Helping you build your Clinical Outcome Assessments strategies

Mapi Research Trust

ePROVIDE™

5,800+ COAs described
2,000+ drugs with COA claims
250+ guidelines on COAs
15,000+ requests per year

eprovide.mapi-trust.org
About Clinical Outcome Assessments

The concept of measuring patient quality of life with patient-centered outcomes research emerged in the 1990s along with health related quality of life questionnaires. These questionnaires are now broadly known as Clinical Outcome Assessments (COAs). According to the Food and Drug Administration (FDA), “a clinical outcome assessment is a measure that describes or reflects how a patient feels, functions, or survives”. COAs are categorized as follows:

- **Patient-Reported Outcome (PRO) measures**
- **Observer-Reported Outcome (ObsRO) measures**
- **Clinician-Reported Outcome (ClinRO) measures**
- **Performance Outcome (PerfO) measures**

**ePROVIDE™: The centralized platform to build your COA and eCOA strategies**

The aim of Mapi Research Trust is to facilitate access to information for all stakeholders in the field of Patient Centered Outcomes, particularly for Clinical Outcome Assessments (COAs). This is why Mapi Research Trust has centralized all its resources and services into the ePROVIDE™ platform.

Physicians, academic researchers and students, healthcare organisations, pharma companies, eVendors, ePROVIDE™ gives you access to up-to-date scientific and operational information on COAs.

**Three interconnected databases**

- **PROqolID™** Find the appropriate COAs for your research or practice
- **PROlables™** Develop a successful patient-centric endpoint strategy
- **PROInsight™** Review guidelines and regulatory requirements

**A comprehensive information and request management service**

- Research and selection of appropriate COAs
- Streamlined licensing process
- Support on electronic versions
Intelligent Interface

Intuitive search engines & refining filters

Easy information retrieval

Regular updates

Custom & flexible access levels

Centralized & interconnected resources

Human support only a click away
A unique database referencing validated & published COAs

Choose the appropriate COAs for your research or practice:
- 5,800+ COAs classified by therapeutic indications and types of COAs

Understand how to use the COAs you select:
- COA developers’ information, conditions of use, and translations
- COA description, reliability, validity, ability to detect change

Free access
Minimum level of information:
- Name of authors/developers
- Copyright notice
- Objective
- Therapeutic area
- Therapeutic indication
- Type of COA
- Original language(s)
- Bibliographic references used for the description

Members access
Additional scientific and operational info:
- Contact information and conditions of use*
- Review copy*
- Available translations*
- E-versions
- Domains covered
- Scoring
- Administration mode
- Recall/observation period
- COA development information
- COA validation information

*Freely accessible for COAs distributed by Mapi Research Trust

Information on COA label claims approved by the FDA and EMA, since 1995

Quickly identify competitive landscape
Find up-to-date information on COAs mentioned in label claims
Develop a successful patient-centric endpoint strategy in a drug approval process

If at least one concept of interest is measured with a COA in the efficacy or safety sections of the labelling claim documents, the corresponding medical product is described in PROLABELS™.

New releases from EMA and FDA are implemented within a month.

For all drugs and devices, different COA types (PRO, ClinRO, ObsRO, PerfO) have been considered.
Published regulatory recommendations on the use of COAs for different indications

- Access guidelines on the development of drugs, drug treatments, and methods for economic evaluation
- Check the concepts and COAs that should be considered to assess a disease’s impact on patients’ life
- Capture regulatory COA requirements in clinical settings

Guidance sources

- Drug approval regulatory agencies (FDA, EMA, Health Canada)
- Health technology assessment agencies (CADTH, EunetHTA)
- Healthcare stakeholders’ boards (IQWIG, NICE)

Content provided in PROINSIGHT™ *

- Guideline description: health authority, publication date, guideline status, source document
- Therapeutic area and therapeutic indication
- Target population (for each targeted technology and for each concept of interest)
- Efficacy/study design, statistics and results presentation considerations
- COA endpoint information: positioning, type of COA, COA name if stated, recommended type of measure and level of COA recommendation

*PROINSIGHT™ is a supplementary option within the PROLABELS™ subscription.
Comprehensive COA management services*

- **Patient-centered endpoint intelligence**
- **COA information search**
  - Identifying copyright holder(s), clarifying conditions of use, availability of translations
- **Streamlined COA licensing process**
  - Licensing expertise and support for any COAs
  - Overall scale management: coordination with copyright holders and other parties for eCOA implementation
  - Organizing printing & shipping of the material to sites for paper studies
- **Coordination of translation projects** (collaboration with ICON Language Services)
- **COA scoring guides and manuals** (access to existing material or development in collaboration with COA developers)
- **eCOA solutions**
  - Guidance, review, approval and certification of electronic versions
- **COA Repository**
  - A unique repository for all COAs used in your clinical studies

*For any COA, distributed by Mapi Research Trust or not

**Focus on the patient-centered endpoint intelligence**

Thorough searches carried out in a collaborative and transparent process, to answer all your strategic questions, save you time and meet your deadlines:

- Which COAs are used in **specific indications**? (published and on-going interventional and observational clinical studies)
- What **content validity** and **psychometric properties** do specific COAs have and how are they scored?
- What are the relevant concepts that describe patients’ experience of the disease from the **patient or the HCP perspective**?
- Which COA strategies did your **competitors use**?
- Have **competing drugs obtained a COA claim** from the FDA, the EMA or other health authorities?
- Have **competitors used a COA** during the development of their product which was **not recognized in the label**?
- Which **COAs are recommended** by health authorities, HTA bodies?

Submit a request
About our streamlined COA licensing process

1. Agreement:
   Terms and conditions of this service: enabling Mapi Research Trust to negotiate and manage the licensing process on behalf of our clients.

2. Study details:
   Nature and scope of the licenses required: study information (e.g., study title, # of expected patients, # of administrations, mode of administration for each instrument, etc.) to support the licensing process.

3. Information search:
   For COAs not distributed by Mapi Research Trust, an in-depth search is completed to obtain all needed information (already available for distributed COAs), such as conditions of access and use, availability of derivatives and gap analysis (translations, electronic versions), measure-specific information, etc.

4. Permission to use:
   Upon approval of the conditions of use (legal and financial) by the client, Mapi Research Trust facilitates the exchange between the client and the licensing authorities until all parties are in agreement and until the contracts are finalized: license agreements*.

*It should be noted that Mapi Research Trust does not perform legal reviews of the license agreements. The clients handle discussions on legal clauses with the licensing authorities directly.

Focus on eCOA solutions

Support in the development of officially approved and certified original eVersions of the COA:
- Managing e-migration / e-implementation assessment
- Providing specifications for electronic implementation in collaboration with the developers (e-Booklet)
- Maintaining data knowledge and retaining existing material
- Reviewing screenshots of the original electronic versions with experts’ and developers’ involvement
- Checking the overall usability with expert review and patient involvement
- Providing a specific certificate for each approved eCOA version

Why build your own COA Repository?
Distributed by Mapi Research Trust or by another vendor, developed by the sponsor, in the public domain, any COA can be documented in your COA Repository.

Centralized information
Manage and add COAs, study information and documents.

Enhanced search
Quick and easy searches filtered by COAs and studies.

Controlled access, shared knowledge
Secured access for authorized staff, administered by the sponsor.

COA history
Information on the versions and translations used, as well as licenses.

Smart alerts
Automatic notifications prior to license expiration.

Downloadable format
Data export in Excel files.
Our collaborations

cdisc  COSMIN  BibliopRO

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