

OFF-X ユーザーガイド

製薬企業・保健当局における研究と意思決定のための
実用的な毒性・安全性情報プラットフォーム

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OFF-X

前臨床毒性から臨床有害事象まで全世界の医薬品安全性情報を収集し、製薬企業・保健当局における様々な研究や意思決定を支える実用的な毒性・安全性情報プラットフォーム

OFF-X

The translational safety intelligence portal

Data※

-318万+ 毒性・安全性アラート

-15,600+ ターゲットと遺伝子

-43,600+ 医薬品と生物製剤
(前臨床から市販後まで)

-14,700+ 有害事象エンドポイント

※As of July 2025

Source coverage

-査読付き文献

-会議/会議録

-臨床試験登録

-規制関連文書

-企業広報

-FAERSおよびJADER

博士号取得および医学博士レベルの研究専門家チームによる100%のマニュアルキュレーション

- 医薬品の研究開発から市販後までの全段階における安全性情報の包括的な「ワンストップ」リソース
- 統合された幅広いデータソース
- 専門家のキュレーションによる前臨床－臨床安全性情報と高度な分析
- すべての薬剤モダリティをカバー
- 毎日更新

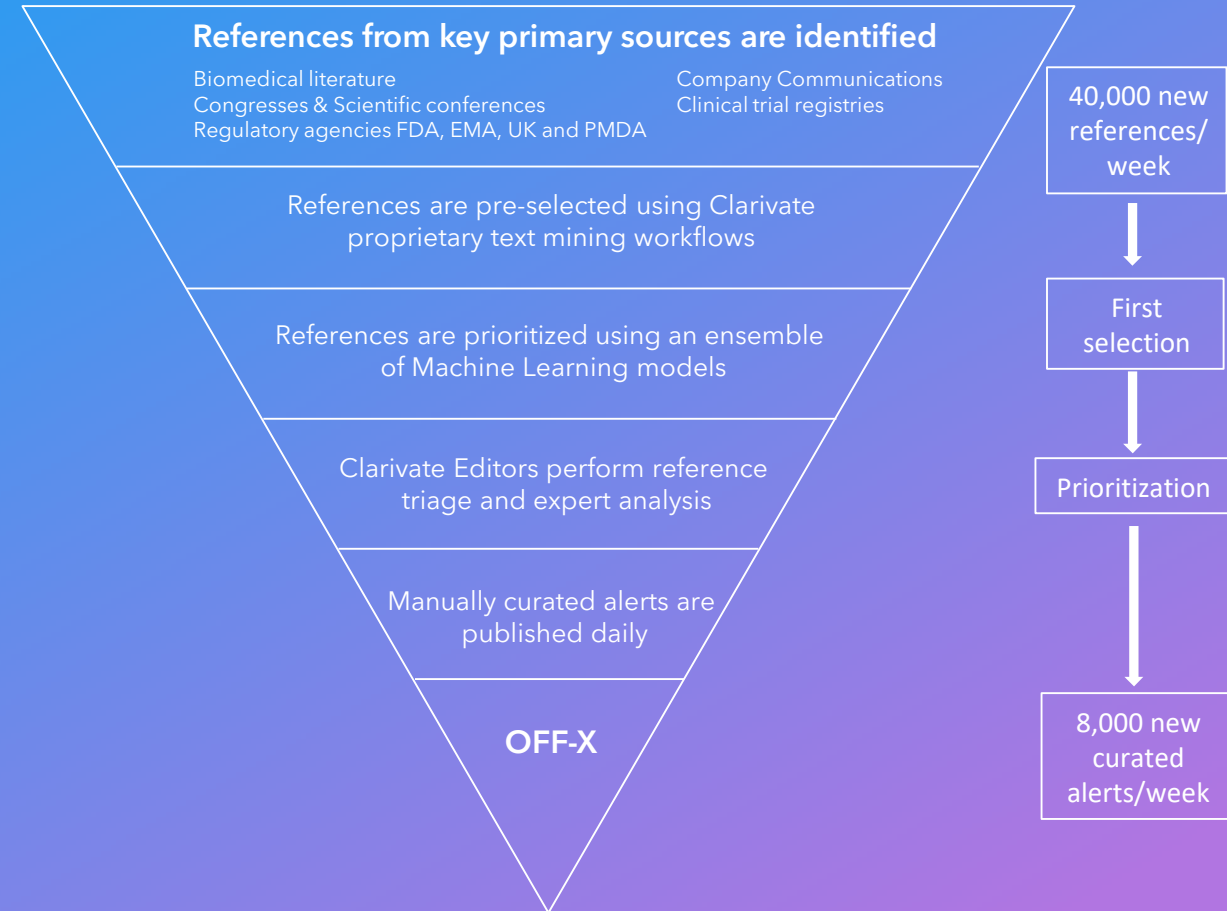
医薬品とターゲットの安全性情報へ、より効率的にアクセスすることで、調査時間を節約

Sources of information

PhDおよびMDレベルの研究専門家チームによる100%マニュアルキュレーション：

- **生物医学文献**：PubMed (Medline + PubMed Central) および優先度の高い非インデックスジャーナル
- **会議および科学会議**：年間550の科学イベントをカバー
- **企業発表**： >1,800以上の機関
- **主要臨床試験レジストリ**
- **規制当局**：FDA、EMA、PMDA、MHRAの承認パッケージの
手動キュレーション + FDAのSummary Basis of Approval (SBA)文書のテキストマイニング
- **規制当局**：（FDA、EMA、UK MHRA、PMDA、カナダ保健省、
オーストラリア TGA、スペイン AEMPS、フランス ANSM、ブラジル ANVISA、スイスメディック、ニュージーランド MARC、シンガポール HSA、マレーシア NPRA）からの安全性情報およびラベル変更
- **RWD**：FAERS, JADER

Editorial workflow and analysis



セーフティアラート：あらゆる情報源をカバーしタイムリーな安全性情報を提供

February 16, 2017 • Journal Confirmed/Reported

Exhaustive review of scientific literature to identify the most likely functional and pathological outcomes associated with interactions of 70 molecular targets with established links to adverse effects. In humans, androgen receptor antagonists caused osteoporosis, sexual dysfunction, impaired memory and attention, depression, hot flushes, anemia, increased triglycerides, insulin resistance, increased body weight, bone metastasis, bone pain and death (due to heart attack).

Adverse Event **Anaemia**
Alert Phase **Clinical/Postmarketing**

On-Target Causality

Type **Class Alert** On/off-target **On-Target**

Source information [See all alerts](#)

Reference date	Title	Citation
February 16, 2017	Potential functional and pathological side effects related to off-target pharmacological activity	J Pharmacol Toxicol Methods. 2017 Feb 16. pii: S1056-8719(16)30147-2 PubMed 28216264

● ON/OFF-ターゲット：有害事象がターゲットの直接修飾によるものか非直接的な機序によるものかを区別

● アナリスト（生物学者、薬事学者、メディカルケミスト、毒性学者、MD）によるアラートサマリ

● アラートタイプ：ターゲットと有害事象の関連性が、薬理学的クラス全体に認められるものか、特定の薬物に関連するものかを区別

● エビデンスレベル：ターゲット・薬物と有害事象の関連性に関するエビデンスの度合い

● アラートフェーズ：有害事象が報告された開発段階（ターゲットの発見～前臨床、臨床試験、上市医薬品）

OFF-X 知識分野



専門家によるOFF-Xのセーフティーアラートは、**3つの知識分野**に統合、毎日更新されます。幅広く、かつ深いコンテンツは**一つの統合された環境**で提供され、各分野間の**クロスリンク**が、重要なインサイトの発見と意思決定をサポートします。

Target: Androgen receptor / Antagonists

Snapshot Safety alerts Target safety profile Comparative views Biological context

Heat map showing various medical conditions: Nervous system disorders, General disorders and ad..., Gastrointestinal disorders, Musculoskeletal and..., Cardiac disor..., Metabolism, Psychia..., Reproductive system, Infections a..., Respiratory, L..., Vascular disorders, Blood and ly..., Renal and ur..., Endo..., Neoplasms be..., Con..., Ear...

Class: Nuclear Hormone Receptors
OFF-X target ID: 1580
Family: Steroid hormone receptors
Subfamily: 3-Ketosteroid receptors

Aliases (8): AR, DHTR, Dihydrotestosterone receptor, Kennedy disease, NR3C4, ...
Gene (1): AR

UniProt ID (1): P12275
Coriell Drug Discovery Intelligence (2): G367
MetaCore (2): -1467284547, 4423

Open heat map

Drug: mirikizumab

Snapshot Safety alerts Drug safety profile Comparative views

Heat map showing various medical conditions: Infections and infestations, Investigations, Skin and subcutan..., Gastrointestinal d..., Musculoskeletal an..., Neoplasms benign..., Psychiatric dis..., Respiratory..., Metabolic..., Cardiac..., Injury, poisoning an..., Blood and ly..., Hepatic..., Reproductiv..., General disorders and admin..., Nervous system dis..., Immune sys..., Vascu..., Renal...

Drug type: Biologic
Highest phase: Launched - 2021
OFF-X drug ID: 142617

Product category/modality (1): Humanized Monoclonal Antibodies

Drug names (5): mirikizumab-merz, Omvoh, LY-3074828, LY3074828, Z7HYV03PHP

Organizations (2): Eli Lilly and Company

Coriell Drug Discovery Intelligence (2): 826704
Coriell Competitive Intelligence (1): 87792
DrugCentral (1): mirikizumab
ChEMBL (1): CHEMBL3990014

Open heat map

Adverse event: Anaemia

Targets Drugs and biologics

Master view
Showing 1,614 target-actions

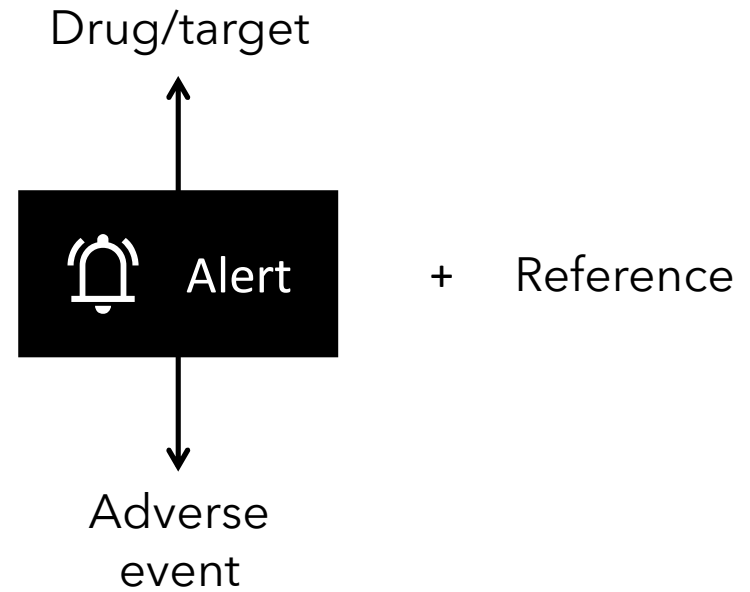
Filter 1 hidden column

Target * Action	OFF-X Target/Class Score	Classifier tags	Number of alerts	Class alerts	Drug alerts	Preclinical	Clinical
ABL1 + Inhibitors	Very high	Causality, Severity, Pharmacogenomics	258	15	5	6	258
ACE + Inhibitors	Very high	On-Target, Causality	36	13	11	4	33
Androgen receptor + Antagonists	Very high	On-Target, Causality, Severity	101	12	4	0	101
BCR/ABL + Inhibitors	Very high	Causality, Severity, Pharmacogenomics	262	15	6	6	262
CAR T-cell therapy + (no specific action)	Very high	On-Target, Causality, Severity	603	117	18	3	603

What is an OFF-X safety alert?

薬物または標的分子への作用と有害事象との間に報告された関連性とその情報源

これら三つはOFF-Xの重要な構成要素であり、ユーザーによる評価と安全性の洞察を容易にするため、編集チームによって手作業で情報のキュレーションを行い、インデックス化された追加データ（40以上のフィールド）と合わせて提供されます。



June 1, 2024 • Congress Alert

Title: Anti-PD-1/TGF-βRII bispecific antibody fusion protein LBL-015 in patients with advanced malignant tumors: A phase I, first-in-human, open-label, multicenter, dose-escalation study

Citation: ASCO Annual Meeting 2024 - J Clin Oncol 42, 2024 (suppl 16; abstr 2591)

Showing 1 safety alert

Target-centric Drug-centric Collapse all

Phase I/II study analyzing the safety and efficacy of LBL-015 (PD-1 inhibitor; 0.3-20 mg/kg IV q2w) in 25 patients with advanced malignant tumors. The most common grade ≥3 treatment-emergent adverse events (TEAEs) included anaemia (any grade 16 patients [64%], grade ≥3 4 patients [16%]) and hypoalbuminemia (5 [20%], 1 [4%]). Other most common TEAEs were increased AST (8 [32%]), proteinuria, pyrexia, increased GGT and bleeding gingival (7 [28%] each). Other safety issues are listed.

