

Insife HALOPV 6.1.3 Release Notes
Final
Version 1.0
Department: Product Management

Table of Contents

1. Overview	3
2. Upgradability	3
3. Compatibility	4
4. Changes since the last release	5
5. Bugs resolved in HALOPV 6.1.3	6
6. Configuration updates	14
7. Features removed from HALOPV 6.1	15
8. Known Issues & Workarounds	16
9. Contact	22

1. Overview

HaloPV 6.1.3 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 6.1.3 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 143, and Edge was on version 143.

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	DSUR cumulative summary tabulation counting logic updated	The DSUR Cumulative Summary Tabulation Report previously relied on the product designation defined in the selected Clinical Trial record to determine which unblinded column (Study Drug, Placebo, or Comparator) adverse events were counted under. This meant that ICSRs were excluded from counts when the study arm was not configured in the Clinical Trial record or not entered on the ICSR. The report now uses the product designation configured by the user on the Summary Tabulation Products tab of the Aggregate Report Configuration form. This ensures adverse events are counted correctly even when no study arm is present on the Clinical Trial or ICSR record.	MEDIUM - This change is related to regulatory reporting and incorrect categorization may results in incorrect data in the resultant report.	CUST-2353	INSIFE-HALOPV-OOB-DSUR-SPEC-445

