

**Insife HALOPV 6.0 Release Notes  
Final  
Version 1.0  
Department: Product Management**

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# 1. Overview

HALOPV 6.0 is a major release that builds on the features of HALOPV 5.1, incorporating enhancements from patches 5.1.1, 5.1.2, 5.1.3, and 5.1.4. 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 6.0 is eligible for upgrade from HALOPV 5.1 installations with patches applied up to version 5.1.4, and it can also be deployed as a standalone full installation.

## 3. Compatibility

HALOPV 6.0 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 HALOPV 4.0 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 124, and Edge was on version 124.

## 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, Clinical Trial Management, ICSR, Signal Management, System Config	Removal of CLOSE - X button	Updated the Record Creation and Forms page of HALOPV, the option to Hard Close a form (using top right X button) has been removed, users can now use the HALOPV implemented Close button or Return button to move away from a form. This change will prevent accidental Record lock.	Low - This feature was a duplicate option to hard close a form which causes a record to remain lock.	HLP-9830	*
Aggregate Reporting	Multi-Select in Searchable List Box for Aggregate Reports	Fixed the functionality for users to be able to select multiple values from a searchable list box in the Aggregate Report configuration without closing the list box.	Low - Enhancement to existing functionality	HLP-9306	*
Aggregate Reporting, ICSR, Risk Management, Signal Management, System Config	Unlock locked Records	Updated HALOPV to allow Admin users to unlock a locked record. The feature can be used only by users having "User Lock Manager" role and when a record is locked by another user.	Low - This is a change to allow admin user to change state of a record.	HLP-8469	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Aggregate Reporting	Updated ICSR_EVENT_PROD UCT_LINE in HALOPV 6.0 uses new dimension for ICSR_EVENT_PROD UCT_LINE having separate columns to display all values and only distinct values. Users can now select which one to include in their reports.	Only show distinct values for list aggregations in the event-product Aggregate report	Low - This column is adding a new column to display Distinct values while keeping the existing values in existing columns	HLP-8201	INSIFE-HALOPV-OOB-ICSR Event Product Line-SPEC-715

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Aggregate Reporting, ICSR, Signal Management, System Config	Configurable PII condition to hide a field at Local or Global Level	<p>Added a new configuration at ICSR Fields, the fields can now be configured to Show/ Hide based on Local (country specific) / Global rules.</p> <ol style="list-style-type: none"> <li>1. The rule will restrict the users without "Privacy data access" role to view/ access the fields.</li> <li>2. The configuration can be made at Entity Level.</li> <li>3. The Configuration can be applied for all Patient Details/ fields and below fields of Reporter Details - <ul style="list-style-type: none"> <li>Reporter first name</li> <li>Reporter Middle Name</li> <li>Reporter last name</li> <li>Reporter Address 1</li> <li>Reporter Address 2</li> <li>Reporter city</li> <li>Reporter state</li> <li>Reporter postal code</li> <li>Reporter phone number</li> <li>Reporter fax number</li> <li>Reporter email address</li> <li>Reporter institution</li> <li>Reporter Department</li> </ul> </li> </ol>	Medium - This is a new configuration to hide or show a field, there is no impact on data. However, its accidental exposure of PII is a risk.	HLP-8692	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39

<p>Aggregate Reporting</p>	<p>Aggregate Reporting Enhancements</p>	<p>With the release of HALOPV 6.0, the Aggregate Report feature has been revised to improved efficiency, expand data inclusion and new reporting options. The update introduces five key reports, offering granular insights on various aspects of Individual Case Safety Reports (ICSRs):</p> <ol style="list-style-type: none"> <li>1. ICSR Event-Product Per Line Report</li> <li>2. ICSR Submission Per Line Report</li> <li>3. ICSR Revision Per Line Report</li> <li>4. ICSR Case Per Line Report</li> <li>5. ICSR Activities Per Line Report</li> </ol> <p>HALOPV 6.0 now also supports individualized workflows for both standard aggregate reports and ad-hoc reports. The new workflows provide specific configurations for the following report types:</p> <ol style="list-style-type: none"> <li>1. Periodic Benefit-Risk Evaluation Report (PBRER)</li> <li>2. Development Safety Update Report (DSUR)</li> <li>3. Postmarket Adverse Drug Experience Report (PADER)</li> <li>4. CIOMS II Reports</li> <li>5. Reconciliation Reports (for Clinical Trials or Partner Data)</li> <li>6. Compliance/Submissions Reporting</li> <li>7. Productivity/Worklist Management Reports</li> <li>8. Expert Reporting (Ad-Hoc Reports)</li> </ol> <p>Standard aggregate reports display only the relevant fields based on the selected workflow, streamlining the reporting process.</p> <p>Key Functional Updates</p> <ol style="list-style-type: none"> <li>1. Blinded Product Inclusion: HALOPV now uses the G_K_2_5 indicator to determine if an ICSR is blinded. Blinded records will be included only when the</li> </ol>	<p>High - The enhanced Aggregate Report functionality in HALOPV 6.0 enables users to generate more comprehensive and customized reports</p>	<p>HLP-8576</p>	<p>INSIFE-HALOPV-OOB-ICSR Case LINE View-SPEC-1122, INSIFE-HALOPV-OOB-ICSR Event Product Line-SPEC-715, INSIFE-HALOPV-OOB-ICSR Revision LINE View-SPEC-1123, INSIFE-HALOPV-OOB-Line Per Activities-SPEC-1124, INSIFE-HALOPV-OOB-Line Per Submissions-SPEC-1125</p>
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Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
		<p>corresponding prompt is selected.</p> <p>2. Event Listedness: For ICSRs where any product-event combination is listed, HALOPV displays all case and revision details in the "Case per line" and "Revision per line" reports, while filtering by product-event combinations that match the listing criteria.</p> <p>3. Product Filtering: When specific products are selected, HALOPV retrieves all records directly or indirectly coded to the selected product at either the MPID or license level.</p> <p>4. License-Based Prompting: The Product License Prompt filters records coded specifically to the product license for direct matches only.</p> <p>5. Migration of Existing Reports: All previously created aggregate reports are automatically migrated to the new Expert Reporting (Ad-Hoc) workflow, ensuring continuity of existing data and reports without interruption.</p>			
Clinical Trial Management, Defective Medicine / Customer Complaint, Devices, Dictionary and Terms, Entities, ICSR	Deletion Confirmation for Data/Records	Implemented a confirmation prompt for record soft deletion across multiple pages in HALOPV to prevent accidental deletions. Users will now be asked to reconfirm before any data is soft deleted.	Low - Introduced a reconfirmation message for deletion	HLP-8743	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
Dictionary and Terms	Update to Dynamic Actions for Free-Floating PT Field in CMQ Queries	The dynamic actions for the "Contains Free-floating PTs?" field have been updated to ensure proper display when the query type is set to CMQ. The "Contains Free-floating PTs?" field is now calculated and shown for CMQ-type collections. Unnecessary dynamic actions were removed, and business-specific configurations were adjusted.	Medium - Ensures correct display of free-floating PT field for CMQ queries	HLP-10056	*
Dictionary and Terms	Support for Local Language Drug Coding in WHO Drug Browser	Enabled HALOPV to support drug coding in local languages if the record's master language isn't English and is WHO Drug-compatible. Users can search and code drugs in the local language, with fields displaying English-to-local language translations.	Low - Enhances HALOPV's versatility in non-English languages	HLP-9598	INSIFE-HALOPV-ICSR-CODING-SS-608, INSIFE-HALOPV-PROD-API-EXP-SS-539, INSIFE-HALOPV-PROD-API-IMP-SS-514
Dictionary and Terms, ICSR	Support for Local Language Coding in MedDRA Browser for Event Data	HALOPV now supports coding for Events, Patient/Parent Medical History, and Drug Indications in local languages. When a record's master language is non-English, users can code event data in local language fields. MedDRA Browser opens in the selected language with 1-to-1 mapped translations between local and English fields	Medium - Improves multi-language compatibility by adding local language coding for event-related data	HLP-9597	*
Dictionary and Terms	Fixed Column Sequence on IMDRF table	Re-sequenced the column order on IMDRF table, to improve the readability of the table.	Low-Impact as all data was present.	HLP-9363	*