Alert date: June 10, 2024
Clinical trial ID (1): NCT05107011
Clinical Trial record 1 alert
Cortellis Clinical Trials Intelligence

Target • Action	Adverse Event • System Organ Class	Classifier Tags	Association based on reference	On/off-target	Alert type	Alert phase	Drugs and combinations	Tools
PD-1 • Inhibitors	Alanine aminotransferase increased • Investigations	On-Target	Confirmed/Reported	On-Target	Drug Alert	Phase I/II	LBL-015	🔗
PD-1 • Inhibitors	Anaemia • Blood and lymphatic system disorders	On-Target Severity	Confirmed/Reported	On-Target	Drug Alert	Phase I/II	LBL-015	🔗
PD-1 • Inhibitors	Aspartate aminotransferase increased • Investigations	On-Target	Confirmed/Reported	On-Target	Drug Alert	Phase I/II	LBL-015	🔗

OFF-X Drug Score, Target/ Class Score, Drug Combination Score

安全性に関するインサイトを導きだすための独自指標

- ※ 一定の「ルール」に基づく分類であり統計的な手法ではありません
- ※ これらのScoreは以下を示すものではありません
 - ・ 医薬品・医薬品クラスと有害事象の因果関係
 - ・ 有害事象の発生率
 - ・ 有害事象の重篤度

OFF-X Drug Score

特定の「**医薬品ー有害事象**」の組み合わせについて蓄積されたセーフティアラートに基づき、当該「**医薬品ー有害事象**」の関連性を示すエビデンスの強さを計算して分類

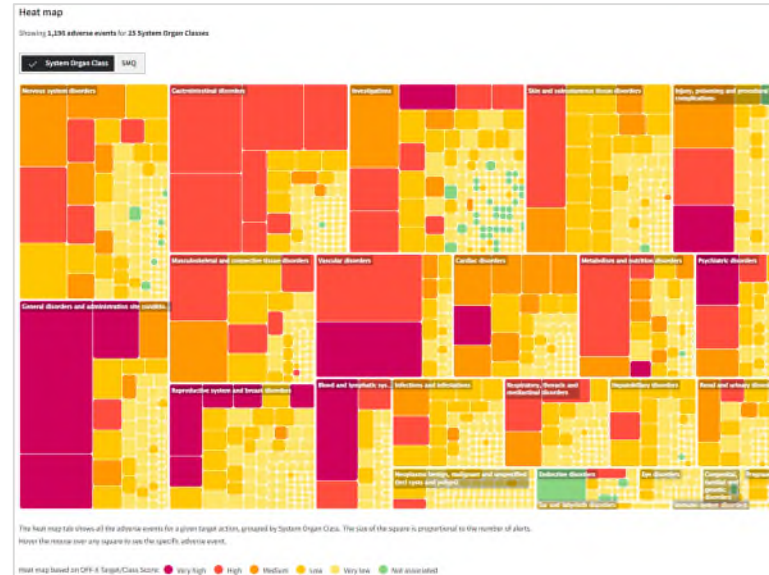
例：Androgen receptor Antagonistsの有害事象プロファイル Drug Scoreのヒートマップで比較



OFF-X Target / Class Score

特定の「**(同じターゲットに作用する) 医薬品クラスー有害事象**」の組み合わせについて蓄積されたセーフティアラートに基づき、当該「**医薬品クラスー有害事象**」の関連性を示すエビデンスの強さを計算して分類

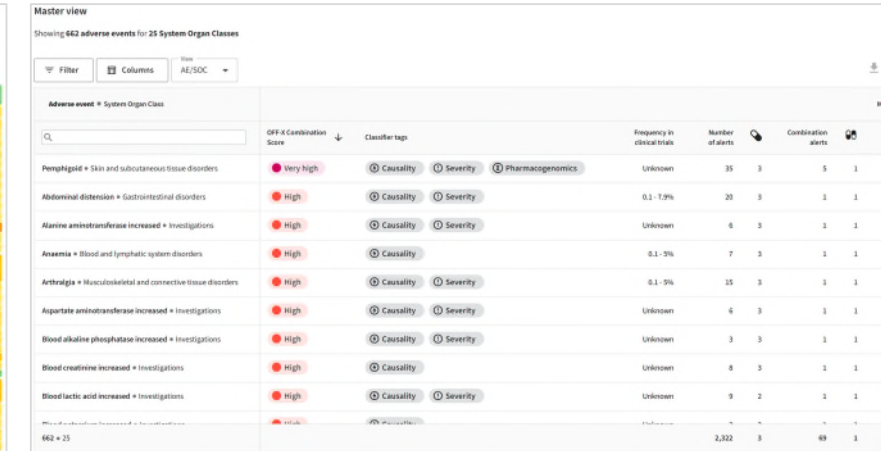
例：医薬品クラス (Androgen receptor Antagonists) の有害事象のプロファイル Target/Class Coreのエビデンスのヒートマップで把握



OFF-X Drug Combination Score

特定の「**コンビネーションー有害事象**」の組み合わせについて蓄積されたセーフティアラートに基づき、当該「**コンビネーションー有害事象**」の関連性を示すエビデンスの強さを計算して分類

例：Combination (alogliptin/metformin) の有害事象のプロファイル Drug Combination Scoreのエビデンスを含めて Master viewで把握



OFF-X アクセス方法

<https://access.clarivate.com/login?app=safety>

上記URL、もしくは御社のご案内に準じてアクセスしてください。

The image shows two parts of the OFF-X website. On the left is the homepage, which features the title "OFF-X, the translational safety intelligence portal" and a list of key features: "Access daily updated data from a broad range of sources", "Anticipate toxicity of novel targets and drug candidates", "Enable dynamic target safety assessments", "Understand how preclinical toxicities may translate to humans", "Benchmark drug and target safety", "Assess unexpected toxicity", and "Support PV signal prioritization and validation". Below this is a "Not yet a subscriber?" section with a "Learn more" button. On the right is the login page, which includes the Clarivate logo, the text "OFF-X", and tabs for "Login" and "Register". The login form has fields for "Email address *" and "Password *", a "Forgot Password?" link, a purple "Sign in" button, and a "Sign in with SSO" button. At the bottom of the login page, it states "By signing in, you acknowledge and agree to our Terms of Use and Privacy Statement." and "Need help? Contact Life Sciences Customer Care."

Email address(ID)とPasswordを入力し、Sign inをクリックしてプラットフォームに接続します。

既に以下のクラリベイト製品にユーザ登録がある場合、ID/Passwordはすべて共通です。

- Cortellis Competitive Intelligence
- Cortellis Clinical Trials Intelligence
- Cortellis Deals Intelligence
- Cortellis CMC Intelligence
- Cortellis Regulatory Intelligence
- Cortellis Digital Health Intelligence
- Cortellis Generics Intelligence
- Cortellis Drug Discovery Intelligence
- Drug Research Advisor
- Key Pathway Advisor
- Web of Science
- Researcher ID
- Derwent Innovation
- InCites
- EndNote

※初めてユーザー登録する際には、ご所属先のデータベースご担当者様にご確認ください。初回登録にお困りの際やログイントラブルの際には、本資料最終頁に記載した弊社カスタマーケアにお問合せください。

※SSOアクセスをご利用のユーザー様については、Sign in with SSOをクリック後に貴社企業名を入力し、専用のGatewayを介してアクセスください。



新インターフェース基本操作

新たなOFF-Xのプラットフォーム

System Organ Class	OFF-X Target/Class Score	Biological Role & Preclinical Pharmacological Evidence			Clinical Pharmacological Evidence				
		Target Expression	In vitro Data / Patient samples	Preclinical	Phase I	Phase II	Phase III	Clinical Regulatory	Postmarketing
Investigations	High		Species 1: 2 2	Species 4: 118 14	214 17	148 5	57 2	37 1	20 2
Gastrointestinal disorders <small>DME</small>	High			Species 2: 7 2	212 17	119 6	39 2	28 2	12 1
General disorders and administration site conditions <small>DME</small>	Medium			Species 4: 9 7	66 14	60 4			
Metabolism and nutrition disorders	Medium			Species 3: 10 3	66 15	39 5			
Blood and lymphatic system disorders <small>DME</small>	Medium			Species 3: 6 2	48 13	28 4			
Skin and subcutaneous tissue disorders <small>DME</small>	Medium		Species 1: 1 1	Species 1: 3 2	39 9	30 5			
Nervous system disorders <small>DME</small>	Medium			Species 2: 2 2	26 5	25 4			

What's new in OFF-X



Faster

OFF-X records load up to 80% faster



More intuitive

The OFF-X you know but with a new look and feel to improve your experience.



Customizable

Choose the content you want to see in the different tables and visualizations.

2024年7月、OFF-Xはユーザーからのフィードバックを受け、新たな技術スタックを用いて全く新しいプラットフォームにて提供開始されました。

Home page

アラート機能の管理ページへアクセスし、設定の変更等が可能

OFF-Xに搭載されている分析ツールへ直接アクセス

The screenshot shows the Clarivate OFF-X Home page. At the top left is the Clarivate logo and 'OFF-X'. The navigation bar includes 'Home', 'Analytics', and 'Your saved work'. A 'Notification center' icon is in the top right. Below the navigation bar is a 'Welcome back,' message. A search bar is present with tabs for 'Targets', 'Drugs and biologics', 'Drug combinations', and 'Adverse events'. Below the search bar are three main sections: 'Your notifications', 'Latest alerts', and 'Congress reports'. The 'Your notifications' section shows two alert cards with details like dates, journal names, and citations. A 'See all alerts' link is at the bottom of each card. A 'Support' icon (a question mark) is in the bottom right corner.

Comparative table builderで作成した比較表の保管庫

クリックすることでHome pageへ戻ります

作成したアラートに関する直近の通知を表示

規制当局由来の新薬承認情報、添付文書改訂情報、臨床保留命令情報、試験・開発中止情報を表示

Targets, Drugs (Drugs & biologics, Drug combinations), Adverse Eventsの3軸で検索が可能。検索時にはいずれかを選択。

直近で開催された学会情報を基に作成されたセーフティアラートへのアクセスや直近で開催予定の学会一覧を表示

製品サイトやナレッジベース、機能強化のお知らせ通知等のサポートコンテンツへアクセス

Analytics (分析ツールへの直接アクセス)

The screenshot displays the OFF-X Analytics dashboard. At the top, there is a navigation bar with 'OFF-X', 'Home', 'Analytics' (highlighted with a purple box), and 'Your saved work'. To the right, there is a search bar labeled 'Targets' with a dropdown arrow and a search icon, with the placeholder text 'Type target or gene or UniProt ID and select'. Below the navigation bar, a green callout bubble points to the 'Analytics' tab with the text '活用用途を選択' (Select use cases). The main content area is titled 'Data in action to de-risk your R&D programs'. Below this title, there is a row of use case buttons: 'All use cases' (highlighted with a purple box), 'Target safety assessment', 'Toxicity exploration', 'Secondary pharmacology profiling', 'Preclinical to clinical translation', 'Structure-toxicity assessment', 'Mechanistic toxicity evaluation', 'Drug vs class assessment', and 'Safety profile benchmark'. Below the buttons, there is a grid of eight tool cards, each with an icon and a description. A purple box highlights the entire grid of tool cards. A green callout bubble at the bottom points to the grid with the text '活用用途に応じた分析ツールを表示' (Display analysis tools according to use cases).

OFF-X Home **Analytics** Your saved work

Targets

Data in action to de-risk your R&D programs

All use cases Target safety assessment Toxicity exploration Secondary pharmacology profiling Preclinical to clinical translation Structure-toxicity assessment Mechanistic toxicity evaluation Drug vs class assessment Safety profile benchmark

Safety risk evaluation

- Comparative table builder**
Anticipate safety for new treatments, benchmark drugs, targets, and combinations, assess mechanisms of toxicity, and explore multiple AEs, HLTs, or SMQs.
- Mounting evidence chart**
Discover and compare drug-safety trends to anticipate emerging concerns
- Pathway maps**
Anticipate and understand safety issues of targets based on upstream or downstream genes in their signaling cascade
- Real-world evidence analysis**
Assess and validate potential pharmacovigilance signals to optimize risk management plans
- Secondary pharmacology panels**
Explore an integrated view of safety-related targets to keep your in vitro panels updated
- Structure-toxicity explorer**
Correlate chemical structures with safety liabilities.
- Translational safety**
Assess the correlation of safety insights of targets and drugs from discovery to clinical
- Unexpected toxicity evaluation**
Assess the mechanisms behind unpredicted adverse events

アラート機能の設定と管理

②アラート名を編集し、通知を受け取る情報の範囲を設定後にApplyボタンをクリックすることで、当該レコードに対してアラートが設定されます。

Targetsレコード 例：PD-1

OFF-X Home Analytics Notification center Targets

Target PD-1 / Inhibitors

Comparative table builder **Keep me posted**

Snapshot Safety alerts Target safety profile Comparative views Biological context

Drugレコード 例：Pegcetacoplan

OFF-X Home Analytics Notification center Drugs and biologics

Drug pegcetacoplan

Comparative table builder **Keep me posted**

Snapshot Safety alerts Drug safety profile Comparative views

①DrugおよびTargetレコード上では、画面右に表示された「Keep me posted」をクリックすることでアラート機能の設定が可能です。

Set up your email notification

See customized content on your home page and receive email notifications.

Drug pegcetacoplan

Notification name* pegcetacoplan_keep me posted Frequency Weekly

Add description

What do you want to get notified about?

All new safety alerts New regulatory alerts only New adverse events only

Select adverse events Select SOCs Select SMQs

Include safety alerts of drugs belonging to the same class ⓘ

Include combination therapies of this drug

Include retrospective content

Cancel Apply

アラート機能の設定と管理

The screenshot shows the 'Notification center' page in the OFF-X application. The page title is 'Notification center' and the subtitle is 'Manage and edit your notifications'. Below this, there is a section for 'Your notifications' which contains a table with columns: Active, Notification name, Knowledge area, Date created, Description, and Actions. Two notifications are listed: 'pegcetacoplan_keep me posted' (created Mar 21, 2025) and 'androgen receptor_keep me posted' (created Sep 11, 2024). Each notification has a toggle switch in the 'Active' column and edit/delete icons in the 'Actions' column. At the bottom of the page, there is a 'Your weekly report' section with a toggle for 'Receive the weekly report' and two radio buttons for 'Target-centric' and 'Drug-centric'.

③ Notification centerをクリックすることで、設定済みのアラートの管理画面を表示

④ アラートごとに通知のON/OFF管理が可能

⑤ アラートの削除や編集が可能

週に一度、期間中に新たな作成、通知された Safety Alertのリストを受信するか否か設定可能

アラート機能の設定と管理

Home画面上のYour notificationsに、設定した内容に基づく最新のアラート通知を表示

Targets **Drugs and biologics** **Drug combinations** **Adverse events**

🔍 Type target or gene or UniProt ID and select

Your notifications Latest alerts Congress reports

androgen_receptor_keep me posted

March 20, 2025 • Journal

Retrospective pharmacoepidemiologic study evaluating the drug-induced pulmonary fibrosis using data from Russian national pharmacovigilance database. The drugs induced pulmonary fibrosis included rituximab (5.5% patients), methotrexate (4.4%), etanercept (4.2%), leflunomide (4%) and adalimumab (3.7%). Other drugs are listed.

Citation
Biomedicines. 2024 Nov 21;12(12):2650 PubMed [39767557](#) **See all alerts**

androgen_receptor_keep me posted

March 14, 2025 • Congress Alert

Retrospective study evaluating the adverse events associated with androgen receptor pathway inhibitors (including abiraterone and enzalutamide) in 153 patients with metastatic prostate cancer and castration-resistant prostate cancer. The most common reason for enzalutamide discontinuation was fatigue.

