HALOPV

Signal detection and management based on ICSRs and Device incidents with an intuitive user interface

Signals
MODULE EXPLAINER

HALOPV

the world's first fully comprehensive and cohesive solution.

insife

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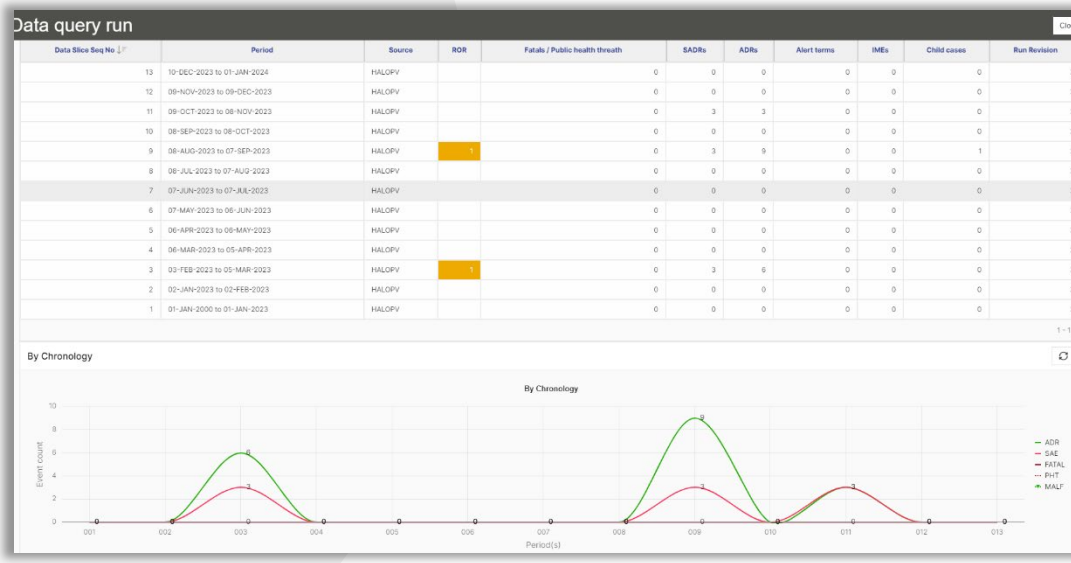
Why use this module?

Quantative signal detection software has been on the market for decades. In the ideal scenario, data analysis, especially using various statistical methods, allow for exposing proportionalites and dispropotionalities that can confirm or enlighten what we know about the safety profile of a product, in clinical as well as realworld settings. Unfortunately, signal detection is often slow to establish and operate and can cause a lot of additional work with little enlightenment in the end.

For signal management, most organizations tend to use semi-compliant tracking tools, often in Excel, as there haven't been software options that can provide the combined power of logging dates and decisions together with a potential large volume of document and linked evidences that support the decision-making.

At Insife, we set out to solve these needs in a flexible and powerful way, using our standardized approach to workflows and using workflows, automators, interactive reports, dashboards and templates wherever meaningful. The Signals HALOPV module is a multi-sourced signal detection tool with flexible scheduling capabilities, as well as an analytics tools that displays data over time "slices". The slice approach is unique and offers a responsive user interface that do more than provide static statistics, you can actually analyze and explore the data, through filters and visualization. It is also a very capable signal management tool, that provides best-in-class tracking, decision documentation and document storage – all in one place.

HALOPV
Signals



Example screen from the module. Data is collated into periods, also called "slices", from where all the proportionalies are calculated for each drug-event / device-event combination and shown over time in a chronological graph.

