

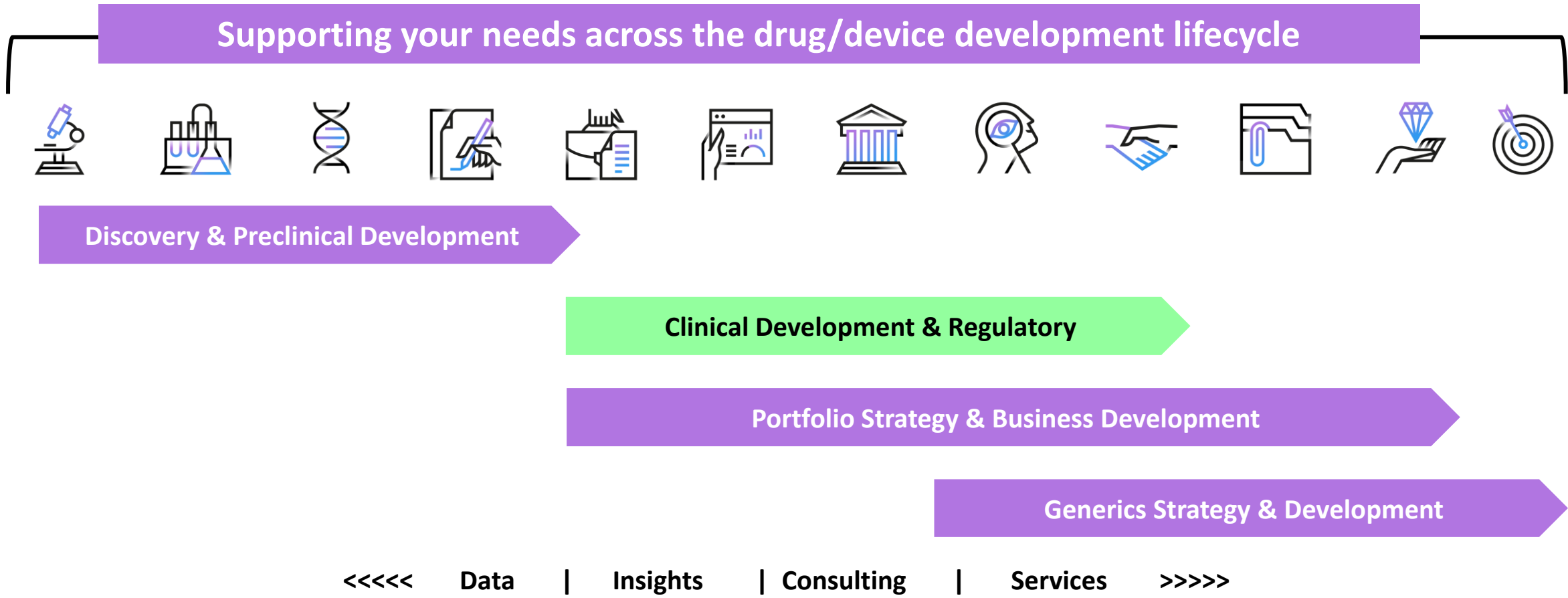
AstraZeneca training: Cortellis Regulatory Intelligence essentials and enhancements

Agenda

- What is Cortellis and how to access it?
- Live demo
- Cortellis Regulatory Intelligence enhancements
- Feedback, wrap up, Q&A

Unlock hidden insights and bring life to science

Make data-driven decisions with speed and certainty



What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities



290K+ official documents



9.5K Value-add regulatory reports, analyses and global comparisons



Exclusive English translations



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



Updated daily



Regulatory experts & local consultants

What you will learn today:

1. How to subscribe to the Weekly Newsletter and set up your own alerts to keep track of changes
2. How to easily compare key requirements across countries & regions
3. Where to find up-to-date English language information on the legislation & guidelines you need to follow
4. Take advantage of recent enhancements, including machine translations and multiple search improvements.

