Insife HALOPV 5.1 Release Notes
Final
Version 1.0
Department: Product Management

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1. Overview

Insife HALOPV 5.1 is a minor release enhancing the capabilities of HALOPV 5.0 and provides various new features to its users. It contains several updates and changes, as detailed in section 4, addresses some key identified bugs along with some limited new/ updated features.

2. Upgradability

HALOPV 5.1 can be upgraded from HALOPV 5.0, and it can also be deployed as a standalone full installation.

3. Compatibility

HALOPV 5.1 is compatible with the following systems:

- Argus 8.2.1.1 and Argus 8.2.3 (Please contact us for compatibility with earlier/ later versions)
- 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 124, and Edge was on version 124.

4. Changes since the last release

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

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
Aggregate Reporting	Aggregate report UI Updates	Updated Aggregate reports UI to provide - - Help texts to each prompt. - Updated Dropdown to Multiselect for following - -- Event listedness -- Datasheet - A new checkbox added to select concomitant drug (CM) at Role of Product - Added an option to select a Country in the report form, system shall use this field to bring the cases where the selected country is used either as Event occurrence country or as Reporter country (Primary or other). - Provide additional column study arm in report O/P. - Added option insert case numbers, this will help user to run report based on case series.	LOW - Minor UI updates and addition of new filter options	HLP-7552 / INSIFE-HALOPV-SS-39
Aggregate Reporting	Aggregate Report UI Updates - Adding Help Text	Updated Aggregate Reports UI, HALOPV now displays Help Text for all the fields, this will help users in configuring Aggregate reports.	LOW- Added help text, no change in functionality	HLP-8483 / *
Aggregate Reporting	Aggregate Reporting Template	Fixed aggregate reporting template (DSUR/PBRER) to add a placeholder to display the name of the company	Low - Update to a Template	HLP-8262 / *
Aggregate Reporting	Aggregate Reports - Case Study type filters added	Updated "Aggregate Report" configuration screen, new filter options have added to filter based on "Study Case type".	LOW - New filter options, no change on existing options.	HLP-7865 / INSIFE-HALOPV-SS-39

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
Aggregate Reporting	Aggregate Reports updated to add-'Event adjudication result' and 'Ring and 'Messmer Grade' as selectable columns	Updated Aggregate reports, 'Event adjudication result' and 'Ring and 'Messmer Grade' are now available as selectable columns. By default, they will remain not selected "Do Not Display" list, users can add them to their view as per need in any of the below reports - - ICSR Product-Event Line Listing - ICSR Case Line Listing - ICSR event analytics	LOW - No impact on data, addition if two more optional columns	HLP-7783 / INSIFE-HALOPV-OOB-ICSR Event Data-SPEC-715, INSIFE-HALOPV-OOB-DSUR-SPEC-445
Agreements	Records should not tick first possible box	Updated the auto first selection, now HALOPV will not auto select the country.	LOW - UI update	HLP-6565 / *
Clinical Trial Management, ICSR, Products	Dosage Information display for study products	Updated to display dosage information for the unblinded products within a study from the respective Products record when a study is selected in the ICSR. The dosage information for blinded products is displayed once the user unblinds them.	LOW - Enhancement to existing functionality	HLP-8025 / *
Devices, System Config	Advance Medical reporting (Workflow) Timeline	Updated Medical reporting timeline, with this update users can now configure workflow timeline based on individual data elements (fields) such as Reaction Outcome (E.I.7).	LOW - Enhancement of existing functionality.	HLP-7353 / *
ICSR, Products	HALOPV ICSR Form Update	Updated ICSR Form with below changes - - At Events section, Now HALOPV will automatically fill the default country and language as per logged in user profile. - At Task action, Now HALOPV will allow auto-closure of "child records". - While performing Incident merge, attachment copy feature will now display a selectable list of attachments to include in the merge.	LOW - Enhancement to existing features	HLP-7452 / *

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
Data Collection Programs	Data Collection Program new field added	Introduced a new field "SDEA ID" added on 'External Parties' tab in the 'DCP' form. The Field will display HALOPV "SDEA Record ID" for a record (external party).	LOW - New field added, no change in existing functionality.	HLP-1470 / *
Devices	Devices Worklist Performance has been optimized.	Devices Worklist Performance Improvement	LOW - Just Performance Optimization	HLP-7207 / *
Dictionary and Terms	Approved Term Collection PT report	HALOPV now provides Approved Term Collection PT Report, this report displays all approved Term Collections (i.e. MedDRA Queries) defined in HALOPV and a full list of all included and excluded terms that constitute the collection.	LOW - This is a new feature, no impact on existing functionalities.	HLP-8236 / INSIFE-HALOPV-OOB-Approved-Term-Collection-PT-Report-SPEC-854
Dictionary and Terms	Compare collections revisions report	HALOPV now provides Compare Collection Revisions Report this report provides a comparison between two selected revisions of a single term collection (i.e. MedDRA Query), or a comparison between two selected MedDRA versions for one term collection. To see this report there must be at least two revisions of a Term collection, otherwise no data is displayed.	LOW - This is a new feature, no impact on existing functionalities.	HLP-8234 / INSIFE-HALOPV-OOB-Compare-Collection-Revisions-Report-SPEC-857

