



Solution Sheet

Drug Label Claim Development Accelerator

For pharmaceutical companies, drug labeling is a highly regulated and complex process. Drug labels need to provide accurate information around the safe usage of a drug without any promotional, misleading, or unsubstantiated claims.

However, the drug label content development process is often manual, disjointed, and inconsistent. The label content development teams struggle with disparate, distributed data sources with largely unstructured content. This can cause inaccuracies in label claims leading to a barrage of consequences such as delays in pending drug approvals, potential withdrawal of existing drugs from the market, higher scrutiny from regulators, and lower drug adoption with consequent cost escalations.

High amounts of disparate, unstructured data.

Lack of easy access to regulatory guidelines and labeling best practices.

Inability to integrate knowledge access into label development workflows.

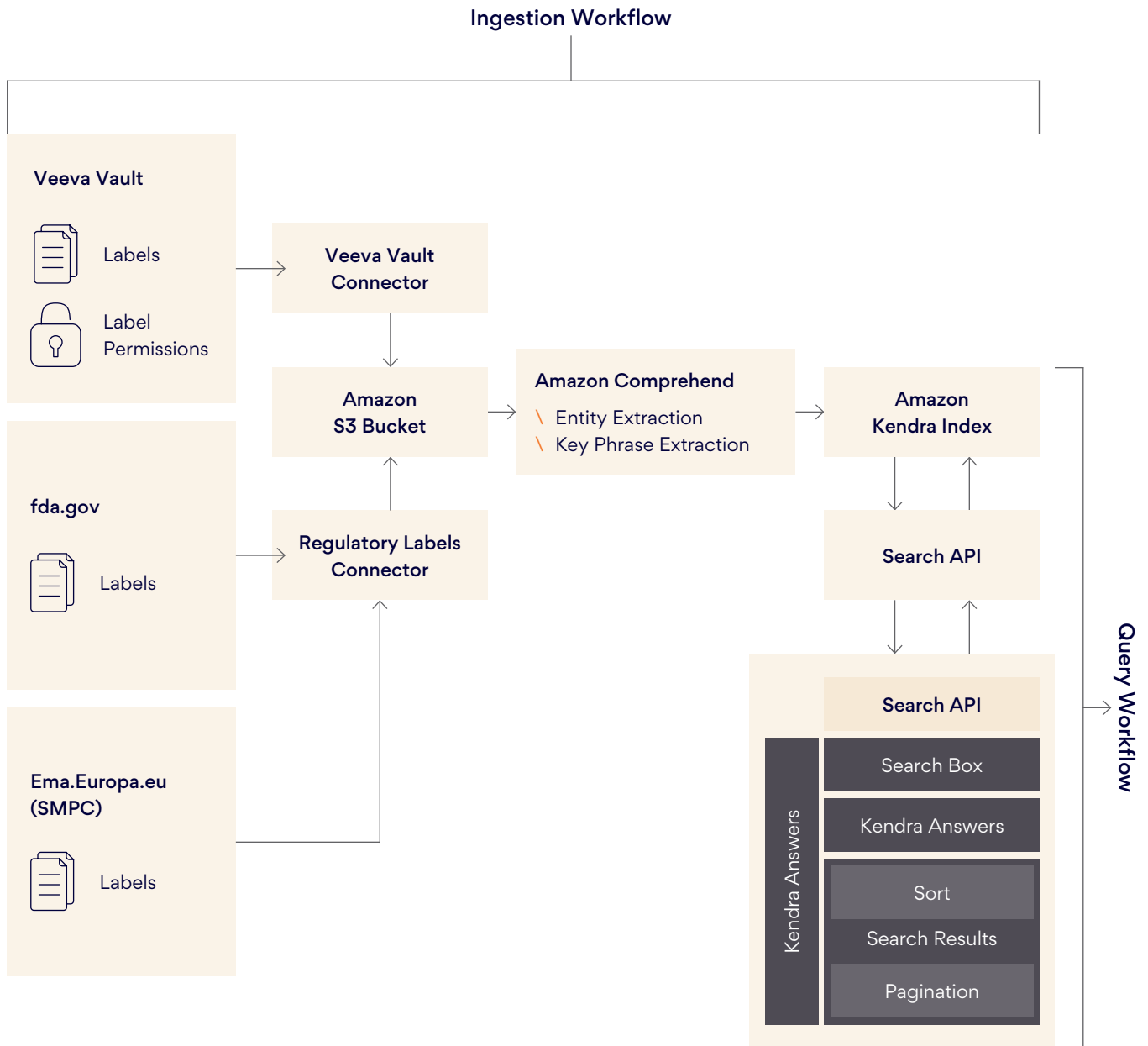
Persistent's Drug Label Claim Development Accelerator

Powered by machine learning and AWS Kendra's natural language-based intelligent search along with AWS Comprehend's text analytics capabilities, Persistent's drug label claim development accelerator helps you fast track the creation of claim labels and improve compliance by finding relevant and precise information from highly technical drug label documents and regulatory guidelines. It helps you ensure consistency and accuracy of drug safety and usage claims and thus enhances drug adoption.

With this solution in place, you can simplify claim development using:

- \ Natural language interpretation based on keyword and phrase queries
- \ Intuitive output delivering actionable insights such as answers, FAQs, relevant snippets
- \ Accuracy of results based on built-in optimization for pharmaceutical and healthcare industries
- \ Search across internal data sources such as Veeva Vault and external data sources such as the United States FDA website
- \ Filtering of results based on system and derived metadata
- \ Ability to view current results with notifications for labeling updates
- \ Guidance for query and navigation such as custom synonyms, spell-check, auto query completion, etc.

