

Insife HALOPV 6.1 Release Notes
Final
Version 1.0
Department: Product Management

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1. Overview

HaloPV 6.1 is a minor release that builds on the features of HaloPV 6.0. It provides various new features to its users. It contains several updates and changes, as detailed in section 4, and addresses some key identified bugs along with some limited new/updated features.

2. Upgradability

HaloPV 6.1 is dependant on an APEX software upgrade to Oracle APEX 24.1.3.

3. Compatibility

HaloPV 6.1 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)
- Compatible with any E2B R3 XML enabled systems
- 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: **Microsoft Internet Explorer** is no longer supported by HaloPV4.0 onwards

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 134, and Edge was on version 134.

4. Changes since the last release

The following features have been updated or added in this release:

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Aggregate Reporting	Aggregate Report Prompt update - IMDRF Queries	Updated Aggregate Reports prompt functionality for querying IMDRF data. This will now consider device related cases coded using IMDRF Annexes A, B, C, D, G.	LOW - This is an update in existing functionality.	HLP-11479	*
Aggregate Reporting	Aggregate Reporting template - PBRER V2	The Aggregate Reporting standard template "PBRER Summary Tabulation" has been updated to use the dimensions released in 6.0 to generate the report data which results in improved performance.	MEDIUM - This is a new template to generate PBRER Report, can be used in regulatory reporting	HLP-11296	INSIFE-HALOPV-OOB-PBRER-SPEC-618
Aggregate Reporting	Case per line and Product-event per line dimension update	The Case per line and Product-event per line dimensions have been updated to display all products marked as concomitant and interacting in ICSR records in respective columns, aggregated and separated by ; (semicolon).	LOW - Change in logic of existing column in dimension	HLP-11087	INSIFE-HALOPV-OOB-ICSR Event Product Line-SPEC-715, INSIFE-HALOPV-OOB-ICSR Case LINE View-SPEC-1122

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Aggregate Reporting	Aggregate Reporting template - SAE Line Listing V1	The Aggregate Reporting standard template "SAE Line Listing" has been created which uses the dimensions released in 6.0 to generate ICSR report data.	MEDIUM - This is a new template to generate SAE Line Listing, can be used in regulatory reporting	HLP-10965	INSIFE-HALOPV-OOB-SAE Line Listing-SPEC-1235
Aggregate Reporting	Aggregate Reporting template - PADER V6	The Aggregate Reporting standard templates "PADER Drug Report" and "PADER Malfunction Report" have been updated to use the dimensions released in 6.0 to generate the report data which results in improved performance.	MEDIUM - This is a new template to generate PADER Report, can be used in regulatory reporting	HLP-10885	INSIFE-HALOPV-OOB-PADER-SPEC-440
Aggregate Reporting	Aggregate Reporting template - DSUR V3	The Aggregate Reporting standard template "DSUR Cumulative Summary Tabulation" has been updated to use the dimensions released in 6.0 to generate the report data which results in improved performance.	MEDIUM - This is a new template to generate DSUR Report, can be used in regulatory reporting	HLP-10876	INSIFE-HALOPV-OOB-DSUR-SPEC-445
Aggregate Reporting	Aggregate Reporting template - E2F Line Listing V1	The Aggregate Reporting standard template "E2F Line Listing" has been updated to use the dimensions released in 6.0 to generate the report data which results in improved performance.	MEDIUM - This is a new template to generate E2F Line Listing, can be used in regulatory reporting	HLP-10833	INSIFE-HALOPV-OOB-E2F Line Listing-SPEC-1233

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Aggregate Reporting	Aggregate Reporting Prompt - Bulk Case Number	New functionality added to allow bulk upload of (comma (,)) separated case numbers (C.1.1) to the Aggregate Report "List of case numbers" prompt. This option supports up to 4000 Characters. When an invalid case number is entered, an error message is displayed to notify the user.	LOW - A new UI based option provided to add bulk case numbers in existing prompt.	HLP-10645	INSIFE HALOPV SS-39
Aggregate Reporting	Aggregate Reports - reports POPUP to display the last refreshed time	Updated the Aggregate Reports Interactive Reports (dimensions) popup window to display - - Title - Report Title - Version - Report Versions - Date - Date of report - Last Refreshed On - Date time of last data refresh.	LOW - These are view only changes	HLP-10173	*
Aggregate Reporting	Placeholder for LLT in E2F View	Added an additional placeholder "INCIDENT_EVENT_MEDDRA_LL_T_D" to the E2F line listing template. If required, this can be used to print Event LLT in the template.	LOW - This is a additional placeholder which is not in use in the standard template.	HLP-12204	INSIFE-HALOPV-OOB-CIOMS-SPEC-434
Agreements, Entities	Field is added: Local Organization (Local Language)	A new field 'Local Organization (Local Language)' is available under tab Countries (Territories) at PV Country Contacts form. User is able to insert and view special Characters in the field such as - ä, ö, ü, ß	Medium: A new field is added at PV country contacts.	HLP-11063, HLP-9292	*
Agreements	Agreement Party Roles	A new column 'Agreement Party Roles' is added under Agreement worklist to see if any party roles are present	Low: New column in agreement worklist is added	HLP-11300	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Agreements	Master PVA checkbox	Added a new checkbox 'Master PVA' under Agreement Info tab. Also, captures the audit logs	Low- A new checkbox is added	HLP-10028	INSIFE-HALOPV-AGRMNTS-TDS-612
Case Intake and Processing	Consolidation of Race Field in Patient Tab	The China-specific Race field in the Patient tab has been removed from the UI, and one Race field has been introduced in the Patient section. The LOVs have been merged to ensure all race options are preserved.	Low - One race field	HLP-12253	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Removal and Rearranging fields on Sender and Case Info	The following fields have been removed from the Sender and Case Info pages: Date of Submission, Manufacturer Awareness Date, Date of Incident (From), Date of Incident (To), and Submission Required. Additionally, the following fields have been relocated to the Device Admin Info page: Report Type and Expected Date of Next Report.	Low - Removal of redundant fields	HLP-12192	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Configurable Event Adjudication Tab	The Event Adjudication tab is now configurable, allowing administrators to enable or disable it based on business needs.	Low - Configurable Event Adjudication tab	HLP-12091	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	Updated Report Generation and Scheduling Logic	The report generation function and scheduling procedure have been updated to accommodate the removal of the C.1.7 Does This Case Fulfil the Local Criteria for an Expedited Report? field from the UI while ensuring proper handling of automated and manual submissions.	Medium - Change to report generation and scheduling logic	HLP-12037	INSIFE-HALOPV-AUTOMATIONS-170
Case Intake and Processing	Removal of Advanced Coding Section in Product Tab - Device Related section	Removed the fields in the Advanced Coding Section on the Device Related tab on Products	No impact - Removed unnecessary fields from UI	HLP-12030	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Correct Date Format Display	The system now correctly displays selected dates in the appropriate format DD-MM-YYYY HH:MM. Note: HH:MM only for applicable fields	Low - Date format changes	HLP-11892	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	Auto-Population of Null Flavors	Introduced auto-population of Null flavors for the following fields in Case Intake (Manual/XML/Email) if no information is selected. The following fields will be updated accordingly: Patient Race Code → Populate nullFlavor: UNK Patient Ethnicity Code → Populate nullFlavor: NI Required Intervention → Populate nullFlavor: NI FDA Additional Information on Drug (Coded) → Populate nullFlavor: NA Device Brand Name → Populate nullFlavor: NI	Low - Fields will be auto-populated with null flavors if no information is available	HLP-11889	INSIFE-HALOPV-ICSRs-TDS-410

