



# Easily interpret official documents with English translations in Cortellis Regulatory Intelligence

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# Quick quiz

1. Cortellis Regulatory Intelligence provides which types of English translations?

- A) Machine translations
- B) Cortellis expert translations
- C) Authority translations
- D) All of the above

2. TRUE or FALSE: You can search across the full text of all native source documents and their English translations?

- A) True
- B) False



# Quick quiz - answers

1. Cortellis Regulatory Intelligence provides which types of English translations?

- A) Machine translations
- B) Cortellis expert translations
- C) Authority translations
- D) All of the above

2. TRUE or FALSE: You can search across the full text of all native source documents and their English translations?

TRUE: The Source Document Search enables you to search the pdf full text including the English translations

# Agenda

- Cortellis Regulatory Intelligence
- Types of English Translations
- Searching English Translations
- Feedback and Q&A

# What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities



**300K+ official documents**



**8K+ Value-add regulatory reports, analyses and global comparisons**



**English translations for all native language documents**



**81 countries and regions  
Drugs & Biologic and  
75 Medical Devices & IVDs**



**Updated daily**



**Regulatory experts & local consultants**



# Handout

- Slide 7: Types of English translations in Cortellis
- Slides 8-10: How to identify and access different translation types
- Slides 11-12: Easily find human translations
- Slides 13-15: Search keyword(s) in English translations of document PDFs
- Slide 16: Get assistance with Cortellis

# Types of English Translations in Cortellis

Access via the Translation Status Filter

The screenshot shows the Cortellis search interface. At the top, there is a 'Quick Search' section with a text input field labeled 'Quick search English keywords', a blue 'Search' button, and a grey 'Advanced search' button. Below this is a 'Filter' section with several buttons: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters'. A purple arrow points to the 'Translation Status' button, which has a purple 'New' badge above it. To the right of the filters is a 'Reset Filters' link. Below the filters is a search bar with a magnifying glass icon, and buttons for 'Select all', 'Clear all', and 'Sort by' with a dropdown menu set to 'Frequency'. At the bottom, a purple box highlights a row of five filter buttons: 'Machine Translation (34533)', 'Authority Official (6382)', 'Authority Unofficial (4506)', 'Cortellis Translation (3212)', and 'Cortellis in Progress (1)'.

**Authority Official:** Translations published in the Official Journal, or translations from medicines Agencies identified as official.

**Authority Unofficial:** Translations from Medicines Agencies which are identified as unofficial, or translations provided by non-authority source(e.g. association or research institute).

**Cortellis Translation:** Human translations curated by experts (Clarivate contract translator, consultant, or internal content specialists).

**Cortellis in Progress:** The local language version is already available and once the Cortellis human translation is finished it will be added to the same document.

**Machine Translation:** Automated English translations powered by Google. Available for all Source Documents that do not have human translations.

# English Translations of Source documents

## Human Translations

**Federal Law N 61-FZ of 12-Apr-2010: On Circulation of Medicinal Products (Consolidated Version up to Amendment the Federal Law N 1-FZ of 30-Jan-2024)**

Valid 209259 Russian Federation Reference Document Law **Translation: Cortellis Translation**

Drugs and Biologics

Clinical Research Comp

File 1  
▶ Cortellis Translation English version  
▶ Original file

12 April 2010 No. 61-FZ

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**RUSSIAN FEDERATION**  
**FEDERAL LAW**  
**ON CIRCULATION OF MEDICINAL PRODUCTS\***