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Dictionary and Terms	Non latest dictionary versions marked as non-current	Updated the previous versions of MedDRA dictionary on the version dropdown with a suffix 'non-current'.	Low - Highlighted non latest dictionaries to ensure users selects the latest version	HLP-9276	*
Dictionary and Terms	Validation Rules for Term Collections	Introduced validation rules for the following: 1. If "Scope Allowed" is set to Yes and "Algorithmic" is N/A, the "Term Scope" field must be populated for every child term in the collection. 2. If "Scope Allowed" is set to Yes and "Algorithmic" is Yes without weights, both "Term Scope" and "Category" fields must be populated for every child term in the collection. 3. If "Scope Allowed" is set to Yes and "Algorithmic" is Yes with weights, the "Term Scope," "Category," and "Weight" fields must all be populated for every child term in the collection.	Low - Enhancement to existing functionality	HLP-9237	*
Dictionary and Terms, System Config	Scroll Bar in Term Collection Worklists	Enhancement to see scroll bar at the top and bottom of the term collection workflows' worklists.	Low - User interface setting update in Apex to display scroll bar at top of page	HLP-9207	*
Dictionary and Terms	ICSR Import and Export Support for Custom Type Values in JSON	Added new feature for the ICSR import and export packages to be updated to support custom type values. The master record type (gom_process_master.master_type) is now mapped to the new JSON element MASTER_TYPE during both import and export processes, enhancing compatibility for custom types in E2B R3 JSON handling.	Medium - Added new feature to support custom type values	HLP-9120	INSIFE-HALOPV-ICSR-JSON-API-EXP-MAP-SS-584, INSIFE-HALOPV-ICSR-API-IMP-MAP-SS-279
Dictionary and Terms	Avoid auto-coding to non-current terms (MedDRA)	Auto-coding of cases via the MEDDRA_CODING package now no longer picks non-current terms in MedDRA	Low - fixed an existing issue	HLP-8998	*

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Dictionary and Terms	Automated Completion and Cleanup of Retired Term Collection Workflow	<p>1. Streamlined Workflow Completion: Once a query is retired, both the Request Term Collection and Retired Term Collection workflows will be automatically completed. The "Complete Task" button will no longer be displayed, and the retired query will be locked, making it read-only to prevent any further updates.</p> <p>2. Assignee Fields Cleanup: Upon completion of the workflow, the following fields in the Retired Term Collection worklist will be cleared for the retired query:</p> <ul style="list-style-type: none"> <li>- Assigned to</li> <li>- Assignment Date</li> <li>- Other Assignees</li> <li>- Other Assignees (Assignment Date)</li> </ul>	Low - improves workflow efficiency by automating the completion of related tasks upon query retirement	HLP-8775	*
Dictionary and Terms	Integration of Latest IMDRF	Introduced new dictionary browser IMDRF Annex A to Annex G	Low - New functionality	HLP-6829	INSIFE-HALOPV-IMDRF-BROWSER-TDS-920
Dictionary and Terms	Term collections - Remove Entity specific lists ID's	Term collections - Remove Entity specific lists ID's from the core product.	Low - Data fix only	HLP-9185	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
ICSR	Event listedness and datasheet updates	Updated "Event listedness and datasheet", now users can use the new workflow "Summary of Product Characteristics Records" to create product characteristics which can later used in selectable list while entering "Event listedness and datasheet". Further button "Autocalculate" renamed to "Auto-labelling"	Low - Enhancements in existing functionality	HLP-10554	INSIFE-HALOPV-ICSRs-TDS-410, Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR	Updated the Sender's and Case Info > Case Safety Report tab to hide the Korean and Chinese section.	Hide Fields from Sender and Case Info tab	High - Removal of fields	HLP-10089	*
ICSR	ICSR - Submission Scheduling Rule Analysis	Created a new report "Submission scheduling rule analysis" available as tab for ICSR's eligible for submission. The report display HALOPV analysis of submission rule on ICSR products with respect to selected destinations.	Low - This change is to display a new report.	HLP-9933	*
ICSR	Enable Reason for Nullification	The field "wf_notes_switch" was updated for requirement intelligence workflows to enable the reason for nullification.	Low - Enabled a field	HLP-9909	*
ICSR	Enhanced Patient Age Calculation	Updated logic for patient age calculation when date of birth is provided but no reaction start date reported then null flavor MSK is populated in date of birth field and age calculated based on date of initial report submission.	Low - Patient Age Calculation	HLP-9659	*
ICSR	Enhancement for Datasheet Name Field - Event Listedness and Assessment	The Datasheet Name field on the Event Listedness and Assessment page has been enhanced from a free-text field to a dropdown. The new dropdown contains a predefined list of datasheet names depending on the configuration within the summary of product characteristics workflow	Low - New feature adding pre-defined datasheet to the event listedness screen	HLP-9625	*

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ICSR	Attachment Names of a Correspondence record to appear in "Correspondence and alerts" section of parent record	Updated "Correspondence and alerts" section of a record to display the Titles of attached files. The grid now reflects real-time changes to attachment status, including adding, deleting, and updating files, even those with special characters in their names.	Low - This is minor enhancement to display an already existing data.	HLP-9541	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR, Submissions, System Config	Fix for MedDRA Selection in CIOMS and Narrative Templates	Updated the MedDRA queries to ensure proper filtering by MedDRA version and language on CIOMS and Narrative templates. Additionally, inconsistencies in how language codes are stored (2-character vs. 3-character) were addressed.	Low - Fixed the filtering on CIOMS and narrative templates	HLP-9444	*
ICSR	Updates to ICSR_CODING Package, WHODD Enhancements, and APEX Page Changes	Enhancements were made to the ICSR_CODING package. The WHODD_LOAD_ROOT package was optimized to improve search speed and add support for non-unique KR MPID/IDF JP Code lookups.	Low - Enhancement to WHO DD.	HLP-9411	INSIFE-HALOPV-ICSR-CODING-SS-608

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
ICSR, System Config	C.1.1 - Sender's (case) Safety Report Unique Identifier - Standard and Configurations update	<p>HALOPV Updated to make "Sender's (case) Safety Report Unique Identifier (C.1.1)" and "Worldwide Unique Case Identification (C.1.8.1)" population using Standard Configuration or Custom Configuration in below order -</p> <ol style="list-style-type: none"> <li>1. HALOPV will retain the values received while importing the ICSR.</li> <li>2. If Blank - HALOPV will populate C.1.1 and C.1.8.1 using -               <ol style="list-style-type: none"> <li>2.a. Client Configuration</li> <li>2.b. HALOPV Standard Configuration</li> </ol> </li> </ol> <p>Added setting to disable overwriting of C1.1. and C.1.8.1 field if the value does not match ICH format.            Added setting to add a reference in C.1.9.1.R block if C.1.1 is overwritten</p> <p>HALOPV Standard Configuration will populate these using ICH Guidelines, which means -</p> <ul style="list-style-type: none"> <li>-- It will be of three parts separated by '-'               <ol style="list-style-type: none"> <li>1. 2 digit Country code as per ISO 3166 - will be picked from Primary reporter &gt; Event Occurrence Country</li> <li>2. Company identifier - its a Config value in HALOPV</li> <li>3. Report Number - HALOPV Record Master ID</li> </ol> </li> </ul>	Medium - C.1.1 is widely used to uniquely identify a case and should be populated correctly.	HLP-9346	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR	Patient and Parent Race field type updated to Multiselect	Updated Patient and Parent Race fields, this fields now supports multiple values, further new values as per FDA Guidelines added to the list of values.	Medium - Field type updated from Single select to multi-select.	HLP-9309	INSIFE-HALOPV-ICSRs-TDS-410

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
ICSR	Display "Validation Issues" at ICSR/ Submission Worklist	Updated HALOPV ICSR and Submission Worklist to display a new column "Validation Issues", the column will display "Yes" - When there are open validation issues at an ICSR/ Submission, else it will display "No".	Low - This is addition of a new calculated column at worklist, has no impact on data.	HLP-9213	*
ICSR	Changing Study or Study ARM for an ICSR with data	If the Study and/or Study Arm is changed in the ICSR by a user, HALOPV will remove existing Study Products from the ICSR and replace them with the Study Products per the new Study selection. The system has been updated to now display a message box for the user to confirm that the existing Products will be replaced, or to cancel the activity.	Low - This change is to give flexibility to the users, to proceed with existing implementation or retain the data.	HLP-9089	*
ICSR	Parent Case Not Up-versioning After Manual Merge	ICSR up-versioning has been updated to handle ICSR post follow-up merge. HALOPV will now allow user to up-version/ create new revision of an ICSR post follow-up merge.	Low - This was an issue fixed in existing functionality.	HLP-8993	*
ICSR, System Config	New Logic for QC Checklist with Configurable Actions	The QC change page (page 2) now supports a configurable list of QC check questions / checkboxes to be defined for each QC (configurable per workflow task)	Low - The changes are mostly additive, involving configuration updates and minor logical checks	HLP-8977	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR	New automation allowing overwrite of original c.1.1 in imported XMLs	Automation allowing forced update of c.1.1 with HALOPV identifier (old identifier pushed to "Other identifiers"). To utilize the automation, add it to the workflow in the desired workflow step - i.e., after duplicate search (during duplicate search it might be desirable to have the original c.1.1 value in the case).	Low - No impact on existing customers. The automation is optional (added via workflow configuration)	HLP-8892	*



Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
ICSR, Products	Enhanced Drug Coding Functionality with IDF JP and WHO Drug Browsers Support	The HALOPV system has been updated to enable seamless drug coding in both Japanese (IDF JP) and English (WHO Drug) dictionaries based on record language. Users can select coding languages, access the appropriate drug browser, and search for drugs using predefined local language.	Medium - This enhancement improves multi-language coding workflows.	HLP-8841	INSIFE-HALOPV-ICSR-CODING-SS-608, INSIFE-HALOPV-PROD-API-EXP-SS-539, INSIFE-HALOPV-PROD-API-IMP-SS-514
ICSR, System Config	The "Score review" intake (Metadata intake) is updated to support CLOB sized values	Updated Metadata intake (used for intake of unstructured source data - i.e., NLP/AI extracted information) now support narrative fields above 4000 characters.	Low - Update to existing field type.	HLP-8617	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR	Pending Action Filter on Status Icon for ICSR Record Tabs	Introduced a feature where users can now click on the red validation status icon for any ICSR record tab to view specific issues on that data form. When clicked, the system will display a "Pending Action" popup, filtered for the respective tab. Users can switch between tabs and see the corresponding filtered pending actions. The existing "Pending Action" button will continue to display the unfiltered list.	Low - Introduction of pending action filter for validations	HLP-8585	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR	Score Review Screen and Metadata Enhancements	Updated the score card feature: 1. Unused score columns have been hidden 2. Color coding has been updated for better user experience	Low - Update to existing functionality	HLP-8517	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
ICSR, System Config	Enhanced Email Processing and Automation in Azure Mail Integration	<p>1. Email Integration Updates:</p> <ul style="list-style-type: none"> <li>- Simplified Azure Mail processes and improved mailbox handling.</li> <li>- Added support for specifying sender addresses and blocking "noreply" replies.</li> </ul> <p>2. Recipient and Template Support:</p> <ul style="list-style-type: none"> <li>- Enhanced multi-recipient and template functionality for emails.</li> <li>- Added attachment uploads and dynamic template generation.</li> </ul> <p>3. Auto-Reminder Feature:</p> <ul style="list-style-type: none"> <li>- New auto-reminder process automates sending reminders based on configurable criteria.</li> </ul>	Low - Enhancement to existing functionality	HLP-8335	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR, Requirement Intelligence	ICSR / Device requirement Details form - Reporting Criteria Updated	<p>Updated ICSR / Device requirement Details form to remove few Old retired fields in the reporting criteria:</p> <ul style="list-style-type: none"> <li>-- Casualty (Relatedness) – Following reporting criteria has been removed</li> <li>---- Exclude Unknown/unrelated reports from study source</li> <li>-- Basic Info – Following selection criteria has been default to "Yes" and Null value selection has been removed.</li> <li>---- Is submission of expedited reports required?</li> <li>-- Product Criteria – Following selection criteria has been removed, Null value selection has been removed and Updated Default selection to first option.</li> <li>---- Schedule on licenses with the same ingredient</li> </ul>	Low - Removed retired fields from the page.	HLP-8305	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
ICSR, System Config	D.2.1 E2B ID is added to Date of birth label in patient's tab	Updated the E2B ID '(D.2.1)' to the Date of Birth label on the Patient tab. Users now able to see the tag D.2.1 in label of date if birth.	Low - only User Interface label update	HLP-7526	*
ICSR	AI Term Extraction Status Note for NLP Processing	Introduced a new feature which adds a note for users when no terms are extracted by AI during NLP processing. If no entities are identified, the message "The AI could not find any terms to extract from the narratives" will be automatically recorded in task notes	Low - Added new feature	HLP-3988	*
ICSR	Field Additions for Multiple Features	Several fields have been added to support various functionalities, including local language translation, Japan-specific requirements, combination products, devices, and action items. These updates enhance the system's capabilities in managing a wide range of product and regulatory scenarios.	Medium - Various field additions on different forms on ICSR	HLP-9360	INSIFE-HALOPV-ICSRs-TDS-410
ICSR	Introduction of Action Items feature in HALOPV	Introduced a new feature to create action items in HALOPV to provide the user with an ability to track/take appropriate action on a record.	Low - new functionality	HLP-8867	INSIFE-HALOPV-ACT-ITEM-HANDLING-SPEC-1025

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ICSR	Language Translation Functionality	<p>Implemented language translation functionality across multiple ICSR pages, including mapping and synchronization of LOVs and number fields. The toggle button enables seamless switch between the local language and English, and vice versa.</p> <p>User can use the functionality menu "Translate ICSR" to translate an ICSR in local language in one go.</p> <p>Note -</p> <ul style="list-style-type: none"> <li>-- Local languages can be set only once for an record and cannot be updated once saved. Also only users with "Local ICSR management" role can set local language for an ICSR.</li> <li>-- Translation functionality is not available for Device specific pages in HALOPV 6.0</li> <li>-- As standard configuration "Translate ICSR" functionality issue will be available only for ICSR in "ICSR Processing" workflow and at "Process ICSR Information" workflow step</li> </ul>	Medium - Introduction of local language translation	HLP-8854	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39, INSIFE-HALOPV-ICSRs-TDS-410
ICSR	Introduction of Side-by-Side view feature	Introduced side-by-side PDF viewing with Apryse annotations across multiple pages Added support for extracting and saving annotations and redactions using Lambda functions, with enhanced metadata synchronization between HALOPV and annotated PDFs.	Low - New Functionality	HLP-8788	INSIFE-HALOPV-SBS-View-SS-1018

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ICSR	Addition of forms and fields for medical devices and combination products	Introduced various forms relevant for medical device reporting and combination products on the different tabs of the ICSR form - Reporter, Events and Products.	Medium - Introduced forms for processing medical devices and combination product records.	HLP-7548	INSIFE-HALOPV-ICSRs-TDS-410, Insife HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR	Updates for Case Intake and follow up	Updated the Intake and Follow-up workflow: <ul style="list-style-type: none"> <li>MANUAL Keyword is added for a record created from ICSR Manual Intake Workflow</li> <li>For records in either ICSR Follow-up Ingestion or ICSR Follow-up Queries/Correspondence: The type of the link and optional tag will always display Follow-up</li> <li>For records in ICSR Duplicates workflow: The type of the link and optional tag will display Duplicate</li> </ul>	Low - Changes impact the linking of record and keywords added for Intake and Follow-up workflow	HLP-8950	*
ICSR, System Config	Auto-Population of Substance Data for Suspect Products	An issue was reported where substance data was not automatically populated when a suspect product was coded in the case. The configuration was updated by enabling the feature that auto-populates the ingredients from the coded suspect medicinal product into the Substance tab. Note - Clients need to choose if they want this enabled per default	Medium - Substance data was not populated for the coded product.	HLP-10325	*
PSMF Management	Enhanced Word File Merging	Word file merging has been enhanced to support placeholders, improving the flexibility and accuracy of merging.	Low - enhancement enables HALOPV to merge files into specific document sections	HLP-8318	*

