Insife HALOPV 5.0 Release Notes
Final
Version 2.0
Department: Product Management

Table of Contents

1. Overview

Insife HALOPV 5.0 is a major release enhancing the capabilities of HALOPV 4.2 to become a multitenant solution. It contains several updates and changes, as detailed in section 4, to address some key identified bugs and issues, along with some limited new/ updated features.

2. Upgradability

HALOPV 5.0 can be upgraded from HALOPV 4.2. And it can also be deployed as a standalone full installation.

3. Compatibility

HALOPV 5.0 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)
- ARISg 7.2 (Please contact us for compatibility with earlier/ later versions)
- Browser Compatibility
HALOPV requires a JavaScript enabled browser and supports the current and prior major release of **Google Chrome**, **Mozilla Firefox**, and **Microsoft Edge**. HALOPV leverages Oracle APEX framework and is compatible with browsers supported by it.

    OBS: **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 119, and Edge was on version 119.

4. Changes since the last release

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

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
Aggregate Reporting	Flexibility to reuse aggregate reports in multiple records	A new enhancement has been introduced enabling the utilization of aggregate report configuration across multiple records through the addition of new field on the form 'Use linked configuration record'.	**Minor** Reusing existing feature. No impact on existing customers.	INSIFE-HALOPV-SS-39 (SS-39- PAGE-143) HLP-4379
Aggregate Reporting	Aggregate Reporting configuration form updates	Few of the fields are added and/or updated within the configuration form. They are listed as below: • Form header renamed as "Data Query Configuration Form" • "Case Classifications (Keywords)" renamed to "Keywords to Include" • "Keywords to exclude" field is added • "MedDRA SMQ" renamed to "MedDRA Term Collection to Include." • "MedDRA Term Collection to Exclude" field is added • Flexibility to select substance • "Set Reporting Values" tab is added for the International Birth Date field, report header, title, and footer. This tab will be displayed based on certain defined criteria • "PADER Configuration" and "Summary Tabulation" tabs will be displayed based on certain defined criteria	**Minor** Renaming and Addition of few fields. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-3113

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
Aggregate Reports	Aggregate report screen update	The aggregate report ("ICSR Product-Event Line Listing") now includes a column showing the C.1.8.1 - Case Number.	**Minor** Addition of a field. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-6148
Agreements	Agreements Title	Updates have been made to display Agreements Title and Type on Agreements form page	**Minor** Usability Enhancement. No impact on existing customers.	* HLP-4058
Agreements	Tab 'Involved Organizational Entries' is now Configurable	Agreements workflow has been updated to include a new configuration to display 'Involved Organizational Entries' tab.	**Minor** Configuration Enhancement. No impact on existing customers.	* HLP-2891
Clinical Trials	Clinical Study Form Update	A new feature has been introduced for the purpose of automating the transfer of the selected Record Type from the dropdown during Clinical Study record creation in Clinical Trials - Clinical Studies, directly to the Study Phase field on the Clinical Study form (Periodicity and Status tab).	**Minor** Automating a field selection. No impact on existing customers.	INSIFE-HALOPV-CLIN-STUD-TDS-420 HLP-6120
Clinical Trials	Clinical Project Details Form addition	A new form named "Clinical Project Details" has been introduced for the Clinical Trials module. This form comprises of the following sections and fields: Project Details tab: - Project ID: Free text field - Description: Free text field - Studies tab: A display-only list of Studies associated with the Project	**Minor** New Functionality. No impact on existing customers.	INSIFE-HALOPV-CLIN-STUD-TDS-420 HLP-3269

