パブリックウェブセミナー
Cortellis Regulatory Intelligenceを使った競合品の先行承認事例の調査

クラリベイト ライフサイエンス&ヘルスケア | 2023年9月20日

本日の内容

1. 既承認医薬品/医療機器の審査･承認関連文書の検索

2. 製品承認情報の分析やリスク管理計画等の入手に役立つCortellis独自レポートのご紹介

- Product Approval Tracker
- Regulatory Authority Product Approval Trend
- Risk Management System Tracker

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Cortellis Regulatory Intelligence
製品承認関連文書の収録状況

収録対象国

- 医薬品：Brazil, Canada, China, European Union, Japan, Switzerland, Taiwan, USA
- コンビネーション製品：European Union, USA
- 医療機器：Canada, USA

European Unionは中央審査方式の承認品目が収録対象です

医療機器の情報取得にはCortellis Regulatory Intelligence Medical Devices & IVDsのご契約が必要になります

承認情報への主なアクセス方法

- 一般名/販売名で検索
- Intelligence Reports – Product Approval Tracker等

特定の疾患領域や競合製品の承認審査関連文書の情報を効率的に入手、分析できます。

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1.既承認医薬品/医療機器の審査・承認関連文書の検索

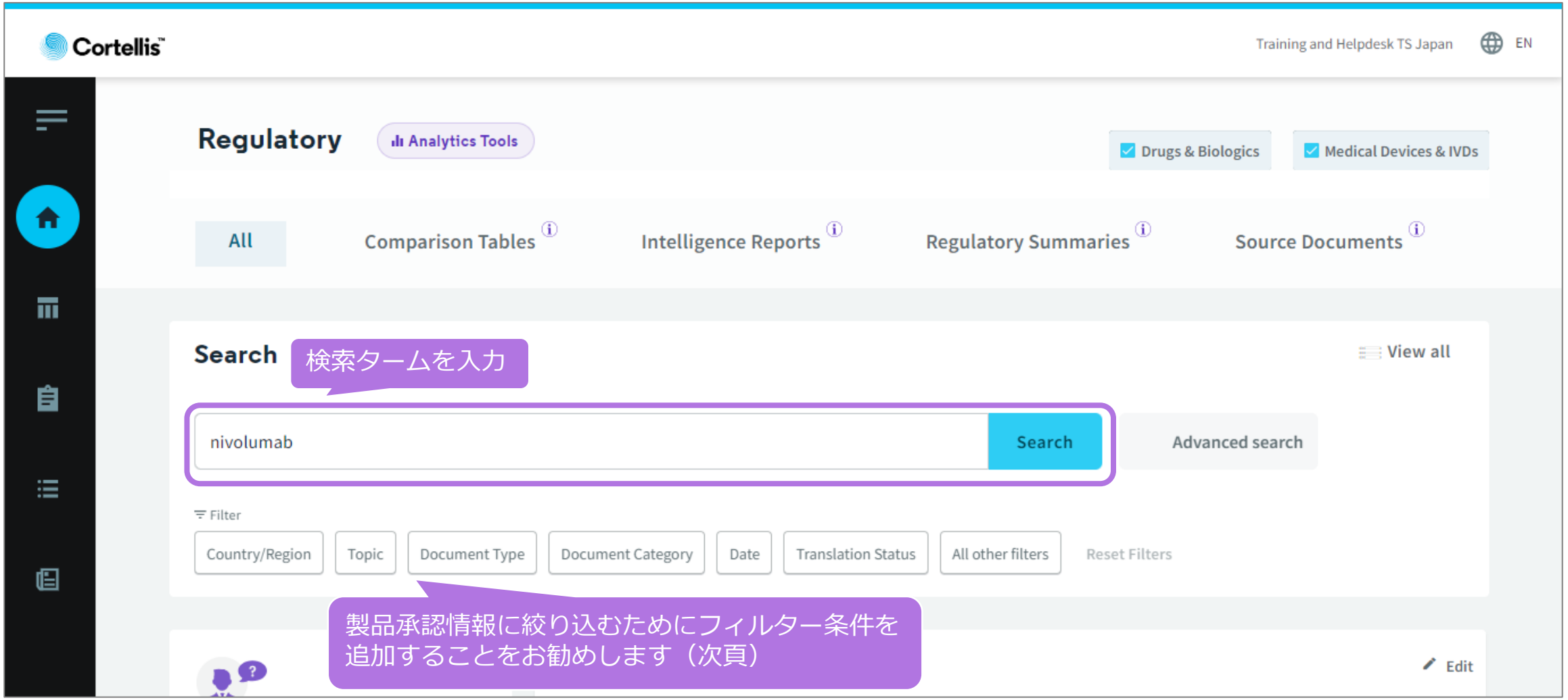
- 医薬品一般名や販売名、医療機器名称や企業名で検索し、各国の審査報告書、Approval Package等を入手する

- 本日の検索例 “nivolumab”