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
Dictionary and Terms	Creation of Custom MedDRA Query (CMQ)	Introduced the workflow to create Custom MedDRA Queries (CMQ) with following features: • Request Creation of query • Designate Narrow or broad scope to a query • Assign different hierarchical level to the query • Request an update and Update existing query • Create new version of queries with each update • Associate each CMQ with the MedDRA dictionary • Activation of query after creation/update • Create new CMQ by copying existing Non-Standard/Standard MedDRA Query	LOW - New Functionality	HLP-6792 HLP-6736 / *
Dictionary and Terms	CRS - Case Retrieval Strategy	HALOPV now supports to receive Case Retrieval Strategy (CRS) data from the Commonwealth Vigilance Workbench (CVW). The main objective of the Case Retrieval Strategies Report is to display current and previous CRS records that exist in HALOPV that have been received from CVW.	LOW - This is a new feature, no impact on existing functionalities.	HLP-8238 / INSIFE-HALOPV-OOB-CRS-Report-SPEC-853
Dictionary and Terms	Duplicate/ Similar Term collection report	HALOPV now provides Similar Term Collections/Duplicates Report is to display Term collections defined in HALOPV and how much of an overlap there is of constituent/ child terms with other term collections. The report provides the ability to: a) Select a target term collection and display the comparison to other collections with the percentage overlap score, based on % similarity with other approved term collections b) Return a full list of all term collections, with the % similarity with all other approved term collections based on similarity of PTs c) Display the included PTs in a matrix view enabling a comparison between Term collection definitions	LOW - This is a new feature, no impact on existing functionalities.	HLP-8235 / INSIFE-HALOPV-OOB-Similar-Term-Collections-Duplicates-Report-SPEC-856
Dictionary and Terms	Integration of Latest IDF Japan	Introduced the functionality to load the most recent version of the IDF Japan.	LOW - New Functionality	HLP-6827 / *

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
Dictionary and Terms	Integration of Latest WHO Drug CRT Japan	Introduced the most recent version of the WHO Drug CRT Japan into the HALOPV.	LOW - New functionality	HLP-6828 / *
Dictionary and Terms	Introduction of IDF Japan Browser	Introduced the IDF Japan Browser with the following features: • Ability to view latest IDF Japan dictionary • Ability to search and browse terms	LOW - New Functionality	HLP-6855 / INSIFE-IMS-WHODD-DEP-GDL-413 INSIFE-HALOPV-WHODD-LOADER-TDS-927
Dictionary and Terms	Introduction of WHO Drug Browser	Introduced the WHO Drug Browser with the following features: • Ability to select any supported language • Ability to search and browse terms	LOW - New Functionality	HLP-6852 / INSIFE-IMS-WHODD-DEP-GDL-413 INSIFE-HALOPV-WHODD-LOADER-TDS-927

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
Dictionary and Terms	Introduction of WHO Drug CRT Japan	Introduced the WHO Drug CRT Japan Browser with the following features: • Ability to select any supported language • Ability to search and browse terms	LOW - New functionality	HLP-6857 / INSIFE-IMS-WHODD-DEP-GDL-413 INSIFE-HALOPV-WHODD-LOADER-TDS-927
Dictionary and Terms	Load WHO Drug Dictionary	Introduced the functionality to load latest WHO Dictionary (B3, C3, ATC, CRT, Standard Drug Group (SDG)) in HALOPV.	LOW - New Functionality	HLP-6822 / *
Dictionary and Terms	MedDRA Browser Enhancement	Introduced the MedDRA browser with following features: • View and select the various dictionary versions loaded • View and select various languages supported by MedDRA • View and select the various Standard MedDRA Queries (SMQ)/Custom MedDRA Query (CMQ) • Export SMQ/CMQ in an excel spreadsheet • Select/Deselect and Drag and drop multiple terms into CMQ term collections • Filter PTs by Primary or Secondary paths	LOW - Enhancement to existing feature	HLP-6836 / *
Dictionary and Terms	Promote CMQ to Non-Standard MedDRA Query	Introduced a functionality to promote an existing Custom MedDRA Query (CMQ) to Non-Standard MedDRA Query	LOW - New functionality	HLP-6791 / *
Dictionary and Terms	PT Matrix report	Introduction of PT Matrix report that provides details of distinct PTs amongst different CMQs and SMQs.	LOW - New Functionality	HLP-6735 / *
Dictionary and Terms	Similar/Duplicate Term collection report	Introduction of Similar/Duplicate Term collection report to identify similar or duplicate CMQs or SMQs, providing a % match of 100, 80 or 60.	LOW - New Functionality	HLP-6734 / *

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
Entities	Entities and Product relation updated	Updated Entities and Products relationship, now if products are listed as products of an Entity, the entity name will be used as market authorization holder.	LOW - Fix in existing functionality	HLP-6850 / *
ICSR	Added central receipt date to E2B R3 form and data model	Updated E2B R3 Intake and Forms to support Central receipt date, this change improve/ Impact following dependent objects - audit log, cloning, up-versioning, and database tables The Argus-HALOPV integration also updated for this.	LOW - Support of a new field using existing functionalities.	HLP-8144 / INSIFE-HALOPV-ICSRs-TDS-410
ICSR	Auto Population of Study Details at ICSR	Updated the Study details population in an ICSR form for - - Sender and case info - Drugs and Drugs reaction matrix	Minor - Usability Enhancement. No impact on existing customers.	HLP-7301 / INSIFE-HALOPV-ICSRs-TDS-410
ICSR	Auto-listedness button for the event-listedness tab	Update event-listedness and provided a button "Calculate" to auto calculate event listedness. HALOPV uses the values in Event(s) and Drug(s) to calculate it. User can update the auto calculated values to use "Reset" button to reset the listedness details.	LOW - New functionality, to add automation in existing fields. No change in existing records.	HLP-7739 / INSIFE-HALOPV-OOB-ICSR Event Data-SPEC-715
ICSR	Automated Duration of Event and Dosage	Updated, fields Duration of Event, Dosage and Onset Latency have been automated using below logic - -- Dosages timeline: G.K.4.R.6.a and G.K.4.R.6.b Using delta of - G.K.4.R.4 & G.K.4.R.5 -- Event timeline: E.I.6.a and E.I.6.b Using delta of - E.I.4 & E.I.5 -- Time between drug admin and reaction start (value) (G.K.9.I.3.1a) - delta of (Smallest (G.K.4.R.4) and E.I.4) -- Time between Last Dose and reaction start(value) (G.K.9.I.3.2a) 0 delta of (largest (G.K.4.R.5) and E.I.4)	LOW - Automated few fields	HLP-8008 / INSIFE-HALOPV-ICSRs-TDS-410