Citation
[77th Annual Scientific Meeting of the Urological Society of Australia and New Zealand 2025 - BJ...](#) **See all alerts**

androgen_receptor_keep me posted

March 13, 2025 • Congress Alert

Phase III study of darolutamide (androgen receptor antagonist) in patients with metastatic hormone-sensitive prostate cancer. The most common treatment-emergent adverse events (TEAEs) included fatigue (223/652 patients [34%] with darolutamide vs 214/650 [33%] with placebo), rash (116 [18%] vs 88 [14%]) and hypertension (96 [15%] vs 60 [9%]). Other TEAEs are listed.

androgen_receptor_keep me posted

March 13, 2025 • Journal

Real-world pharmacovigilance study evaluating the association between drugs and dementia risk using data from FAERS database. Study showed that rivastigmine (ROR: 46.3 [95% CI: 43.51-49.28]), nicergoline (43.34 [15.75-119.25]), aducanumab (30.19 [19.68-46.29]), amlodipine/atorvastatin (22.68 [11.67-44.09]) and dihydroergometrine (22.57 [9.25-55.06]) had higher risk of dementia. Other

レファレンスの一括出力

Adverse Eventsごとに作成されたセーフティアラートのレファレンスを一括で外部出力することが可能です。

Target
PD-1 / Inhibitors

Snapshot Safety alerts Target safety profile Comparative views

Adverse Events

- > Blood and lymphatic system disorders DME 1726
 - On-Target
 - Causality
 - Severity
 - Pharmacogenomics
- > Cardiac disorders DME 1739
 - On-Target
 - Causality
 - Severity
 - Pharmacogenomics
- > Congenital, familial and genetic disorders DME 30
 - On-Target
 - Causality
 - Severity
- > Ear and labyrinth disorders DME 62
 - On-Target
 - Causality
 - Severity
- > Endocrine disorders 3364
 - On-Target
 - Causality
 - Severity

① 出力したいSOCグループを選択
※AE, SMQ単位でも出力することが可能

Adverse Events

Showing 62 safety alerts for Ear and labyrinth disorders

Filter View AE/SOC Expand all

1 March 20, 2025 Journal Suspected On-Target Severity

Case report of a 87-year-old man with metastatic cutaneous squamous cell carcinoma who developed severe hypersensitivity reactions after receiving pembrolizumab (200 mg IV) and cemiplimab (350 mg IV). Other adverse events are listed.

Drugs (1) pembrolizumab Show structures

Adverse Event Ear swelling Alert Phase Postmarketing

2 February 13, 2025 Regulatory Agency Communication On-Target Causality

Confirmed/Reported

Adverse reactions reported in clinical trials with Hetronify with frequency not known included myositis, chronic obstructive pulmonary disease, respiratory failure, mouth ulceration and proctitis. Other adverse drug reactions are listed. [Data from EMA...]

Drugs (1) serplulimab Show structures

Adverse Event Tinnitus Alert Phase Clinical Frequency Unknown

② 出力ボタンをクリック

レファレンスの一括出力

セーフティアラートごとにリンク先のレファレンス情報へ直接アクセス頂けます。

	A	B	C	D
1			Association based on reference	
2	2025-03-20	Journal	Suspected	Case report of a 87-year-old man with metastatic cutaneous squamous cell carcinoma who developed severe hypersensitivity reactions after receiving pembrolizumab (200 mg IV) and cemiplimab (100 mg IV). Other adverse events are listed.
3	2025-02-13	Regulatory Agency Communication	Confirmed/Reported	Adverse reactions reported in clinical trials with Hetronify with frequency not known included chronic obstructive pulmonary disease, respiratory failure, mouth ulceration and proctitis. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Hetronify (serplulimab; PD-1 inhibitor)]
4	2025-02-13	Regulatory Agency Communication	Confirmed/Reported	Uncommon (≥1/1,000 to <1/100) adverse drug reactions reported in clinical trials with Hetronify included septic shock, skin infection and enteritis infectious. [Data from EMA European public assessment report for Hetronify (serplulimab; PD-1 inhibitor)]
5	2024-09-30	Regulatory Agency Communication	Confirmed/Reported	Common (≥1/100 to <1/10) adverse drug reactions reported in clinical trials with Loqtorzi included pneumonia, leukocytosis and hyperthyroidism. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Loqtorzi (toripalimab-tpzi; PD-1 inhibitor)]
6	2024-09-30	Regulatory Agency Communication	Confirmed/Reported	Common (≥1/100 to <1/10) adverse drug reactions reported in clinical trials with Loqtorzi included pneumonia, leukocytosis and hyperthyroidism. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Loqtorzi (toripalimab-tpzi; PD-1 inhibitor)]
7	2024-09-30	Regulatory Agency Communication	Confirmed/Reported	Common (≥1/100 to <1/10) adverse drug reactions reported in clinical trials with Loqtorzi included pneumonia, leukocytosis and hyperthyroidism. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Loqtorzi (toripalimab-tpzi; PD-1 inhibitor)]
8	2024-09-30	Regulatory Agency Communication	Confirmed/Reported	Common (≥1/100 to <1/10) adverse drug reactions reported in clinical trials with Loqtorzi included pneumonia, leukocytosis and hyperthyroidism. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Loqtorzi (toripalimab-tpzi; PD-1 inhibitor)]
9	2024-09-30	Regulatory Agency Communication	Confirmed/Reported	Common (≥1/100 to <1/10) adverse drug reactions reported in clinical trials with Loqtorzi included pneumonia, leukocytosis and hyperthyroidism. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Loqtorzi (toripalimab-tpzi; PD-1 inhibitor)]
10	2024-09-30	Regulatory Agency Communication	Confirmed/Reported	Common (≥1/100 to <1/10) adverse drug reactions reported in clinical trials with Loqtorzi included pneumonia, leukocytosis and hyperthyroidism. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Loqtorzi (toripalimab-tpzi; PD-1 inhibitor)]
11	2024-09-30	Regulatory Agency Communication	Confirmed/Reported	Common (≥1/100 to <1/10) adverse drug reactions reported in clinical trials with Loqtorzi included pneumonia, leukocytosis and hyperthyroidism. Other adverse drug reactions are listed. [Data from EMA European public assessment report for Loqtorzi (toripalimab-tpzi; PD-1 inhibitor)]

V	W	X	Y	Z
Reference date	Reference Title	Citation	PubMed ID	Clinical trial ID
2024-10-19	Severe hypersensitivity reactions to 2 immunotherapy agents in a patient with cutaneous squamous cell carcinoma	Am J Health Syst Pharm. 2024 Oct 19:zxae286	39425965	
2025-02-11	Hetronify (serplulimab)	EMA European public assessment report. Hetronify (serplulimab)		
2025-02-11	Hetronify (serplulimab)	EMA European public assessment report. Hetronify (serplulimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		
2024-09-24	Loqtorzi (toripalimab)	EMA European public assessment report. Loqtorzi (toripalimab)		



検索事例1

特定のターゲットに関連した安全性情報を網羅的に収集

Target Record Snapshot

Targets

分子に関連したMOA,リガンド、バリエントを選択し、該当する安全性情報を表示

情報更新時のアラート通知受信設定機能へのアクセス

Search results for 'androgen':

- Androgen receptor [Androgen receptor]
- Androgen-induced growth factor [FGF-8]
- Androgen-regulated protein 6 [FKBP prolyl isomerase 5]
- Androgen receptor complex-associated protein [DDB1- and CUL4-associated factor 6]
- Androgen receptor splice variant 7 [Androgen receptor splice variant 7]

Target Record Snapshot for Androgen receptor / Antagonists

Heatmap categories: Nervous system disorders, Investigations, Skin and subcutane... Injury, poison..., General disorders and ad..., Musculoskeletal and..., Cardiac disor..., Metabolism, Psychiatri..., Gastrointestinal disorders, Reproductive system..., Infections a..., Respiratory, t..., Hepatobili..., Vascular disorders, Blood and ly..., Renal and uri..., Endo... Ey..., Neoplasms be..., Con... Ear..., Prea... Im...

External database links:

- Gene (1): AR
- UniProt ID (1): P10275
- Cortellis Drug Discovery Intelligence (1): G367
- MetaCore (2): -1467284547, 4423

Bottom navigation:

- Related drugs
- Latest and pinned alerts
- Regulatory relevance
- Therapeutic applications

検索ボックスにて特定のTarget分子名を入力。[]内に記載された候補一覧から該当分子を選択

HeatmapをSnapshotへ搭載。“Open heat map”をクリックすることでフルスクリーンビューへ切り替え。

他のデータベース（外部またはクラリベイト製品）へのリンク

各ポートレットを選択展開することで、分子の作用カテゴリ別に関連医薬品、最新または警告関連の安全性情報、規制当局発表の安全性情報、対象となる治療領域を表示

Safety alerts – 個々の安全性報告の内容を確認

Targets

The screenshot displays the Clarivate safety alerts interface. At the top, the target is identified as "Androgen receptor / Antagonists". The main navigation includes "Snapshot", "Safety alerts", "Target safety profile", "Comparative views", and "Biological context". A sidebar on the left lists various adverse events, with "Agranulocytosis" highlighted. A callout box explains that the display format (SOC/SMQ classification) and filters can be used to limit the display of adverse events. The main content area shows a detailed view of a safety alert for "Agranulocytosis" (Blood and lymphatic system disorders), dated January 17, 2025, with a "Suspected" severity. The alert text describes a pharmacovigilance study comparing safety signals of adverse events associated with novel hormonal agents (abiraterone, apalutamide, enzalutamide, and darolutamide) using data from the FAERS database. The alert phase is "Postmarketing". A table below provides source information, including a reference date of December 16, 2024, and a citation to "Expert Opin Drug Saf. 2024 Dec 16:1-10" with a PubMed link (39668443).

Target: Androgen receptor / Antagonists

Comparative table builder | Keep me posted

Snapshot | Safety alerts | Target safety profile | Comparative views | Biological context

Adverse Events

- Blood and lymphatic system dis... DME
- Agranulocytosis DME**
- Anaemia macrocytic
- Anaemia megaloblastic
- Anaemia
- Aplasia pure red cell DME
- Aplastic anaemia DME
- Blood disorder
- Bone marrow disorder

Showing 2 safety alerts for Agranulocytosis (Blood and lymphatic system disorders)

Filter | View: AE/SOC

^ Collapse all

January 17, 2025 • Journal Suspected

Severity: Adverse Event **Agranulocytosis** DME
Alert Phase **Postmarketing**

Pharmacovigilance study comparing the safety signals of adverse events associated with novel hormonal agents (abiraterone, apalutamide, enzalutamide and darolutamide) using data from the FAERS database. Safety issues are listed.

Drugs (1) **apalutamide** Show structures

Type: On/off-target
Drug Alert: Not Specified

Source information See all alerts

Reference date	Title	Citation
December 16, 2024	A 13-years pharmacovigilance analysis of novel hormonal agents in prostate cancer using the FDA adverse event reporting system database	Expert Opin Drug Saf. 2024 Dec 16:1-10 PubMed 39668443

Safety alertsが作成されたAE一覧について表示形式 (SOC/SMQ分類) を変更したり、フィルターにより AEの表示を限定することが可能

Safety alertsごとに関連医薬品の構造式やリファレンスへの外部リンク、当該リファレンスを基に作成されたその他のSafety alerts一覧へアクセス可能

Additional references – 安全性情報に関連したその他のレファレンスを検索

Additional referencesでは、安全性や毒性のキーワードと機械学習法を用いて同定された標的分子または対象薬剤を含む文献をリストアップして表示します。 ※これらの文献は編集員によるマニュアルキュレーションは実施されていません。

ターゲット分子、遺伝子、医薬品名および安全性・毒性のキーワードを選択したのちに言及箇所を指定し、レファレンスを検索可能。

フィルターが無効の場合、最も関連性の高い文献（キーワード近接性に基づく）のみ表示。フィルターを有効にすると、すべての文献（関連性の低いものを含む）が表示

Show all references (including less relevant ones)

Target/Gene/Drug	Found in	Safety Keyword	Section	Title	Citation	Reference date	PMID ↓
ar	Title/Abstract	rhinitis	Title/Abstract	Nutraceuticals and non-pharmacological remedies for managing patients with allergic rhinitis.	Minerva Pediatr (Torino) 2022 10 25;	2022-10-25	36282486
ar	Title/Abstract	allergic asthma	Title/Abstract	A real-world retrospective study of safety, efficacy, compliance and cost of combination treatment with rush immunotherapy plus one dose of pretreatment anti-IgE in Chinese children with respiratory allergies.	Front Immunol 2022 13; 1024319	2022-01-01	36268011
		allergic rhinitis	Title/Abstract				
		asthma	Title/Abstract				
		retrospective study	Title/Abstract				
		rhinitis	Title/Abstract				
Reference's MeSH terms							
ar	Title/Abstract	allergic rhinitis	Title/Abstract	The Association between Allergic Rhinitis and COVID-19: A Systematic Review and Meta-Analysis.	Int J Clin Pract 2022 2022; 6510332	2022-01-01	36249911
		coronavirus disease 2019	Title/Abstract				
		rhinitis	Title/Abstract				

Target safety profile

Master view – ターゲットに関連したSafety Alertsの総計を表示

Target Androgen receptor / Antagonists

Snapshot Safety alerts Target safety profile Comparative views Biological context

Master view

Showing 1,188 adverse events from 1188 classes

Filter 1 hidden Heat map

Adverse event • System Organ Class	OFF-X Target/Class Score	Classifier tags	Alert type				Alert phase				Tools		
			Number of alerts	Class alerts	Drug alerts		Preclinical	Clinical					
Anaemia • Blood and lymphatic system disorders	Very high	On-Target Causality Severity	97	12	4	0	93	12	0	0	97	12	⋮
Asthenia • General disorders and administration site conditi...	Very high	Causality Severity	90	12	5	0	85	12	0	0	90	12	⋮

Anaemia • Blood and lymphatic system disorders

Alerts

Showing 97 alerts for Androgen receptor Antagonists and Anaemia

- March 4, 2025 • Congress Alert Confirmed/Reported

Phase I study of enzalutamide (androgen receptor antagonist) with or without metformin (EZH2/PRC2 inhibitor) in 82 patients with metastatic castration-resistant prostate cancer. The most common treatment emergent adverse events (TEAEs) with enzalutamide/metformin were diarrhea (78% patients [n=41]), decreased appetite and dyspepsia (58.5% each). TEAEs with...

