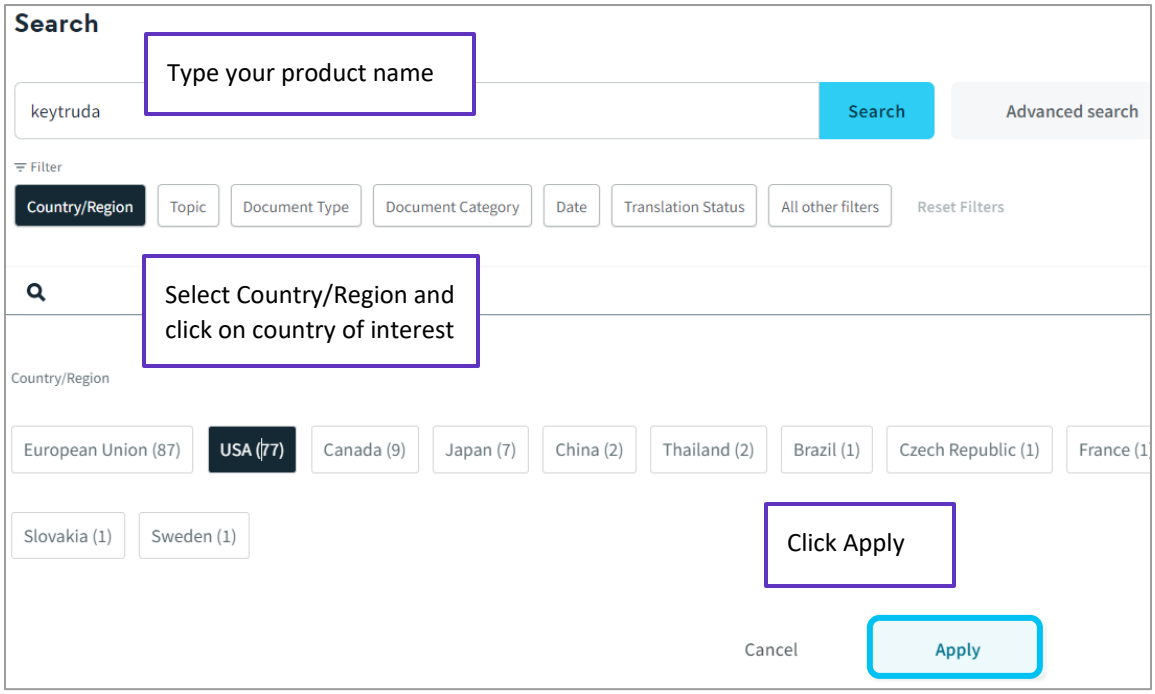
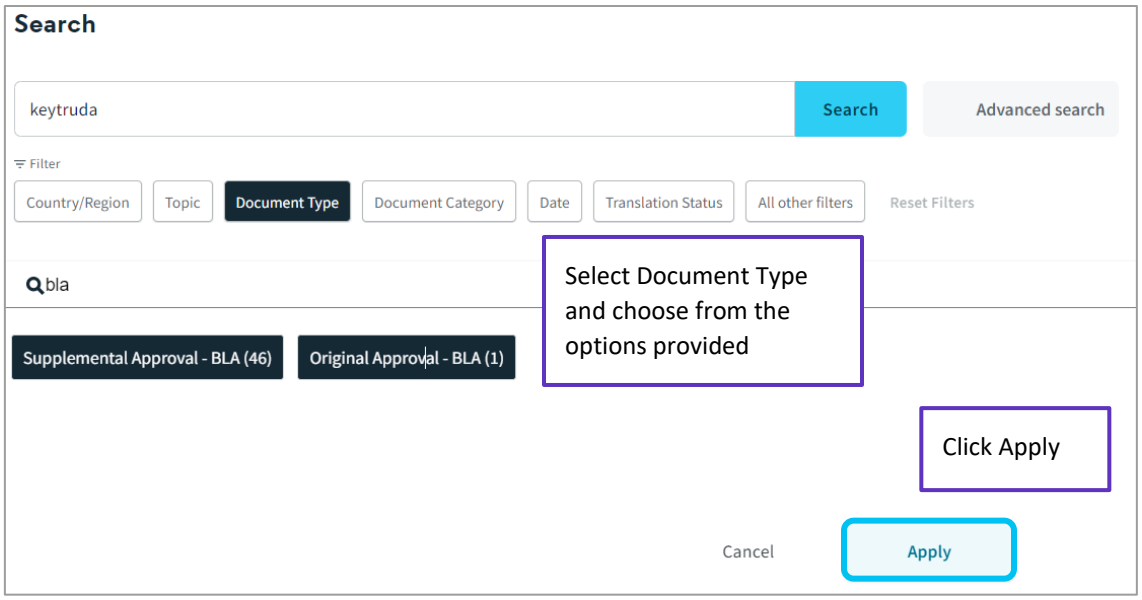
Searching for NDAs and BLAs by drug, indication and more criteria