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
Clinical Trials	Clinical Study Project ID Field Update	The "Study Project ID" field has been updated to a pop-up selector that displays the Project IDs of completed records from the Clinical Trials - Projects workflow. The field also allows users to manually enter the Project ID if required.	**Minor** Enhancing field selection. No impact on existing customers.	INSIFE-HALOPV-CLIN-STUD-TDS-420 HLP-3250
Clinical Trials	Addition of fields for report type – 'Report from Study'	New free text fields have been added to the case form when the report type is "Report from Study". • Patient ID • Randomization Number	**Minor** New Functionality. No impact on existing customers.	INSIFE-HALOPV-ICSRs-TDS-410 (PAGE-684) HLP-3246
Clinical Trials	Flexibility to select study arms	A new enhancement has been made in case report type is "Report from Study" and the clinical study selected has multiple arms, the user has the flexibility to select an arm from a dropdown for a Clinical Study that's been established in the Clinical Trials workflow.	**Minor** Enhancing field selection. No impact on existing customers.	INSIFE-HALOPV-CLIN-STUD-TDS-420 HLP-3233
Clinical Trials	Study Configuration for Product Type	Study Product configuration has been updated to include ability to select – • Product type (Investigational Medicinal Product, Comparator, Placebo, Non-investigational Medicinal Product) • If a study product is blinded or not • Study Arm(s), including designation of study products to the respective Study Arm(s)	**Minor** Configuration Enhancement. No impact on existing customers.	INSIFE-HALOPV-CLIN-STUD-TDS-420 HLP-3242 HLP-3243 HLP-3244 HLP-3252
Document Management	Attachment Page PDF enhancement	New enhancements have been made to the document page with the introduction of a new switch to incorporate PDF Tron URL. This functionality allows the editor to view PDF attachments in an external online editor, do changes and save the change back to HaloPV.	**Minor** Enhancement. No impact on existing customers.	* HLP-5994

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
E2B	R3 Export Mapping Enhancement	R3 export mapping has been updated to specifically target the fields D.10.7.1.r.3 – Continuing and D.7.1.r.6 - Family History to ensure correct order within the E2B report and accurate alignment of null flavors.	**Minor** Enhancement. No impact on existing customers.	INSIFE-HALOPV-ICSR-JSON-API-EXP-MAP-SS-58 HLP-6268
E2B	Mask Reporter information	The E2B R3 has been updated to mask the reporter information – Telephone when the privacy checkbox "Hide the reporter information" is selected.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-ICSR-JSON-API-EXP-MAP-SS-58 HLP-6148
Entities - Organisation	Tenant level enhancements	Enhancements have been made to ensure that as a multi-tenant user: • Only records associated with the user organizations will be visible, preventing the display of records from other organizations • Only studies associated with the user organization will be visible to an individual user, preventing the display of studies from other organizations • User will be able to view only products specifically listed for their organization, ensuring cross-tenant product visibility	**Minor** No impact on existing customers. HALOPV maintain individual data segregation.	INSIFE-HALOPV-FRS-17 (URS 05.300) INSIFE-HALOPV-SS-39 (SS-39- PAGE-128, PAGE-166) HLP-4857 HLP-4855 HLP-4854
Entities–-Organisation	New Field 'Outbound File prefix'	A new field 'Outbound File Prefix' has been added to Organization, the values in this field will come from configured code list.	**Minor** Addition of few fields. No impact on existing customers.	INSIFE-HALOPV-ENTITIES-TDS-414 HLP-4440

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
Factory Lock	Factory Lock on all Forms	Factory lock has been implemented on all HALO forms.	**Minor** Configuration Enhancement. No impact on existing customers.	* HLP-3180
Home Screen	Dashboard Updates	The following section have been removed from the landing screen of the user: • My top 5 open tasks • Processing Compliance • Charts	**Minor** UI Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 (S S-39-PAGE-1) HLP-5493

ICSRs (Medicine Incidents)	ICSR Case form	ICSR Case Form has been updated with below changes –
		• Add – the following fields have been added at 'Study Identification' form 'Sender(s) and Case info' section –
		    o Observe Study Type (i. e. Study Type where Reaction(s) / Event(s) were observed)
		    o Study Registration (Registration Type, Study Registration Number and Study Registration Country)
		    o Korean use (Other Studies Type)
		• Hide–- the following fields have been removed from users view -
		    o ''Coded Substances in Tria'',
		    o ''Active Ingredient(s''
		    o ''Study Drug Identifie''
		• Text Update – text of following field has been updated –
		    o The field''Study has been unblinde'' updated to''Study is eligible for unblindin''
			Minor Renaming and Addition of few fields. No impact on existing customers.	INSIFE-HALOPV-CLIN-STUD-TDS-420
				
				 HLP-3251

| ICSRs (Medicine Incidents) | Linking ICSR with Clinical Trial Workflow Details | A new feature has been introduced for the purpose of auto-populating the below sections and fields in the ICSR using details from the selected study in the Clinical Trials workflow when a Clinical Study (and optionally an Arm) is selected in the case form.

