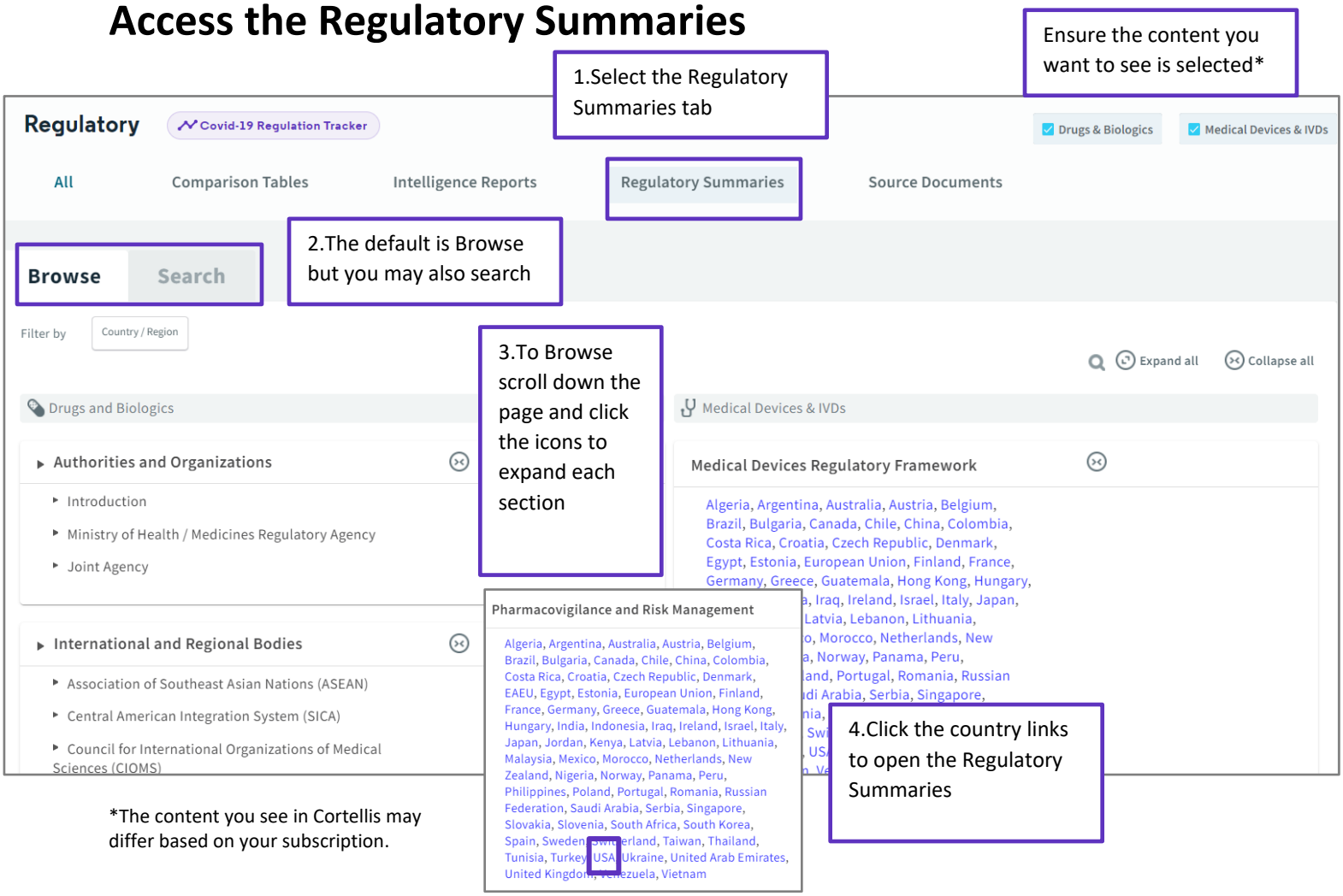
Cortellis Regulatory Intelligence

Regulatory Summaries

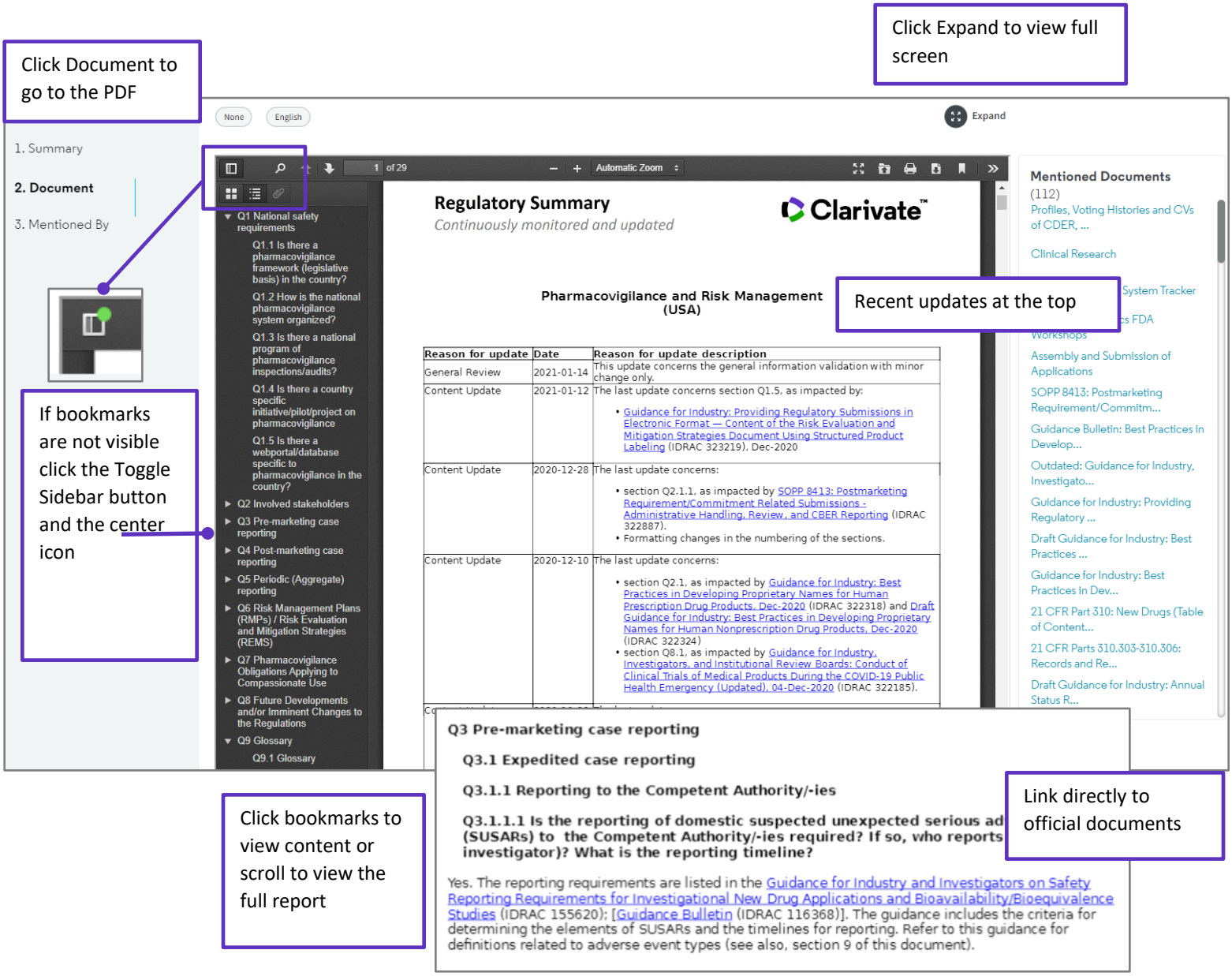
The Regulatory Summaries are time saving value add reports created by Cortellis Editors and Consultants that help you get your products to market faster. These English language documents provide step-by-step instructions on common regulatory procedures from compiling and submitting dossiers, market authorization, clinical trials, PV, QA and so much more. They are a great starting point when you need to understand a procedure – especially if you don't speak the native language. Plus, all relevant official documents from the authorities on a topic are easy to access from the Regulatory Summaries.

Access the Regulatory Summaries



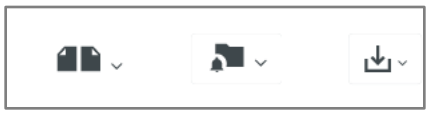
*The content you see in Cortellis may differ based on your subscription.

Navigating the Regulatory Summaries



Reason for update	Date	Reason for update description
General Review	2021-01-14	This update concerns the general information validation with minor change only.
Content Update	2021-01-12	The last update concerns section Q1.5, as impacted by: • Guidance for Industry: Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling (IDRAC 323219), Dec-2020
Content Update	2020-12-28	The last update concerns: • section Q2.1.1, as impacted by SOPP 8413: Postmarketing Requirement/Commitment Related Submissions - Administrative Handling, Review, and CBER Reporting (IDRAC 322887). • Formatting changes in the numbering of the sections.
Content Update	2020-12-10	The last update concerns: • section Q2.1, as impacted by Guidance for Industry: Best Practices in Developing Proprietary Names for Human Prescription Drug Products, Dec-2020 (IDRAC 322318) and Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products, Dec-2020 (IDRAC 322324) • section Q8.1, as impacted by Guidance for Industry, Investigators, and Institutional Review Boards: Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (Updated), 04-Dec-2020 (IDRAC 322185).

Add the Regulatory Summary to the Side By Side Viewer, Set up an alert to be notified of future updates and export using the tools in the upper right hand corner.



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