

Insife HALOPV 6.1.2 Release Notes
Final
Version 1.0
Department: Product Management

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1. Overview

HaloPV 6.1.2 is a minor release that builds on the features of HaloPV 6.1. It provides new features and bug fixes 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 6.1.2 is dependant on an APEX software upgrade to Oracle APEX 24.1.3.

3. Compatibility

HaloPV 6.1.2 is compatible with the following systems:

- Argus 8.2.1.1 and Argus 8.2.3 (Please contact us for compatibility with earlier/ later versions)
- 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	Issue ID	Specification ID
Aggregate Reporting	Update in PBRER template to count distinct Preferred Term's (PT's) of an ICSR	Updated PBRER template to count Distinct Preferred Terms (PTs) from an ICSR from all its revisions. This is irrespective of the value selected in filter function for the record revision "Record Revision" prompt.	LOW - This update is to make sure PT's are counted only once across all the revisions of an ICSR	HLP-15400/ (CUST-2040)	* Not Required
Case Intake and Processing	EMA ICSR Submissions – Masking and Blank Field Compliance Update	HALOPV has been enhanced to comply with EMA's updated requirements on masking of personal data per GVP Module VI Addendum II. Specific ICSR fields will now be automatically masked or left blank when submitting to EudraVigilance, ensuring no identifiable reporter, patient, or sender information which is required to be masked is transmitted.	High - Affects EMA ICSR submissions.	HLP-14723	TDS EMA Submission Masking and Blanking TDS-1430, TDS HaloPV-E2B_R3 FDA Reporting Criteria TDS-1429

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing	HALOPV Configurations updated to support FDA reporting - Business rules	A new keyword, “FDA,” is now applied to cases where either C.2.r.3 Reporter’s Country Code or E.i.9 Identification of the Country is set to the US and the Reaction/Event Occurred field is also marked as US. Based on this keyword: - Existing FDA rules have been updated to remove embedded country logic. These rules are now fully configurable and will trigger only when the FDA keyword is present (via <i>Scheduling Required > FDA</i>). - Existing validation rules have been reviewed and updated or added as needed to align with current FDA guidelines.	MEDIUM - This changes extends the existing validations for FDA reporting compliance for full covering of FDA requirements. The validations only run on ICSRs where FDA reporting in in scope. ICSRs in scope must be tagged with the keyword Scheduling Required > FDA. The out-of-the-box keyword is not automatically marking any cases and the exact logic in the keyword must be populated as part of implementation or upgrade projects.	HLP-15499	New IQ Created to deploy CIL, INSIFE-HALO-ICSR-R3-TO-JSON-FULL-297, INSIFE-HALO-ICSR-R3-TO-JSON-FULL-296, INSIFE-HALO-ICSR-API-IMP-MAP-SS-279