Drug (s): enzalutamide Show structures
- January 29, 2025 • Journal Confirmed/Reported

Phase III study of enzalutamide (E; androgen receptor antagonist; 160 mg qd) alone or in combination with talazoparib (T; PARP-L1 inhibitor; 0.5 mg qd) in patients with metastatic castration-resistant prostate cancer. The most common all causality treatment-emergent adverse events (TEAEs) included anaemia (80%/396 patients with E; 17%/461 with E; talazoparib (38%...)

Drug (s): enzalutamide Show structures
- December 12, 2024 • Journal Suspected

Systematic review evaluating the risk associated with denegest in patients with endometriosis. The most adverse reactions included abnormal uterine bleeding (55 [95% CI: 3.7-7.3]) and amenorrhoea (3 [7.2-4.2]). Other safety issues are listed.

Drug (s): denegest Show structures

Anaemia • Blood and lymphatic system disorders

Alerts

Showing 12 drugs in 97 alerts for Androgen receptor Antagonists and Anaemia

<p>apalutamide</p> <p>Small molecule • Launched</p> <p>High 3 3 0</p> <p>FDA</p>	<p>bicalutamide</p> <p>Small molecule • Launched</p> <p>High 3 1 0</p> <p>FDA PMDA</p>	<p>cyproterone acetate</p> <p>Small molecule • Launched</p> <p>High 3 0 0</p>	<p>darolutamide</p> <p>Small molecule • Launched</p> <p>High 3 5 0</p> <p>PMDA</p>
<p>deutazulutamide</p> <p>Small molecule • Phase III</p> <p>Low 1 1 0</p>	<p>dienogest</p> <p>Small molecule • Launched</p> <p>High 1 5 0</p> <p>PMDA</p>	<p>enzalutamide</p> <p>Small molecule • Launched</p> <p>Very high 24 22 0</p> <p>PMDA</p>	<p>flutamide</p> <p>Small molecule • Launched</p> <p>High 2 0 0</p> <p>PMDA</p>
<p>masofaniten</p> <p>Small molecule • Discontinued</p> <p>Low 1 0 0</p>	<p>proxalutamide</p> <p>Small molecule • Launched</p> <p>Medium 7 2 0</p>	<p>rezlutamide</p> <p>Small molecule • Phase III</p> <p>Low 1 1 0</p>	<p>seviteronel</p> <p>Small molecule • Phase II</p> <p>Low 0 1 0</p>

MedDRA hierarchy classification [v27.1]

Non-MedDRA terms are included to expand coverage.

- [SOC] - Blood and lymphatic system disorders [DME]
 - [HLT] - Anaemias nonhaemolytic and marrow depression [DME]
 - [HLT] - Anaemia deficiencies
 - [HLT] - Anaemia NEC
 - [PT] - Anaemia macrocytic
 - [PT] - Anaemia megaloblastic
 - [PT] - Anaemia
 - [PT] - Normochromic anaemia
 - [HLT] - Marrow depression and hypoplastic anaemias [DME]
 - [HLT] - Coagulation and bleeding diatheses (excl thrombocytopenia) [DME]
 - [HLT] - Haematological disorders NEC
 - [HLT] - Haemolyses and related conditions [DME]
 - [HLT] - Platelet disorders [DME]
 - [HLT] - Spleen, lymphatic and reticuloendothelial system disorders
 - [HLT] - White blood cell disorders [DME]
 - [SOC] - Cardiac disorders [DME]
 - [SOC] - Congenital, familial and genetic disorders [DME]
 - Very high On-Target Causality Severity Pharmacogenetics 221
 - Very high On-Target Causality Severity 106
 - Very low 1
 - Very high On-Target Causality Severity 102
 - Very low Causality 3
 - Very low Causality 1
 - Very high On-Target Causality Severity 97
 - Very low 3
 - Very low Severity 1
 - Very low Causality Severity 4
 - Very low Causality Pharmacogenetics 14
 - Very low Causality Severity Pharmacogenetics 7
 - High Causality Severity 26
 - Very low On-Target Causality Severity 9
 - High Causality Severity 53
 - Very high On-Target Causality Severity Pharmacogenetics 345
 - Low On-Target Causality Severity 34

Safety alerts数または関連Drug数を選択すると、選択したAE区分におけるAlert一覧および関連医薬品ごとのAEとの関連度、Alert数・構造式を表示

Toolコラムにて「・・・」を選択すると該当のAEについてMedDRAの階層を表示

Target safety profile

Translational safety – 前臨床・臨床・市販後までの有害事象を俯瞰し関連性を考察

Target Androgen receptor / Antagonists

Comparative table builder Keep me posted

Snapshot Safety alerts Target safety profile Comparative views Biological context

Translational safety Master view Translational safety Heat map

Showing 1,188 adverse events

Filter 2 hidden Heat map

Adverse event * System Organ Class

OFF-X Target/Class Score

| Adverse event * System Organ Class | OFF-X Target/Class Score | Biological Role & Preclinical Pharmacological Evidence | | | | | | | | | | | | Tools |
|--|--------------------------|--|------------------------|-------------------|---------------------------------|---------------|-------|-------|-------|------------|-------|-------|-------|-------|
| | | Target Expression | Human Genetic variants | KO/KD Animal data | In vitro Data / Patient samples | Preclin | Phase | Phase | Phase | Clinic Reg | Phase | Phase | Phase | |
| Infertility male * Reproductive system and breast disorders | Very high | INI | | | Species 1 1 1 | 20 9 | 2 2 | 6 3 | 6 3 | 6 4 | 22 6 | 3 2 | ? | |
| Reproductive toxicity * Reproductive system and breast disorders | Low | INI | | | 11 7 | 10 6 | 20 4 | 29 4 | 11 4 | 6 2 | 10 5 | ? | | |
| Azoospermia * Reproductive system and breast disorders | Very high | INI | | Species 2 3 | | 8 4 | | | 2 1 | | 1 | ? | | |
| Testicular atrophy * Reproductive system and breast disorders | Low | INI | | | | 8 5 | | | 2 1 | 1 1 | | ? | | |
| Weight abnormal * Investigations | Very low | | | | | 8 6 | | | 2 1 | | | ? | | |
| Seizure DME * Nervous system disorders | Low | INI | | | Species 1 2 4 | Species 3 7 5 | | 2 2 | 20 3 | 8 2 | 11 2 | 12 3 | ? | |
| Sexual dysfunction * Reproductive system and breast disorders | Very high | INI | | | | Species 1 6 2 | | | 1 1 | 1 1 | 3 2 | 5 2 | ? | |

Excel出力

Tools

特定のAEを検索して表示

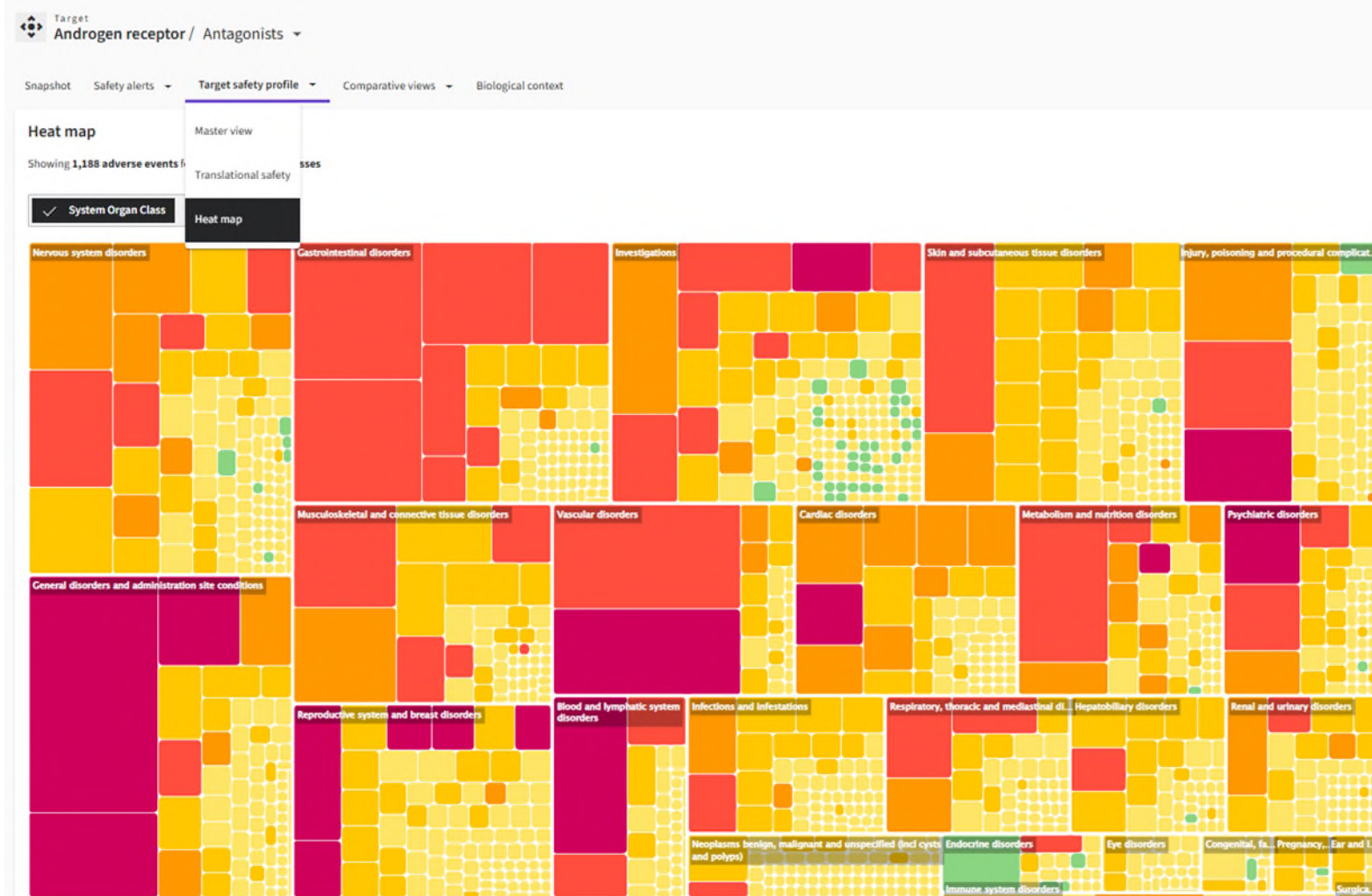
Toolsを選択すると、特定のAE区分におけるSafety Alert数を同じMOAをもつ医薬品ごとに内訳参照、特定のAEのTranslational safetyに移行、MedDRAの階層を表示

カーソルを合わせ数値をクリックし、報告された動物種、個々のSafety alertsや関連医薬品の一覧へアクセス

Target safety profile

Heat map – 特定のターゲットアクションに関するすべての有害事象をグループ化

Heatmapでは特定のターゲットアクションに関する全ての有害事象が、SOCまたはSMQごとにグループ化されて表示されます。



- 四角の色は「同じターゲットに作用する医薬品クラスー有害事象」の組み合わせについて蓄積されたセーフティアラートに基づき、当該「医薬品クラスー有害事象」の関連性を示すエビデンスの強さを計算した Target/Class Scoreから分類しております。
- 四角の大きさはアラートの数に比例します。

Comparative views

Comparative drug safety evidence – 特定のターゲットアクションをもつすべてのドラッグを比較表示

Target: Androgen receptor / Antagonists

Comparative table builder

Keep me posted

Snapshot Safety alerts Target safety profile Comparative views Biological context

Comparative drug safety evidence

Comparing 35 Androgen receptor Antagonists

Filter 3 hidden columns View: AE/SOC Number of alerts Sort drugs: Highest phase

Adverse event • System Organ Class

OFF-X Target/Class Score

Tools

Heat map based on OFF-X Drug Score: Very high High Medium Low Not associated Target/class evidence only

同いターゲットアクションをもつドラッグを羅列

ドラッグの特定のAEに関するSafety Alertの数と特定の「医薬品-有害事象」の関連性を裏付けるエビデンスの強度であるDrug Scoreに基づいた色の分類

| Adverse event • System Organ Class | cyproterone...
Launched 1973 | flutamide
Launched 1983 | nilutamide
Launched 1987 | bicalutamide
Launched 1995 | dienogest
Launched 2008 | enzalutamide
Launched 2012 | apalutamide
Launched 2018 | darolutamide
Launched 2019 | casrotone
Launched 2021 | prololutamide
Launched 2021 | deutenalut...
Phase III | KX-826
Phase III | rezvilutamide
Phase III |
|--|---------------------------------|----------------------------|-----------------------------|-------------------------------|----------------------------|-------------------------------|------------------------------|-------------------------------|----------------------------|--------------------------------|----------------------------|---------------------|----------------------------|
| Anaemia • Blood and lymphatic system disorders | 3 | 2 | | 4 | 6 | 46 | 6 | 11 | | 9 | 2 | | 2 |
| ... | 1 | 2 | | 4 | 1 | 49 | 9 | 19 | | 3 | | | 1 |
| ... | 3 | 2 | | | | | 2 | 1 | | | | | |
| ... | | 1 | | 3 | 2 | 6 | 2 | 4 | | | | | |
| Carcinogenicity • Injury, poisoning and procedural complica... | 16 | 5 | 1 | 6 | 3 | 13 | 3 | 3 | 1 | 1 | 1 | | |
| Death • General disorders and administration site conditions | 1 | 3 | 1 | 4 | | 24 | 11 | 10 | | | | | |
| Depression • Psychiatric disorders | 5 | 2 | | 2 | 8 | 17 | 2 | 2 | | 1 | | | |

Comparative views

Comparative table builder – 関心のあるターゲットアクション（ドラッグ）の比較表を独自に作成・保存

検索しているターゲットがデフォルトで組み込まれます

JAK1が新たに表に追加

関心のあるターゲットを追加

MOA、バリエーションを選択

Targets

Type target, gene or UniProt ID and select

Add drugs acting on any selected target-actions

Add drugs sh...