- 検索にはRegulatory Home画面のQuick Search機能を使用

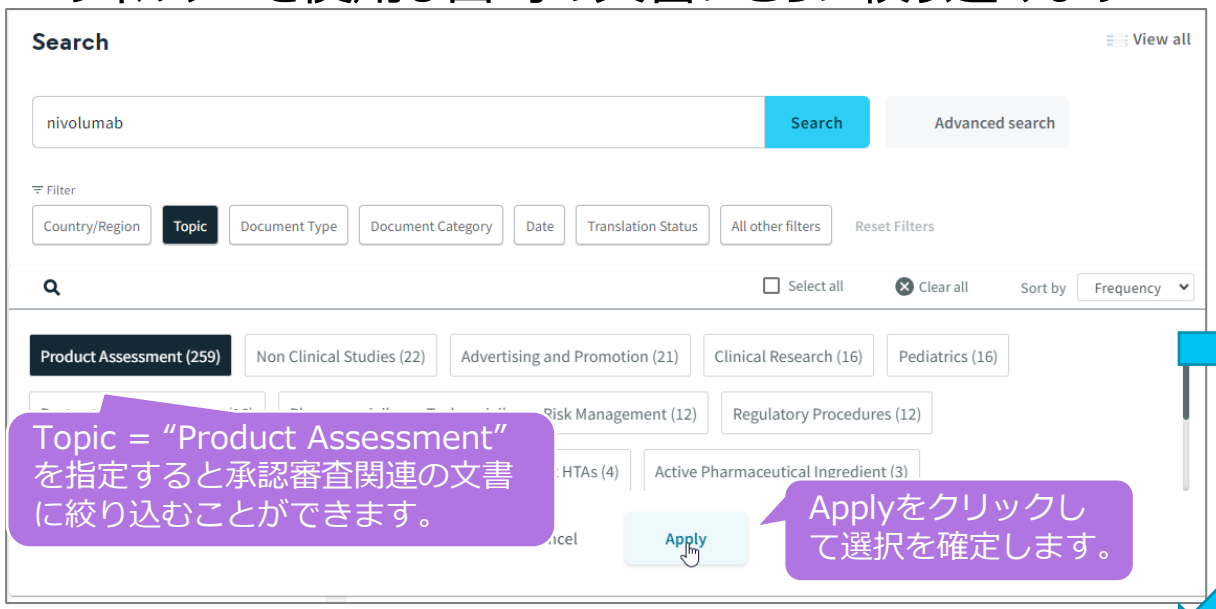
Quick Searchを使った検索

医薬品名や企業名等で検索可能です



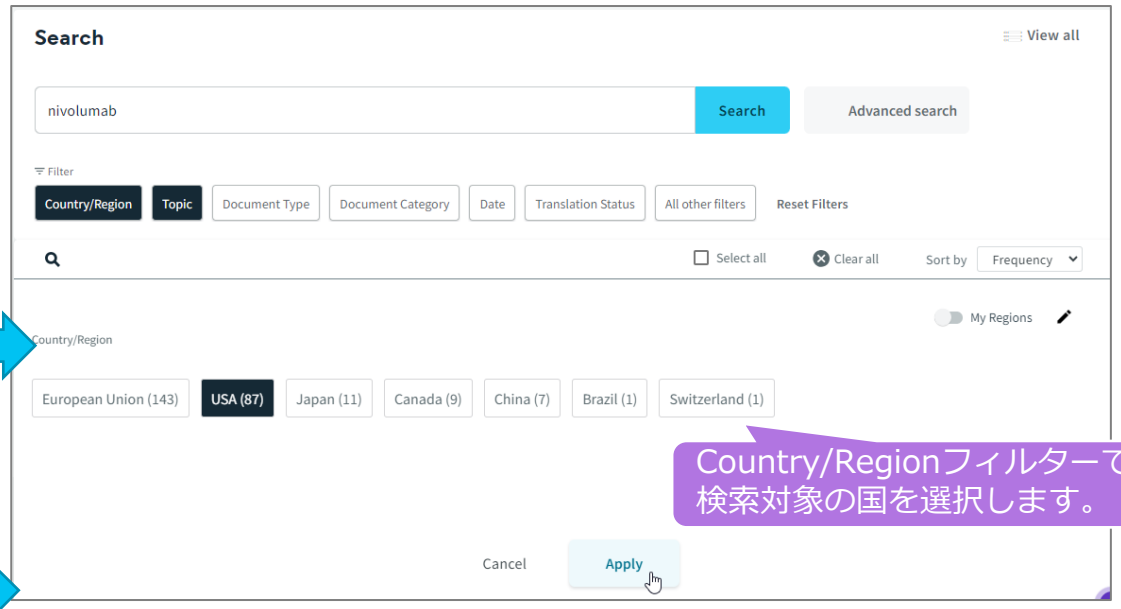
Quick Searchを使った検索

フィルターを使用し目的の文書にさらに絞り込みます

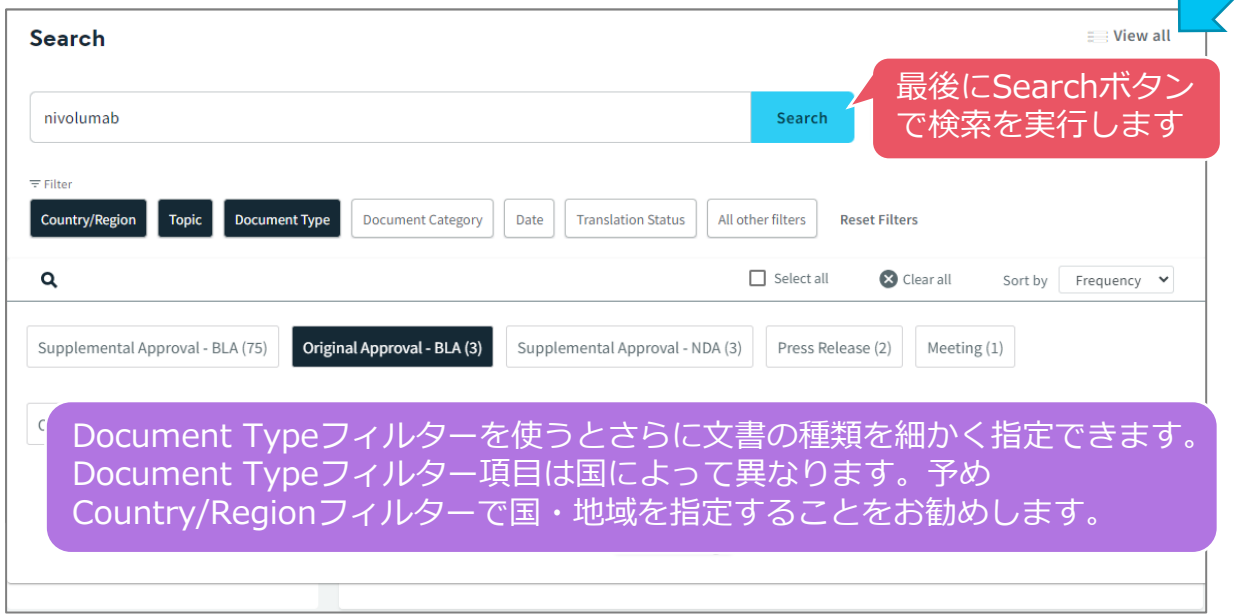


Topic = “Product Assessment”を指定すると承認審査関連の文書に絞り込むことができます。

