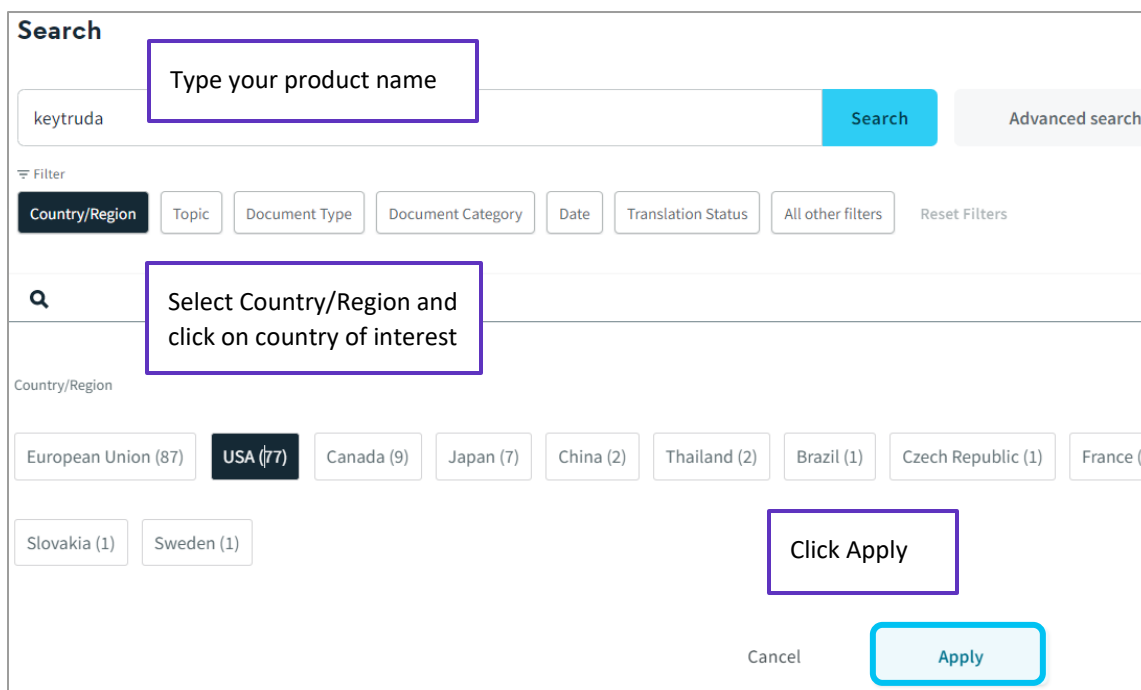


# Searching for NDAs and BLAs by drug, indication and more criteria

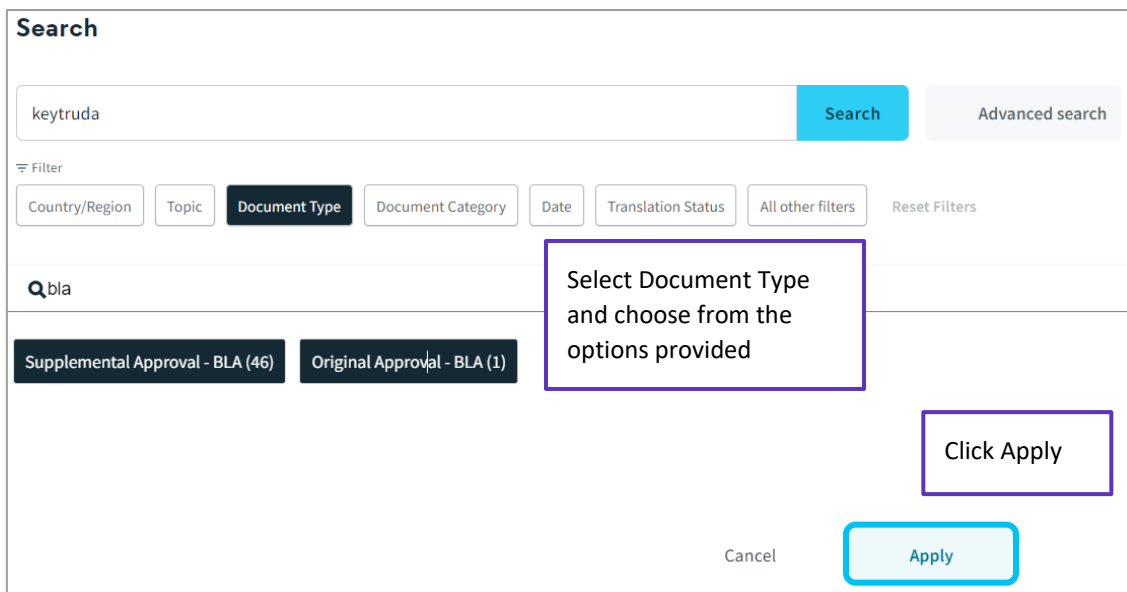
This guide shows you how to quickly access and fully benefit from US New Drug Applications (NDAs) and Biologics License Applications (BLAs) in *Cortellis Regulatory Intelligence* from 1997 to the present day.