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	Addition of local field Daily Dosage	Added a field for Daily Dosage for local language	Low - New field added	HLP-11875	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Additional Coding Section Fields Set to Read-Only	The fields in the Additional Coding section are now read-only across multiple pages: - Medical History - Past Drug History - Results of Test - Relevant Medical History - Relevant Past Drug History - Indication - Diagnosis - Reported Cause of Death - Determined Cause of Death - Events	Low - Additional Coding information fields made red only	HLP-11635	*

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Case Intake and Processing	Renamed Labels in Additional Coding Section	The labels in the Additional Coding section have been updated to: SOC Term and Code HLGT Term and Code HLT Term and Code PT Term and Code	Low - Renamed labels	HLP-11480	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Renaming fields on Case Intake and Processing	Renamed the fields on the Case Intake and Processing to remove the Data-element name alongside the field label.	Medium - Renamed fields	HLP-11331	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Product Selection in Case Intake Wizard	The system now includes a product selection dropdown in the Case Intake wizard when users manually create a record. This enhancement ensures that users can select a company product efficiently within the workflow.	Medium - User can select the product at record creation	HLP-11314	*
Case Intake and Processing	Validations for FDA	Validations for the following fields have been implemented to ensure compliance with FDA regulations: Reporter's Email, Patient Race Code, Patient Ethnicity Code, Required Intervention, FDA Other Characterisation of Drug Role, IMDRF Code (Annex A) / Device Problem Code, and Device Product Code	Medium - Implemented new validations	HLP-11284	*
Case Intake and Processing	Addition of fields on Event Adjudication	Added the below fields on Event Adjudication Page: Event PT (PT Code) Adjudication Scale	Low - Addition of fields	HLP-10468	INSIFE-HALOPV-ICSRs-TDS-410

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	Default Normal Range Units Based on Test Result Unit	The system will now auto-populate Normal Low and Normal High values with the correct units based on the selected Test Result Unit	Low - Normal range units same as test result units	HLP-1955	*
Case Intake and Processing	Enhancement to Product(s)-Reaction(s) / Event(s) Matrix Population	The Drug(s)-Reaction(s) / Event(s) Matrix will now be automatically populated, regardless of whether Event(s) or Product(s) are entered first.	Medium - eliminates manual entry	HLP-1537	*
Case Intake and Processing	ICSR Reporter Comment Character Limit Increased to 500	The system has been updated to allow up to 500 characters in the Reporter Comment field.	Low - No impact on other fields	HLP-75	*
Case Intake and Processing	Relocation of Reportable Malfunction Flag	The Reportable Malfunction Flag field has been removed from the Incident Manufacturer Analysis and Device Problem Information tabs and moved in the FDA Information tab.	Low - Change in field position	HLP-12052	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Configurable FDA Validation Rules	All FDA validation rules will now trigger only when the Reporter and/or Event Country and/or product license territory is US. Applicable Workflows: All Case Intake and Processing workflows Excludes Manual Intake Additional Configurability: Validation rules can be configured at the entity level. Users can enable or disable existing rules as needed.	Medium - New Validation rules for FDA	HLP-11891	*

Case Intake and Processing	QC Check Criteria Update	The QC Check process has been updated to ensure that only serious cases not created in the XML Intake Workflow are tagged for Quality Check. Additionally, a duplicate QC Check tag has been removed. Records Meeting the Following Conditions Will Go for Quality Check For Medicine Products: • 100% Fatal/Life Threatening cases should go for QC • 50% of cases with remaining serious criteria should go for QC • 10% of Non-Serious cases should go for QC • 0% of cases that were ingested as XML/E2B • 100 % if user experience is set to new hire For Device Products: • 100% Death • 100% Serious public health threat • 50% Unknown or Unanticipated serious deterioration in state of health • 10 % of any other category • 0% of cases that were ingested as XML • 100 % if user experience is set to new hire For Combination Products: • 100% Fatal/Life Threatening cases should go for QC	High - Update to QC criteria	HLP-11790	*
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Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
		50% of cases with remaining serious criteria should go for QC 10% of Non-Serious cases should go for QC 0% of cases that were ingested as XML 100 % if user experience is set to new hire			
Case Intake and Processing	Field Name Update on Products Tab	The field 'Medicinal Product name as Reported (G.k.2.2)' on Products tab has been renamed to 'Medicinal Product name as Reported / Common device name'	Low - Renamed field labels	HLP-11450	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Manual Overwrite Checkbox for Duration Fields	A Manual Overwrite checkbox has been introduced for drug and event duration to allow users to disable auto-calculation of duration fields and manually enter values. When unchecked, HaloPV will continue to auto-calculate durations, and fields will remain disabled for manual entry.	Low - Introduced a checkbox to stop auto-calculation of drug and event duration	HLP-11235	*
Case Intake and Processing	Validation Rule for Product-Event Listedness Consistency	A hard validation rule has been implemented in HALO to ensure that only one listedness value is allowed per product-event combination in the Drug(s)-reaction(s) Matrix - Entry at Listedness tab.	Low - Addition of a new validation rule	HLP-11084	*
Case Intake and Processing	Local Language Support for Case Narrative	The existing Case Narrative template has been updated to support Local Language, allowing users to generate narratives in either Local Language or English, based on the field	Medium - introduced local narrative template	HLP-10966	INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	Addition of Treatment Period and Symptom Fields	Two new fields have been added: 1. Treatment Period – Added to Events tab under Treatment section 2. Symptom – Added to Events tab under Seriousness section	Low - Addition of new fields	HLP-9599	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	Hospitalization Fields Enabled Based on Selection	Selecting "E.i.3.2c: Caused/Prolonged Hospitalization" as "Yes" will now enable additional hospitalization-related fields in the form. Newly Enabled Fields: Hospital Name City State Hospitalization Start Date Hospitalization End Date Duration of Hospitalization	Low - Addition of new fields	HLP-7798	INSIFE-HALOPV-ICSRs-TDS-410

