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Complete package of pre-configured workflows and standardized templates.

Agreements

MODULE EXPLAINER

HaloPV

the world's first fully comprehensive and cohesive solution.

Qinecsa



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Why use this module?

The HALOPV Agreements module streamlines the management of Pharmacovigilance (PV) Agreements, including Safety Data Exchange Agreements (SDEAs), with partners and affiliates. It enables organizations to efficiently create and oversee these agreements, ensuring compliance and transparency. Key features include -

- › **Auto-generation of SDEA documents**, formatted using Word templates for consistency and ease of customization.
- › **Standard clauses**, known as snippets, can be selected to tailor agreements based on specific requirements.
- › The module supports **electronic signatures**, facilitating fully digital workflows, even for users who are not part of the HALOPV system.
- › **Integration with the PSMF** (Pharmacovigilance System Master File) module allows automatic population of Annex A, B, and C, ensuring comprehensive documentation.
- › Additionally, the module **links to the Requirements Intelligence** module, enabling the configuration of partner obligations in alignment with regulatory expectations.

With its automation capabilities and compliance-driven design, the HALOPV Agreements module enhances operational efficiency, reduces administrative burden, and ensures seamless collaboration with partners.

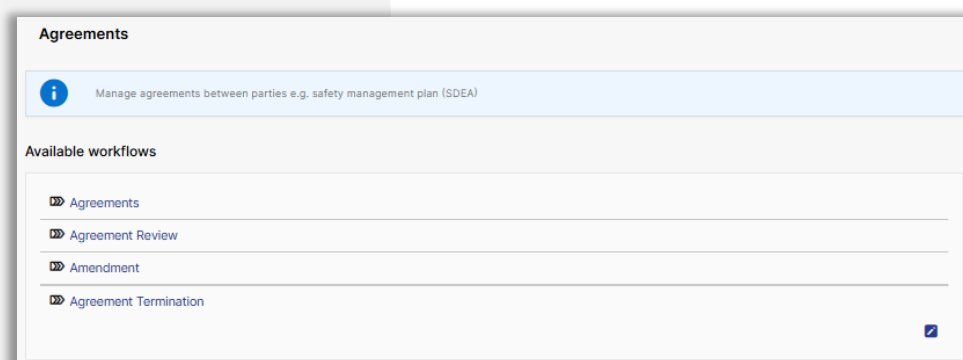
The module is ready for deployment in the cloud, offering reliability and efficiency in regulatory and operational PV management.



HaloPV Agreements

Image from Agreements Module landing page.

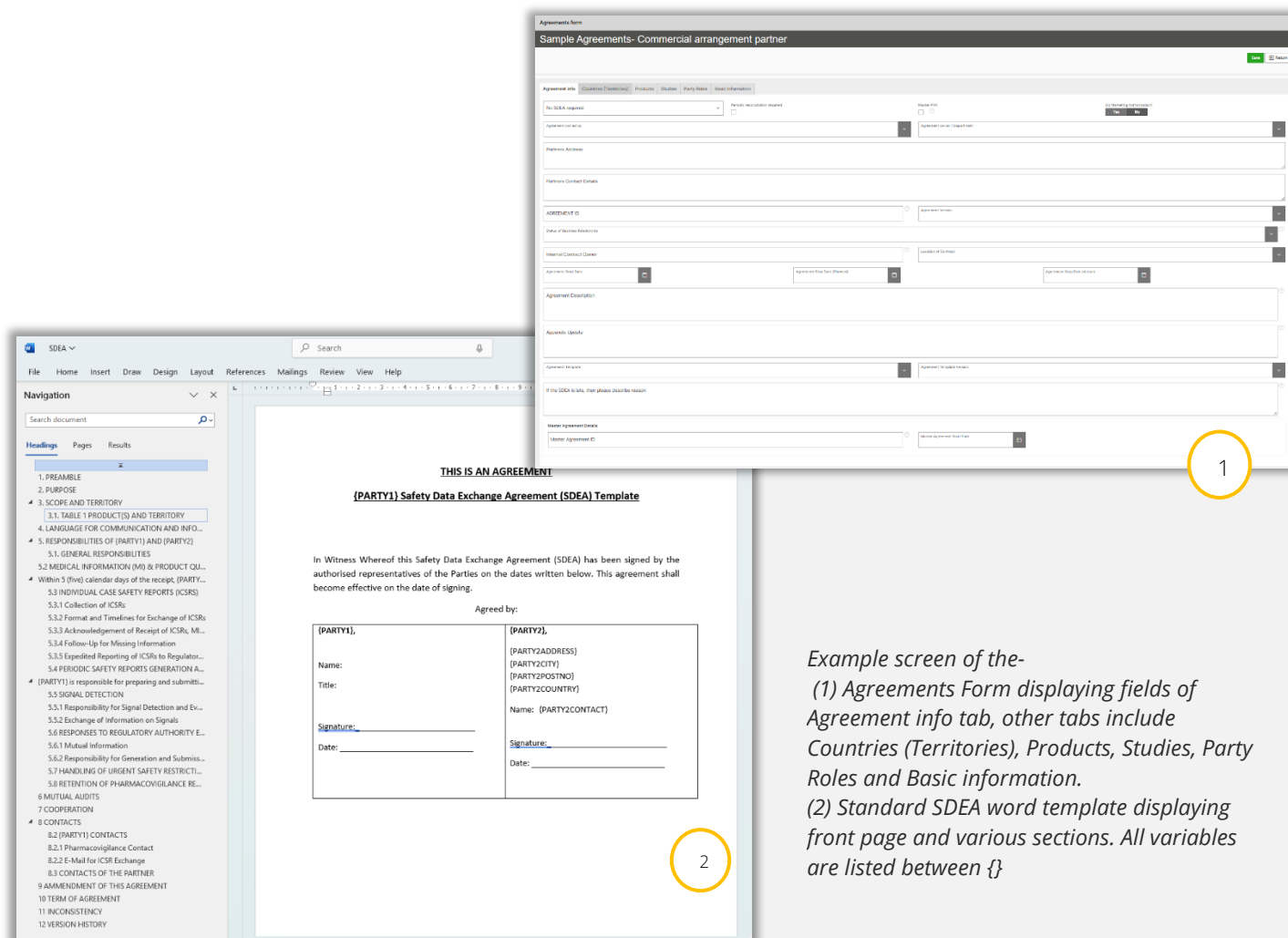
Image displays all the standard workflows available for the module.