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Requirements Intelligence	Delta Transfer Logic Update for Record Versioning	Implemented delta transfer logic to synchronize record versions across systems. Now, if new information is available, records are up-versioned automatically, ensuring alignment with system revision numbers.	Low - Record versioning was not displayed properly	HLP-10266	*
Requirements Intelligence	Removal of "Solicited - Drug" from Type in Requirements Intelligence Module	Removed the option "Solicited - Drug" from the Type field in the Requirements Intelligence module for ICSR and device reporting requirements.	Low - Removal of Drug Type field	HLP-10212	*
Requirements Intelligence	Enhancements to ICSR/Device Reporting UI for Post-Marketing and Clinical Workflows	New fields have been added to the UI for ICSR/Device reporting requirements in the Records workflow for both Post-Marketing and Clinical devices. Updates include checkboxes for Seriousness/Health Impact criteria, a new section for Listedness (expectedness)/anticipatedness, and modifications to existing fields	Medium - Enhances user experience by adding critical fields for device reporting	HLP-9925	*
Signal Management	Logging the Signal JSON, the JSON is too large to log + Change in the way Safety Topics are counted	Change the way HALOPV Log the Safety topics using Signal Inbound JSON, this was done to manage the over size JSON's, also there is a change in method to count Safety Topics	Medium - Change in counting the safety topics for Signal analysis	HLP-9470	*
System Config	User Performance Metrics Report	Added the User Performance Metrics report to the Dashboards menu configuration. The report lists the names of users and the tasks assigned to them over 7-day, 30-day, and 90-day periods. It also includes the percentage of tasks completed late if deadlines are not met	Low - Report is added to Dashboards	HLP-10352	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
System Config	"All Time" option added to "Show Last" dropdown	Updated "Show Last" dropdown to add "All Time" option, users can use this to see records of all date range (Other filters will remain applied). HALOPV will confirm user action for this.	Low - New option added to existing feature, just to filter records.	HLP-10043	*
System Config	Enhanced Record ID Accessibility on Summary Page	Improved the user experience by making the record ID easily accessible on the Summary page in HALOPV. Users no longer need to click on the record revision number to view or copy the record ID. The record ID is now prominently displayed near the "About" section on the Summary page, allowing users to quickly view and copy it using new Copy Icon.	Low - Improved the existing functionality	HLP-9690	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	Display Last Worked User for Each Record Revision	Improved the User Visibility in Revision Popup, users can now see the username of the last person who worked on each revision of a record directly within the Revision popup. This enhancement eliminates the need to open previous records to check work logs.	Low - Enhancement to existing functionality	HLP-9688	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
System Config	Multi-Record Viewing	<p>1. Simultaneous Multi-Record Access: Users can now open and compare multiple records from different workflows.</p> <p>2. Isolated Record Updates: Each record can be updated independently without affecting others.</p> <p>3. Precise Audit Logs: HALOPV accurately logs updates for each record, maintaining a clear audit trail.</p> <p>4. Open new tab from search results: User can not open a record in new tab from search results using button "Open in new tab". This will help users to open and work on multiple records from search results.</p> <p>Note - If a user opens a record from Session 1 and then try to open the same record from another Session 2, the record will be visible (for view only) as it remains Locked from Session 1.</p>	Low - Enhancement to existing functionality	HLP-9685	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	Persistent Search Results	<p>1. Persistent Search Results: After performing a global search, users can now retain and revisit their search results without needing to re-run the search.</p> <p>2. Multiple Record Exploration: Users can open and explore multiple records from the search results</p>	Low - Enhancement to existing functionality	HLP-9683	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	Ability to display Announcement to users	<p>Added the ability to configure and display announcements, announcements can be added by Application Manager for users of their "Tenant" by Adding a new System Configuration using below details -</p> <ul style="list-style-type: none"> <li>- "Parameter" = "Announcement"</li> <li>- "Key" = "Enabled", can be removed to hide it.</li> <li>- "Value"= is the message you want to display</li> <li>- "Description" = Help text</li> </ul>	Low - This is a display-only field at Home page, no impact on other data.	HLP-9641	*



Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
System Config	Enhanced Restrictions on "Create Related Records" to Prevent Incorrect Record Linkages	To reduce errors in record creation on Page 136, we've made relation type and workflow fields read-only, similar to the Core Process configuration. This prevents users from unintentionally altering critical link information.	Low - This update minimizes user errors in creating linked records by enforcing consistency in relation type and workflow settings.	HLP-9548	*
System Config	UI Enhancements for Term Collections: Improved Column Headers and Button Labels	<ol style="list-style-type: none"> <li>1. Updated Column Header: Renamed "File," "File1," and "File2" to "View Online," "Download," and "Edit".</li> <li>2. Button Labeling: The "Edit" button is now correctly labeled as "Review" to match its functionality.</li> <li>3. Conditional Button Visibility: "View Online" and "Edit Online" buttons are hidden when no file is attached or for file other than PDF and DOC</li> </ol>	Low - UI Enhancements	HLP-9437	*
System Config	Addition of manual record classifications using keywords	Updated HALOPV Tags and Keywords feature, with this update classifications can also be added to a record manually by a user.	Master record features	HLP-9434	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	Add Related Records - Filtered list of available "Core Process" and "Workflow"	Updated the selection logic on Page 136 to ensure users only see and select Core Processes and workflows where they have 'create' access. Users can now create related records only in permitted workflows.	Low - This update is to filter the list of values while creating a related record.	HLP-9425	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	Record Revision Timestamp to have Modified Date	Updated Record Revision popup, HALOPV now displays Modified date along with Created Date for each revision.	Low - This is display only, just added a new column to UI.	HLP-9303	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
System Config	Dropdown change at Form Dataelement link form	Update Dropdown type at Form Dataelement link form, users can now use "search as you type" feature to search quickly.	Low - This is enabling a new feature on an existing Dropdown tool.	HLP-9215	*
System Config	User Role Description Added	Added description to user group roles, this will help user admin to identify a role required easily.  NOTE - Role description has been added only to user groups which are used in Workflow/ Workflow tasks or in Functionality menu.	Low - Just added description to the existing roles.	HLP-9176	*
System Config	UI Refinement for Linked Records	UI Refinement for Related/ Associated records - - Removed the Associated records section. Users can view the associated records at the related records grids. - Hide the Correspondence records section when there are no correspondence for the records.	Low - UI Refinement	HLP-8964	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	Default Options in Global Search	Update in Global search, users can now configure Global Search for a default selection of Process/ Module and Sub Process / Workflow at Entity level. This configuration will work only when user invokes Global search form Home page, if invokes Global Search from within a module HALOPV will populate the respective Process and Sub Process as default selection.	Low - This update is to allow configuration of Global Search default selection at Entity level.	HLP-8399	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
System Config	Working files (Sharepoint integration) now supports use of environment- and module specific folder naming configuration	Updated HALOPV-SharePoint Integration, HALOPV now supports creation of subfolders (Levels) at SP. SharePoint now supports multi-level folder structure like - -- Level 1: <Environment/ ENTITY> -- Level 2: <HALO Core Process> e.g. PSMF, AGGREGATEReporting -- Level 3: <WF_RECORDPREFID-MASTER_ID> , e.g. AGG_RPT-1099057	Low - Impacts the naming of Sharepoint Folders	HLP-8304	Insife-HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	R3 XML Generation Enhancements and Fixes	Updated R3 XML generation: 1. Patient Death (D.9) section is excluded when no death details are available 2. tag corrections were made for Dosage, Dosage Unit, and EU Product Name fields to ensure accurate data representation in XML submissions	Medium - Changes for R3 generation as per EMA request	HLP-9109	*