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
ICSR	Chinese causality mapping issue	Fixed the issue - Chinese causality results now support many-to-one mapping from the code list "Result of assessment (China).	Low - fixed existing functionality	HLP-3641 / INSIFE-HALOPV-SS-39
ICSR	Configurable ICSR Fields for EMA R3 XML Output	Updated HALOPV Configuration, now It is possible to configure specific fields in ICSR case form to be hidden / excluded/ unreachable from the EMA R3 XML output files.	LOW - New configuration added for existing fields.	HLP-7478 / *
ICSR	Duplicate search and compare updated for better comparison	Updated duplicate search to enhance keyword calculation and recalculation and routing rules, summary of Changes - 1. Updated Source Identifiers (C.1.9.1.r) logic: - 1.a. Duplicate merge: If C.1.8.1 in FU is different that C.1.8.1 in master, then C.1.8.1 from FU should be inserted as Source identifier in new revision of master record as below: 1.a.1. C.1.9.1.r.1 = DKMA Duplicate WWC number / [C.3.2] (from duplicate record) 1.a.2. C.1.9.1.r2 = [C.1.8.1] (from duplicate record) 1.b. Follow-up merge: If C.1.1 in FU is different that C.1.1 in master, then C.1.1 from FU should be inserted as Source identifier in new revision of master record as below: 1.b.1. C.1.9.1.r.1 = [C.3.2] (from follow-up record) 1.b.2. C.1.9.1.r2 = [C.1.1] (from follow-up record) 1.b.3. But if C.1.1 is already inserted in Source Identifiers, it should not be inserted again (e.g. nullifications) 3. Keyword/ TAGs calculation and recalculation updated for an ICSR (its more institutive now). 4. Duplicate compare page will now auto switch ON the fields which are changed.	LOW - Existing functionality enhanced.	HLP-6920 / INSIFE-HALOPV-SS-39
ICSR	Filter narrow or full SMQ	Introduced the functionality to filter narrow SMQ or full SMQ by the user.	Low - New functionality	HLP-6733 / *

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
ICSR	ICSR - Default Sender and Case details	Updated default configuration for below fields - - Type of Report (C.1.3) - First sender of the case (C.1.8.2) they are now defaulted to BLANK.	LOW - Existing functionality updated.	HLP-7273 / *
ICSR	ICSR - Medical Review Temporal relationship	Updated ICSR Data form, a new link Temporal relationship has been added. It will display the time relationship between the drug administration (Date of therapy start date, therapy duration) and occurrence of adverse event in a graphical way.	LOW - This is a new UI based report generated using existing data.	HLP-7632 / INSIFE-HALOPV-ICSRs-TDS-410
ICSR	ICSR - new page "Event Adjudication" added	Introduced a new page "Event Adjudication" for ICSR processing, this can be used to capture - - Event adjudication result - Ring and Messmer grade The page can be configured in the workflow as needed.	LOW - New page added, no impact on existing functionality.	HLP-7700 / INSIFE-HALOPV-SS-39
ICSR	ICSR - Study Details Updated to capture multiple "EudraCT number" and "EU trial number"	Updated "Study Details" form to improve the capture and display of "EudraCT number" and "EU trial number". Users can now capture multiple values of these fields for a study at "Study Details" tab of "Study Details" form and all the values will be displayed in the ICSR form when the study is selected.	LOW - Existing functionality updated	HLP-7278 / *
ICSR	ICSR - Study Selection refined	Updated ICSR "Create from Wizard" page, list of studies in "Select Study" dropdown has been refined, now it will not list completed studies.	LOW - Update in existing functionality	HLP-7350 / *

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ICSR	Patient and Medical History	Updated ICSR Intake Patient and Medical History Section with below details - - Added new sub-region for the D.1.1. section and added the E2B title there for user readability. - Modified the page layout to make it more readable and compact. - Modified pregnancy tab, now it will not be displayed for male patients. - Modified Patient ID configuration, it is now configurable to be Displayed or Hidden.	Low - Updates to existing functionality	HLP-7460 / *
ICSR	Patient ID can be Alpha numeric	Updated Patient ID, now it can be Alpha numeric	LOW - Field type change	HLP-5705 / *
ICSR	Record Title Updates	Update Automatic Record Title feature, HALOPV will now add record number in record title field as prefix for ICSR Processing.	LOW - Update to existing feature of automatically populating record title.	HLP-7367 / INSIFE-HALOPV-SS-39
ICSR, Products	Product approval numbers - China	Added support for adding Chinese product approval numbers (G.K.CN.4) Clients can enable this in the system config if they want to enable this feature	LOW - Using existing configuration.	HLP-7081 / INSIFE-HALOPV-ICSR-CODING-SS-608
ICSR, Submissions	CIOMS Form Updated	Updated CIOMS form template to fetch manufacturer address first form entity and then from system config.	LOW - Updated in existing functionality.	HLP-7107 / *