Applyをクリックして選択を確定します。

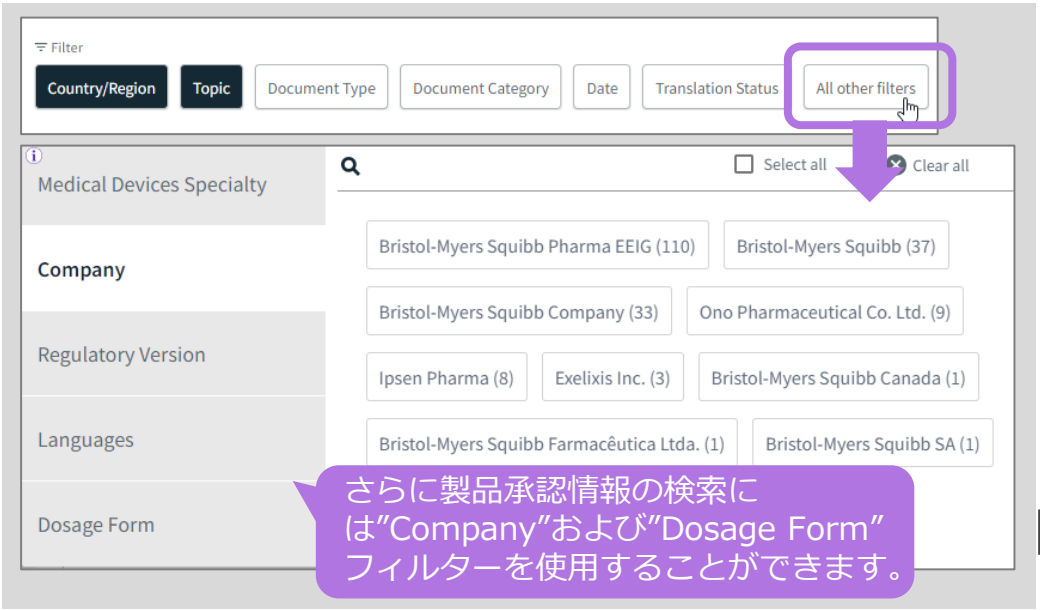


Country/Regionフィルターで検索対象の国を選択します。



最後にSearchボタンで検索を実行します

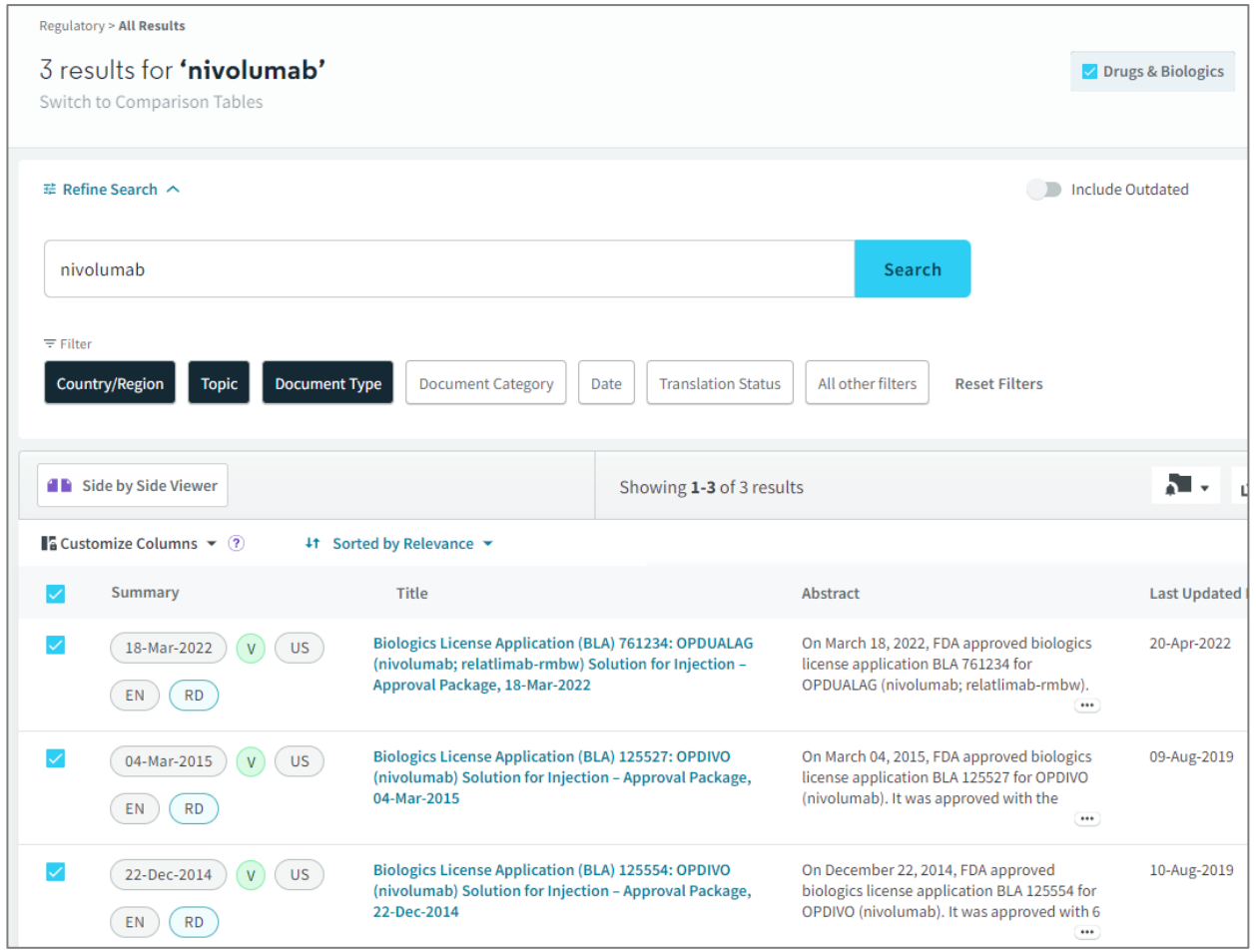
Document Typeフィルターを使うとさらに文書の種類を細かく指定できます。
Document Typeフィルター項目は国によって異なります。予めCountry/Regionフィルターで国・地域を指定することをお勧めします。