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

## 5. Bugs resolved in HALOPV 6.0

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Aggregate Reporting, ICSR	HALO generating empty PBRRER Summary Tabulation	Fixed PBRRER Summary Tabulation to handle CLOB fields, this was causing the report to fail.	Low - This fix was to handle document generation for large data (CLOB fields).	HLP-10144	*
Aggregate Reporting	Update to include Missing Options in Causality Field Dropdown in Structured Output Line Listing	Fixed an issue to include certain options like "Possibly Probable" and "Definitely Related" from the Causality Field, preventing cases with these classifications from being included in the structured output line listing.	Medium - Cases with missing causality assessment options were prevented from being included in line listing.	HLP-10097	*
Aggregate Reporting	Fix for Incorrect Display of Case Narrative in Line Listings	Fixed an issue where case narratives displayed strange characters (e.g., &nbsp;) when generating Ad Hoc report line listings.	Low - ensures proper narrative formatting in line listings	HLP-10745	*
Clinical Trial Management	Updated Cloning and Up-versioning of study Table	Updated the cloning and up-versioning functionality, which was missing for the GOM_PROCESS_MASTER_X_STUDY_REG table. This issue caused the Study details to disappear as soon as user reinitiate the study workflow.	Medium - Study details disappeared on re-initiating the workflow	HLP-9098	*
Devices	Fix for Duplicate Record Insertion in Device Trend Report	Fixed an issue causing the ORA-00001 error during Device Trend Report initiation, due to duplicate row insertion for the same record revision.	Low - Fixed an existing issue	HLP-10307	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Dictionary and Terms	Fix for MQ Duplication Issue in Staging Schema Due to Workflow Manager Access	Addressed record duplication in the staging schema caused by workflow managers triggering last update timestamps on completed records. Updated server-side conditions on page 119 to prevent unnecessary saves, ensuring last modified dates remain consistent.	Low - Issue caused unintended last update timestamp changes by workflow managers when no actual updates are made	HLP-10727	*
Dictionary and Terms	Fix for Filter Functionality in WHO Browser (Drugs by SDG)	Filter functionality in the WHO Browser for "Drugs by SDG" has been corrected. Previously, filters like "Exact Match Only," "Preferred/Generic Term Only," "Umbrella Records Only," and "Expand to Base and Salts" did not work. Relevant page items have been added to ensure proper filtering across all tabs.	Medium - Improves search accuracy and filter functionality in the WHO Browser	HLP-10886	*
Dictionary and Terms	Fix for WHODD Load Count Discrepancy in ATC Classification	The WHODD_B_ATC_CLASSIFICATION count discrepancy has been resolved. The DEDUP_B_LOAD_TABLES procedure now includes ATC_CODE in the grouping, ensuring accurate record counts after loading.	Medium - Improves data accuracy in WHODD loads by ensuring correct record counts	HLP-9749	*
Dictionary and Terms	Change in SMQ Name Population from CVW in HALO	The process for populating MQ Term names from CVW has been updated. Instead of using the MQ Term name provided by CVW, the system now retrieves the master ID from the CVW JSON and looks up the corresponding MQ Name in HALO.	Medium - Ensures correct MQ Term names are populated from HALO based on CVW master ID	HLP-9696	*
Dictionary and Terms	Auto-Refresh for MedDRA Hierarchy Browser Query Selection	Fix has been implemented for the MedDRA Hierarchy Browser where query selections in the queries tab were not automatically refreshing the contents tab. Now, upon selecting a query, a dynamic action will force the browser to refresh automatically.	Low - Enhances user experience with automatic content refresh on query selection	HLP-9682	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Dictionary and Terms	Duplicate Rows Removed from MedDRA Impact Assessment Report	Fixed an issue where duplicate rows appeared in the MedDRA Impact Assessment Report for the same data and collection ID has been resolved. The functionality was updated to return only distinct rows, filtering out duplicates. Additionally, revisions are now correctly applied when the master_id is used as a filter. The view GOM_PAGE_327_MEDDRA_IMPACT_REPORT_MANUAL has been updated to reflect these changes.	Medium - Duplicate Data displayed	HLP-9673	*
Dictionary and Terms	Fix for Data Consistency in MedDRA Impact Assessment Reports	Resolved a data mismatch issue between the MedDRA Impact Assessment Report via two different workflows (One under functionalities on Term collection page and another under the links and activities of a particular term collection. The root cause was the all-collection report not correctly handling collection revisions. The views GOM_PAGE_327_MEDDRA_IMPACT_REPORT and GOM_PAGE_327_MEDDRA_IMPACT_REPORT_MANUAL were updated to only consider the latest collection revisions, ensuring consistent data across both reports.	Medium - Data mismatch between the same report accessed via two different workflows	HLP-9670	*
Dictionary and Terms, System Config	Status code missing at HALOPV MedDRA Query (MQ) List, Content and import API	Fixed HALOPV MedDRA Query (MQ) List, Content and import API, status code was missing in them.	Medium - SMQ's are industry standard terms and data SYNC issue may result in compliance failure.	HLP-9570	*
Dictionary and Terms	Data and data display fix for IDF Japan Dictionary	Data and data display fix for IDF Japan Dictionary to make sure HALOPV displays complete data.	Medium - Due to unavailability of index, data would not be synced correctly	HLP-9485	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Dictionary and Terms	Read only Access for completed query	Updated MedDRA tree browser to add a page level read-only setting so users can only edit if record is in workflow, not locked by a different user and not locked by other locking mechanisms (following the standard record locking principles in HALOPV).	Medium - User was able to update a completed query	HLP-9464	*
Dictionary and Terms, System Config	Update to HALOPV – HALOPV Mart ETL Job	Updated the ETL job to ensure correct revision-handling of “flattened” MedDRA queries (MEDDRA_X_COLLECTION) when transferring data between HALOPV and the HALOPV Mart.	Medium - The change affects the ETL job that transfers data between HALOPV and the HALOPV Mart.	HLP-9435	*
Dictionary and Terms	Update MedDRA Browser Procedure to Load Correct Dictionaries	Updated the MedDRA browser refresh procedure to correctly load data into the shared / common entity to ensure that all entities and organizations have access to the dictionary data in the MedDRA tree browser.	Low - The impact was limited to MedDRA Tree browser.	HLP-9427	*
Dictionary and Terms	Fix for MedDRA Hierarchy Browser LLT Popup Display Issue	An issue with the MedDRA hierarchy browser's LLT popup, where data was either not displayed or incorrectly displayed, has been resolved. A dynamic action was added to refresh the LLT popup window when SOC code changes, ensuring that only correct data, including primary links for the selected PT, is shown.	High - Improves accuracy and display of LLT popup data in MedDRA hierarchy browser by ensuring correct refresh on SOC code changes.	HLP-9409	*
Dictionary and Terms	SMQ CODE should populate instead of HALOPV MASTER_ID	Fixed MQ_DICT_OUTBOUND_APIS, to send SMQ Code instead of HALOPV Master ID for SMQ's (Standard MedDRA Queries).	Medium - SMQ's are used for analysis on case data, its incorrect SYNC may cause compliance issues.	HLP-9351	*
Dictionary and Terms	Issue with LLT's not being displayed in the browser	Fixed "MedDRA LLT terms" section to show all LLTs if no path is available and to show the SOC along with Primary flag in the grid.	Medium - LLT's were not displayed in the browser	HLP-9335	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Dictionary and Terms	Fixed Scope Filter on SMQ	Fixed Scope Filter on SMQ, to only show "narrow" items when scope set to "narrow".	Low - Impact as "Narrow" items were still selectable	HLP-9277	*
Dictionary and Terms	MedDRA Impact Assessment Report Fix and Index Enhancements	<p>1. Manual Review Tab Correction: The "Manual Review" tab in the MedDRA Impact Assessment Report has been updated to correctly filter and display rows with impact.</p> <p>2. New Materialized Views: GOM_PAGE_327_MEDDRA_IMPACT_REPORT_MANUAL_MAT is created to optimize the display and filtering of impacted rows on the Manual Review tab. GOM_PAGE_327_MEDDRA_IMPACT_REPORT_MAT is re-created to support the correct functioning of the MedDRA Impact Assessment Report.</p> <p>3. Index Management: Removed outdated indexes and added new indexes to improve performance and ensure data retrieval efficiency</p>	Medium - Improved performance and data retrieval in MedDRA Impact assessment report.	HLP-9275	*
Dictionary and Terms	Enable Validations rules for Requested Terms Collections	Enable Validations rules for Requested Terms Collections for page 251 and 291. UI validation marks have been removed from the forms, as validation rules can be configured.	Medium-Validation rules were not triggered	HLP-9274	*
Dictionary and Terms	Performance Improvement for Approved Term Collection Report	Updated to fix the performance issue with Approved Term Collection Report.	Medium - Performance improved for existing Approved Term Collection Report	HLP-9228	*
Dictionary and Terms	API Enhancement for Term Collections	Update MQ_DICT_OUTBOUND_APIS and GOM_PUSH_MQ_CONTENT to standardized to 'MQ' in the API output when a term collection is built using the Halo UI and an NMQ or CMQ is added to prevent data transfer blockages.	Low - The change involves standardizing term collection values in the API output	HLP-9227	*



Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Dictionary and Terms	Fixed PTs duplication for primary and secondary	Fixed PTs duplication for primary and secondary, where associated with multiple SOCs	Low - Compact as items were still available	HLP-9206	*
Dictionary and Terms	Data and data display fix for IDF Japan Dictionary	Data and data display fix for IDF Japan Dictionary to make sure HALOPV displays complete data.	Medium - This is just data fix, however any variance in this may cause compliance issue.	HLP-9195	*
Dictionary and Terms	MedDRA Query Scope Value need to change from Yes (Broad and Narrow) and No (Narrow only) to Y and N respectively	Fixed the MedDRA Query (Custom and Standard) Data structure at HALOPV and reflected same in HALOPV Data Mart, Now MedDRA Query Scope will use FLAG Y for Yes (Broad and Narrow) and N for No (Narrow only), this fix is done to enable HALOPV data SYNC with external system.	Medium - MedDRA Query scope is used for analysis on case data, its incorrect SYNC may cause compliance issues.	HLP-9139	*
Dictionary and Terms	Fix for Data not displaying on MedDRA tree browser	Fix on MedDRA tree browser columns which were not displaying data.	High - Data items were not searchable as not showing in the browser.	HLP-9110	*
Dictionary and Terms	Correction of MedDRA Version and Primary SOC FLAG Loading	Fixed issues with the incorrect loading of MedDRA version, Status, and SMQ algorithm attributes in the MedDRA data import process.	Medium - Correct MedDRA Version, Status and SMQ algorithm attributes were not displayed.	HLP-9064	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Dictionary and Terms	Column Name Mismatch Issue Resolved in Selected Query Tree Browser	Resolved a column name mismatch issue in the Selected Query tree browser by correcting in the HTML code and XML, where data from the "Category," "Scope," and "Weight" columns was not copied correctly when dragging rows to a different tree browser.	Low - Fixed existing data issue	HLP-8902	*
Entities, System Config	Audit log display for multiple values in a cell	Fixed display of audit logs for fields where multiple values exist in a cell. This issue was limited to display of data only for fields having multiple values.	Low - This was a display only issues	HLP-8868	*
ICSR	Update in E.i.1.1b auto population	Auto-population of E.i.1.1b - Event reported language has been updated. Previously HALOPV uses User Profile default language to populate this field, now HALOPV uses ICSR Local Language field to populate this field. Further this field is now updated to display only field and users will not be able to edit it.	Low - This is an update in existing automation	HLP-10939	*
ICSR	Fix for Event Addition in New Revision	Resolved an issue preventing event addition in new revisions	Medium - Unable to add new event in the new revision	HLP-10806	*
ICSR, System Config	Pagination implemented at Halo Attachments	Updated HALOPV attachment page, pagination has been implemented on the attachment grid of page.	Low - Pagination implemented at existing Halo Attachments page grid	HLP-10749	*
ICSR, System Config	Bug Fix for Duplicate Tags Display	Resolved an issue where duplicate tags were displayed in the About section on Page 119 by updating queries.	Low - Improved tag display accuracy	HLP-10883	*
ICSR, System Config	Fix for Privacy Fields Visibility Without Privacy Data Access Role	Resolved an issue where privacy fields such as patient initials, age, age group, and sex were visible to users without the Privacy Data Access role. These updated functionality now checks field visibility settings based on the user's role and data element configuration.	Medium - Ensures compliance with privacy requirements	HLP-10888	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR	Fix for Incorrect Sender Safety Report ID Update on Follow-Up Case Creation	Resolved an issue in the ICSR Manual Intake workflow where the C.1.1 field (Sender Safety Report Unique Identifier) of the parent case was incorrectly updated with the FUP case identifier.	Low - Fixed an existing issue	HLP-10663	*
ICSR, System Config	Attachment Access Update for Privacy Section in ICSR Form	Resolved an issue preventing users with required permissions ("Blinding flag edit," "Unblinding," "Privacy data access," and "Privacy flag edit") from accessing attachments in the Privacy section of the ICSR form.	Medium - User with right access unable to view attachments	HLP-10652	*
ICSR	ICSR Import Enhancement for Seriousness Assessment in Cases	Updated the ICSR import process, the CASE_SERIOUS field, previously read but unused. Now, if any associated event is marked as serious, the CASE_SERIOUS field in the case will automatically reflect this status.	Low - Setting the CASE_SERIOUS field to "serious" if any event in the case is serious	HLP-10603	*
ICSR	Autocalculation of E_I_6a & E_I_6b for completed ICSR	Fixed Autocalculation of E_I_6a & E_I_6b fields, now HALOPV will not autocalculated these fields if the ICSR is completed.	Low - This is a display only issue as the ICSR cannot be saved once locked	HLP-10587	*
ICSR	Fix for Revision Consistency in Multiple Tabs	Resolved an issue where multiple tabs displaying the same record showed the latest revision, regardless of selected revisions. The Return button in workflows now retains correct master_id and revision values, ensuring accurate revision display across tabs	Low - Fixed an existing issue with incorrect revision value being displayed	HLP-10577	*
ICSR	Product Selection for Blinded Studies Disabled in ICSR Create Wizard	Disabled product selection for blinded studies on page 466, ensuring correct workflow behavior.	Low - Disabled product selection on ICSR Wizard page	HLP-10415	*
ICSR, Submissions	Fix for Rechallenge/Dechallenge Inconsistencies on CIOMS Form	Resolved an issue to ensure correct Rechallenge and Dechallenge entries for products in the CIOMS form. Additionally, fixed the missing product rankings for all products in the form.	Low - Minor issues in CIOMS form	HLP-10383	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR, Submissions	Fix for Narrative Truncation in CIOMS Report Due to 4000-Character Limit	An issue was fixed where the narrative section of the CIOMS report was being truncated at 4000 characters. This led to missing content in the generated reports.	Low - Some content was missing from the generated CIOMS	HLP-10299	*
ICSR, System Config	Fix for Locked Record Hindered by Multiple Users	Fixed an issue where a second user accessing a locked record could hinder the first user (who holds the lock) has been resolved. Conditions were added to ensure that only users with the lock can perform actions that affect the record, preventing data conflicts and errors.	Medium - Ensures users holding a lock on a record can navigate subpages without being hindered by other users accessing the record.	HLP-10218	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39
ICSR	Blinded Product Handling in Event Listedness and Datasheets Tab	Fixed an issue in the ICSR case's Event Listedness and Datasheets tab (Page 643) where rows couldn't be added when the product was blinded.	Low - Fixed an existing issue	HLP-9983	*
ICSR	Aggregate Reporting Prompts - MedDRA Query and Reference Filter	Fixed Aggregate Reports prompts of MedDRA Query and Reference date filter, now users can now use these filters to filter reports.	Low - This was a fix of existing functionality.	HLP-9600	*
ICSR	Extract narrative from the XML	Fixed an issue by updating the ICSR_IMPORT_XML package to extract the narrative in the field when present in the XML.	Low - Fixed an existing issue	HLP-9471	*
ICSR	Word formatting in the document template containing "\"	Updated the GOM_FORMAT_WORD_TEXT function to ensure backslashes (\) have correctly escaped in JSON for DOCX templates, preventing template-based report generation failures.	Low - This fix is to handle a special character "\" while printing a template.	HLP-9328	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR, System Config	Event rank is empty for imported ICSR's (imported via XML)	Fixed Event and Drug rank, HALOPV will not insert Rank as per Alphabetic Sort order. These fields are not in the ICSR E2B Standard but need to be inserted to properly population of Drug Event matrices and CIOMS form.	Low - This fix is to insert Rank as per sort order.	HLP-9301	*
ICSR	Use of decoded values in List of values	Fixed XML R3 profile to use the R3 decode value if provided in List of values.	Medium - Values from XML were not defaulted to decoded values	HLP-9291	*
ICSR	Column addition to Intake and Processing worklist	Included a column Nullification/amendment to the intake and processing worklists.	Low - Addition of a column to the worklist	HLP-9235	*
ICSR	Event Additional coding information save on recoding via Quick Dropdown selector	Fixed Event Quick Dropdown selector to populate correct MedDRA Event Hierarchy when user changes the already selected event.	Medium - This may cause wrong MedDRA hierarchy to be saved with the record. Although happens only when user uses the Quick Dropdown selector to change the coded event, RECODE EVENT button is working as expected and first-time event selection is also working as expected.	HLP-9234	*
ICSR	Missing values for element G.K.4.r	Fixed ICSR_CODING.CODE_ICSR_DRUG_DOSAGE and loaded EDQM codelist to include missing dosage forms and route of admin for the element G.k.4.r.	Low - Added new values	HLP-9222	*
ICSR	Issue with C.3 sender block	Fixed the field length for C.3.4.7 (senderfaxr3) and C.3.4.6 (sendertelr3) to match allowed ICH values.	Medium - C.3.2 (senderorganization) was missing	HLP-9208	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR	Update LOV for G.K.4.R.3	Fixed GOM_GET_XML_R3 to allow the values for the element G.K.4.R.3: 10.a, {as necessary}, {cyclical}, {total}, {trimester}	Low - Added values to the allowed list	HLP-9155	*
ICSR	Performance Fix for Document Upload	Fixed a performance issues identified on Documents page when users attempted to copy or upload documents from SharePoint to the Working Files section. Some files took over two hours to transfer, and files were not being removed from the Working Files section after uploading.	Low - Fixed an existing performance issue	HLP-9028	*
ICSR	ASPR Trigger Country Code Handling for Foreign Cases	Fixed an issue where ASPRs were inconsistently triggered for foreign cases. The system has been updated to ensure that valid country codes are correctly identified in GOM_SCHEDULE_SUBMISSION_RECORDS. Cases with non-valid codes will no longer trigger inconsistencies in ASPR generation.	Low - Fixed an existing issue	HLP-8954	*
ICSR	Issue with records without timestamp	Fixed gom_process_master to ensure users are able to create records with the timestamp and the record appears in the worklists.	Medium - Few existing records without timestamp did not appear in the worklist	HLP-8943	*
ICSR	Product Blinding Status Update G.K.2.5	Fixed auto selection of product blinding status based on study selection, now HALOPV will set G.K.2.5 Set to NULL if in study it is set as NULL.	Low - This is a fix in auto selection of Product Blinding status	HLP-8901	*
ICSR	UI Label update	UI Label update on Event Listedness and Datasheets page. 'Button' Label is now removed.	Low - As there is no impact on anything on removing the label name from the page.	HLP-8862	*
ICSR	Comments on attachments	Fixed, users can now add comments for any attachment of a record.	Low - Ability to add comments	HLP-8836	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR, System Config	Downloading and Opening of XML	Bug fix to open the XML having literature reference embedded in it from the attachments.	Medium - As this one included corrupted PDF Literature in XML which was manually uploaded in the ICSR, it didn't follow ICSR Intake Workflow.	HLP-8724	*
ICSR	Attachments and Literature Section C.4.r in a clone ICSR	Fixed the issue in record cloning, HALOPV will now keep the ICSR literature reference in a cloned records. NOTE - In the cloned record HALOPV is not copying the attachments, for literature section we are linking the literature of cloned record with original record.	Low - Cloned records to be linked with source record for literature references	HLP-8504	*
ICSR, System Config	Country code population in C.1.8.1 and C.1.1 fields	Fixed an issue identified in populating country code in C.1.8.1 and C.1.1 ID's, the issue occurs when the primary reporter is not selected for an ICSR. HALOPV will now treat the only reporter as primary reporter and use its Country.	Medium - C.1.1 is widely used to uniquely identify a case and should be populated correctly.	HLP-8364	*
ICSR	Fix for Missing Extraction of G.k.10.r Section in Case Data	Fixed an issue that caused the data inserted into section G.k.10.r (Additional Information on Drug) to not be extracted by the case converter. This issue has been resolved by adding the missing line of code, ensuring proper data extraction.	Low - Fixed issue with extraction of G.k.10.r	HLP-8137	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR	Drug/ Substance Name in Navigation Pane	<p>Updated Drug/ Substance name display, now HALOPV will display Durg/ Substance name in below order: For the Drugs levels (Products/ Patient /Parent Past Drug History)</p> <ul style="list-style-type: none"> <li>• Target PI name, otherwise;</li> <li>• Drug Name Override, otherwise;</li> <li>• Drug Name Verbatim, otherwise;</li> <li>• Literal “Drug #” + Drug record rank/sequence/position</li> </ul> <p>For the Substance levels (For above drugs)</p> <ul style="list-style-type: none"> <li>• Target Substance Preferred Name, otherwise;</li> <li>• Substance Name Override, otherwise;</li> <li>• Substance Name Verbatim, otherwise;</li> <li>• Literal “Substance #” + Substance record rank/sequence/position</li> </ul>	Low – Display change	HLP-11201	*
ICSR	Automatic Rank Adjustment for Products and Events in ICSR	Fixed an issue where deleting a product or event with lower rank in ICSR did not automatically adjust the ranks of subsequent products or events.	Low - Ensures rank consistency for products and events	HLP-11073	*
Products	Fix for Multi-Country Selection in Products Grid	Fixed an issue where multiple country codes separated by colons caused errors and prevented data from being displayed in the Products Interactive Grid.	Low - Fixed error to add multiple countries	HLP-9928	*
Products	Error while Nullifying or deactivating device product	Fixed EVENT_MANAGEMENT.PRODUCT_NULLIFIED to allow user to be able to nullify or deactivate a device product.	Medium - Unable to deactivate existing device product	HLP-8978	*



Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Products	Products - Clear Manual Coding	Fixed Clear manual coding to clear all PI, WHO and IDF JP together on click on Clear Manual Coding button, however this can be overwritten if Exact Match Autocoding may overwrite this.	Low - Fix in existing functionality	HLP-11057	*
Requirements Intelligence	Fix for Filtering Issues in Whom and When Operational Report	The Whom and When operational report in the Regulatory Intelligence module now correctly applies filters when generating reports. The issues with the export function pulling all data regardless of selected filters have been resolved. Additionally, the decode logic for the 'E2B Message Type' column has been fixed.	Medium - Enhances report accuracy by ensuring proper filter application	HLP-9666	*
Requirements Intelligence	Updated GRIP Sync for Multi-Tenant Support	Fixed an issue that ensured that GRIP data can be synchronized across multiple tenants without ID conflicts.	Medium - Data synchronization issue for multi tenants	HLP-9041	*
Submissions	Deadlock issues front-end HALOPV and the HALOBOT while triggering auto Submission	Fixed HALOPVBOT to trigger auto submission for records which are open by user, now HALOPV will not trigger auto submission for such records and will wait till user closes the records.	Low - This fix is to update an existing Functionality and to avoid Deadlock	HLP-9709	*
Submissions	Fix for Country of Occurrence Display in Submission Details	Fixed the issue to ensure that the "Country of Occurrence" is now correctly populated and visible in the Submission Details form for all relevant submissions	Low - Data fix for a column in submissions.	HLP-9439	*
System Config	Fix for Medicine Incident Intake Workflow Search Discrepancies	Resolved inconsistent search results in the ICSRs workflow by adjusting date handling in worklist filtering. Enforced explicit date conversion on date filters to ensure accurate case counts across different date ranges.	Low - The date conversion was causing inconsistent results on different worklists.	HLP-10862	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
System Config	Fixed Audit logs, HALOPV will now capture and display 'SYSTEM' when ICSRs imported from external databases via JSON import. Note- this bug was limited only for above scenario.	Updated the Audit logs as default value 'SYSTEM' when an ICSR is imported to HALOPV.	Medium - Updates in Audit logs, no retrospective changes	HLP-9917	*
System Config	Update to System Access Log for Tenant-Specific User Visibility	Fixed an issue where under Application Management > System Access Log, logins from all tenants were previously shown. The Interactive Report SQL on Page P102 has been updated which ensures that the System Access Log will display all users who have access to the current entity.	Medium - Enhanced visibility of users across tenants in the system access log	HLP-9280	*
System Config	Fix for Workflow Completion Error in Duplicate Search Auto-Routing	A bug was identified when the duplicate search configuration auto-routed cases to the "ICSR Duplicate" workflow step. The system encountered an error, stating "Workflow for the provided task ID not found," due to the absence of a next step in the workflow. The issue has been resolved by updating the GOM_COMPLETE_WF_STEP_NEW_TASK procedure to handle scenarios where no subsequent workflow step exists, preventing task completion errors.	Medium - Prevents errors when completing workflows with no subsequent steps	HLP-11199	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
System Config	Fix for Displaying SharePoint Files on Working Files Page	Resolved an issue on the "Working Files" page that caused failures when retrieving SharePoint files, ensuring proper file retrieval and display.	Medium - Fixes file retrieval from SharePoint on Working Files page, ensuring accurate display of individual documents without errors	HLP-9782	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	Improved ETL Process for Data Synchronization	Addressed the ETL issue of missing new data due to timezone discrepancies and deferred commits. Implemented an offset to allow the ETL process to capture records slightly older than the last half-hour window.	Medium - Enhances ETL reliability by capturing more records	HLP-9736	*
System Config	Fix for Line Break Formatting in Notification Emails	Fixed an issues where line breaks were being removed from notification emails.	Low - Fixed formatting issue	HLP-9542	*
System Config	SMTP mailer not supporting UTF encoding	Updated HALOPV SMTP Library to support UTF encoding, this is important to support non English languages.	Low - This is update in existing library to support UTF encoding	HLP-9524	*
System Config	Users with READ ONLY role are able to update completed records	Fixed an issue in HALOPV user roles, now user with READ ONLY roles will only be able to view the records.	High - User with Read only access should not be able to update any record.	HLP-9481	Insife HALOPV System Specification - INSIFE-HALOPV-SS-39
System Config	AWS API's timeout issue	Created indexes on CORE DB for CRS-related tables to improve performance and resolve the AWS API gateway timeout issue.	Medium - This issue was causing the AWS API to stop working and thus resulting in performance issues in CRS content.	HLP-9413	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
System Config	P26_LV_REQUIREMENT field update to add the description for any LOV.	User is now able to add/update/save description for all the LOVs	Low - Added description for LOV	HLP-9412	*
System Config	Correspondence reminder automation bug fixes	Bug fix (no changes to intended logic) to the reminder automation (GOM_SEND_AUTO_REMINDER_V2) to ensure correct workflow routing and re-transmission of the email to the recipients	Low - Added Email reminders	HLP-9406	*
System Config	Correction of ACK.M.4 Acknowledgement Date in ICSR Acknowledgement Files	Fixed an issue where the ACK.M.4 field in the ICSR Acknowledgement file was incorrectly populated with the case creation date (C.1.2). The ACK.M.4 field will correctly populate with the date and time when the ICSR Acknowledgement batch file was transmitted. This fix ensures accurate reflection of the batch transmission time in line with the R3 XML format.	Low - Incorrect value populated in the ACK.M.4	HLP-9414	*
System Config	Fix for CRS Organizational Entity ID Misconfiguration	Resolved the issue of CRS master records not being visible in the Case Retrieval Strategies workflow due to misconfiguration of the assignment assigned record owner organization (assigned via system switch).	Medium - CRS records did not appear in the workflow when imported via the Signal module API	HLP-9390	*
System Config	Display of Nullified Records on all worklists	Bug fix to display the nullified records on all the worklists if only 'Nullified' is checked on the screen.	Medium - As user shall be able to see the nullified records when required.	HLP-9325	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
System Config	Fix for Missing Attachments in Azure Mail Component	Resolved the issue with the Azure mail component where email attachments were not being included. The code in AZURE_MAIL.GET_ATTACHMENTS_JSON has been updated to correctly filter the mapping of MIME types to file extensions.	Medium - Improves email functionality	HLP-9305	*
System Config	User Provisioning API Response Issue	Fixed the User Provisioning APIs to return responses which align with the expected results.	Medium - User Provisioning API was not returning expected data	HLP-9240	Insife HALOPV ICSR API Import Mapping - INSIFE-HALOPV-ICSR-API-IMP-MAP-SS-279
System Config	Description on Term Collection Page	Updated the description on Term Collection Page to 'The Dictionaries and terms module allows for managing terms and collections of medicinal concepts like products, events including managing labeled medicinal terms (listedness), Product Insert Leaflets (PIL) / Summary of Product Characteristics (SmPC).'	Low - Description update on a page	HLP-9236	*
System Config	Enhanced E2B Case Mapping and Automated Linking of Follow-Up Cases	The mapping of incoming E2B cases now supports configuring the target record type using the c.3.1 Sender type code list. Additionally, automated linking of Follow-Up (FU) cases to an initial case via the Duplicate search automation will now automatically trigger up-versioning of the initial case.	Low - This update streamlines the process of mapping E2B cases by enabling configuration of the target record type through the sender type code	HLP-9113	*