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ICSR, Submissions	Updates in E2B R3 xml	Updated E2B R3 xml to provide MedDRA codes for the test results, with this update - - Patient test results will now generate either the MedDRA Code (f_r_2_2a/b) OR the Unstructured Name (f.r.2.1). - Added UNK as default null flavor for f.r.1 (test date), this is a mandatory field.	LOW - Existing functionality enhanced	HLP-7088 / INSIFE-HALOPV-ICSR-API-EXP-MAP-SS-282
ICSR, System Config	ICSR Drug/Reaction Matrix updates for XML Import	Updated ICSR Drug/Reaction Matrix the free text field has been updated to selectable list, users are advised to get their LOV's configured to use the standard LOV's for "Method of Assessment (G.K.9.I.2.R.2)" or "Result of Assessment (G.K.9.I.2.R.3)" and use the LOV's ID for importing values in XML.	MEDIUM - Field types changed, LOV's need to be configured before importing.	HLP-7498 / *
Products	MedDRA auto coding updated to make the update of E_I_3_2F from the IME list configurable	Updated MedDRA Coding, a new configuration has been added for automatic population of the "Other seriousness" field based on the always serious term list. If not configured it will default to preserve current logic (align with the term list if a list is present).	LOW - New configuration for existing functionality.	HLP-8243 / *
Products, System Config	Reactivate a Retire Query	Created a new feature to reactivate and retired query, this will help user to create a new version of retired query,	LOW- New feature to reactive a retired query.	HLP-8518 / INSIFE-HALOPV-OOB-Compare-Collection-Revisions-Report-SPEC-857

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
PSMF Management	PSMF Module - New Worklist Added	Introduced worklist/ records grid at "Annex H.1 - List of Medicinal Products Records".	LOW - New functionality	HLP-7547 / INSIFE-HALOPV-PSMF-TDS-717
PSMF Management, Submissions	PSMF ANNEX F1 For Late Submission YTD Calculation	Updated PSMF ANNEX F1 For Late Submission YTD Calculation, The data for late submissions now incorporates a Year-to-Date (YTD) calculation in HALOPV. In the Submissions, tabular per destination type section HALOPV now adds totals calculations of all submissions; Late Submissions, Timely Submissions and Compliance %	LOW - Update in existing functionality.	HLP-8010 / INSIFE-HALOPV-SUBMSN-TDS-421
Submissions	Column "Case Type" added at Submission record overview	Update Submission record overview, a new column "Type" has been added, this will display the 'Case Type' of each case.	LOW - Update in existing functionality.	HLP-6946 / INSIFE-HALOPV-SUBMSN-TDS-421
Submissions	Submission Email distribution	Updated HALOPV logic to send the submission report, now system will use the email addresses available under the Persons tab of the "Reporting To" destination (entity) defined in the Reporting Rule.	LOW - Updated to existing configuration	HLP-7443 / INSIFE-HALOPV-SUBMSN-TDS-421
Submissions	Submission Overview - Submission details report	Updated: Add columns C.1.4 and C.1.5 to the Submission Overview report	LOW - Addition of new columns	HLP-7642 / INSIFE-HALOPV-SS-39

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Submissions	Submission Overview will limit data for user organization	The Submission Overview has been updated to filter (hardcoded) to the current users' organizations. The user will now only see submissions owned by the users' organization (or other organizations where the user has access)	LOW - This was required for multi-tenant environment so existing client deployments will have no impact.	HLP-7401 / *
Submissions	Submission Reporting Rules Update	Updated reporting rules for cases where Ignore license is selected, HALOPV will now consider valid products and ignore product license.	LOW - Change in existing configuration.	HLP-6476 / *
Submissions	Submission worklist - new column "current task" added	Updated: The Submissions worklist page now has the "Current task" column shown in the default view. To use the work-list, it must be selected in the workflow configuration.	LOW - New column added, no updates to existing columns.	HLP-7541 / *
Submissions	Updates in Submission Overview Graphs	Updated Submission Overview page, updates - - Submission Overview graph - now it displays Timely submission % W.R.T Submission Month + year - - Submission overview by reporting destination graph - now it displays Timely submission % W.R.T Reporting Destinations W.R.T Submission Month + year -	LOW - Updates only in display using existing data.	HLP-7861 / INSIFE-HALOPV-SUBMSN-TDS-421
Submissions, System Config	Auto-scheduling downgrades are now configurable	Updated System configuration in submissions, added a new configuration to control Auto scheduling downgrades. This update will allow users to turn off downgrade logic entirely via system switches. If turned off, it applies to all rules.	LOW - New configuration for existing feature.	HLP-7499 / INSIFE-HALOPV-SS-39
Submissions, System Config	New validation Rule for Record Submission	Added a new validation rule for record submission, now each submission record shall have below fields before moving to next workflow step - -- Report Type -- Reporting To -- Parent ICSR Record	LOW - New configuration to increase compliance.	HLP-8246 / *

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Submissions, System Config	Submission Scheduling Rule Analysis	Updated ICSR Submissions, a new tab "Submission scheduling rule analysis" has been added to the ICSR Submission records using which users can now view which product-event-destination combinations were evaluated by the HALOPV for a given case, this will add clarity why a certain report was/wasn't scheduled for a specific case/revision.	LOW - We are just displaying existing data to user and added more clarity to the logs.	HLP-7241 / INSIFE-HALOPV-ICSR-SCH-SS-275
Submissions, System Config	Various scheduler Updates	Update Scheduler Logic with below changes - - Removed the filter for blinded records - Removed the Schedule on same ingredient option due to performance reasons - If default license based scheduling is selected case needs to either match on the study filter selected in the rule (CT cases) or the product in the ICSR needs to have a corresponding license that belongs to a country that the rule is configure too. - If Ignore license option is selected a coded product must exist in HALOPV and the study criteria must be met	MEDIUM - Users are advised to review their rules and switch off any/ update the schedulers where the option "schedule on the same ingredient" is selected. Users are advised to review if the coded product exists in HALOPV.	HLP-8386 / *
System Config	Ability to assign Manager to a User	Update user creation, a new field Manager has been added to create/ edit user page. The manager field will be just a placeholder for now with no additional role.	LOW - Will just act as a placeholder.	HLP-8181 / *
System Config	Ability to assign more than one user to a record	Update HALOPV System Configuration to allow more than one user to be assigned to a record. Users can use this field to assign a secondary user (deputy/ designee) to a record if required. Both users will be able to work with and receive notifications for the record.	LOW - No change for existing records; users can choose to add a secondary user/ designee for a record or leave it blank.	HLP-7093 / INSIFE-HALOPV-SS-39
System Config	Automated user onboarding	Introduced the functionality to automatically create/update user accounts using API.	Low - New functionality	HLP-6083 / *

