

# Creating a Repository for the Assessment of Tobacco-Related Behavioral Outcomes: A Case Example

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## Introduction and Objectives

- To systematize the use of measurement instruments assessing behavioral outcomes to study tobacco- and nicotine-containing products (TNP), the Philip Morris International (PMI) Behavioral Science team has launched the development of a specific Repository with the support of Mapi Research Trust (MRT).
- The goals of the Repository are :
  - ✓ To assess, select, store, and use up-to-date and official versions (original and translations) of instruments in a standardized environment as well as to facilitate the consultation of related documentation (e.g., publications or scoring).
  - ✓ To harmonize the use of these instruments among all PMI researchers by transferring them to the study operation teams during the study set-up phase.
  - ✓ To list and keep track of all studies using these instruments, allowing a global view of ongoing researches.
- This poster presents the development and implementation of such a knowledge base since June 2016.

## Methods

### Development Process (2016)

#### Structure

To enable optimal management and use of the instruments, MRT developed the Repository by establishing a structure in two folders interacting with each other: one instrument-related folder, and one focusing on the studies.

- The instrument folder**, in which each available instrument is listed and stored, enables access, selection, and update of the original instruments, their study-specific versions, the translations and their certificates, and related metadata. The information available about each instrument is modeled on the structure of the Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID™). PROQOLID™ was developed by MRT in 2002 to provide healthcare researchers with an accurate, up-to-date, and centralized source of information on Clinical Outcome Assessments (Emery et al. HQLQ 2005 3:12). As such, it offers access to 16 categories of information for each instrument (e.g., name of authors/developers, condition of use and copyright notice, objective of the instrument, measurement properties, original language of development, translations, characteristics (concept of interest, number of items, population of intended use, recall period, time of completion, administration mode), domains covered, scoring instructions, and content validity documentation).
- The study folder** compiles PMI-sponsored studies, using instruments measuring tobacco-related behavioral outcomes. Each study, identified by its protocol number, provides information with respect to the study manager and the study's start date and end date.

#### Maintenance rules

- The Repository is dedicated for internal use among PMI researchers (i.e., the Behavioral Science team and the study operation teams). It is maintained and updated by MRT and by PMI's Behavioral Science team. Two levels of accounts were developed:
  - The **administrator account** is controlled by the Behavioral Science team researchers and enables the update of the studies' and instruments' metadata and the management of the members' accounts.
  - The **member account** allows PMI researchers to view the metadata and access to the instruments, versions, and certificates.
- The PMI Repository is hosted on the **ePROVIDE™** platform.

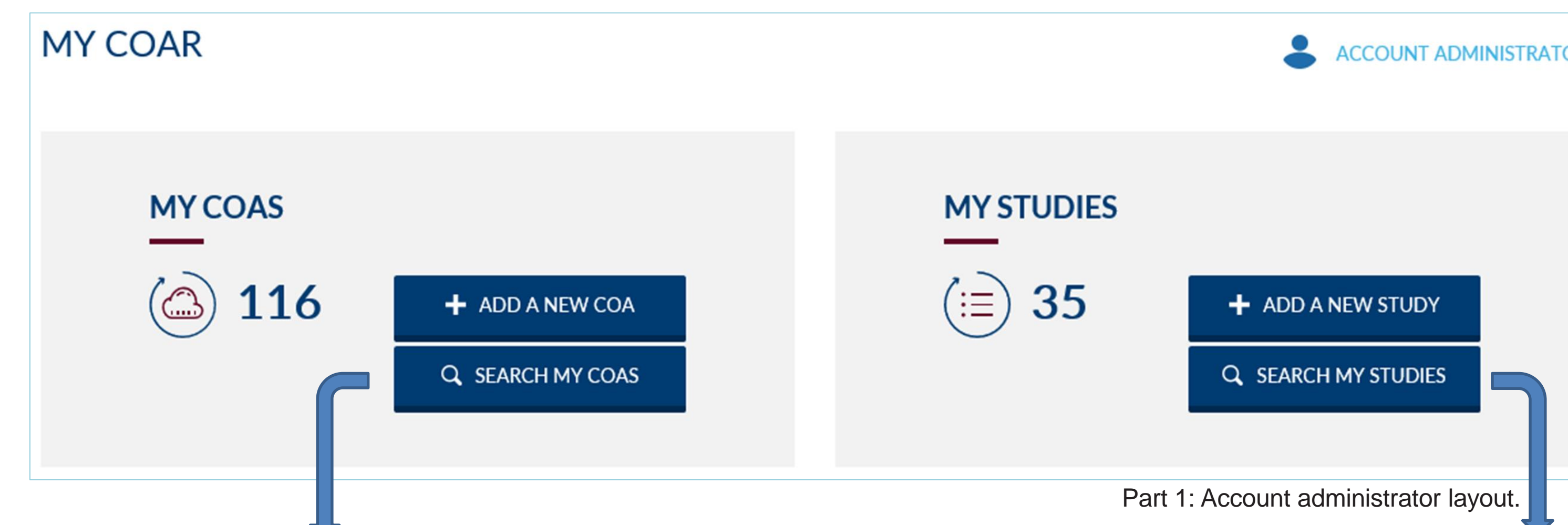
### Review (Dec 2018)

- The Repository was searched to provide an overview of its content, characteristics, and properties two years after its development.
- The collaborative processes between parties (MRT, the Behavioral Science team, and the study operation teams) were also reviewed to describe their interaction with the tool and its use.

