

ATC/DDD system implementation, maintenance and reporting

Project kick-off meeting 21 December 2023

Agenda

1) Introduction of team members

1) Project proposal Recap

1) Strategy for project implementation

- definition members per each of the three project objectives
- meeting schedule

1) Introduction of team members

Chairs of the project proposal:

- Giuseppe Roberto (ARS Toscana, Florence, Italy)
- Mina Tadrous (University of Toronto, Canada)

Project advisor:

- Robert Vander Stichele (University of Ghent, Belgium)

Australia/Asia/Pacific:

- Gillian Caughey

Europe/Africa:

- Rosa Gini, Elisabetta Poluzzi, Ursula Kirchmayer, Robert Vander Stichele, Björn Wettermark, Ilse Truter, Carlos E. Durán, Mikael Hoffmann, Lotte Rasmussen, Hege Blix, Anna Girardi, Giulia Hyeraci

North America:

- Macarius Donneyong

South America:

- Luciane Cruz Lopes, Danielle Santos, Martín Cañas, Juan Roldan, Lysien Ivana Zambrano, Juan Carlos Sánchez Salgado

2) Project proposal Recap

Proposal in Response to 2023 ISPE Call for Manuscripts

1. Title: A cross - country survey and literature review on the implementation, maintenance and reporting of the ATC/DDD methodology

Response expected by the end of this year...

Background

- Linking a national medicinal product dictionary to the most updated ATC/DDD list and to correctly calculate the number of DDD per package is recommended by WHO to be a national responsibility.
- Lack of consistency in the implementation, maintenance of the ATC/DDD system, as well as insufficient transparency of reporting in published studies, can hamper reproducibility of pharmacoepidemiological research
- Divergent ATC/DDD versions, divergent assignment of ATC codes and/or DDDs for combination products and the use of unofficial/national DDDs were already documented as an actual methodological problem when collecting comparable data on drug use across European countries
- The implementation of ISO/CEN standards for global identification of medicinal products, provides an opportunity to facilitate international comparisons and validation of national implementation of the ATC/DDD system

Objectives:

- 1.To collect information on national procedures for the creation and maintenance of national registers with a link between the ATC/DDD index and the National Medicinal Product Dictionary, the corresponding calculated number of DDD per package and their availability in the public domain.
- 1.To describe how pharmacoepidemiologists report on the use ATC/DDD methodology in the published literature.
- 1.To develop recommendations for the design and creation of a prototype online application for the certified calculation of number of DDDs per package

Objective 1 (responsible: Giuseppe)

1) Survey

- Target population:
 - Users of the ATC/DDD systems, including researchers and regulators, reached out through the ISPE DUR SIG, ISPE Regional Interest Groups (RIGs) and EURODURG networks
- Information to be collected:
 - governance and methodology to create and maintain a national register with a link between the ATC/DDD Index and the national Medicinal Product Dictionary, including the calculation of the number of DDDs per package
 - governance and methodology for provisional solutions to missing DDDs
 - timing and availability of updates of the reference ATC/DDD drug registry (e.g., in the public domain, upon payment)
- Target number of respondents:
 - ≥ 30 countries, ≥ 2 countries per continent

Objective 2 (responsible: Mina)

2) Targeted literature review

- Inclusion criteria:
 - Papers published in Pharmacoepidemiology and Drug Safety between 2018 and 2022
 - use of the ATC/DDD methodology to define any of study variables
 - use of provisional solutions for missing DDDs to define their variables
- Data extraction:
 - information reported to describe/identify the reference ATC/DDD drug registry used for the study

Objective 3 (responsible: Rosa)

3) Recommendations on design/creation of a DDD per package calculator

- Sources intended to be leveraged:
 - Previous initiatives and already available resources for the calculation of the number of DDD per package
 - API of the WHO ATC/DDD index website (https://www.whocc.no/atc_ddd_index/), in order to use the most updated release of the ATC/DDD index, and the
 - ISO/CEN standards for global identification of medicinal products for input data format
 - R function CreateDoT for calculation (developed by the IMI-ConcePTION project and available in the public domain <https://github.com/IMI-ConcePTION/CreateDoT/wiki>)

3) Strategy for project implementation

- definition members per each of the three project objectives
- meeting schedule

- Please mark your affiliation to 1 or more of the 3 objectives at this link:

https://docs.google.com/spreadsheets/d/11TvK_mRjqqqyylAl6V7dzIB3bR_034vQgPaFshSNsNJs/edit?usp=sharing

- Is there anybody willing to engage in task leadership?

3) Strategy for project implementation

- definition members per each of the three project objectives
- meeting schedule

Proposed meeting schedule

- **General calls** (all project members): 1 hour / every 2 months

Time slot proposal: Every 8 Thursday starting 15 February

- 5pm CET one meeting
- 8am CET the next meeting

- **Objective-specific calls**: 1 hour / every 4 weeks

Calls will be organized by the Objective lead

Next steps

- 1) Each project member will join at least one task force/objective
- 1) General and objective-specific calls for January/February will be scheduled by the end of the year
- 1) Objective-specific kick-off meeting to be held by mid-January