HALOPV

Data analytics, listings, tabulations and dashboards from ICSRs and Device incidents with an intuitive user interface

Aggregate reporting
MODULE EXPLAINER

HALOPV

the world's first fully comprehensive and cohesive solution.

insife

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Why use this module?

Aggregations of data into reports and dashboards is the scientific backbone of PV. Both important for the analysis of ICSR and device incident data to better understand the safety profile of products, it is as well a necessity for regulatory compliance. The are a number of pre-structured reports that are needed in order to develop and market medicinal products in most areas of the world, most of them recurring periodically.

Many safety systems are focused on getting data in, perhaps also sending out messages to authorities, but it is often much harder to get data out again. We often see organizations using several tools to analyse and report on these aggregations, store the outcome and also plan the deliverables and responsibilities. Often, PV science professionals are left with spreadsheet for generic document filestores for handling their work, which can be challenging for both productivity and compliance.

Insife set out to solve these needs in a flexible and powerful way, using our standardized approach to workflows and using interactive reports, dashboards and templates wherever meaningful. The Aggregate Reporting HALOPV module is both a planning and process management tools, as well as a analytics tools – and also includes templated reports for a high degree of control of the formatted output. Finally, it also allows for storing final outputs and adding electronic signatures, hence being a single application that truly assists PV science professionals.

HALOPV
Aggregate
Reporting

Example screen from the module. Using configurable templates, various forms of line listings and tubular formats can be generated.

Aggregate Reporting
Feature highlights

› Configure query search criteria for a report, including a rich set of parameters across ICSR and Device incident data, including period, products / product groupings / active ingredients, studies, event MedDRA collections, seriousness, causality, patient attributes etc.

› Extract results into various output formats including product-event listings, case listings and interactive dashboards with "flat" views of 80+ data elements from the cases.

› 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

› Utilize Word-based templates for accurately formatted outputs. Out of the box templates include DSUR SAE Line Listing, (blinded / unblinded), DSUR Summary Tabulation (period/cumulative), SAE Line listing, CIOMS II Line Listing, PADER including device malfunctions. More can be configured. Also, "snippets" of text, such as optional clauses can be included into selected reports, allowing for user control of merging together sections of pre-defined texts.

› Schedule activities, e.g. plan for reports into the future and see the upcoming report activities in a calendar view. Includes the possibility to have multiple teams. e.g. Therapeutic Area groups to have their own reports 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.

› Use workflows to manage work across tasks for the more complex reports such as the DSUR / PBRER

› 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 **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 pharmas, 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 Aggregate Reporting 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.

Ad hoc reports

Workflow for creating ad hoc reports, where there is no need for multiple tasks and planning of roles, reviews and signatures etc. Allows for quick query configuration and output generation
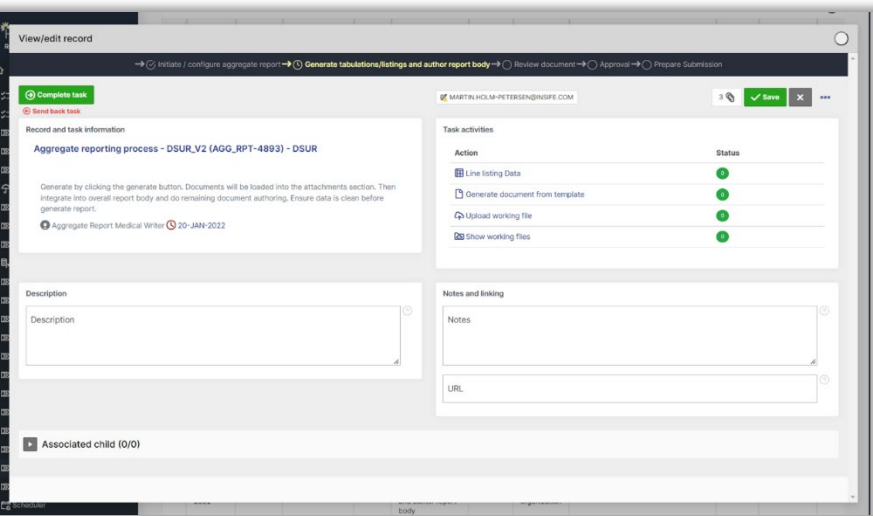
Periodic reports

Pre-defined task steps and timelines allow for a process to configure query filters, generate and author content, review, sign and optionally track submission to destination(s).

Collaborative reports

Pre-defined task steps and timelines allow for a process to configure query filters, generate and further get input and review from numerous stakeholders that can review the document, prior to approvals.
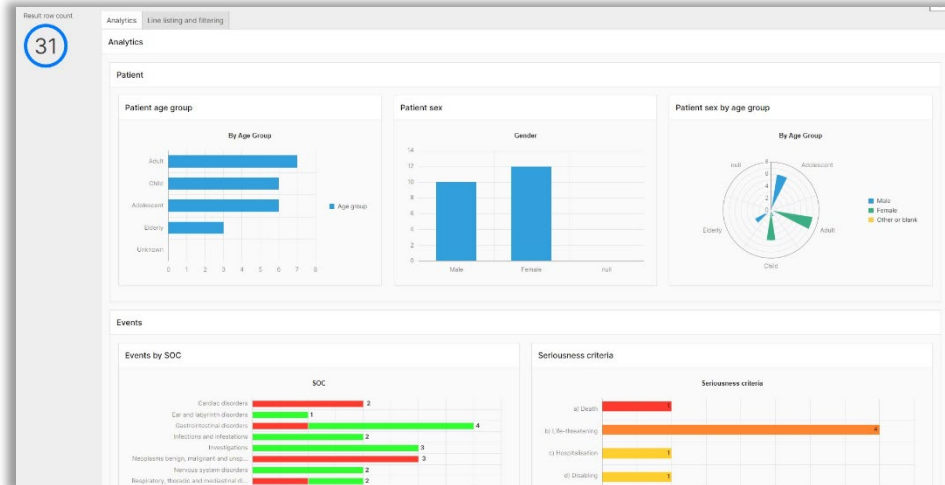
Collaborative report review

The Collborative reports contributor workflow that link to the Collarborate report in order to assign multiple users to individual contributions

Example screen from the module. Upon completing initial tasks in the workflow (shown in the top of screen), various activities for working with reporting becomes available. Generating document from template provides templates that are relevant / contextual to the workflow and the type of report, e.g. for a DSUR, the DSUR SAE line listings and tabulations are selectable

Example screen from the module. The analytics dashboard allows for graphic representation of the queried data. 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 Aggregate Reporting 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 report types

› Entity (organizational) ownership to report record for segration of report 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

› 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. product-event line listings, case listings, analytic dashboard, electronic signature

› Scheduling of activities, such as opening up for periodic 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

Aggregate Reporting module user manual and other user guides and manuals:

HALOPV guides and training (insife.com)

HALOPV including Aggregate Reporting 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

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.

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WINNER

PHARMA SUPPLIER OF THE YEAR

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