Adopted  
by the State Duma  
on 24 March 2010

Approved  
by the Council of Federation  
on 31 March 2010

(as amended by Federal Laws No. 192-FZ of 27/07/2010,  
No 271-FZ of 11/10/2010, No. 313-FZ of 29/11/2010,  
No. 409-FZ of 06/12/2011, No. 93-FZ of 25/06/2012,  
No. 262-FZ of 25/12/2012, No. 185-FZ of 02/07/2013,  
No. 317-FZ of 25/11/2013, No.33-FZ of 03/12/2014,  
No.313-FZ of 10/22/2014, No 429-FZ of 22/12/2014,  
No 34-FZ of 08/03/2015, No. 160-FZ of 29/06/2015,  
No. 233-FZ of 13/07/2015, No. 241-FZ of 13/07/2015,  
No. 262-FZ of 13/07/2015, No. 374-FZ of 14/12/2015,  
No. 389-FZ of 29/12/2015, No. 163-FZ of 02/06/2016,  
No. 261-FZ of 03/07/2016, No. 305-FZ of 03/07/2016,  
No. 350-FZ of 03/07/2016, No. 242-FZ of 29/07/2017,  
No. 278-FZ of 29/07/2017; No 425-FZ of 28/12/2017;  
No. 140-FZ of 04/06/2018, No. 449-FZ of 28/11/2018,  
No. 511-FZ of 27/12/2018, No. 134-FZ of 06/06/2019  
No. 240-FZ of 26/07/2019, No. 297-FZ of 02/08/2019,  
No. 462-FZ of 27/12/2019, No. 475-FZ of 27/12/2019,  
No. 67-FZ of 26/03/2020, No. 98-FZ of 01/04/2020,  
No. 105-FZ of 03/04/2020, No. 206-FZ of 13/07/2020,

1. View at the top what type of translation is available for that document

2. Human Translations will be indicated by either Cortellis Translation, Authority Official or Authority Unofficial

3. The translation will be contained in the pdf document with the native language version



# English Translations of Source documents

## Human Translations

**Austrian Federal Office for Safety in Health Care (BASG): Questions and Answers on Summary of Product Characteristics and Package Leaflets, 21-Aug-2024**

Valid 389205 Austria Reference Document Questions & Answers **Translation: Authority Official**

Drugs and Biologics

Generics and Biosimilars Authorities and Organizations Regulatory Procedures Pharmacovigilance Technovigilance Risk Management ...

File 1

- ▼ Authority Official English version
  - ▶ SmPC and PL
  - ▶ Original file

### SmPC and PL **New**

- 1. For which proprietary medicinal products do the readability, clarity, and user-friendliness have to be assessed in a readability test? When do the results of the readability test have to be submitted?
- 2. Are there exceptions to the requirement to submit a readability test?
- 2.1. Are the QRD templates also binding for Package Leaflets that have already undergone a readability test?
- 2.2. Does a readability test have to be performed when a Package Leaflet is adapted to the new QRD template?
- 3. Does the Package Leaflet (PL) of a new application for marketing authorisation for a generic medicinal product have to undergo readability testing even if the PL directly corresponds to the PL of the reference medicinal product?
- 4. Does a readability test also have to be submitted for already authorised proprietary medicinal products?
- 5. In what form and where in the dossier should the readability test results be presented?

1. View at the top what type of translation is available for that document

2. Human Translations will be indicated by either Cortellis Translation, Authority Official or Authority Unofficial

3. The translation will be contained in the pdf document with the native language version

# English Translations of Source documents

## Machine Translations

**Medicinal Products Act of 24-Aug-1976 (Arzneimittelgesetz - AMG) (Amended Version of 03-Jun-2021)**

Valid 347848 Germany Reference Document Law **Translation: Machine Translation**

Drugs and Biologics

Document

Revision 09-Jun-2021 German

Ein Service des Bundesministeriums  
sowie des Bundesamts für

**Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz - AMG)**

AMG

Ausfertigungsdatum: 24.08.1976

Vollzitat:

"Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 (BGBl. I S. 3394), das zuletzt durch Artikel 9 des Gesetzes vom 3. Juni 2021 (BGBl. I S. 1309) geändert worden ist"

**Stand:** Neufassung durch Bek. v. 12.12.2005 I 3394;  
zuletzt geändert durch Art. 1 V v. 19.5.2021 I 1164

**Hinweis:** Änderung durch Art. 9 G v. 3.6.2021 I 1309 (Nr. 28) textlich nachgewiesen, dokumentarisch noch nicht abschließend bearbeitet

