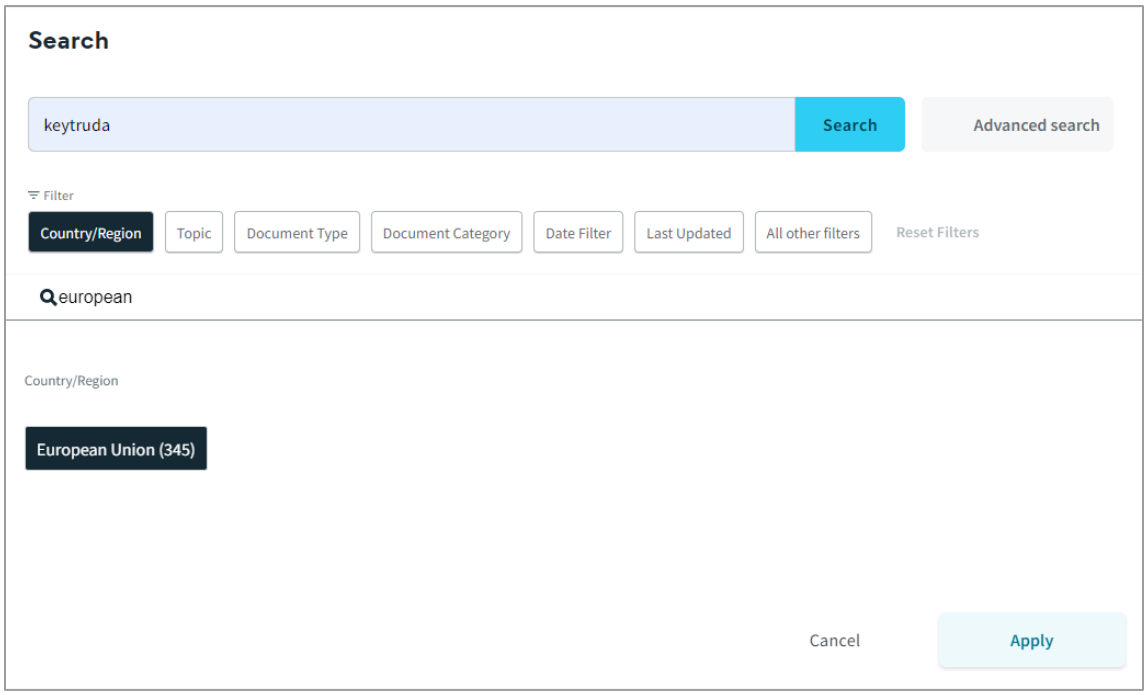
Cortellis Regulatory Intelligence

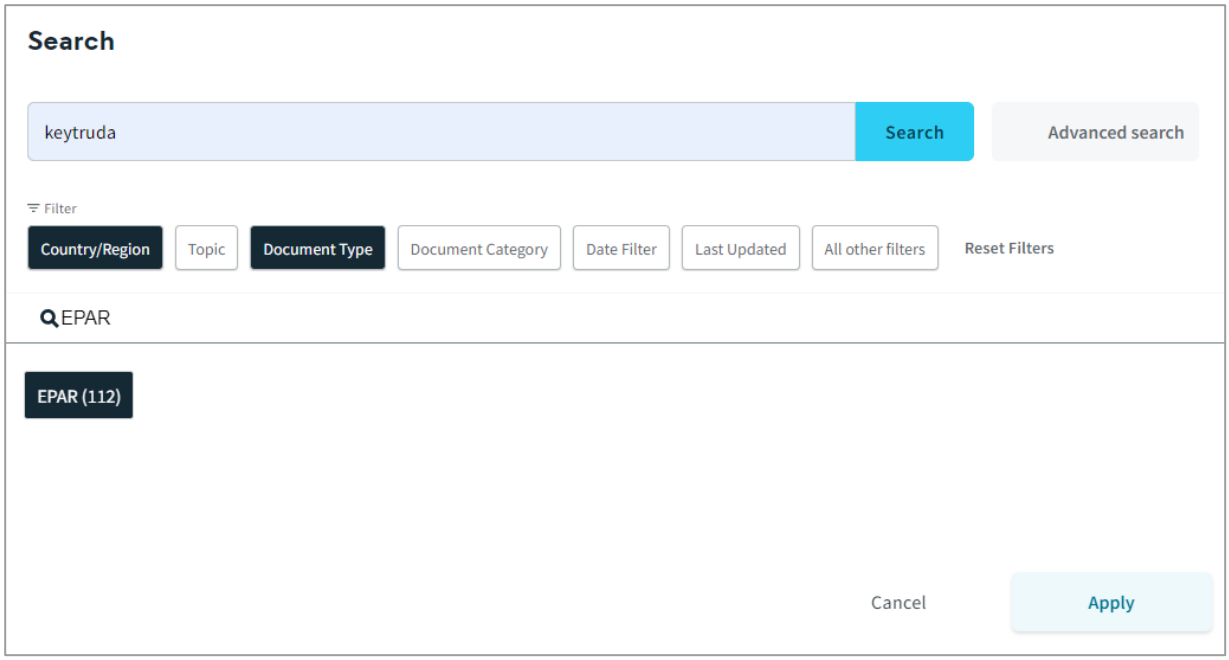
European Public Assessment Reports (EPARs)

