INTEGRATE
INTEGRATING EURESIST DATA BASE
WITH INTEGRASE RESISTANCE DATA
FOR OPTIMIZED ANTIRETROVIRAL TREATMENT

euresist network

INTEGRATE

STANDARD DATUM

for collection of INSTI treatment and resistance information

The Standard Datum, i.e. the set of information building the case record for the INTEGRATE project includes mandatory and optional, but highly recommended, information.

Mandatory fields are necessary for reimbursement: following administrative agreement with the INTEGRATE Steering Committee, complete Standard Data (i.e. cases including all mandatory information) will be reimbursed.

Optional information enhances the possibility that the provided data can be used for multiple studies, subject to the INTEGRATE SOPs with authorship rules that include data providers.
In particular this refers to Standard Data that are complete except for integrase sequence.

The description of the Standard Datum is given below in two different ways: condensed and graphical, clarifying the study flowchart and indicating the mandatory and optional information.

We also provide an Excel file for data capture. While we can collect data in any digital format, we strongly recommend to follow the Excel structure to expedite data import into the INTEGRATE database. Please consult with your data manager whenever possible.

Standard Datum for treatment naïve patients:

MANDATORY

- Anonymous Patient ID
- Patient demographics (year of birth, ethnicity, gender, HIV risk group)
- Pre-treatment VL, CD4, and major clinical events, each with dates. Major clinical events are defined as follows:
    - any AIDS event
    - non-AIDS defining cancer (any type, specify) (except hepatocellular carcinoma) (exclude AIDS-defining cancers = cervical carcinoma, non-Hodgkin lymphoma, Kaposi sarcoma, primary brain [or CNS] lymphoma)
    - cardiovascular disorder (myocardial infarction, stroke, non-haemorrhagic stroke, revascularization, arterial stenting, other, unspecified)
    - chronic kidney disease (decreased glomerular filtration rate (GFR) of less than 60 mL/min)
    - liver failure (Child Pugh C) or hepatocellular carcinoma
- Pre-treatment resistance genotype, in the form of FASTA file(s) (protease, reverse transcriptase and integrase*)
- Starting treatment regimen (drugs employed and doses, indication of co-formulations)
- All VL during follow up, with dates
- Date of INSTI and/or companion drug discontinuation and reason for discontinuation or last follow up date if not discontinued.

OPTIONAL but preferable

- All CD4 during follow up (as many as possible, with dates)
- In case of viral load >200 copies/mL after 6 months, viral genotype (protease, reverse transcriptase and integrase in the form of FASTA file(s)), with date with concurrent VL level, with date

(*) In case integrase sequence is not available, otherwise complete Standard Data are still highly valuable for several scientific studies. Data providers will be included in authorship following the INTEGRATE SOPs.

Standard Datum for treatment experienced patients (both InSTI-naïve and InSTI experienced):

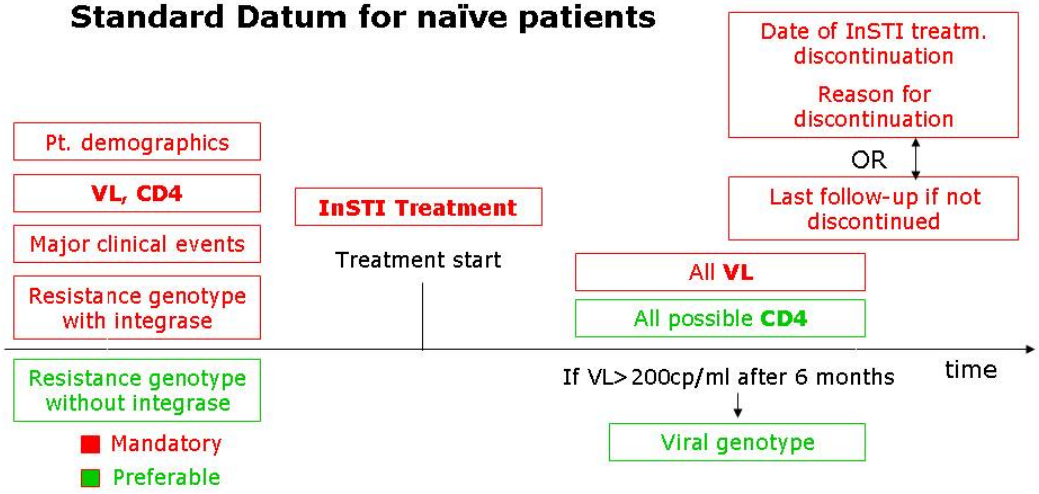
MANDATORY

- All the elements in the Standard datum for treatment naïve patients plus:
- Last treatment regimen
- Previous virological failure under NNRTI, PI, INSTI (each YES/NO) defined as: any HIV-1 RNA >200 copies/mL > 6 months after drug initiation
- previous exposure to individual drugs YES/NO, OR the following (first bullet of optional items):

OPTIONAL but preferable

- Complete treatment history, i.e. treatment regimen with start and stop dates and reason for treatment change (pre-defined choices)
- All the elements in the OPTIONAL Standard datum for treatment naïve patients.

Standard Datum for naïve patients



Standard Datum for experienced patients