# vigicaen: : CHEAT SHEET

Optionally, set local paths to files as R objects

```
path_main  <- '/your/path/to/vigibase/main/'
path_sub   <- '/your/path/to/vigibase/sub/'
path_who   <- '/your/path/to/vigibase/who/'
path_meddra <- '/your/path/to/meddra/'
```

## Build Tables

Do it **once** per database version

To get started, you will need Vigibase ECL and MedDRA licenses.

*! Remember to unzip source files.*

**VigiBase and WHO Drug tables**


**tb_vigibase**(path_main, path_sub)
**tb_who**(path_who)

**MedDRA tables**


**tb_meddra**(path_meddra)

## Load and assign Tables

Do it **every time** you work on VigiBase®

```
demo  <- dt_parquet(path_main, 'demo')
drug  <- dt_parquet(path_main, 'drug')
(same for adr, link, out, srce, suspdup)
mp    <- dt_parquet(path_who, 'mp')
(same for thg)
meddra <- dt_parquet(path_meddra,
                     'meddra_hierarchy')
smq_list <- dt_parquet(path_meddra, 'smq_list')
smq_content <- dt_parquet(path_meddra,
                          'smq_content')
```

*Hint: Leave tables OUT of memory with arg in_memory = FALSE*

## Set up dictionary

Create named **lists** for drugs and adverse drug reactions (adrs).

**drug** list

```
d_sel <-
 list(analgesics = c('paracetamol',  'tramadol'))
a_sel <-
 list(hepatitis = c('Hepatitis'))
```

**adr** list — Both are **named** lists

*With Standardized MedDRA queries*

```
smq_sel <-
 list(ihd = c('Ischaemic heart disease (SMQ)'))
```

*With Anatomical and Therapeutical Classes (ATC)*

```
atc_sel <- list(cardiac_drugs = c('C01'))
```

*Syntax for multiple drugs or adrs is the same*

```
a_sel_many <-
 list(analgesics = c('paracetamol',  'tramadol'),
      nivolumab = 'nivolumab',
      ici = c('nivolumab', 'ipilimumab'))
```

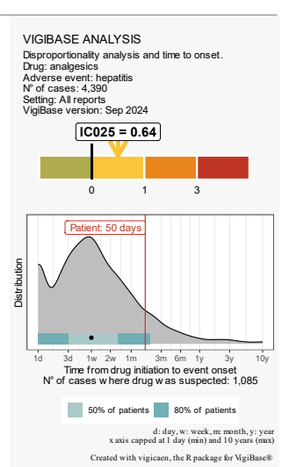
PV Routine

## Plot graph

You must use lists with a single item for drugs and adrs – like d_drecno and a_llt here.

```
vigi_routine(
  demo, drug, adr, link,
  d_code = d_drecno,
  a_code = a_llt,
  case_tto = 50,
  vigibase_version = 'Sep 2024')
```

*Export with export_to = 'graph.svg'*




## Collect IDs

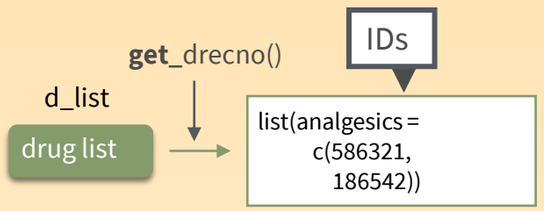
IDs

Ids are numbers that identify drugs and adrs

| ID | Description |
|---|---|
| DrecNo | Drug Record Number, a single drug |
| LLT | Low level term ID of an adr |

*(also MedicinalProd_Id, see ?get_atc_code)*

**get_*** functions collect IDs




DrecNo

```
d_drecno     <- get_drecno(d_sel , mp)
d_drecno_atc <- get_atc_code(atc_sel, mp, thg)
```

LLT

```
a_llt <- get_llt_soc(a_sel, term_level = 'pt',
                     meddra)

a_llt_smq <- get_llt_smq(smq_sel,
    smq_list     = smq_list,
    smq_content = smq_content)
```

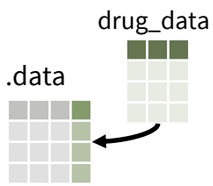

PV Advanced

## Add drug & adr columns

Once you've collected drugs and adrs **IDs**, Add columns to the desired dataset

| Table | Purpose |
|---|---|
| **demo** | Study drugs and adrs at CASE level |
| **drug** | Screen co-reported drugs |
| **adr** | Study adrs outcome |
| **link** | Study at DRUG-ADR PAIR level |