This guide shows you how to quickly access and fully benefit from the European Public Assessment Reports (EPARs) in *Cortellis Regulatory Intelligence*, which covers all current and outdated versions since the beginning of the centralized procedure in 1995.

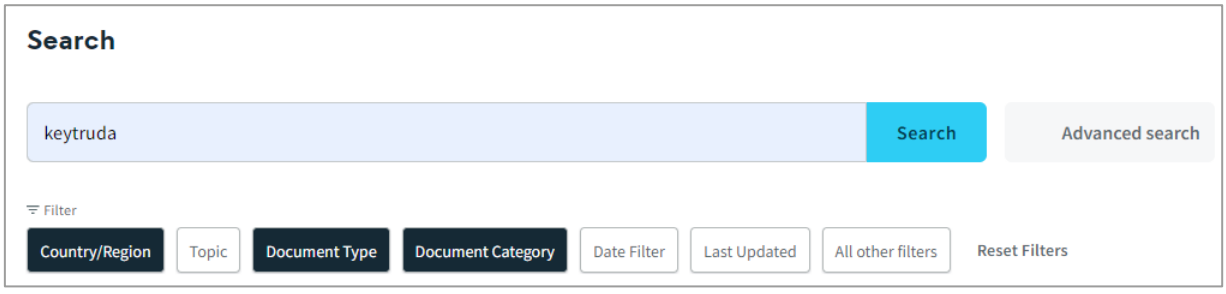
1. Use the Search Tool from the Regulatory Home Page. Type Keytruda into the Search Bar. Then select the **Country/Region** Tab and click on **European Union**. Then click **Apply**. Once you've applied a filter to a tab it turns black.



2. Next Select **Document Type** and **EPAR**. Again click Apply. Select **Document Category** in the same way. Choose **Reference Document**.

