Complete package of pre-configured workflows and standardized templates.

Aggregate reporting

MODULE EXPLAINER

HaloPV

the world's first fully comprehensive and cohesive solution.

Qinecsa

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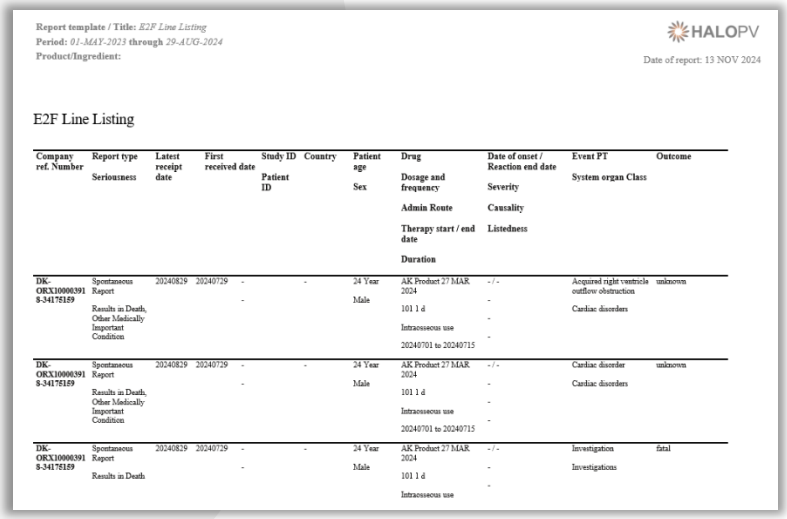
Why use this module?

Aggregation of data into reports and dashboards is the scientific backbone of PV. Important for the analysis of both ICSR and device incident data to better understand the safety profile of products, it is also a necessity for regulatory compliance. The are number of pre-defined reports that are needed to meet regulatory requirements when developing and marketing 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 aggregated data out again. We often see organizations using several tools to analyse and report on these aggregations, store the outcome and plan deliverables and responsibilities based on the resultant data. Often, PV science professionals are left with spreadsheets or generic document file stores for handling their work, which can be challenging for productivity and pose a risk to maintaining compliance.

Qinecsa 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 tool, as well as an analytics tool – and includes standard template reports for a high degree of control of the formatted output. Finally, it allows for storing the final outputs and adding electronic signatures, hence being a single solution that truly assists PV science professionals with their aggregate reporting needs.

HaloPV
Aggregate
Reporting



Report template / Title: *E2F Line Listing*
Period: *01-MAY-2023* **through** *29-AUG-2024*
Product/Ingredient:

HALOPV
Date of report: 13 NOV 2024

E2F Line Listing

Company ref. Number	Report type / Seriousness	Latest receipt date	First received date	Study ID / Patient ID	Country	Patient age / Sex	Drug / Dosage and frequency / Admin Route / Therapy start / end date / Duration	Date of onset / Reaction end date / Severity / Causality / Listedness	Event PT / System organ Class	Outcome
DK-ORX10000391 8-34175159	Spontaneous Report / Results in Death, Other Medically Important Condition	20240829	20240729	- / -	-	24 Year / Male	AK Product 27 MAR 2024 / 101 1 d / Intraosseous use / 20240701 to 20240715	- / - / - / - / -	Acquired right ventricle outflow obstruction / Cardiac disorders	unknown
DK-ORX10000391 8-34175159	Spontaneous Report / Results in Death, Other Medically Important Condition	20240829	20240729	- / -	-	24 Year / Male	AK Product 27 MAR 2024 / 101 1 d / Intraosseous use / 20240701 to 20240715	- / - / - / - / -	Cardiac disorder / Cardiac disorders	unknown
DK-ORX10000391 8-34175159	Spontaneous Report / Results in Death	20240829	20240729	- / -	-	24 Year / Male	AK Product 27 MAR 2024 / 101 1 d / Intraosseous use	- / - / - / - / -	Investigation / Investigations	fatal

Example screen from the E2F Line listing template.

Using configurable templates, various forms of line listings and tabular 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 with "flat" views of 100+ 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 sets 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. Provides the option to use out of the box standard templates (like DSUR, PBRER etc.) and/or configure any custom templates.
- 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, and further edit documents within the module. Perform electronic sign-off for an end-to-end process. The module also seamlessly integrates with the HaloPV Submissions module for managing outbound distribution of aggregate reports to Authorities, 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 usual compliance with GxP, audit trail, CFR21 part 11 and EU Annex 11.

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 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.

Expert Reporting (Ad-hoc)

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.

Other Collaborative reports

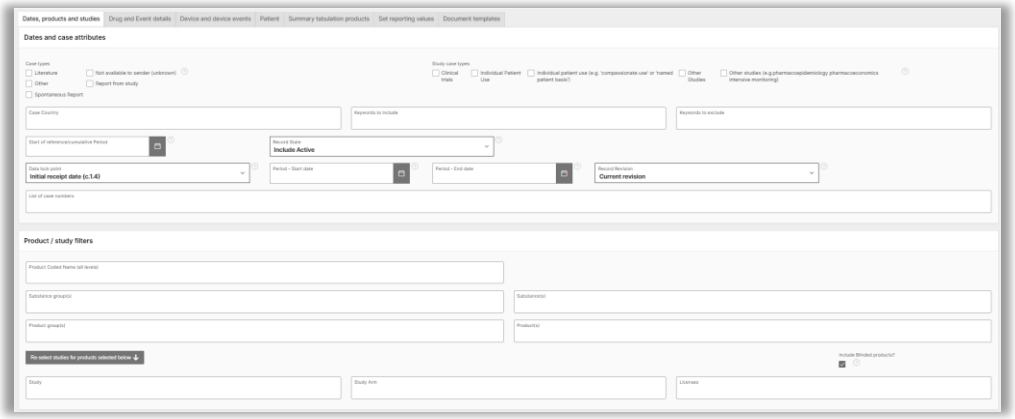
Pre-defined reports for other important assessments such as –