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	New FDA Fields Added and Updated	To meet FDA requirements, the following new fields have been added: Added: Malfunction If follow-up, what type? Remedial Action Initiated Required Intervention FDA Specialized Product Category FDA Other Characterisation of Drug FDA Additional Information on Drug Updated the field ' Study Registration Type' to add the following LOV values: IND Number Where AE occurred, Pre-ANDA Number Where AE occurred, IND number of cross-reported IND	Low - Addition of new fields	HLP-2202	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing, Clinical Trials	ICSR Study details population from the selected Study	Updated 'Study Registration section on the 'Study Identification' ' tab in the ICSR; now Study Registration Type, Study Registration Country and Study Registration Number will be captured in a grid format so that multiple values can be captured and transferred from the respective Clinical Studies record.	LOW - Update in fields selection.	HLP-6315	Insife HALOPV ICSR API Import Mapping - INSIFE-HALOPV-ICSR-API-IMP-MAP-SS-279, Insife HALOPV ICSR Export JSON API - INSIFE-HALOPV-ICSR-JSON-API-EXP-MAP-SS-584

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing, Clinical Trials	New Unblinding Fields in Case Safety Report Tab	For 'Report from Study' ICSRs, new fields have been added to the Case Safety Report tab to capture and display information about the unblinding of the ICSR: 1. ICSR Unblinded by User (read only) 2. Unblinding Date (read only) 3. Reason for Unblinding (list value: unblinded by Investigator, unblinded by Sponsor, unblinded at the end of Study) 4. Unblinding Comment	Low - New fields addition	HLP-11358	INSIFE-HALOPV-ICSRs-TDS-410
Case Intake and Processing	CIOMS 4.0 Update - Added product labelling info	CIOMS 4.0 Updates - CIOMS form will now include product labeling details from case data, the details will be printed in CIOMS additional details section.	LOW - New values printed in CIOMS form addition details section, no change in case data.	HLP-12586	INSIFE-HALOPV-OOB-CIOMS-SPEC-434
Case Intake and Processing	Daily Dosage Logic Update	Updated Daily Dosage logic on the CIOMS I form to reflect the following: If the product is still blinded then the daily dosage text will be displayed (G.k.4.r.8 field). When it is not blinded, the structured dosage values will be displayed (G.k.4.r.1, G.k.4.r.2, and G.k.4.r.3) if populated. If not the structured fields are not populated then the dosage text (G.k.4.r.8) will be displayed.	Low - Existing functionality update	HLP-10055	INSIFE-HALOPV-OOB-CIOMS-SPEC-434