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

5. Bugs resolved in HALOPV 6.1.3

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Aggregate Reporting	Study Case Type filtering corrected for mixed report types in the Aggregate Report module.	An issue has been resolved in the Aggregate Report Configuration Details form where the Study Case Type filter was applied to all ICSRs, regardless of report type. This prevented aggregate reports from correctly including both Spontaneous cases and Report from Study cases when study case types were also filtered. The Study Case Type filter now applies only to ICSRs with Report Type = Report from Study, allowing spontaneous cases and relevant post-market study cases to be included together in the same aggregate report. Additional help text has been added to clarify that the Study Case Type filter applies only to study cases.	LOW - This change will result in an increase in the scope of the Aggregate report inclusion criteria. Previously, users had to create multiple Aggregate reports for each Report Type and merge them manually.	CUST-2342	INSIFE-HALOPV-SS-39
Dictionary and Terms	Product Index generation now supports mixed-case WHODrug substance names	An issue has been resolved where Product Index (PI) generation failed during automated workflows when a new medicinal product was created using a mixed-case WHODrug substance name. The PI generation logic has been updated to handle mixed-case substance names correctly, ensuring successful PI generation during product registration.	High – Impact is limited to Product Index (PI) generation during medicinal product creation. This update ensures successful PI generation regardless of substance name casing.	CUST-2291	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Dictionary and Terms	Product Index generation now handles NULL creation dates	An issue has been resolved in the Product Index (PI) generation logic where records with NULL creation dates could cause PI creation to fail. Although a utility function to correctly handle NULL values was previously implemented, the PI generation package continued to use Oracle's native LEAST/GREATEST functions, which return NULL when any input is NULL. The PI generation logic has now been updated to use the NULL-safe utility functions, ensuring PI creation completes successfully when creation dates are missing.	Medium – Impact is limited to Product Index (PI) generation. This update ensures stable PI creation when source records contain NULL creation dates.	HLP-15597	* Not Required
Dictionary and Terms	Saved terms can now be removed from Summary of Product Characteristics	An issue has been resolved in the Summary of Product Characteristics where previously saved terms could not be removed from a record. When users attempted to delete a term, the form refreshed and the deleted term reappeared on reopening the record. This behaviour has been corrected, and saved terms can now be reliably deleted as expected.	LOW – This workflow is infrequently used and is limited to saving a small number of fixed values (for example, Serious terms). No data loss occurred.	HLP-15322	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR	CIOMS Fixed to Handle null flavours in e_i_4 (event onset date) or d_7_1_r_2 (medical history date). Manufacturer address now populates correctly on CIOMS form.	An issue has been identified in the CIOMS form when displaying Null Flavour values in the fields e_i_4 (event onset date) and d_7_1_r_2 (medical history date). This was causing date conversion issues and was resulting in the Seriousness Criteria section not being populated. This has now been resolved so that when Null Flavour values are entered into the fields e_i_4 (event onset date) or d_7_1_r_2 (medical history date), this displays correctly in the respective fields on the CIOMS and does not affect the Seriousness section. Additionally, an issue has been resolved where the manufacturer address did not populate on the CIOMS form when the record revision was greater than 1. The manufacturer address now populates correctly for all record revisions.	MEDIUM - This may impact regulator submission.	CUST-2371	* Not Required
ICSR	Primary Source reporter validation corrected	An issue has been resolved on the Case Processing > Reporters page where selecting more than one reporter as Primary Source of Regulatory Purpose resulted in an application error. The behaviour has been corrected so that only one Primary Source reporter can be designated, with a validation message displayed when this rule is violated, in line with EMA business rules.	High – Impact is limited to reporter data validation and regulatory compliance. This update ensures EMA business rules are correctly enforced without system errors.	CUST-2297, CUST-2046	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR	Product Indications now code correctly for ICSR Intake XML cases	An issue has been resolved where Product Indications imported via the ICSR Intake XML workflow were not being coded, despite being present in the XML file. Product Indications imported from ICSR XML files are now correctly coded during case creation.	MEDIUM – Product Indication coding was not applied for cases created via ICSR Intake XML, which could affect downstream review and reporting. No data loss occurred.	HLP-15657	* Not Required
ICSR	HaloPV Behavior of Product Unblinding in the Narrative, Reporter Comments, and Company Remarks sections of an ICSR.	When an ICSR is unblinded, HaloPV will not blind the Narrative, Reporter Comment or Company Comment. Users are advised to incorporate necessary data entry guidelines for these fields to ensure accidental unblinding does not occur.	Low – There is no change to HaloPV behaviour	HLP-15633	* Not Required
ICSR	Event Listedness and Datasheet section made configurable on CIOMS template	The Event Listedness and Datasheet section has been removed from the standard CIOMS template and is now available as an optional configurable parameter. By default, this section is no longer included in the CIOMS template. Users may request configuration of this parameter if the section is required.	LOW - Existing section removed, this section is not required form regulatory.	CUST-2313	INSIFE-HALOPV-OOB-CIOMS-SPEC-434
ICSR	Follow-Up Data Review page now renders correctly	An issue has been resolved where the Follow-Up Data Review page did not fully render after linking a follow-up case via Duplicate Search (Case Intake) and selecting “Show and process follow-up data”. The page layout now displays correctly, allowing full access to follow-up details.	High – Impact is limited to follow-up case processing. This update ensures full visibility and accessibility of follow-up information for users.	HLP-15625	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR	E2B Receiver Identifier Validation Update	An issue has been resolved where the E2B Receiver Identifier field in the Generate Regulatory Report window only allowed alphanumeric characters and spaces. This prevented entry or selection of valid FDA receiver identifiers (for example, CDER_IND) and could cause errors during report generation. The field validation has been updated to allow non-alphanumeric characters, enabling successful generation of FDA regulatory reports with valid receiver identifiers.	High – Impact is limited to regulatory report generation behavior. This update ensures valid receiver identifiers with non-alphanumeric characters can be entered and selected when generating regulatory reports.	HLP-15611	* Not Required
ICSR	Unselected Follow-Up Data is now not Merged During Manual FU Review	An issue was detected where, during manual Follow-Up data review, unselected data was still merged into the parent case. The logic has been corrected to prevent FU data from being unintentionally merged, ensuring that only user-selected data is merged into the existing ICSR record.	High – Impact is limited to manual Follow-Up (FU) processing behavior. This update ensures that only explicitly selected FU data is merged into the parent ICSR, preserving data integrity.	HLP-15606	* Not Required
ICSR, Products	Product Index Substance Auto-Coding Fixed	An issue was identified where the Product Index did not always automatically code the Substance for some medicinal products sourced from the WHODrug dictionary. An additional route for substance coding has been established to ensure that all eligible products are correctly evaluated for substance auto-coding even when the usual path to the Scientific Product yields no results.	Medium – Impact is limited to Product Index substance auto-coding behavior. This update ensures consistent substance coding for applicable WHODrug entries.	CUST-2304	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR, Submissions	Multiple FDA.C.5.6.r values now imported as separate Study Registration entries.	An issue has been resolved where inbound XML files containing multiple FDA.C.5.6.r (IND number of cross-reported IND) values were incorrectly consolidated into a single Study Registration row using colon-separated values. Multiple FDA.C.5.6.r values will now import as separate entries in the Study Registration table on the ICSR record.	Medium – Impact is limited to how FDA cross-reported IND values are displayed in the ICSR Study Registration section.	HLP-15704	* Not Required
ICSR, Submissions	IND Number (FDA.C.5.5a) Not Populated in FDA E2B R3 XML	An issue has been resolved where the IND Number where AE Occurred (FDA.C.5.5a) was not populated in the generated FDA E2B(R3) XML. This field is now correctly included for study reports (Type of Report = 2) submitted to FDA.	High – Impact is limited to FDA E2B R3 XML file generation. This update ensures correct population of required fields in generated FDA E2B R3 XML files.	CUST-2328	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR, Submissions	FDA Validation Error When Null Flavor 'NA' Selected for FDA.C.5.6.r (Study Registration Number)	Resolved an issue identified where the Null flavor = 'NA' was selected for FDA.C.5.6.r (Study Registration Number). Although the E2B R3 Reporting Requirements allow the use of Null flavor NA for this field, the system validation failed due to missing configuration values. The required 'NA' null flavor values have now been added and updated in the configuration, ensuring that FDA regulatory XMLs pass validation when Null flavor NA is selected.	Medium – Impact is limited to FDA validation during regulatory report generation. This update ensures FDA study registration rules are correctly supported If incorrectly selected 'NA' for an not applicable field (below), it may cause to fail E2B submission - - D.2.3 - Patient Age Group (as per reporter) - D.5 - Sex - D.7.1.r.3 - Continuing - D.10.6 - Sex of Parent - D.10.7.1.r.3 - Continuing	HLP-15749	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
ICSR, Submissions	CIOMS Narrative Special Character Rendering Fix	Resolved an issue where special characters entered in the case narrative (e.g., &, %, @) were incorrectly displayed as encoded text (such as &) in the generated CIOMS report.	Medium – Impact is limited to CIOMS report rendering. This update ensures special characters entered in the case narrative are displayed correctly in generated CIOMS reports.	HLP-15753	* 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
ICSR	"Substance missing" validation correctly handled for blinded ICSRs	An issue has been resolved where the "Substance missing" validation error was triggered even when a product was marked as Blinded = Yes, incorrectly blocking case processing for blinded ICSRs. The validation logic has been updated so this rule does not fire when Blinded = Yes, allowing blinded ICSRs to proceed through the workflow as expected.	High – Impact is limited to case processing for blinded clinical trials. This update ensures processing is not blocked when the product is intentionally blinded.	CUST-2317	* Not Required
ICSR	E2B E.i.7 Additional Fatal Outcome validation removed from standard configuration	Disabled - Validation Rule for - E2B - E.i.7 - Additional Fatal Outcome, the rule checks that only one event should results in Fatal Outcome and was not required as per E2B guidelines. The rule was requested by particular client and now disabled from standard configuration of HaloPV. Users can request to enable this in their environment (if required).	LOW - Disabled an existing rule. No impact on data or compliance.	CUST-2298	* Not Required

