A novel repository for consumer-reported outcome measures in tobacco research: Development, implementation, and evolution from 2016 to date

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Introduction and Objectives

- The Behavioral Science team of Philip Morris International (PMI) has launched the development of a specific knowledge-base Repository with the support of Mapi Research Trust (MRT) to systematize the use of self-reported measures for assessing behavioral outcomes related to tobacco- and nicotine-containing products (TNP) in the context of PMI studies.

- The Repository enables:
  - ✓ To identify, select, and store self-reported measures used for assessing tobacco-related consumer outcomes
  - ✓ To consult primordial information related to the measure of interest (e.g., concept of interest, number of items, and scoring)
  - ✓ To localize measures used in past and on-going in-house studies
  - ✓ To harmonize the use of these measures across PMI studies during the set-up phase.

- This paper presents
  1. The development and implementation of the Repository
  2. The evolution of its content and functionalities from its implementation to date.

Methods

Development (June 2016): Repository structure

- To enable optimal management and use of the self-reported measures, MRT developed the Repository by establishing a structure in two folders interacting with each other: **an instrument-related folder**, in which available self-reported measures are listed and stored, and **another focusing on studies**.

Review (April 2019)

- The Repository was searched to conduct a comparison between its initial implementation and actual content.
- Internal reports, Quality Checks, and meeting minutes were searched to identify new functionalities implemented in the Repository from its development until April 2019.

Results

Development/Structure

- **The instrument folder** enables access, selection, and update of the original measures, their study-specific versions, the translations and their certificates, and related metadata. The information available about each measure is modeled on the structure of PROQOLID™, the Patient-Reported Outcome and Quality of Life Instruments Database. PROQOLID™ was developed in 2002 by MRT to provide healthcare researchers with an accurate, up-to-date, and centralized source of information on Clinical Outcome Assessments (COA) (Emery et al. HQLO 2005 3:12). As such, it offers access to 16 categories of information for each instrument, including the name of authors/developers, condition of use, 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, and administration mode), domains covered, scoring instructions, and content-validity documentation.

- **The study folder** compiles PMI-sponsored studies by using measures that assess tobacco-related behavioral outcomes. Each study, identified by its protocol number, provides information with respect to the study manager and start and end dates of the study.

- The PMI Repository is hosted on the ePROVIDE™ platform.

Results

Content Evolution

The first Quality Check took place in April 2017:

- The instrument folder comprised **58 measures**, with 44 focusing on tobacco behavior (76%).
- The remaining 14 measures focused on health-related quality of life (HRQL) (n=3), health status (n=7), other substance addiction (n=2), or demographics (n=2).
- The study folder comprised **6 studies**.

The latest Quality Check took place in April 2019:

- The instrument folder comprised **113 measures**, with 66 focusing on tobacco behavior (58%).
- The remaining 47 measures focused on HRQL (n=4), health status (n=12), other substance addiction (n=2), demographics (n=2), mental health (n=9), physical functioning (n=5), social functioning (n=10), or others (n=3).
- The study folder comprised **35 studies**.

The pie charts in Figure 1 and Figure 2 illustrate the domains covered by the instrument-folder content of the Repository and allow visual comparison between April 2017 and April 2019.