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	CIOMS 4.0	CIOMS 4.0 release - The following changes have been made: - Updated narrative to handle special characters - Added new placeholders to capture: -- Event Preferred Term (MedDRA) -- Patient ID, Weight and Height -- Other relevant history - Performance improvements made	MEDIUM - Major changes in CIOMS to increase its performance and addition of new fields	HLP-9371	INSIFE-HALOPV-OOB-CIOMS-SPEC-434
Case Intake and Processing	Document/ Attachments page enhancements	Updated Documents popup, a new checkbox is added 'Show attachments from previous revisions' under attachment section, on selecting this HALOPV will display all the attachments of the record linked with any record version. Further user can edit on those attachments where record version is not completed.	Low- this is view only change, files were already there.	HLP-11019	INSIFE-HALOPV-SS-39
Case Intake and Processing	Display "Validation Issues" at HALOPV Worklist for all Records	Updated HALOPV all Worklists to display a new column "Validation Issues", the column will display "Yes" - When there are open validation issues at record, else it will display "No".	LOW - This is addition of a new calculated column at worklist	HLP-10464	*
Case Intake and Processing, System Config	Attachment Section Enhancement	A new column has been added to the attachment section to display the timestamp of when a document was uploaded. A user column has been introduced to track who uploaded each document. The existing "Author" column, which previously only logged system-generated documents, now also records user-uploaded documents.	Low - Improved traceability of document uploads	HLP-2527	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing, Submissions	CIOMS update - Patient DOB	Updated CIOMS I form to display "UNK" when patient DOB is null/not entered.	LOW - Change in display of null values	HLP-9012	INSIFE-HALOPV-OOB-CIOMS-SPEC-434
Case Intake and Processing, Submissions	MedWatch 3500A form	New version of MedWatch form created inline with latest FDA format. In V1.0 - below sections gets printed - A, B, C, D, E Sections F, G, H will be included in V 2.0 of MedWatch form	Low - New functionality	HLP-2757	INSIFE-HALOPV-OOB-MedWatch-SPEC-1234
Device Vigilance	Introduction of Active Device Report Page	A new Active Device Report page has been added, including columns for Device Product Name, Device Name, Device Event Description, Device Event Classification, Device Manufacturer Reference ID, and Device Reference Number assigned by NCA.	Low - Introduced new report	HLP-3638	*
Entities, PSMF Management	Worklist added in Entities module	Worklist added in Entities module	There is no impact as a new worklist 850 is just displayed on UI	HLP-12184	INSIFE-HALOPV-SS-39
Entities, PSMF Management	Addition of new Worklist	Under Entities module, a new Worklist for PV Country Contacts is added.	Low - Just new worklist is added, no impact on functionality	HLP-9575	*
Entities, System Config	Organizations Tab - Display Additional Information	The Organisation tab on the Entity form has been enhanced to include the Entity Type and Workflow of the assigned organisation.	Low - Ease of distinguishing different types of assigned organizations.	HLP-7436	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Literature	Updates to Literature Module	Literature Module has been updated with the following features: Define search criteria based on date range, ingredients, products, and studies. Search and list articles from PubMed using the defined criteria. Redact or annotate articles for review. Assess article relevance for Signal Detection, Case Intake & Processing, and PSUR	Medium - Added literature article review capability	HLP-12475	INSIFE-HALOPV-LITERATURE-TDS-1257
Literature	Automatic Tagging in Literature Article Review Workflow	The system now automatically tags records based on user selections in the Safety Information Review Page under the Assessment Result Tab. When users click "Yes" on any of the following criteria, the system adds the appropriate tag: Criteria Set as Yes Tag Added to Record Relevant for PSUR? --> PSUR relevant Relevant for ICSR? --> ICSR relevant Relevant for Signal Detection? --> Signal relevant	Low - Automatic tagging	HLP-11677	*
Literature	Enhancement to search products and ingredients	Introduced the capability to search on products and ingredient lists.	Low - Added search capability	HLP-11573	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Literature	Merging Assessment Tabs	1. The Literature, Surveillance, and Case Assessment tabs are now combined into a single tab called "Literature Assessment." 2. The button "Relevant for ICSR" is now renamed to "Relevant for Case Intake and Processing." 3. The additional free text field will only be displayed when "Relevant for any process" is selected.	Medium - Combined the tabs	HLP-11676	*
Literature	Removal of Outcome and Record Information Tabs	The Outcome and Record information tab have been removed from the Literature Search form.	Low - Removed unnecessary forms	HLP-7884	*
Literature	Enhanced Duplicate Search in Literature Workflow	A new duplicate search automator is created: 1. Automatic Duplicate Detection Based on Digital Object Identifier (DOI) 2. Keyword-Based Duplicate Search: Article Title , Author, Journal Title, Publication Date, ISBN, ISSN 3. If records with at least 50% matching on these keywords are found, the workflow will stop at the Duplicate Search task. The duplicate search screen will now display all records meeting the 50% match criteria for manual review by the user.	Medium - Updated duplicate search logic	HLP-10951	*
PSMF Management	Sorting of Working Files	Name of the output in Working files will be sorted alphabetically.	Low - Sort out the name of working files in UI alphabetically.	HLP-11173	*
Regulatory Intelligence	Help text added for ICSR / Device Reporting Requirements Workflow	Help text added for ICSR / Device Reporting Requirements Workflow form, users can click on help icon "?" of a field to view its help text.	LOW - this is implemented using existing Apex functionality	HLP-11116	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Regulatory Intelligence	ICSR reporting requirement form - enhancement	A new field "Local Language Reporting Required" has been added to indicate if reporting in the local language is required. If Local Language Reporting Required is set to "Yes", an additional field will appear for users to provide further details on the requirement.	Medium - New field for Local reporting requirements	HLP-10879	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236
Regulatory Intelligence, PSMF Management	Changes to PSMF workflow in Requirements Intelligence	The PSMF workflow form is now streamlined with only the essential fields and a new layout. Key changes include renaming tabs, adding radio button selections, introducing conditional visibility for specific fields, and enabling free text inputs where necessary. New fields such as "Applicable Guideline," "PSMF Location," and "How to Submit to Regulatory Authority" have been added for improved data capture.	Low - Improved Usability	HLP-10163	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236
Regulatory Intelligence	Changes to RMP workflow in Requirements Intelligence	The Risk Management Plan (RMP) workflow in the Requirements Intelligence module has been renamed to Risk Management Requirements. The updated form now includes a more structured layout, with new radio button fields, multi-select options, and conditional visibility based on user selections. New fields such as "Applicable Guidelines," "Risk Minimization Measures," and "How to Submit to Regulatory Authority" have been introduced.	Low - enhanced user experience	HLP-10164	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Regulatory Intelligence	Changes to Signals workflow in Requirements Intelligence	The Signals workflow in the Requirements Intelligence module has been streamlined. The Signal Notification tab has been renamed to General Requirements, and the form has been restructured. New fields such as "Are Signal Detection Activities Required?" and "Applicable Guidelines" have been added, while conditional visibility has been implemented for Country/Regional specific information. Additionally, the Requirement Verbatim and Notes tab has been renamed to Timelines and Formatting, and the Implementation Details tab is now simply Notes.	Low - enhanced user experience	HLP-10190	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Regulatory Intelligence	New operational report which shows what has changed since last delta transfer	A new operational report has been added to the Requirements Intelligence module, providing real-time insights into data changes. This report is positioned next to the list of workflows and focuses only on user-updated information, excluding system changes. It includes: • Date of last delta transfer for tracking updates • Total count of updated records since the last delta • Graphical visualizations to show updates by territory, workflow, and record type • Filters for territory, workflow, and record type in a multi-select dropdown format • A detailed table view displaying Record ID, Workflow Type, Old & New Values, Last Updated Date, and User	Medium - Streamlined tracking, enhanced usability and reporting	HLP-10292	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236