Selected target-actions

JAK1 Inhibitors

Androgen receptor Antagonists

- Modulators
- Antagonists
- Agonists
- Degraders

Apply

Clear all 2 targets selected Build table

Comparative table builder

Edit table Filter View SOC Heat map Number of alerts

| System Organ Class | Androgen re... Antagonists |
|--|----------------------------|
| General disorders and administration site conditions DME | 734 |
| Gastrointestinal disorders DME | 711 |
| Investigations | 676 |
| Injury, poisoning and procedural complications | 441 |
| Reproductive system and breast disorders | 414 |
| Vascular disorders | 401 |
| Cardiac disorders DME | 358 |
| Metabolism and nutrition disorders | 329 |
| Psychiatric disorders DME | 252 |
| Blood and lymphatic system disorders DME | 233 |
| 25 | 7,500 |

Comparative table builder

Edit table Filter View SOC Heat map Number of alerts

| System Organ Class | Androgen re... Antagonists | JAK1 Inhibitors |
|--|----------------------------|-----------------|
| General disorders and administration site conditions DME | 734 | 987 |
| Gastrointestinal disorders DME | 711 | 1287 |
| Investigations | 676 | 2626 |
| Injury, poisoning and procedural complications | 441 | 685 |
| Reproductive system and breast disorders | 414 | 184 |
| Vascular disorders | 401 | 766 |
| Cardiac disorders DME | 358 | 594 |
| Metabolism and nutrition disorders | 329 | 428 |
| Psychiatric disorders DME | 252 | 100 |
| Blood and lymphatic system disorders DME | 233 | 1558 |
| 26 | 7,500 | 19,408 |

Comparative views

Comparative table builder – 関心のあるターゲットアクション（ドラッグ）の比較表を独自に作成・保存

Targets

Comparative table builder

Edit table Filter View SOC Heat map Number of alerts

保存した比較表の呼び出し

Open table

Save

作成した比較表を保存

Nameをクリックして開く

Name (必須) とDescription (任意) を入力しSaveをクリックして保存

| System Organ Class | Androgen re...
Antagonists | JAK1
Inhibitors |
|---|-------------------------------|--------------------|
| General disorders and administration site conditions DME | 734 | 987 |
| Gastrointestinal disorders DME | 711 | 1287 |
| Investigations | 676 | 2626 |
| Injury, poisoning and procedural complications | 441 | 685 |
| Reproductive system and breast disorders | 414 | 184 |
| Vascular disorders | 401 | 766 |
| Cardiac disorders DME | 358 | 594 |
| Metabolism and nutrition disorders | 329 | 428 |
| Psychiatric disorders DME | 252 | 100 |
| Blood and lymphatic system disorders DME | 233 | 1558 |
| 26 | 7,500 | 19,408 |

| Name | Description | Date last updated ↓ |
|---|-------------|---------------------|
| Androgen receptor, JAK1 | | 07/14/2025 |
| ipilimumab | | 07/10/2025 |
| ipilimumab, ipilimumab/niraparib, ipilimumab/nivol... | | 07/10/2025 |

Items per page: 10 Page 1 of 1

Save table

Name*
Androgen receptor, JAK1 (1)

Description (optional)

Cancel Save

Comparative views

Targets

Comparative table builder – 関心のあるターゲットアクション（ドラッグ）の比較表を独自に作成・保存

OFF-X

Home

Analytics

Your saved work

Targets

🔍 Type target or gene or UniProt ID and select

Saved tables

Build new table

| Name | Description | Date last updated ↓ | Actions |
|---|-------------|---------------------|---|
| Androgen receptor, JAK1 | | 07/14/2025 |   |
| ipilimumab | | |   |
| ipilimumab, ipilimumab/niraparib, ipilimumab/nivolumab/tranilast + 138 more | | | |

Nameをクリックして作成した比較表を開く

Edit : NameとDescriptionを編集
Delete : 作成した比較表の削除

Items per page:

10

Page 1 of 1

⏪ ⏩

Biological context

Pathway Maps- 病理学的・生理学的パスウェイを視覚的に表示

関心のあるターゲットを軸にした周辺のターゲットとの比較表の作成

Targets

The interface is divided into several sections:

- Left Panel:** A list of pathway maps. The selected item is "Androgen receptor activation and downstream signaling in Prostate cancer".
- Top Center:** "Pathway maps" section with tabs for "Default" and "Safety alerts". A "Description" tab is active, showing a detailed signaling pathway diagram with nodes like PTEN, STAT3, ERK1, ERK2, and Androgen receptor.
- Top Right:** "Comparative table builder" section. It prompts to "Please select the targets you want to compare" with two options: "All targets in the highlighted cascade" (selected) and "Direct interactions (shown in the interactions table)".
- Right Panel:** "Androgen receptor" target profile. It shows "Transcription factor", "Highest Phase: Launched", and "19154 Safety Alerts" and "3833 Serious/severe safety alerts". Below is a table of interactions.

| From | Mechanism | To |
|----------------|-------------------|-------------------|
| STAT3 | + Binding | Androgen receptor |
| ERK2 | + Phosphorylation | Androgen receptor |
| Rb protein | + Binding | Androgen receptor |
| NCOA1 (SRC1) | + Binding | Androgen receptor |
| ESR2 (nuclear) | + Binding | Androgen receptor |

Annotations:

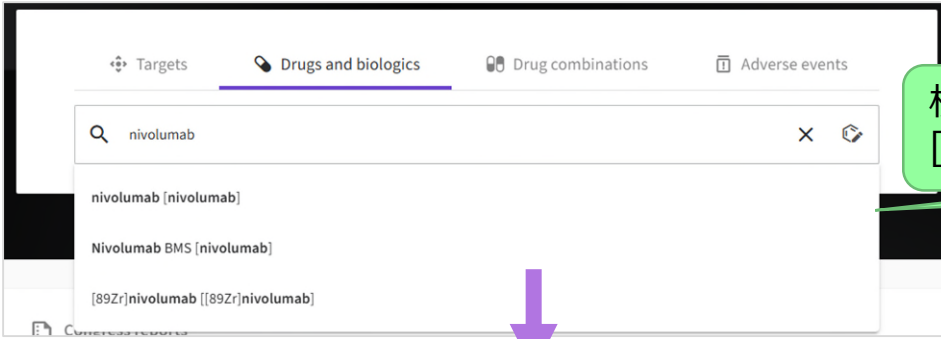
- Pathway Mapsや各アイコン等の説明:** Points to the pathway diagram and its legend.
- ターゲットに紐づく Safety Alertの数を表示:** Points to the "Safety alerts" tab in the pathway maps section.
- ターゲットに紐づく Safety Alertを特定のAEやActionによって絞り込み:** Points to the "Filter" dropdown in the "Safety alerts" view.
- パスウェイに存在する全てのターゲットの比較表を作成:** Points to the "Build comparative table" button in the comparative table builder.
- パスウェイマップを出力:** Points to the download icon in the comparative table builder.
- ターゲット情報に加え、相互作用情報もリスト:** Points to the interaction table in the target profile.



検索事例2

特定の医薬品に関する安全性報告を確認

医薬品の安全性報告を確認する



検索ボックスにて特定の医薬品名を入力
[]内に記載された候補一覧から該当医薬品を選択

情報更新時のアラート通知
受信設定機能へのアクセス

Drug **nivolumab**

Snapshot Safety alerts Drug safety profile Comparative views

HeatmapをSnapshotへ搭載。“Open heat map”をクリックすることでフルスクリーンビューへ切り替え。

他のデータベース（外部またはクラリベイト製品）へのリンク

- Pharmacology profile
- Latest and pinned alerts
- Regulatory relevance
- Related combinations
- Therapeutic applications

各ポートレットを選択展開することで、

- ・ 医薬品の区分
- ・ 最新または警告関連の安全性情報
- ・ 規制当局発表の安全性情報
- ・ 関連するコンビネーション
- ・ 対象となる治療領域を表示

Master view - AEごとのFDA Approval packageにおける記載を確認する

Drug Safety Profileタブをクリックし、Master Viewを選択

Drug nivolumab

Comparative table builder

Keep me posted

Snapshot Safety alerts **Drug safety profile** Comparative views

Master view Translational safety Clinical patient safety Real-world evidence analysis Mounting evidence chart

Showing 2,717 adverse events for 25 System Organ Classes

Filter 1 hidden column View AE/SOC

| Adverse event • System Organ Class | type | Alert phase | | | | | | | | | | Label Reference | | | | |
|---|------|-------------|----------------|-----------------------|-------------|----------|------------------------|-----|------|------|-------|-----------------|--|--|--|--|
| | | ass
erts | Drug
alerts | Combination
alerts | Preclinical | Clinical | Text mining
FDA SBA | FDA | EMA | PMDA | Tools | | | | | |
| Death • General disorders and administration site conditions | 43 | 1 | 233 | 1 | 304 | 85 | 3 | 1 | 577 | 86 | 0 | | | | | |
| Diarrhoea • Gastrointestinal disorders | 36 | 1 | 332 | 1 | 647 | 223 | 2 | 1 | 1013 | 224 | 4 | | | | | |
| Hypothyroidism • Endocrine disorders | 33 | 1 | 264 | 1 | 353 | 119 | 1 | 0 | 649 | 120 | 2 | | | | | |
| Immune-mediated adverse reaction • Immune system disor... | 76 | 1 | 638 | 1 | 475 | 97 | 14 | 1 | 1275 | 98 | 1 | | | | | |
| Pneumonitis • Respiratory, thoracic and mediastinal disorders | 67 | 1 | 302 | 1 | 290 | 100 | 5 | 1 | 654 | 101 | 5 | | | | | |
| Pruritus • Skin and subcutaneous tissue disorders | 34 | 1 | 232 | 1 | 425 | 146 | 0 | 0 | 691 | 147 | 3 | | | | | |
| Rash • Skin and subcutaneous tissue disorders | 40 | 1 | 266 | 1 | 438 | 151 | 1 | 0 | 743 | 152 | 3 | | | | | |

Text Mining FDA SBAの列にて、AEごとのカウント数をクリック

Master view - AEごとのFDA Approval packageにおける記載を確認する

OFF-X text mining FDA Summary Basis of Approval (SBA)

The following table lists FDA Summary Basis of Approval (SBA) documents where particular adverse event terms have been found by our proprietary text mining tools. The original document with the adverse event terms highlighted is accessible via the Source link.

| Adverse Event | Document type | Term | Number of occurrences | Source |
|---------------|---|-----------|-----------------------|------------------------|
| Diarrhoea | Clinical Pharmacology Biopharmaceutics Review | diarrhea | 1 | Source |
| | | diarrhoea | 3 | Source |
| | Medical Review | diarrhea | 28 | Source |
| | Pharmacology Review | diarrhea | 4 | Source |
| | Summary Review | diarrhea | 2 | Source |

Sourceをクリックすると、ドキュメントタイプごとに記載箇所を確認可能

どのAEが、どのDocumentに、どの用語で、どのくらいの記載数があるかを表示

AE、Document typeの表示の切り替え

AE軸、Document type軸で表示の切り替え

関連用語の切り替え

Documentの出力

記載箇所を黄色ハイライト

nivolumab

Text mining FDA SBA

Search by

Adverse event Document type

Adverse event: Diarrhoea

Document type: Clinical Pharmacology Biopharmaceutics Review

Associated term: diarrhea (1)

VIEWER'S ANALYSIS

OBJECTIVE

The analysis objectives are to compare the exposure distributions between different groups and to explore exposure-response relationship for each specific adverse event including uveitis, autoimmune neuropathy, facial paresis, viral infection, ALT increased, AST increased, infusion related reaction, blood alkaline phosphatase increased, liver function abnormal, colitis, hyperglycaemia, amylase increase, lipase increase, tubulointerstitial nephritis, hypotension, pneumonitis, hypoxia, diarrhea, fatigue, herpes zoster, post herpetic neuralgia, lymphopenia, rash, arthritis, pancreatitis, ventricular arrhythmia, demyelination, abdominal pain upper, vomiting, and lymphocyte count decreased.

Clinical patient safety

–臨床における安全性リスクを患者特性に応じて評価・分析

- 臨床試験
 - 患者疾患
 - 患者疾患 (+ 健常ボランティア)
 - 健常ボランティア
 - 性別
 - 年齢
 - 人種
- を選択

Filterで更なる絞り込み

縦軸オプション

横軸オプション

Drug: nivolumab

Snapshot Safety alerts Drug safety profile Comparative views

Translational safety Clinical patient safety Real-world evidence

Filter 3 hidden columns View: AE/SOC Data type: Patient condition Sort conditions: Alphabetically

Alert type (1) Clear all filters

Adverse event • System Organ Class

| | Acute leukemia | Acute myelogenous leukemia | Adenocarcinoma | Adenoid tumor | Adenosquamous cell carcinoma | Adrenal cortical carcinoma | Adrenal gland hypofunction | Adult T-cell lymphoma | Advanced solid tumor | Advanced synovial sarcoma | Aggressive fibromatosis | Anal tumor | Anaplastic large cell lymphoma | Tools |
|---|----------------|----------------------------|----------------|---------------|------------------------------|----------------------------|----------------------------|-----------------------|----------------------|---------------------------|-------------------------|------------|--------------------------------|-------|
| Death • General disorders and administration site conditions | 1 | 2 | 4 | | | | | | 3 | | | 1 | | + |
| Diarrhoea • Gastrointestinal disorders | | 2 | 9 | 2 | | | | 1 | 9 | | 1 | 6 | 1 | + |
| Hypothyroidism • Endocrine disorders | | 1 | 2 | 2 | | | | | 4 | | | 4 | | + |
| Immune-mediated adverse reaction • Immune system disorders | 1 | 3 | 3 | | | | | | 3 | | | 1 | | + |
| Pneumonitis • Respiratory, thoracic and mediastinal disorders | | 2 | 6 | | | | | | 5 | 1 | 1 | 2 | | + |
| Pruritus • Skin and subcutaneous tissue disorders | | 1 | 5 | 2 | | | | 1 | 6 | 1 | | 3 | 1 | + |

OFF-X Drug Score ↓

Very high

Real-world evidence analysis

Main view—当局集計（JADER・FAERS）の安全性報告一覧を確認する

Drug: nivolumab

Comparative table builder | Keep me posted

Snapshot | Safety alerts | **Drug safety profile** | Comparison

① Drug safety profileを選択し、Real-world evidence analysisをクリックする

Master view | Translational safety | Clinical patient safety | **Real-world evidence analysis** | Mounting evidence chart

