Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

HaloPV Patch 6.3.1
Release Notes — What's New

Document Approval Signatories are aware of their responsibilities, as defined in Qtech-SOP-002 (Document Control Procedures).	
Role	**Signature and Date**
Author	Signed by: Sanchita Khanduri Signer Name: Sanchita Khanduri Signing Reason: I am the author of this document Signing Time: 09-Oct-2026 | 7:33:26 PM IST EF4EBAAEBA46408683F5EDFC75B090D8
Technical & Business Review / Approval	Signed by: Gyongyi Mezey Signer Name: Gyongyi Mezey Signing Reason: I have reviewed this document Signing Time: 09-Oct-2026 | 7:35:15 PM IST A8F35A243E8742B694C533627EE0D6CE
Quality Review / Approval	Signed by: Rishu Ranjan Signer Name: Rishu Ranjan Signing Reason: I approve this document Signing Time: 09-Oct-2026 | 7:47:40 PM IST BC91C600D89E4ED9915124FE94ABEF3C

Do not copy without permission

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Contents

1. *Release Overview* 3
2. *Epics* 5
3. *Stories* 8
4. *Bugs* 21
5. *Known Issues* 27

Internal
Do not copy without permission

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

1. Release Overview

HaloPV Release 6.3 introduces regulatory and reporting enhancements, case-processing and workflow improvements, audit trail and traceability enhancements, direct REST APIs, dictionary processing improvements, and platform modernization.

Key Areas	Summary
Platform & Infrastructure	HaloPV 6.3 modernises the core platform by consolidating services into unified architecture, upgrading the software stack and strengthening security. The release also simplifies ICSR configuration and supports more consistent delivery of future enhancements and fixes.
Regulatory Compliance	Expanded support for ICH E2B(R3) and ICH E2D(R1) includes new study and organised data collection values, authority-specific validation and updated aggregate reporting. Further refinements improve regulatory submission outputs such as CIOMs and device MIR reporting for clearer, regulator-ready results.
Application Stabilisation & Performance	Case processing is faster and easier through bulk actions, improved filtering and sorting, multi-select term based coding, introduced copy functionality to more ICSR related screens and enhanced coding automations and workflow automation. Dictionary deployment and audit log enhancements improve performance, administrative control and traceability.
Integration	Secure, authenticated APIs and scheduled CSV exports support reliable exchange of MedDRA, WHODrug, MedDRA Query, Company Reference Safety and IDF Japan dictionary data with Veeva and other authorised systems. Pagination, delta synchronisation, retries and failure alerts reduce manual intervention and improve resilience.

Do not copy without permission

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key Areas	Summary
Application Enhancements	ICSR simplification — Local language pages and translation capabilities removed; E2B Event and Narrative fields consolidated onto standard English screens for a cleaner, compliant case form. Workflow improvements — Bulk coding actions, batch processing performance gains, ability to comment on cases without restarting workflows, and enhanced correspondence automation with customer specific template support. Full module configuration — Entities, clinical trials, products, regulatory intelligence, submissions, terms collection, dictionaries, device incidents, medicine case intake, and user management all configured to support customers pharmacovigilance operations. Device MIR regulatory alignment — EU MIR 7.3.1 fixes applied, including report generation corrections, validation error resolution, and enforcement of IMDRF Annex A / Other Reporting Code mutual exclusivity in line with the latest European Commission requirements.

