

An exploratory pilot study to assess the feasibility of linking real world over-the-counter (OTC) analgesics use through consumer survey data to personal health record (PHR) data (My Medications and Medical Records (MyMMR))

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Study

Planned

Administrative details

EU PAS number

EUPAS50081

Study ID

50082

DARWIN EU® study

No

Study countries

Study description

Capturing over-the-counter (OTC) medication use and health-related outcomes is historically difficult, limiting the ability to generate real-world evidence (RWE) about OTC products since data sources are scarce and disjointed. Recent US regulations regarding individuals' access to their health records along with the broad adoption of smartphones and advances in digital technology hold promise to overcome these challenges. The intent of the pilot study is to determine the feasibility and scalability of using a mobile application (app)-based technology as a means to enable collection/assessments and integration of real world OTC medication usage information and patient reported outcomes (PROs) with health records data (PHR data). The pilot study will enroll a cohort of patients with ongoing acute or chronic (non-cancer) pain in order to serve as a proof-of-concept project to uncover insights into the feasibility of employing such technology across a diverse population. A key goal of the pilot will be to determine how best to capture these types of data in an unobtrusive manner to minimize burden on the study population and to determine the concordance of select PHR data captured via patient-mediation as compared to EHR data extraction via an integrated delivery network (IDN).

Study status

Planned

Research institutions and networks

Institutions

[Sutter Health](#)

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Institution

Contact details

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Primary lead investigator

Yan Sherry

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2023

Actual: 01/11/2022

Study start date

Planned: 07/02/2023

Date of final study report

Planned: 31/08/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson & Johnson, LLC

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Main study objective:

Participant usability of the mobile app within the context of the pilot study

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pain

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

100

Study design details

Outcomes

Concordance between patient-mediated PHR data and EHR-extracted data, Willingness to participate in the pilot study and its procedures for data collection Distribution of entry methods (portal import, pick-list, NDC, or free-text) for medications

Data analysis plan

All study variables will be summarized descriptively. Summary statistics for continuous variables include number of observations, mean, standard deviation, median, minimum, and maximum. Summary statistics for categorical data (dichotomous and polychotomous variables) include counts in the number of missing, and the number of observations, as well as percentages for each level. Concordance will be assessed as the percentage of completeness and accuracy of data elements across select structured data domains/fields comparing patient-mediated PHR data against EHR-extracted data (considered as benchmark)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Subject data entry and Patient mediated portal data

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