Clarivate for AstraZeneca Resource Page

Quick links to all Clarivate resources available to you

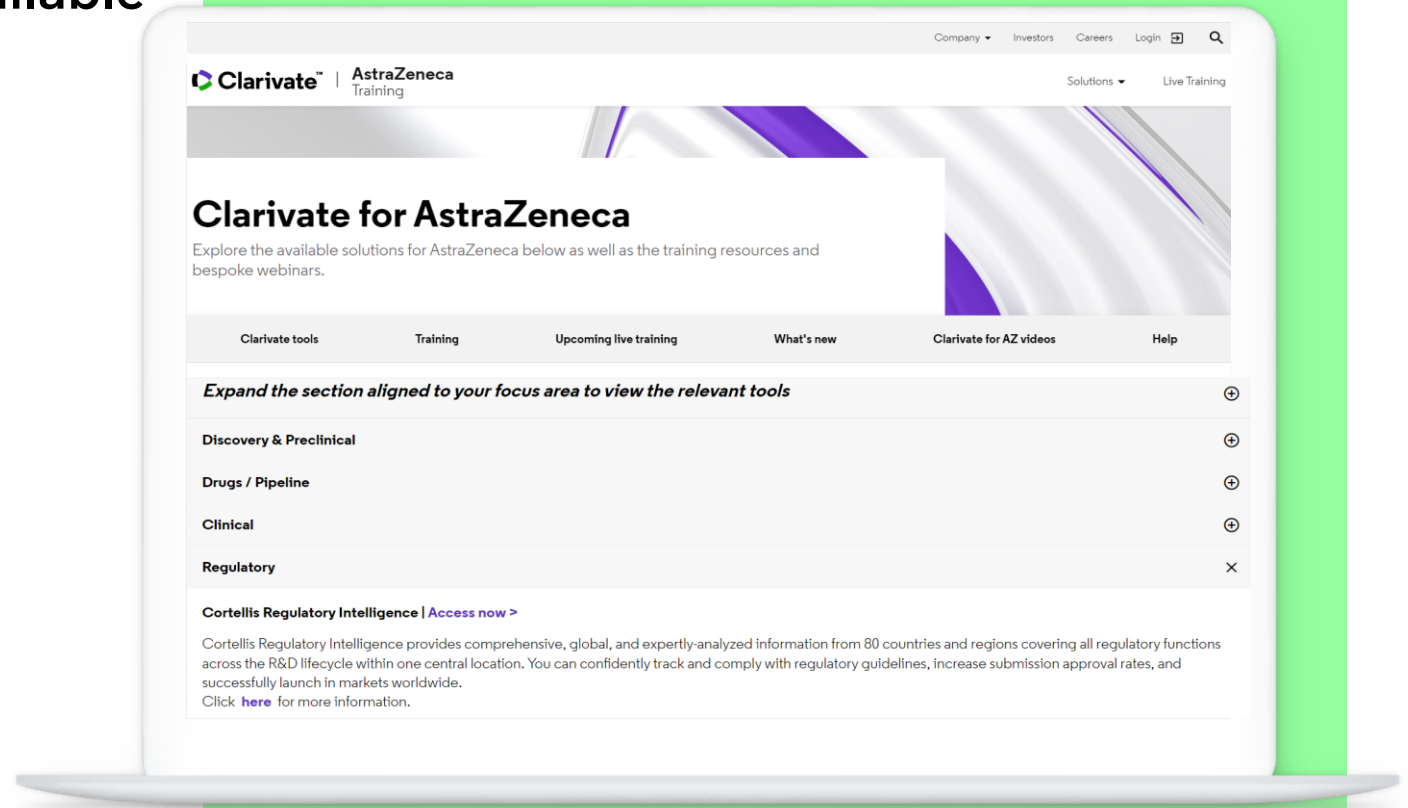
✓ Easy access to all platforms **including Cortellis access**

