Test Name
PFCAT	Category for Test
PFMETHOD	Method of the Test
PFGENRI	Genetic Region of Interest
PFORRES	Result or Finding in Original Units
PFALLELC	Allele (Chromosome) Identifier
PFSPEC	Specimen Type
PFREFID	Reference ID (Specimen Identifier)
VISITNUM	Visit Number
VISIT	Visit Name
PFELTM	Planned Elapsed Time from Time Point Ref
PFTPTREF	Time Point Reference
PFXFN	Raw Data File or Life Science Identifier

Physical Examination Domain

Physical Examination Domain

Description

The Physical Examination data of an ImmPort study is reformated to the CDISC SDTM Physical Examination (PE) domain model, and is a list of 2 data frames containing 1) Physical Examination data PE and 2) any supplemental Physical Examination data SUPPPE

`Protein Quantification Domain`
Protein Quantification Domain

Description

The ImmPort study data generated from assays of types: ELISA and MBAA are grouped into the Cellular Quantification Domain. The data is reformated to a custom Protein Quantification domain model in CDISC SDTM standards, and is a list of 2 data frames containing 1) Protein Quantification data ZA and 2) any supplemental Protein Quantification data SUPP

`Protocol Deviations Domain`
Protocol Deviations Domain

Description

The Protocol Deviations data of an ImmPort study is reformated to the CDISC SDTM Protocol Deviations (DV) domain model, and is a list of 2 data frames containing 1) Protocol Deviations data DV and 2) any supplemental Protocol Deviations data SUPPDV

`QS` *Questionnaires Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
QSSEQ	Sequence Number
QSTEST	Questionnaires Test Name
QSCAT	Category for Questionnaires
QSORRES	Results or Findings in Original Units
QSORRESU	Original Units
VISITNUM	Visit Number
VISIT	Visit Name
QSDY	Study Day of Finding

Questionnaires Domain *Questionnaires Domain*

Description

The Questionnaires data of an ImmPort study is reformated to the CDISC SDTM Questionnaires (QS) domain model, and is a list of 2 data frames containing 1) Questionnaires data QS and 2) any supplemental Questionnaires data SUPP

RImmPort *RImmPort: Enabling ready-for-analysis immunology research data*

Description

The 'RImmPort' package simplifies access to ImmPort data for analysis, as the name implies, in the R statistical environment. It provides a standards-based interface to the ImmPort study data that is in a proprietary format.

serialzeStudyData *Serialize the Study Data*

Description

Load specific studies from the database and save it in .rds format in a local file directory

Usage

```
serialzeStudyData(study_ids, data_dir)
```

Arguments

study_ids	List of study indentifiers
data_dir	Path to a file folder where the .rds study files will be saved into

Value

List of study indentifiers that were serialized successfully

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
# the folder where the .rds files will be stored
rds_dir <- file.path(studies_dir, "Rds")
study_ids <- c('SDY139', 'SDY208')
serialzeStudyData(study_ids, rds_dir)
```

`setImmPortDataSource` *Set ImmPort data ource*

Description

The function `setImmPortDataSource` sets the data source variable in RImmPort environment, to the connection handle to the MySQL or SQLite database, or to the file directory where the pre-created RImmPort-formatted files are stored.

Usage

```
setImmPortDataSource(data_src)
```

Arguments

`data_src`	A connection handle to ImmPort (MySQL or SQLite) database instance or a directory handle to folder where study RImmPort-formatted (.rds) files located

Value

1 if successful

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
```

Skin Response Domain *Skin Response Domain*

Description

The Skin Response data of an ImmPort study is reformated to the CDISC SDTM Skin Response (SR) domain model, and is a list of 2 data frames containing 1) Skin Response data SR and 2) any supplemental Skin Response data SUPP

SpecialPurpose-class *Special Purpose class*

Description

Special Purpose class

Fields

dm_l Demographics data DM and supplemental Demographics data SUPP

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
sdy139 <- getStudy("SDY139")
dm_df <- sdy139$special_purpose$dm_l$dm_df
```

SR *Skin Response Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
SRSEQ	Sequence Number
SRTEST	Skin Response Test or Examination Name
SROBJ	Object of the Observation

SRCAT	Category for Test
SRORRES	Results or Findings in Original Units
SRORRESU	Original Units
SRLOC	Location used for Measurement
VISITNUM	Visit Number
VISIT	Visit Name
SRDY	Study Day of Visit/Collection/Exam

`Study-class` *Study class*

Description

Study class

Fields

`special_purpose` SpecialPurpose

`interventions` Interventions

`events` Events

`findings` Findings

`trial_design` TrialDesign

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
sdy139 <- getStudy("SDY139")
```

