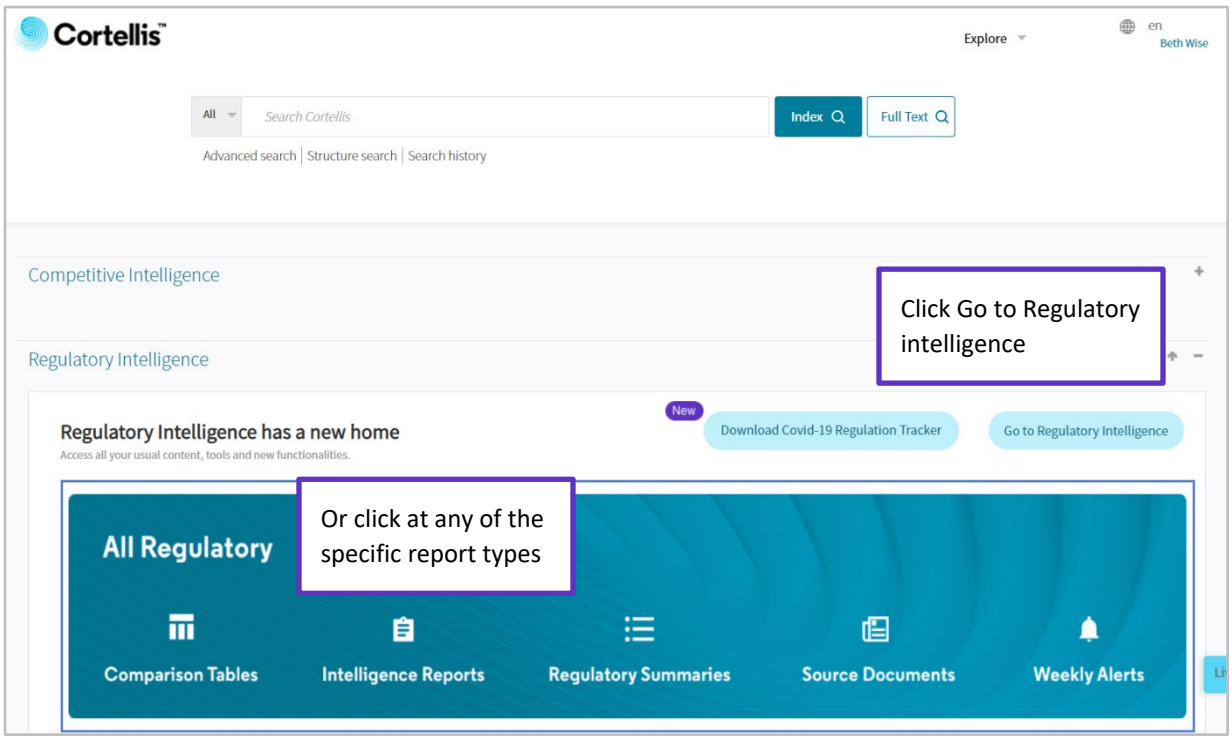
Locating the new P&R and HTA reports in Cortellis

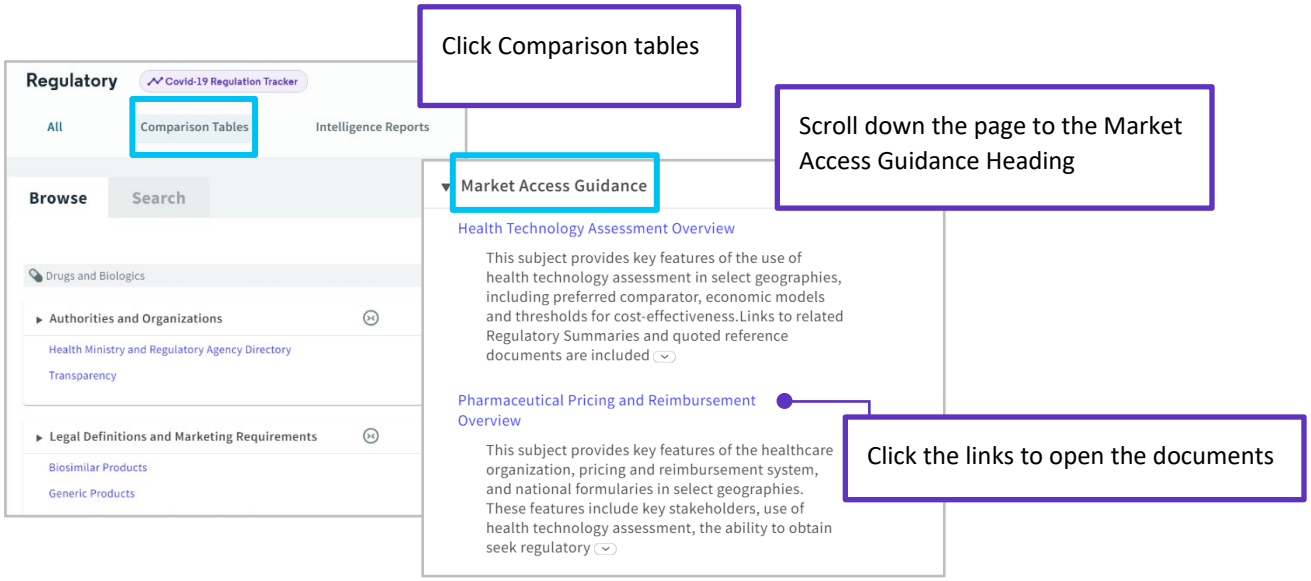
This guide shows how to access the new Pricing and Reimbursement and Heath Technology Assessment content in Cortellis added in July of 2021.