How It Works



Persistent's Drug Label Claim Development Accelerator in Action

Looking up storage conditions and type of products

Search Query: Drug refrigeration requirement for paediatric

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1-10 of 921 results

Amazon Kendra suggested answers

Ruzurgi

The suspension can be stored under **refrigeration** for up to 24 hours. Discard any unused portion of the suspension after 24 hours. 2.3 Patients with Renal Impairment The recommended starting dosage of RUZURGI in **pediatric** patients weighing 45 kg or more with renal impairment (creatinine clearance 15 to 90 mL/min) is 15 mg daily taken orally in divided doses. The recommended starting dosage for **pediatric** patients weighing less than 45 kg with renal impairment is 7.5 mg daily taken orally in divided doses [see Dosage and Administration (2.1) and Use in Specific Populations (8.6)]. No dosage recommendations for RUZURGI can be made for patients with end-stage renal disease.

https://www.accessdata.fda.gov/drugsatfda_docs/.../209321s000lbl.pdf

👍 🗨

What are Amazon Kendra suggested answers? [Info](#)

Sort: ⌵

Ruzurgi

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https://www.accessdata.fda.gov/drugsatfda_docs/.../209321s000lbl.pdf

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Ultomiris


...under **refrigeration** at 2°C - 8°C (36°F - 46°F) must not exceed 24 hours taking into account the expected infusion time. Once removed from **refrigeration**, administer the diluted ULTOMIRIS infusion solution within 6 hours...

https://www.accessdata.fda.gov/drugsatfda_docs/.../761108s001lbl.pdf

👍 🗨

Understanding drug dosage and administration

Search Query: How is Dupixent administered for Chronic Rhinosinusitis?





1-10 of 873 results


Amazon Kendra suggested answers

[dupixent label](#)

1.3 **Chronic Rhinosinusitis** with Nasal Polyposis **DUPIXENT** is indicated as an add-on maintenance treatment in adult patients with inadequately controlled **chronic rhinosinusitis** with nasal polyposis (CRSwNP). 2 **DOSAGE AND ADMINISTRATION DUPIXENT is administered by subcutaneous injection, either by pre-filled syringe or pre-filled pen.** The **DUPIXENT** pre-filled pen is only for use in adults and adolescents aged 12 years and older. 2.1 Atopic Dermatitis Dosing in Adults The recommended dose of **DUPIXENT** for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W).



https://s3.us-west-2.amazonaws.com/sanofi-drugs/dupixent_label.pdf  

What are Amazon Kendra suggested answers? [Info](#)

Sort: Relevance ▼ 



[dupixent label](#)

...asthmaticus. 1.3 **Chronic Rhinosinusitis** with Nasal Polyposis **DUPIXENT** is indicated as an add-on maintenance treatment in adult patients with inadequately controlled **chronic rhinosinusitis** with nasal polyposis (CRSwNP). 2 **DOSAGE AND ADMINISTRATION DUPIXENT is administered** by subcutaneous...

https://s3.us-west-2.amazonaws.com/sanofi-drugs/dupixent_label.pdf  

[Daypro Alta](#)

...of Asthma Related to Aspirin Sensitivity A subpopulation of patients with asthma may have aspirin-sensitive asthma which may include **chronic rhinosinusitis** complicated by nasal polyps; severe, potentially fatal bronchospasm; and/or intolerance to aspirin and other NSAIDs. Because cross...

https://www.accessdata.fda.gov/drugsatfda_docs/.../020776s008lbl.pdf  

Conducting a comparative label analysis

1\ Select labels to compare

The screenshot shows a search interface for drug labels. At the top right, there is a red button labeled 'Compare Now'. Below it, a search bar contains the text 'Tysabri'. The search results are displayed in a list format. The first result is 'Campath', with a snippet: '...LEMTRADA is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use...'. The second result is 'Zinbryta', with a snippet: '...age, or weight for patients with relapsing forms of multiple sclerosis. Drug Interaction Studies ZINBRYTA 150 mg administered subcutaneously every 4 weeks for 12 weeks in patients with multiple sclerosis did not significantly affect the systemic exposure of concomitantly...'. There are 'Add to compare' buttons next to each result. At the bottom right, there is a 'Sort: Relevance' dropdown menu.

2\ Choose to compare

The screenshot shows a side-by-side comparison of drug labels. The top section is titled 'LABEL COMPARISON' and has two columns: 'LABEL - Campath' and 'LABEL - Zinbryta'. Below this, the detailed text of the labels is displayed. The 'Campath' label includes sections such as 'INDICATIONS AND USAGE', 'CONTRAINDICATIONS', 'ADVERSE REACTIONS', and 'DRUG INTERACTIONS'. The 'Zinbryta' label also includes similar sections. The comparison tool highlights differences between the two labels. At the bottom right, there is a 'Print' button.

3\ Side by side comparison

Improve compliance and de-risk your drug labeling processes today.

Request Demo

About Persistent

With 12,000+ employees around the world, Persistent Systems (BSE & NSE: PERSISTENT) is a global solutions leader delivering digital business acceleration, enterprise modernization, and next-generation product engineering across industries and geographies. With deep expertise in legacy and modern IAM platforms and a robust partner ecosystem, Persistent delivers Identity, Access & Privacy solutions that enhance and secure the digital experience.

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