

# A cookbook for estimating treatment duration from databases of routinely collected electronic health data participating in multi-source studies

Judit Riera-Arnau<sup>1</sup>, Nicolas H. Thurin<sup>2</sup>, Giuseppe Roberto<sup>3</sup>, Patrick Souverein<sup>4</sup>, Rosa Gini<sup>3</sup>, Romin Pajouheshnia<sup>4</sup>

<sup>1</sup>Clinical Pharmacology Service, Vall d'Hebron Hospital Universitari Hospital, Autonomous University of Barcelona, Spain. <sup>2</sup>Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX, France. <sup>3</sup>Agenzia regionale di sanità della Toscana, Osservatorio di epidemiologia, Florence, Italy. <sup>4</sup>Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University, The Netherlands.

**Introduction.** Different information on prescribed and dispensed medicinal products is captured across electronic health data sources (EHD). The number of days' worth of treatment in a box (NoDT), used to estimate the duration of exposure, is rarely directly captured in EHD. When conducting pharmacoepidemiologic studies with multiple data sources (e.g. cross-national studies), approaches are needed to harmonize calculation of NoDT across data sources.



Incomplete



Heterogenous

Lead to



Challenge in cross-national studies



No one-size-fits-all approach

### Objectives.

1. Identify standard terms that can be used to calculate NoDT across EHD.
2. Develop a cookbook of recipes to combine component information on prescribed/dispensed medicines and harmonize definitions of NoDT.

### Methods.

1. Review of Guidelines of European standard terms for medicines.
2. Generate a core set of standard terms and recipes to create harmonized definitions of NoDT, considering different types of unit of presentation and administrative dose form

**Results.** A core set of variables describing prescribed/dispensed medicines was identified (see Table 1) and applied to two different types of medicinal product.

Three main recipes were created for NoDT calculation on the basis of the variables included in a database (see Table 2)

**Table 1.** Example of a core set of standard terms of medicines and products that can be used to define NoDT.

Variable	Description	TABLETS	SYRUP
person_id	Foreign key. Unique person identifier.	P1	P1
medicinal_product_id	Foreign key. Unique identifier of a specific medicinal product.	6841716	6661079
date_dispensing	Date when the medicinal product was dispensed.	2020-01-09	2020-01-02
date_prescription	Date when the medicinal product was prescribed.	2020-01-01	2020-01-01
disp_number_medicinal_product	Number of dispensed units of medicinal_product_id.	3	2
presc_quantity_per_day	Prescribed quantity of medicinal product to be taken daily.	10	3
presc_quantity_units	Unit of measure of the prescribed daily quantity.	mg	spoons
unit_of_presentation_num	Number of unit of presentation type within a medicinal product.	30	1
subst1_amount_per_form	Quantity of the first active principle of the medicinal product.	10	150
subst1_amount_unit	Unit of measure of the quantity of the first active principle.	MG	ML

**Table 2.** Examples of NoDT estimation for 1 box of Acitretin EFG 30 capsules of 10mg; dd = daily dose (e.g. defined).

Recipe	Recipe formula	Description	Calculation
1 - Prescribed quantity	$\text{disp\_num\_medicinal\_product} * \text{unit\_of\_presentation\_num} / \text{presc\_quantity\_per\_day}$	Number of units of medicinal product dispensed * Number of dosage units within a box / Number of dosage units to be taken daily	$1 * 30 / 2 = 15 \text{ days}$
2 - Substance amount	$\text{disp\_num\_medicinal\_product} * \text{subst\_amount\_per\_form} * \text{unit\_of\_presentation\_num} / \text{dd}$	Number of units of medicinal product dispensed * Quantity of the active principle per dose forms * Number of dose forms within a box / Daily dose (e.g. defined, prescribed, other)	$1 * 10 \text{ (mg)} * 30 / 20 \text{ (mg)} = 15 \text{ days}$
3 - Total substance amount	$\text{disp\_num\_medicinal\_product} * \text{total\_amount\_per\_medicinal\_product} / \text{dd}$	Number of boxes dispensed of medicinal product * Quantity of the active principle per unit of presentation / Daily dose (e.g. defined, prescribed, other)	$1 * 300 \text{ (mg)} / 20 \text{ (mg)} = 15 \text{ days}$ $1 * 300 \text{ (mg)} / 35 \text{ (mg)} = 8.57 \text{ days}$

### Conclusion.

- I) Rich vocabularies are needed to capture information to define exposure across data sources;
- II) Tools are needed to flexibly incorporate the nuances between the meanings of component information in calculations of exposure in multi-datasource studies.

**Future steps:** The standard set of vocabularies and recipes will be applied to and further developed in a study of oral retinoid utilization across 7 EHD from 5 countries (EUPAS31095).