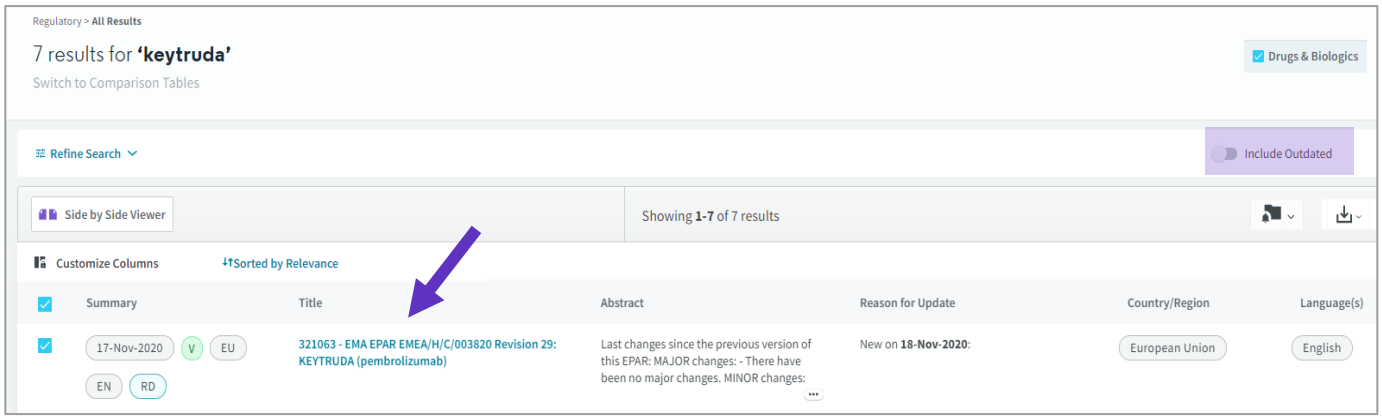


3. Once your search is complete click the blue **Search** button.

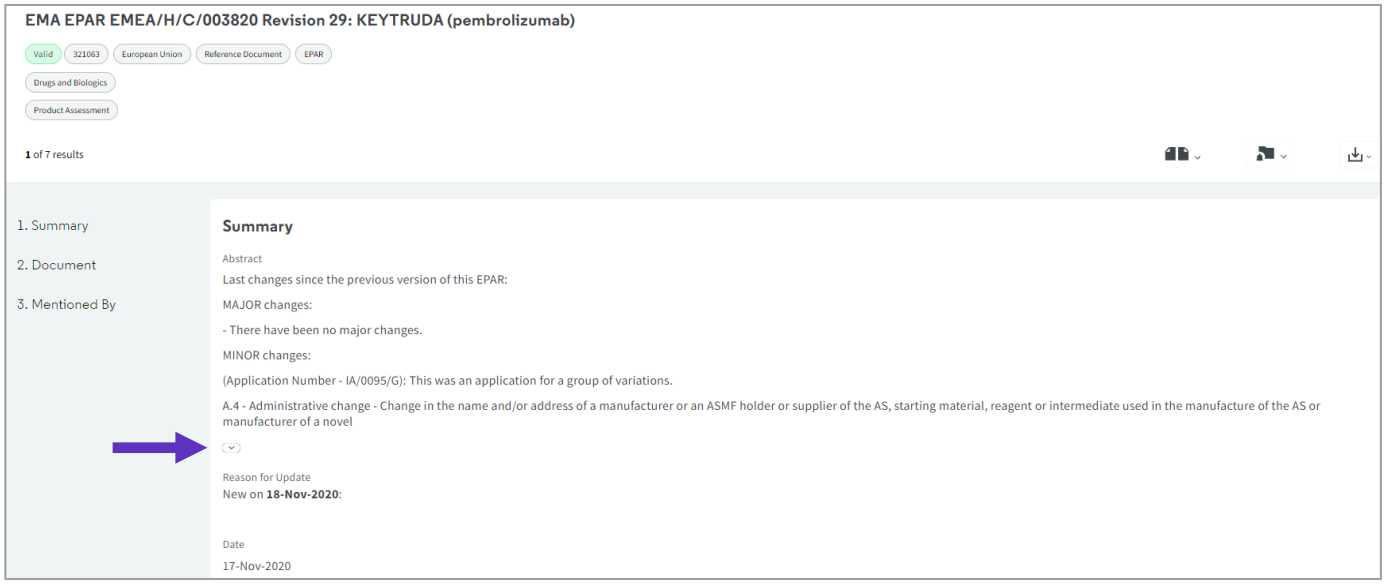


4. Once the results page is displayed, click the **blue title hyperlinks** to view the EPAR documents. The valid EPAR version of the product requested appears at the top of the list. Other products' EPARs might be listed if the product name requested is mentioned in those documents.

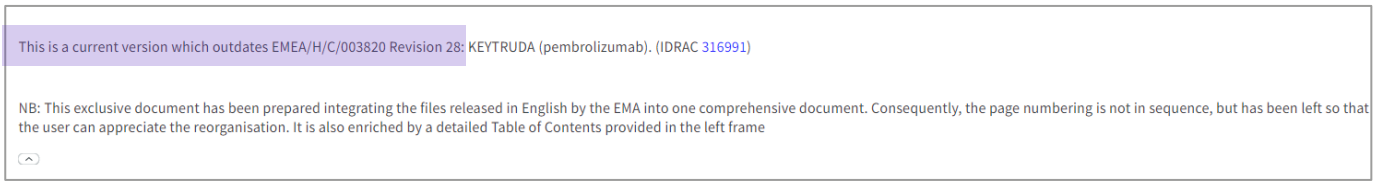
   Tip: Toggle on **Include Outdate**d to include previous EPAR versions in the results list.