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

5. Bugs resolved in HALOPV 6.1.2

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Aggregate Reporting	Aggregate report Dimension displaying Event Adjudication	The Aggregate report Dimensions event-product per line, and case per line have been updated to display Event Adjudication values irrespective of if a PT is selected or not. Now for such cases where a PT is not selected in an Adjudication row, HaloPV will display the Adjudication values for all the events of that case.	MEDIUM - This is an update in Aggregate Reports dimension, users will not be able to see the updates till full data refresh of Aggregate Reports.	HLP-15363/ (CUST-2084)	INSIFE-HALOPV-OOB-ICSR Revision LINE View-SPEC-1123, INSIFE-HALOPV-OOB-ICSR Event Product Line-SPEC-715, INSIFE-HALOPV-OOB-ICSR Case LINE View-SPEC-1122
Aggregate Reporting	Aggregate Report - Event product per line dimension fix for "Drug Event Assessment Datasheet D"	It was discovered that the values shown in the "Drug Event Assessment Datasheet D" column in the reporting dimension "Event-product per line" was showing the code values and not the decoded values. This has now been resolved so the report correctly shows the decoded values.	LOW - Fix to displays decoded values in place of ID	HLP-15167/ (CUST-2035)	INSIFE-HALOPV-OOB-ICSR Event Product Line-SPEC-715
Clinical Trial Management, Case Intake and Processing	User was able to see studies that are not assigned to their organization	Fixed an issue in the Case form Study selection list which was causing users that were not linked to study organisations to see the studies in the list. This has been fixed to limit the list of studies where the study organisation matches the user's Organizations and which are not obsolete.	MEDIUM - Due to this bug users may select incorrect study, however this bug is limited to a non production environment.	HLP-15198/ (CUST-2056)	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Clinical Trial Management	Study Linking – Display Only Active Clinical Projects	The Study → Project dropdown has been updated to correctly display only active (non-nullified) Clinical Projects.	Medium - Users will now see only valid, active Clinical Projects when linking studies, improving data accuracy and user experience.	HLP-15197/ (CUST-2016)	* Not Required
Clinical Trial Management	Linked studies are not visible at Project details form	Fixed an issue where Studies linked to a Project were not visible on the Project details form on the Studies tab.	LOW - Fix in existing feature	HLP-14823/ (CUST-2017, CUST-2108)	* Not Required
Case Intake and Processing	FDA Auto-Scheduling – Ignore Capitalization in Causality Fields	The FDA auto-scheduling logic has been enhanced to ensure that rules are triggered correctly regardless of capitalization differences in causality source and causality result values. Previously, configuration values in the Drug Event Matrix were case-sensitive. When capitalization differed between system releases, rules were not considered, even for otherwise qualifying cases. With this update, the scheduler now ignores capitalization in these fields, ensuring consistent rule triggering across all environments.	High - Impact is limited to FDA auto-scheduling behavior. This update ensures consistent rule triggering.	HLP-15482/ (CUST-2172)	TDS HaloPV-E2B_R3 FDA Reporting Criteria TDS-1429
Case Intake and Processing	Audit Log – Prevent Duplicate Entries for Expiration Date Field (Chinese Use)	The audit log was recording multiple entries for the Chinese use > Expiration Date/Date of Expiry field. The audit trigger has been updated to correctly reference the Chinese use > Expiration Date/Date of Expiry field, ensuring that the trigger executes only once per update event.	High - The Audit Log now records a single, accurate entry for each change made to the field	HLP-15460	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing	Audit Log – Capture Updates for Hospitalization and Intervention Fields	The audit log trigger has been updated to: 1. Include the Hospitalization Duration/Unit (HOSPITALIZATION_DURATION_UNIT) and Required Intervention (FDA_E_I_3_2H) fields in audit log. 2. Prevent duplicate audit log entries for Treatment Period updates.	High - The Audit Log now correctly records changes for all relevant event fields, ensuring complete traceability of updates.	HLP-15459	* Not Required
Case Intake and Processing	Audit Log – Correct Initial and Duplicate Entries for EU Strength and Form Name Fields	The audit log behavior for the fields EU Strength Name and EU Form Name under Product(s) Information has been corrected. Previously, when entering values for these fields for the first time, the Audit Log incorrectly displayed the same value for both Old Value and New Value. Additionally, these fields were being logged multiple times whenever any other product field was updated, even though their values had not changed. This has also been fixed.	High - Audit logs now correctly record the first-time entry for these fields and no longer generate duplicate entries when unrelated fields are updated.	HLP-15426	* Not Required
