HALOPV

Intake and process ICSRs (Individual Case Safety Reports) with world class automations and an intuitive user interface

ICSRs

MODULE EXPLAINER

HALOPV

the world's first fully comprehensive and cohesive solution.

insife

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Why use this module?

Adverse events and other relevant safety information can come from a multitude of sources, across clinical research, marketing programs, literature, spontaneous reporting. Common for all sources is the presence of source data that needs to be processed and evaluated.

In reality, many companies, as they grow, end up with several tools and (sometimes quite manual) systems to make up a compliant setup, e.g. collecting emails, forms, pdf's, data files such as E2b/xml etc. The data potentially arrives from call centers, partners, affiliates, CROs, distributors, healthcare professionals or even directly from patients. It is complicated and time consuming to encompass all scenarios and for some companies there are significant volumes of transactions, leading to scalability issues too. It is most commonly a central unit at HQ, or an outsourcing partner, that does the actual case processing / medical evaluation in a safety database.

Further to the complications, there are requirements to pursue follow-up information from the source reporter and document the attempts made. Data and processing responsibilities are essentially dispersed across the whole chain, which then leads to additional work reconciling if all data actually ended up in the final reports that were submitted to Authorities and partners. These data also make up the basis for signal detection and risk management.

Knowing the importance of being able to deliver a cost effective yet compliant approach to intaking/capturing ICSRs with quality and managing follow-ups, we have invested in making a PV tool that improves the processing of adverse event data, enhances collaboration between local and global stakeholders and uses advanced forms of automation. It is called HALOPV ICSRs module.

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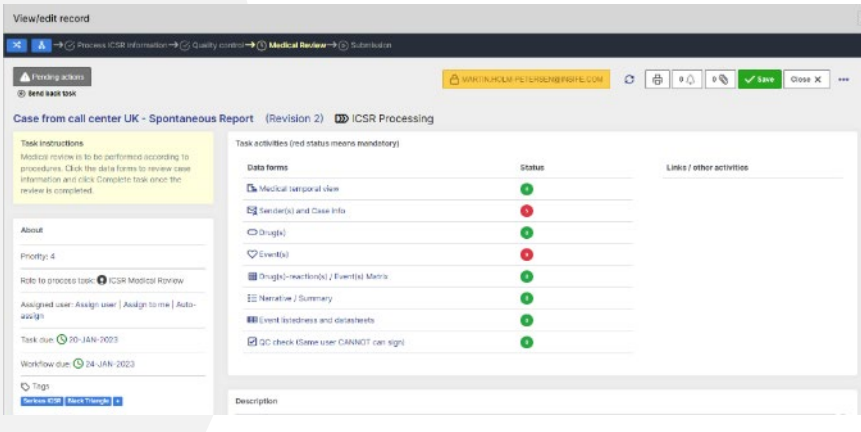


Example screen from the module. The screens are designed for optimal overview of the case as it is processed, across a workflow, including highlighting where mandatory data are required.

ICSRs
Feature highlights

- Intake ICSR information from many sources, e.g. in structured forms or unstructured text from affiliates, partners/contractors – or even directly from consumers. Upload documents or allow the tool to receive emails for automatic intake of new case information. The built-in automations handle a lot of complex tasks, making it easier to intake adverse event information.
- Works for clinical, post-marketed and solicited sources.
- As a Safety Database, perform case full processing in HALOPV including all relevant fields for global compliance across EMA GVP Module VI / FDA / Health Canada / MHRA / NMPA / MFDS requirements, including advanced auto-coding & assessments.
- Use AI translation for e.g. narrative transformation to and from local language.
- Create and action follow-ups from the module, allows for sending out follow-up queries through email and automatically attempting multiple times to obtain follow-up from the reporter.
- Field validations expose if mandatory information is missing or not acceptable as per rules.
- Plus of course all the usuals around GxP, audit trail, CFR21 part 11 and EU Annex 11 compliance.
- Duplicate scoring / search feature makes it fast and easy to understand when new information is already in the system.
- Follow-up query generation via templates to help managing follow-up process with reporters.
- Follow-up ingestion screen for selective import of new information into the existing master case.
- Integrates to the Submissions module, to auto-generate a number of formats such as E2B(R3), E2B(R2) including Combination product reporting. This also allows for tracking the number of actual ICSR reports sent out based on requirements (auto-scheduling available if Requirements Intelligence module is enabled).
- Using our standard APIs, you can also integrate and transfer from your previous/existing Safety Database, .e.g. Argus Safety or ARISg.