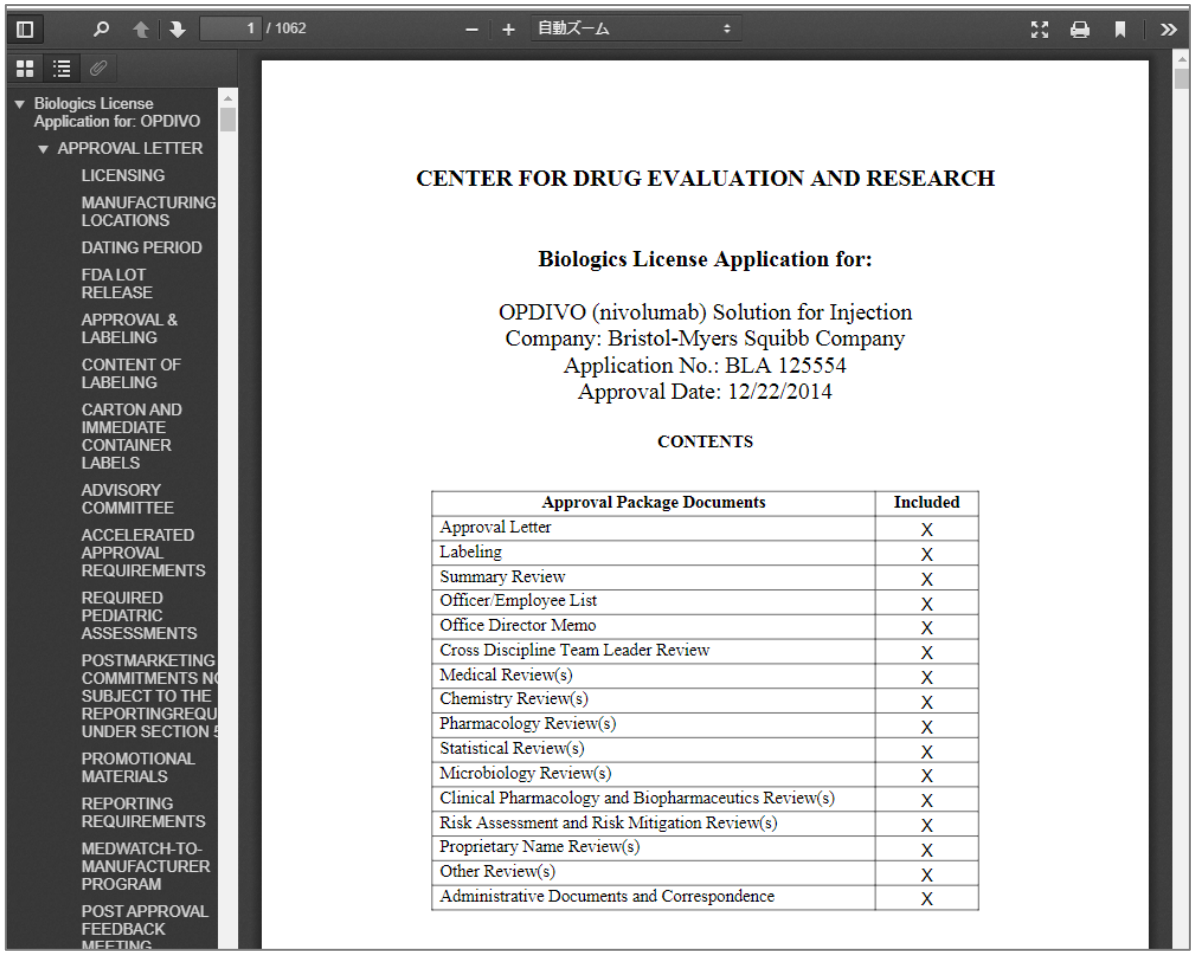


さらに製品承認情報の検索には”Company”および”Dosage Form”フィルターを使用することができます。

Quick Searchを使った検索

検索結果画面から目的の文書をクリックして開きます





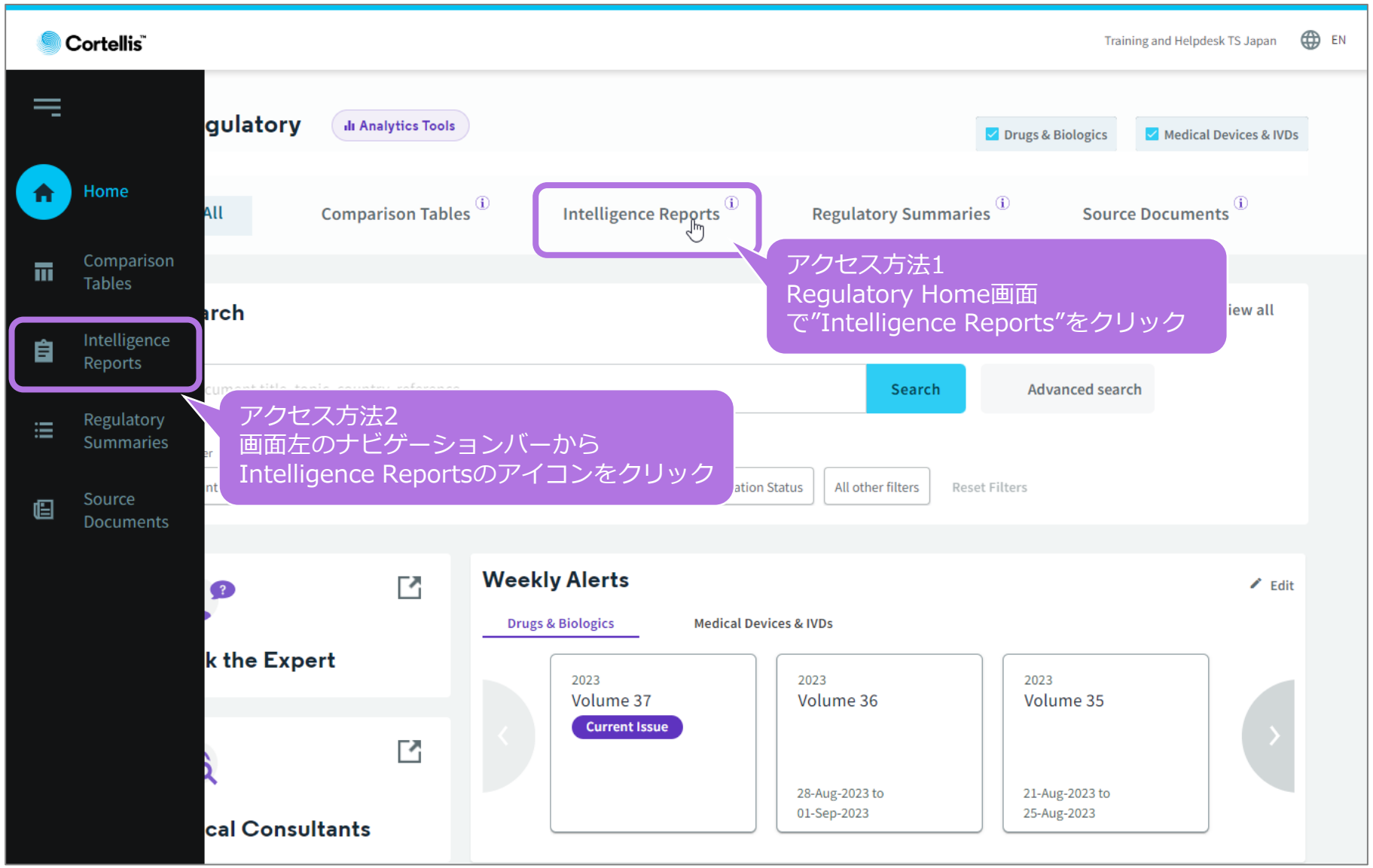
2. 製品承認情報の分析やリスク管理計画等の入手に役立つ Cortellis独自レポートのご紹介

- Product Approval Tracker（医薬品および医療機器）
  - 収録対象各国の審査報告書・承認文書パッケージに一括アクセス
    (収録内容は各国規制当局の公開情報の範囲によって異なります)

- Regulatory Authority Product Approval Trend (医薬品のみ, EU & US)
  - 医薬品承認トレンドの集計分析レポート

- Risk Management System Tracker (医薬品のみ EU & US)
  - データベースに収録されたEU EPAR, FDA Approval Packageのうち、承認されたリスク管理計画が含まれるものをリストアップ（市販後のリスク管理計画の更新を含みます）

Intelligence Reportへのアクセス



Intelligence Report – Product Approval Informationのセクションを開く

Drugs & Biologics

- **Product Approval Information**
  - Drug and Biologics Registration | Product Approval Tracker
    - Brazil, Canada, China, European Union, Japan, Switzerland, Taiwan, USA
  - Combination Product Registration | Product Approval Tracker
  - Pediatric Studies | Product Approval Tracker
  - Regulatory Authority Product Approval Trends | Summary Charts
  - Risk Management System Tracker
  - EMA CHMP Referral Opinions | Opinion Tracker
  - EMA Committee for Advanced Therapies | Classification Recommendations
  - EMA Committee for Orphan Medicinal Products | Public Summary of Opinions for Orphan Designation
  - EMA Harmonisation of Risk Management Plans Project (HaRP) | Assessment Report Directory
  - EU HMA Pediatric Public Assessment Report | Assessment Report Tracker
  - EU HMA PSUR Work Sharing Summary Assessment Report | Assessment Report Tracker

Medical Devices & IVDs

- **Product Approval Information**
  - Medical Device Registration | Submission and Approval Tracker
    - Canada, USA
  - Combination Product Registration | Submission and Approval Tracker
    - European Union, USA

