HALOPV 4.2 Release Notes
Final
Version 1.0
Department: Release Management

Document Approvals

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1. Overview

Insife "HALOPV" 4.2 is a minor release enhancing the capabilities of HALOPV 4.1. It contains a number of updates, as detailed in section 4, to address some key identified bugs and issues, along with some limited new/ updated features.

2. Upgradability

HALOPV 4.2 can be upgraded from HALOPV 4.1. It can also be deployed as a standalone full installation.

3. Compatibility

HALOPV 4.2 is compatible with the following systems:

- Argus 8.2.1.1 and Argus 8.2.3 (Please contact us for compatibility with earlier/ later versions)
- ARISg 7.2 (Please contact us for compatibility with earlier/ later versions)
- Browser Compatibility
  HALOPV requires a JavaScript enabled browser and supports the current and prior major release of **Google Chrome**, **Mozilla Firefox**, and **Microsoft Edge**. HALOPV leverages Oracle APEX framework and is compatible with browsers supported by it.

  OBS: Support of **Microsoft Internet Explorer** was no longer supported by HALOPV 4.0

The following Oracle Support documents should be considered for compatibility:

Oracle Software Web Browser Support Policy

https://docs.oracle.com/en/database/oracle/application-express/20.2/htmig/apex-installation-requirements.html#GUID-02BE4A34-B631-412C-8A82-EB92DABBACE0

At the time of release, Chrome was on version 110, and Edge was on version 110.

4. Changes since the last release

The following features have been updated in this release:

Area/Process/Group	Title	Description	Impact
MedDRA	MedDRA search	Functionality updated. MedDRA lookup query updated to copy event.	**Minor** No impact on existing customers
Configuration Item List Generation	New functionalities	New functionalities were added to allow users to generate an excel file of HALOPV configuration, e.g., workflows, list of values.	**Minor** New functionality. No impact on existing customers
Narrative / Summary	Auto Narrative	When using the functionality 'Narrative / Summary,' field 'Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information (H.1)' in ICSR records, it is possible to generate or append a case narrative based on a HALOPV Template when clicking at the 'Auto-narrative' button.	**Minor** New functionality. No impact on existing customers
Device Submissions	Devices	Scheduler logic updated for devices to trigger submissions without coding the device. Updates are included in the 'ICSR/Device requirement details' form	**Minor** Minor configuration update, no impact on existing customers
Duplicate Search	Duplicate Search	Capability was added to attach duplicate search results to the case. Two new columns are added to the List "Duplicate search workflow configuration." And a new document template was added (Basic sample template, which can be extended as needed.)	**Minor** Minor configuration update, no impact on existing customers
Translation Automation	New Automator	New automation for the translation of narrative in attachment records was added. The new functionality translates local language	**Minor**

Area/Process/Group	Title	Description	Impact
		narratives into the main narrative. The automation is currently limited to process max. 100 pages per translation.	New functionality. No impact on existing customers
Submissions	Form update	A new 'revision' field has been added in the 'Submission details form' to populate when the auto-scheduler triggers the submission. Now, Submission records will include the current ICSR revision at the time of transfer of the Submission.	**Minor** Enhancement. Minor configuration. Existing customers should review the current configuration
Devices	Form update	New fields added to the 'Incident Patient information' form to include IMDRF' Health Impact' codes (Annex F), Clinical sign, symptoms, and conditions codes (Annex E)	**Minor** New functionality. No impact on existing customers
QC Check form	Form update	The 'Save' button has been added to the form. Now, users can add comments without the need to 'Approve' which automatically completes the step. Users can save changes and return later to complete the task.	**Minor** New functionality. No impact on existing customers
Print Functionality	Functionality Update	Enhancement to the functionality Print-Menu to print a PDF via HTML templates on standard records. The update allows for ad-hoc printing of HTML templates.	**Minor** New functionality. No impact on existing customers
Device Incident – NCAR Details	New form	New form is available to allow users to register NCAR details.	**Minor** New functionality. No impact on existing customers
Task Scheduler	New form	A new form is configured to replace the old form. New functionalities and tabs were added to include: specified day(s) in the period,	**Minor**