✓ Upcoming live sessions

✓ Recorded videos

✓ What's new

✓ Contact support



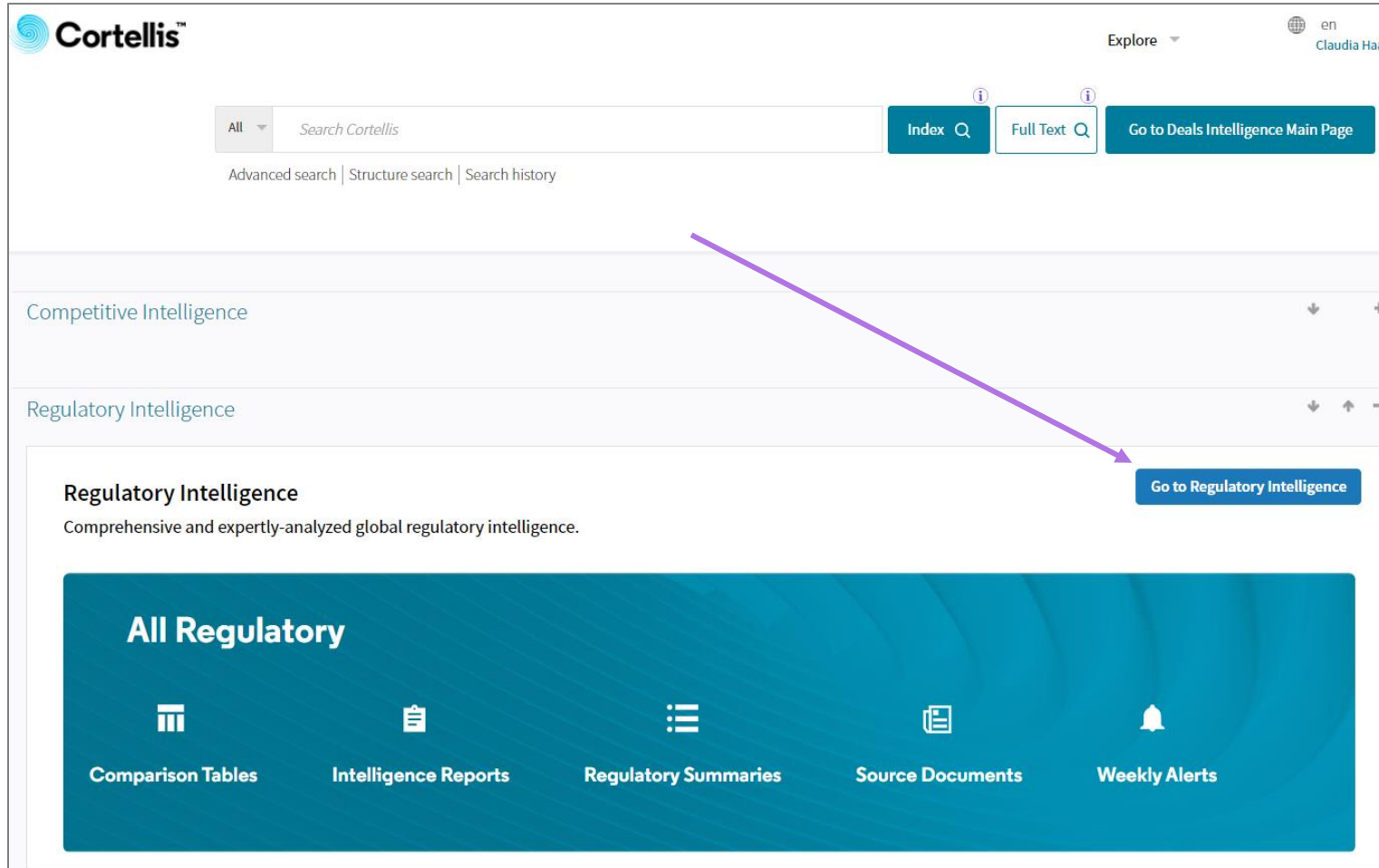
ACCESS HERE



Handout

Cortellis Landing Page

Click the “**Go to...**” button to access Cortellis Regulatory Intelligence



The screenshot shows the Cortellis landing page. At the top left is the Cortellis logo. To the right, there is an 'Explore' dropdown menu and a user profile for 'en Claudia Haa'. Below the logo is a search bar with a dropdown menu set to 'All' and the placeholder text 'Search Cortellis'. To the right of the search bar are two buttons: 'Index' and 'Full Text', both with search icons. Further right is a button labeled 'Go to Deals Intelligence Main Page'. Below the search bar are links for 'Advanced search', 'Structure search', and 'Search history'. The main content area is divided into sections. The first section is 'Competitive Intelligence'. The second section is 'Regulatory Intelligence', which is expanded. Inside this section, there is a sub-section titled 'Regulatory Intelligence' with the description 'Comprehensive and expertly-analyzed global regulatory intelligence.' To the right of this sub-section is a blue button labeled 'Go to Regulatory Intelligence'. Below this is a large teal banner titled 'All Regulatory' with five icons and corresponding labels: 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', 'Source Documents', and 'Weekly Alerts'. A purple arrow points from the top of the 'Regulatory Intelligence' section down to the 'Go to Regulatory Intelligence' button.

Cortellis Regulatory Homepage

Start searching through all documents, click the tabs to browse value-add tables, reports and summaries or access the Cortellis Weekly Alerts newsletter.

The screenshot displays the Cortellis Regulatory homepage. At the top left, the Cortellis logo is visible. The user's name, Claudia Haas, is in the top right corner. Below the logo, there are navigation tabs for 'Regulatory', 'Analytics Tools', and 'Covid-19 Regulation Tracker'. On the right side, there are checkboxes for 'Drugs & Biologics' and 'Medical Devices & IVDS', both of which are checked. A purple box highlights a row of navigation tabs: 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. Below this is a search section with a text input field containing the placeholder 'Document title, topic, country, reference', a 'Search' button, and an 'Advanced search' button. Underneath the search bar are filter buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters', along with a 'Reset Filters' button. On the left side, there are two sections: 'Ask the Expert' and 'Local Consultants'. A purple box highlights the 'Weekly Alerts' section, which shows a carousel of newsletters. The current issue is '2022 Volume 49' with a 'Current Issue' badge. Other issues shown are '2022 Volume 48' (dated 21-Nov-2022 to 25-Nov-2022) and '2022 Volume 47' (dated 14-Nov-2022 to 18-Nov-2022). An 'Edit' button is located in the top right corner of the Weekly Alerts section.

Cortellis Weekly Alert

Monday newsletter containing new and updated documents for all countries & regions of the previous week: Available in html format or Excel.

Weekly Alerts

Drugs & Biologics Medical Devices & IVDs

2023
Volume 33
Current Issue
HTML X
PREVIEW DOWNLOAD

2023
Volume 32
31-Jul-2023 to
04-Aug-2023

2023, Volume 33 of Monday 07 August to Friday 11 August 2023

International (4)	USA (159)
EUROPE	
European Union (101)	Finland (6)
EAEU (1)	France (12)
Austria	Germany (2)
Belgium	Greece
Bulgaria	Hungary
Croatia	Iceland
Cyprus	Ireland
Czech Republic	Italy (2)
Denmark (1)	Latvia
Estonia (1)	Lithuania (1)
ASIA - PACIFIC	
Asean	India (3)
Australia (1)	Indonesia (1)
China (7)	Japan (5)
Hong Kong	Malaysia (3)
LATIN AMERICA	
Mercosur	Brazil (6)
SICA	Chile (1)
Argentina (3)	Colombia
AFRICA - MIDDLE EAST	
Gulf Cooperation Council (1)	Israel (1)
Algeria	Jordan
Egypt (7)	Kenya (4)
Iraq	Lebanon

Cortellis Weekly Alert

Monday newsletter containing new and updated documents for all countries & regions of the previous week: Available in html format or Excel.