Case Intake and Processing	Attachments – Fix for Deletion Error on Literature Documents	Users can now successfully delete Literature-type documents from the Attachments section without encountering an error. Previously, when attempting to delete a document classified as Literature (added through the Add Literature Reference button), the system displayed a database error and the file could not be removed.	Low - Users can now delete Literature attachments without errors.	HLP-15411	* Not Required
Case Intake and Processing	Audit Log – Correct Value Capture for Parent Social Security Number Field	The Audit Log behavior for the Parent Social Security No. (Non-E2B) field under the Parent tab has been corrected. Previously, when users entered or updated a value in this field, the Audit Log displayed an incorrect or altered value rather than the one actually entered.	High - The Audit Log now correctly records the actual value entered in the Parent Social Security No.	HLP-15395	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing	Audit Log – Capture Updates for Pregnant and Patient Race Fields	The Audit Log has been enhanced to correctly record changes to the Pregnant and Patient Race fields under the Patient / Parent → Patient tab. Previously, updates to these dropdown fields were not being logged, resulting in missing audit log entries when users saved changes to patient information.	High - The Audit Log now accurately records all changes made to the Pregnant and Patient Race fields.	HLP-15389	* Not Required
Case Intake and Processing	Literature References – Synchronization and User Interface Enhancements	The behavior for managing Literature References in ICSR cases has been improved to ensure proper synchronization between the ICSR form and the Attachments page. Previously, newly added or edited literature references were not syncing correctly between the two pages. Title changes, classification updates, and deletions on the Attachments page were not reflected on the ICSR form, and vice versa. Additionally, the “Download” button was active even when no file was attached, leading to potential errors.	Medium - Literature reference data is now consistently synchronized between the ICSR and Attachment sections.	HLP-15386	* Not Required
Case Intake and Processing	Audit Log – Capture Updates for Reporter Type Field	The Audit Log has been enhanced to correctly record updates made to the Reporter Type field under the Reporter(s) tab within the Source(s) of Information – Entry Form section. Previously, any selection or change to the Reporter Type was not being tracked in the Audit Log, resulting in missing audit trail entries for this field.	High - The Audit Log now accurately captures and displays changes for the Reporter Type field, including both old and new values.	HLP-15379	* Not Required
Case Intake and Processing	Audit Log – Capture Updates for Device Admin Information Fields	The Audit Log functionality has been enhanced to ensure that updates made under the Device Admin Info tab > Corresponding competent authority section of the ICSR workflow are now properly recorded. Previously, when users modified these fields, the changes were not reflected in the Audit Log.	High - The Audit Log now provides full traceability for updates to Device Admin Info tab	HLP-15369	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing , System Config	MedWatch Templates – Literature and Event Information Updates	The Literature section has been updated to display literature references in the relevant section of the MedWatch Report form. Additionally, the Event Abated and Event Reappeared fields have been updated to ensure they reflect the correct information from the ICSR.	Medium - Improves accuracy of information in regulatory submission templates	HLP-15364	* Not Required
Case Intake and Processing , Submissions	HaloPV generated XML for FDA submission failed for FDA	The FDA E2B R3 field N.1.2 was found to be missing when generating an FDA XML from a case where there ICSR WF has completed. This has now been fixed so the field N.1.2 is present in the XML.	MEDIUM - This was causing failed Submissions for FDA.	HLP-15354/ (CUST-2089)	TDS HaloPV-E2B_R3 FDA Reporting Criteria TDS-1429
Case Intake and Processing	Case Intake - XML fix for G.K.8 Action Taken field	An issue was identified where when importing an ICSR from an XML file, product information (e.g. G.K.8 - Action Taken) was being linked to the incorrect product. This has now been resolved.	MEDIUM - May results in data loss, however the impacted environment is a non production	HLP-15348/ (CUST-2049)	* Not Required