レポートを開くには各トピックのメニューから調査対象国・地域のリンクをクリックします。

Drug and Biologics Registration | Product Approval Trackerの例

USAのレポート例

Name	Active Ingredient(s)	Application/ Submission Type	Application Number	Active Substance Status	FDA Biological Type	FDA Chemical Type	Boxed Warning	Medication Guide	REMS	Pediatric Use	FDA Supplement Type	FDA Supplement Rationale	Link to Product Approval Document
MEN'S ROGAINE	minoxidil	sNDA	21812/016	Known active substance	Not applicable	New dosage form							
CADUET	amlodipine ; atorvastatin	sNDA	21540/047	Known active substance	Not applicable	New combination							
GONAL-F RFF	follitropin alfa	sBLA	21765/013	Known active substance	Therapeutic biologic	Not applicable							
GONAL-F RFF	follitropin alfa	sBLA	21765/014	Known active substance	Therapeutic biologic	Not applicable							
GONAL-F RFF	follitropin alfa	sBLA	21765/044	Known active substance	Therapeutic biologic	Not applicable							
PROGRAF	tacrolimus	sNDA	210115/004	Known active substance	Not applicable	New dosage form							
ASTAGRAF XL	tacrolimus	sNDA	204096/009	Known active substance	Not applicable	New dosage form							
GONAL-F	follitropin alfa	sNDA	20378/045	Known active substance	Therapeutic biologic	Not applicable							
GONAL-F	follitropin alfa	sNDA	20378/067	Known active substance	Therapeutic biologic	Not applicable							
GONAL-F	follitropin alfa	sNDA	20378/075	Known active substance	Therapeutic biologic	Not applicable							
JALYN	dutasteride ; tamsulosin hydrochloride	sNDA	22460/011	Known active substance	Not applicable	New combination							
MARGENZA	margetuximab-cmkb	NDA	761150	New active substance	Therapeutic biologic	Not applicable							
OPDIVO	nivol						No	No	No	No	Non-efficacy supplement	For revised container (can) label, consumer informat	323584
							No	No	No	Yes	Non-efficacy supplement	For revise the drug product established name to "An	323583
							No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labelir	323519
							No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labelir	323519
							No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labelir	323519
							Yes	No	No	Yes	Non-efficacy supplement	Provided for updates to sections of the labeling base	323517
							Yes	Yes	No	Yes	Non-efficacy supplement	Provided for updates to sections of the labeling base	323510
							No	No	No	No	Non-efficacy supplement	Provided to include updated safety information consi	323372
							No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labelir	323372

米国の承認医薬品一覧とApproval Packageへの一括アクセスを提供する分析表を活用した他社事例収集

承認情報の取得方法の例はこちら↓でも確認できます
CortellisクイックガイドNo.4（ユーザーサポートサイト内）

FDA Approval PackageをCortellisで入手するメリット

Product Approval Tracker (USA) の活用

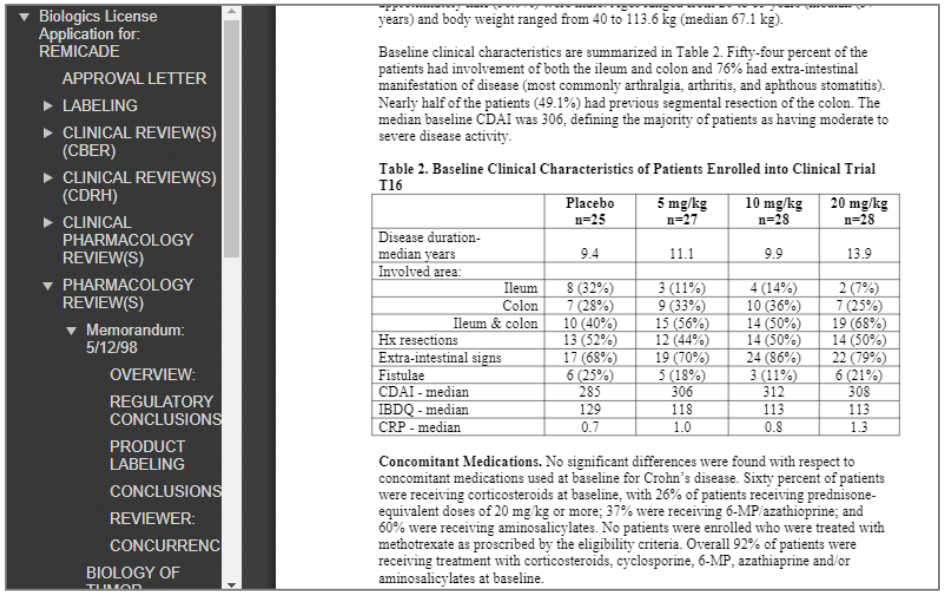
米国の1997年以降の承認済みNDA, BLA, Efficacy SupplementについてFDAの公開情報に基づきExcel形式でリストアップされている

- 流通名、一般名
- 疾患領域、適応症
- 剤型、投与経路
- 申請日、承認日、審査回数（Review Cycle）
- Priority Review, Breakthrough Therapyなどの審査・承認区分
- オーファンドラッグ指定の有無
- REMS（リスク管理計画）添付の有無
- Approval Packageへのリンク（Cortellis内）　など

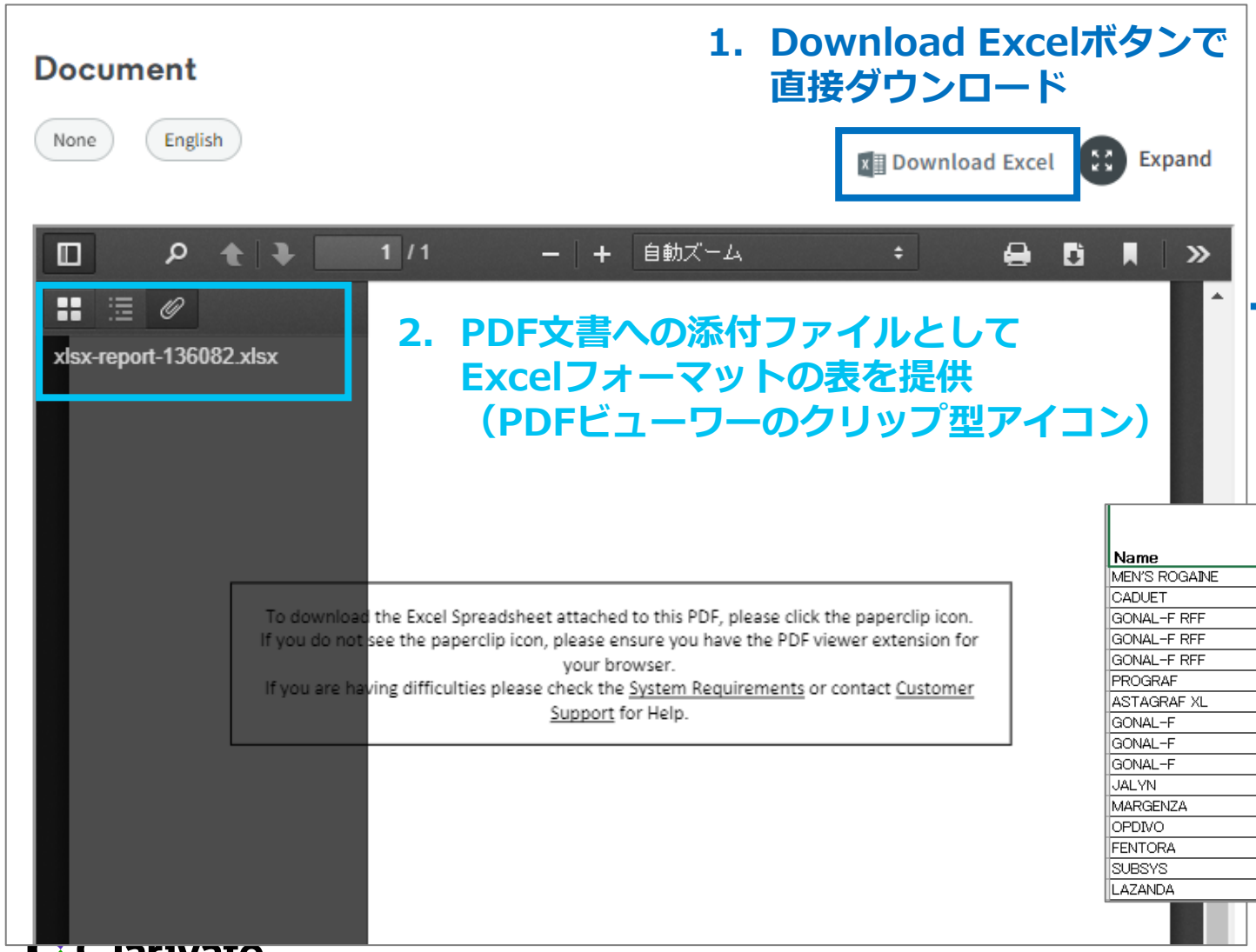
活用例
- 特定の医薬品が承認に要した期間を調べる
- 疾患領域や承認パスウェイごとに医薬品の承認に要した期間を分析する
- FDAからComplete Response Letterが発行され、再審査を要したケースについて、FDAの指摘事項を確認する