SU *Substance Use Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
SUSEQ	Sequence Number
SUTRT	Reported Name of Substance
SUCAT	Category of Substance Use
SUDOSE	Substance Use Consumption
SUDOSTXT	Substance Use Consumption Text
SUDOSU	Consumption Units
SUDOSFRQ	Use Frequency per Interval
SUROUTE	Route of Administration
SUSTDTC	Start Date/Time of Substance Use
SUENDTC	End Date/Time of Substance Use
SUSTDY	Study Day of Start of Substance Use
SUENDY	Study Day of End of Substance Use

`Subject Visits Domain` *Subject Visits Domain*

Description

Actual subject visits data of an ImmPort study is reformated to the CDISC SDTM Subject Visits (SV) domain model, and is a list of 2 data frames containing 1) Subject Visits data SV and 2) any supplemental Subject Visits data SUPP

`Substance Use Domain` *Substance Use Domain*

Description

The Substance Use data of an ImmPort study is reformated to the CDISC SDTM Substance Use (SU) domain model, and is a list of 2 data frames containing 1) Substance Use data SU and 2) any supplemental Substance Use data SUPP

SUPP *Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

SUPPDV *Protocol Deviations Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
DVRELAE	Is Deviation Related to an Adverse Event?
DVREASON	Reason for Deviation
DVRESOL	Resulotion of Deviation
DVCONT	Did Subject continued in Study?

DVSTDY	Study Day of Start of Deviation
DVENDY	Study Day of End of Deviation

SUPPFA *Findings About Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
FASEQ	Sequence Number
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
FATOD	Time of Day of Collection

SUPPLB *Laboratory Test Results Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label

QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
LBSPECSB	Specimen Subtype
VISITMIN	Planned Visit Minimum Start Day
VISITMAX	Planned Visit Maximum Start Day

SUPPMH *Medical History Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
MHSEQ	Sequence Number
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
MHAGE	Age at Onset
MHAGEU	Age at Onset Units
MHTOD	Time of Day

SUPPPE *Physical Examination Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
PESEQ	Sequence Number
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
PETOD	Time of Day

SUPPPF *Genetics Findings Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
PFPOPAR	Geographic Area of the Population
PFSPECSB	Specimen Subtype
PFREFIDP	Source Specimen Identifier
VISITMIN	Planned Visit Minimum Start Day
VISITMAX	Planned Visit Maximum Start Day
PFSPTRT	Specimen Treatment
PFTRTAMV	Specimen Treatment Amount Value
PFTRTAMU	Specimen Treatment Amount Unit
PFTRTDUV	Specimen Treatment Duration Value
PFTRTDUU	Specimen Treatment Duration Unit
PFTRTTMV	Specimen Treatment Temperature Value
PFTRTTMU	Specimen Treatment Temperature Unit

SUPPVS *Vital Signs Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
VSSEQ	Sequence Number
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
VSTOD	Time of Day

SUPPZA *Protein Quantification Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
ZAMFI	MFI
ZAMFICRD	MFI Coordinate
ZASPECSB	Specimen Subtype
ZAREFIDP	Source Specimen Identifier
VISITMIN	Planned Visit Minimum Start Day
VISITMAX	Planned Visit Maximum Start Day
ZASPTRT	Specimen Treatment
ZATRTAMV	Specimen Treatment Amount Value
ZATRTAMU	Specimen Treatment Amount Unit
ZATRTDUV	Specimen Treatment Duration Value
ZATRTDUU	Specimen Treatment Duration Unit
ZATRTTMV	Specimen Treatment Temperature Value
ZATRTTMU	Specimen Treatment Temperature Unit

SUPPZB *Cellular Quantification Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
ZBSPECSB	Specimen Subtype
ZBREFIDP	Source Specimen Identifier
ZBFCF	Control Files Names
VISITMIN	Planned Visit Minimum Start Day
VISITMAX	Planned Visit Maximum Start Day
ZBSPTRT	Specimen Treatment
ZBTRTAMV	Specimen Treatment Amount Value
ZBTRTAMU	Specimen Treatment Amount Unit
ZBTRTDUV	Specimen Treatment Duration Value
ZBTRTDUU	Specimen Treatment Duration Unit
ZBTRTTMV	Specimen Treatment Temperature Value
ZBTRTTMU	Specimen Treatment Temperature Unit

SUPPZC *Nucleic Acid Quantification Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label

QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
ZCSPECSB	Specimen Subtype
ZCREFIDP	Source Specimen Identifier
VISITMIN	Planned Visit Minimum Start Day
VISITMAX	Planned Visit Maximum Start Day
ZCSPTRT	Specimen Treatment
ZCTRTAMV	Specimen Treatment Amount Value
ZCTRTAMU	Specimen Treatment Amount Unit
ZCTRTDUV	Specimen Treatment Duration Value
ZCTRTDUU	Specimen Treatment Duration Unit
ZCTRTTMV	Specimen Treatment Temperature Value
ZCTRTTMU	Specimen Treatment Temperature Unit

SUPPZD *Titer Assay Results Domain Supplemental Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
RDOMAIN	Related Domain Abbreviation
USUBJID	Unique Subject Identifier
IDVAR	Identifying Variable
IDVARVAL	Identifying Variable Value
QNAM	Qualifier Variable Name
QLABEL	Qualifier Variable Label
QVAL	Data Value

Note

The following table enumerates the values in QNAM and QLABEL variables

QNAM	QLABEL
ZDSPECSB	Specimen Subtype
ZDREFIDP	Source Specimen Identifier

VISITMIN	Planned Visit Minimum Start Day
VISITMAX	Planned Visit Maximum Start Day
ZDSPTRT	Specimen Treatment
ZDTRTAMV	Specimen Treatment Amount Value
ZDTRTAMU	Specimen Treatment Amount Unit
ZDTRTDUV	Specimen Treatment Duration Value
ZDTRTDUU	Specimen Treatment Duration Unit
ZDTRTTMV	Specimen Treatment Temperature Value
ZDTRTTMU	Specimen Treatment Temperature Unit

SV *Subject Visits Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
VISITNUM	Visit Number
VISIT	Visit Name
SVSTDY	Study Day of Start of Visit

TA *Trial Arms Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
ARMCD	Planned Arm Code
ARM	Name of Planned Arm
ARMDESC	Description of Planned Arm
ARMRULE	Population Selection Rule

TI *Trial Inclusion Exclusion Criteria Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
IETEST	Inclusion/Exclusion Criterion
IECAT	Inclusion/Exclusion Category

Titer Assay Results Domain
Titer Assay Results Domain

Description

The ImmPort study data generated from assays of types: HAI and Neut Ab Titer are grouped into the Titer Assay Results Domain. The data is reformated to a custom Titer Assay Results domain model in CDISC SDTM standards, and is a list of 2 data frames containing 1) Titer Assay Results data ZD and 2) any supplemental Titer Assay Results data SUPP

Trial Arms Domain *Trial Arms Domain*

Description

The Trial Arms data of an ImmPort study is reformated to the CDISC SDTM Trial Arms (TA) domain model, and is a list of 2 data frames containing 1) Trial Arms data TA and 2) any supplemental Trial Arms data SUPP

Trial Inclusion Exclusion Criteria Domain
Trial Inclusion Exclusion Criteria Domain

Description

The Trial Inclusion Exclusion Criteria data of an ImmPort study is reformated to the CDISC SDTM Trial Inclusion Exclusion Criteria (TI) domain model, and is a list of 2 data frames containing 1) Trial Inclusion Exclusion Criteria data TI and 2) any supplemental Trial Inclusion Exclusion Criteria data SUPP

Trial Summary Domain *Trial Summary Domain*

Description

The Trial Summary data of an ImmPort study is reformated to the CDISC SDTM Trial Summary (TS) domain model, and is a list of 2 data frames containing 1) Trial Summary data TS and 2) any supplemental Trial Summary data SUPP

Trial Visits Domain *Trial Visits Domain*

Description

Information on the planned visits of an ImmPort study is reformated to the CDISC SDTM Trial Visits (TV) domain model, and is a list of 2 data frames containing 1) Trial Visits data TV and 2) any supplemental Trial Visits data SUPP

TrialDesign-class *Trial Design class*

Description

Trial Design class

Fields

- `ta_l` Trial Arms data TA and supplemental Trial Arms data SUPP
- `tv_l` Trial Visits data TA and supplemental Trial Visits data SUPP
- `ti_l` Trial Inclusion Exclusion Criteria data TI and supplemental Trial Inclusion Exclusion Criteria data SUPP
- `ts_l` Trial Summary data TS and supplemental Trial Summary data SUPP

Examples

```
library(DBI)
library(sqldf)
studies_dir <- system.file("extdata", "ImmPortStudies", package = "RImmPort")
db_dir <- file.path(studies_dir, "Db")
sqlite_conn <- dbConnect(SQLite(), dbname=file.path(db_dir, "ImmPort.sqlite"))
setImmPortDataSource(sqlite_conn)
sdy139 <- getStudy("SDY139")
ts_df <- sdy139$trial_design$ts_l$ts_df
```