Case Intake and Processing , System Config	Validation error failing when a product is not coded	An issue was found where by no validation error message was shown when a product in the product(s) tab was not coded. This has been fixed to display a validation error to alert the user to an uncoded product.	LOW - This fix applies on an existing validation rule (configuration).	HLP-15301	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing	ICSR Case Intake-XML - E2B Intake fix	An issue was found where by the below fields were not imported when uploading an XML file into HaloPV: 1. Reporters email address 2. Patient Ethnicity (FDA.D.12) 3. Patient Race (FDA.D.11.r.1) 4. Product indication G.k.7.r.2b is imported but not coded 5. Event seriousness details which has Null flavor value 'nullFlavor="NI"' in XML file are not imported 6. FDA.E.i.3.2h - required intervention This has now been resolved and all fields now upload into HaloPV.	MEDIUM - Fix to import complete data, may have resulted in data loss	HLP-15292/ (CUST-2088)	* Not Required
Case Intake and Processing	New Tag/ Keyword - Invalid added for Case Intakes	A new tag/ keyword "Invalid" has been added for Case Intake and Processing module. This tag is an automated tag which will be applied to ICSRs identified as Invalid as per HaloPV standard config.	LOW - Its a new Tag added as Standard Config on user request.	HLP-15241/ (CUST-2045, CUST-2097)	* Not Required
Case Intake and Processing	Report type mismatch for E2B R2 rules	An issue was identified where by an XML file generated using the E2B R2 format was generating an error caused by the system being unable to find a report type for the resultant XML file. This has now been fixed.	LOW - Updated in existing configuration.	HLP-15239/ (CUST-2071)	* Not Required
Case Intake and Processing	Case Up versioning/ cloning issue - P620_FDA_E_I_3_2H field missing	An issue was identified when up-versioning or cloning a record in the Case Intake and Processing Workflow where data from the field "P620_FDA_E_I_3_2H" and new Device related fields were not copied to the new revision or cloned record. This has now been fixed.	MEDIUM - Was causing data loss, however bug limited to non production environments	HLP-15231/ (CUST-2174)	* Not Required
Case Intake and Processing	Case form - Study details not auto populated	An issue was identified where sometimes, when changing the study an ICSR is assigned to in the Sender and Case Info > Study Identification tab, the system would not save the new study details selected. This has been fixed.	LOW - Fix in existing feature.	HLP-15201/ (CUST-2054, CUST-2099)	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing , Submissions	Submission scheduling rule analysis is not showing the submission record logs	An issue was identified where the submission record log report on the Submission scheduling rule analysis page within an ICSR record would sometimes show an error message. This was due to an issue with decoding of the Excluded tag column. This has now been fixed.	LOW - This is a display/ view only issue.	HLP-15200/ (CUST-2057)	* Not Required
Case Intake and Processing	XML Import – Correct Mapping of Drug-Level Fields in G.k Block	The XML import process in ProHalo Sandbox has been enhanced to ensure that drug-level information from the G.k (Drug) block is correctly matched to each product. Previously, fields such as Action(s) Taken with Drug (G.k.8), Country of Authorization (G.k.3.2), and Name of the Holder (G.k.3.3) were being linked based on their list position rather than the drug’s unique UUID from XML. This caused incorrect data associations. With this update, the system now uses the actual product sequence identifiers to correctly map these fields to their respective drugs.	High - Ensures accurate linkage of all drug-level data when importing XML files.	HLP-15165/ (-2049)	* Not Required
Case Intake and Processing	CIOMS 4.0 updates	Below issues were identified in the CIOMS 4.0 when generating a blinded version (i.e. a version which masks unblinded product information) - 1. The unblinded product in the Suspect Drugs section is masked correctly but in the Product Reaction level section the unblinded product information was shown. 2. The numbering in suspect drugs displayed as ' 1)' and '2)' whereas in indications for use it showed as '1' and '2' (braces were missing) 2. The Route of administration in the concomitant drug section displayed the code instead of the decoded value. The above issues have been fixed in the CIOMS 4.1 template.	LOW - The issues have been identified in CIOMS 4.0 version which is not released yet at production.	HLP-15151/ (CUST-2027, CUST-2048, CUST-2080, CUST-2085, CUST-2101)	INSIFE-HALOPV- OOB-CIOMS-SPEC- 434