For "Sender(s) and Case Info - Study Identification" section:
• "Sponsor Study Number (C.5.3)" is populated from "Clinical Trials - Protocol Number"
• "Study Name (C.5.2)" is populated from "Clinical Trials - Protocol Title"
• "Study Type where Reaction(s) / Event(s) were observed" is populated from "Clinical Trials - Observe Study Type"
• "Study Registration" details (including Registration Type, Study Registration Number, and Country) are populated from "Clinical Trials - Study Registration"
• "Korean use (Other Studies Type)" is populated from "Clinical Trials - Korean use"

For "Drugs" section:
• "Medicinal Product Name as reported" (G.K.2.2) is populated from "Clinical Trials – Product"
• Product MPID
• "Characterization of Drug Role" (G.K.1) is populated to "Suspect" by default
• "Investigational Product blinded" status is populated from "Clinical Trials – (Product) Blinded"
• Study
• Additional non-investigational medical products (if checkbox is marked)

For "Drug(s)-reaction(s) Matrix":
• "Product" is populated from "Clinical Trials - Product" | **Minor** Automating field values. No impact on existing customers. | INSIFE-HALOPV-ICSRs-TDS-410 (PAGE-600, PAGE-640, PAGE660)

HLP-3234
HLP-3603 |

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
ICSRs (Medicine Incidents)	Batch Case Re-submission Feature Added	An enhancement has been made to allow batch re-processing of cases.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-2317
ICSRs (Medicine Incidents)	Alphanumeric Patient ID Support	The Field Patient ID now supports alphanumeric characters.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-5705
ICSRs (Medicine Incidents)	Addition of Manual Re-run Button for Duplicate Search	New features have been introduced on the "Duplicate Search" page: • Allowing user to manually re-run the duplicate search • Added a column 'Matching Keywords' to highlight the keywords from the case that matched the duplicate search criteria	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-5522
ICSRs (Medicine Incidents)	Updated XML Encoding for EMA	XML encoding has been updated for GOM_GET_XML_R3 to encode the correct sender organisation in the generated XML to EMA.	**Minor** Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-5440
ICSRs (Medicine Incidents)	Duplicate search screen enhancement	The Workflow task along with the record Revision, have been incorporated on the duplicate search screen.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-6148
ICSRs (Medicine Incidents)	Enhanced Medicine Incident Intake Search Performance	A performance boost has been introduced to the search screen for Medicine Incident Intake. It narrows down the search to only display records currently open in the workflow. Additionally, search results are refined to show exclusively the primary serious event and the primary suspect product.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-5272

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
ICSRs (Medicine Incidents)	MedDRA Coding Update	Updates have been made to automatically populate below values for an Event which is coded using a medically serious term (configurable list) • Select "Always serious term' checkbox • Select "Yes" on "Other Medically important Condition (E.1.2.3f)	**Minor** Automating few field values. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-4928
ICSRs (Medicine Incidents)	MedDRA Coding Update	Updates have been made to display MedDRA term text along with MedDRA codes for the coded Verbatim.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-4785
ICSRs (Medicine Incidents)	Reported Term Event Update	An update is implemented to the event auto-coding process. If an event verbatim is available for any of the following fields then it is not replaced by the coded MedDRA term: • E.i.1.2 - Reaction / Event as Reported • G.K.7.r.1 - Indication as Reported by Primary source • D.9.2.r.2 - Reported Causes of Death • D.9.4.r.2 - Autopsy-determined cause of Death	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-5725
ICSRs (Medicine Incidents)	Null flavours on Event Fields	An enhancement ensures that when the 'Reaction Outcome' is 'Unknown', then the following fields shall be populated with the Null flavor 'No Information': • E.i.3.2a - Results in Death • E.i.3.2b - Life Threatening • E.i.3.2c - Caused/Prolonged Hospitalisation • E.i.3.2d - Disabling/Incapacitating • E.i.3.2e - Congenital Anomaly/Birth Defects • E.i.3.2f - Other Medically Important Condition	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-ICSRs-TDS-410 (PAGE-620) HLP-4927
ICSRs (Medicine Incidents)	Updates to capture Reason for record 'Deactivation'	Updates have been made to capture the Reason of Record 'deactivation' and "Re-activation", the captured reasons will be displayed in record Notes and Workflow history.	**Minor** Addition of few fields. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-2472