Regulatory Intelligence	Changes to PSUR workflow in Requirements Intelligence	The PSUR form within the Requirements Intelligence module has been updated. This form now resides under the Aggregate Reporting workflow and only appears when PSUR/PBRER is selected upon record creation. Tab 1: General Requirements - Field Updates: - Country: Multi-select territory drop-down list - Are periodic safety reports required? (Radio buttons: Yes / No / Unknown): If No or Unknown is selected, all other options will be hidden - Which report format is required? (Tick boxes, select multiple) - PSUR / PBRER / PADER / Other / Unknown - If Other is selected, free text field appears - Applicable guideline: (Tick boxes, select multiple) - ICH E2C(R2) / GVP Module VII / Other / Unknown - If Other is selected, free text field appears - Country/Regional Specific Information: (Radio buttons: Yes / No / Unknown) - If Yes is selected, free text field appears - Additional Information: (Free text field) Tab 2: Timelines and Formatting - Field Updates: - Reporting requirement starts from: (Tick boxes, select multiple)	Medium - enhanced usability and reporting	HLP-10312	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236
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		▪ International Birth Date (IBD) ▪ When Marketing Authorization is obtained in the country ▪ Other / Unknown ▪ If Other is selected, free text field appears ○ How frequently should reports be submitted? (Tick boxes, select multiple) ▪ According to the EURD list ▪ Every 6 months for the first 1-2 years after marketing authorization ▪ Once a year in the 3rd or 4th year after marketing authorization ▪ Once every 3 years from the 5th year of marketing authorization ▪ At the time of first MA renewal ▪ On request from the agency or if safety issues arise ▪ Other / Unknown ▪ If Other is selected, free text field appears ○ Timeline for submission: (Tick boxes, select multiple) ▪ 70 calendar days after DLP (≤ 1 year reports), 90 calendar days (> 1 year reports) ▪ Other / Unknown ▪ If Other is selected, free text field appears ○ What should be submitted? (Tick boxes, select multiple) ▪ Full document / Executive summary only / Other / Unknown			
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Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
		▪ If Other is selected, free text field appears ○ Format: (Tick boxes, select multiple) ▪ eCTD / PDF / Compact Disk (CD) / Unknown / Other ▪ If Other is selected, free text field appears ○ Reporting language: (Tick boxes, select multiple) • English / English with executive summary in local language / Other / Unknown ▪ If Other is selected, free text field appears ○ How to submit to Regulatory Authority: (Tick boxes, select multiple) ▪ Online Portal / Email / Post / Gateway / Other / Unknown ▪ If Other is selected, free text field appears ○ Additional submission information: (Free text field) Tab 3: Notes • Field Updates: ○ Notes (Free text field)			

Regulatory Intelligence	Changes to DSUR workflow in Requirements Intelligence	The DSUR form within the Requirements Intelligence module has been updated to include only the necessary fields. Tab 1: General Requirements - Renamed: Periodic Reporting → General Requirements - Field Updates: - Country: Multi-select territory drop-down list - Are DSURs required? (Radio buttons: Yes / No): If No is selected, all other options will be hidden - When are DSURs required? (Tick boxes, select multiple) - When there is an open IND - When there is an ongoing clinical trial in the country - Other (If selected, free text field appears) - When do reporting obligations start/end? (Free text) - Report type: (Tick boxes, select multiple) - DSUR / ASR (Annual Safety Report) / Not Specified / Other - If Other is selected, free text field appears - Applicable guideline: (Tick boxes, select multiple) - ICH E2F / Other (If selected, free text field appears) - Country/Regional Specific Information: (Radio buttons: Yes / No / Unknown) - If Yes is selected, free text field appears	Medium - enhanced usability and reporting	HLP-10316	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236
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		Tab 2: Timelines and Formatting • Renamed: Requirement Verbatim and Notes → Timelines and Formatting • Field Updates: ○ Timeline for Submission from DLP (Data Lock Point): (Tick boxes, select multiple) ❖ 30 / 60 / 90 Calendar Days ❖ 60 Working Days ❖ Report submitted by request ❖ Within 3 months after annual safety data cutoff date ❖ 70 calendar days after DLP (1 year or less), 90 calendar days (>1 year) ❖ Other (If selected, free text field appears) ○ Format: (Tick boxes, select multiple) ❖ eCTD / Hard Copy / CD / Not Specified / Other ❖ If Other is selected, free text field appears ○ Reporting Language: (Tick boxes, select multiple) ❖ Full DSUR in English ❖ Full DSUR in English with translated summary ❖ Executive Summary in English ❖ Other (If selected, free text field appears) ○ How to Submit to Regulatory Authority: (Tick boxes, select multiple) ❖ Portal / Email / Post / Gateway / Other ❖ If Other is selected, free text field appears			
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Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
		○ Additional Submission Information: (Free text field) Tab 3: Notes • Renamed: Implementation Details → Notes • Field Updates: ○ Notes (Free text field)			

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Regulatory Intelligence	New operational report which shows overview of ICSR data	A new GRIP Expedited Reporting Overview Report has been introduced in the Requirements Intelligence module, designed specifically for the ICSR workflow. This report allows users to generate customized or full datasets. New Features & Enhancements: • New Functionality Menu Option: The GRIP Expedited Reporting Overview Report is now accessible next to the "Whom and When" report. • Filters for Customization: Multi-select drop-down (Hidden until ICSR/Device WF is selected). ○ Clinical - Device ○ Clinical - Drug ○ Post-marketing - Device ○ Post-marketing - Drug ○ Drug-Device Combination ○ Vaccine • Territory: Multi-select drop-down menu with a full country list. • Filters based on ICSR form fields: Users can filter records using all available ICSR-specific fields. • Logical Column Arrangement: Report columns directly mirror the ICSR form fields for consistency. • Data Extraction & Export: Downloadable in Excel (XLSX) or PDF format	Medium - enhanced usability and reporting	HLP-10690	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Regulatory Intelligence	New operational report which shows LQPPV overview of data	A new GRIP L-QPPV Overview Report has been introduced in the Requirements Intelligence module, designed specifically for the L-QPPV workflow. This report allows users to generate customized or full datasets. New Features & Enhancements: • New Functionality Menu Option: The GRIP L-QPPV Overview Report is now accessible next to the "Whom and When" report. • Filters for Customization: • Territory: Multi-select drop-down menu with a full country list. • Filters based on QPPV form fields: Users can filter records using all available QPPV-specific fields. • Logical Column Arrangement: • Report columns directly mirror the QPPV form fields for consistency. • Data Extraction & Export: • Downloadable in Excel (XLSX) or PDF format for easy reporting and sharing.	Medium - enhanced usability and reporting	HLP-11320	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236