**Fußnote**

(+++ Textnachweis Geltung ab: 6.6.1986 +++)  
(+++ Zur Anwendung vgl. §§ 63j, 109, 141 +++)  
(+++ Amtlicher Hinweis des Normgebers auf EG-Recht:  
Umsetzung der  
EURL 84/2010 (CELEX Nr.: 32010L0084)  
EURL 62/2011 (CELEX Nr.: 32011L0062)  
EURL 24/2011 (CELEX Nr.: 32011L0024) vgl. G v. 19.10.2012 I 2192 +++)

Das G wurde als Artikel 1 G v. 24.8.1976 I 2445 vom Bundestag mit Zustimmung des Bundesrates beschlossen.  
Es ist mit Ausnahme d. § 78 am Art. 10 dieses G am 1.1.1978 in Kraft getreten.

1. View at the top what type of translation is available for that document
2. Scroll to the Document
3. Click the Machine Translation Document icon and select preferred format to open

Machine Translated by Google

A service of the Federal Ministry of Justice and Consumer Protection  
and the Federal Office of Justice | www.gesetze-im-internet.de

**Law on the trade in medicinal products (Medicines Act - AMG)**

AMG

Date of issue: August 24, 1976

Full quote:

"Medicinal Products Act in the version published on December 12, 2005 (BGBl. I p. 3394), the most recent has been changed by Article 9 of the law of June 3, 2021 (BGBl. I p. 1309)"