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System Config	Capability to configure HALOPV Tags style	Updated HALOPV Tags configuration, users can now update Tags style, this will help them in identifying/ highlighting specific tag. HALOPV supports "Apex colour and status modifiers" as Tag style.	LOW - There will be no impact on existing tags, this is an improvement on existing feature.	HLP-8009 / INSIFE-HALOPV-SS-39
System Config	Change/optimize master search	Updated Master Search/ Global search to enhance the search results for speed and accuracy. Users can now use the new filter "Search Field" to select a desired field, this will narrow down the search criteria and improve efficiency.	LOW - Enhanced search logic.	HLP-7119 / *
System Config	Configuration for Delete Assignee	Introduced a new system configuration "Delete Assignee", when switched ON system will not delete a records assignee once the record completes its workflow.	LOW - New system configuration	HLP-7629 / *
System Config	Correspondence Type added in "Correspondence and alerts" list	Updated Correspondence and alerts, HALOPV now displays Correspondence type in the "Correspondence and alerts" list. Correspondence type is a configurable list at HALOPV.	LOW - We are displaying an existing value in a list.	HLP-8680 / *
System Config	Date Time Selection added in record view lists	Added date selection in all the record lists to display records created in last 30 days (default to 30 days), users can update this to 60, 90 or a custom date. This will help user - - By loading page faster. - Ability to filter records based on record Created Date. Note - This field is not configurable in 5.1	Low - Just limiting the records in a view, to improve user experience.	HLP-8589 / *
System Config	Depreciated, "Last updated records" section	Depreciated, "Last updated records" section from "Core Process" page, this has been done to improve the performance of page. This page is used as landing page for all the major modules such as ICSR, Clinical trials, Submissions etc.	MEDIUM - No change in records. A section removed from Core Process; users are advised to contact HALOPV support if they want to enable it again.	HLP-7320 / *

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System Config	E2BR3 values added in Document Type	Update Document Type, new configuration added to add E2BR3 values for document types. The field is a free text field.	LOW - Configuration update	HLP-8081 / *
System Config	HALOPV now supports API's for accessing MedDRA Dictionary.	MedDRA integration API	LOW - New API's, no impact on existing features.	HLP-8240 / INSIFE-HALOPV-DICTIONARY-API-TDS-905
System Config	Label Update for 'Open Case' Search	Updated label of the 'Open Case' search on the HALOPV Front Page to 'Open Record'.	LOW - Label update	HLP-7681 / *
System Config	New Records to be assigned to creator (ICSR, Studies, Products, etc)	Updated Record (ICSR, Studies, Products, etc) Creation, the records will now get auto assigned to their respective creators. This update is configurable for each tenant.	LOW - Configuration upgrade for existing functionality, configurable update.	HLP-7132 / *
System Config	HALOPV Configuration - Workflows configurable at Entity level	Updated HALOPV Workflow configurability, now workflows can be configurable at Entity level. Workflows configuration will follow below rules - -- If WF has been configured for Entity other than entity 1(Parent Entity), than that WF configuration will be applicable only for respective entity. -- For WF's configured for Entity 1 (Parent Entity), than that WF configuration will be applicable all the entities of the environment, except for entities where it is configured individually (Above rule).	LOW - Will only impact multitenant environment (i.e. HALOPV for now), this update will not impact client data.	HLP-8186 / INSIFE-HALOPV-SS-39

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System Config	HALOPV multitenancy updated to support that one user can access multiple tenants	Updated HALOPV multitenancy, users can now be assigned to multiple tenants, and they can access/ work on any of those tenants using same user account. - Individual audits will be maintained with unique user sessions. - Users will be able to access only data of one tenant at a time. - Data view/ update/ transfer is not allowed from across tenants.	MEDIUM - Impact only on HALOPV multi-tenant environments, still users can only access data of their assigned tenants (may be more than one).	HLP-7332 / INSIFE-HALOPV-SS-39
System Config	Records linking Update	Update HALOPV Records linking capability, now HALOPV captures Records version clearly and displays linked records only for the respective applicable versions.	LOW - Update in the existing record linking functionality.	HLP-7583 / INSIFE-HALOPV-SS-39
System Config	Selecting Organization is now mandatory field while creating a record	Updated Record creation in HALOPV, selecting an organization is now mandatory field. The Users of multi-tenant environment having access to more than one tenant will now need to select the organization for which they are creating record.	MEDIUM - This will impact users having access to multiple organizations in a Multi-tenant environment only, NO impact on dedicated environment. The records will be visible only for the selected organization, if user selects an incorrect organization, he will not be able to see the record.	HLP-8150 / INSIFE-HALOPV-SS-39
System Config	System access log retention	Updated system config to retain system access logs to 100days, this is a system configuration and can be updated as per need.	LOW - Update in system config.	HLP-7940 / *

Area / Process / Group	Title	Description	Impact	REQ ID / Specification
System Config	View and Edit HALOPV PDF Docs online	Updated HALOPV Document PDF Viewer, now users can Edit an attached PDF document (User Uploaded/ HALOPV Generated) in a record.	LOW - This is a change in tool used to handle PDF files, for end user there will not no change.	HLP-6527 / *