Regulatory Intelligence	New Regulatory News workflow and form	The Regulatory News Form has been introduced in the Requirements Intelligence module to facilitate the creation of Monthly and Weekly Regulatory Review Reports. New Features & Enhancements: • New Workflow: Created a new "Regulatory News" workflow with two tasks: • Register/Update News Item • Review and Approve News Item • New Form Fields: • Region & Territory: Drop-down lists for structured categorization. • Regulatory Authority: Selectable from a predefined list. • Application & Product Type: Multi-select tick-box options. • Document Type: Single-choice drop-down menu. • Title & Summary of Changes: Free text fields. • Date of Change: Calendar selection (supports partial dates where applicable). • Version/Document Number: Free text for tracking document updates. • Regulatory Impact Assessment: Single-choice drop-down (Yes/No). • External Link Field: Allows URL input for referencing documents. Data Management & Reporting:	Medium - Streamlined reporting, enhanced reporting, usability and data filtering	HLP-10839	INSIFE-HALOPV-OOB-REG-INTEL-GRIP-SPEC-1236
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Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
		- Database Integration: A dedicated Regulatory News Table is now included in the system. - Filtering Options: Users can filter reports by date, document type, region, and other relevant fields. - Export Functionality: Reports can be downloaded in DOCX or PDF format for distribution and reference.			
System Config	Email Notification column	Email Notification column is added displaying values as Yes or No on Page 5 under 'Template IRs - User Review Report'	Medium-Email Notification Column is added and displayed to the worklist	HLP-11317	INSIFE-HALOPV-SS-39
System Config	Workflow configurations for default display of records	HALOPV Configuration for workflows has been updated to provide ability to set default display of records at respective workflow worklist, workflows can be configured individually for - -- Show Last dropdown -- Completed records checkbox -- In Workflow records checkbox If left up selected, HALOPV will keep application-level configurations.	LOW - New way for existing configuration	HLP-10773	Insife HALOPV Functional Requirement Specification - INSIFE-HALOPV-FRS-17

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
System Config	Enhancements to Correspondence Worklist	Added a "Created By" column in the Correspondence Worklist to display the user who created the correspondence record. Users can now see the sent date and time (timestamp) in the worklist. If correspondence was not sent due to errors, the system will display "Not sent" in the timestamp column, indicating when it was supposed to be sent	Low - Improvements provide better tracking	HLP-10258	INSIFE-HALOPV-SS-39
System Config	Enhancements to Correspondence Email Selection	Expanded Email Selection: Users can now select email recipients beyond HALO users from a preconfigured list of external recipients. Preconfigured Recipient List: A linked external partner email list (from the Entities module) is now available in the correspondence email dropdown. Email Groups: Users can now create email groups containing multiple email addresses for easier selection in the correspondence workflow. Multiple Recipients Selection: Users can now select multiple recipients at once instead of adding them one by one. Email Format Validation: HALOPV will validate email formats while configuring new email addresses to prevent errors.	Medium - improvements reduce manual errors, enhance compliance and streamline the process of sending correspondences to multiple recipients, including external partners	HLP-9197	INSIFE-HALOPV-SS-39
System Config	Template Placeholder updates	Field is now added under Template placeholder where user can add the template requirement description	Low- there is no impact on functionality.	HLP-8780	INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
System Config	Workflow Configuration Updates	User is now able to set the by default display of the completed records and In workflow records for the Worklists. User is also able to set the by default configuration for 'Show Last' as well.	Medium-Configuration is added on create/edit workflow tasks.	HLP-7822	INSIFE-HALOPV-SS-39, Insife HALOPV Functional Requirement Specification - INSIFE-HALOPV-FRS-17
System Config	UI update to sort Revision number	Enhancement Under Attachment section, Revision number is now sorted in ascending order.	Low- There is no impact on functionality	HLP-7754	*
System Config	Related Record Timestamp Addition	Under Related record section for any record, a new column 'Related Record Created' is added to display the time when the related record is created.	Low - there is no current functionality, a new column is added.	HLP-7531	INSIFE-HALOPV-SS-39
System Config	Updates on User Information Page	Some organizations have multiple entities and users are now can be assigned in different workflows and entity types. Entity Type and Entity Workflow columns are added to Organizational data view access under User Information.	Medium-Implemented new columns on user information page.	HLP-7432	*
System Config	Correct Login Behaviour for ENTER Key Press	Pressing ENTER after entering credentials now trigger the Log In button instead of attempting SSO	High – Impacts the login behaviour	HLP-7239	*
System Config	Enhancement: Display whether a Role is Read-Only	Added a new column under User Settings > My roles to display whether a role is Read-Only or not. The column indicate "Read-Only" as Yes or No based on the role permissions	Low - Ease of allowing users to identify their access levels	HLP-11173	INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Submissions	Introduction of FDA R3 Submissions	Implemented the generation of FDA R3 XML from HaloPV to ensure compliance with FDA regulations, utilizing the required fields.	Medium - Introduction of ability to generate FDA R3 XML	HLP-11267	INSIFE-HALOPV-AUTOMATIONS-170
Submissions	Introduced new column OBS in Worklist	In Submission worklist, a new OBS column has been added. This column displays an exclamation mark when a record is failing or stuck in an automation step.	Low – Addition of a column	HLP-7693	INSIFE-HALOPV-SUBMSN-TDS-421
Submissions	Stop Workflow on XML Generation Failure	If GOM_GET_XML_R3 or GOM_GENERATE_R2 fails during XML generation, the submission record will now stop at the generation step instead of continuing through the workflow. Error messages will be logged in WF history and the application log.	Medium - easier debugging and issue resolution	HLP-5774	*
Term Collections	Product Term Collections	Collections of WHO Drug Dictionary terms at any level can be created and saved as Custom Drug Groupings (CDGs)	New feature	HLP-11505	INSIFE-HALOPV-TERM-COLLECTIONS-TDS-859_V1
Term Collections	WHO Drug Builder	Analogous to the MedDRA Tree Builder, a WHO Drug Builder supports exploration and selection of products from WHO Drug, including Standard Drug Groupings (SDGs), for inclusion in Custom Drug Groupings (CDGs).	New feature	HLP-12294	INSIFE-HALOPV-TERM-COLLECTIONS-TDS-859_V1
Term Collections	Product Term Collection Content Report	A report displays the content of Product Term Collections whose workflow is complete.	New feature	HLP-11617	INSIFE-HALOPV-TERM-COLLECTIONS-TDS-859_V1