## Results

- To date, the Repository includes **116 measurement instruments** in the instrument folder and **35 studies** in the study folder (Part 1).
- About two-thirds of the available instruments focus on tobacco behavior. The table in Part 2 presents a selection of available instruments, which are sorted by related concepts of interest.
- A directory is available for each instrument, in which all available versions are listed. Under each version, researchers can find the original-language instrument in MS Word and PDF formats and its available translations as well as the certificate of translation describing the linguistic validation method performed (Part 3). If the instrument is used in a specific study, the study protocol number appears.
- On the study folder side, Part 4 shows the layout of a study. For each study, a drop-down menu enables access to a list of all of the instruments used in the study. Access to each instrument is also possible from this localization (Part 5).

### The Repository Structure



Instrument	Concepts
Lifestyle Questionnaire	Behavioral functioning
Smoking Questionnaire	History of product use
ABOUT™-Dependence	Nicotine dependence
FTND	Nicotine dependence
ABOUT™-Perceived Risk	Perceived risk
PROMIS® Toolkit	E.g., positive expectancies
<b>ABOUT™-Product Experience</b>	Product experience
Product Use Questionnaire	Product use e-diary
QSU-Brief	Psychological functioning
Euroqol EQ-5D	Quality of life
Cough Assessment	Respiratory symptoms
Sensory Questionnaire	Sensory effects

### Cross-Sectional Survey To Assess Tobacco Use Prevalence And Patterns Of Tobacco Product Use In The Japanese Population

DESCRIPTION

STUDY PROTOCOL NUMBER: P1-PMX-01-JP  
START DATE: 05-Dec-2016

STUDY MANAGER: Oliver Brown  
END DATE: 27-Sep-2019

Last update: November 2018

Part 4: Study description.

ABOUT-PRODUCT EXPERIENCE\_(P3P)\_TS1.0

+ ADD A TRANSLATION HIDE DETAILS

File name	Date	Language	Original	Format	Type of device	Study protocol number	Download
ABOUT-Product Experience_(P3P)_TS1.0_eng-USori	31-Oct-2018	English for the USA	✓	Paper			File 1 File 2
ABOUT-Product Experience_(P3P)_TS1.0_rus-RU	05-Oct-2018	Russian for Russia		Paper		P3P-SE-02-RU	File 1 File 2 Certificate

Part 3: An instrument's version and available translation.

COAS USED

ON-GOING

SELECT COA

The study uses the following questionnaires

(Clinical) Product Use Questionnaire SEE MORE

Cough Assessment SEE MORE

FTND SEE MORE

Part 5: Instruments used in the study.

### Interactions Between Teams

- To integrate or use an instrument within the catalogue of the Repository, a back-and-forth process takes place between MRT, PMI's Behavioral Science team, and the study operation teams:
  - PMI (behavioral or operation) selects an instrument per their study needs.
  - MRT searches for copyright clearance and authorization for translation and modification if required.
  - MRT creates the instrument entry and the categories in the Repository.
  - PMI (behavioral) formats the original-language instrument per the right template.
  - PMI (behavioral) uploads the original-language instrument in the Repository.
  - MRT uploads the translations and certificates in the Repository.
  - PMI (behavioral) links the instrument to the corresponding studies.
  - PMI (operation) uses the right instruments (original or translations).

### PMI Instruments

In the context of a current need for valid and reliable measurement instruments designed to assess consumer responses to modified risk tobacco products, PMI has developed the **ABOUT™ Toolbox** (Assessment of Behavioral Outcomes related to Tobacco and nicotine products), currently comprising five measurement instruments, and covering high-priority tobacco-related domains :

- The **ABOUT™-Perceived Risk** assesses risk perception.
- The **ABOUT™-Use History** assesses frequency and intensity of current and past TNP use behavior, initiation, and cessation.
- The **ABOUT™-Product Experience** encompasses a range of self-reported expressions of an individual's experience using a TNP, including satisfaction, psychological reward, and craving.
- The **ABOUT™-Dependence** assesses nicotine dependence.
- The **ABOUT™-Health and Functioning**, currently in development, will accurately reflect the health and functioning status of individuals who use TNPs, with a particular focus on healthy adult smokers who switch to MRTPs.

The **ABOUT™ Toolbox** instruments, catalogued in the Repository, will be available to the scientific community through PROQOLID™ and will be freely available for non-commercial use.



## Discussion/Conclusions

- At an internal level, communication and collaboration between involved team members (behavioral and study operation) is greatly facilitated at various stages of study implementation.
- Through the Repository, researchers are able to :
  - ✓ View frequently used measurement instruments in one single location
  - ✓ Easily compare available versions of an instrument
  - ✓ Keep track of the history of modifications of an instrument
  - ✓ Update an instrument's version
  - ✓ Directly access available translations
  - ✓ Localize certificates of translations
- The access to regularly used instruments is centralized, allowing an optimization of their management in addition to a user-friendly and global view of instruments. Selection and distribution of the measurement instruments to the study operation teams are greatly improved in terms of time saved and quality.

To conclude, the Repository is a unique initiative that enables PMI researchers :

- To assess, select, and use up-to-date and official versions (original and translations) of instruments in a standardized environment and to transfer them to the study operation teams during the study set-up phase.
- To share their own instruments (i.e., the **ABOUT™ Toolbox**) with other researchers through PROQOLID™.