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

5. Bugs resolved in HALOPV 5.1

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Aggregate Reporting	Audit Trail Update for Child Forms	Fixed audit trail capture for child forms for Date fields.	LOW- Minor fix for old values in date field.	HLP-8366 / *
Entities, ICSR, System Config	Record Assignee List update	Fixed Record Assignee User list, now HALOPV will display all users that has access to the current record org in place of just users in the specific org.	LOW - No impact in existing records, this update is to filter user list.	HLP-6747 / *
ICSR	Duplicate case WWC (C.1.8.1) was inserted as Case identifier (in c.1.9.1.r.2)	Fixed in ICSR, Duplicate case WWC (C.1.8.1) was inserted as Case identifier (in c.1.9.1.r.2) field and Source (c.1.9.1.r.1) was not populated	LOW - Minor adjustment of GOM_ICSR_DUPLICATE_SEARCH (moving the reference copy from the auto-merge section to the general section (always add references when linking as FU - also when auto-merging is not applicable)	HLP-7342 / *
ICSR	Addressing Database Performance Issue while recoding events	Fixed the performance issue encountered during recording of events (Always serious terms) in ICSR by introducing an additional filter in the database query	LOW - Update to existing Functionality	HLP-8125 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
ICSR	Attachment handling when up-versioning records (ICSRs only)	When up-versioning an ICSR, literature- and additional doc. references are now preserved. If a file is uploaded with the reference, this is NOT included in the new revision. Files / attachments can be retrieved from the previous revision of the case if needed. Non-E2B attachments are not automatically included in new revisions of the case.	ICSR record up-versioning. Literature / additional doc. references in ICSRs.	HLP-7705 / *
ICSR	Body weight of parent is not displaying decimals values in the readable file	Fixed the display of Body weight of parent, the field will now capture display decimals values on UI and generated records.	LOW - Minor update in existing functionality.	HLP-7971 / *
ICSR	Creating valid file names from print functionality	Implemented a universal function to sanitize filenames by escaping forbidden characters when generating reports in any format. This function ensures that titles containing characters such as <, >, :, ", /, , |, ?, *, ., or ending with a space are properly handled.	LOW - Fixed existing functionality	HLP-7728 / *
ICSR	Data Discrepancies between XCOMP and HALOPV	Fixed data discrepancy issue between XCOMP and HALOPV for data element E.i.9 'Country where reaction occurred'.	LOW - Fixed existing Functionality	HLP-8166 / *
ICSR	Decimal Formatting and Sign Preservation Fix	Updated Decimal formatting now truncates instead of rounding up, preventing incorrect results like 1.5 from 0.5. Negative numbers now preserve their sign when values are > -1 and < 0, addressing issues like -0.5 becoming positive.	LOW - Fixed existing functionality	HLP-7424 / *
ICSR	Display of Indication (D.8.R.6b) and Reaction (D.8.R.7b)	Implemented: For Indication (D.8.R.6b) and Reaction (D.8.R.7b) MedDRA Codes are displayed along with Preferred Term.	LOW - Update to existing functionality	HLP-7950 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
ICSR	Drug-Event Matrix	Updated the logic to display the coded product rather than reported product on the drug-event matrix.	LOW - Update to existing functionality	HLP-7414 / *
ICSR	Drug-reaction matrix and blinded IMP	Fixed Display of Durg Name in Drug Reaction Matrix for Blinded products. Now HALOPV will display "Blinded product" as drug name in place of hiding the field.	LOW - Existing field display issue.	HLP-8398 / *
ICSR	Duplicate Search Logic Update	Updated the Duplicate search logic to use the score of the Follow-up cases rather than initial case	LOW - Enhancement to existing logic	HLP-7782 / *
ICSR	Enhancements for Study Registration Grid	Added improvements have been made to the Study Registration grid: - Users can now manually add and delete registrations - "Add new source" button has been renamed to "Add new study registration" - Audit log and versioning/cloning scripts now capture c.5.1.r.1 and c.5.1.r.2 changes	LOW - enhancement to existing functionality	HLP-8307 / *
ICSR	Event population on Drug-Event Matrix	Updated the logic to populate the event on the Drug-Event matrix from E.i.2.1b.	LOW - Update to existing functionality	HLP-7929 / *
ICSR	Fix in ICSR import package for cases containing at least one product and at least one substance	Fix in ICSR import package for cases containing at least one product and at least one substance are/were impacted. This was due to custom tags.	MEDIUM - Update only in Import function for R2 cases, Only those cases are impacted having least one product and at least one substance.	HLP-8049 / *
ICSR	ICSR Autocoding Update	Fixed Autocoding for a particular use case.	LOW - Fixed existing functionality.	HLP-7784 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
ICSR	ICSR substance dropdown issue if product has more than one substance	Fixed product substance list for cases where a product has more than one substance.	LOW - Update to existing functionality.	HLP-8163 / *
ICSR	ICSR up versioning fix for Product and Event field	Fixed the up-versioning procedure to handling the IDs (Primary keys) for the event and product properly while up-versioning. The product- and event names will now display the verbatims and in place of their coded names	LOW - It is a display issue; data remains as it is.	HLP-8208 / *
ICSR	Max field length validation errors updates	Updated ICSR_IMPORT_XML package to add the configuration to hold the NACK (negative acknowledgement) message. Create new validation rules for H.2 and D.7.2	LOW - Configuration updated for validation	HLP-7688 / *
ICSR	Narrative / Summary display issues in locked cases	Issues with the display of narrative and summary fields in locked ICSR cases are now resolved, ensuring that the fields correctly displays in both open and locked cases. This impacts the display only - not the actual storage of narratives and summary fields.	ICSR Narrative / Summary tab	HLP-8054 / *
ICSR	Population of G.k.10.r	Update R3 generation function to populate G.k.10.r section.	LOW - Minor update	HLP-7413 / *
ICSR	Primary Reporter and Patient Gender	Fixed: The primary reporter is now set by default only for the first report. For subsequent reporters, the primary reporter will not be set if a primary reporter already exists. The Patient Gender displays only compliant E2B values.	LOW - Update to existing functionality	HLP-7484 / *
ICSR	Refresh button display issue	Fixed the issue to not display a menu once a refresh button has been clicked.	LOW - Display Issue	HLP-8206 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
ICSR	Unblind Functionality Fix for Clinical Trials	Fixed an issue where clicking the 'Unblind' button in cases with C.5.3 matching the Trial ID failed to display products in the dropdown menu, despite G.K.2.5 set to 'Yes'.	LOW - Fixed an existing functionality	HLP-8050 / *
ICSR	Update in E2B R3 profile for G.k.2.5	Updated E2B R3 profile for G.k.2.5, now the field G.k.2.5 will not display FALSE in case of E2B XML has not value for the field.	LOW - Update in existing mapping	HLP-7292 / *
ICSR	Updated configuration to always send AR Submission - TestsAndProceduresRelevantToTheInvestigation	Update configuration to always send AR Submission. As per the EMA scientific guideline, In the 'TestsAndProceduresRelevantToTheInvestigation' if F.r.1: Test Date is populated and F.r.2.2b: Test Name (MedDRA code) is not populated then F.r.2.1: Test Name (free text) is required to be in AR submission xml.	LOW - Configuration updated to always send AR Submission	HLP-7685 / *
ICSR	Validation check updated for C.1.11.1 - Report Nullification	Fixed validation check for C.1.11.1 - Report Nullification, HALOPV will now send back NACK (Negative Acknowledgement) in case of invalid value received for the field.	LOW - Configuration fix for a validation	HLP-7828 / *