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
System Config	MedDRA Version Update in XML from 27 to 27.0	Updated R2/R3 generation function for MedDRA Version from 27 to 27.0 for XMLs	Low Impact - As Its a minimal update of version number in R2/R3 generation function.	HLP-9069	*
System Config	Special characters in filenames from E2B R3 files	Fixed the handling on E2B R3 files where file names contain special character "/"	LOW - Update in file name handling	HLP-8689	*
System Config	UCUM Code List for Patient Tests	Updated UCUM code list for patient tests to align with EMA guidelines.	Low - Update to UCUM Codes	HLP-8546	*
System Config	Calculation of non-mandatory workflow steps	Fixed Calculation of non-mandatory workflow steps, HALOP now only include validation checks relevant for mandatory workflow steps.	LOW - this is an update in WF steps configuration	HLP-8248	*
System Config	Correction of C.1.1 and C.1.8.1 Overwrite Issue in ICSR Reports	An issue was discovered where the C.1.1 and C.1.8.1 fields in ICSR reports were erroneously generated and replaced the original values in the XML. This has been resolved by updating the ICSR_IMPORT_XML and GOM_ADD_ICSR_WWUID processes to prevent this from occurring.	Low - Fixed an existing issue	HLP-8110	*
System Config	Text Formatting Cleanup in GOM_FORMAT_WORD_TEXT	Fixed an issue where special characters (e.g., &nbsp;) and text formatting like bold, italic, and underline were not being cleaned by GOM_FORMAT_WORD_TEXT before inserting content into placeholders or templates. The function has now been updated to remove unwanted text formatting and clear &nbsp;.	Low - Fix to a formatting issue	HLP-6748	*

**\*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
Aggregate Reporting	New Workflows Added to Aggregate Reporting Module	Expanded the Aggregate Reporting Module in HALOPV to include new workflows: PBRER, DSUR, PADER, CIOMS II, Reconciliation Reporting, Compliance Reporting, Productivity Reporting, and Expert Reporting (Ad-Hoc).	High - This update enhances the Aggregate Reporting Module by providing users with additional workflows	HLP-10345	*
Aggregate Reporting	Update to Adhoc Aggregate Reports Workflow – Standardize Report Type	Updated report type in the Adhoc workflow from blank to "Adhoc."	Low - Update to report type	HLP-10752	*
Aggregate Reporting	Updates to Aggregate Reporting Workflow Names and Records Migration	Updated the naming conventions and record workflows in the Aggregate Reporting: <ol style="list-style-type: none"> <li>1. Renamed <i>Aggregate Reporting Process (Ad-hoc)</i> to <b>Expert Reporting (Ad-Hoc)</b>.</li> <li>2. Renamed <i>DSUR Process Test</i> to <b>DSUR</b>.</li> <li>3. Migrated all existing records in the <i>Aggregate Reporting Process</i> workflow to "Expert Reporting (Ad-Hoc)" workflow with report type "Ad-hoc".</li> </ol>	Low - Updates to aggregate reporting Workflow	HLP-10381	*
ICSR	Correction of EU Reporting Mapping for "No Reasonable Possibility"	Corrected the EU reporting configuration where "No reasonable possibility" was previously mapped to value 1. This value now correctly maps to 2, aligning with EU reporting standards where 1 represents "Related" and 2 represents "Not related."	Medium – Update to reporting assessment	HLP-10480	*

Area / Process / Group	Title	Description	Impact	Requirement ID	Specification ID
ICSR	Enhancement of Ethnicity and Race LOV Values	Enhanced the List of Values (LOV) options for <i>Ethnicity</i> and <i>Race</i> fields <ol style="list-style-type: none"> <li><b>Ethnicity LOV:</b> Hispanic or Latino, Not Hispanic or Latino, Unknown, No Information.</li> <li><b>Race LOV:</b> Caucasian, Black, Asian, Other, African American, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, White, Australian.</li> </ol>	Low - Configuration of LOV	HLP-9475	*
ICSR	Tenant-Specific Configuration for Default Country Value in E.I.9 Field	Updated the default configuration of the <i>Identification of the Country where the Reaction/Event Occurred (E.I.9)</i> field. This field will now be set to blank by default for manually created ICSR records.	Low - support a tenant-specific requirement	HLP-10202	*
System Config	Multi-Tenant Normal Login Disabling with SSO Integration	Enhanced login configuration to support multi-tenant customers using SSO, allowing tenants to disable normal login.	Low - This update improves login control for multi-tenant environments by enabling an option to restrict access exclusively to SSO	HLP-10880	*

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



## 7. Features removed from HALOPV 6.0

- Support for the Internet Explorer browser was removed from HALOPV 4.0 onwards
- In HALOPV 6.0, we have shifted from a view-based approach to a dimension-based approach, significantly improving performance. Users can now access aggregate reports almost instantly. However, aggregate report data will no longer be real-time; instead, it will synchronize with the ETL process.

## 8. Known Issues & Workarounds

Area / Process / Group	Title	Description	Workaround	Issue ID
ICSR	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 secs.	HLP-10621 *
ICSR	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.	The correct license is linked to the record. This is a display issue which shall be fixed in upcoming versions.	HLP-11190 *

\*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](mailto:support@insife.com)) for any query related to installation or changes in this release.