Approval Package PDFファイルの利便性

- 各Reviewファイルが1つに統合されている
- クラリベイト編集者による目次付き
- 検索可能なフォーマットに変換済み



参考：Regulatory Intelligence Reports – 2つのExcelファイルダウンロード方法



どちらの方法でも
同一のExcelファイルを
ダウンロードできます

Name	Active Ingredient(s)	Application/ Submission Type	Application Number	Active Substance Status
MEN'S ROGAINE	minoxidil	sNDA	21812/016	Known active substance
CADUET	amlodipine ; atorvastatin	sNDA	21540/047	Known active substance
GONAL-F RFF	follitropin alfa	sBLA	21765/013	Known active substance
GONAL-F RFF	follitropin alfa	sBLA	21765/014	Known active substance
GONAL-F RFF	follitropin alfa	sBLA	21765/044	Known active substance
PROGRAF	tacrolimus	sNDA	210115/004	Known active substance
ASTAGRAF XL	tacrolimus	sNDA	204096/009	Known active substance
GONAL-F	follitropin alfa	sNDA	20378/045	Known active substance
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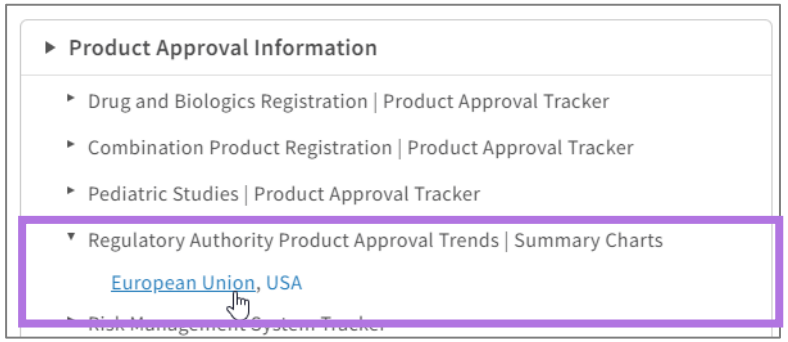
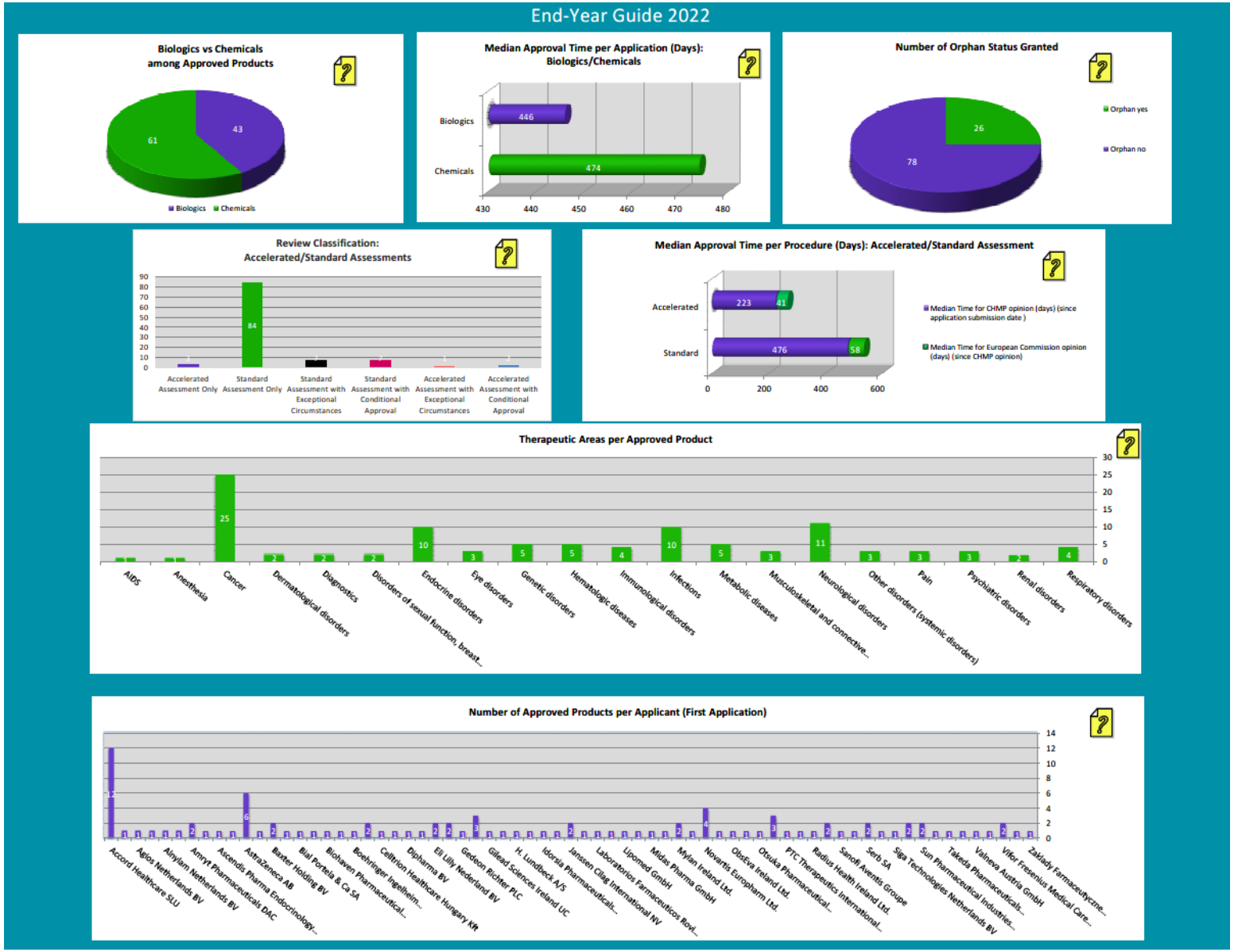
GONAL-F	follitropin alfa	sNDA	20378/075	Known active substance
JALYN	dutasteride ; tamsulosin hydrochloride	sNDA	22460/011	Known active substance
MARGENZA	margetuximab-cmkb	NDA	761150	New active substance
OPDIVO	nivolumab	sBLA	125554/095	New active substance
FENTORA	fentanyl citrate	sNDA	21947/030	Known active substance
SUBSYS	fentanyl	sNDA	202788/021	Known active substance
LAZANDA	fentanyl	sNDA	22569/029	Known active substance