Agreements

Feature highlights

- Supports Agreements and their termination –
 - Preconfigured workflows to support Agreements, their review, amendments and terminations.
- Compliance with Regional Guidelines –
 - Ensures regulatory compliance across various jurisdictions within a single platform.
- Collaboration & Document Sharing -
 - Eliminates the need for emailing documents for review, improving efficiency.
 - Stakeholders can directly review and approve documents within the system.
- Automated Document Generation –
 - Focuses reviews on content rather than manual data collation.
 - Uses Word templates and structured text snippets for standardization.
 - Enhances document formatting for professional presentation.
- Audit Trail & Document Control --
 - Tracks all changes and updates, ensuring transparency and compliance.
- Integration with Other Modules -
 - Links seamlessly with related modules such as PSMF and Requirement Intelligence.
- Workflow Management –
 - Allows multiple contributors to work on different annexes independently.
 - A powerful workflow engine enables review, approval, and management of each data point within the PSMF.
- Plus of course all the usuals around GxP, audit trail, CFR21 part 11 and EU Annex 11 compliance



Example screen of the-

(1) Agreements Form displaying fields of Agreement info tab, other tabs include Agreement (Territories), Products, Studies, Party Roles and Basic information.

(2) Standard SDEA word template displaying front page and various sections. All variables are listed between {}

Pre-configured workflows

The HaloPV **Agreements** module comes with a complete package of pre-configured workflows that allow efficient management of Agreements, their review and Amendments and terminations. The workflows typically comes with Manual steps to Create and Review/ Approve a record. If required, the new workflow steps can be configured to your specific processes and adding review and approvals.




Workflows

- › Agreements
 - The agreements workflow allows for content management of individual agreements.
- › Agreement Review
 - The agreements review workflow allows to document the regular review of an active agreement.
- › Amendment
 - The amendment workflow allows the amendment of an active agreement.
- › Agreement Termination
 - The agreements termination workflow allows for managing the activities upon the termination of an agreement.

Example screens of Standard Agreements Workflows displaying standard workflow steps

Agreements / Agreements Records


Process and workflow description

 The agreements workflow allows for content management of individual agreements

→ ☐ Create/update agreement → ☐ Internal Review → ☐ External Review → ☐ Agreement Signed → ☐ Agreement Completed

Agreements / Agreement Review Records

Process and workflow description

 The agreements review workflow allows to document the regular review of an active agreement.

→ ☐ Review Agreement → ☐ Approve Review

Agreements / Amendment Records


Process and workflow description

 The amendment workflow allows the Management of PV Clauses.

→ ☐ Create / update Amendment → ☐ Internal Review → ☐ External Review → ☐ Amendment signed

Agreements / Agreement Termination Records

Process and workflow description

 The agreements termination workflow allows for managing the activities upon the termination of an agreement

→ ☐ Termination Initiated → ☐ Perform Final Reconciliation → ☐ Safety Information Received → ☐ Safety Information Archived → ☐ Termination Completed

What can be configured in the module?

HaloPV, including the **Agreements** 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. 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 record types
- › Entity (organizational) ownership to report record for segregation of report records, e.g. into different regional 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.
- › Scheduling of activities, such as initiating the 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 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

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

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](#)

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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