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
ICSRs (Medicine Incidents)	Study selection in ICSR	While creating a new ICSR via wizard, users can now select following study fields – • Study Type • Study Arm • Study Product	**Minor** Configuration Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-3361
ICSRs (Medicine Incidents)	EU specific New Fields Added	An enhancement has been made to add following new EU specific fields on Drugs Tab of ICSR form to capture – • INVENTED NAME • SCIENTIFIC NAME • TRADEMARK NAME • STRENGTH NAME • FORM NAME these fields will be available on all the applicable modules.	**Minor** Addition of few fields. No impact on existing customers.	INSIFE-HALOPV-ICSR-JSON-API-EXP-MAP-SS-584 HLP-4622
ICSRs (Medicine Incidents)	Organization selection on Sender Tab	A new feature has been added on 'Sender Details' page, users can now search the configured organization and copy its details into the page using the 'Copy Details from Entity' button.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-4483
ICSRs (Medicine Incidents)	A new tab to capture Sender Details	A new tab has been added to capture the Sender Details, the tab is available in 'Reporter and Sender Information' part of an ICSR form. It can be used to capture sender's Organization and Contact details.	**Minor** Addition of new Tab. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-4244
Mailbox	Multiple email support	An update ensures to remove the one-mailbox-per-workflow limit.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-6454

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
Notifications	Enhancement to notifications	An enhancement has been made to send the notifications only to users who belong to the same organization as the record.	**Minor** Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-6052
Notifications	Custom Notification	Custom Notifications have been updated to send the notification to the user who has created the record, previously it was configured to send the notification to the user who has last viewed the record.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 (SS-06-20) HLP-3958
Products	MedDRA Synonyms Enhance Search Capabilities	A new enhancement integrates official multilingual synonyms from the MedDRA Desktop Browser.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-PROD-MGMT-TDS-417 HLP-5229

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
Products	Drug Coding	An enhancement has been made on PI Browser/ Drug Browser page, users can now use the following new tabs to select the source, browse and code accordingly – • Company Products • WHO Drug	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-PROD-MGMT-TDS-417 (6.1.10., 6.1.11., 6.1.12., 6.1.13., 6.1.14., 6.1.15., 6.1.16., 6.1.17., 6.1.18., 6.1.19., 6.1.20.) HLP-6115
Products	Searching non-consecutive words	An enhancement has been made while using Drug Browser and Searching on a non-consecutive word. The search results have been refined in such cases and a hint has been added.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-PROD-MGMT-TDS-417 HLP-4391
Products	Updates to use 'Product filter' and 'Same Ingredient' together	Updates have been made to allow users to use Product Filters (ability to include/exclude specific products) while applying 'Schedule on same ingredient'.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-PROD-MGMT-TDS-417 HLP-2890

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
Requirements Intelligence	Tab 'Requirement verbatim and notes' is now Configurable	Requirements intelligence module forms have been updated to include a new configuration to display 'Requirement verbatim and notes' tab.	**Minor** Usability Enhancement. No impact on existing customers.	* HLP-3147
Risks	Risk form enhancement	The risk management tree view and the Risks child form have been updated.	**Minor** Enhancement. No impact on existing customers.	* HLP-5999
Scheduler	Updates to record workflow scheduler	Few updates have been made to the task scheduler configuration with the ability to define: • Start date and stop date for the task • Frequency of the task • Workflow to initiate	**Minor** Usability Enhancement. No impact on existing customers.	* HLP-5995
System Configuration	Configuration enhancement	A new enhancement has been made to auto-calculate the due date for a case based on case seriousness.	**Minor** Automating a field. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-5835
System Configuration	Introduction of Entity and Environment-Specific Controls with Block Distribution Functionality	A new enhancement introduces three pivotal fields for configuration and distribution control: • EntitySpecific: Denotes client-specific configuration settings that are automatically applied to all subsequent entities • EnvironmentSpecific: Represents settings that are intrinsically tied to their individual environments, discouraging replication across different environments • BlockDistribution: Engineered to control the progression of new distribution functions, this feature can halt the transfer of specific entries to succeeding environments	**Minor** Addition of few fields. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-6263