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing , Submissions	MedWatch/ CIOMS template Issue - when Case Narrative contains special characters	An issue was found on the MedWatch and CIOMS report form templates where by when "<" or ">" are used in the narrative, generation of the form fails. This has now been fixed.	LOW - This is an update in existing template placeholders, limited to selected records having these special characters.	HLP-15145/ (CUST-2039, CUST-2015, CUST-2107)	INSIFE-HALOPV- OOB-MedWatch- SPEC-1234_V2, INSIFE-HALOPV- OOB-CIOMS-SPEC- 434_V5
Case Intake and Processing	Create from Wizard - Report from Study - Studies selectable list update	On the Create from Wizard screen in the Case Intake and Processing module, the Studies drop down list included studies which had a study status of Completed. This has now been changed so this list only contains studies that do not have a status value of "Completed" or "COMPLETED".	LOW - This update will impact only new record created and there is no change in study selectable via case form.	HLP-15140/ (CUST-2023, CUST-2106)	* Not Required
Case Intake and Processing	Case form - Pharmaceutical dose form value issue in special characters	An issue has been identified in the Case form - Pharmaceutical dose form displaying of special characters was not handled correctly. This has now been fixed.	LOW - No change in data, fix is to display/ allow special characters.	HLP-15109/ (CUST-2014, CUST-2098)	* Not Required
Case Intake and Processing	Issue while opening pdf in side-by-side view	An issue was sometimes observed while opening an attached PDF in HaloPV Side by Side view. This has been resolved.	LOW - This was a technical issue due to missing policy, no impact on users.	HLP-15104/ (CUST-2013)	* Not Required
Case Intake and Processing	Error message while creating task in "ICSR XML pre-intake" workflow	An issue has was identified in the Case Intake - "ICSR XML pre-intake" workflow where an error was sometimes displayed while creating a new record. This was preventing the creation of new records. This has now been fixed.	LOW - This issue was limited to non-production environments.	HLP-15101/ (CUST-2001)	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing	Users are unable to code patient/ parent past drug history using Company products	An issue was identified which meant that when coding a product manually into the company products dictionary in the patient/parent past drug history tabs of HaloPV, the selected product was not displayed in the "Coding Target to Product Index" field. This has now been fixed.	LOW - This will impact only users having HaloPV 6.1.1 patch, user were still able to code these drugs for WHO Drug.	HLP-14600/ (CUST-2042)	* Not Required
Products	Error while generating product index for records having NULL in dates	An issues was identified which occurs while generating Product Index at HaloPV products module for records having Null in date fields causing the Product Index to not update. This has now been fixed.	LOW - Fix in existing functionality.	HLP-15437/ (CUST-2091)	* Not Required
Products	Issue in Products - Medicinal Products - Name Variation	An issue was identified in the Products module - Medicinal Products workflow, which prevented users from adding entries to the Name Variations table in the Product Names tab. This has now been fixed.	LOW - Fix in existing feature.	HLP-15202/ (CUST-2030, CUST-2096)	* Not Required
System Config	Added a new Config Switch to Clear Assigned user on workflow Completion	A new Config Switch "DELETE ASSIGNEE" to Clear Assigned user on workflow Completion was added. As standard it is configured to not delete the assignee. Users can request this to be configured it as required.	LOW - Its configured to Not clear as standard configuration thus no impact on existing customers.	HLP-15003	* Not Required