Regulatory Authority Product Approval Trendの例

対象：European Union, USA





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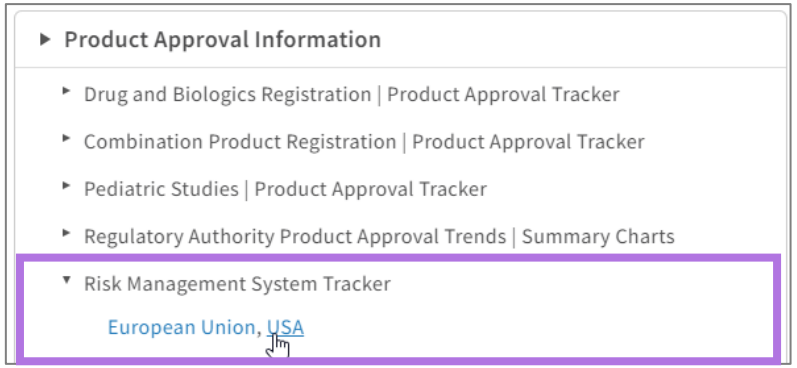
Risk Management System Trackerの例

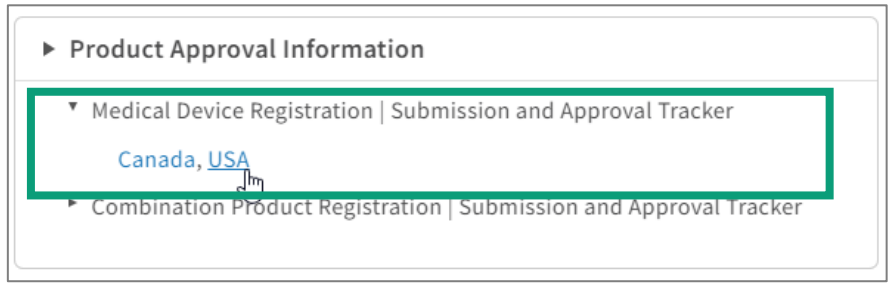
対象：European Union, USA



	A	B	C	D	J	K	L	M	N	
1	Link to Product Approval Document	Regulatory date	Name	Active Ingredient(s)	REMS Status	REMS/RMiM – Rationale	Identified Risk	Population at Risk	REMS Type	REMS – Medi
2	370933	08-Sep-2023	LOTRONEX	alosetron hydrochloride	Rescinded	The elements to assure safe use are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for LOTRONEX.	Ischemic colitis and serious complications of constipation	Not specified	Individual	Not applicable
3	370312	24-Aug-2023	TYSABRI	natalizumab	Updated	Modified to make change to the REMS Document, Prescriber Enrollment Form, Patient Enrollment Form - Multiple Sclerosis, Patient Enrollment Form - Crohns Disease, Pharmacy Enrollment Form, Infusion Site Enrollment Form, Educational Slide Set, Overview, Understanding PML for Gastroenterologists - Crohns Disease, Pre-Infusion Patient Checklist, Patient Status Report and Reauthorization Questionnaire, Initial Discontinuation Questionnaire and 6-Month Discontinuation Questionnaire materials.	Progressive multifocal leukoencephalopathy (PML)	Not specified	Individual	Yes
4	370305	24-Aug-2023	TYRUKO	natalizumab-sztn	Approved	Initial REMS.	Progressive multifocal leukoencephalopathy with the presence of anti-JCV antibodies	Not specified	Individual	Yes
5	369960	14-Aug-2023	ELREXFIO	elranatamab-bcmm	Approved	Initial REMS	Cytokine Release Syndrome (CRS), and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	Not specified	Individual	No
6	369714	14-Aug-2023	HEPZATO KIT	melphalan hydrochloride	Approved	Initial REMS.	Severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events	Not specified	Individual	No
7	369485	09-Aug-2023	TALVEY	talquetamab-tgvs	Updated	Modified to update the REMS name from TECVAYLI REMS to TECVAYLI and TALVEY REMS in the labeling and proposed modifications to the approved TECVAYLI REMS to form a combined REMS with talquetamab.	- Cytokine Release Syndrome (CRS) - Neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	Not specified	TECVAYLI and TALVEY	No

医療機器承認情報
Medical Device Registration | Submission and Approval Trackerの例

対象：Canada, USA



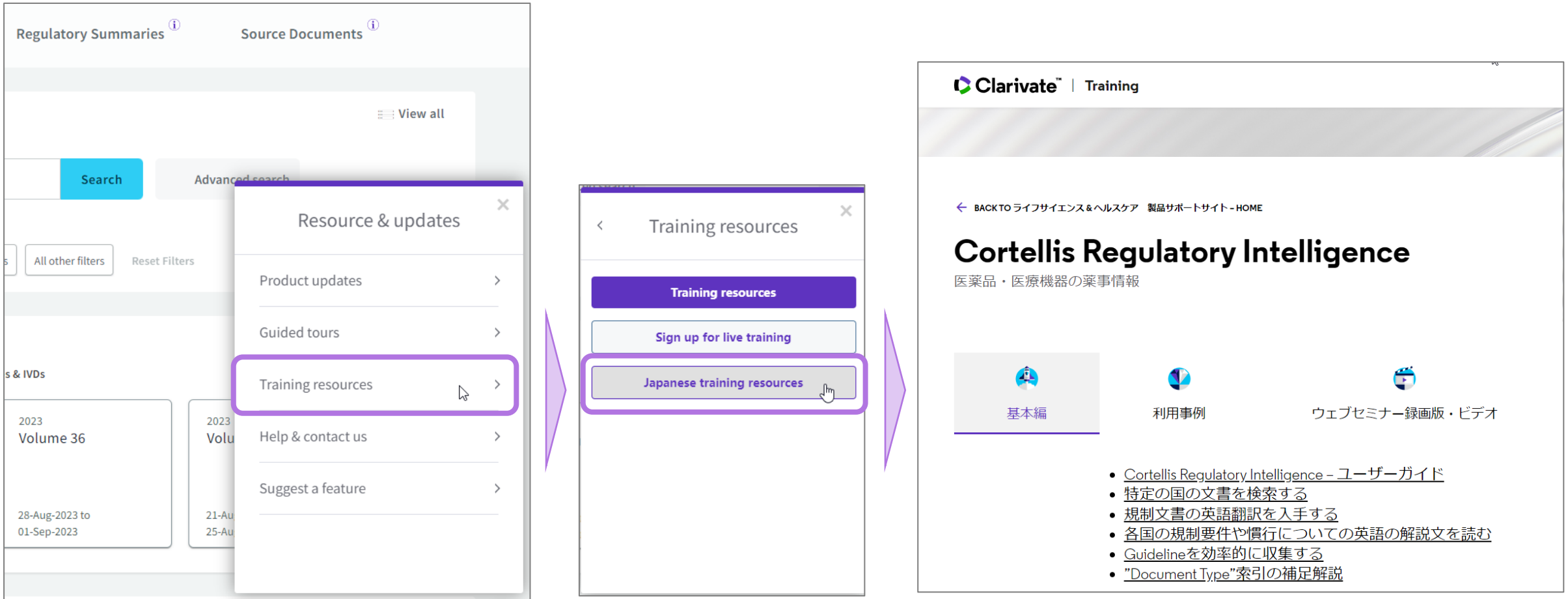
※医療機器関連の情報取得にはCortellis Regulatory Intelligence Medical Devices & IVDsのご契約が必要になります