Weekly Alerts

Drugs & Biologics
Medical Devices & IVDs

2023
Volume 33

<

Current Issue

HTML

X

Excel

PREVIEW DOWNLOAD

2023
Volume 32

A	B	C	D	E	G
Country/Region	Title	Abstract	Link to full document	Authority Acceptance	Type
Argentina	Authorities / Organizations: Argentine Medicines Regulation	This document describes the structure, organization and	Full report (IDRAC 26936)	9-Aug-23	Expert Report
Argentina	How to Market Herbal Products	This Regulatory Summary relates to plant based medicina	Full report (IDRAC 26808)	9-Aug-23	Expert Report
Argentina	Decree 405/2023: Approves the Regulation of Law 27.669	This Decree approves the regulation of Law 27.669 (IDRAC	Full report (IDRAC 369145)	4-Aug-23	Decree
Australia	Public Comments Tracker	This Regulatory Intelligence Report provides the Consult	Full report (IDRAC 56646)	11-Aug-23	Public Comment
Brazil	Public Comments Tracker	This Regulatory Intelligence Report provides the Consult	Full report (IDRAC 205712)	11-Aug-23	Public Comment
Brazil	Guide: Submission of Import Application through the LPC	ANVISA has created this guide aiming to explain the Impc	Full report (IDRAC 369219)	4-Aug-23	Guideline
Brazil	Public Consultation 1.188: Proposes a Resolution on the A	This Draft is a Resolution that proposes to amend Resolut	Full report (IDRAC 369244)	3-Aug-23	Resolution
Brazil	Resolution RDC 768: Establishes the Rules for the Labeling	This resolution aims at improving the format and content	Full report (IDRAC 369363)	4-Aug-23	Resolution
Brazil	Resolution RDC 807: Importation of Goods and Products S	This Resolution provides for the criteria and procedures f	Full report (IDRAC 369354)	4-Aug-23	Resolution
Canada	Legal Definitions and Marketing Requirements	This document provides the definition of medicinal prod	Full report (IDRAC 91648)	9-Aug-23	Expert Report
Canada	Marketing Authorization Procedures: Procedure for Apply	This document provides general information on the proce	Full report (IDRAC 130705)	10-Aug-23	Expert Report
Canada	Marketing Authorization Procedures: Withdrawal / Suspe	This document provides information about the Procedure	Full report (IDRAC 24054)	8-Aug-23	Expert Report
Canada	Combination Products Regulatory Framework	This regulatory summary is related to Combination Produ	Full report (IDRAC 48210)	7-Aug-23	Expert Report
Canada	Announcement: Exceptional Importation and Sale of Drug	This announcement informs about exceptional importati	Full report (IDRAC 309645)	9-Aug-23	Announcement
Canada	Announcement: Health Product Advertising Incidents Rel	The health and safety of all Canadians is Health Canada's	Full report (IDRAC 310589)	10-Aug-23	Announcement
Canada	Notice: Drug and Vaccine Authorizations for COVID-19, 04	This notice provides information about Health Canada ev	Full report (IDRAC 318331)	4-Aug-23	Announcement
Canada	Patented Medicines (Notice of Compliance) Regulations	Please note that this consolidated version include the las	Full report (IDRAC 24640)	25-Jul-23	Announcement
Canada	Access to Information Act, Consolidated Version as of 25-	This Act provides the legislation under which Canadians c	Full report (IDRAC 24622)	25-Jul-23	Law

Search

Enter keywords and use dynamic filters to narrow down your search.

The screenshot displays the Clarivate Regulatory search interface. At the top, the 'Regulatory' section includes tabs for 'Analytics Tools' and 'CMC Intelligence'. On the right, two filter buttons are checked: 'Drugs & Biologics' and 'Medical Devices & IVDs'. Below this, navigation tabs include 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Quick Search' section features a search input field containing the text '"adr reporting"', a 'Search' button, and an 'Advanced search' button. A filter panel below the search bar includes a 'Filter' icon, a 'Country/Region' dropdown, a 'Topic' dropdown, and several filter categories: 'Document Type', 'Document Category', 'Date', 'Translation Status', 'All other filters', and 'Reset Filters'. At the bottom of the filter panel, there are 'Cancel' and 'Apply' buttons. The main content area shows a list of filter categories with their respective counts, such as 'Pharmacovigilance Technovigilance Risk Management (103)', 'Product Assessment (30)', 'Clinical Research (25)', 'Legislative Framework (18)', 'Authorities and Organizations (16)', 'Compliance and Inspection (15)', 'Packaging and Labelling (9)', 'Regulatory Procedures (6)', 'GXP (5)', 'Prescription Requirements (3)', 'Advertising and Promotion (2)', 'Distribution (2)', 'Environment (2)', 'Generics and Biosimilars (2)', 'GVP (2)', 'Post authorization Studies (2)', 'eHealth (1)', 'Manufacturing and Control (1)', and 'Pediatrics (1)'. A 'View all' link is visible in the top right of the search results area. A purple arrow points from the text 'Filter to Drugs & Biologics or Medical Devices & IVDs content' to the filter buttons at the top right.

Browse Comparison Tables

Quickly browse Comparison Tables and click a topic of interest to open them.

The screenshot displays a web interface for browsing comparison tables. At the top, there are navigation tabs: 'All', 'Comparison Tables' (highlighted with a purple box), 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. Below the tabs, there are two main sections: 'Drugs and Biologics' and 'Medical Devices and IVDs'. Each section contains a list of topics, each with a right-pointing arrow icon. The 'CTD/eCTD Acceptability Framework' link under the 'Drugs and Biologics' section is highlighted with a purple box. The 'Browse' button in the top left corner is also highlighted with a purple box.

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

Browse Search

Drugs and Biologics Medical Devices and IVDs

► **Authorities and Organizations**
Health Ministry and Regulatory Agency Directory

► **Legal Definitions and Marketing Requirements**
Legislative/Regulatory Framework: Biosimilar Products
Legislative/Regulatory Framework: Generic Products
National Pharmaceutical Laws and Regulations Directory
National Pharmacopeia Directory

► **Format and Content of Applications**
CTD/eCTD Acceptability Framework
Finished Product Stability Data Requirements

► **Marketing Authorization Procedures**

► **Authorities and Organizations**
IVD Regulatory Agency Directory
Medical Device Regulatory Agency Directory

► **Legal Definitions and Product Classification**
IVD Classification Summary
IVD Laws and Regulations Summary
Medical Device Classification Summary
Medical Device Laws and Regulations Summary

► **Market Clearance**
IVD Marketing Application Procedures
IVD Post-Marketing Procedures
Medical Device Marketing Application Procedures

Comparison Tables - Example

Compare key requirements across countries & regions in one single place. Link out to connected documents to learn more.