Do not copy without permission

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

2. Epics

Key	Summary	Release Note
HPV-609	Rel 6.3 > Device MIR updates	MIR generation for device cases has been updated to ensure full compliance with EU MIR 7.3.1. Addressed issues included report generation failures, incorrect validation errors, and data import inaccuracies that could have affected submission quality.
HPV-416	Rel 6.3 > Regulatory Compliance > Aggregate Reporting: ICH E2B(R3) Study Case Type Alignment	**Aggregate Report — C.5.4 Study Case Type Alignment with ICH E2B(R3)** The Aggregate report data query configuration now supports the three new C.5.4 Study Case Types introduced in the ICH E2B(R3) Information Paper (adopted Dec 2025): Patient Support Programme (C.5.4 = 4), Market Research Programme (C.5.4 = 5), and Organised Data Collection System with source data from a digital platform (C.5.4 = 6). These options have been added to the "Study case types" checkbox group in the Data query configuration form, and the underlying data query has been updated so that selecting any of these new checkboxes correctly retrieves cases tagged with the corresponding C.5.4 value.
HPV-285	Rel 6.3 > Regulatory Compliance > Case Intake & Processing — ICH E2B(R3) C.5.4 Alignment	**Case Intake and Processing — C.5.4 Study Type Update per ICH E2B(R3)** The C.5.4 "Study Type Where Reaction(s)/Event(s) Were Observed" field in the Case Intake and Processing module has been updated to support all six valid ICH E2B(R3) values: 1 – Clinical trials, 2 – Individual patient use, 3 – Other studies, 4 – Patient Support Program, 5 – Market Research Program, and 6 – Organised Data Collection System with source data from a digital platform. Three new values (Individual patient use, other studies, and Organised Data Collection System with source data from a digital platform) have been added to the picklist, and the field is now correctly mapped to the E2B(R3) ICSR XML for all six values in accordance with ICH E2B(R3) requirements. These values are configured to be hidden as a standard configuration but are available in application management for users to activate them whenever required.
HPV-266	Rel 6.3 > Application Stabilisation > WHO DD Dictionary Load Usability Improvements	**WHO DD Dictionary Load Optimisation**

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		WHO DD dictionary versions and related components are now staged once on a central dictionary server and managed per client environment via Dictionaries - Manage Dictionaries. HaloPV Administrators can install components ahead of go-live, activate them on a defined Visible Start Date, sunset a prior version with a Visible End Date, and uninstall obsolete components to reclaim storage - with all load processing run during configurable quiet time windows to avoid impacting client performance.
HPV-259	Rel 6.3 > Application Stabilisation > MedDRA Dictionary Load Optimisation	**MedDRA Dictionary Load Optimisation** MedDRA dictionary versions and related components are now staged once on a central dictionary server and managed per client environment via Dictionaries - Manage Dictionaries. HaloPV Administrators can install components ahead of go-live, activate them on a defined Visible Start Date, sunset a prior version with a Visible End Date, and uninstall obsolete components to reclaim storage - with all load processing run during configurable quiet time windows to avoid impacting client performance.