	A	B	C	D	E	F	G	H	I	J	K	
1	Product Name	Application Number	Product Class	Review Category	Intended Use(s)	Legal Basis	Product Code	Company	Receipt Date	Approval Date	Review Type	Li
2	BD Vacutainer K2EDTA & K3EDTA Blood Collection Tubes	K213670	II	Clinical chemistry ; Hematology	BD Vacutainer EDTA Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, and transport of human venous blood specimens used for in vitro diagnostic testing; BD Vacutainer K2EDTA and K3EDTA Blood Collection Tubes are used for testing in hematology including white blood cells (WBC), red blood cells (RBC), red blood cell distribution width (RDW), hemoglobin (HgB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, and 5-part white blood cell (WBC) differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils).	21 CFR 862.1675	GIM	Becton Dickinson and Co.	22-Nov-2021	25-Aug-2023		37
3	MONTAGE Settable, Resorbable Hemostatic Bone Putty	K213418	II	General ; Plastic surgery	For the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. MONTAGE is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.	Not available	MTJ	Orthocon	20-Oct-2021	30-Aug-2023		37
4	Mediclose System	K213271	II	Gastroenterology products ; Urology	A single-use suturing device indicated for approximation of tissues and percutaneous suturing of port-site fascia wounds following laparoscopic surgery.	21 CFR 876.1500	OCW	Health Value Creation BV trading as Corporis Medical	30-Sep-2021	31-Aug-2023		37
	Accu-Chek Solo micropump system with interoperable technology	K213134	II	Clinical chemistry	For the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin; Able to communicate with compatible, digitally connected devices, including	21 CFR 880.5730	QFG	Roche Diabetes Care Inc.	27-Sep-2021	10-Aug-2023		37

サポートのご案内

画面右下の”？”アイコンからサポート情報にアクセス

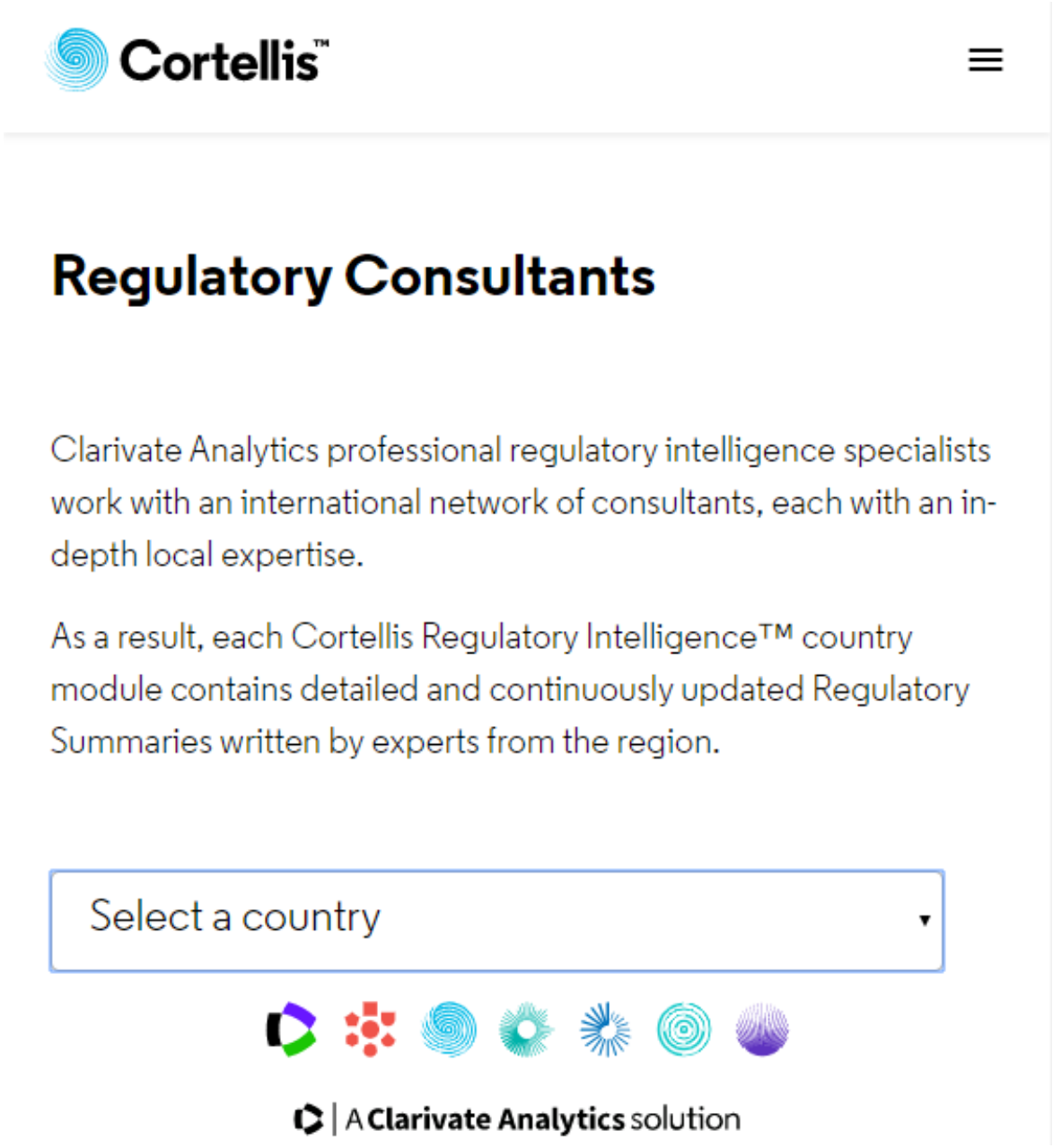
Training Resources > Japanese Training Resourcesの順にクリック



規制調査のサポート

エキスパートの知見を活用

- 各国規制の専門エディター、ローカルコンサルタントに規制の内容について問い合わせ可能
- カスタマーケアを通じて日本語対応



データベースの使用方法や規制情報に関するお問い合わせ先

クラリベイト
カスタマーケア

Tel：0800-170-5577（フリーダイヤル）
　　または 03-4589-3107

Email: ts.support.jp@clarivate.com