Area / Process / Group	Title	Description	Impact	Issue ID	Specification ID
Submissions	FDA Message Receiver Identifier Configuration Update	Resolved an issue where N.2.r.3 (Message Receiver Identifier) was not populated in the generated FDA XML, despite being defined separately from N.1.4 (Batch Receiver Identifier). The system previously configured both identifiers to use the same E2B receiver value, resulting in N.2.r.3 being omitted from the XML. The FDA XML profile has now been updated so that when the receiver ID is ZZFDA or ZZFDATST, the Message Receiver Identifier (N.2.r.3) is correctly set to CDER, ensuring alignment with FDA requirements.	Medium – Impact is limited to FDA XML header configuration for automated submissions. This update ensures correct population of FDA receiver identifiers.	HLP-15770	* 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

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
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
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 display 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

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
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
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

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
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
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

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
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
Case Intake and Processing, Submissions	Submission scheduling rule analysis > Eligible products showing blank licenses	An issue has been identified in Submission scheduling rule analysis > Eligible products showing blank licenses, where HaloPV does not displays the product license for some products. This is display only bug and has no impact on data or compliance.	LOW - This is display only issue and has no impact on data or compliance. Workaround - Users can view the product license details by visiting Product Module.	CUST-2329
Dictionary and Terms	For Medicinal Products form > Pharmaceutical Product(s) > Ingredient list the dropdown concentration type is blank	"Concentration Type" dropdown of Medicinal Products form > Pharmaceutical Product(s) > Ingredient list tab is not displaying configured values, in place it is blank.	MEDIUM - Will impact users while trying to create products and wants to select this field - "Concentration type"	HLP-15324
<Module Independent>	Audit log does not decode some code list values.	Known Issue: An issue has been partially addressed whereby the audit log was displaying value codes instead of the decoded values for some fields. This has been partially resolved with some values still showing as codes.	LOW - This affects only value displayed to the user. The data stored remains unaffected.	CUST-2315

Area / Process / Group	Title	Description	Impact/ Workaround	Issue ID
Case Intake and Processing, Submissions	E2B R3 XML Submission for Death or Life-threatening cases	Know Issue: A bug has been identified when an E2B R3 XML Submission for "Death" or "Life-threatening" cases is submitted within 7 to 15 Days of case reporting, it worked when a case is submitted after 15 days.	HIGH – This may cause reporting issues in Serious cases. Although it may be issue in FDA Validator tool	HLP-15750
Case Intake and Processing, Submissions	E2B R3 XML Submission for follow-up Nullification scenario	Know Issue: It has been observed that FDA Validation does not acknowledge the revision number in their tool and due to which it fails to identify accept the revision 2 of a case (follow-up) as a Nullification record.	LOW – As per our internal assessment, this is an issue with FDA Tool and HaloPV is working as expected	HLP-15741
System Config	Worklist default option of "Send as Email" is not working	Worklist default option of "Send as Email" is not working. This is Oracle APEX issue, HaloPV will remove this option in future versions.	LOW – Link present in email sent like this will not work. Users can download report manually. Workaround – Users should not use this option and instead download the output file and send them manually, HaloPV will remove this option in future versions.	HLP-15745
Products	Medicinal Products Linked Parent Title Display issue	Known Issue: It has been observed that at Medicinal Products and Product License worklist the respective Linked Parent Title is displayed repeatedly for each revision of Product.	LOW - This is display only issue, users may ignore the repetition.	HLP-15662

9. Contact

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