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.



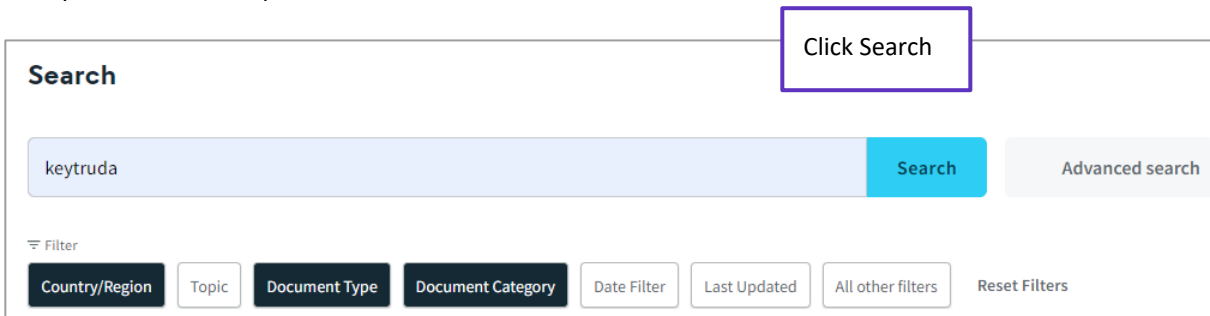
The screenshot shows the Clarivate Search Tool interface. At the top, there is a search bar with the text "keytruda" and a blue "Search" button. To the right of the search bar is a link for "Advanced search". Below the search bar is a "Filter" section with several tabs: "Country/Region", "Topic", "Document Type", "Document Category", "Date", "Translation Status", and "All other filters". The "Country/Region" tab is selected and highlighted in black. Below the tabs is a list of countries and regions with their respective counts: European Union (87), USA (77), Canada (9), Japan (7), China (2), Thailand (2), Brazil (1), Czech Republic (1), France (1), Slovakia (1), and Sweden (1). The "USA (77)" button is highlighted in black. At the bottom right, there is a blue "Apply" button and a "Cancel" link. Three purple boxes with white text provide instructions: "Type your product name" points to the search bar, "Select Country/Region and click on country of interest" points to the "Country/Region" tab, and "Click Apply" points to the "Apply" button.

- 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.



The screenshot shows the 'Search' interface with the search term 'keytruda' in the search bar. Below the search bar, there are filter buttons: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters'. The 'Document Type' button is highlighted. Below the filter buttons, there is a search bar with the text 'bla'. Below the search bar, there are two filter buttons: 'Supplemental Approval - BLA (46)' and 'Original Approval - BLA (1)'. A callout box points to the 'Document Type' filter with the text 'Select Document Type and choose from the options provided'. Another callout box points to the 'Apply' button with the text 'Click Apply'. The 'Apply' button is highlighted in blue.

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



The screenshot shows the 'Search' interface with the search term 'keytruda' in the search bar. Below the search bar, there are filter buttons: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date Filter', 'Last Updated', 'All other filters', and 'Reset Filters'. The 'Search' button is highlighted in blue. A callout box points to the 'Search' button with the text 'Click Search'.