Global Comparison					
Apply Filters					
Country/Region	CTD Acceptability	CTD Acceptability Notes	eCTD Acceptability	eCTD Acceptability Notes	Online Electronic Submission (Agency portals, email addresses, etc.)
Algeria	Yes	Article 25 of the Executive Decree No. 20-325: CTD format is mandator ...	Yes	Although not officially stated in the regulations, electronic submiss ...	Not applicable
Argentina	Yes	The format and content of a Marketing Authorization Application depen ...	No	N/A	Yes, for Article 3 and 4 products, and for biologics and vaccines, vi ...
Australia	Yes	Mandatory	Yes	As of eCTD sub	
Austria	Yes	Mandatory	Yes	Mar pro vari	
Belgium	Yes	Mandatory	Yes	Mar ren	

Regulatory Summary on CTD/eCTD	Reference Document(s) on CTD	Reference Document(s) on eCTD	Reference Document(s) on Validation Criteria
Application Format, Content and Submission	Executive Decree n° 20-325 Related to Pharmaceutical Products ...	N/A	N/A
Application Format, Content and Submission	Circular 11: Registration procedure for Biological and Radiopharmaceutical ...	Disposition 0680/2013: Adopts the "Electronic Management System with ...	N/A
Application Format, Content and Submission	Guideline: CTD Module 1: Administrative Information and ...	Frequently Asked Questions: Australian eCTD Submissions, 19-Sep-2016Guideline: ...	Guideline: AU eCTD Specification: Module 1 and Regional Information, Version ...
Application Format, Content and Submission	Guideline History: NTA Volume 2B: Presentation and Format of the Dossier ...	BASG / AGES MEA: Guidance to Electronic Submission Decree ...	Guidance Bulletin: Eudralex Volume 2B: EU Module 1 eCTD Specification, Version 3.0.4EU ...
Application Format, Content and Submission	Guideline History: NTA Volume 2B: Presentation	Questions and Answers: Variations in eCTD Format	Revised Implementation Guide for EU Module 1

Browse Regulatory Summaries

Easily browse Regulatory Summaries and click a country of interest to open them.

The screenshot shows the 'Regulatory Summaries' page on the Clarivate website. The navigation bar includes 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries' (highlighted), and 'Source Documents'. Below the navigation bar, there are 'Browse' and 'Search' buttons. A filter dropdown is set to 'Country / Region'. The main content area is divided into two sections: 'Drugs and Biologics' and 'Medical Devices and IVDs'. Under 'Medical Devices and IVDs', there is a section titled 'Medical Devices Regulatory Framework' which lists various countries. The 'European Union' is highlighted in this list. A callout box provides a detailed view of the 'Registration Application | Application Format, Content and Submission' section, listing the same countries.

Filter by

Drugs and Biologics **Medical Devices and IVDs**

Authorities and Organizations

- ▶ Competent Health Ministries and Regulatory Agencies | Country Summaries
- ▶ European Institutions and Bodies | Overview
- ▶ European Heads of Medicines Agency |

International and Regional Bodies

- ▶ Association of Southeast Asian Nations

Medical Devices Regulatory Framework

Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, EAEU, Egypt, Estonia, **European Union**, Finland, France, Germany, Greece, Guatemala, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Mexico, Morocco, Netherlands, New Zealand, Nigeria, Norway, Panama, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, SICA, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, USA, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam

Regulatory Summary - Example

Topic's key questions answered at-a-glance

☰ ☰ ☰

▼ Q1 Application Format and Content

Q1.1 Is ICH CTD format required/accepted in the country/region? For which type of application?

Q1.2 What is the legal basis and regulatory framework for ICH CTD implementation in the country/region?

Q1.3 If a local application format/non-ICH standard applies in the country/region, what are its structure and content requirements?

Q1.4 What is the legal basis for local format in the country/region?

Q1.5 What are the Module 1 country/region-specific content requirements?

Q1.6 Are there other country/region-specific content requirements?

▶ Q2 Application Submission Format

▼ Q3 Future Trends

Q3.1 What future developments are planned regarding electronic submission and/or the disuse of paper format?

▼ Q4 Additional Information

Q4.1 What are the language requirements?

Q4.2 What are the stability data package requirements? Under which climatic zone does the country/region fall?


Q4.3 What Pharmacopoeia is applicable in the country/region?

Q4.4 Are drug substance/product samples required to be submitted with the application?

Q5 Annex

Regulatory Summary

Continuously monitored and updated



Application Format, Content and Submission (European Union)

Reason for update	Date	Reason for update description
Content Update	2024-01-24	This update revised the IRIS guide for (IDRAC 377678) and added the EMA/31 (Regulatory Procedure Management for Management) – Frequently Asked Questions (IDRAC 377655) in section Q2.1.4.
Content Update	2024-01-19	This update revised the EMA/246173/2 Release Notes (IDRAC 377634) and the Guidance on Paediatric Submissions - (IDRAC 377407) in section Q2.1.3. This update added also the EMA eSubmission Submit SEND Data Packages with New Applications (IDRAC 377210) in section Q3.1.
Content Update	2024-01-10	This update revised the Human Variability Form (eAF) - Key Steps and Milestones Q3.1, the EMA-H-19984/03 Rev. 107: Post-Authorisation Procedural Advice for (IDRAC 376208) in section C

Q3 Future Trends

Q3.1 What future developments are planned regarding electronic submission and/or the disuse of paper format?

a) SEND data packages with new Market Authorisation Applications
 From January 2024, EMA is launching a proof-of-concept study to evaluate the added value of using SEND data in the evaluation of new Marketing Authorisation Applications. Applicants are encouraged to submit their SEND data packages, in addition to the eCDT format, as part of their MAA submission. The SEND package must be provided outside the eCTD, inside the working documents folder to avoid eCTD technical validation failure.

In this proof-of-concept study, the use of SEND data in the assessment of the non-clinical dossier will be evaluated. This could lead to improved and more consistent quality of assessments, to more science-driven questions to Applicants, and to faster completion of the non-clinical dossier assessment. Please see the [EMA eSubmission News](#) (IDRAC 377210).

b) Electronic submission processes in Europe
 An [eSubmission roadmap](#) (IDRAC 296554) (Note) describes the issues that need to be addressed and changes required to fully harmonise electronic submission processes in Europe.