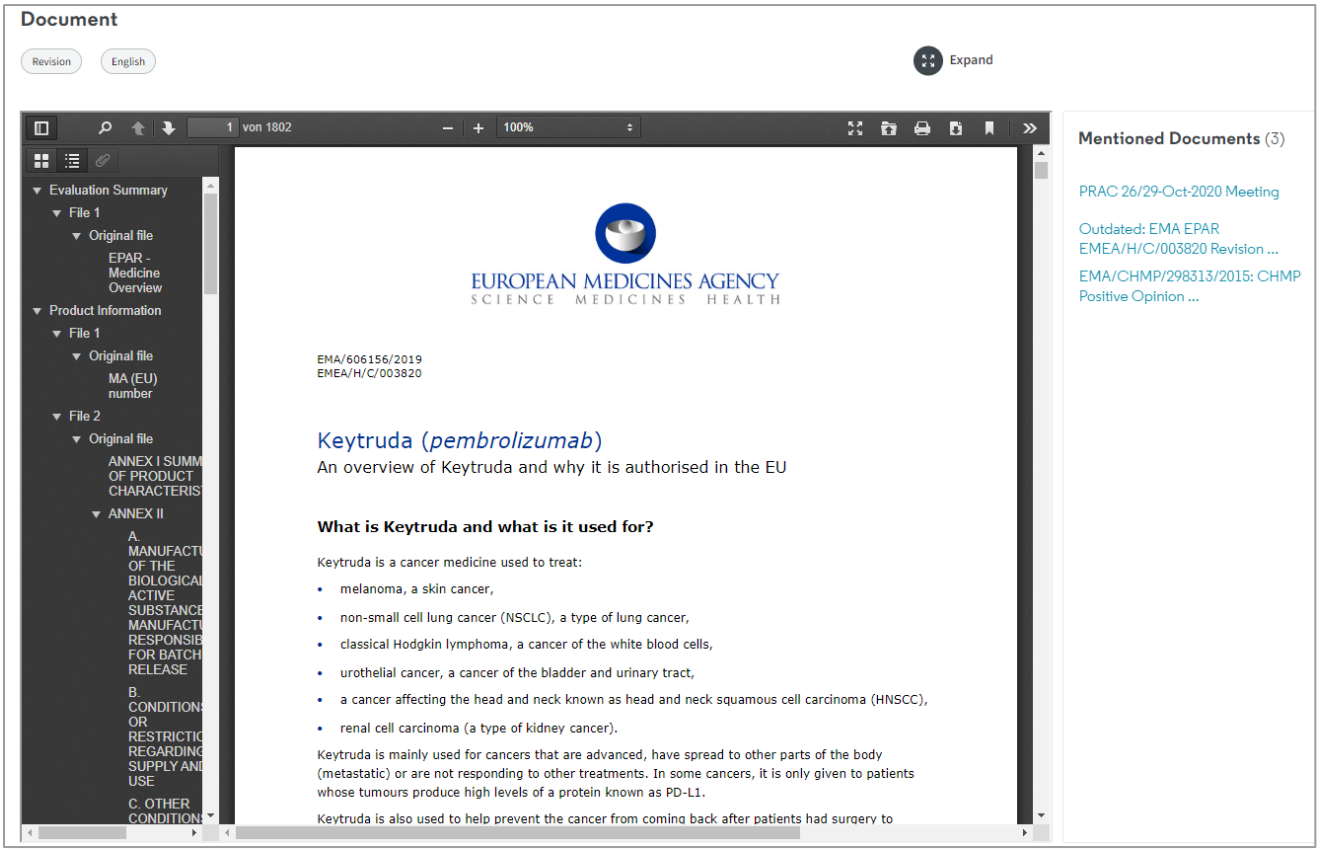
5. On the document page the **Summary** section will be displayed that includes a value-added **Abstract** written by Cortellis experts. This provides key data on the product, such as indication, pharmaceutical form, administration routes and packaging. Each abstract highlights the major and minor changes compared to the previous version. 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.



Tip: If an earlier version exists, you can link to it in the Abstract and information on the previous version including the EMA reference, revision and hyperlinked IDRAC number are provided. Previous versions are identified by a red **Outdated** stamp.



6. On the document page, scroll down to access the **full EPAR document**. In Cortellis all files released in English by the EMA relating to a specific version are compiled into one single PDF file. Documents are fully searchable and include the product information comprising the summary of product characteristics, labelling, package leaflet as well as the scientific evaluation, discussion and conclusion. EPARS are also enriched by a hyperlinked table of contents provided on the left, which allows you to directly go to the sections of interest (depending on your browser, you may need to click the table of contents symbol first or download the PDF first in order to see the details on the left). From **Mentioned Documents** you can link out to other documents cited by the EPAR.



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