ICSR	Workflow History User Display	Fixed the Workflow History incorrectly displayed the last username as the creator of the record. Workflow history now accurately reflects the user who entered the master title.	MEDIUM - Fixed an existing issue	HLP-3711 / *
ICSR	Workflow Task Completion Enhancement	Updated to ensure that when a user manually completes a workflow task, the system checks if the next step is conditional	LOW - Enhancement to existing functionality	HLP-6000 / *
ICSR, Products	Read Only user can modify and recode products on ICSRs	Updated configuration for Read Only users, now they will not be able to modify or recode product coding at ICSR.	LOW - Change in User Configuration	HLP-7492 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
ICSR, Submissions	CIOMS Form Updated	Updated CIOMS form to capture all the fields, the updates came as impact analysis of multiple other changes in the application.	LOW - Updated in existing functionality.	HLP-7323 / *
ICSR, Submissions	Fix to stop duplicate record creation	Fix related record creation, system will now check and step duplicate record creation while adding a related record.	LOW - This issue only occurs when user intentionally creates it.	HLP-7238 / *
ICSR, Submissions	Submission Automator	Fixed the submission Automator failure.	MEDIUM - Fixed existing functionality	HLP-7610 / *
ICSR, Submissions	Updates to CIOMS	The following fields in the CIOMS are updated: Initial Reporter, Reporter Title, Reporter Last Name, Reporter Name, Reporter State, Reporter Country, Name and Address of Manufacturer. The following fields are updated to differentiate between blinded, unblinded case and for blinded case, blinded or unblinded product.	LOW - Update to existing functionality	HLP-8183 / *
ICSR, System Config	Narrative language import using XML	Fixed narrative language import using XML, HALOPV now pics the narrative language codes send in XML to display them in the ICSR. NOTE - HALOPV uses ISO2 (2-digit codes).	MEDIUM - Used are advised to use the 3 Digit codes while sending ICSR's into HALOPV.	HLP-6241 / *
ICSR, System Config	Validations shouldn't trigger a negative acknowledgement or be included in the error reason	Fixed Internal validations that should not trigger a negative acknowledgement or be included in the error reason for below validations - 1. Fatal/Death details not matching 2. Missing patient identifier validation triggered incorrectly when case had patient age group populated 3. Reaction start date must be before reaction end date validation triggered when reaction end date was a partial date	LOW - Fix in existing functionality	HLP-6513 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Products	Fix in Pharmaceutical Dose Form (G.K.4.R.9.1 for Bulk Import	Fixed Pharmaceutical Dose Form (G.K.4.R.9.1), it was displaying coded - number instead of the corresponding verbatim due to some field conflict.	MEDIUM - Fix in existing field names to avoid Duplication. For Future, Deduplication check by Name will now consider the Source as well. Workaround - Reload of EDQM list post import.	HLP-7941 / *
Products	Medicinal Product Description is displaying old values although Strength of Product is changed	Fixed Product Dictionary: Medicinal Product Description to get updated when Strength of Product is changed.	LOW - Tt is keeping the description in alignment with data being sent in	HLP-7143 / *
Products	Scientific Product ingredients getting unnecessary strength information	Fixed Scientific Product ingredients, they are being created for name variations of Scientific Product Ingredients and Scientific Product Ingredients + Pharm Form, the records were getting strength information added to them although they shouldn't.	LOW - Minor fix.	HLP-7165 / *
Products	Specific medicinal product (MPID) reverting back to old revision of drug name	Fixed Specific medicinal products (MPID), as user updates the name of medicinal product while up-versioning the record the name of products was getting revert back to its old version name. This is now fixed and will impact only those products where product name was updated in its subsequent versions.	MEDIUM - The error causes all records in HALOPV to be updated (title reset to the previous version of the record) when a FU ICSR is auto-merged. It has no impact on records that have not had their title updated.	HLP-8165 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
Products	Strength of substance is available in product management config, but not displayed in ICSR case when product coded manually.	Fixed the display of Strength of substance if it is available in product management configuration.	LOW - Fix in existing functionality.	HLP-7144 / *
Products	Suppress Coding does not get copied/cloned into new revision	Fixed product revision to copy Suppress Coding setting in the up-visioned product.	LOW - No impact on existing records.	HLP-6686 / *
Submissions	"License Triggering the Submission" to display distinct records.	Fixed "License Triggering The Submission" dropdown, previously this dropdown was considering all the license revisions as individual records and thus displaying duplicate licenses.	LOW - Fix only	HLP-7500 / *
Submissions	Calculation of Submission Due Date	Updated GOM_SCHEDULE_SUBMISSION_RECORDS to ensure correct calculation of the Submission due date	LOW - Enhancement ot existing functionality	HLP-5534 / *
Submissions	Logic update for submission auto-scheduler	Updated the logic of submission auto-scheduler to make the license status as an optional check.	LOW - Update to existing functionality	HLP-7319 / *
Submissions	Removed "Copy of" from Title of the Downgrade submission record	Removed "Copy of" from the title of Downgrade submission records, record title will still display "DOWNGRADE"	LOW - This is minor text tweak.	HLP-8290 / *
Submissions	Submission Rule Fix	Fixed the submission rule to cater to requirements for serious cases along with non-serious cases.	LOW - Update to existing functionality	HLP-8309 / *
Submissions, System Config	AR Submission validation rules re-analysed	AR Submissions have been re-analysed and fixed where required to ensure HALOPV applies Validation rules to secure only valid information is send to EMA. This might be applicable to two types of error: -- Validation rules that is violated -- EudraVigilance error somewhere in the XML (AR Submission)	LOW - Updates in existing API's and configurations.	HLP-7623 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
System Config	Automatic keywords - search for blank values	A new attribute is added to the code-list controlling keywords: "Generate if blank" (Yes/No). If "Yes" is selected, the keyword is generated also when the keyword calculates as blank. This is useful if you want to be able to use the general keyword-based search (page 80) to find cases with blank values in specific fields (keywords).	Keywords (Auto-calculation), Global Search (page 80)	HLP-7710 / INSIFE-HALOPV-SS-39
System Config	Azure Mail	Fixed the logic to link the response email to the correspondence parent email.	LOW - Update to existing functionality	HLP-8325 / *
System Config	Fetch Device List API update for big list	Updated Fetch Device List API, now it will send the data in batches. This will help when there is a large list to export.	LOW - Existing functionality updated	HLP-7532 / *
System Config	Fixed the issue with R3 report generation for Reporter Qualification	Fixed the issue with R3 report generation when a Null Flavor is entered for C.2.r.4 Reporter Qualification.	Low - Fixed issue with existing functionality	HLP-8776 / *
System Config	Increased size of Medical History	Updated Medical History field type NUMBER (2) to NUMBER (4), this will allow to capture and generate XML for cases where field size is more than 4K.	LOW - Existing functionality updated.	HLP-7813 / *
System Config	Issue with Workflow initiation for ICSR records	Fixed GOM_GET_E2B_FILES to initiate the workflow once the XML file is attached.	LOW - Fixed existing functionality	HLP-8548 / *
System Config	Record due data calculation update	Fixed record due data calculation, now HALOPV will not consider the disabled tasks to calculate due date.	LOW - This is a configuration change in the existing functionality.	HLP-6222 / *

