HALOPV 4.0.1 Release Notes
Final
Version 1.0
Department: Release Management

Document Approvals

Name	Date and Signature	Role/Meaning
Richard Salter		Release Manager (Author)
Martin Holm-Petersen		System Owner

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1. Overview

Insife "HALOPV" 4.0.1 is a minor release enhancing the capabilities of HALOPV 4.0. It contains a small number of updates as detailed in section 3 to support some legislative updates, along with some other key identified issues and new/ updated features.

1.1. Upgradability

HALOPV 4.0.1 can be upgraded from any previous HALOPV release. It can also be deployed as a standalone full installation.

2. Compatibility

HALOPV 4.0.1 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: Support of **Microsoft Internet Explorer** was no longer supported from HALOPV 4.0

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 104 and Edge on version 102.

3. Changes since the last release

The following features have been updated in this release:

Area/Process/Group	Title	Description	Impact
China and Korea support	NMPA E2B R3	Product coding updates to provide new China and updated Korea product coding, along with the addition of an NMPA E2B R3 Submissions profile and associated fields on the relevant pages	**Minor** New functionality, no impact on existing customers
Audit Log	Audit Log Report	Audit log and report updated to include the applicable time zone	**Minor** New functionality, no impact to existing customers
User Maintenance	Password Change Log	The password change form has been updated so that it logs all changes in the application log	**Minor** New functionality, no impact to existing customers
System Configuration	Data Privacy	Data privacy element code list (ref ID 1500 and 1501) obsoleted, and the functionality is handled by the DATAELEMENTS code list	**Medium** Each client should review current configuration and switch to the new methodology if required
Submission and Scheduler	Submission Updates	This update impacts the Submission details form and the scheduler to include two new fields. The actual scheduling logic is updated to schedule based on the sorting of products in the ICSR (rather than just sorting randomly and finding any product that matches the reporting criteria).	**Medium** Each client should review the current configuration and switch to the new methodology if required
R2 and R3 Reports	Country specific license name	R3 and R2 reports have been updated to include the country-specific license name when available, instead of the reported product name	**Minor** Updated functionality, no impact on existing customers

Code Modules	Support for EU BR 30.Jun.22	Various updates to support the regulation changes, including the switch to submit EU Trial number, as the EudraCT number to EMA, selection of local tradename for the suspect product triggering the submission, ability to set Italian and Spanish state codes and include the same in the E2B, and the availability of EUDRACT numbers	**Minor** Updated functionality, no impact on existing customers
Quality Management Module	Non-conformity process	A new page has been added to the module for this purpose	**Minor** New functionality, no impact on existing customers

4. Bugs resolved in HALOPV 4.0.1

Area/Process/Group	Title	Description	Impact	Issue traceability
Narrative Incident Summary and Further Information	Narrative Incident Summary - Narrative Truncated	In the Narrative form, the second box named "Narrative in native language (H.1 local substitution) does not allow the user to save any information – This has been resolved	None - Fix only	HLP-1023
Reload Button	Help text for Reload button incorrect.	When hovering over the Reload button, the help text that was displayed showed as "Create New", when it should be "Reload". Now fixed.	None - Fix only	HLP-757
Product Configuration	It is not possible to edit AUTH_TYPE_ID on the Medicinal Product form	The field was read-only so cannot be updated by an end-user; this has now been resolved	None - Fix only	HLP-1044

5. Features removed from HALOPV 4.0.1

Support of Internet Explorer browser was removed from the HALOPV 4.0 release.

6. Known issues & workarounds

Area/Process/Group	Title	Description	Workaround	Issue traceability
Product Coding	Product Not Getting Coded in an Unblinded Case	An issue was identified with product coding when the Case blinding status / Investigational Product Blinded (G.K.2.5) are set to UNBLINDED / No, respectively. When a case has any product as unblinded, it is not possible to code new products, or recode that same product via the refresh button next to Coding details.	It is possible to leave a product uncoded without causing downstream issues.	HLP-1228
Age Group	Age Group (D.2.3) Not Updating After Entering a New Age at onset (D.2.2a) Value	If age at onset (D.2.2a) is entered without entering the patient's date of birth, then changed the Age at onset (D.2.2a) and save the case, the Age Group (D.2.3) was not auto-calculated / updated to the correct new value (Child) and remained as Adult.	It has been identified that the Age Group (D.2.3) does update if the Unit is changed to Unknown after entering a new Age at onset (D.2.2a).	HLP-1194

7. Contact

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

8. Change Log

Revision	Date	Author	Description
1.0	05-JUN-2022	Richard Salter	New document