- Reconciliation Reports (for Clinical Trials or Partner Data)
- Compliance/Submissions Reporting
- Productivity/Worklist Management Reports

Periodic reports

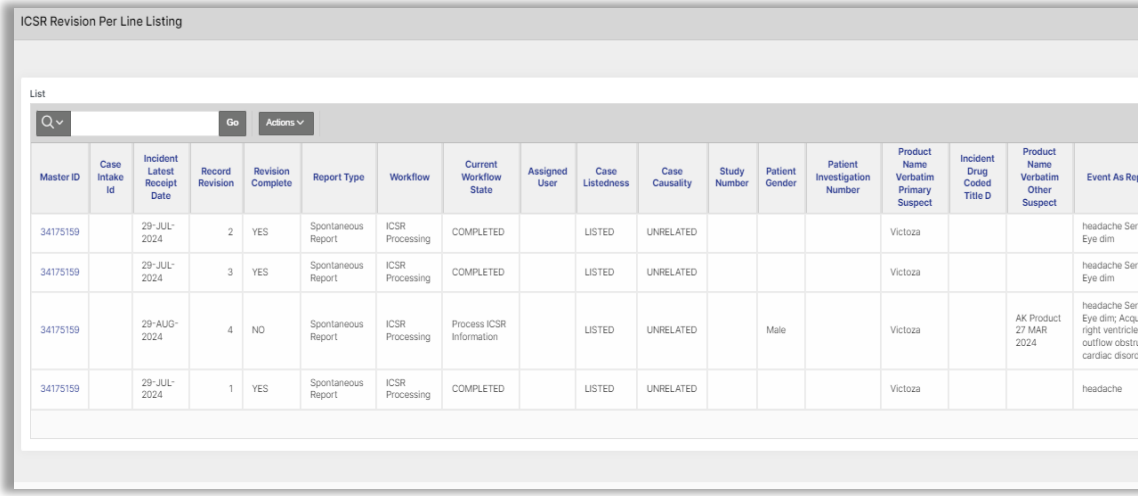
Pre-defined fields classified for standard periodic report such as –

- Periodic Benefit-Risk Evaluation Report (PBRER)
- Development Safety Update Report (DSUR)
- Post-market Adverse Drug Experience Report (PADER)
- CIOMS II



Example screen from the module for Expert Reporting (Ad-hoc), displaying form.

Example screen from the module for Revision Per Line report for an Ad-hoc report.



Pre-configured Output Reports

The HaloPV Aggregate Reporting module comes with five Pre-configured Output reports capturing 100+ data elements of ICSRs.

Output Reports	Report Description
ICSR Event-Product Per Line Report	This report lists all the Event-product combinations possible for an ICSR record and their respective details.
ICSR Submission Per Line Report	This report lists all the Submissions (Automated or Manual) for an ICSR record. This report lists the record details required for submission and the Submissions details such as Destination and agency details.
ICSR Revision Per Line Report	This report lists all the revisions of an ICSR record.
ICSR Case Per Line Report	This report lists one row per ICSR Record revision.
ICSR Activities Per Line Report	This report lists the Activities (action items) on an ICSR record.

Pre-configured Report Templates

The HaloPV Aggregate Reporting module comes with following Pre-configured Reports Templates, which can be customised as per requirements –

- SAE Listing
- DSUR Cumulative Tabulation
- PBRER Cumulative Tabulation
- PBRER Summary Tabulation
- PADER Drug Report
- PADER Malfunction Report
- E2F Line Listing

Example screen from the module for PBRER Summary Tabulation.

Report template / Title: *PBRER Summary Tabulation / Ad-hoc Aggregate Report Demo*
Period: *01-MAY-2023* **through** *29-AUG-2024*
Product/Ingredient:
IBD:

Insife Test
Date of report: 13-Nov-2024

Numbers of adverse reactions by preferred term from post-authorisation sources *

SOC	MedDRA PT	Spontaneous, including competent authorities (worldwide) and literature					Non-interventional post-marketing study and reports from other solicited sources **	
		Serious		Non-serious		Total Spontaneous	Serious	
		Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Blood and lymphatic system disorders	Anaemia folate deficiency	4	4	2	2	6	0	0
	SUBTOTAL	4	4	2	2	6	0	0
Cardiac disorders	Acquired right ventricle outflow obstruction	1	1	0	0	1	0	0
	Adams-Stokes syndrome	0	0	1	1	1	0	0
	Arrhythmia	0	1	4	5	6	0	0
	Cardiac arrest	3	3	9	9	12	0	0
	Cardiac disorder	1	1	0	0	1	0	0
	Cardiogenic shock	2	2	0	0	2	0	0
	Myocardial infarction	11	12	10	13	25	0	0
	SUBTOTAL	18	20	24	28	48	0	0
Congenital, familial and genetic disorders	11-beta-hydroxylase deficiency	2	2	18	23	25	0	0
	17-alpha-hydroxylase deficiency	0	0	0	1	1	0	0
	1p36 deletion syndrome	1	1	0	0	1	0	0
	2-Hydroxyglutaric aciduria	1	1	0	1	2	0	0

What can be configured in the module?

HaloPV, including the Aggregate Reporting module, is extremely configurable. The standard HaloPV configuration provides a functional starting point with the pre-configured workflows right out of the box. However, it is possible to enhance and tailor the application to support your organization even further. Qinecsa 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 segregation 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 automatically up-versioning and restarting a Workflow 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 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 Qinecsa. You can also explore the following additional resources

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

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

8,

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