**Was standing:** Rewritten by Bek. December 12, 2005 I 3394;  
last amended by Art. 1 V v. May 19, 2021 I 1164

**Note:** Change by Art. 9 G v. June 3, 2021 I 1309 (No. 28) proven textually, still documented not finalized

**footnote**

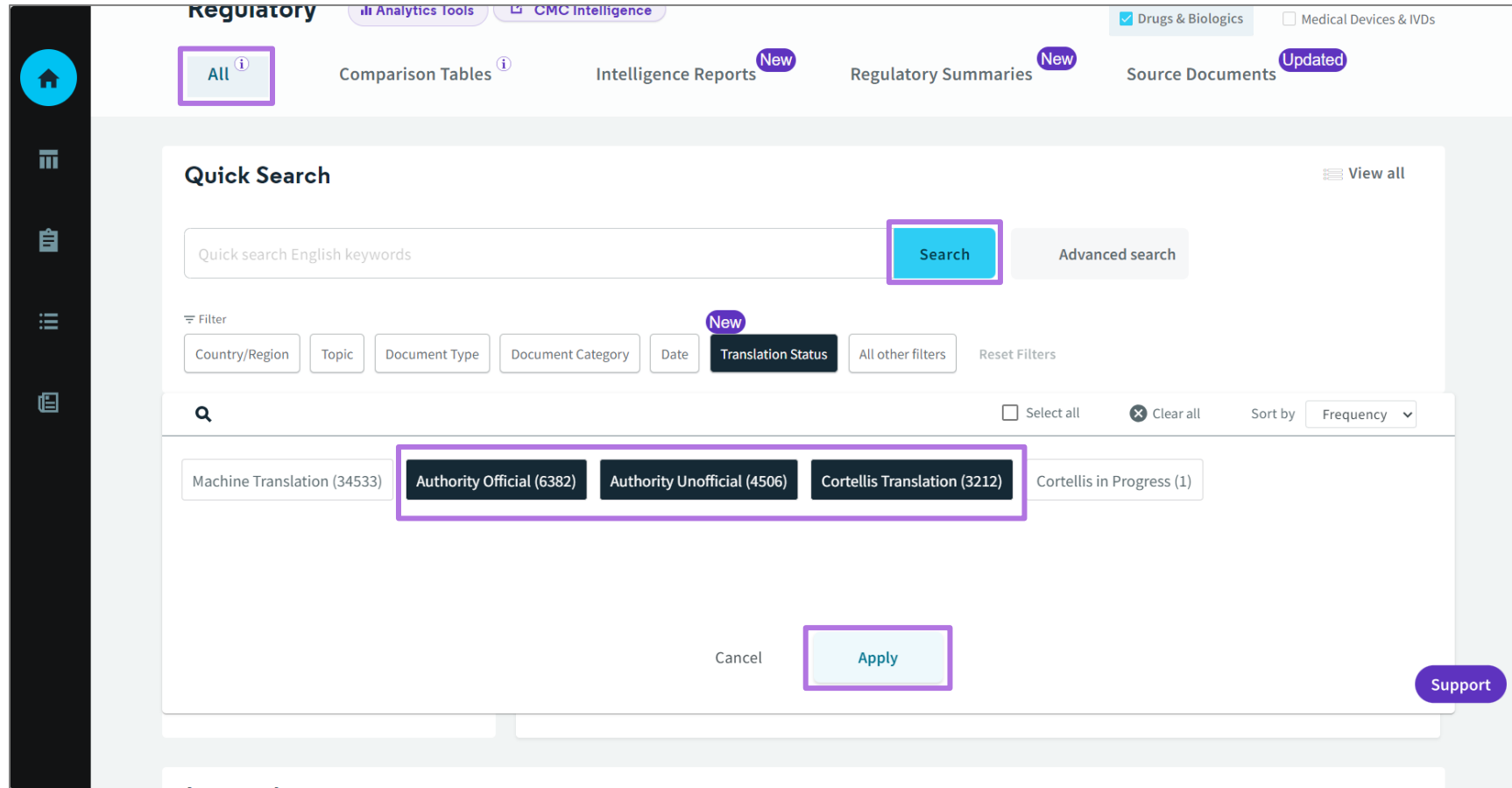
(+++ Text reference valid from: June 6, 1986 +++)  
(+++ For application see §§ 63j, 109, 141 +++)  
(+++ Official reference from the standard provider to EC law:  
Implementation of  
EURL 84/2010 (CELEX No.: 32010L0084)  
EURL 62/2011 (CELEX No.: 32011L0062)  
EURL 24/2011 (CELEX No.: 32011L0024) cf. G v. 10/19/2012 I 2192 +++)

The G was introduced as Article 1 G of. August 24, 1976 I 2445 passed by the Bundestag with the consent of the Bundesrat.  
It is with the exception of d. § 78 according to Article 10 of this G came into force on January 1, 1978.  
Legal abbreviation: Inserted. by Art. 1 No. 1 G v. July 30, 2004 I 2031 mWv August 6, 2004

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# Quick Search

Easily find Human Translations



1. Go to Quick Search

2. Click the Translation Status filter

3. Select Authority Official, Authority Unofficial and Cortellis Translation

4. Click Apply

5. Add other filters if desired

6. Click the blue Search button

# Quick Search

Easily find Human Translations (Results list)

Customize Columns   Sorted by Relevance

Summary	Title	Reason for Update	Country/Region	Language(s)
<div><div>30-Sep-2024</div><div>EN,JA</div><div>RD</div></div>	Notification: PSB/PED No. 0930/7: Methods for Description and Procedures for Change in Manufacturing Methods of Drugs, 30-Sep-2024	This source document has been revised to add a Cortellis exclusive English language translation.	Japan	<div>English</div> <div>Japanese</div>
<div><div>09-Jul-2024</div><div>EN,KO</div><div>RD</div></div>	MFDS Guide-0056-05: Guidelines for the Compassionate Use of Investigational Products, 09-Jul-2024	This source document has been revised to add a Cortellis exclusive English language translation.	South Korea	<div>English</div> <div>Korean</div>
<div><div>20-Jun-2024</div><div>EN,JA</div><div>RD</div></div>	Notice: PSB/PED: Points to Note on the Use of Master Protocol in Drug Development, 20-Jun-2024	This source document has been revised to add an official translation published by PMDA as of 11-Jul-2024.	Japan	<div>English</div> <div>Japanese</div>

1. Languages are listed on the results page:

Documents that list the native language and English have human translations; (those that list only the native language have machine translations).