Area/Process/Group	Title	Description	Impact
		specified month(s) in the period, and specified year(s). The form also supports scheduling in a specific workflow step. The audit log is available in the form.	New functionality. No impact on existing customers
Clinical Study form	Form update	Two new fields added to the tab 'Study details: 'Blinding type' and 'Study has been unblinded'.	**Minor** New functionality. No impact on existing customers
Clinical Study form	Form update	The 'Products' tab has been updated with new fields. Now, it is possible to select; study arms, product type, and mark blinded products to support ICSRs records.	**Minor** New functionality. No impact on existing customers
Audit Log	Audit Log	The Audit Log shows '-' when APIs or the system creates records. Now, it is updated to display 'SYSTEM' in the column 'user' when the system creates the record.	**Minor** No impact on existing customers
PSMF	Form update	A new field, 'Change Lock Start Date,' was added to capture the previous data lock point.	**Minor** No impact on existing customers
Agreements	Form update	Layout updated.	**Minor** No impact on existing customers
Record Worklists	ICSR / Device Incident	In the ICSR and Device Incident worklist, the column 'Assignment date' is available to reflect user's assignment date. Device Incidents worklists can display the columns' Parent record title' and 'Parent Record ID'	**Minor** No impact on existing customers
Related Records	Logic update: Lock release	When opening a related record from a master (parent) record, both the related and master gets locked. Now, if the user closes any record, the lock in both records is released.	**Minor** Enhancement. No impact on existing customers

Area/Process/Group	Title	Description	Impact
ICSR	ICSR Intake	Update of XML import for ICSR R3 codes. The field 'email address' has been updated to 'Reporter Email Address', and a new field has been added, 'Reporter Fax'.	**Minor** No impact on existing customers
Product	Medicinal Products and Licenses	'Medicinal Product' and 'Medicinal Product Licenses' forms have been updated: • The field 'Trade Name' has been renamed as 'Full Presentation Name.' Now, the value auto-populates after the record's name. • The new field 'Medicinal Product Description' auto-populates in the product form after the record 'Description.' The record 'Description' (text box) should be configured as part of the record view.	**Minor** Enhancement. Existing customers should review existing configuration
Requirement Intelligence	ICSR / Device requirement form	Causality values are no longer ticked per default.	**Minor** No impact on existing customers
ICSR	Case Follow-up intake: Attachments for the automated follow-up	Follow-up cases with attachments: New functionality allows users to merge attachments from the incoming (FU) case into the original case (in the new revision). Functionality is applicable for ICSR Duplicate Search.	**Minor** New functionality. No impact on existing customers
Product	Product Import	HALOPV can receive product information via the products API from an external sender (e. g., Argus, Veeva). Functionality has been enhanced for Product inbound to accept either an 'internal code' or the 'sender code' when importing product information.	**Minor** Enhancement. No impact on existing customers
Defective Medicines	Defective Incident Details (New form)	A new page, 'Defective Incident Details' was created to support the Defective Medicines Module.	**Minor** New functionality. No impact on existing customers

Area/Process/Group	Title	Description	Impact
Requirement Intelligence	New form	Requirement Impact Assessment form to cover requirements for the Requirement Intelligence Module	**Minor** New functionality. No impact on existing customers
Devices and Medicines	Automator update	Validate inbound XML against XSD: Automator has been updated to check the XML and either tagging (or stopping) if the XML is not valid. Validation rules for keywords and routing rules are required to be configured front-end.	**Minor** Enhancement. No impact on existing customers
Agreements	Form updated	Two new fields have been added to the Agreements form: 'Partners Address' and 'Partners Contact Details'.	**Minor** New fields. No impact on existing customers
Correspondences	Notifications: Reminders for non-HALOPV users	New Automator to trigger auto reminders for correspondence records: Correspondence outbound records that are pending (meaning no answer was received from email recipient) in Correspondence workflow > awaiting Information task should send the same template to the same email recipient.	**Minor** New functionality. No impact on existing customers
ICSRs / Devices	Event(s) form updated	The Reaction/Event form has been updated to copy an existing MedDRA reaction event if fields are the same for multiple events. Two buttons were added: 'Copy event' and 'Copy Event to History'.	**Minor** New functionality. No impact on existing customers
Products	Product Index Browser	Now, it is possible to select 'only company products'. A checkbox has been added to the 'Product Index Browser,' making it easier to code products in ICSRs cases.	**Minor** New functionality. No impact on existing customers
ICSRs / Medicine Incidents	ICSRs forms updated	It is possible to hide the sections 'China' and 'Korea'. The update is configurable per client.	**Minor** No impact on existing customers

