HALOPV

Literature search with world class automations and an intuitive user interface

Literature
MODULE EXPLAINER

HaloPV

the world's first fully comprehensive and cohesive solution.

Qinecsa

TABLE OF CONTENTS

Why use this module?

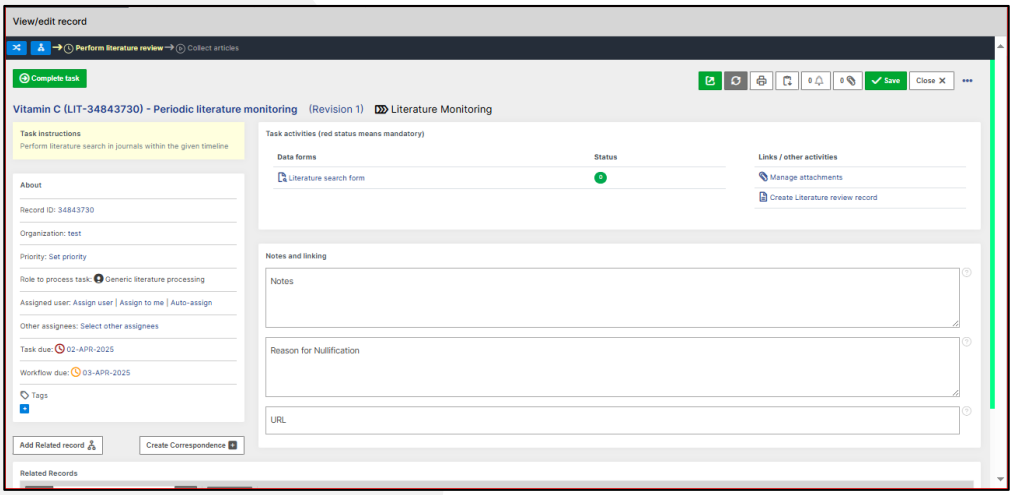
Pharmacovigilance literature searches are crutcial for ensuring the safety of medicinal products and medical devices. Marketing Authorisation Holders (MAHs) and manufacturers are legally required to conduct systematic searches of scientific literature to identify Individual Case Safety Reports (ICSRs) and other safety-related information. Similarly, manufacturers of medical devices must perform literature searches as part of Post-Market Clinical Follow-up (PMCF) to ensure ongoing product safety.

Building a robust search strategy is essential for retrieving relevant articles needed for regulatory periodic reports such as Development Safety Update Reports (DSURs) and Periodic Safety Update Reports (PSURs). However, the vast volume of available literature makes it challenging to efficiently review and identify the most relevant articles. Crafting precise search strings that meet regulatory requirements further complicates the process.

Many pharmacovigilance teams face constraints in terms of budget and staffing, which can impact the efficiency and effectiveness of literature searches. Additionally, detecting duplicate case reports and ensuring that adverse events are not entered twice into the safety database present significant challenges. Given the overwhelming amount of literature data, identifying new safety signals remains a persistent concern.

To address these challenges, HALOPV offers pre-configured Literature Module, designed to streamline literature searches, enhance accuracy, and reduce manual workload. This module provides an affordable, efficient solution that:

- Automates literature search and review processes.
- Helps eliminate duplicate entries to maintain data integrity.
- Ensures compliance with regulatory requirements for literature monitoring.



Example screen from the Literature Monitoring.

Literature search form including validation messages if relevant information was missing..

Literature
Feature highlights

- Configure search criteria for literature monitoring with a rich set of parameters including product names, active ingredients, study names - ensuring precise targeting of relevant articles for both ICSR and device incident identification
- Supports automated and manual literature monitoring from sources, including PubMed, Embase.
- Flexible ingestion options for literature articles. Upload directly or enable automated intake through integrated vendor connections.
- Built-in intelligent article screening interface supports efficient triaging and classification of literature abstracts. Use customizable keywords and watchlists to improve relevance detection.
- AI-assisted content extraction and smart highlighting of key sections help accelerate article review
- Integrated deduplication engine prevents repeated review of identical or previously screened articles
- When a valid ICSR is identified, create a new case directly from within the Literature module to Case Intake and Processing Module. Auto-population of case fields from article content is supported, along with linkage to the source PDF.
- Tag articles that are relevant for signaling activities or for periodic reports for easier filtering.
- Side-by-side view supports user to review article and make comments in the case record at the same time.
- Fully compliant with regulatory requirements for pharmacovigilance literature monitoring, including GxP, audit trail, CFR21 part 11 and EU Annex 11 compliance