2. Click the hyperlinked titles to open documents of interest



# Source Document Search

Search keyword(s) in English translations of document PDFs

**Regulatory**

All ⓘ Comparison Tables ⓘ Intelligence Reports ⓘ Regulatory Summaries ⓘ **Source Documents ⓘ**

**Search**

nitrosamine\* **Search** Advanced search

Filter

Document type ⓘ Country/Region Topic Date Translation Status Medical Devices Specialty All other filters Reset Filters

Guideline

1. Go to Source Documents
2. Type in keywords;  
example: nitrosamine\*  
(use asterisk (\*) as wildcard if desired)
3. Add other relevant filters if desired
4. Click the blue Search button

# Source Document Search

Search keyword(s) in English translations of document PDFs - (Results list)

Customize Columns   Sorted by Authority Acceptance Date

Summary	Title	Country/Region	Language(s)
<div><div><input checked="" type="checkbox"/></div><div>24-Sep-2024</div><div>V</div><div>TW</div><div>ZH</div><div>RD</div></div> <div>TFDA Announcement No.1131411994: Soliciting Public Comments on ICH M3(R2): Guidelines for Nonclinical Safety Studies for the Conduct of Human Clinica</div> <div>Taiwan</div> <div>Chinese</div>	<div><div><input checked="" type="checkbox"/></div><div>20-Sep-2024</div><div>V</div><div>TW</div><div>ZH</div><div>RD</div></div> <div>CDE Guideline: Technical Guidelines for Starting Material Selection Strategy in the Manufacturing of Chemical Active Pharmaceutical Ingredients, Vers</div> <div>Taiwan</div> <div>Chinese</div>	<div><div><input checked="" type="checkbox"/></div><div>12-Sep-2024</div><div>V</div><div>BR</div><div>PT</div><div>RD</div></div> <div>ANVISA Library of Medicinal Products, 12-Sep-2024</div> <div>Brazil</div> <div>Portuguese</div>	

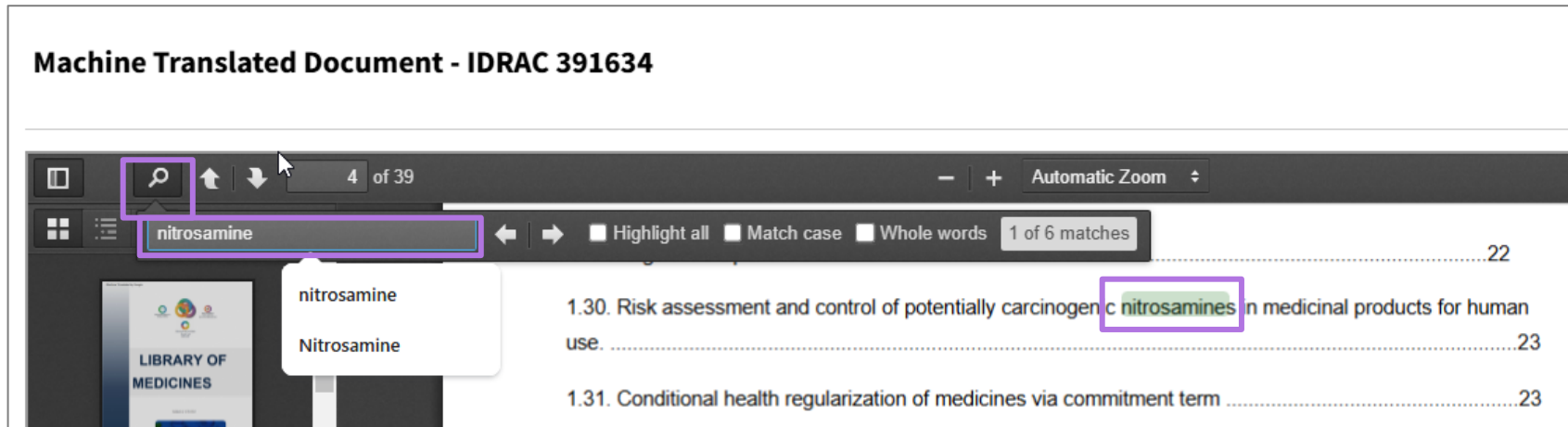
1. Languages are listed on the results page:

Documents that list only the native language have machine translations; (those that list the native language and English have human translations).