Main view ▾ Showing 6,248 adverse events for 27 System Organ Classes

- 表示するAEのフィルタリング
- 表示形式区分の変更 (AE/SOC)
- 表示するコラムの選択

安全性報告数、報告割合、第1報からの経過年数

Main view

- Comparative report analysis
- Concomitant drug analysis
- Report details and analysis

4つの機能をプルダウンで切り替え

特定のAEを検索して表示

当局発表のLabel情報に基づく Safety alertへアクセス

| Adverse event • System Organ Class | OFF-X Drug Score | FDA | EMA | PMDA | FAERS 86,457 case IDs (all drug roles)
Last update: Q1 2025 | Evans | X-squared | PRR025 | ROR025 | GPS (EB05) | IC025 | Tools |
|--|------------------|-----|-----|------|--|--------------|----------------|--------|--------|------------|-------|-------|
| | | | | | Number of reports | % of reports | First reported | | | | | |
| Malignant neoplasm progression • Neoplasms benign, mali... | Very high | | | | 10,976 | 4.3 | >5 years | | | | | |
| Diarrhoea • Gastrointestinal disorders | Very high | | | | 4,701 | 1.9 | >5 years | | | | | |
| Fatigue • General disorders and administration site conditions | High | | | | 3,804 | 1.5 | >5 years | | | | | |
| Pyrexia • General disorders and administration site conditions | High | | | | 3,377 | 1.3 | >5 years | | | | | |

該当のAEについて MedDRAの階層を表示

Real-world evidence analysis

Comparative report analysis—同じ作用機序の薬剤間で安全性報告数を一覧比較する

Drug
nivolumab

一覧比較する医薬品を指定する

Snapshot Safety alerts **Drug safety profile** Comparative views

Master view

Translational safety

Clinical patient safety

Real-world evidence analysis

Comparative report analysis Comparing 13 drugs (launched, sharing primary target action)

Filter

View
AE/SOC

Database
FAERS

| Adverse event • System Organ Class | nivolumab
Launched 2014 | | | pembrolizumab
Launched 2014 | | | cemiplimab
Launched 2018 | | | camrel | Tools |
|--|----------------------------|----------------------|-----------------|--------------------------------|----------------------|-----------------|-----------------------------|----------------------|-----------------|-----------------|-------|
| | OFF-X
Drug Score | Number of
reports | % of
reports | OFF-X
Drug Score | Number of
reports | % of
reports | OFF-X
Drug Score | Number of
reports | % of
reports | OFF-X
Drug S | |
| Death • General disorders and administration site conditions | | 10,976 | 4.3 | | 4,815 | 1.9 | | 133 | 1.9 | | |
| Malignant neoplasm progression • Neoplasms benign, mali... | | 9,231 | 3.6 | | 9,618 | 3.8 | | 16 | 0.2 | | |
| Off label use • Injury, poisoning and procedural complications | | 5,404 | 2.1 | | 3,829 | 1.5 | | 118 | 1.7 | | |
| Diarrhoea • Gastrointestinal disorders | | 4,701 | 1.9 | | 4,521 | 1.8 | | 65 | 0.9 | | |
| Fatigue • General disorders and administration site conditions | | 3,804 | 1.5 | | 4,211 | 1.7 | | 129 | 1.8 | | |
| Pyrexia • General disorders and administration site conditions | | 3,377 | 1.3 | | 3,114 | 1.2 | | 94 | 1.3 | | |
| Intentional product use issue • Injury, poisoning and proce... | | 3,296 | 1.3 | | 88 | | | 2 | | | |

Edit drugs

Drugs sharing primary target action: PD-1 Inhibitors

Launched

cadonilimab camrelizumab cemiplimab dostarlimab pembrolizumab
pucotenilimab retifanlimab serplulimab sintilimab tislelizumab
toripalimab zimberelimab

In development

Any other drugs

Reset Cancel **Apply**

Real-world evidence analysis

Concomitant drug analysis—単剤時と併用時の安全性報告数を確認する

Drug: nivolumab

Comparative table builder | Keep me posted

Snapshot | Safety alerts | **Drug safety profile** | Comparative views

Master view | Translational safety | Clinical patient safety | **Real-world evidence analysis** | Mounting evidence chart

Concomitant drug analysis

Adverse event: **Death** (SMQ) | Broad SMQ terms

Case ID

Filter: Database: **FAERS**

| Drug • Highest phase | Death | Concomitant reports | Reports |
|--|--------------------|---------------------|---------|
| nivolumab • Biologic • Launched 2014 | FDA
EMA
PMDA | | 10,976 |
| ipilimumab • Biologic • Launched 2011 | FDA
EMA
PMDA | 2,811 | 3,712 |
| ondansetron • Small molecule • Launched 1990 | | 410 | 9,082 |
| oxycodone • Small molecule • Launched 1917 | FDA | 283 | 29,453 |
| acetaminophen • Small molecule • Launched 1955 | FDA | 245 | 15,023 |
| levothyroxine • Small molecule • Launched 1955 | | 234 | 12,083 |

関心のあるAEを入力

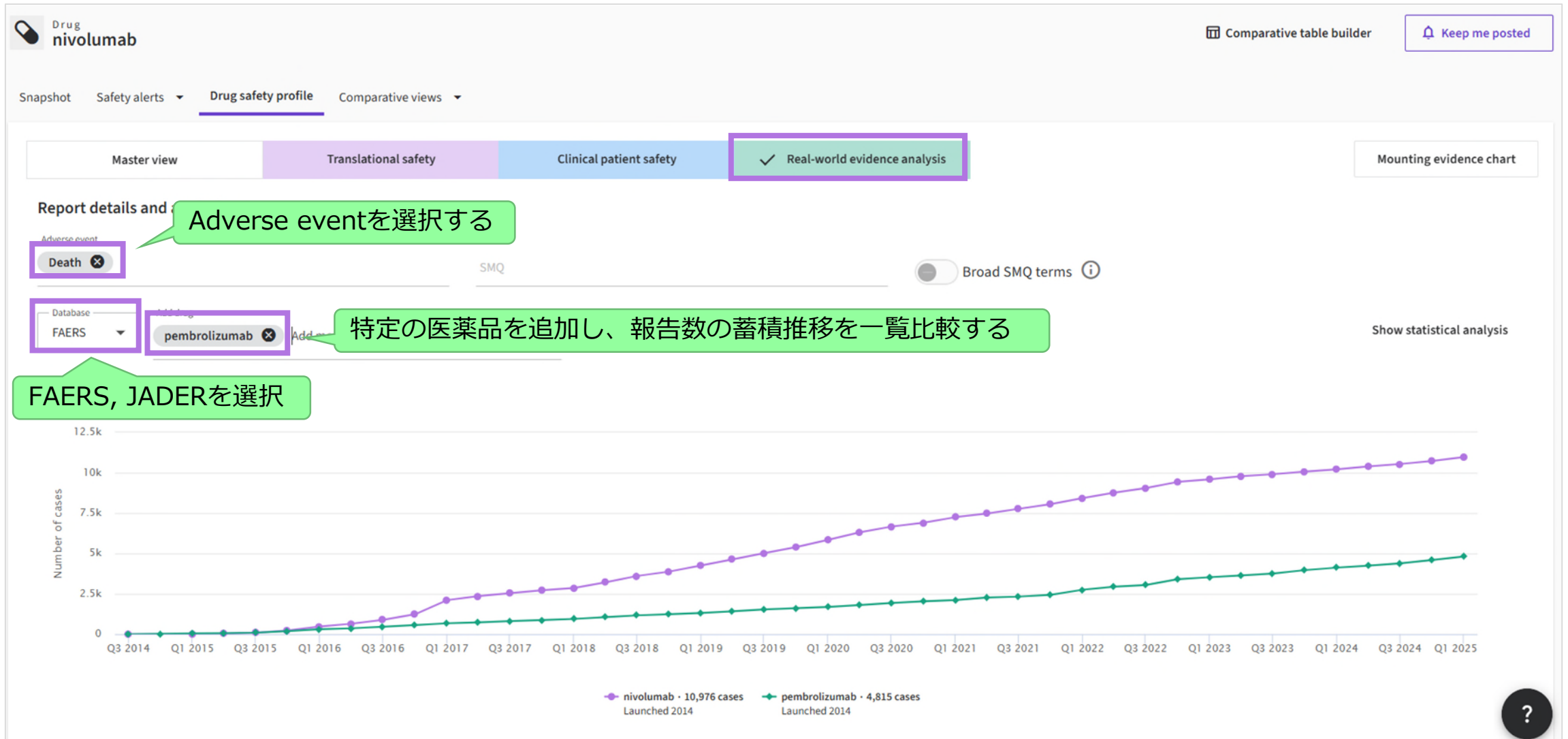
FAERS, JADERの選択

併用時の安全性報告数

単剤時の安全性報告数

Real-world evidence analysis

Report details and analysis—安全性報告の蓄積推移を一覧比較する



Adverse eventを選択する

特定の医薬品を追加し、報告数の蓄積推移を一覧比較する

FAERS, JADERを選択

Real-world evidence analysis

Report details and analysis – 安全性報告の蓄積推移を一覧比較する

Report details

Showing 10,976 cases for Death

Filter

Case毎の情報を掲載



| Database | Case ID ↓ | Primary ID | Drug • Highest phase | Reason for use | Administration route | Drug role | Concomitant drug analysis | Serious | Outcome | Therapy start |
|----------|--------------------------|------------|---------------------------|--|---------------------------------------|-------------------|---------------------------|---------|---------------|---------------|
| FAERS | 25111126 | 251111262 | nivolumab • Launched 2014 | Non-small cell lun... | Intravenous drip | Secondary Suspect | Analyze | Serious | Other Serious | - |
| FAERS | 25107049 | 251070491 | nivolumab • Launched 2014 | Product used for u...
Uterine cancer | - | Primary Suspect | Analyze | Serious | Other Serious | - |
| FAERS | 25103118 | 251031181 | nivolumab • Launched 2014 | Oesophageal carci... | - | Secondary Suspect | Analyze | Serious | Other Serious | - |
| FAERS | 25102786 | 251027861 | nivolumab • Launched 2014 | Herpes simplex en...
Lung adenocarcin...
Prophylaxis | - | Concomitant | Analyze | Serious | Death | - |
| FAERS | 25102745 | 251027451 | nivolumab • Launched 2014 | Renal cell carcinoma | - | Secondary Suspect | Analyze | Serious | Other Serious | - |
| FAERS | 25102250 | 251022501 | nivolumab • Launched 2014 | Renal cell carcinoma | - | Secondary Suspect | Analyze | Serious | Other Serious | - |
| FAERS | 25099891 | 250998911 | nivolumab • Launched 2014 | Product used for u...
Renal cell carcino... | - | Secondary Suspect | Analyze | Serious | Other Serious | - |
| FAERS | 25099852 | 250998521 | nivolumab • Launched 2014 | Neoplasm malignant | Intravenous (not otherwise specified) | Primary Suspect | Analyze | Serious | Death | 2024-04-08 |
| FAERS | 25090402 | 250904021 | nivolumab • Launched 2014 | Malignant melanoma | - | Secondary Suspect | Analyze | Serious | Other Serious | - |

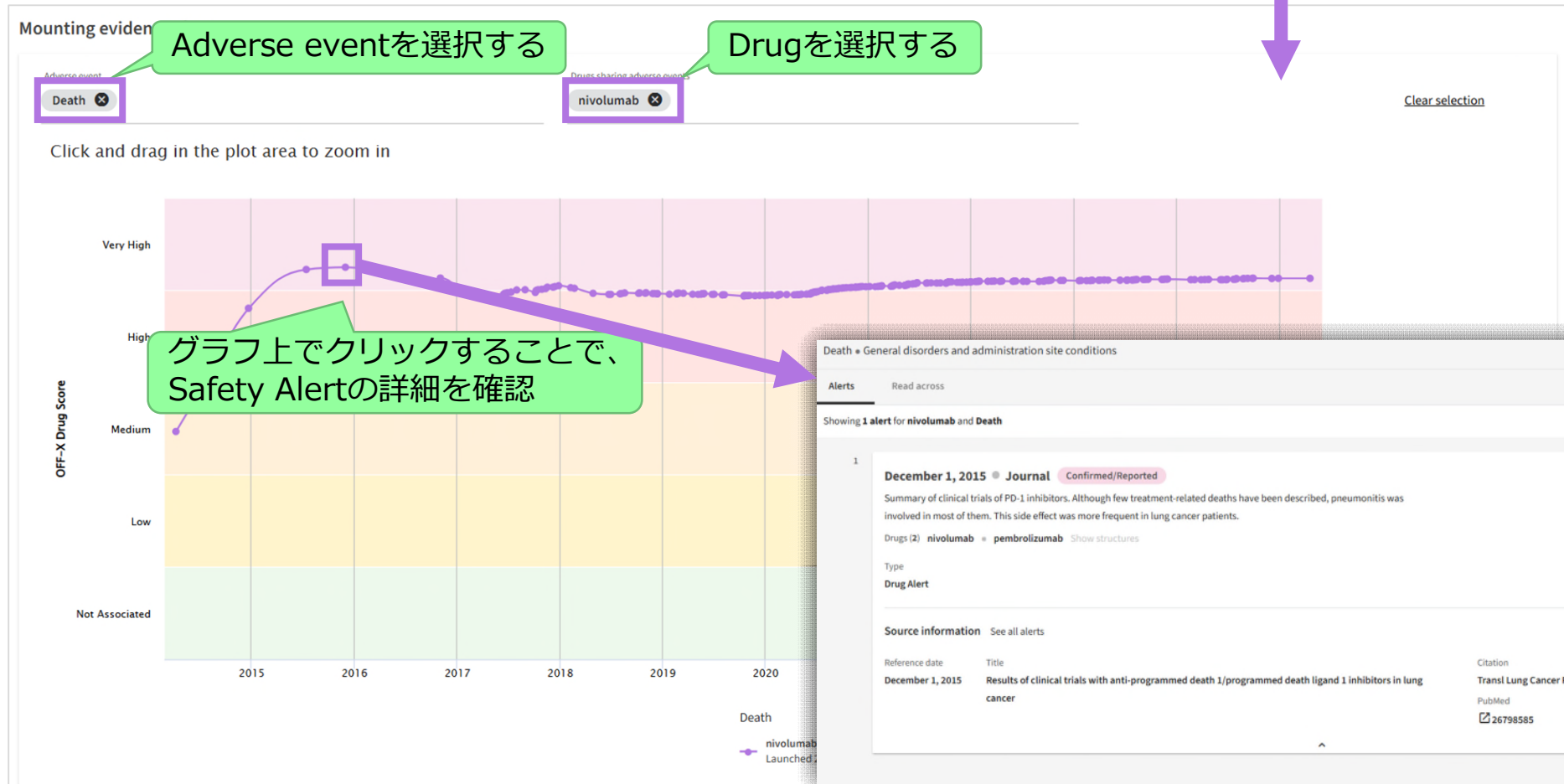
Mounting evidence chart

特定のAEについてOFF-X Drug Scoreに基づくエビデンスレベルの推移を表示

Drug nivolumab

Snapshot Safety alerts **Drug safety profile** Comparative views

Master view Translational safety Clinical patient safety Real-world evidence analysis **Mounting evidence chart**



Death • General disorders and administration site conditions

Alerts Read across

Showing 1 alert for nivolumab and Death

1

December 1, 2015 • Journal **Confirmed/Reported**

Summary of clinical trials of PD-1 inhibitors. Although few treatment-related deaths have been described, pneumonitis was involved in most of them. This side effect was more frequent in lung cancer patients.