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
System Configuration	Config Switch for Preserving or Updating Timestamps and ICSR Case Identifier	A new enhancement introduces config switch "Preserve original timestamps and case identifier." By default, this feature is set to "Yes". When set to Yes, it retains the values of the following tags from the XML provided. - C.1.2 - Date of Creation - C.1.4 - Date report was first received from source - C.1.5 - Date of receipt of the most recent information for this report Conversely, if set to "No", the system will update these fields with the current date and time upon receipt.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-6258
System Configuration	New switch to ICSR merge Follow-up information	A new checkbox has been incorporated, granting users the option to bypass the mandatory event/product update logic. When a Follow-Up is merged into a pre-existing case, the system either refreshes (overwriting events/products) or retains the master case's original events/products, depending on the selection made in the new checkbox.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 HLP-6224
System Configuration	Code List Configuration	Updates have been made to ensure Code list configuration can only be Created/ Updated or Deleted (Soft deleted) by Global Admin User, Other users can only View them.	**Minor** Configuration Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 (S S-39- PAGE-97, PAGE-25, PAGE-26) HLP-3932
System Configuration	Ability to store Entity ID	The system configuration has been updated with the ability to store Entity ID.	**Minor** Usability Enhancement. No impact on existing customers.	INSIFE-HALOPV-SS-39 (SS-39- PAGE-4, PAGE-17, PAGE-19, PAGE-26, PAGE-123) SS-03-01 HLP-3928 HLP-3934

Area / Process / Group	Title	Description	Impact	Specification/ REQ ID
User Administration	Updates in 'Workflow Manager' Role	The 'WORKFLOW MANAGER' role has been updated to provided additional access of COMPLETE TASK button, after assigning the record to a user.	**Minor** Configuration Enhancement. No impact on existing customers.	* HLP-1084

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

5. Bugs resolved in HALOPV 5.0

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Acknowledgements	Negative Acknowledgments from MHRA	A fix ensures that negative acknowledgments received from MHRA are accurately reflected in the system.	None. Fix only.	* HLP-6035
Attachments	Attachments with invalid character	An update ensures that file names containing invalid characters are preserved as attachments, and users can download these files in readable format.	None. Functionality enhancement.	* HLP-5788
Data Collection Programs	Master Parent Title Link Fix	A fix ensures the 'Master Parent title' link works as expected for all the Views of 'Data Collection Programs'.	None. Fix only.	* HLP-1090
Data Collection Programs	Alignment of 'Type' Selection with Relevant 'Party Roles Group' in Agreements	A fix ensures that the available roles in the 'SDEA Party role groups' section are consistent with the overall Type of the SDEA selected on the main form, streamlining role selection under specific Data collection programs	None. Functionality enhancement.	* HLP-4509
Device Incidents Processing	Refined MIR_IMPORT_XML Device Data Import	MIR_IMPORT_XML package has been updated to ensure Device information is populated accurately from the imported MIR form.	None. Functionality enhancement.	* HLP-6252

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Device Incidents Processing	Reporter Details Save	A fix ensures that when a user switches between tabs on 'Device Reporter/ Manufacturer' page the application does not loses the 'Manufacturer Information'.	None. Fix only.	* HLP-4544
Device Incidents Processing	MHRA Device Incidents	Issue in Device Incidents processing workflow have been fixed where application was displaying error message while clicking on Device Tab.	Record revisions that have corrupt data will need be handled from halo.	* HLP-3783
E2B	E2B Mapping Logic Update for D.9.3	A fix ensures that E2B mapping is updated to import information from the tag D.9.3 - patientautopsyyesno correctly into the case form.	None. Fix only.	INSIFE-HALOPV-ICSR-R3-TO-JSON-FULL-MAPPING-296 HLP-5554
E2B	E2B Mapping logic update for E.i.2.1b	An update to the E2B mapping logic ensures that E.i.2.1b - reactionmeddrallt, full hierarchy of the event term is imported in the system.	None. Fix only.	INSIFE-HALOPV-ICSR-R3-TO-JSON-FULL-MAPPING-296 HLP-5528
E2B	E2B Mapping logic update for C.1.1	A fix ensures that cases imported from PVS with an invalid C.1.1 - Sender's (Case) Safety Report Unique Identifier, are linked with a freshly created C.1.1. Furthermore, cases featuring an invalid C.1.8.1 - Worldwide Unique Case Identification Number will be associated with the valid C.1.1.	None. Functionality enhancement.	INSIFE-HALOPV-ICSR-R3-TO-JSON-FULL-MAPPING-296 HLP-6030