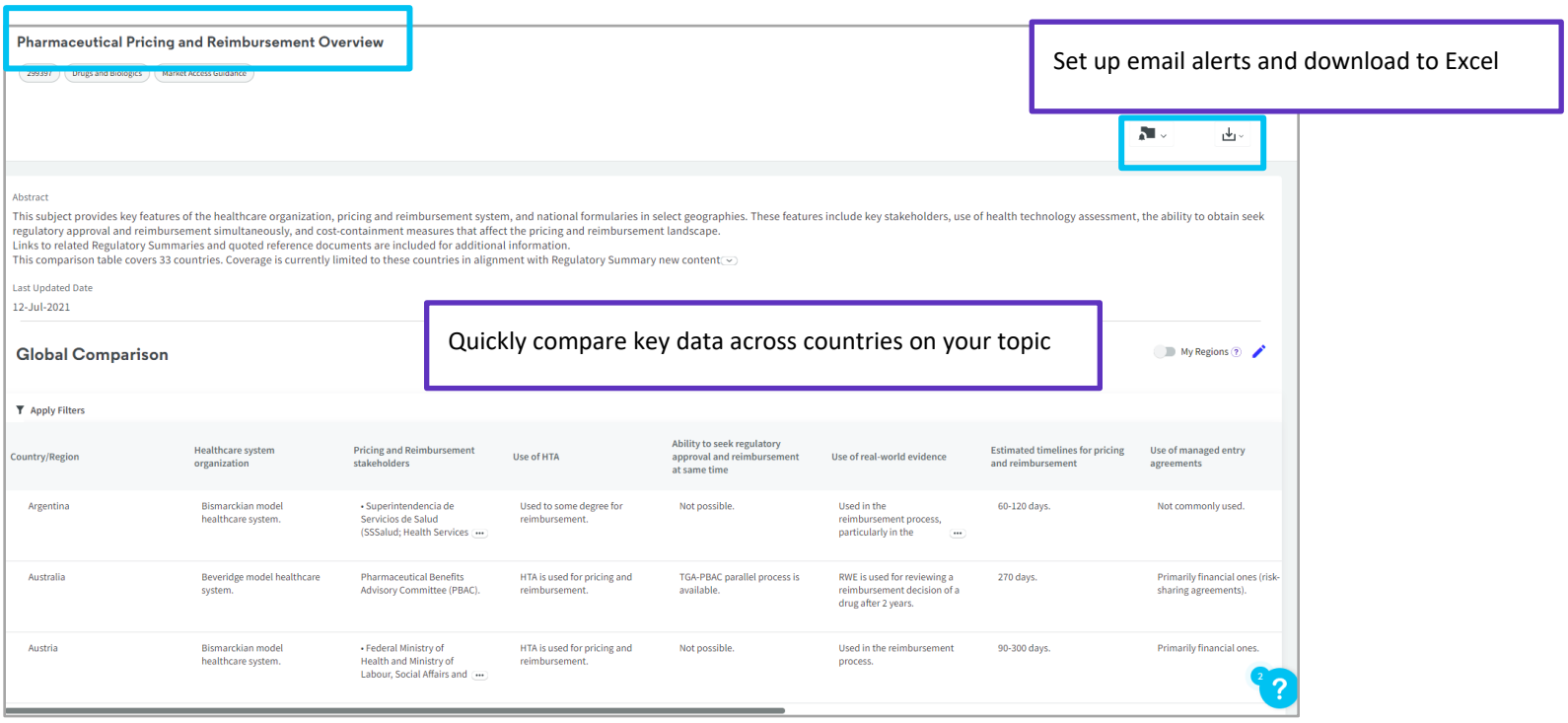
If your account is entitled to access more than one Cortellis module (Regulatory plus Competitive Intelligence for instance) you will see the Cortellis Homepage upon logging in. Otherwise, you will land directly on the Cortellis Regulatory Homepage and you can skip this first step.