Note: European Medicines Regulatory Network: [eSubmission roadmap](#) (IDRAC 296554) , Jun-2019. See also [visual representation of the timelines](#) (IDRAC 296558) :

- [Annex 1](#) (IDRAC 278589) : Implementation of eCTD v.4.0, Jun-2018
- [Annex 2](#) (IDRAC 301677) : implementation of mandatory use of eCTD format for regulatory submission, Nov-2018
- [Annex 4](#) (IDRAC 278590) : Replacement of the current PDF electronic application forms (eAFs) with the CESP Application Dataset Management Module (CESP Dataset Module), Jun-2018
- [Annex 5](#) (IDRAC 278592) : Mandatory use of the Common Repository for EMA led procedures, Jun-2018



What's new

NEW: English Machine translations (>34.000 added to Cortellis as of today)

Easily access, search and download documents machine translated by Google*

The screenshot shows a document viewer interface. At the top left, there are language selection buttons for 'None' and 'Swedish'. A purple arrow points to a translation icon (a square with 'A' and a globe) in the top right corner. Below this, a sidebar on the left shows a file tree with 'Original file' and 'Machine Translated by Google' highlighted. The main content area displays a Swedish document titled 'Om tjänsten Sök restanmälda läkemedel'. A purple box highlights the Swedish text: 'I tjänsten Sök restanmälda läkemedel publiceras information om läkemedel som läkemedel har restanmält till Läkemedelsverket. I söktjänsten kan du söka efter alla kommande, pågående och avslutade anmälda restsituationsmeddelanden.' Below this, a purple box highlights the English translation: 'About the service Search for backlogged medicines. In the service Sök residue-notified medicines, information is published about medicines that the pharmaceutical companies have notified as residue to the Swedish Medicines Agency. In the search service, you can search for all upcoming, ongoing and completed reported residual situations. You can filter the content to find what you are looking for. All residual situations that have been reported since 2018 are published. Search for which medicines have been reported to the Swedish Medicines Agency. **To the search service** Content and responsibility The search service contains information on all pharmaceutical packaging that has been reported to the Swedish Medicines Agency.' To the right of the document, a purple box highlights a 'Machine Translated Document' panel with options for 'Preview (English)', 'Download (English)', and 'View on Side by side', along with a disclaimer: 'Disclaimer: AUTOMATED TRANSLATIONS POWERED BY GOOGLE are not modified or altered by Clarivate and are provided "as is" without warranty. Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the translated information, please refer to the official source language version.'

NEW: Intuitive Search for Regulatory Summaries and Intelligence Reports

Get better results with autosuggestions and easily compare

The image displays a screenshot of the Clarivate Regulatory Intelligence platform. The interface is divided into several sections:

- Header:** "Regulatory" with a "CMC Intelligence" tag. Navigation tabs include "All", "Comparison Tables", "Intelligence Reports", "Regulatory Summaries" (marked "New"), and "Source Documents" (marked "Updated").
- Search Bar:** A search bar with the text "timeline" entered. A dropdown menu below it shows autosuggestions for search queries related to "timelines".
- Search Results:** A list of results for the query "How is the application reviewed and according to which timelines? When does the clock start?". Each result includes a date, a version indicator (V), and a document title: "Marketing Authorization Procedures: Review, Communication and Approval".

Smarter search outcomes and suggestions with our new intuitive search!

Search input:

Autosuggestions:

- How is the application reviewed and according to which **timelines**?
- Which PAC category does a safety-related change belong to? Are there specific requirements concerning procedural ...
- Are there official **timelines** for Competent Authority/-ies to respond to CTA/IND Applications?
- Are there official **timelines** for the IEC/IRB to respond to applications?
- What are the **timelines** for approval/clearance/certification of a product?
- How is the application reviewed and according to which **timelines**? When does the clock start?

Search Results:

71 results found for 'How is the application reviewed and according to which timelines? When does the clock start?'

Region: [dropdown] Topic: [dropdown] Last Updated Date: [dropdown]

Relevance [dropdown] Expand All Collapse All

Jun-2023 [V] EN RS
Marketing Authorization Procedures: Review, Communication and Approval
This document provides detailed, practical information and flow charts about the national authority review process, for the products (see Definitions in Decree 150/92), - Biological and biosimilar products.
Country/Region: Argentina
IDRAC Number: 26800
Last Updated Date: 01-Jun-2023
How is the application reviewed and according to which timelines? When does the clock start? [dropdown]
Submission clock starts once the application is done. A) Approval process for the registration of a New Product Article 3 [dropdown]

Mar-2023 [V] EN RS
Marketing Authorization Procedures: Review, Communication and Approval
This document provides the principal marketing authorization application stages through the national procedure in Jordan
Country/Region: Jordan
IDRAC Number: 215584
Last Updated Date: 23-Mar-2023
How is the application reviewed and according to which timelines? When does the clock start? [dropdown]
The MA includes three main steps: File submission; File evaluation; Final decision. File Evaluation Once the file is received [dropdown]

3 25-Oct-2023 [V] IQ EN RS
Marketing Authorization Procedures: Review, Communication and Approval
This document provides the principal marketing authorization application stages through the national procedure in Iraq
Country/Region: Iraq
IDRAC Number: 216318
Last Updated Date: 25-Oct-2023
How is the application reviewed and according to which timelines? When does the clock start? [dropdown]
Iraq The MAA process for imported and locally manufactured drugs includes the following phases; some of these are done [dropdown]

UPGRADED: Source Document Search

Search all source documents including the pdf full text using English or local language keywords

27 results for 'qualifikation and inspektor*'