This guide shows you how to quickly access and fully benefit from US New Drug Applications (NDAs) and Biologics License Applications (BLAs) in *Cortellis Regulatory Intelligence* from 1997 to the present day.

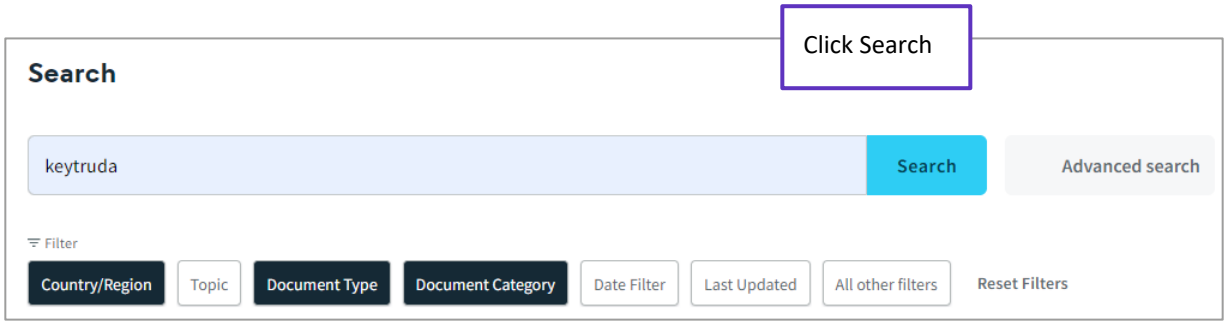
1. Use the Search Tool from the Regulatory Home Page. Type your **product name**, for example, Keytruda into the Search Bar. Select the **Country/Region** Tab, click on **USA and** then click **Apply**. Once you've applied a filter to a tab it turns black.



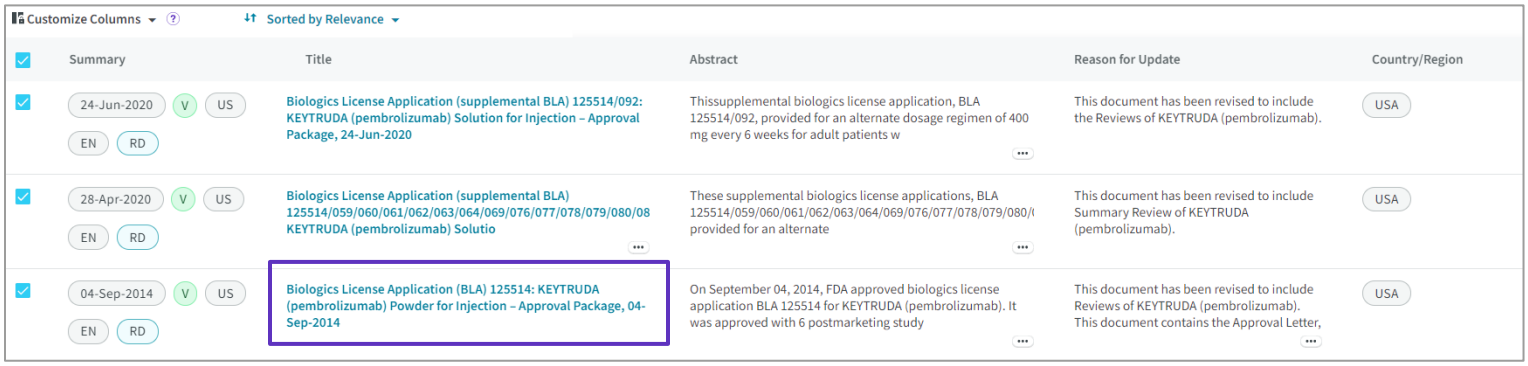
2. Next select **Document Type** and **BLA** and choose from the options provided. Again, click **Apply**. Then select **Document Category** in the same way. Choose **Reference Document**. For NDAs follow the same procedure.



