

Helping you build your Clinical  
Outcome Assessments strategies



**PROQOLID**<sup>TM</sup>

5,800+ COAs described

**PRO**✓**LABELS**<sup>TM</sup>

2,000+ drugs with COA claims

**PRO**↑**INSIGHT**<sup>TM</sup>

250+ guidelines on COAs

**ePRO**↓**VIDE**<sup>TM</sup>

15,000+ requests per year



## 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

**PROLABELS™**

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



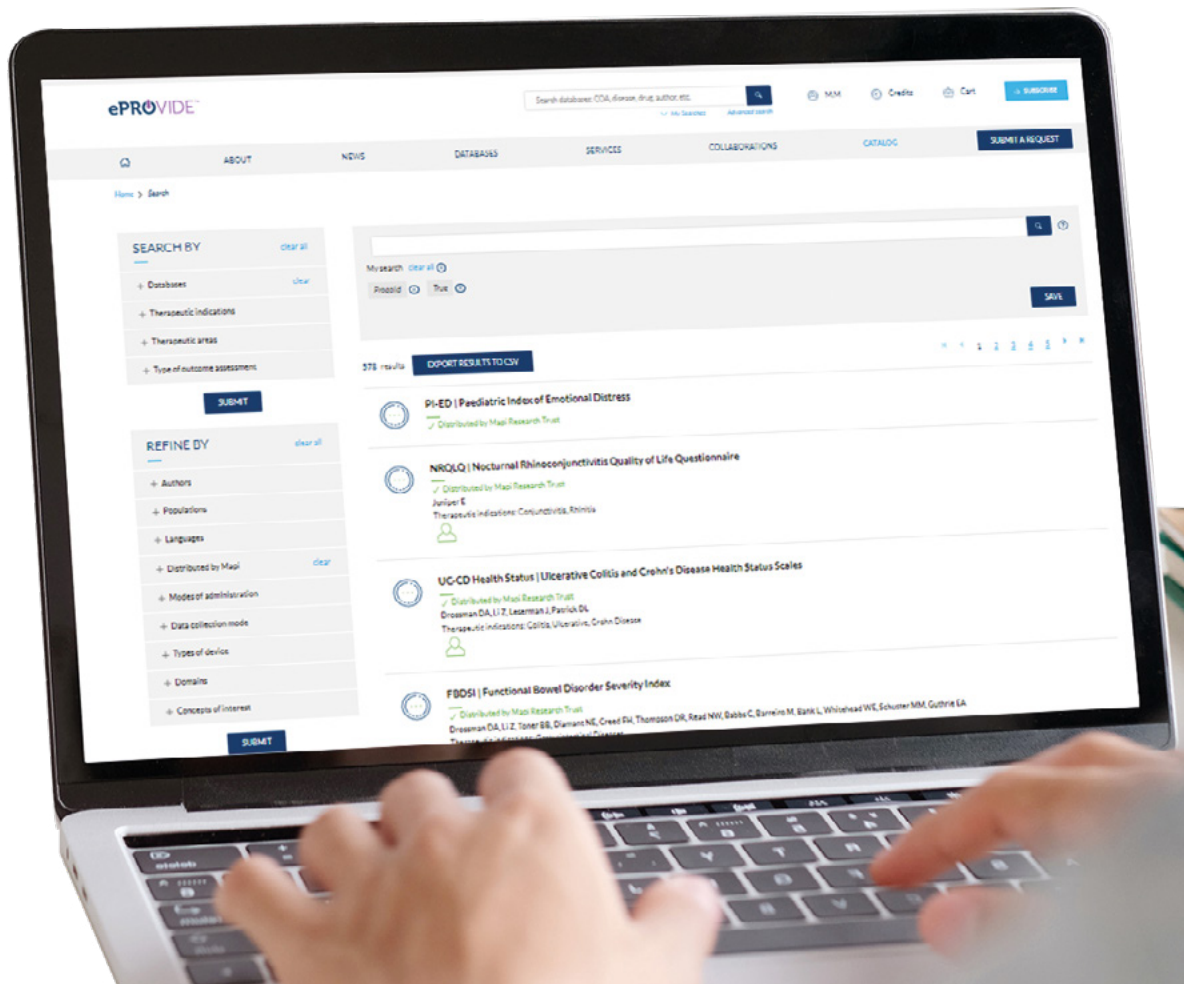
Custom & flexible access levels



Centralized &  
interconnected resources



Human support only a click away



[eprovide.mapi-trust.org](http://eprovide.mapi-trust.org)

## 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 all COAs approved by the FDA and EMA (label claims), 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.