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Home Screen	Quick searches integrate with User Role	A fix ensures when a user searches for a record using Quick Search, the system limits search results to logged in "user access roles".	None. Functionality enhancement.	INSIFE-HALOPV-SS-39 (SS-03-22) HLP-4423
ICSRs (Medicine Incidents)	Accepting decimal values for various fields	The following fields will now be able to accept and retain decimal values: • D.2.2a - Age at Time of Onset of Reaction / Event • D.2.2.1a – Gestation Period When Reaction / Event Was Observed in the Foetus • D.4 – Height (cm) • D.10.2.2a – Age of Parent • D.10.4 – Body Weight (kg) of Parent • D.10.5 – Height (cm) of Parent • E.i.6a – Duration of Reaction / Event • G.k.2.3.r.3a – Strength • G.k.4.r.6a – Duration of Drug Administration • G.k.5a – Cumulative Dose to First Reaction • G.k.6a – Gestation Period at Time of Exposure	None. Functionality enhancement.	INSIFE-HALOPV-SS-39 HLP-5463
ICSRs (Medicine Incidents)	Concomitant Medication Coding for Blinded Case	A fix ensures user can code a CM (Concomitant Medication) of a Blinded case.	None. Functionality enhancement.	INSIFE-HALOPV-SS-39 HLP-4820
ICSRs (Medicine Incidents)	PI/SP Substance Processing	A fix ensures that in case only Preferred name (PN) of the substance system is entered in the case then it is copied as the Preferred Name into the Child name.	None. Fix only.	INSIFE-HALOPV-SS-39 HLP-4415

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
ICSRs (Medicine Incidents)	Recoding for a Completed Case	A fix ensures that a user will not be able to Code a Verbatim of a completed case, Re-Code button has been disabled in such cases.	None	INSIFE-HALOPV-SS-39 HLP-4292
ICSRs (Medicine Incidents)	Blinded Study Records	A fix ensures that a record involving a blinded study does not display product names within the record list.	None. Fix only.	INSIFE-HALOPV-SS-39 HLP-6431
ICSRs (Medicine Incidents)	Substance Entry Form	A fix ensures that on the left pane of the Substance Entry Form, the Coded Substance is displayed. In scenarios where this is absent, the Selected Substance Name (override) field is given precedence. If neither of these fields is available, then the Substance/Selected Substance Name Verbatim is presented.	None. Functionality enhancement.	INSIFE-HALOPV-SS-39 HLP-5451
ICSRs (Medicine Incidents)	Dates with leading Zero	A fix ensures users can save dates having leading '0'(Zero). This issue is only applicable for deployments running on APEX 21.1 or later.	None. Functionality enhancement.	INSIFE-HALOPV-ICSRs-TDS-410 (PAGE- 600, 620, 640, 641, 650, 660, 669, 669, 672, 675, 678, 681, 683, 684, 685, 333, 336) HLP-4119
ICSRs (Medicine Incidents)	PI Code Transfer to MPID Override	A fix ensures that when a reported drug is coded using the PI Browser: the selected PI Code is transferred correctly into the MPID Override field	None. Fix only.	INSIFE-HALOPV-SS-39 HLP-5663

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Notifications	Nullified Record Notification Trigger Prevented	A fix ensures no notifications are triggered for a nullified record.	None. Fix only.	INSIFE-HALOPV-SS-39 HLP-5180
Notifications	Overdue emails sent only on record modification	A functionality refinement has been executed; an overdue notification email will now be dispatched only when modifications are made to a record. The system will refrain from triggering the email notification upon a user accessing or opening the record.	None. Functionality enhancement.	INSIFE-HALOPV-SS-39 HLP-6113
Products	Product dictionary enhancement	On the product browser, updated the "Name Variation Type filter" to blank and not "Specific Medicinal Product (MPID)".	None. Functionality enhancement.	INSIFE-HALOPV-PROD-MGMT-TDS-417 HLP-4954
Products	Products Unspecific Terms	A fix to ensure that unspecific terms in products can be created, edited, nullified, De-nullified.	None. Fix only.	INSIFE-HALOPV-PROD-MGMT-TDS-417 HLP-6060
Submission	Argus Integration - Case Mismatch	HALOPV-Argus Integration (From Argus to HALOPV) updated for case submission records.	None. Functionality enhancement.	* HLP-3370 HLP-5040 HLP-5041 HLP-5042 HLP-5044