Awarded innovation for our community

The HALOPV Aggregate Reporting module is powerful and configurable and is a core ingredient for success for significant regulatory agencies such as the MHRA as well as a number of pharma's, as it allows them to generate outputs that are needed to maintain control and understanding the safety of products

100%

The HALOPV Aggregate Reporting module enjoys 100% customer retention, as a proof to it's capabilities and performance to the community of PV professionals in the industry.

Pre-configured workflows

The HaloPV Literature module comes with a complete package of pre-configured workflows that allow for standardized and effective handling of literature articles. If required, the new workflows can be configured to your specific processes.

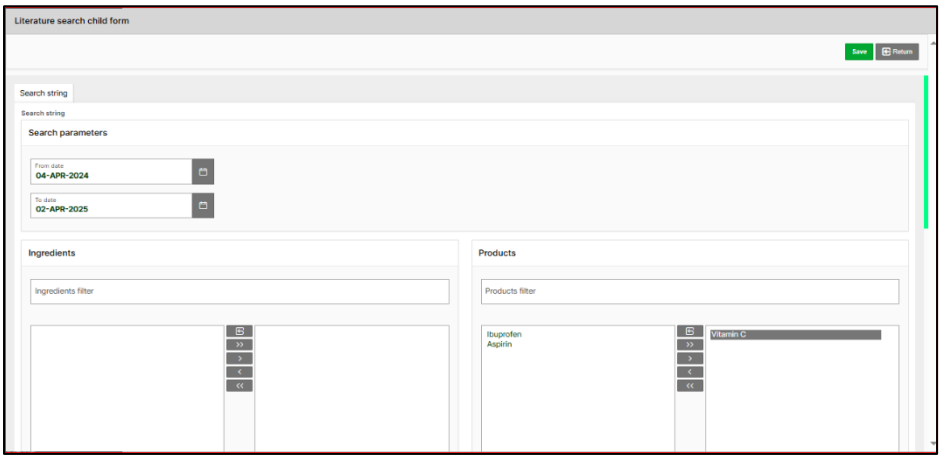
Literature Monitoring

Designed for automated or semi-automated retrieval of literature data from sources like PubMed and Embase, this workflow enables users to define search criteria based on date range, products, ingredients, and studies. Seamlessly integrating with other literature database systems, it ensures accurate, compliant, and streamlined literature monitoring.

Use only one system for creating search stings and retrieving articles from integrated literature databases. All in one place.