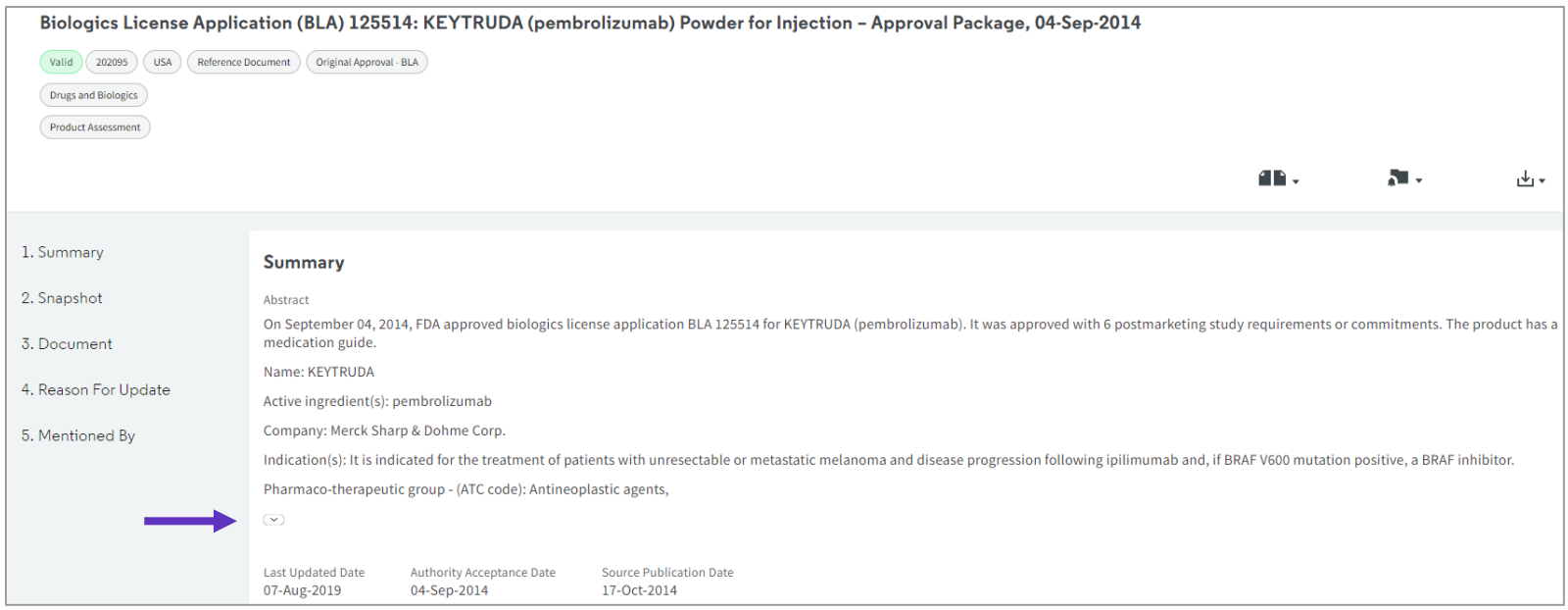
3. Once your search is complete, click the blue **Search** button.