Area/Process/Group	Title	Description	Impact
ICSRs / Medicine Incidents	ICSRs forms updated: Unblinded button added	New fields have been added to the 'Sender(s) and Case Info' form. The tab 'Study Identification' allows users to include 'Study Name (C.5.2)', 'Sponsor Study Number (C.5.3)', 'Study Type Where Reaction(s)/Event(s) Were Observed (C.5.4)' and 'Study Arm.' The fields are required for unblinding products in the 'Drug(s) info' form. E.g., when the field 'Investigational Product Blinded (G.k.5.2)' is marked as 'Yes' (and the form is saved), the 'Unblind' button will display.	**Minor** Enhancement. Existing customers should review the current configuration
Dosage	Dosage Information	'Dosages – Entry form' enhanced to auto-populate 'free-text' fields when the user selects the drop-down fields. Free text fields get auto-populated when the users select values using drop-downs on the 'Pharmaceutical Dose form (G.K.4.R.9.1)', 'Route of Administration (G.K.4.R.10.1)' , 'Parent Route of Admin (G.K.4.R.11.1)', the fields available as a 'free-text' will auto-populated with the same values.	**Minor** Enhancement. Existing customers should review the current configuration

5. Bugs resolved in HALOPV 4.2

Area/Process/Group	Title	Description	Impact
Scheduler	Nullified records were scheduled	Scheduler setup will consistently execute instances for individual records – including nullified records. The Automator was updated to exclude schedules on nullified records.	None – Fix only
Substance Groups	Substance Groups without a HALOPV Code do not show member substances in the overview	Worklist shows Business Groups even when HALOPV Code is not available.	None – Fix only
Medicinal Product form	Two fields update in the form after the record is reinitiated	New record revisions do not reset the values in the fields' Source of Information' or the up version of the 'Source system local code.''.	None – Fix only
Read/Write permission controls	User Admin role with 'Read-only' access	Read/Write permission controls: Role ' User Admin' with read-only access to respect the 'read-only' condition	None – Fix only
Requirement Intelligence	View update	Locked forms show overlapping text in the 'Document Process Scope' section when records are at rest. This has been fixed.	None – Fix only
Related Records	Missing 'Type' in related records.	When users create child/linked records and forget to add the 'Relation type,' the record shows in the 'Related record' section without a link in the 'Link type' column. This has been fixed by setting 'Type' as mandatory.	None – Fix only

Area/Process/Group	Title	Description	Impact
Create Record	Create Record Wizard and Create/edit list values pages update	Users were able to update factory-locked records. This has been updated and restricted to the Insife technical team with the 'Global Admin' role.	None – Fix only
Requirement Intelligence	Requirement Intelligence details form, Local QPPV/Safety responsible requirements form, Impact assessment form	Factory lock required configuration for the below forms. • Requirement Intelligence details form (Factory locking logic added for Implementation tab + "banner" shown at the top of the page) • Local QPPV/Safety responsible requirements form (Factory locking logic added for Implementation tab + "banner" shown at the top of the page) • Impact assessment form (Factory locking logic added for Implementation tab + "banner" shown at the top of the page)	None - Fix only
Requirement Intelligence	Country selection	Despite being selected in the 'Record Details, ' the country was not displayed in some forms. This has been fixed in Requirement Intelligence workflows.	None - Fix only
Roles implementation	Auto assignment of roles	Access granting did not overwrite 'read-only' roles. Reassigning roles with new permissions like read-only or full access was not possible. This has been resolved to respect new attributes.	None – Fix-only

6. Features removed from HALOPV 4.2

- Support of the Internet Explorer browser was removed from the HALOPV 4.0 onwards.
- PAGE 92 'Task Scheduler' has been replaced by a new PAGE 93 Task Scheduler.
- PAGE 620 'Reaction/Event' > 'Additional Coding details' section, the field 'LLT' has been removed from the form.

7. Known Issues & Workarounds

Area/Process/Group	Title	Description	Workaround
Entities and Clinical Trials	Affiliates/Partners access	When users add products in the 'Entity form', tab 'Products,' it is not possible to access the complete list of products in the 'Study details form' tab 'Products' in Clinical Trials Module.	When users create a new entity, the new entity record is owned by the 'Root Organization' or 'HQ' and not to the newly created entity. Thus, users will be able to see the list of products when creating a clinical trial record. Note: Restriction of products to user's organization is expected to be fixed in HALOPV 5.0
Functionality Menu / Tabular Reports	Access to drop-downs	Some drop-downs show records across organizations. Example 'products' drop-downs.	Public Reports should be restricted to 'Root organization' or 'HQ' users. Restriction of values based on user's organization is expected to be fixed in HALOPV 5.0
ICSR	Case Safety Report	Issues when saving dates in 'Date Report Was First Receive from Source C.1.4' and Date of Most Recent Information for this Report C.1.5'	When users click on 'Save' before the system updates the dates' values, it might be that values do not save, and an error message will pop up. Therefore, clicking on the 'tab' (on the keyboard) after completing the field 'YYYY' will ensure values get saved

8. Contact

Contact Insife Service Desk (support@insife.com) for any query related to installation or changes in this release.

9. Change Log

Version	Date	Author	Description
1.0	14-MAR-2023	Richard Salter	New document