

Insife HALOPV 6.1.5 Release Notes
Final
Version 1.0
Department: Product Management

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1. List of Abbreviations

ODCS	Organised Data Collection Scheme
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report
IT	Information Technology
WHODD	World Health Organization Drug Dictionary
APEX	Oracle Application Express
ATC	Anatomical Therapeutic Chemical

2. Overview

HaloPV 6.1.5 is a minor release that builds on the features of HaloPV 6.1 including other releases 6.1.1, 6.1.2, 6.1.3 and 6.1.4. It contains several updates and changes, as detailed in section 4, and addresses some key identified bugs in section 5.

3. Upgradability



HaloPV 6.1.5 is dependant on an APEX software upgrade to Oracle APEX 24.1.3.

4. Compatibility

HaloPV 6.1.5 is compatible with the following systems:

- Argus releases (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.

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 148, and Edge was on version 148.

5. Changes since the last release

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

Area / Process / Group	Title	Description	Impact
Data Collection Program	Updated Report Type Options in ODCS	Updated the report type options available in ODCS to meet the latest regulatory guidelines (ICH E2D R1 comes in effect on 18 Sep 2026). Existing cases are not affected.	Medium- The updated options will appear automatically — no action is needed on user end. This keeps the reporting in line with current industry standards.
Data Collection Program	Data Collection Programs — ICH Updates	The Data Collection Programs form now includes a new ICH Information section to capture how data is collected, reviewed, and from whom - including respondent types, digital platforms, and lookback period. User can also add or create external partners and agreements directly from the form. All new fields are optional, and dropdown options can be managed by the admin without IT support.	Medium- Users managing Data Collection Programs in HaloPV will see a reorganised form with new fields to support ICH compliance. The existing data remains unchanged.

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

6. Bugs resolved in HALOPV 6.1.5

Area / Process / Group	Title	Description	Impact
Aggregate Reporting	Updated the listedness Value in Report	Updated the Event-Product Line Listing report so the listedness value now reflects the value recorded in the ICSR case.	Medium - Users will see listedness information in their reports, ensuring reliable safety data for reviews and submissions.
Aggregate Reporting	Age Unit "Decade" Now Correctly Displayed in Event-Product Per Line Report	Resolved an issue where the age unit "Decade" was not showing up in the Event-Product per line report. This value is now present in the listing if selected within the ICSR.	Medium- Users will see complete and accurate age information in their reports without any missing values.
Case Intake and Processing	Improved WHODD coding for products where a number was reported with the product term	Updated the system so where a number was reported with product terms the system is now able to code successfully to WHODD. Previously, the coding engine treated the numbers reported in product reported terms as a strength value, which prevented the product from being matched to the WHODD dictionary — even when the correct ATC code was selected.	Medium- Products with numbers reported in product terms will code correctly to WHODD when the appropriate ATC code is selected and no manual workaround is needed.

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

7. Configuration updates

Not Applicable as a part of this release

8. Features removed from HALOPV 6.1.5

Not Applicable as a part of this release

9. Known Issues & Workarounds

Not Applicable as a part of this release

10. Contact

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