4. On the results page click the **blue title hyperlinks** to view the approval documents.

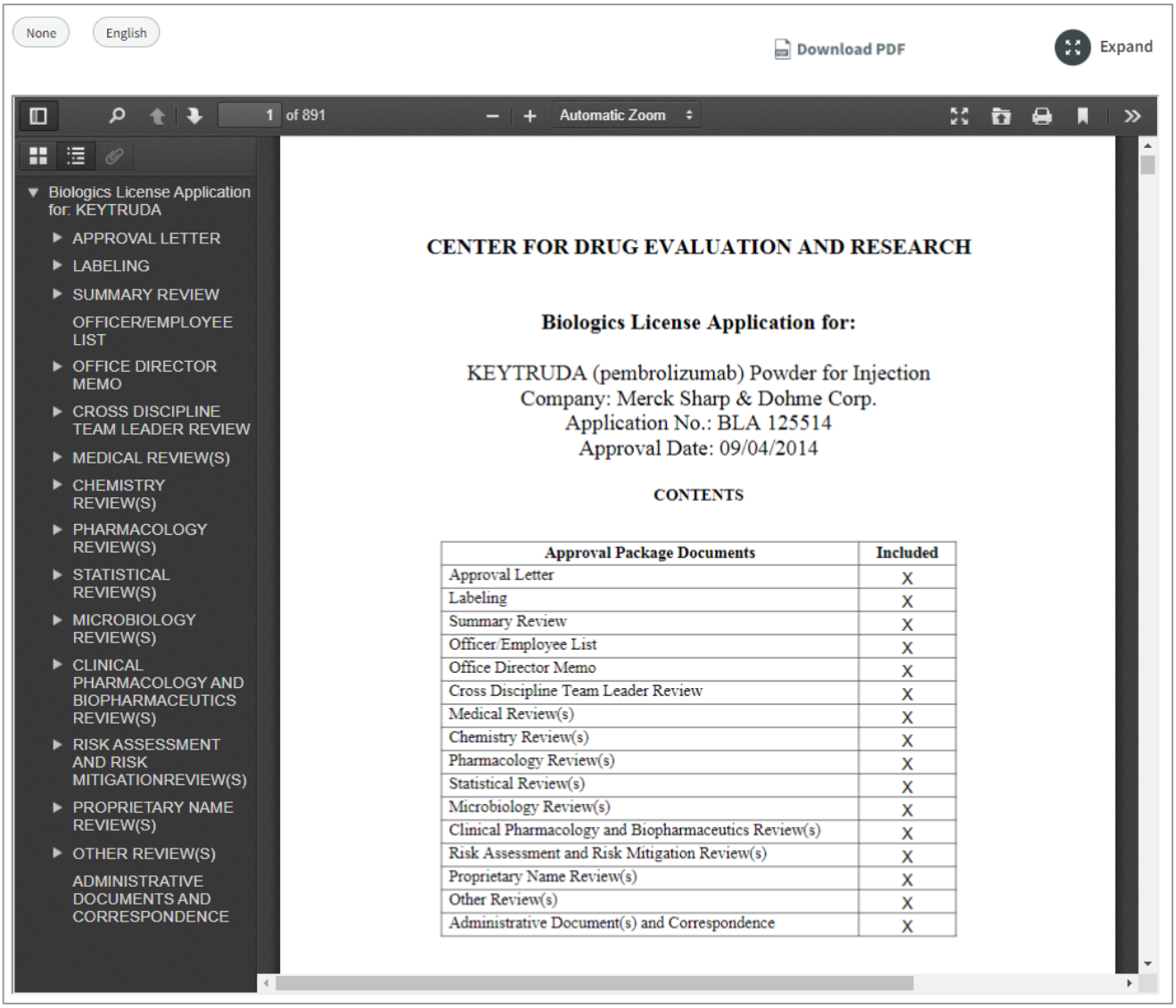


5. On the document page the **Summary** section will be displayed which includes a value-added **Abstract** written by Cortellis experts. This provides key data on the product, such as indication, pharmaceutical form, administration routes and packaging. If the product is an orphan drug, has a pediatric indication or if a Risk Management Plan is in place, the abstract also provides this information. Click the **arrow** to expand or collapse the abstract text.



6. On the document page, scroll down to access the **full approval document**. In Cortellis all files released by the FDA are compiled into one single PDF file.