***This ticket does not require an update to System Specification/ Design Specification.**

5. Bugs resolved in HALOPV 6.1

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Aggregate Reporting	Aggregate report Case per line dimension update	Fixed columns Events Nonserious D1 & Event Nonserious Pt D1 in the case per line dimension. These columns will now consider all events where all serious fields are either No or Null.	LOW - Update in logic of existing columns	HLP-12189	INSIFE-HALOPV-OOB-ICSR Case LINE View-SPEC-1122
Aggregate Reporting	Updated logic of column CASE INTAKE ID in aggregate report dimensions	Fixed the logic of the column "Case Intake Id" in the revision per line, case per line and event product per line dimensions. This column will now correctly display the Master Id of follow-up and duplicate records linked to an ICSR record.	LOW - Update in logic of an existing column	HLP-10961	INSIFE-HALOPV-OOB-ICSR Case LINE View-SPEC-1122, INSIFE-HALOPV-OOB-ICSR Event Product Line-SPEC-715
Aggregate Reporting	The Update to include Missing Options in Causality Field Dropdown in Structured Output Line Listing	Fixed an issue where causality in the ICSR is "possibly", "probably" and "defiantly related" and where the causality is missing, which was preventing cases with these classifications from being included in the Aggregate Reporting template line listings.	Medium - Cases with missing causality assessment options were prevented from being included in line listing.	HLP-10097	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Aggregate Reporting	Updated data truncation in downloaded PDF output in Aggregate report dimensions to be more consistent.	Fixed/ Added a new option Custom which will allow user to use A2 page size while downloading data dimension output in PDF format.	LOW - This is a new option to download report data. No change in actual data.	HLP-3894	INSIFE HALOPV SS-39
Case Intake and Processing	Drug Override Fields Set to Read-Only	Following fields are now read-only to prevent user edits 1. Selected Drug Name (override) field on Relevant Drug Past History of the Parent 2. Selected Product Name (override) on Products 3. Patient Past Drug Name (override) on Past Drug History	Low - Fields are made non-editable	HLP-12255	*
Case Intake and Processing	Fix for Product Recoding Issue	Fixed an issue where recoding a product from Specific Pharmaceutical Product (PhPID) to Specific Medicinal Product (MPID) was not working, leaving the product coded to PhPID. Recoding now functions as expected.	Medium - Product was not recoded from PHPID to MPID	HLP-12124	*
Case Intake and Processing	Preserve Data When Closing Side-by-Side Document View	Users can now close the side-by-side document view without losing any entered data in the data form.	High - Data was lost while the side by side view was selected.	HLP-11633	*
Case Intake and Processing	Display of “Unblinded” in License Column	An inconsistency was identified where the “License” column did not display “Unblinded” as the datasheet and product name columns on the Event Listedness and Datasheets page.	Low - Display issue	HLP-11190	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing	Fix for MedDRA Version Overwrite in Diagnosis Tab	An update to the MEDDRA_CODING package ensures that the manually selected MedDRA Version on the Diagnosis tab of the Narrative page in the ICSR workflow is retained after submission.	Medium - System now retains the MedDRA version selected by user	HLP-11952	*
Literature	Fixed Issue with "Open Location" Button on Safety Information Review form	The button now correctly navigates to the stored location of the literature article.	Medium - Fixed the navigation issue of the button	HLP-11576	*
Products	License is added to Product worklist	License which are deactivated are not displayed in Product worklist now.	Low- Query update to not display the nullified licenses in product worklist	HLP-11683	*
System Config	Master Description is set to 4000 characters	Master Description is set to 4000 characters to prevents the linked or child record from being opened.	Low- As description varchar2(2000) updated to description varchar2(4000) in query.	HLP-11342	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
System Config	Audit log captures the information on adding new workflow task.	Bug Fix to ensure that Audit trail captures information on adding new workflow task which was missing earlier. New column 'WF_TASK_CONDITION' is added to table GOM_WF_TASKS_TEMP_AUDIT and In the trigger TRG_GOM_WF_TASKS_AUDIT entry of column 'WF_TASK_CONDITION' is made for insert and delete.	Medium - Information about missing workflow task added	HLP-11332	*
System Config	Fix for Workflow Task Save Error	Resolved an issue encountered in the "Application Management > Process Workflow" module where adding or updating workflow tasks in a newly created workflow resulted in an error.	Medium - Prevents errors during task creation or updates in workflows	HLP-11707	*
System Config	Task Notification Update	System is updated to send the notification on Create or on Complete of a workflow task for one specific record on selecting backend setting.	Medium - code for custom notifications from backend is added.	HLP-8524	INSIFE-HALOPV-SS-39
System Config	User List File name update	When user downloads user list from User Administration, the name of the downloaded file is now updated to 'User List' by default.	Low- Its just name update of the downloaded file and there is no impact on functionality	HLP-8391	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
System Config	Fix for Notification Issue Due to Special Characters	Fixed email notification failure caused due to special character ".".	Medium - Ensures all notifications are delivered	HLP-6102	*
Term Collections	Disallow term collections with the same name	Validation check prevents completing the workflow if a medical event term collection does not have a unique name.	Low	HLP-11585	INSIFE-IMS-HALOPV-MODULE-STD-CFG-SPEC-TMPL-441_V1

***This ticket does not require an update to System Specification/ Design Specification.**

6. Configuration updates

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	Introduction of states for country US	Implemented the list of states for country US to appear for Reporter states field.	Low - Addition of states configuration	HLP-12258	*
Case Intake and Processing	Renaming User groups	Renaming the following user groups: 1. Local ICSR handling to Local case handling 2. Local ICSR management to Local case management 3. ICSR Case Processing to Case Processing 4. Generic ICSR processing to Generic case processing 5. Central ICSR management to Central case management 6. Signal Assesor to Signal Assessor 7. Study List Data Owner to Study List Data Owner	Low - Only user groups names that appear in HALO have been changed. No impact on their functionality.	HLP-11629	*
Case Intake and Processing	Renaming Core Processes	Renamed the following Core processes: 1. ICSR (Medicines incidents) to Case Intake and Processing 2. PSMF to PSMF Management 3. Risks to Risk	Low - Only core processes names that appear in HALO have been changed. No impact on their functionality.	HLP-11627 HLP-11625	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Case Intake and Processing	Renaming the Workflows	Renamed the following workflows: 1. Aggregate reporting process (Ad-hoc) to Expert Reporting (Ad-Hoc) 2. ICSR Processing to Case Processing 3. ICSR Follow-up Ingestion to Follow-up Ingestion 4. ICSR Manual Intake to Case Intake - Manual 5. ICSRs Refuted to Refuted Cases 6. ICSRs Duplicate to Duplicates 7. ICSR intake - XML to Case Intake - XML 8. DSUR Process to DSUR 9. ICSR Follow-up Queries/Correspondence to Follow-up Queries/Correspondence	Low - Only workflow names that appear in HALOPV have been changed. No impact on their functionality.	HLP-11626	*

