

Insife HALOPV 5.1.3 Release Summary Notes Final Version 1.0 Department: Product Management



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1. Overview

Insife HALOPV 5.1.3 is a patch release of bug fixes for HALOPV 5.1. It contains fixes and changes as detailed in section 3, to address some key identified bugs/tweaks. Further Patch 5.1.3 also includes few configuration updates as detailed in section 4, to enable users to access few existing HALOPV functionalities.

None of the issues included in this patch release have required any specification updates.

2. Upgradability

HALOPV 5.1.3 requires the environment to be on the HALOPV 5.1 version with the 5.1.1 and 5.1.2 patch applied.



3. Bug fixes and changes in this patch

The following features have been updated or added in this patch release. Note that the listed Impact is associated with the issue *not* being resolved or implemented:

Area / Process / Group	Title	Description	Impact	Issue ID/ Specification
		Fixed an issue where special characters (e.g.,) and text		
		formatting like bold, italic, and underline were not being		
	Text Formatting	cleaned by GOM_FORMAT_WORD_TEXT before inserting		
	Cleanup in	content into placeholders or templates. The function has now		
	GOM_FORMAT_W	been updated to remove unwanted text formatting and clear	Low - Fix to a formatting	
System Config	ORD_TEXT	 .	issue	HLP-6748
	UCUM Code List	Updated UCUM code list for patient tests to align with EMA	Low - Update to UCUM	
System Config	for Patient Tests	guidelines.	Codes	HLP-8546
	Updated GRIP		Medium - Data	
Requirements	Sync for Multi-	Fixed an issue that ensured that GRIP data can be synchronized	synchronization issue	
Intelligence	Tenant Support	across multiple tenants without ID conflicts.	for multi tenants	HLP-9041
	Updated Cloning	Updated the cloning and upversioning functionality, which was missing for the GOM_PROCESS_MASTER_X_STUDY_REG table.	Medium - Study details	
Clinical Trial	and Up-versioning	This issue caused the Study details to disappear as soon as	disappeared on re-	
Management	of study Table	user reinitiate the study workflow.	initiating the workflow	HLP-9098
	Enable Reason for	The field wf_notes_switch was updated for all workflows to		
ICSR	Nullification	enable the reason for nullification.	Low - Enabled a field	HLP-9909
	Fix for Multi-	Fixed an issue where multiple country codes separated by		
	Country Selection	colons caused errors and prevented data from being displayed	Low - Fixed error to add	
Products	in Products Grid	in the Products Interactive Grid.	multiple countries	HLP-9928



Area / Process /	Title	Description	Impact	Issue ID/
Group				Specification
		Addressed errors in Event Analytics LL when enabling all		
		columns. Updated subquery on page 1013 to handle CLOB data		
	Error Resolutions	longer than 4000 characters, including special character	Medium - Columns	
	for Event Analytics	conversions. Fixed data-fetching issues for column C.5.1.r.1 to	were missing from the	
Aggregate Reporting	LL	ensure all columns display	output	HLP-9220
	Fix for Narrative			
	Truncation in			
	CIOMS Report Due	An issue was fixed where the narrative section of the CIOMS	Low - Some content	
	to 4000-Character	report was being truncated at 4000 characters. This led to	was missing from the	HLP-10299
ICSR, Submission	Limit	missing content in the generated reports.	generated CIOMS	
	Aggregate			
	Reporting Prompts			
	- MedDRA Query	Fixed Aggregate Reports prompts of MedDRA Query and	LOW -	
	and Reference	Reference date filter, now users can now use these filters to	This was a fix of existing	HLP-9600
ICSR	Filter	filter reports.	functionality.	
	Attachment	Resolved an issue preventing users with required permissions		
	Access Update for	("Blinding flag edit," "Unblinding," "Privacy data access," and	Medium - User with	
	Privacy Section in	"Privacy flag edit") from accessing attachments in the Privacy	right access unable to	HLP-10652
ICSR	ICSR Form	section of the ICSR form.	view attachments	
	Fix for Event		Medium - Unable to add	HLP-10806
	Addition in New		new event in the new	
CSR	Revision	Resolved an issue preventing event addition in new revisions.	revision	
	Removal of			
	"Solicited - Drug"			
	from Type in			
	Requirements	Removed the option "Solicited - Drug" from the Type field in the		
Requirements	Intelligence	Requirements Intelligence module for ICSR and device	Low - Removal of Drug	HLP-10212
Intelligence	Module	reporting requirements.	Type field	
	Delta Transfer		Low - Record versioning	
Requirement	Logic Update for	Implemented delta transfer logic to synchronize record	was not displayed	HLP-10266
Intelligence	Record Versioning	versions across systems. Now, if new information is available,	properly	



Area / Process / Group	Title	Description	Impact	Issue ID/ Specification
		records are up-versioned automatically, ensuring alignment with system revision numbers.		

4. Configuration updates in this patch

The following configuration updates have been included in this patch:

Area / Process / Group	Title	Description	Issue ID
System Config, Requirement Intelligence	Whom and when report	HALOPV configuration updated to enable users access "Regulatory Intelligence rules overview ("Whom and When")" report under "Requirement Intelligence" module.	HLP-10045
System Config, ICSR	E.I.9 default value removed	HALOPV configuration updated to remove the default country for "Identification of the Country where the Reaction / Event Occurred (E.I.9)" field in ICSR.	HLP-10202
System Config, ICSR	Workflow import mapping for ICSR intake	HALOPV configuration updated for the target workflow of incoming ICSRs it will now be entity specific.	HLP-10221
ICSR, Products, System Config	Auto-Population of Substance	HALOPV configuraiton updated to automatically population of substance data when a suspect product was coded in the case. The configuration was updated	HLP-10325



Area / Process /	Title	Description	Issue ID
Group	Group		
Data for Suspect		by enabling the feature that auto-populates the ingredients from the coded	
	Products suspect medicinal product into the Substance tab.		
		Note - Clients need to choose if they want this enabled per default	



5. Contact

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