100%

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

Awarded innovation for our community

The HALOPV ICSRs module is so feature rich and configurable that is has been selected by some of the most significant regulatory agencies such as the MHRA as well as big pharma, as it allows them to automate more than any other safety database on the market. It is also loved by smaller companies for its' easy and fast user interface.

Pre-configured workflows

The HALOPV ICSRs module comes with a complete package of pre-configured workflows that allow for standardized and effective handling of individual cases. If required, the new workflows can be configured to your specific processes.

ICSR Intake

Optimized for automated or semi-automated ingestion of ICSR data from email, forms, E2B files, gateway or manual entry. Takes the case through duplicate scoring/search, QC checks and triage. The intake can use a range of AI and rule based automation features to allow for less manual work, while retaining control as a user.

ICSR Processing

The primary workflow for processing cases in order to achieve quality data that complies with ICH guidelines. Allows for Medical review, QC and scheduling submissions for partners and authorities (can use Requirements Intelligence rules for auto-scheduling). Submissions requires the dedicated Submissions module.

ICSR Follow-up Queries

Raise follow-ups queries using this workflow, which allows for correspondance via email or creation of letters in PDF or Word format, through templates that make it easy to generate a list of queries to ask reporters for additional claifications or missing information.

ICSR Follow-ups

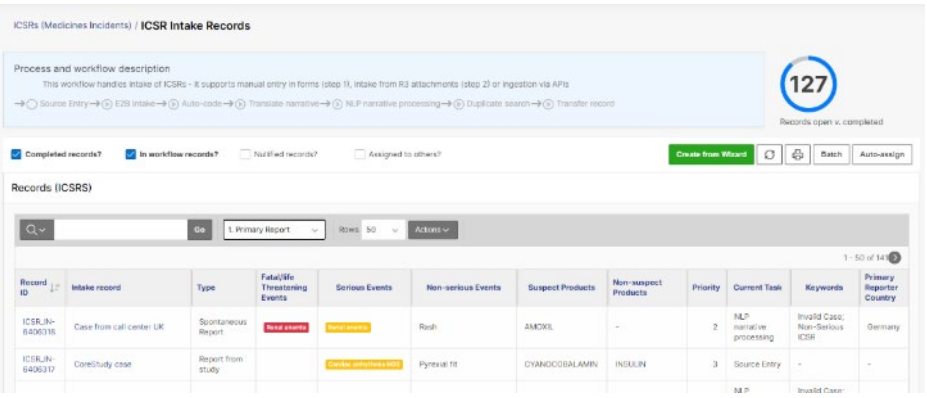
Received information generally comes into the Intake workflow, if it is determined to be a follow-up of an existing ICSR, it will go through this workflow for the linking and merging of information into the ICSR processing mastercase. Follow-up information is retained in this workflow, in case later analysis needs to be made of the flow of updates.

ICSR Duplicates

Once information is found to be a duplication, either through the automatic duplicate search or manually marked, the duplicate record will be placed in this workflow – and if relevant, be linked against the ICSR processing master case that it was found to be a duplicate of.

Refuted ICSRs

Data that come through the ICSR Intake workflow and are triaged to be not relevant for the other ICSR workflows will be transferred to this workflow, for archival or other further action.



Each workflow has an associated worklist, where the most important information to be able to identify, prioritize and take action, is available.

Worklists are highly configurable, also on the fly by the end-users

What can be configured in the module?

HALOPV, including the ICSRs 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 most 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 case records.
- Validation rules for each field in the forms.
- All dropdown (list) values in forms.
- Entity (organizational) ownership to case record for segration of case records.
- Users and user details, such as email and experience level and assigned roles.
- Unblinding rights, workflow manager rights and management rights.
- AI-thresholds for predictions to allow for confidence-based acceptance or rejection.
- Keyword for tagging to case records and scripted auto-tagging based on case information.
- Duplicate search composition and keyword weights.
- Templates for emails, letters and reports, based on MS-Word or HTML.
- Scheduling of activities, such as multiple email follow-up attempts.
- 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 advice 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 bi-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

ICSRs module user manual and other user guides and manuals:

HALOPV guides and training (insife.com)

HALOPV including ICSRs module standar 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

hello@insife.com

About insife

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.

Read more about us on insife.com

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 your 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