HPV-228	Rel 6.3 > Regulatory Compliance > Validation Rule Improvement	**Enhanced Validation Configuration and Execution** Users can run validations on demand at the workflow level which is now a configurable option. Admin users can configure each workflow individually if this functionality was required. Validation rules can be assigned to specific regulatory authorities. Application Managers can enable or disable individual List of Value (LOV) entries without deleting them.
HPV-204	Rel 6.3 > Regulatory Compliance > Data Collection Programs — ICH E2D R1 Compliance	**Data Collection Programs — Updated for ICH E2D R1** The Data Collection Programs module now supports the latest ICH E2D R1 requirements. The Report Type list includes three new options and updated numbering for existing ones, the form has new fields for tracking non-protocol data collection activities (like collection process, data review method, and lookback dates).
HPV-153	Rel 6.3 > Application Stabilization > Audit Log Changes	**Audit logs display** have been updated for the following areas: record revisions for multi-revision records, track changes to templates and placeholders, and show decoded values for improved readability.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-86	Rel 6.3 > Integration API: Veeva	System modernizes how downstream systems (for example: Veeva) receive reference and dictionary data (MedDRA, WHODrug, IDF Japan, CRS, MQ) by exposing clean, authenticated REST endpoints and S3 CSV bulk exports, replacing outdated adaptor schemas and ETL dependencies.
HPV-40	Rel 6.3 > Maint > Update Software Stack and consolidate platform APIs from v1 to a unified v2 architecture	**HaloPV 6.3 Platform Modernisation** System now consolidates all HaloPV platform services into a single, unified codebase with the latest software upgrades and tightened security controls, replacing multiple fragmented client-specific versions. This unified foundation enables faster, consistent delivery of fixes and new features across all clients.
HPV-39	Rel 6.3 > Customer requested Enhancements	This release introduces enhancements across case intake and processing, coding, correspondence, reporting, and workflow automation to improve the overall efficiency and usability of HaloPV. The updates reduce manual processing through improved workflow automation and reprocessing, enhance product and term coding capabilities, and provide more consistent filtering, sorting, copying, and bulk actions across case data forms. Improvements have also been made to correspondence generation and notifications, Negative ACK handling and regulatory field visibility. Together, these enhancements provide a more streamlined and consistent user experience, improve visibility of records requiring attention, and reduce repetitive manual activities across Case and Device processing.
HPV-38	Rel 6.3 > Local language page update for 6.3	The ICSR module has been streamlined by removing local pages, local language-specific functionality, and translation capabilities that are no longer required. Associated local language configuration, including the Local Language Code, has also been removed to reduce configuration complexity.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-10	Bug fixes / Small Improvements	Improvements across core safety operations, regulatory compliance, and system reliability. Key updates include resolving generation and layout defects in CIOMS and MedWatch reports, ensuring accurate blinded study handling in aggregate tabulations (PBRER and line listings), and correcting FDA R3 XML export formatting to prevent submission rejections. In addition, this release enhances workflow and dictionary stability notably for MedDRA impact analysis and WHO Drug builders while reinforcing multi-tenant data isolation and administrative security across client environments