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

6. Configuration updates

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing , System Config	Master Types updates for "Product Licenses (Authorisations)" and "ICSR / Device reporting requirements" workflow	To stay aligned with the latest FDA guidelines, we've updated and added several Master Types/Record Types across key workflows. 1. ICSR / Device Reporting Requirements New Record Types Added: - 104190 – Clinical: Drug–Device Combination - 104189 – Clinical: Vaccine Existing Record Types Updated: - 18780433 – Postmarketing: Vaccine - 18780414 – Postmarketing: Drug–Device Combination 2. Product Licenses (Authorisations) New Record Types Added: - 104194 – Clinical: Drug–Device Combination - 104193 – Clinical: Vaccine - 104192 – Postmarketing: Vaccine - 104191 – Postmarketing: Drug–Device Combination Existing Record Types Updated: - 100073 – Postmarketing: Drug - 100303 – Postmarketing: Device	MEDIUM - These updates ensure that our record types remain consistent with FDA standards, improving compliance and data accuracy across workflows. We have kept the Master Type ID same for updated records thus user will see the updated type names. User can use the new Record Type for new records.	HLP-15511/ (CUST-2190)	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing	Configuration updated for E2B R3 - TRUE-FALSE Select List	Configuration has been updated for "E2B R3 - TRUE-FALSE (Ref 502)" and value No (R2) has been removed from the selection. This is in line with ICH guidelines and in all select list only Yes/ No along with Null Flavours values will be displayed. This value No(R2) was incorrectly added.	MEDIUM - This change requires a data fix for existing records in multiple fields of the case form where users had selected "No (R2)".	HLP-15391	* Not Required
Case Intake and Processing , System Config	Configuration update for Patient Last Menstrual Period Date	Configuration has been updated for Patient Last Menstrual Period Date. Now users can enter all FDA approved null flavours (MSK, ASKU, NASK) in this field.	LOW - This will help users to enter all FDA approved null flavour values	HLP-15352	* Not Required
Case Intake and Processing	Case Intake Workflows – Updated Task Instruction for Duplicate Search Step	The task instruction for the Duplicate Search step has been updated across the following workflows: Case Intake – Emails and Forms, Case Intake – Manual and Case Intake – XML. The new instruction provides clearer guidance on how the system handles automated and manual duplicate detection: "This is a semi-automated task. Records with matching World Wide Unique ID (C.1.8.1) will be tagged as 'Automated Follow up' and linked to the Initial record by the system. Device records will be matched based on NCA, manufacturer, and healthcare facility number. If a direct match is found, the system will automatically link the records together. Records that match another record in the system based on keyword duplicate search will stop at this task. The user should perform a manual case comparison on the records identified as potential matches by the system."	Low - Improves clarity of instructions for users performing duplicate checks	HLP-15339	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Case Intake and Processing , System Config	Removed duplicate values for Individual patient use and other studies in study type drop down	HaloPV Standard Config has been updated to remove duplicate values for Individual patient use and other studies in study type drop down. These updates are in line with E2B business rules.	LOW - This is no impact on uses, they were added in internal version of HaloPV	HLP-15315/ (CUST-2162)	* Not Required
System Config	Removed default priority calculation from standard workflows	Standard Configuration for record default priority has been updated for all the workflows - the out-of-the-box workflows will no longer come with preconfigured priority calculations. To use auto-priority the users shall request an update for configuration as desired.	LOW - Now users can request to configure record priority as required.	HLP-15554	* Not Required

***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	Impact/ Workaround	Issue ID
Aggregate Reporting	Aggregate Report Refresh Issue for Deleted Sub Sections	An issue has been observed in the Aggregate Reports module when updating the data in the report dimensions. When the user opens an ICSR record and goes directly to a sub-section and deletes a sub-section (like Drug Dosage, Substance), makes no other change and closes the record without clicking on Save button, this change will not be reflected in the report dimensions in the Aggregate Reports module.	LOW - It's a low impact scenario as the bug will impact only open records where the user follows this specific set of actions. The ICSR data will get updated on the next update and/or when the save button is pressed. Workaround - It should be noted that this is a rare scenario and will impact only those records which are still in progress. As soon as the user performs any other action on the record (like changing its workflow, making any other change to the data, or clicking on the Save button in the main record or its sub sections) the Aggregate reports dimension will pick up all the changes including the deleted sub-section changes.	HLP-15492
Case Intake and Processing, Submissions	Incorrect Null Flavor Options Displayed	According to FDA and EMA E2B R3 guidelines, only specific null flavors are permitted for certain fields. HALO does not yet enforce these field-level restrictions and displays the full list of available null flavors for all fields. As a result, users are able to select null flavors that may be invalid for a given field, and the system does not provide validation or warnings to prevent or flag these selections.	HIGH – This may result in ICSR submission acknowledgement warnings however there are very few fields which have such field level restrictions. Workaround – Users are advised to ensure they select only the correct, regulator-approved null flavors for each relevant field, based on FDA and EMA E2B R3 business rules.	HLP-15405