Area / Process / Group	Title	Description	Impact	Specification/ Bug ID
System Config	Routing comments update	Fixed the logic to not override routing comments in case of normal workflow routing with nullification routing comments	LOW - Fixed existing functionality	HLP-7250 / *
System Config	Singe-case lock-in bug fix	Fixed GET_SPECIFIC_MP_HALO_CODE_FROM_PI to ensure single case locking works with multiple product revisions available in the record.	LOW - Fixed existing functionality	HLP-8573 / *
System Config	UCUM Code List for Patient Tests	Updated UCUM code list for patient tests to align with EMA guidelines.	LOW - Update to UCUM Codes	HLP-8546 / *
System Config	Validation Checks are not reset when moving a record to a new workflow	Fixed the procedure to generate Validation Checks, now HALOPV will clear all the existing open validation checks as soon as a record is moves to a new workflow.	LOW - Just refresh of existing validation checks, no change in data.	HLP-7894 / *
System Config	Warning Message Updated	Updated warning message for all the process master record list page - From "You have read-only access to the current workflow" to "You are not able to create new records"	LOW - Just message text altered.	HLP-8011 / *

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

6. Features removed from HALOPV 5.1

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
Dictionary and Terms	Issue with export functionality of the SMQ	The SMQ details are not exported to a spreadsheet instantly if a user clicks on the Save button on the MedDRA Browser	Implement the following steps: 1. Select any query on the first or second tab 2. Navigate to Selected Queries tab and refresh the browser 3. Hit the button next to refresh to open the export dialogue 4. Actively select which rows should be exported 5. Hit export	HLP-8804 *
Products	Issue with nullifying device product	The system throws an error if the user tries to nullify a device product without saving the product details on 'Device Product Details' form.	The user should save the details for a device product within 'Device Product Details' form to be able to nullify the product.	HLP-8978 *

Area / Process / Group	Title	Description	Workaround	Bug ID
Submissions	Issue with downgrade report as follow-up	Downgrade report is scheduled as Follow-up but with the text as 'Initial' in the report title	Deferred to next release.	HLP-9166 *
Submissions	Issue with submission record for product with multiple licenses	When a submission record is triggered for a product with multiple licenses, then the submission detail form is unable to list all the applicable licenses under 'License Triggering the Submission'.	Deferred to next release.	HLP-9168 *
Submissions	Issue with report generation with special character in Title	The report generation is an issue when special characters are entered in the Title.	Refrain from using special characters in the Report Title.	HLP-8747 *

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

8. Contact

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