Click "Go to Regulatory Intelligence" to access the Regulatory Home Page. This is where the GMAS content now sits. You can also go directly to a specific regulatory report type by clicking "Comparison Tables", "Intelligence Reports" or "Regulatory Summaries" in the panel.

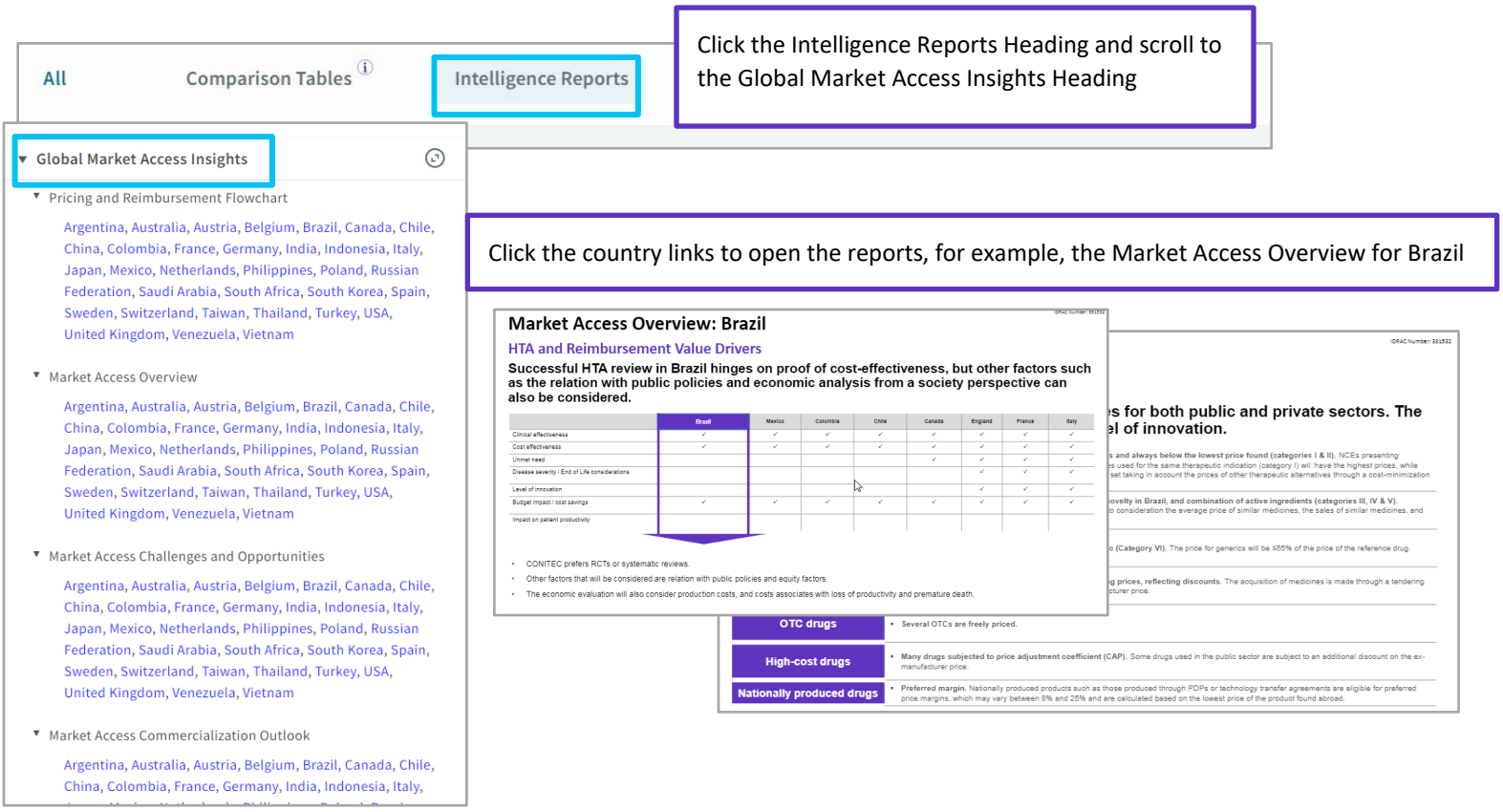


Under the **Comparison Tables Tab find two tables created from GMAS content comparing key Pricing and Reimbursement and Health Technology Assessment content in English** across different countries and regions.