Self-reported measures focusing on tobacco behavior are classified into three main categories according to the taxonomy developed by CORESTA's Consumer Reported Outcome Measures (CROM) Consortium: **response to product** (e.g., craving and dependence), **product perception** (e.g., risk perception and intention to use) **and product-use behavior** (e.g., product-use pattern and history of use).
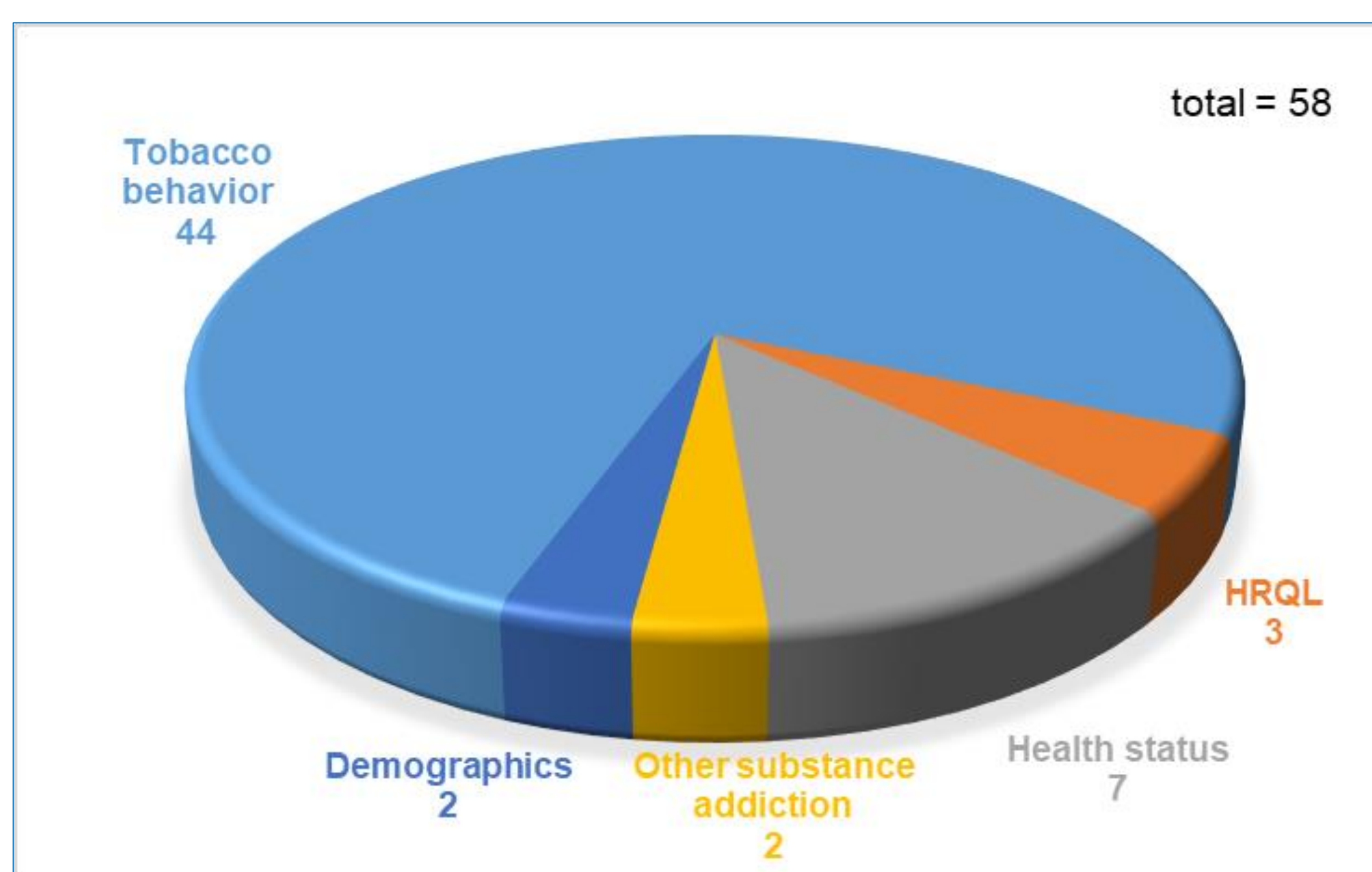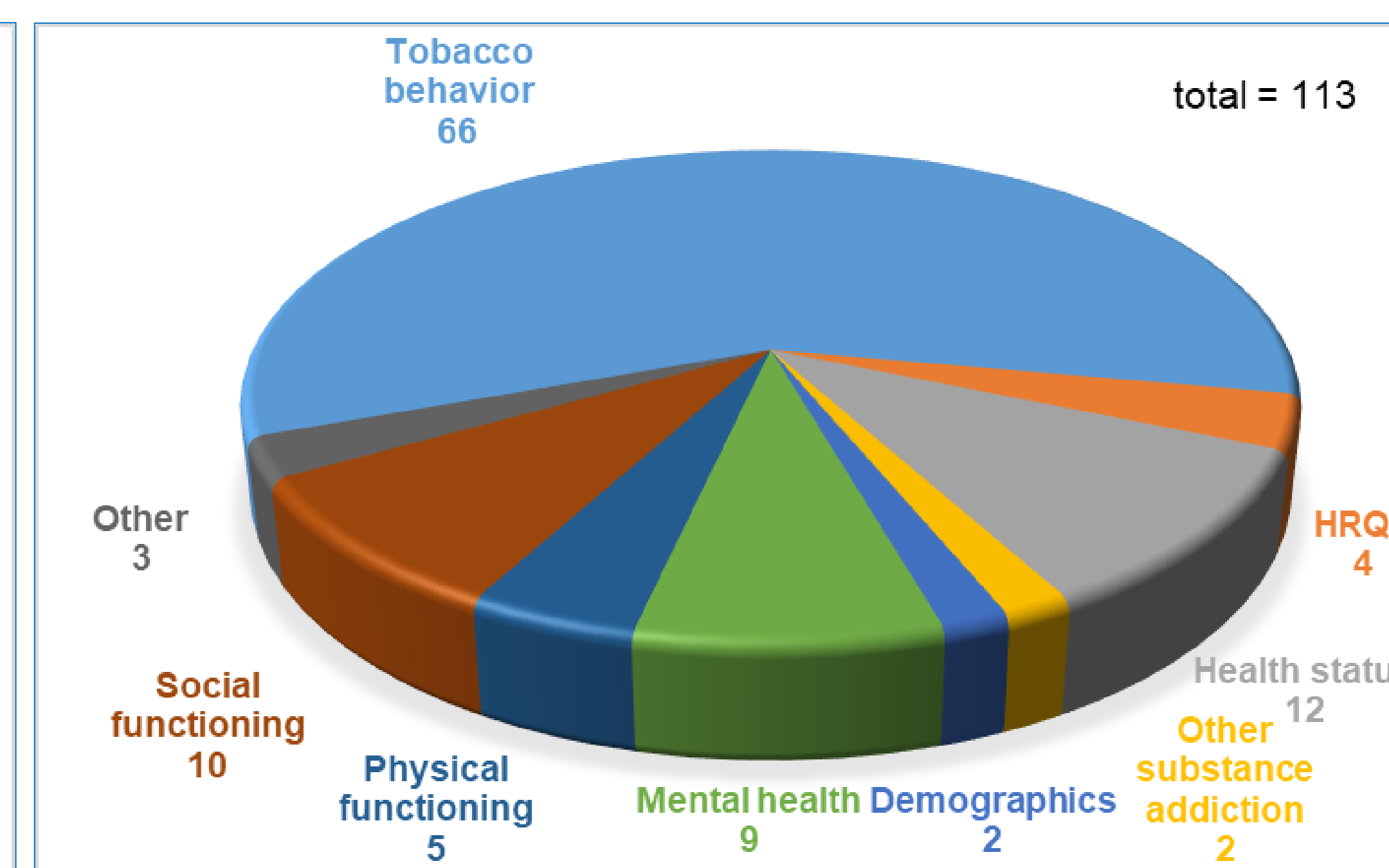