Switch to Comparison Tables

Drugs & Biologics Medical Devices & IVDs

Refine Search ^

qualifikation and inspektor* Search

Filter

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

Showing 1-10 of 27 results

Customize Columns Sorted by Relevance

Summary	Title	Abstract	Last Updated Date	Reason for Update	Country/Region	Language(s)
<input checked="" type="checkbox"/> 07-Dec-2022 (DE) (RD)	ZLG: Training, Assignment and Continuing Education of GCP Inspectors (VAW 04110804), 07-Dec-2022	The present document, issued by the Central Authority of the Länder for Health Protection with regard to Medicinal	15-Jan-2024	This document has been revised to add a file of English text generated by machine translation tool (retagging).	Germany	German
<input checked="" type="checkbox"/> 07-Dec-2022 (DE) (RD)	ZLG Form: Template of a Training Plan for GCP Inspectors (Form 041108_F02_01), 07-Dec-2022	The present document, issued by the Central Authority of the Länder for Health	13-Jan-2024	This document has been revised to add a file of English text generated by machine	Germany	German
<input checked="" type="checkbox"/> 07-Dec-2022 (DE) (RD)						

Original file

Training, Beauftragung und Fortbildung von GCP-Inspektorinnen und

Inspektor, die fortlaufende Fortbildung und die Überprüfung einschließlich der Bewertung sowie den Erhalt und die regelmäßige, dokumentierte Bewertung der Qualifikation von GCP-Inspektorinnen und GCP-Inspektoren bei den Behörden, die für die Durchführung von GCP-Überwachungsaufgaben nach § 64 AMG in Betrieben, Einrichtungen und bei Personen zuständig sind.

qualifikation 1 of 9 matches

Automatic Zoom

EXTENDED: How to market Advanced Therapy Medicinal Products (ATMP)

Regulatory Summaries available for 72 territories with new Q&A structure providing more insights

1 of 10

- Q1 Definitions and Legal Basis
 - Q1.1 What are Advanced Therapy Products in the country/region?
 - Q1.2 What is the regulatory framework for Advanced Therapy Products in the country/region?
 - Q1.3 Are there any new or impending changes to the current Advanced Therapy Products regulations?
- Q2 Advanced Therapy Product Classification
 - Q2.1 How are Advanced Therapy Products classified?
 - Q2.2 What is the procedure for obtaining advice on Advanced Therapy Product classification?
- Q3 Advanced Therapy Product Clinical Investigations
 - Q3.1 Which laws and regulations govern clinical investigations for Advanced Therapy Products?
 - Q3.2 Is there specific information regarding clinical investigations for Advanced Therapy Products?
- Q4 Approval of Advanced Therapy Products
 - Q4.1 Which regulatory bodies oversee Advanced Therapy Products? Is there a specific committee charged with Advanced Therapy Product evaluation?
 - Q4.2 Is there a procedure for authority consultation/scientific advice regarding the requirements for Advanced Therapy Products?
 - Q4.3 What are the requirements for registration, format and content of applications?
 - Q4.4 What are the labelling requirements for Advanced Therapy Products?
- Q5 Post-authorization of Advanced Therapy Products
 - Q5.1 Are there any advanced therapy-specific guidelines regarding pharmacovigilance?
 - Q6 Are there any other specific requirements applicable to Advanced Therapy Products in the country/region?
- Q7 Annex

Regulatory Summary

Continuously monitored and updated



How to Market Advanced Therapy Products (Taiwan)

Reason for update	Date	Reason for update description
Content Update	2024-02-02	This update added the procedure of Cell Therapy Technology Fee-based Consultation in section Q4.2.
New	2024-01-19	

Q1 Definitions and Legal Basis

Q1.1 What are Advanced Therapy Products in the country

In Taiwan, "Advanced therapy products" are regulated as "Regenerative medical techniques".

According to the draft version of [Provisions on Regenerative Medicine](#) (377018), "Regenerative medicines" use cells, genes, and derivatives of body structures or functions, or for treatment or prevention of human "Regenerative medical technique" and "Regenerative medical preparation".

"Regenerative medical technique", is regulated by the [Medical Care and Management Act](#) and [Regulations Governing the Application of Specific Medical Technique and Medical Device](#), the following:

- Specific medical technique (Cell therapy technique, Specific organ transplantation, and other specific medical technique)
- Specific examination, laboratory testing, and medical devices

(B) Regenerative medical preparations

For "Regenerative medical preparations", the clinical investigations shall follow the requirements of [Pharmaceutical Affairs Act \(PAA\)](#) (IDRAC 253489) and [Regulations for Good Clinical Practice \(GCP\), 28-Aug-2020](#) (IDRAC 317460).