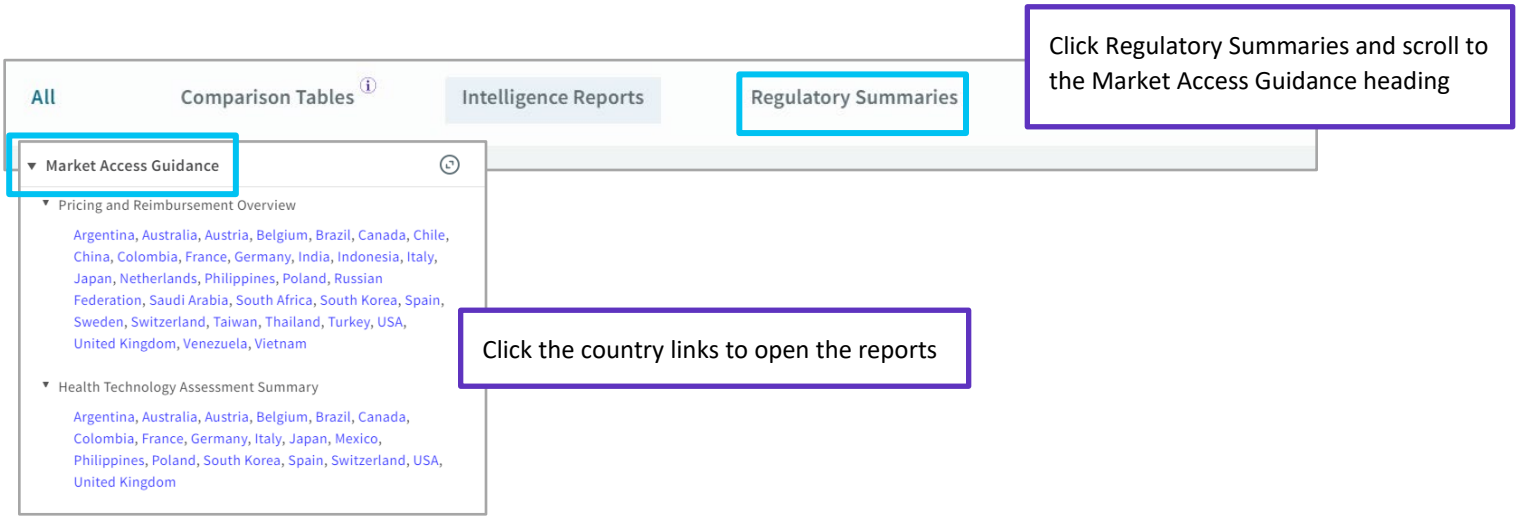




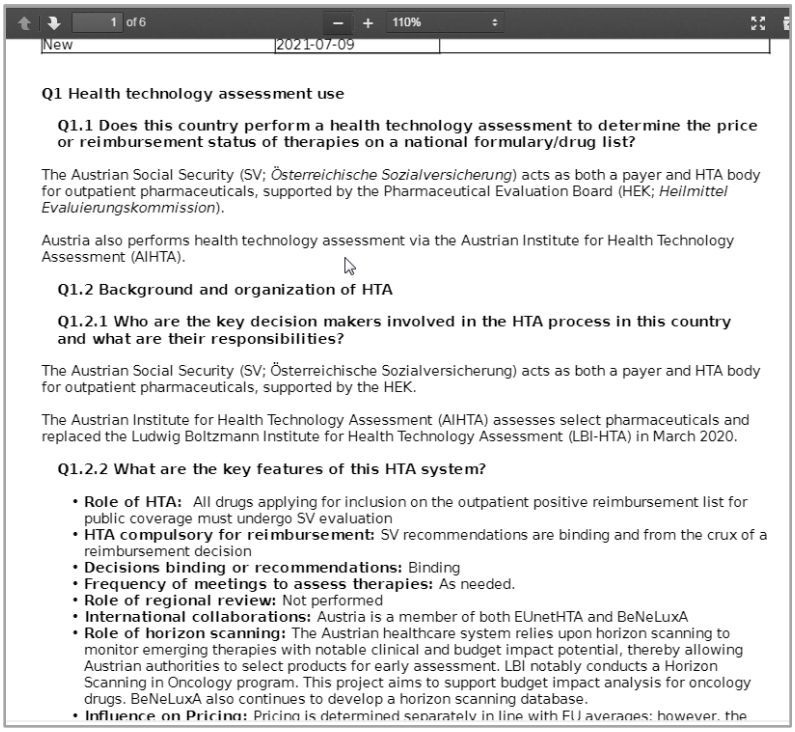
Here's how you can find **the Market Access Overview, Pricing and Reimbursement flowcharts, Commercialization Outlook and Market Access Challenges and Opportunities reports migrated from GMAS**.



The Regulatory Summaries on Pricing and Reimbursement and Health Technology Assessment have been created from the Country Assessment reports in GMAS and follow the consistent Cortellis Q&A format. Regulatory Summaries are English language "how to" documents on policy that help you with your local submissions. They also include links to the official documents from the authorities and are a great way to become familiar with a topic for a country.



Example of a Health Technology Summary



New 2021-07-09

Q1 Health technology assessment use

Q1.1 Does this country perform a health technology assessment to determine the price or reimbursement status of therapies on a national formulary/drug list?

The Austrian Social Security (SV; *Österreichische Sozialversicherung*) acts as both a payer and HTA body for outpatient pharmaceuticals, supported by the Pharmaceutical Evaluation Board (HEK; *Heilmittel Evaluierungskommission*).

Austria also performs health technology assessment via the Austrian Institute for Health Technology Assessment (AIHTA).

Q1.2 Background and organization of HTA

Q1.2.1 Who are the key decision makers involved in the HTA process in this country and what are their responsibilities?

The Austrian Social Security (SV; Österreichische Sozialversicherung) acts as both a payer and HTA body for outpatient pharmaceuticals, supported by the HEK.

The Austrian Institute for Health Technology Assessment (AIHTA) assesses select pharmaceuticals and replaced the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA) in March 2020.

Q1.2.2 What are the key features of this HTA system?

- **Role of HTA:** All drugs applying for inclusion on the outpatient positive reimbursement list for public coverage must undergo SV evaluation
- **HTA compulsory for reimbursement:** SV recommendations are binding and from the crux of a reimbursement decision
- **Decisions binding or recommendations:** Binding
