ADVANCE Proof-of-Concept study (POC):Testing a system for near real-time monitoring of vaccination coverage, benefits and risks in Europe with acellular pertussis vaccines as test case (ADVANCE POC: monitoring)

First published: 02/12/2018

Last updated: 11/12/2018

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26944

EU PAS number

EUPAS26809

Study ID

26944

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

The IMI-ADVANCE project (Accelerated Development of VAccine beNefit-risk Collaboration in Europe project funded by the Innovative Medicines Initiative (IMI)) is a public-private partnership aiming to develop and test a system for rapid B/R assessment and near-real time B/R monitoring of vaccines in the post-market setting using a distributed network of European electronic health record (EU EHR) databases. A set of four proof-of-concept (POC) studies were earlier conducted to assess the feasibility of and to establish processes for generating the required data to perform the B/R assessment of vaccines in Europe. Particularly, these studies assessed the feasibility for generating data for vaccination (1) coverage, (2) benefit and (3) risk, and (4) for synthesizing the obtained evidence using B/R modeling (refs). As test-case for these POC studies, it was assessed if the initial B/R profile of pertussis vaccines was maintained after the switch from whole cell pertussis (wP) vaccines to acellular pertussis (aP) vaccines. The current POC study builds further upon the previous study and assesses the feasibility of obtaining near-real time data from EU EHR databases. The success of near-real time B/R monitoring fully relies on data being timely available, i.e. both frequent up-to-date and small time-lag between the occurrence of the event and it being recorded in the databases. The current study makes use of previously developed methodological work on near-real time and visual monitoring of vaccination coverage, benefits, risks and B/R

using an interactive dashboard, where the developments were based on simulated data. The objectives of the current POC study are therefore twofold: 1. to explore the capacity of EU EHR databases to provide near-real time data and 2. to demonstrate the practical potential of the proposed B/R monitoring methodology using real-world data from various EU EHR databases.

Study status

Ongoing

Research institutions and networks

Institutions

P95 Clinical and Epidemiology Services

- ☐ Belgium
- ☐ Colombia
- ☐ Netherlands
- ☐ South Africa
- ☐ Thailand
- ☐ United States

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Institution | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

Networks

Accelerated development of vaccine benefit-risk collaboration in Europe (ADVANCE)

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kaatje Bollaerts

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/10/2017

Study start date

Planned: 01/03/2018

Actual: 23/03/2018

Data analysis start date
Planned: 04/06/2018

Actual: 03/09/2018

Date of final study report
Planned: 30/01/2019

Sources of funding

- EU institutional research programme

More details on funding

IMI

Study protocol

ADVANCE POC12-Protocol_v2.2_FINAL_amended 160318_signed all_FINAL.pdf
(501.9 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

System testing, testing the ADVANCE system on generating near real-time data on vaccination coverage, benefits and risks.

Main study objective:

The overall objective of the ADVANCE Proof of Concept (POC) studies is to build and test a system (including testing data availability) for benefit-risk monitoring of vaccines in Europe. Specifically, the objective of POC1.2 is to establish the feasibility of continuously and rapidly updating the information on coverage, benefits and risks using electronic healthcare and surveillance databases.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Near real-time monitoring

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07AJ) Pertussis vaccines

Pertussis vaccines

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Estimated number of subjects

200000

Study design details

Data analysis plan

The test case is near real-time (weekly or bi-weekly/monthly, depending on the database) visual monitoring of vaccination coverage, benefits and risks of pertussis vaccination. The monitoring will be facilitated through the use of an interactive dashboard developed based on the POC1 data. The dashboard contains three monitoring tabs with visualizations: - Coverage: number of administered doses per week over calendar time (extrapolated to the population of interest) and vaccination coverage (%) within specific age groups by calendar time- Benefits: observed pertussis incidence in the total population by calendar time- Risks: incidence rates in event specific risk windows and in control periods (out of risk windows) at vaccination eligible ages, separately for each risk outcome by dose, estimated cumulatively over calendar time.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No