Case Intake and Processing	Configuration Updates	The following configuration updates are made to the Case Intake and Processing: Changes for Case Intake - Manual Workflow: 1. Renamed the task "Upload source document" to "Upload source document/Initial Data Entry" 2. Disabled the following tasks: Extract Attachment Text, Process Structured Sources, NLP Process Structured Sources, Process Unstructured Sources, NLP Narrative Processing, Process Metadata, Create File for Annotations/Redactions, Insert Annotations, Extract Annotations 3. The following task actions have been renamed for: - Duplicate search (ICSR) → Duplicate search (Case Intake) - Task relocation (Refuted ICSR) → Task relocation (Refuted Case) - Task relocation (Move to ICSR Processing) → Task relocation (Move to Case Processing) - Task relocation (Medicine Incident duplicates) → Task relocation (Duplicates) - Task relocation (Move to ICSR Follow-up Ingestion) → Task relocation (Move to Follow-up Ingestion) 4. Removed validations for Batch / Lot Number and Invalid D.2.1 value or Invalid D.2.1 format as they are not mandatory fields as per ICH. 5. The module is now restricted to the Case Intake and Processing role with the following updates: - Triage → Removed	Medium - Changes to Workflow and tasks	HLP-11597	*
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		Central case management → Renamed to Case Intake Generic case processing → Renamed to Case Follow-up Local case management → Renamed to Case Intake and Processing 6. The following workflow tasks have been renamed and updated Case Processing: Data Entry → Data Entry/Verification Auto-populate IDs → No change (Now applicable only to manual records; XML records already contain this information.) Duplicates → Duplicate → Manage Duplicates Follow-up Ingestion: Add Follow-up Information → Manage Follow-up (Reconfigured so actions can be performed in Intake workflow at Duplicate Search task.) Completed Follow-up → Disabled Follow-up Queries/Correspondence → Pursue ICSR FU Questions and Register Information → Create Query (Task instruction updated.) Literature Article Review: Review literature abstract/article and report safety info → Download Articles (Task instruction updated.) Relevant for any other PV process → Disabled Completed → Disabled Literature Monitoring (Approve) → Removed			
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Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Submissions	New Standard Message Types for Health Canada Reporting	Added New Message Types to the Code List: sapicsr – Expedite ICSRs as per guidance for Special Access Programmes camicsr – Expedite ICSRs as per guidance for Canada’s Access to Medicine Regime cticsr – Expedite ICSRs from Interventional Clinical Trials	High - Compliance with Health Canada Reporting for ICSR	HLP-3367	*
System Configuration	Configuration Updates	The following configuration updates are made 1. Rename Core Processes: Device Incident to Device Vigilance Entities to Organisational Entities Requirements Intelligence to Regulatory Intelligence Quality Management to Quality	Medium - Changes to Workflow and tasks	HLP-11597	*
Signals	Remove Redundant Workflow - Signal QA Test	Removed the redundant workflow "Signal QA Test" to streamline workflow management.	Low - removal of redundant workflow	HLP-11562	*
Term Collections and Dictionaries	Distinguished Dictionaries from Term Collections	Term Collections no longer include dictionaries in the Functionality Menu. Dictionaries appear in the left pane under “Dictionaries”	Low - simplification	HLP-11511	*
Term Collections	Simplify Medical Event Term Collections workflow	The attributes of a Medical Event Term Collection and its workflow have been simplified. The terminology has been made consistent with Product Term Collections.	Low - simplification	HLP-11506	*

***This ticket does not require an update to System Specification/ Design Specification.**

7. Features removed from HALOPV 6.1

- Support for the Internet Explorer browser was removed from HALOPV 4.0 onwards

8. Known Issues & Workarounds

Area / Process / Group	Title	Description	Workaround	Issue ID
Case Intake and Processing	Tab Navigation Experience on Page Refresh	On the ICSR Device Product page, when any tab is saved, the page displays the device Info tab briefly before switching back to the active tab.	The page automatically reflects the active tab in a couple of seconds.	HLP-10621
Products	Default Values for Device Product Creation & Upversioning	On the Product Details page, when creating or upversioning a Device Product, the Product Type and Authorisation / Visibility Type fields currently default to blank.	The user manually populates the Product Type and Authorisation / Visibility Type fields.	HLP-8751

Area / Process / Group	Title	Description	Workaround	Issue ID
Products	Territory Field Not Updating When Cloning a Product License	When cloning a Product License in the Product module, the Territory field retains the country from the cloned record, even if the user changes the Country field in the data form.	No workaround	HLP-12535
Term Collection	Return Button Behavior in IMDRF Query Builder	The Return button on Advanced IMDRF Query Builder hard closes the record instead of correctly navigating back to IMDRF Collection form.	The user manually opens the IMDRF Collection form again in the View/Edit record.	HLP-10343
Term Collections	WHO Drug Builder: Iterative opening of Level 4 folders in Selected Item Details tab's left pane generates duplicate error in debug window	In the Selected Item Details tab of the WHO Drug Builder, as you expand the folders, duplicate errors can appear in a debug window.	The messages in the debug window can be ignored. They do not impact the selection.	HLP-12735

Area / Process / Group	Title	Description	Workaround	Issue ID
Term Collections	Constituent terms of a nested CMQ are not included unless their individual scope has been set.	If you nest a CMQ inside another CMQ, the nested CMQ's constituent terms will not appear in the following places unless the scope has been set for each term: Medical Event Term Collection Content Report MedDRA Tree Builder's Selected Query Details	In the MedDRA Tree Builder, for each included term, set the Scope to Broad.	HLP-12797 HLP-12792
Term Collections	Term Collection Content reports, when downloaded, include an incorrect title	When downloading the Product Term Collection Content Report or the Medical Event Term Collection Content Report, the title within the report reads "Approved Term Collections PT Report"	If the downloaded format supports editing, modify the title of the report yourself.	HLP-12912
System Config	Master Search Limited to 9 Characters	The Master Search functionality is currently restricted to 9 characters, preventing users from finding records with 10-character identifiers.	No workaround	HLP-12776
System Config	User Review Report Showing Incorrect Data	The User Review Report is only considering users with User Organization linked to a specific entity. It excludes users with Data Access to that entity.	No workaround	HLP-12877

***This ticket does not require an update to System Specification/ Design Specification as these are known issues to be addressed in the next release.**

9. Contact

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