Signals
Feature highlights

- Configure query search criteria for a signal data run, including a rich set of parameters across ICSR and Device incident data, including periodicity, products / product groupings / active ingredients, studies, event MedDRA collections, seriousness, causality, patient attributes etc. Also includes the possibility to select sources and their role in the data run (detection) process.
- Visualize data as counts and frequency statistics and furthermore as trends over a number of periods
- Further work with data filters on the fly and include / exclude data columns and add graphs to visualize the output in interactive reports
- Save filters as private or public filtersets for easy post-processing of queries. Export to a variety of formats including Excel, CSV and PDF
- Configure thresholds for drug/device event pair frequencies in order to automate creation of signal alerts. Or create a signal alert manually
- Analyse signal alert records, add commentaries and supporting attachments and determine whether they should be closed or lifted into a Signal record
- Utilize Word-based template for creating signal assessment reports or other configure other templates for reporting
- Use workflows to manage work activities
- Manage Signal records throughout assessment, validation, prioritization and confirmation steps and track all activities and decision dates etc.
- Possibility to refute / non-validate signals for archival of record. Can be restored and brought back into the signal management process if further data prevails later
- Includes the possibility to have multiple teams. e.g. Therapeutic Area groups to have their own data runs and signals to manage.
- Store document outputs, further edit documents in the module. Perform electronic signature for an end-to-end process. The module also seamlessly integrates with the HALOPV Submissions module for managing outbound distribution of aggregate reports to Authories, partners. Etc. As an example, the tool can create periodic SUSAR line listings and distribute to Investigators and even track receipt.
- Plus of course all the usuals around GxP, audit trail, CFR21 part 11 and EU Annex 11 compliance

Awarded innovation for our community

The HALOPV Sginals 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 pharmas, as it allows them to generate outputs that are needed to maintain control and understanding the safety of products

100%

The HALOPV Signals 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 Signals module comes with a complete package of pre-configured workflows that allow for standardized and effective handling of requirements and rules. The workflows typically are arranged with a review step, to ensure second set of eyes. If required, the new workflows can be configured to your specific processes.

Signal data runs

The workflow is based on analysis on quantative data, configuring how Signals of Disproportionate Reporting (SDR) is to be filtered and calculated. The workflow is partly a manual configuration and partly automated, where the system calculates listings and frequencies.

Signal management

Signal management is the workflow process thata allow for GVP Module XI compliance, through best-practice task steps: Validation/prioritization, Assessment, Confirmation and Closure. The workflow is intended to capture decisions and log various supporting data points.

Signal alerts

Signal Alerts is a workflow that is invoked either via a DEC exceeding a configured threshold or manually created from the frequency overview in the data run. Once an alert is created, it must be completed/closed or move to a Signal record, in the Signal management workflow.

Refuted/non-validated signals

Signals in the Signal Management workflow will either be passing through assessments and be confirmed, or in the process be rejected into a refuted / non-validated signal. These rejected records will be placed in the Refuted / non-validation signals workflow, where they are considered archived. The records can be moved back into a active Signal Management workflow again, if new data emerges.

Example screen from the module. The analytics dashboard allows for graphic representation of the queried data in a period, or across multiple periods. The dashboard dynamically updates when additional filters are applied to the interactive report view, allowing to fast exploration of the data

What can be configured in the module?

HALOPV, including the Signals module, is extremely configurable. Despite the fact that you get a functional starting point with the pre-configured workflows, it is possible to enhance and tailor the application to support your organization in the optimal way. Insife or one of our implementation partners are ready to help you make the most out of the possibilities.

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.
- All dropdown (list) values in forms as well as defining data run and signal types
- Entity (organizational) ownership for segration of signal records, e.g. into different Therapeutic groups
- Templates for reporting, using Word documents with placeholders that can be easily updated with client specific look-and-feel
- Thresholds for alerts, query design including periodicity and sources incl. their role in the data run
- Users and user details, such as email and experience level and assigned roles
- Actions to be performed for each task in the workflow e.g. control which listing formats are available, e.g. data run review, product-event line listing, case listing, analytic dashboard, electronic signature
- Scheduling of activities, periodicity of tasks on specific timeframes
- 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 Insife. You can also explore the following additional resources

Signals module user manual and other user guides and manuals:

HALOPV guides and training (insife.com)

HALOPV including Signals module standard pricing and licensing:

HALOPV pricing and licence (insife.com)

General introduction to HALOPV:

HALOPV - A Safety Database and much more. The most comprehensive drug safety system available (insife.com)

An overview of all available modules of HALOPV

HALOPV Modules overview - the most comprehensive drug safety system available (insife.com)

Contact Insife:

Contact | insife the pharmacovigilance (drug safety) experts

Or write to

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About insife

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Game-changing drug safety technology and consulting

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

Insife 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.

Insife was founded in Denmark in 2017, but is today a global business. We strive to work with you as locally as we can.

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 (see https://www.insife.com/sustainability)

Modular Approach

HALOPV can cover all of 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