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Submissions	New Privacy switch within the submission details form	A fix ensures that the newly added option within the Submission details form, labelled "Show patient/hide reporter", is consistently chosen both during auto-scheduled submissions and during manual submission creation. This allows patient-specific fields to be properly displayed while reporter-associated fields remain hidden.	None. Functionality enhancement.	* HLP-6224
Scheduler	Scheduler new instance creation	A fix ensures that system handles the scenario when user schedules the instance creation for a date less than current date.	None. Functionality enhancement.	INSIFE-HALOPV-SS-39 (S S-39- PAGE-93) HLP-4450
Workflows	Automated Due Date Recalculation on Workflow Transition	A fix ensures that when a record is transferred to next workflow state, the Due Date for the record is recalculated.	None. Fix only.	* HLP-6377

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

6. Features removed from HALOPV 5.0

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

7. Known Issues & Workarounds

Area / Process / Group	Title	Description	Workaround	Bug ID
CIOMS Template	CIOMS Template Manufacturer Address	At the CIOMS template, system is picking Manufacturer Address from system config. Due to this system is limited to only one manufacturer option.	While using CIOMS template, if user requires different manufacturer information based on ICSR record scope, user shall request a custom placeholder from HALOPV Support.	HLP-7107
Device Incidents Processing	Device Intake Record Search	"Last Updated" date time in Device Intake Search is not consistent with the Audit History of the record.	Users can check the audit log of the record to see the last updated date.	HLP-5832
ICSRs (Medicine Incidents)	ICSR Coding	ICSR Recoding Trigger, which codes the uncoded terms to an Unspecific Term by the event-driven coding principle has some issues.	Users are advised to manually code such events.	HLP-6099
ICSRs (Medicine Incidents)	Test Result Value	Application displays an additional ".0" in the "Test Result (value / qualifier) (F.r.3.2)" field.	This has no impact on the actual value, it is just a representation difference.	HLP-6048
ICSRs (Medicine Incidents)	Patient Medical History	<patientepisodename> is appended to <patientepisodecomments> when the former is a Term rather than a Code.	Users can manually locate the correct code from the term and populate it in the HALO structured field.	HLP-5947

Area / Process / Group	Title	Description	Workaround	Bug ID
List of Values	List of values for Route of Admin	For the list of values – Administration Routes, even though the Deprecated checkbox is checked, the value appears on the 'Duration of Drug Administration' field.	The deprecated values will be marked with a prefix - (Deprecated) in the Administration Routes list of values.	HLP-6534
Notifications	Custom Email Notification	Custom Email Notification does not work for Notification's where Notification text contains "(Double Quotes).	Users are advised to ignore the use of " (Double Quotes) while configuring emails notifications.	HLP-6102
Print	Template list under Print	The template list under Print option is not limited to the Workflow (Aggregate Report).	Users are Advised to use Inline search and select the template carefully or use the 'Generate document from template' option.	HLP-6355
Products	Supress Coding Checkbox Activation	When a product record is re-initiated, 'suppress coding checkbox' is not checked.	Users are advised to check the checkbox manually when re-initiating a product record.	HLP-6686
Products	Products Records Search	While searching for a product using "Records (Products)" search screen, application is not considering "Special Measures" as filter criteria.	Users are advised to use other filter criteria's while searching for a product.	HLP-5969
Record Batch Actions	Reflection of batch Action	The Batch actions performed on too many records takes time to reflect in the Records grid as the Activities are asynchronous.	Users are advised to click the "Go" button to see the outcomes.	HLP-4576
Workflows	Dynamic Due Date	Dynamic Due Date calculation in WF is considering Disabled task while calculating Due Date.	User deleted the disabled tasks.	HLP-6222

8. Contact

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