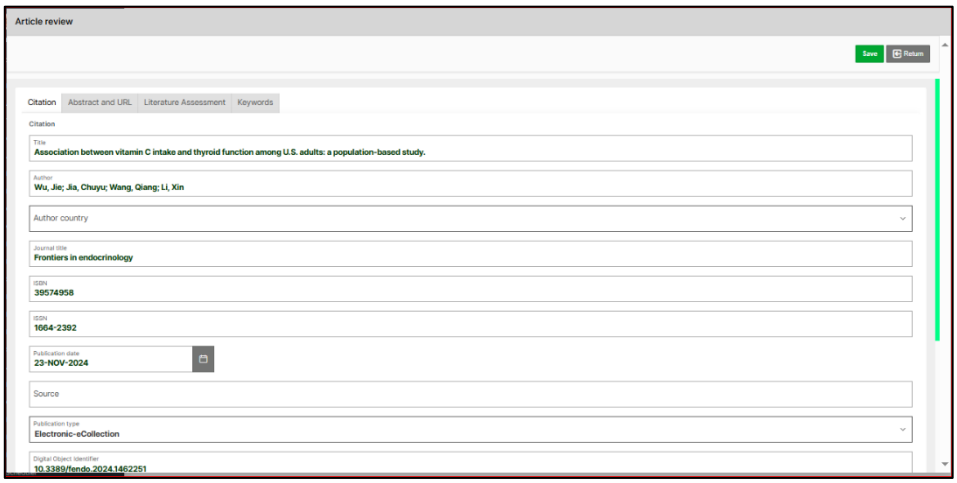
Literature Article Review

Configured to extract articles from sources like PubMed (customizable per client needs), this workflow automates abstract review by extracting key information, populates data forms, annotates documents, and performs automated follow-up detection and duplicate searches. Users can manually assess articles for relevance to ICSRs, PSURs, or signal detection, ensuring accuracy and compliance in literature monitoring. It applies AI-driven and rule-based automation for efficient screening, duplicate detection, and validation.



Example screen from the module for Literature search form.

Example screen from the module for literature article review.



What can be configured in the module?

HaloPV, including the Literature module, is extremely configurable. Despite the fact that it comes with pre-configured workflows, it is possible to enhance and tailor the application to support customers unique needs. Qinecsa or one of our implementation partners are ready to help to make the most out of HaloPV capacilites.

Configurations include:

- Workflow name and order, worklist design, setup record types etc.
- Workflow tasks, task order, including assignment to roles, form actions as well as functionality links.
- Workflow rules for conditional routing of report records.
- Validation rules for each field in the forms.
- Literature search and review forms are configurable
- All dropdown (list) values in forms
- Entity (organizational) ownership to report record for segregation of records.
- Users and user details, such as email and experience level and assigned roles.
- Unblinding rights, workflow manager rights and management rights.
- Keyword for tagging to case records and scripted auto-tagging based on case information.
- Duplicate search composition and keyword weights.
- Task timelines, KPIs and notifications of tasks upon task initiation or days to completion

Nothing else on the PV tech market is this configurable.

Configuration, not customization

We are big on configurability. Not customization. In fact, if you ask our team to help you configure HALOPV, you will also get advise as to how you will optimize the use of the platform, without breaking the boundaries of what we in our consulting capacity would consider industry standard.

Frequent validated releases of the platform

In order to meet the needs of customers, we have developed a release and validation methodology that includes a bin-annual version with new innovation, optimizations, bugfixes etc. As a subscribing customer, you can get new versions along with a comprehensive validation package to document it.

API driven

Do you have data or systems to integrate or migrate from? You would not be the first. Therefore, we have created a large number of standard APIs that are modern REST based tools that we can make good use of together with your IT colleagues.

Additional resources

We hope you like what you see. Should you have questions, feel free to write to us at Qinecsa. You can also explore the following additional resources

User manuals and other user guides:

Guides & Manuals | HALOPV

General introduction to HALOPV:

About | HALOPV

An overview of all available modules of HaloPV

Modules | HALOPV

Contact Qinecsa:

Contact

Or write to

contact@qinecsa.com

About Qinecsa

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Game-changing drug safety technology and consulting

Qinecsa are supporting our clients with high-quality consulting and domain expertise from our global footprint

Qinecsa can provide a fully integrated solution that aligns with the goals of many customers that can be implemented in a phased approach and supported by a global knowledgeable team. Our core values are aligned to the industry and forward-looking trends such as AI/automation and being committed to a sustainable future.

Read more about us on [Qinecsa - Drug Safety Solutions & Pharmacovigilance Services]

Values

Our fabric is woven on industry standards. We are GDPR, ISO 9001, 14001 and 27001 certified. We are passionate about a sustainable environment and reducing climate change, in line with many customer's sustainability goals.

Modular Approach

HaloPV can cover all the customer's desired scope & more (PSMF, PVAs, etc.)

Modular in nature by design, HaloPV eliminates the need for the "big bang" approach enabling core business processes to be replaced in a phased approach

Knowledgeable Team

Knowledgeable team with extensive experience of transformational programs who understand what it takes to succeed, many of whom have had industry roles in the past

Vision for the future

We believe in applying modern technology in a cost-effective way to aid our customers. We partner with customers to establish and realize a long term vision for PV and beyond, not just for singular engagements but across industry and the regulatory landscape