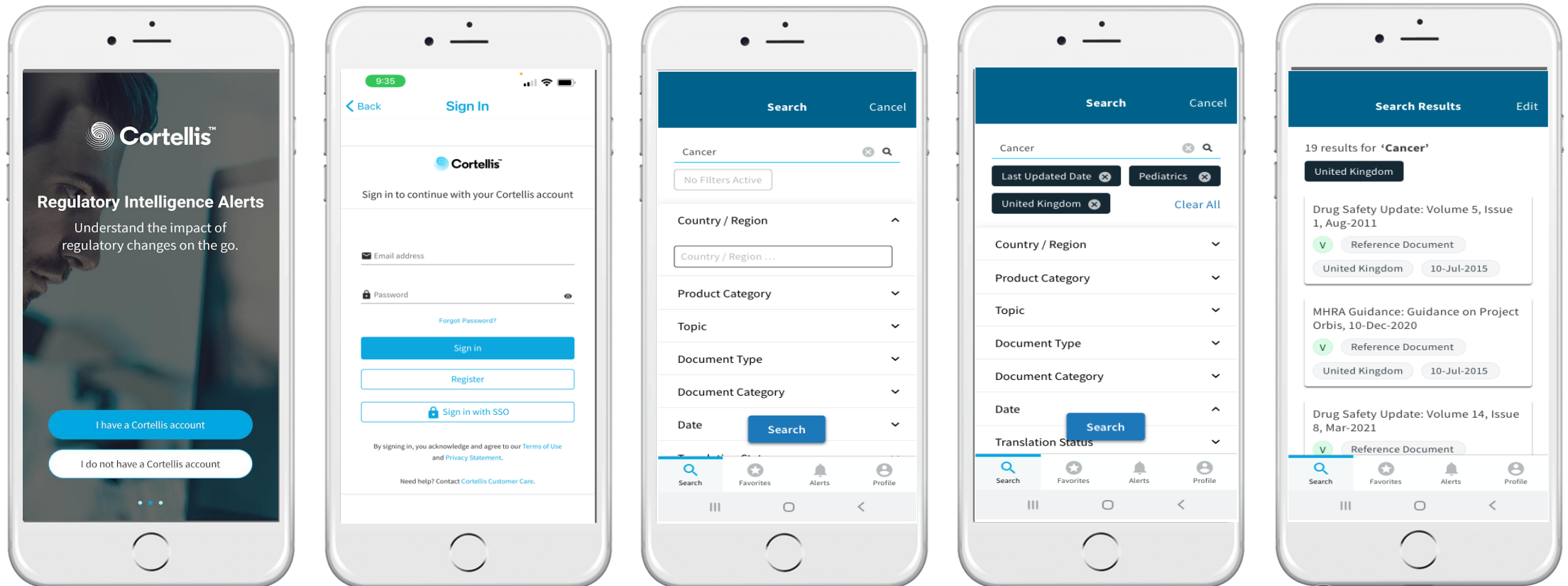
For Cell Therapy Medicinal Product

According to [MOHW Announcement No. 1051413931: Revising Clinical Trials Plan Application Procedures for Human Cell Therapy Products, 17-Jan-2017](#) (IDRAC 239002), the Ministry of Health and Welfare established a provisional dual track system for the clinical trial protocol application for human cells therapy products. An applicant for a clinical trial protocol for a human cell therapy product may either choose the option of a consultation procedure prior to document submission or may choose to forego said consultation procedure and proceed directly to submission of the application for a clinical trial protocol for a human cell therapy product to the Food and Drug Administration under the Ministry of Health and Welfare. The document submissions for applications for clinical trial protocols for human cell therapy products are required to comply with requirements of [MOHW Announcement No.1091401592 & MOHW Letter No.1091401633: Clinical Trials Guidelines for Human Cell Therapy Products \(Revised Version\), 01-May-2020](#) (IDRAC 311518) and [MOHW Announcement No.1091401041: Checklist of Technical Documents for Human Cell Therapy Clinical Trials Applications, 12-Feb-2020](#) (IDRAC 306315).

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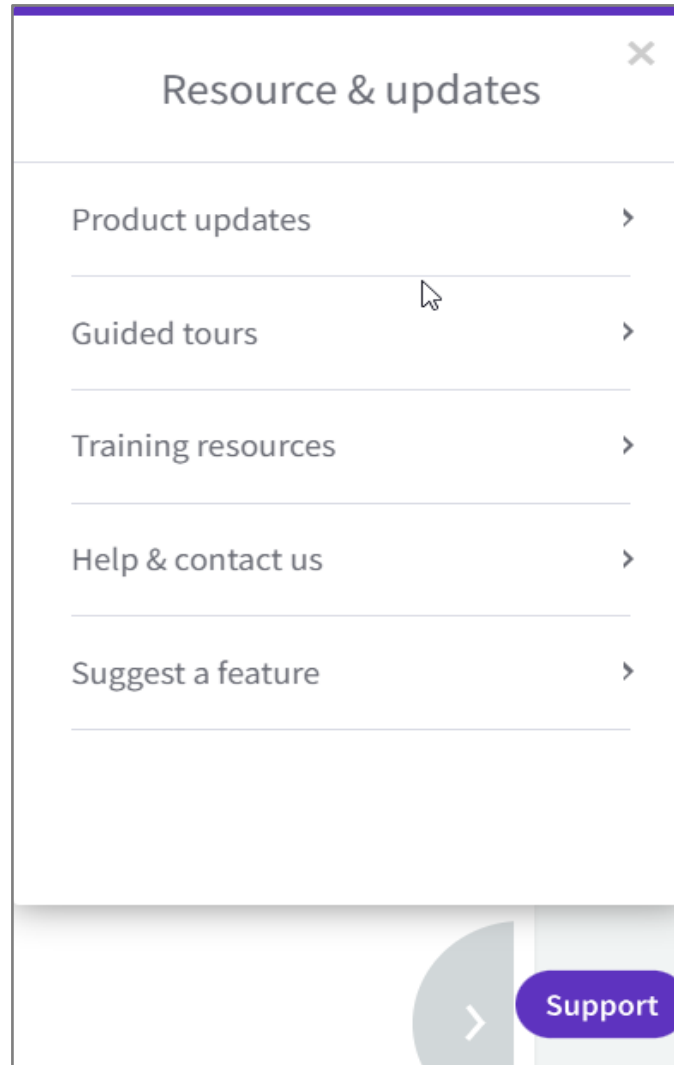
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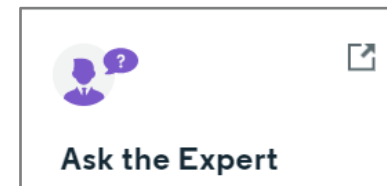
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Thank you! Questions?

Claudia Haas
Claudia.Haas@Clarivate.com

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