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

Customize Columns	Sorted by Relevance				
Summary	Title	Abstract	Reason for Update	Country/Region	
<input checked="" type="checkbox"/> <div>24-Jun-2020</div> <div>EN RD</div>	<a href="#">Biologics License Application (supplemental BLA) 125514/092: KEYTRUDA (pembrolizumab) Solution for Injection – Approval Package, 24-Jun-2020</a>	This supplemental biologics license application, BLA 125514/092, provided for an alternate dosage regimen of 400 mg every 6 weeks for adult patients w	This document has been revised to include the Reviews of KEYTRUDA (pembrolizumab).	<div>USA</div>	
<input checked="" type="checkbox"/> <div>28-Apr-2020</div> <div>EN RD</div>	<a href="#">Biologics License Application (supplemental BLA) 125514/059/060/061/062/063/064/069/076/077/078/079/080/08 KEYTRUDA (pembrolizumab) Solutio</a>	These supplemental biologics license applications, BLA 125514/059/060/061/062/063/064/069/076/077/078/079/080/08 provided for an alternate	This document has been revised to include Summary Review of KEYTRUDA (pembrolizumab).	<div>USA</div>	
<input checked="" type="checkbox"/> <div>04-Sep-2014</div> <div>EN RD</div>	<a href="#">Biologics License Application (BLA) 125514: KEYTRUDA (pembrolizumab) Powder for Injection – Approval Package, 04-Sep-2014</a>	On September 04, 2014, FDA approved biologics license application BLA 125514 for KEYTRUDA (pembrolizumab). It was approved with 6 postmarketing study	This document has been revised to include Reviews of KEYTRUDA (pembrolizumab). This document contains the Approval Letter,	<div>USA</div>	

- 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.

**Biologics License Application (BLA) 125514: KEYTRUDA (pembrolizumab) Powder for Injection – Approval Package, 04-Sep-2014**

Valid 202095 USA Reference Document Original Approval - BLA

Drugs and Biologics

Product Assessment

1. Summary
2. Snapshot
3. Document
4. Reason For Update
5. Mentioned By

**Summary**

Abstract

On September 04, 2014, FDA approved biologics license application BLA 125514 for KEYTRUDA (pembrolizumab). It was approved with 6 postmarketing study requirements or commitments. The product has a medication guide.

Name: KEYTRUDA

Active ingredient(s): pembrolizumab

Company: Merck Sharp & Dohme Corp.

Indication(s): It is indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.