Fig. 1: Repository Content in April 2017

Fig. 2: Repository Content in April 2019

Functionality Evolution

The repository was delivered to PMI in June 2016 with two levels of accounts: administrator and member accounts.

The administrator account, granted to the Behavioral Science team researchers managing the Repository, allows to create instrument folders in the Repository; upload and manage related instrument versions, translations, and translation documentation (such as validation reports and certificates); add studies and their descriptions to the Repository; and update instrument-related information.

New implementations (2016–2019)

Three functionalities intrinsic to the Repository have been implemented:

1. In September 2016, the possibility for administrators to **add new measures, versions, and related documents** as well as licensing information was implemented, allowing more flexibility in instrument management.

2. In May 2017, **automatic alerts for instrument/metadata updates** were sent to administrators by email, ensuring rapid quality check of recent modifications in the Repository.

3. In March 2019, a **full-text search functionality** was implemented in the Repository, enabling users to type a keyword or sentence in the search bar to find catalogued measure(s) in which the keyword/sentence appears, allowing rapid and efficient search and retrieval of existing items. Figure 3 provides an example of this functionality.

One functionality linked to the distribution agreement with MRT:

1. In March 2018, **statistics on external licensing requests** regarding the instruments developed by PMI were made available to administrators, allowing an overview of the country of origin, type of request (e.g., academic, industry, or public health), and request status.
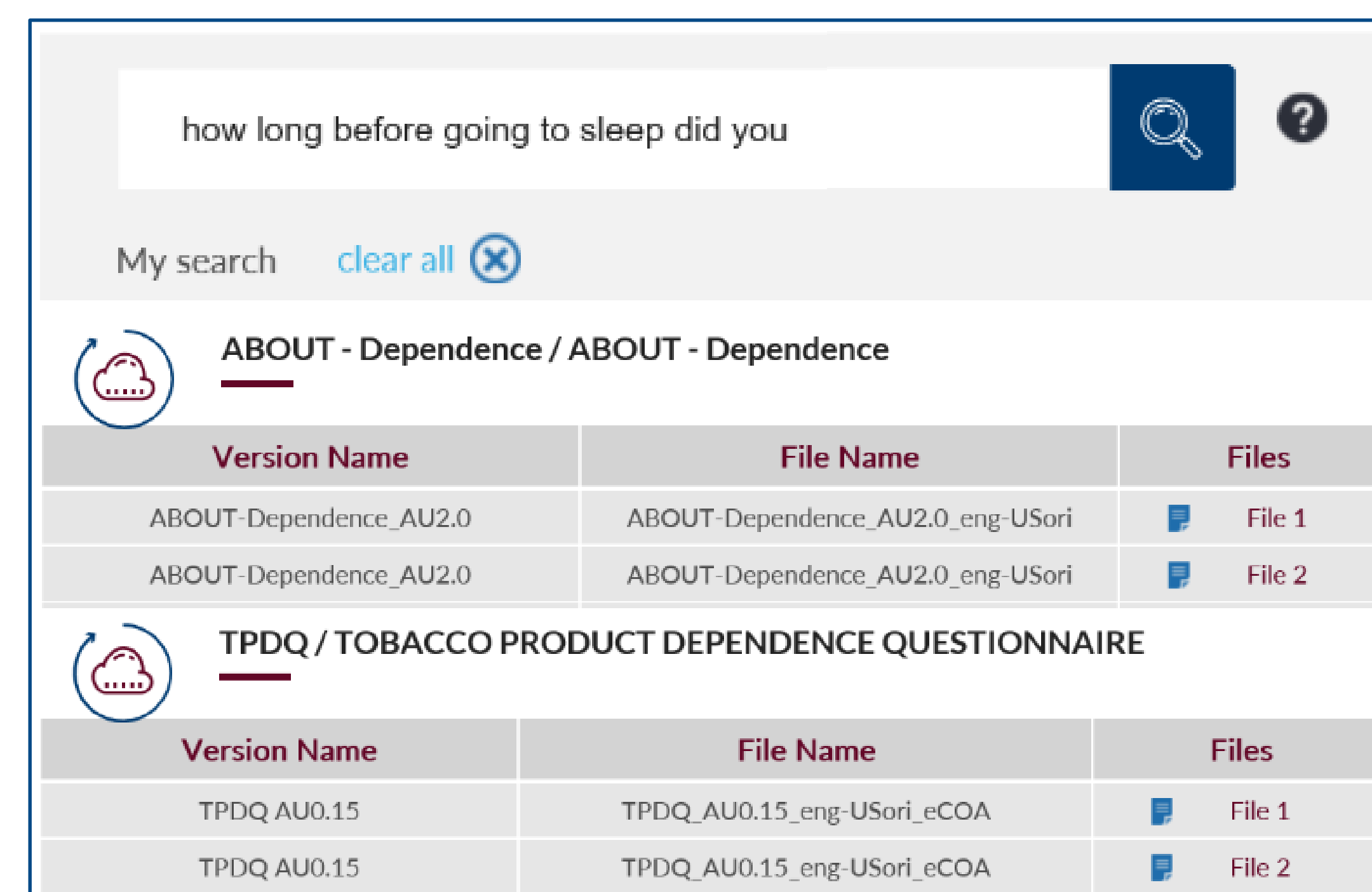

Fig. 3: Example of an item full-text search result

PMI Instruments

Novel tobacco or nicotine products are emerging on the market, such as modified risk tobacco products (MRTP). In this context, there is a need for valid and reliable measurement instruments designed and adapted to assess consumer responses to MRTPs. For this purpose, PMI recently developed the ABOUT™ Toolbox (**A**ssessment of **B**ehavioral **OU**tcomes related to **T**obacco and nicotine products), which currently comprises five measurement instruments and covers high-priority tobacco-consumer-related domains:

1. The ABOUT™—**Perceived Risk** assesses risk perception.

2. The ABOUT™—**Use History** assesses the frequency and intensity of current and past TNP-use behavior, initiation, and cessation.

3. The ABOUT™—**Product Experience** encompasses a range of self-reported expressions of an individual's experience in using a TNP, including satisfaction, psychological reward, and craving.

4. The ABOUT™—**Dependence** assesses perceived nicotine dependence.

5. The ABOUT™—**Health and Functioning**, currently in development, will accurately reflect the health and functioning status of individuals who use TNPs, with particular focus on healthy adult smokers who switch to MRTPs.

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

Discussion/Conclusions

The Repository is a knowledge base providing researchers with primordial self-reported measure information relevant to consumer behavior outcomes research, more specifically in the context of TNPs.

The Repository allows centralization of access to regularly used measures, allowing optimization of their management.

Within two years:

- The number of self-reported measures catalogued in the Repository have doubled.
- With the additional self-reported measures in the Repository, the number of concepts covered has greatly increased, improving the range of available validated assessment tools to be transferred to the study teams.
- Past and ongoing studies are reconciled in the Repository, providing an efficient overview and comparison of self-reported measures used across studies.

The collaboration with MRT allowed new functionalities to be implemented in the Repository, making the tool dynamic and evolutive and thus enabling it to meet researchers' novel needs.

To conclude, the Repository is a unique initiative which enables:

- ✓ To assess, select, and use up-to-date and official versions (original and translations) of self-reported measures in a standardized environment and to transfer them to study operation teams during the study set-up phase.