Drugs (2) nivolumab • pembrolizumab Show structures

Type
Drug Alert

Source information See all alerts

| Reference date | Title | Citation |
|------------------|---|--|
| December 1, 2015 | Results of clinical trials with anti-programmed death 1/programmed death ligand 1 inhibitors in lung cancer | Transl Lung Cancer Res. 2015 Dec;4(6):756-62
PubMed
26798585 |

Combination（合剤/併用）の安全性報告を確認する

The screenshot displays the Clarivate interface for drug combinations. At the top, there are navigation tabs: Targets, Drugs and biologics, Drug combinations (selected), and Adverse events. A search bar contains 'nivolumab/ipilimumab', with a dropdown menu showing suggestions like 'ipilimumab/nivolumab' and 'BMS-986156/ipilimumab/nivolumab'. A purple arrow points from the search bar to the selected combination. The main content area shows the 'Drug combination ipilimumab/nivolumab' page. It features a 'Snapshot' tab, 'Safety alerts', 'Combination safety profile', and 'Comparative table builder'. A heatmap is displayed, showing various adverse event categories such as 'Gastrointestinal disorders', 'Endocrine disorders', 'General disorders', 'Nervous system', 'Respiratory, thoracic, and chest disorders', 'Immune system disorders, infections and infestations', 'Skin and subcutaneous tissue disorders', 'Metabolism and nutrition disorders', 'Cardiac disorders', 'Blood and blood-forming organ disorders', 'Investigations', 'Musculoskeletal and connective tissue disorders', 'Hepatobiliary disorders', 'Eye disorders, injuries, poisoning and ocular drug use disorders', 'Psychiatric disorders', 'Vascular disorders', and 'Neoplasms, benign and malignant'. A green callout bubble points to the heatmap with the text 'コンビネーションのHeatmapを表示'. Below the heatmap, the 'Components' section shows 'ipilimumab' (Launched 2011, Biologic, CTLA-4 Inhibitors) and 'nivolumab' (Launched 2014, Biologic, PD-1 Inhibitors). Other sections include 'Latest and pinned alerts', 'Regulatory relevance', and 'Therapeutic applications'. A 'Comparative table builder' button is visible in the bottom right corner.

コンビネーションのHeatmapを表示

各ポートレットを選択展開することで、

- コンビネーションの構成要素
- 最新または警告関連の安全性情報
- 規制当局発表の安全性情報
- 対象となる治療領域

を表示

Combination（合剤/併用）の安全性報告を確認する

Drug combination
ipilimumab/nivolumab

Snapshot **Safety alerts** Combination safety profile Comparative table builder

Adverse Events

- Blood and lymphatic system disorders DME
- Agranulocytosis DME
- Anaemia
- Antiphospholipid syndrome
- Aplasia pure red cell DME
- Aplastic anaemia DME
- Autoimmune haemolytic anaemia DME
- Autoimmune neutropenia
- Autoimmune pancytopenia
- Blood disorder
- Bone marrow failure DME

Showing 1 safety alert for **Agranulocytosis** (Blood and lymphatic system disorders)

Filter

Showing 1 safety alert for **Agranulocytosis** (Blood and lymphatic system disorders)

May 10, 2020 • Journal Confirmed/Reported

Analysis of the FDA Adverse Event Reporting System database for hematological toxicities with immune checkpoint inhibitors. Adverse events with ROR025 >1 (including fatal cases) of nivolumab, pembrolizumab, cemiplimab, ipilimumab, atezolizumab, avelumab, durvalumab, ipilimumab + pembrolizumab, ipilimumab + nivolumab, ipilimumab + pembrolizumab + nivolumab are listed.

Combinations (1) ipilimumab/nivolumab

Type
Drug Alert

Source information See all alerts

| Reference date | Title | Citation |
|----------------|---|---|
| May 8, 2020 | Hematological Toxicities in Immune Checkpoint Inhibitors: A Pharmacovigilance Study From 2014 to 2019 | Hematol Oncol. 2020 May 8
PubMed
32383782 |

スライダーをONにすることで単剤のSafety Alertを追加表示

併用時のSafety Alertを表示

Combination safety profile

Master view – Combinationに関連したSafety Alertsの総計を表示

Drug combination
ipilimumab/nivolumab

Comparative table builder [Keep me posted](#)

Snapshot Safety alerts **Combination safety profile** Comparative table builder

Master view
Showing 2,329 adverse events

Filter [Comparative table builder](#)

Heat map

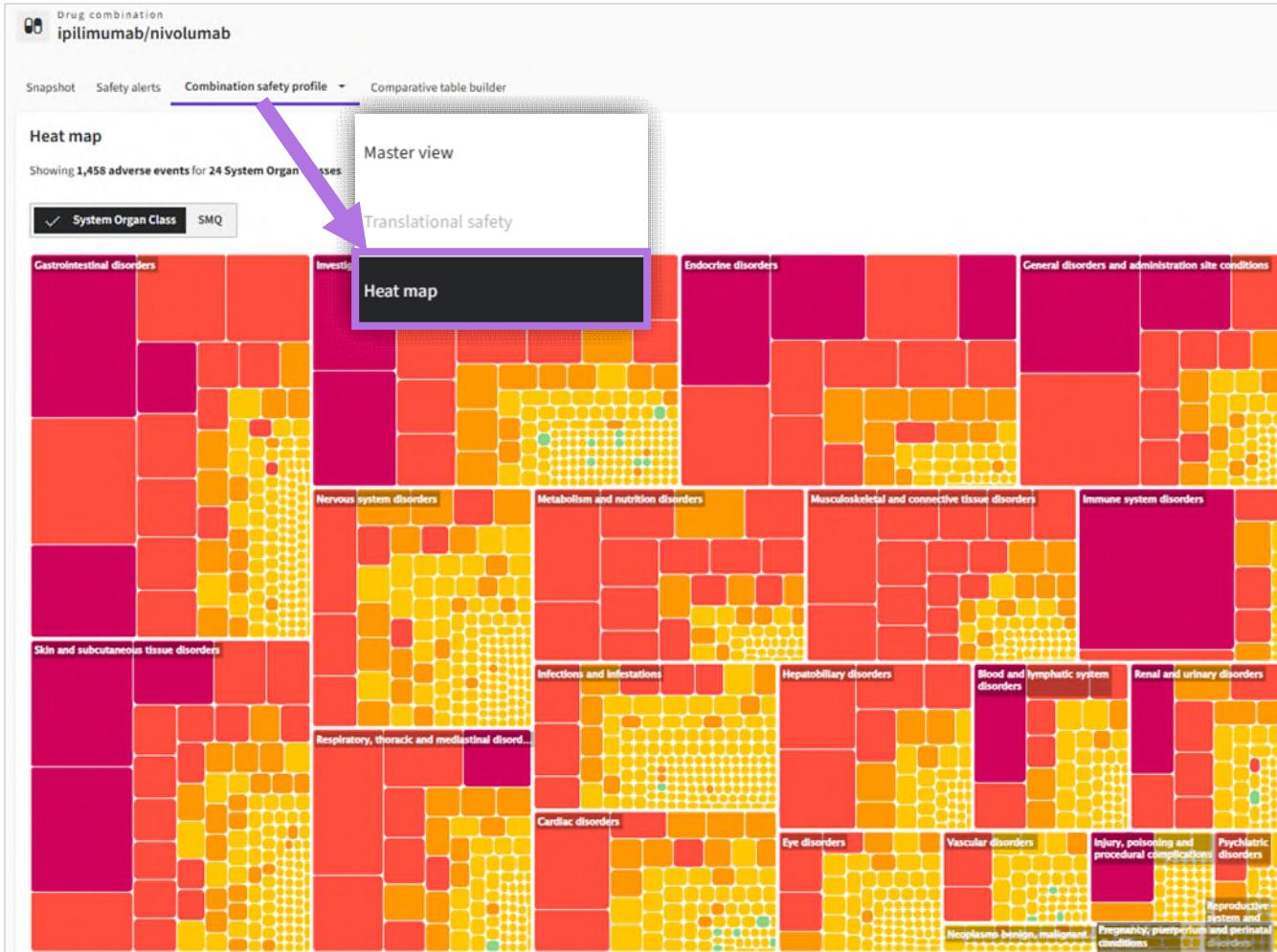
Adverse event • System Organ Class

| Adverse event • System Organ Class | OFF-X Combination Score | Classifier tags | Frequency in clinical trials | Number of alerts | Combination alerts | Mon | |
|--|-------------------------|-------------------------------------|------------------------------|------------------|--------------------|-----|---|
| Abdominal pain • Gastrointestinal disorders | Very high | Causality Severity | 1 - 54.76% | 136 | 3 | 49 | 1 |
| Acute kidney injury DME • Renal and urinary disorders | Very high | Causality Severity Pharmacogenomics | ≥0.1 - 11.9% | 155 | 3 | 58 | 1 |
| Alanine aminotransferase increased • Investigations | Very high | Causality Severity | 1 - 33.33% | 316 | 3 | 116 | 1 |
| Anaemia • Blood and lymphatic system disorders | Very high | Causality Severity Pharmacogenomics | 1 - 85.7% | 224 | 3 | 74 | 1 |
| Aspartate aminotransferase increased • Investigations | Very high | Causality Severity | 1 - 38.1% | 306 | 3 | 114 | 1 |
| Cough • Respiratory, thoracic and mediastinal disorders | Very high | Causality Severity | 1 - 43.8% | 135 | 3 | 47 | 1 |
| Diarrhoea • Gastrointestinal disorders | Very high | Causality Severity Pharmacogenomics | <1 - 50% | 668 | 3 | 202 | 1 |
| Fatigue • General disorders and administration site conditions | Very high | Causality Severity Pharmacogenomics | ≥5 - 85.71% | 535 | 3 | 169 | 1 |

Combination safety profile

Heat map – 特定のCombinationに関するすべての有害事象をグループ化

Heatmapでは特定のコンビネーションに関する全ての有害事象が、SOCまたはSMQごとにグループ化されて表示されます。



- 四角の色は、Drug ScoreやTarget/Class Scoreと同様のルールに基づいたアルゴリズムで算出され、OFF-XにあるすべてのSafety Alertに基づく、特定の「コンビネーション-有害事象」の関連性を示すエビデンスの強さを計算したCombination Scoreから分類しております。
- 四角の大きさはアラートの数に比例します。

Heat map based on OFF-X Combination Score: ● Very high ● High ● Medium ● Low ● Not associated

Comparative table builder

– 関心のあるCombinationの比較表を独自に作成・保存

Comparative table builder

Open table **Save**

Edit table Filter View: SOC Heat map: Number of alerts

コンビネーションの表示・追加

| System Organ Class | Drug Combination |
|---|--------------------------|
| <input type="text"/> | ipilimumab/
nivolumab |
| Gastrointestinal disorders DME | 1235 |
| Skin and subcutaneous tissue disorders DME | 1007 |
| Investigations | 983 |
| Endocrine disorders | 902 |
| General disorders and administration site conditions DME | 714 |
| Respiratory, thoracic and mediastinal disorders DME | 568 |
| Immune system disorders DME | 416 |
| Blood and lymphatic system disorders DME | 299 |
| Renal and urinary disorders DME | 299 |

?

検索事例3

特定の有害事象に関連する作用機序を網羅的に評価

特定の有害事象について原因となる作用機序を網羅的に評価

Adverse events

Targets Drugs and biologics Drug combinations Adverse events

asthenia

Synonyms

MedDRA terminology (27.1)

Asthenia [Asthenia] (General disorders and administration site conditions)

Immune-mediated myasthenia gravis [Immune-mediated myasthenia gravis] (Nervous system disorders)

Myasthenia gravis [Myasthenia gravis] (Nervous system disorders)

Myasthenia gravis crisis [Myasthenia gravis crisis] (Nervous system disorders)

検索ボックスにて特定のAE名を入力 []内に記載された候補一覧から該当AEを選択

特定の有害事象について原因となる作用機序を網羅的に評価

Master view – 作用機序ごとにSafety Alert一覧を表示

Adverse event Asthenia

Comparative table builder

Targets Drugs and biologics

Master view

Showing 1,106 target-actions

Filter 1 hidden column

- フィルターによるAEの限定
- 表示するコラムの選択

| Target • Action | | Alert type | | | | |
|---|----------------------------|---------------------|------------------|----|--------------|-------------|
| | OFF-X Target/Class Score ↓ | Classifier tags | Number of alerts | | Class alerts | Drug alerts |
| alpha1-Adrenoceptor • Antagonists | | On-Target Causality | 47 | 11 | 6 | 41 |
| Androgen receptor • Antagonists | Very high | Causality Severity | 90 | 12 | 5 | 85 |
| beta-Adrenoceptor • Antagonists | Very high | Causality | 56 | 19 | 6 | 50 |
| DNA gyrase • Inhibitors | Very high | Causality Severity | 35 | 14 | 10 | 25 |
| DNA topoisomerase 4 • Inhibitors | Very high | Causality Severity | 35 | 14 | 10 | 25 |
| Hedgehog protein signaling • Inhibitors | Very high | Causality Severity | 31 | 4 | 2 | 29 |
| MAO • Inhibitors | Very high | On-Target Causality | 14 | 7 | 3 | 11 |

特定のAEを検索して表示

?