TS *Trial Summary Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
TSSEQ	Sequence Number
TSPARMCD	Trial Summary Parameter Short Name
TSPARM	Trial Summary Parameter
TSVAL	Parameter Value

Note

The following table enumerates the values in TSPARMCD and TSPARM variables

TSPARMCD	TSPARM
TITLE	Trial Title
DESCR	Trial Description
INDIC	Trial Indication
TRT	Investigational Therapy or Treatment
HYPOTHS	Trial Hypotheses
SSTDTC	Study Start Date
SENDTC	Study End Date
PLANSUB	Planned Number of Subjects
ACTSUB	Actual Number of Subjects
AGEMAX	Planned Maximum Age of Subjects
AGEMIN	Planned Minimum Age of Subjects
AGEU	Age Units
SEXPOP	Sex of Participants
SPONSOR	Clinical Study Sponsor
PUBRLDAT	Public Release Date
ISTRIAL	Study Type
RESFOCUS	Trial Research Focus

TV *Trial Visits Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
VISITNUM	Visit Number
VISIT	Visit Name
ARMCD	Planned Arm Code
ARM	Name of Planned Arm
TVSTRL	Visit Start Rule
TVENRL	Visit End Rule

Vital Signs Domain *Vital Signs Domain*

Description

The Vital Signs data of an ImmPort study is reformated to the CDISC SDTM Vital Signs (VS) domain model, and is a list of 2 data frames containing 1) Vital Signs data VS and 2) any supplemental Vital Signs data SUPPVS

VS *Vital Signs Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
VSSEQ	Sequence Number
VSTEST	Vital Signs Test Name
VSCAT	Category for Vital Signs
VSORRES	Result or Finding in Original Units
VSORRESU	Original Units
VSLOC	Location of Vital Signs Measurement

VISITNUM	Visit Number
VISIT	Visit Name
VSDY	Study Day of Vital Signs

ZA *Protein Quantification Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
ZASEQ	Sequence Number
ZATEST	Protein Quantification Test Name
ZACAT	Category for Protein Quantification
ZAMETHOD	Measurement Technique
ZAANALYT	Analyte
ZAORRES	Result or Finding in Original Units
ZAORRESU	Original Units
ZASPEC	Specimen Type
VISITNUM	Visit Number
VISIT	Visit Name
ZAELTM	Planned Elapsed Time from Time Point Ref
ZATPTREF	Time Point Reference
ZAREFID	Specimen Identifier
ZAXFN	Raw Data File or Life Science Identifier

ZB *Cellular Quantification Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
ZBSEQ	Sequence Number

ZBTEST	Cellular Quantification Test Name
ZBCAT	Category for Cellular Quantification
ZBMETHOD	Measurement Technique
ZBPOPDEF	Cell Population Definition
ZBPOPNAM	Cell Population Name
ZBORRES	Result or Finding in Original Units
ZBORRESU	Original Units
ZBBASPOP	Base Parent Population
ZBSPEC	Specimen Type
VISITNUM	Visit Number
VISIT	Visit Name
ZBELTM	Planned Elapsed Time from Time Point Ref
ZBTPTREF	Time Point Reference
ZBREFID	Specimen Identifier
ZBXFN	Raw Data File or Life Science Identifier

ZC *Nucleic Acid Quantification Domain Variables*

Description

Variable Name	**Variable Label**
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
ZCSEQ	Sequence Number
ZCTEST	Nucleic Acid Quantification Test Name
ZCCAT	Category for Nucleic Acid Quantification
ZCMETHOD	Measurement Technique
ZCENTRZD	Entrez Gene ID
ZCGENNAM	Gene Name
ZCGENSYM	Gene Symbol
ZCORRES	Result or Finding in Original Units
ZCORRESU	Original Units
ZCSPEC	Specimen Type
ZCREFID	Specimen Identifier
VISITNUM	Visit Number
VISIT	Visit Name
ZCELTM	Planned Elapsed Time from Time Point Ref
ZCTPTREF	Time Point Reference

ZD *Titer Assay Results Domain Variables*

Description

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
ZDSEQ	Sequence Number
ZDTEST	Titer Assay Results Test Name
ZDCAT	Category for Titer Assay Results
ZDMETHOD	Measurement Technique
ZDSTRAIN	Virus Strain
ZDORRES	Result or Finding in Original Units
ZDORRESU	Original Units
ZDSPEC	Specimen Type
ZDREFID	Specimen Identifier
VISITNUM	Visit Number
VISIT	Visit Name
ZDELTM	Planned Elapsed Time from Time Point Ref
ZDTPTREF	Time Point Reference
ZDXFN	Raw Data File or Life Science Identifier

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