- **Frequency of meetings to assess therapies:** As needed.
- **Role of regional review:** Not performed
- **International collaborations:** Austria is a member of both EUnetHTA and BeNeLuxA
- **Role of horizon scanning:** The Austrian healthcare system relies upon horizon scanning to monitor emerging therapies with notable clinical and budget impact potential, thereby allowing Austrian authorities to select products for early assessment. LBI notably conducts a Horizon Scanning in Oncology program. This project aims to support budget impact analysis for oncology drugs. BeNeLuxA also continues to develop a horizon scanning database.
- **Influence on Pricing:** Pricing is determined separately in line with EU averages; however, the

The submission should include a Summary of Product Characteristics, European Public Assessment Report, and up to three key clinical studies.

For the health economic evaluation, the MAH should provide clinical, economic and epidemiological data. All the data sources used must be described exactly, their choice justified and their suitability and validity assessed. This involves scrutinizing both internal and external validity. Data demonstrating added therapeutic benefit, should display technical characteristics of the technology; efficacy/ effectiveness; safety; health problem; and other evidence (e.g. patient aspects). In Austria, economic data is not systematically recorded or published. For this reason, health economic evaluations should refer primarily to data from the following sources:

- Austrian data from cost calculations published in cost studies
- Global schedule of fees of the Central Association or a mixed tariff from several schedules of fees (e.g. Vienna, Upper Austria, Styria and Tyrol) or a tariff list from a regional health insurance fund
- All tariff and price lists of social insurance institutions, hospitals, care homes, rehabilitation centers, geriatric centers, health spa clinics and chambers of physicians and pharmacists (e.g. list of products).
- LKF [Austrian DRG System] list of public fund hospitals
- Data from cost calculation by hospitals
- Cost estimates from Delphi surveys
- Empirical surveys
- Expert opinions.