Pharmaco-therapeutic group - (ATC code): Antineoplastic agents,

⌵

Last Updated Date

07-Aug-2019

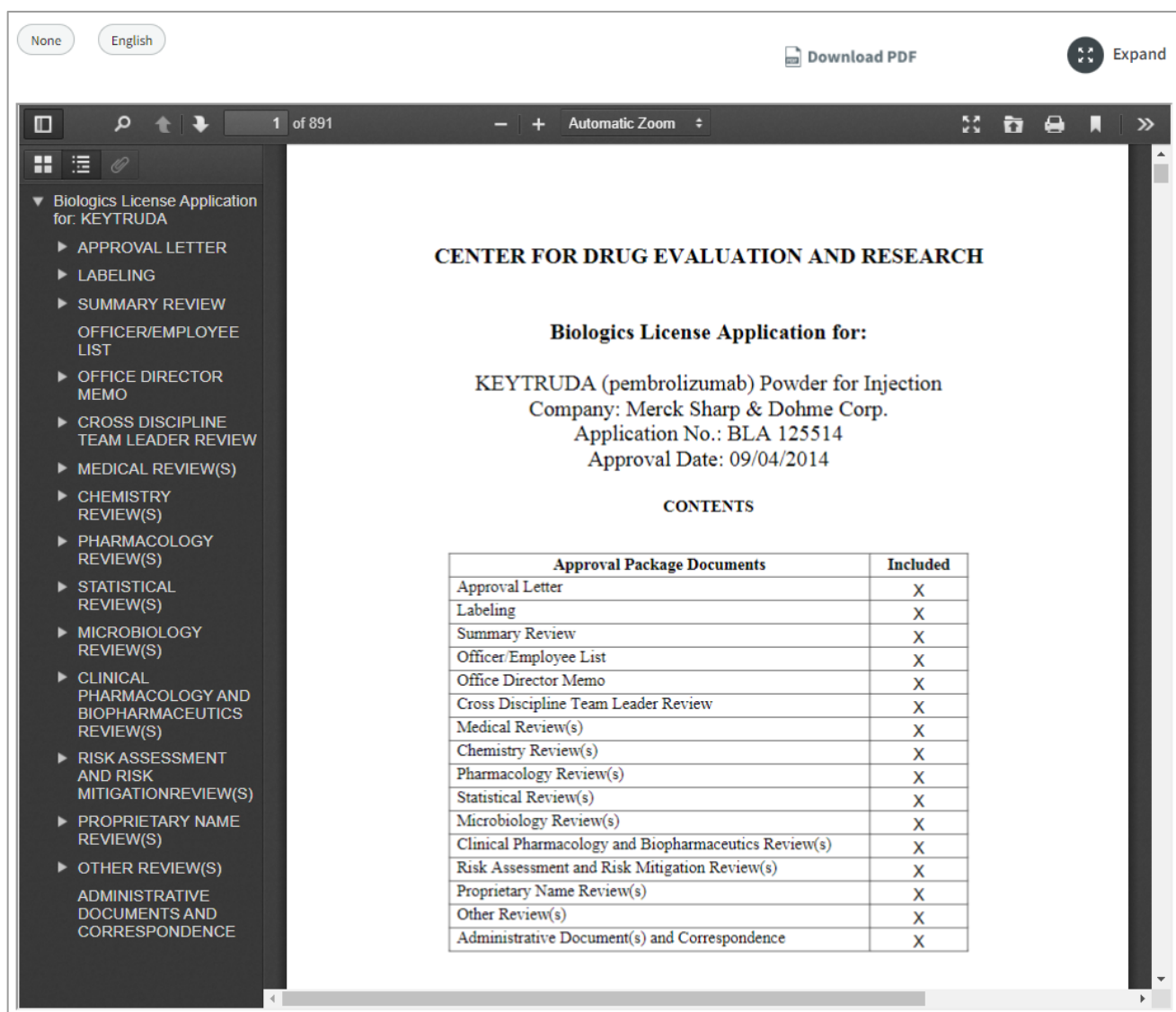
Authority Acceptance Date

04-Sep-2014

Source Publication Date

17-Oct-2014

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.



None English Download PDF Expand

1 of 891 Automatic Zoom

**Biologics License Application for: KEYTRUDA**

- ▶ APPROVAL LETTER
- ▶ LABELING
- ▶ SUMMARY REVIEW
- ▶ OFFICER/EMPLOYEE LIST
- ▶ OFFICE DIRECTOR MEMO
- ▶ CROSS DISCIPLINE TEAM LEADER REVIEW
- ▶ MEDICAL REVIEW(S)
- ▶ CHEMISTRY REVIEW(S)
- ▶ PHARMACOLOGY REVIEW(S)
- ▶ STATISTICAL REVIEW(S)
- ▶ MICROBIOLOGY REVIEW(S)
- ▶ CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)
- ▶ RISK ASSESSMENT AND RISK MITIGATION REVIEW(S)
- ▶ PROPRIETARY NAME REVIEW(S)
- ▶ OTHER REVIEW(S)
- ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Biologics License Application for:**

KEYTRUDA (pembrolizumab) Powder for Injection  
 Company: Merck Sharp & Dohme Corp.  
 Application No.: BLA 125514  
 Approval Date: 09/04/2014

**CONTENTS**

Approval Package Documents	Included
Approval Letter	X
Labeling	X
Summary Review	X
Officer/Employee List	X
Office Director Memo	X
Cross Discipline Team Leader Review	X
Medical Review(s)	X
Chemistry Review(s)	X
Pharmacology Review(s)	X
Statistical Review(s)	X
Microbiology Review(s)	X
Clinical Pharmacology and Biopharmaceutics Review(s)	X
Risk Assessment and Risk Mitigation Review(s)	X
Proprietary Name Review(s)	X
Other Review(s)	X
Administrative Document(s) and Correspondence	X

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

11 results for 'nslc AND "breakthrough therapy"'

Switch to Comparison Tables

Refine Search

nslc AND "breakthrough therapy" Search

Filter

Country/Region Topic Document Type Document Category Date Translation Status All other filters Reset Filters

Side by Side Viewer Showing 1-10 of 11 results

Customize Columns Sorted by Relevance

Summary	Title	Abstract	Reason for Update
<input checked="" type="checkbox"/> 06-May-2020 V US EN RD	New Drug Application (NDA) 213591: TABRECTA (capmatinib) Tablet – Approval Package, 06-May-2020	On May 06, 2020, FDA approved new drug application NDA 213591 for TABRECTA (capmatinib). It was approved with the	This update contains a change to metadata.
<input checked="" type="checkbox"/> 11-Dec-2015 V US EN RD	New Drug Application (NDA) 208434: ALECENSA (alectinib) Capsule – Approval Package, 11-Dec-2015	On December 11, 2015, FDA approved new drug application NDA 208434 for ALECENSA (alectinib). It was approved with the	This document has been revised to include Reviews of ALECENSA (alectinib). This document contains the Approval Letter,
<input checked="" type="checkbox"/> 28-Apr-2017 V US EN RD	New Drug Application (NDA) 208772: ALUNBRIG (brigatinib) Tablet – Approval Package, 28-Apr-2017	On April 28, application (brigatinib).	

Packaging: Bottle

Route of administration: Oral use

Review classification/review pathway:

- Priority review drug
- Orphan review drug
- Accelerated approval
- Breakthrough therapy

NDA chemical type: New molecular entity

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