特定の有害事象について原因となる作用機序を網羅的に評価

Translational safety – 開発ステージ別のSafety alert数を作用機序ごとに一覧表示

Adverse event
Asthenia

Comparative table builder

Targets ▾ Drugs and biologics ▾

Translational safety
Showing 1,085 target-actions

Filter 2 hidden columns

- フィルターによるAEの限定
- 表示するコラムの選択

| Target • Action | OFF-X Target/Class Score | Biological Role & Preclinical Pharmacological Evidence | | | | | Clinical Pharmacological Evidence | | | | | |
|----------------------------------|--------------------------|--|------------------------|-------------------|---------------------------------|------------------|-----------------------------------|----------|-----------|---------------------|---------------|---------------------|
| | | Target Expression | Human Genetic variants | KO/KD Animal data | In vitro Data / Patient samples | Preclinical | Phase I | Phase II | Phase III | Clinical Regulatory | Postmarketing | Phase not specified |
| DNA topoisomerase 2 • Inhibitors | Medium | | | | | 4 2
Species 2 | 8 8 | 13 6 | 6 3 | 11 7 | 3 3 | 4 |
| FAAH • Inhibitors | | | | | | 3 1
Species 3 | 2 2 | | | | | |
| JAK • Inhibitors | Low | | | | | 2 2
Species 1 | 5 4 | 7 5 | 25 5 | 7 4 | 7 4 | 4 |
| beta-Adrenoceptor • Antagonists | Very high | | | | | 2 2
Species 2 | 1 1 | 2 2 | | 38 18 | 9 7 | 4 |
| beta1-Adrenoceptor • Antagonists | High | | | | | 2 2
Species 2 | 1 1 | | | 21 13 | 5 4 | 2 |
| MAO • Inhibitors | Very high | | | | | 2 | 2 2 | | 1 1 | 6 4 | 1 1 | 2 |
| MAO-A • Inhibitors | Very high | | | | | 2 | 1 1 | | | 2 2 | | 1 |
| Tyrosine kinase • Inhibitors | High | | | | | 1 1
Species 1 | 50 34 | 118 43 | 91 22 | 79 25 | 102 19 | 43 |
| PD-1 • Inhibitors | High | | | | | 1 1
Species 1 | 80 23 | 118 18 | 64 7 | 16 7 | 56 8 | 26 |

特定のAEを検索して表示

?

特定の有害事象について原因となる作用機序を網羅的に評価 有害事象の複数選択検索機能

Adverse events

The image shows a software interface for searching adverse events. At the top, there are navigation tabs: Targets, Drugs and biologics, Drug combinations, and Adverse events. A callout bubble points to the Adverse events tab with the text "Select multiple adverse eventsを選択". Below the tabs, there is a search bar and a toggle switch for "Select multiple adverse events". A callout bubble points to this toggle with the text "Select multiple adverse events".

The main interface is titled "Adverse events" and shows "View adverse events by" with options for "Targets" (selected) and "Drugs". Below this, there is a search bar with "aspargate amino" and a callout bubble pointing to it with the text "Targetsを選択".

There are two radio button options: "Show targets related to any selected adverse events" (selected) and "Show targets related to all selected adverse events". A callout bubble points to the "any" option with the text "選択入力した'個々のAE'に関連するターゲット、を選択".

Below these options is a list of "Selected adverse events":

- Alanine aminotransferase increased
- Aspartate aminotransferase increased
- Transaminases increased
- Hepatotoxicity
- Drug-induced liver injury

A callout bubble points to this list with the text "選択入力したAEを確認".

At the bottom, there is a "Build table" button and a callout bubble pointing to it with the text "Build tableをクリック".

On the right side, there is a "Select Adverse Event" dialog box. It shows a search for "alanine amino" and a list of results:

- [SOC] - Investigations
- [HLGT] - Hepatobiliary investigations
- [HLT] - Hepatobiliary function diagnostic procedures
 - [PT] - Alanine aminotransferase
 - [PT] - Alanine aminotransferase abnormal
 - [PT] - Alanine aminotransferase decreased
 - [PT] - Alanine aminotransferase increased
 - [PT] - Alanine aminotransferase normal

A callout bubble points to the dialog box with the text "AEはSOC,SMQごとの検索入力が可能".

特定の有害事象について原因となる作用機序を網羅的に評価 有害事象の複数選択検索機能

Comparative table builder

Edit table Filter Heat map Number of alerts

縦軸はターゲット (MOA)

横軸は選択入力したAE

| | Drug-induced liver injury | Hepatotoxicity | Transaminases increased | Aspartate aminotransferase increased | Alanine aminotransferase increased |
|---|---------------------------|----------------|-------------------------|--------------------------------------|------------------------------------|
| BSEP • Inhibitors | 26 | 19 | | 3 | 9 |
| COX-2 • Inhibitors | 138 | 168 | 24 | 103 | 121 |
| COX-1 • Inhibitors | 125 | 156 | 21 | 82 | 96 |
| Bacterial penicillin-binding protein • Inhibitors | 88 | 34 | 40 | 129 | 141 |
| HMG-CoA reductase • Inhibitors | 65 | 29 | 48 | 52 | 67 |
| PD-1 • Inhibitors | 50 | 95 | 139 | 610 | 610 |
| TNF-alpha • Inhibitors | 50 | 15 | 19 | 65 | 85 |
| Androgen receptor • Modulators | 47 | 32 | 23 | 71 | 76 |
| DNA gyrase • Inhibitors | 46 | 40 | 16 | 82 | 97 |
| DNA topoisomerase 4 • Inhibitors | 46 | 38 | 17 | 82 | 94 |
| 50S ribosomal protein • Inhibitors | 38 | 35 | 21 | 66 | 78 |
| Reverse transcriptase • Inhibitors | 28 | 75 | 21 | 76 | 116 |
| 2,058 | 4,448 | 6,801 | 5,845 | 20,997 | 23,356 |



サポートのご案内

ユーザーサポートのご案内



カスタマーケア

☎ 0800-919-1307(フリーダイヤル)
(土日祝日を除く) 9:30~17:30

✉ lsh.support.jp@clarivate.com

使い方やアクセス、データベースの収録内容に関するご質問はこちらまで。

専門スタッフが対応。使い方、アクセスなどにお困りの際は、気軽に日本語でお問い合わせが可能。



ライフサイエンス&ヘルスケア 製品サポートサイト・Cortellisを初めてお使いになる皆様へ

OFF-X

前臨床からRWDまで網羅する安全性情報

基本編



利用事例

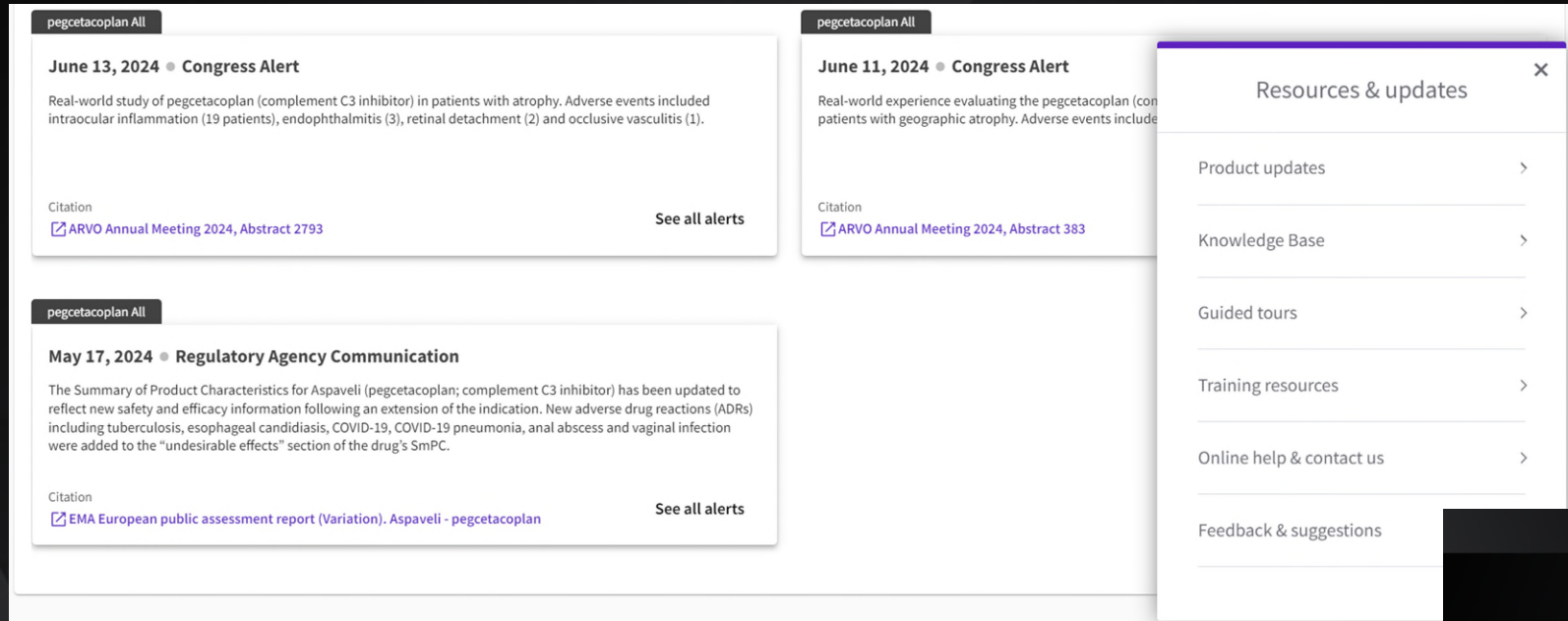


日本語製品サポートサイトへは以下のリンクからアクセスください。

<https://clarivate.com/life-sciences-healthcare/ja/training-support/cortellis/off-x/>

ユーザーサポートのご案内

ナレッジベースでは、各種操作説明資料、ウェブセミナーの録画、コンテンツ情報の詳細解説記事等にアクセス頂けます。



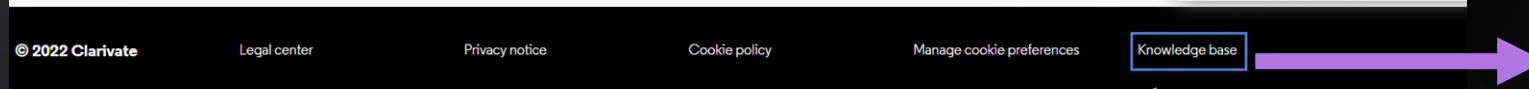
The screenshot shows a user support page for pegcetacoplan. It features two main sections for congress alerts:

- June 13, 2024 • Congress Alert**: Real-world study of pegcetacoplan (complement C3 inhibitor) in patients with atrophy. Adverse events included intraocular inflammation (19 patients), endophthalmitis (3), retinal detachment (2) and occlusive vasculitis (1). Citation: [ARVO Annual Meeting 2024, Abstract 2793](#). [See all alerts](#)
- June 11, 2024 • Congress Alert**: Real-world experience evaluating the pegcetacoplan (complement C3 inhibitor) in patients with geographic atrophy. Adverse events included... Citation: [ARVO Annual Meeting 2024, Abstract 383](#). [See all alerts](#)

Below these is a **Regulatory Agency Communication** from May 17, 2024, regarding updates to the Summary of Product Characteristics for Aspaveli. Citation: [EMA European public assessment report \(Variation\). Aspaveli - pegcetacoplan](#). [See all alerts](#)

A 'Resources & updates' sidebar menu is open, listing:

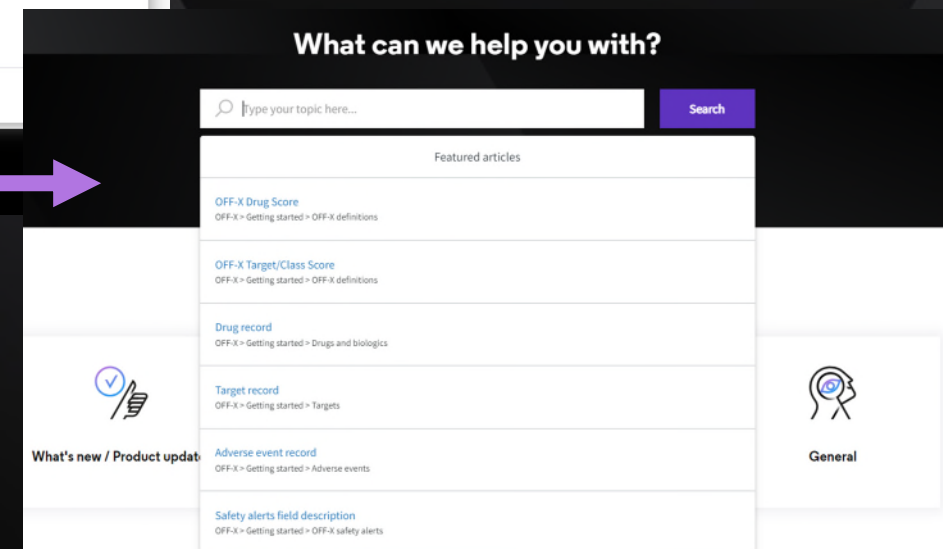
- Product updates
- Knowledge Base
- Guided tours
- Training resources
- Online help & contact us
- Feedback & suggestions



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A purple arrow points from the 'Knowledge base' link in the footer to the right-hand screenshot.

画面最下部までスクロールダウンし、Knowledge Baseをクリックすることでもアクセス頂けます。



The screenshot shows the search interface with the heading "What can we help you with?". It includes a search bar with the placeholder "Type your topic here..." and a "Search" button. Below the search bar are several featured articles:

- OFF-X Drug Score
- OFF-X Target/Class Score
- Drug record
- Target record
- Adverse event record
- Safety alerts field description

On the left side, there is a "What's new / Product updates" section with a checkmark icon. On the right side, there is a "General" section with a person icon.



Think forward

About Clarivate

Clarivate is a leading global provider of transformative intelligence. We offer enriched data, insights & analytics, workflow solutions and expert services in the areas of Academia & Government, Intellectual Property and Life Sciences & Healthcare. For more information, please visit clarivate.com.

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