## PROINSIGHT™

250+ guidelines on COAs

### 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.



[Subscription options](#)



## Comprehensive COA management services\*

15,000+ requests  
per year

- ➔ **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, distributed by Mapi Research Trust or not
  - Information search, conditions of use, availability of translations and eCOA and gap analysis, scoring guides, license agreements
- ➔ **Translation and linguistic validation, in collaboration with ICON Language Services**
- ➔ **COA scoring guides and manuals**  
(access to existing material or development in collaboration with COA developers)
- ➔ **eCOA services**
  - eCOA best practice guidance, screenshot review and certification, and expert review
- ➔ **COA Repository**
  - A unique repository for all COAs used in your clinical studies

## Focus on the Patient-Centered Endpoint Intelligence

Our team of experts performs a targeted but comprehensive landscape analysis. It is customized to answer your key strategic questions through well-known and transparent methodology that will accelerate submission and facilitate the review process at regulatory agencies.

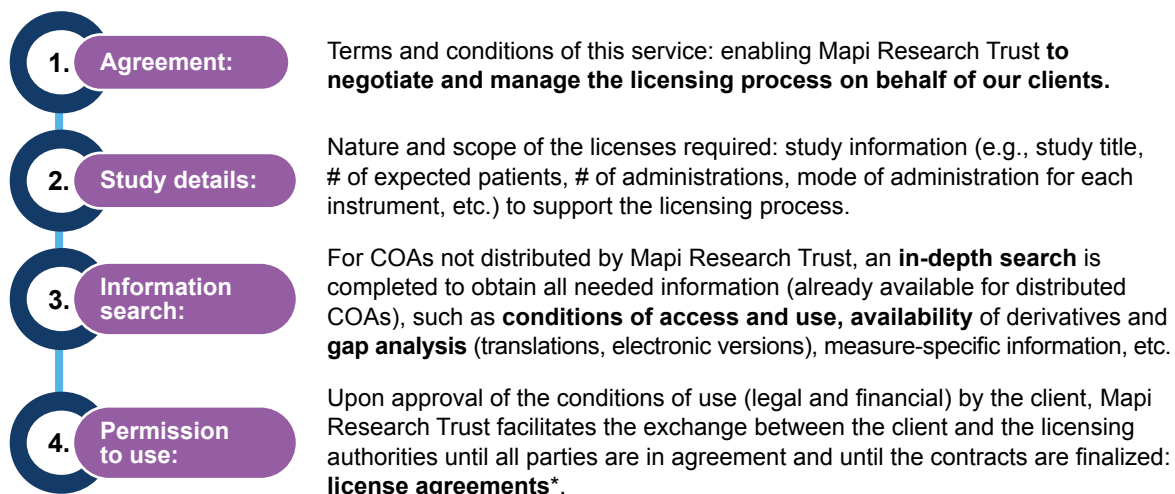
- Which COAs are used in **specific indications?** (published and on-going interventional and observational clinical studies)
- What **content validity and psychometric properties** do specific COAs have and how are they scored?
- What are the relevant concepts that describe patients' experience of the 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



\*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.

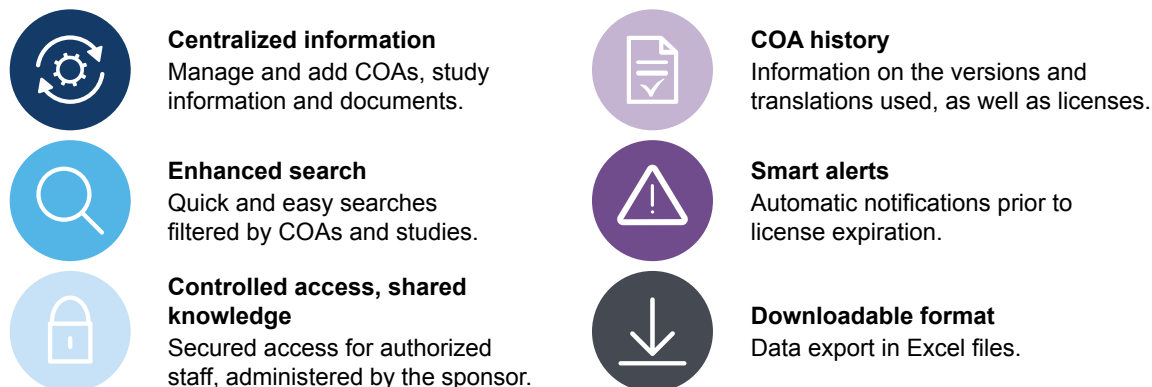
## Focus on eCOA services

### 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.**



# ePRO↓VIDE<sup>TM</sup>

## Our collaborations

**cdisc**



**BiblioPRO**

orphanet

