# 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))

**First published:** 01/02/2023

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Study Planned

## Administrative details

**EU PAS number**

EUPAS50081

**Study ID**

50082

**DARWIN EU® study**

No

**Study countries**

United States

**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

### Study institution contact

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Study contact

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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

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**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)

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**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

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**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