**Add drugs**

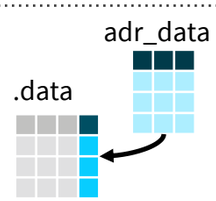



```
demo <-
 add_drug(demo, d_drecno, drug_data = drug)
```

*Arg repbasis to select suspected ('s'), concomitant ('c') and/or interacting ('i') drugs*

```
demo <-
 add_drug(demo, d_drecno_atc, drug_data = drug)
```

**Add adrs**




```
demo <-
 add_adr(demo, a_llt, adr_data = adr)
```

*Replace demo by other tables… link <- add_drug(link…)*

**Check data management**

Wrapper around sum(.x == 1)

**check_dm**(demo, c('analgesics', 'hepatitis'))

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PV Advanced

## Disproportionality

**Univariate Reporting Odds-Ratio and Information Component (IC)**

```
compute_dispro(
  demo, 'hepatitis', 'analgesics')
```

**Multivariate Reporting Odds-Ratio**

```
mod <- glm(hepatitis ~ analgesics + AgeGroup +
Gender, family = 'binomial', data = demo)
summary(mod)$coefficients |>
compute_or_mod(
  estimate = Estimate, std_er = Std..Error)
```

*Hint: be sure to clean AgeGroup and Gender variables before using them*

**Interactions**

```
compute_interaction(
  demo, 'hepatitis', 'analgesics', 'cardiac_drugs')
```

## Subset Tables

Create subsets of VigiBase, based on drug or adr IDs, or AgeGroup

**Subset tables**

```
tb_subset(path_main,
  paste0(path_main, 'subset'),
  subset_var = 'age',
  sv_selection = 7)
```

| Age Groups | |
|---|---|
| 1 | 0-28days |
| 2 | 28 days to 23 months |
| 3 | 2 - 11 years |
| 4 | 12 - 17 years |
| 5 | 18 - 44 years |
| 6 | 45 - 64 years |
| 7 | 65 - 74 years |
| 8 | >= 75 years |

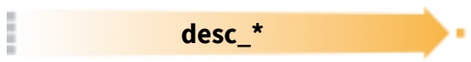
*Subset can be performed on drug or adr* IDs

*Arg subset_var 'drecno' or 'meddra_id'*

PV Advanced

## Description

**desc_*** functions will synthetize data




Use the right table to find your data

| Descriptive variables | Type of analysis | Table |
|---|---|---|
| Drugs, adrs, age, sex | case level | demo |
| Time to onset | drug-adr pair level | link |
| Dechallenge | drug-adr pair level | link |
| Rechallenge | drug-adr pair level | link |
| Adr outcome | adr level | adr |
| Drugs/adrs screening | case level | drug/adr |

**demo table**

**Categorical variables**

```
desc_facvar(demo, vf = c('hepatitis', 'Gender'))
```

Arg format let you change output according to your preference. **n_** is number of cases at this level, **N_** is total number of cases with available data, **pc_** is percentage.
e.g. format = "**n_** out of **N_**, **pc_**%" → "**7** out of **50**, **14**%"

**link table**

```
link <-
  add_drug(link, d_drecno, drug_data = drug) |>
  add_adr(a_llt, adr_data = adr)
```

Remember to add_drug(), add_adr() to link

**Time to onset**


```
desc_tto(link, 'analgesics',
  'hepatitis')
```

**Extract and draw time to onset**

```
ttos <- extract_tto(link,
  'analgesics',
  'hepatitis')
hist(ttos$tto_max)
```

**Dechallenge**




```
desc_dch(link,
  'analgesics',
  'hepatitis')
```

**Rechallenge**


```
desc_rch(link, 'analgesics', 'hepatitis')
```

**adr table**

```
adr <-
  add_drug(adr, d_drecno, drug_data = drug) |>
  add_adr(a_llt, adr_data = adr)
```

Outcome adr → **Outcome?**

```
desc_outcome(adr, 'analgesics', 'hepatitis')
```

## Screen most reported drugs & adrs

Identify top reported drugs/adrs (counting *cases*).

**screen_drug**(drug, mp, 0.10)

**screen_adr**(adr, meddra, 'hlgt', 0.10)

## Built-in data

**Datasets**

You can test the package with built-in datasets

Add "_" to any of demo, adr, drug, link, srce, out, link, mp, thg, meddra, smq_list, smq_content, to use the example table

```
demo <- demo_
drug  <- drug_
…
```

name + '_'

CeCILL 2.1 Charles Dolladille• cdolladille@hotmail.com • github.com/cdolladille • Learn more on GitHub • package version 0.15.1 • Updated: 2025-02