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
Case Intake and Processing	Inconsistency in auto-save function	Within the Case Intake and Processing module, data changes made in the data form tabs are not always autosaved when users switch to another tab. Additionally, in some scenarios, the system does not display a warning about unsaved changes.	MEDIUM – This issue may lead to unintentional data loss when users navigate between tabs without manually saving their changes. Workaround – Users should ensure data is saved manually before navigating between tabs to avoid potential data loss.	HLP-15310
Case Intake and Processing	Strength configured to this substance in Products module is NOT displayed in ICSR	Strength and Route of Administration configured in Product module for the selected product does not displayed in the in the respective fields in the ICSR form in the Case Intake and Processing module when a product is coded.	LOW - This is a display only issue, the data is stored in the database and there is no data loss. Workaround - Users can manually select the product Strength and Route of Administration in the case form.	HLP-15362
Products	For Medicinal Products form > Pharmaceutical Product(s) > Ingredient list the dropdown concentration type is blank	For Medicinal Products form > Pharmaceutical Product(s) > Ingredient list the dropdown concentration type is blank	MEDIUM – Users will not be able to select “concentration type” for an Ingredient. Workaround – Users need to request an update post this fix.	HLP-15324

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
Case Intake and Processing	QC Check is skipped on reinitiation	When an ICSR record completes the QC step but is rejected back to Data Entry from the Medical Review step, the Data Entry step is completed a second time, the record will skip the QC step and move directly to Medical Review.	MEDIUM – This happens only when Quality Check user has approved an ICSR and a case is sent back from the Medical Review step back to the Data Entry step. Workaround – Users can request to update the HaloPV configuration in their tenant to make the QC step mandatory every time.	HLP-15328
System Config	The Worklist default option of "Send as Email" is not working	The Worklist default option of "Send as Email" is not working. This is an Oracle APEX issue. HaloPV will remove this option in future versions.	LOW – Users can download report manually using the "Download" option. Workaround – Users should not use the "Send as Email" option. Instead they should download the output file and send it manually. HaloPV will remove this option in future versions.	HLP-15365
Case Intake and Processing	Incorrect Display of "Personal Identifiable Data Hidden" Message	HaloPV always displays "Personal Identifiable Data Hidden" Message on Reporter, Patient, and Dosage Entry Forms, even when the user has access to view this data.	LOW – This is a display only issue. This statement displaying will be made conditional in a future release. Workaround – Users can ignore this message.	HLP-15374

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
Case Intake and Processing	File Annotated using HaloPV Edit Online feature gets corrupted	Files annotated using the HaloPV Edit Online feature can get corrupted, and users are unable to open these files again. This is related to the tool we use for file annotation.	LOW – Does not impact data integrity and files can be annotated outside of HaloPV. Workaround – Users are advised to annotate a file by downloading it, annotating it locally and re-uploading the annoated file into HaloPV.	HLP-15325
Case Intake and Processing, products	Datasheet listedness for product licenses need to be updated	Users cannot select datasheets linked to a product family of the coded product and can only select datasheets linked directly to a medicinal product.	LOW - This functionality will be added in a future release. Workaround - Users should link the datasheet individually for each medicinal product.	HLP-15406
Aggregate Reports	Product filter does not pull ICSRs where the product is still blinded.	When searching for ICSRs that contain blinded products, selecting one of the blinded product options in the product filter of the Aggregate reports data form will not pull these ICSRs since the ICSR is not coded to that product yet.	LOW - Reports can be generated by selecting the Study. This issue will be resolved in a future release. Workaround - Users are advised to select Study if they need to filter a report on a blinded product	HLP-15417
Requirement Intelligence	Requirement Intelligence: Incorrect WF name is displayed in linked record window	The incorrect Workflow name is displayed in the linked record window when the link to a linked entity is opened.	LOW – This is a display only issue with no impact on data or its linking. Workaround – Workaround is not required for this, it's not blocking record progression. Users can link more records as required without any issue.	HLP-15440

9. Contact

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