2. Click a hyperlinked titles to open a document of interest

# Source Document Search

Search keyword(s) in English translations of document PDFs



1. Consult the English translation (example: machine translation)

2. Use the “Find in Document” tool to locate the keyword in the pdf full text



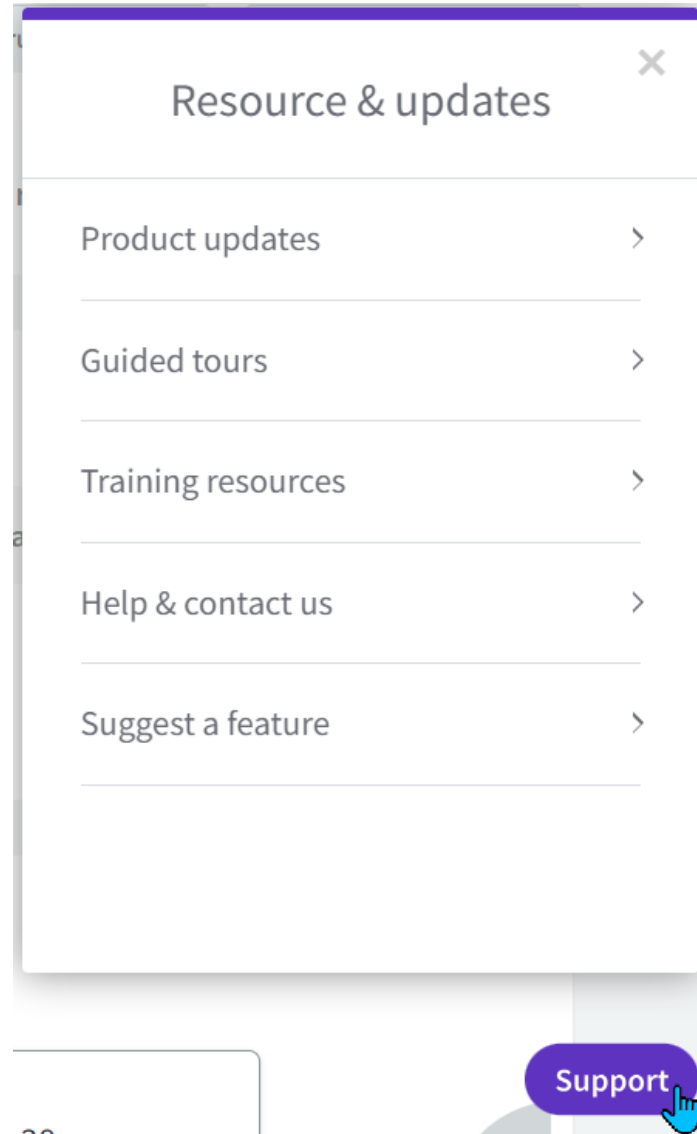
# Get assistance with Cortellis

In-product guidance to assist you with your questions

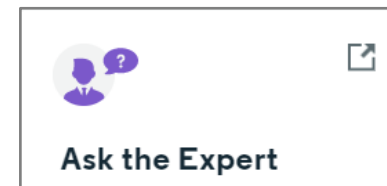
- Click at the Support button at the bottom of the screen

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- Help & contact us - contact Customer Care
- Guided tours - walk through the Cortellis platform
- Training resources - recorded trainings, Quick guides and short videos
- Ask the Expert (on Regulatory homepage)







# Thank you! Questions?

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#### About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit [clarivate.com](https://clarivate.com)

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