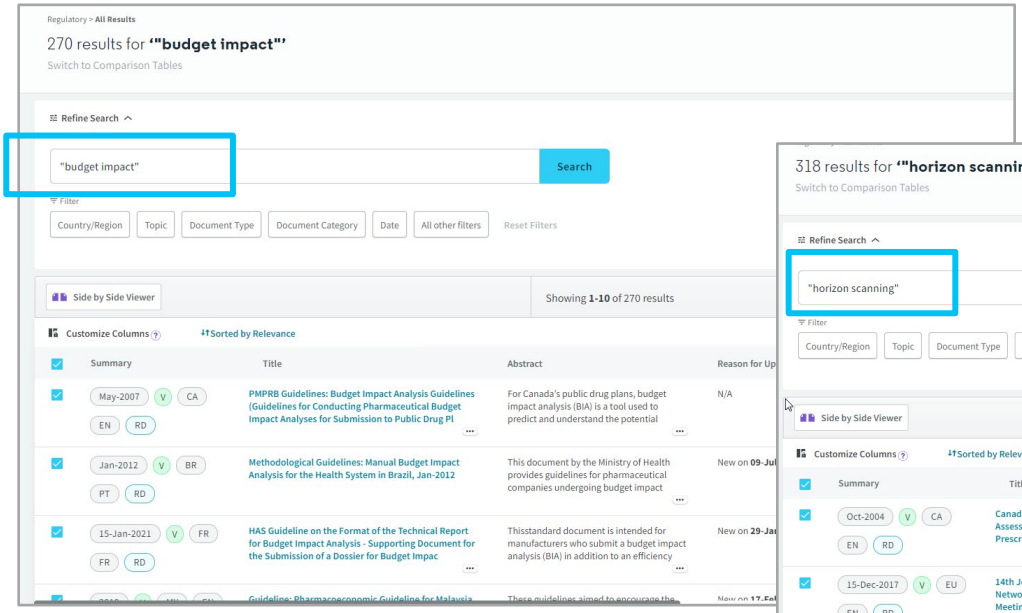
Q2.2.2.2 What trial types are preferred, allowed, or discouraged in this country?

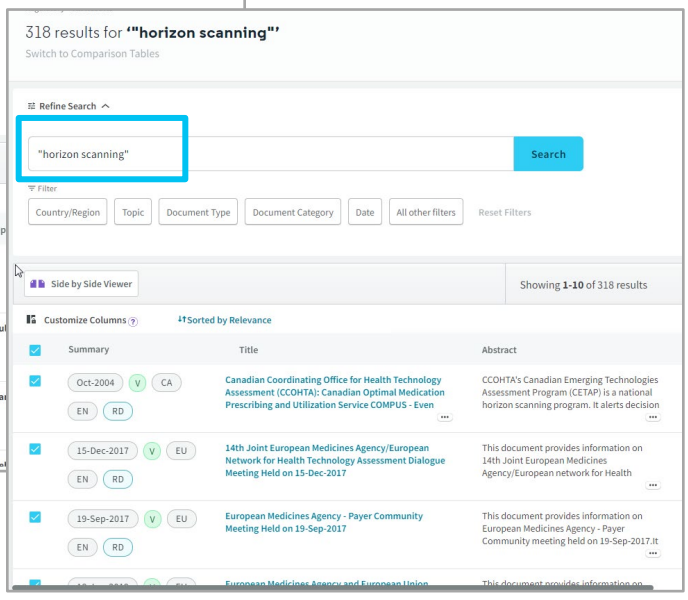
Preferred:

- Prospective, randomized controlled clinical trials with masked outcome assessment in a representative population, large data or meta-analyzes of such studies
- Systematic reviews (e.g. Cochrane review) with meta-analyzes of numerous studies with large patient numbers / numbers of patients, evidence of clearly defined endpoints that provide clear indications for the population for which the recommendations are being made
- Randomized controlled trials (RCTs), smaller data sets (fewer or smaller RCTs, or results inconsistent or study population does not match the target population of the recommendations)

Accepted:

You may also use the dynamic Search from the Regulatory Home Page to find documents containing specific keywords and phrases. In addition to the documents already discussed you are also able to find official documents.





For more information contact Customer Service at **LS Product Support.**