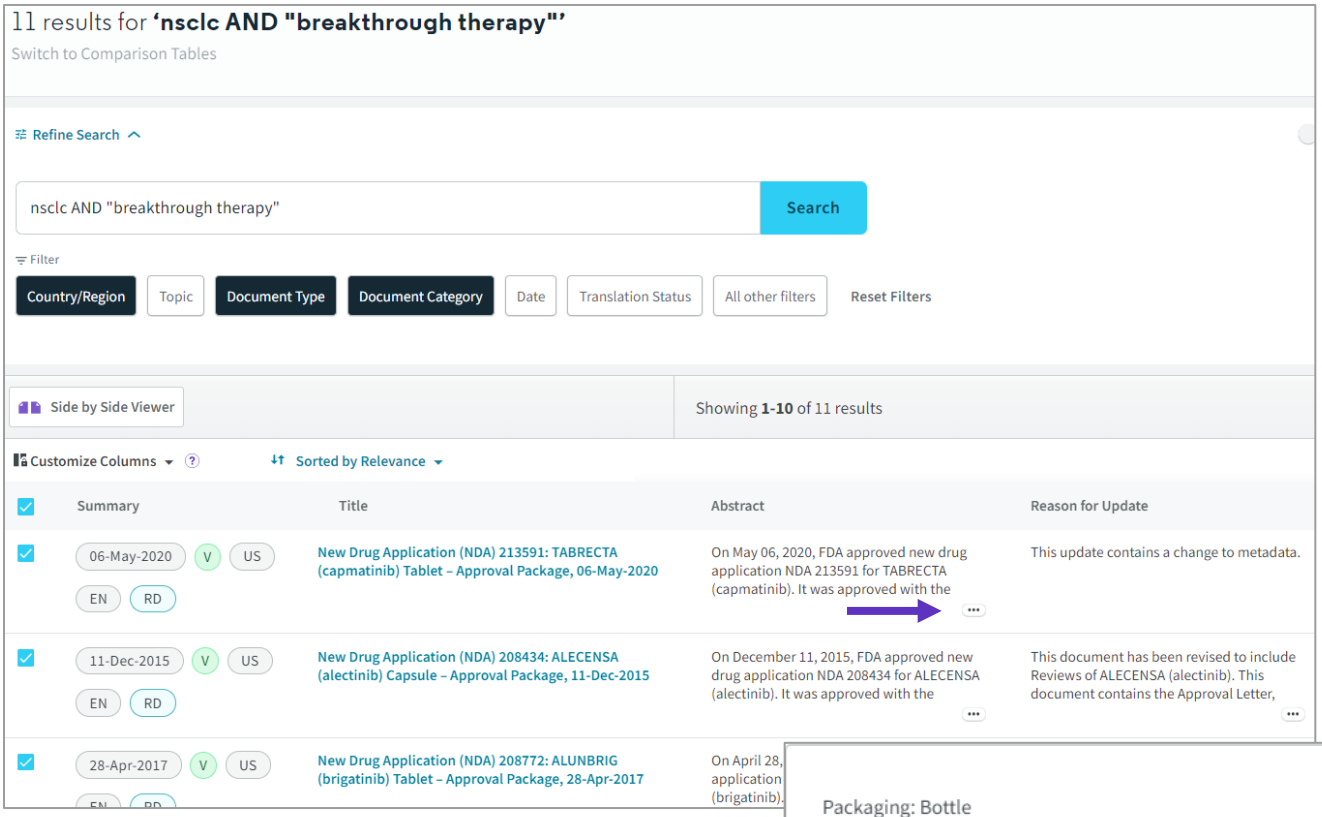
7. Approval documents are also enriched by a **hyperlinked table of contents** provided on the left, which allows you to directly go to the sections of interest.



Since criteria like indications, regulatory designations and more are in the Abstracts for the approval documents, you can easily create searches to find the documents you need.

For example: find all non-small cell lung carcinoma NDAs with the regulatory designation breakthrough therapy.

1. Enter your search terms and apply filters as in the previous example. Use the operators AND, OR or NOT as well as quotes to search phrases
2. Confirm your results by viewing the Abstracts



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