3. Stories

Key	Summary	Release Note
HPV-659	"Not Assessed" Listedness value appears as blank and is unavailable as a filter option	**"Not Assessed" Listedness value now displayed and filterable in reports** "Not Assessed" is now a standard Listedness (non-E2B) value. The “Not Assessed” Listedness value is now supported as a standard option in HaloPV. Cases with this value will no longer appear blank in relevant reports, and business users can now select “Not Assessed” when filtering report results alongside Listed, Unlisted, and Unknown.
HPV-352	Disable automatic nullification of duplicate by default	**Duplicate Case Nullification Update** Automatic nullification of duplicate cases is now disabled by default, preventing nullification/amendment fields from being populated when cases are simply marked as duplicates.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-130	SAE Line listing update for blinded/unblinded product names	**SAE Line Listing now correctly protects blinded study product names** When generating an SAE Line Listing report with the "Generate Blinded" option enabled, any product that has not yet been blinded will now appear as "MASKED" in the report output. This ensures that unblinded product information is never inadvertently disclosed in blinded reports. Where blinding is not required — or the product is already blinded — the actual product name continues to display as normal. The underlying case data is not affected.
HPV-128	E2F Line listing update for blinded/unblinded product names	**E2F Line Listing now masks product-level details for blinded reports** When generating an E2F Line Listing report with the "Generate Blinded" option enabled, product-related information (including product name, dose, frequency, route, treatment dates, and duration) for unblinded products will now display as "MASKED". This ensures that sensitive investigational product data is not disclosed in blinded outputs, supporting trial blinding integrity and regulatory compliance. When blinding is not requested—or where the product is already blinded—information is output as normal. The underlying database values are not altered.
HPV-82	ARM - Add “Generate blinded” selection to Generate Document From Template page for Aggregate Reporting records	**New "Generate blinded" option on Generate Document From Template page** The introduction of the "Generate blinded" radio button on the Generate Document From Template page enhances user control and compliance for Aggregate Reporting workflows. By allowing users to specify whether a generated document should be blinded or not, this change supports regulatory requirements and operational flexibility. The field is context-sensitive, appearing only for Aggregate Reporting records, and defaults to "No" to preserve current behaviour for most users. No downstream document-generation logic is affected by this ticket; existing processes remain unchanged unless the new field is visible and used. This targeted UI enhancement reduces the risk of accidental unblinded document generation and improves clarity for business users, while ensuring that non-Aggregate Reporting workflows are unaffected.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-81	ARM - Correct case classification logic in PBRER Summary Tabulation template	**Corrected case classification logic in PBRER Summary Tabulation template** The PBRER Summary Tabulation_V3 template now correctly classifies ICSRs into the two report sections based on report type and study type. The "Spontaneous, including competent authorities (worldwide) and literature" section includes only ICSRs with report type Spontaneous Report or Other; the "Non-interventional post-marketing study and reports from other solicited sources" section includes only ICSRs with report type Report from study and study type Other studies.
HPV-59	ARM - PBRER Report template - SOC value should only be displayed on first line	**SOC value now displayed only once per SOC group in PBRER Summary Tabulation** The PBRER Summary Tabulation_V3 template has been updated so the System Organ Class (SOC) name is shown only on the first PT row of each SOC group, with subsequent PT rows under the same SOC left blank. When a new SOC group begins, the SOC name is displayed again on its first row. This improves readability and aligns the report with EMA guidance.
HPV-44	ARM - Product filter on P143 does not retrieve ICSRs where the blinded product from a study matches the product filter	**Blinded clinical trial cases now correctly included in aggregate report listings** When setting up an aggregate report on the Aggregate Report Configuration Details page, ticking Include Blinded Products together with selecting Report from Study will now correctly include cases from clinical trials where the investigational product is blinded. Previously, these cases were missing from generated listings because the product had not yet been unblinded and coded — meaning the product filter could not pick them up. The system now checks whether the case is linked to a clinical trial with a blinded investigational product and includes it accordingly. This affects the following aggregate report listings: ICSR Event-Product Per Line, ICSR Submission Per Line, ICSR Revision Per Line, ICSR Case Per Line, and ICSR Activities Per Line.
HPV-42	ARM - Update Header Footnote Markers and Explanatory Text in PBRER Summary Tabulation Template	**Updated footnote markers and explanatory text in PBRER Summary Tabulation template**

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		The PBRER Summary Tabulation_V3 template has been updated to correct footnote marker placement and clarify data-source definitions for regulator-ready output.
HPV-41	Entity Configuration - Batch Receiver/Sender (N.1.4 / N.1.3) field length update	**Entities Module: Batch Receiver/Sender Identifier Field Length Limit** In the Entities module, on the Entity E2B Info configuration page, the character limit for the Batch Receiver/Sender Identifier (N.1.4 / N.1.3) field has been updated from 100 to 60 characters to comply with FAERS regulatory guidelines. If a user enters or pastes a value exceeding 60 characters, the system will display a validation error message: "Batch Receiver/Sender Identifier (N.1.4/N.1.3) must be equal to or less than 60 characters."
HPV-27	Display ICSR Case Number on Subsequent Pages of HALO CIOMS Form	**ICSR Case Number now shown on all CIOMS pages** ICSR case number and page numbers appear on every page from page 2 onwards — including blank trailing pages.
HPV-5	Keywords to be present related to Case Intake workflow	**Automatic Creation Source keyword tagging (Manual / Email / XML)** Cases created in the Case Intake workflow are now automatically tagged based on their source. Records can be identified as Manual, Email, or XML, enabling more efficient routing, filtering, and processing of incoming cases
HPV-3	Default Drug Role for First Product	**First product now defaults to "Suspect" for Characterisation of Drug Role** When a case processor manually adds the first product to a case (via the Add Drug "+" button), HaloPV now automatically defaults the Characterisation of Drug Role to "Suspect", in line with common pharmacovigilance practice. The user can still change this value. Only the first manually added product is defaulted; subsequent products remain blank. There is no impact on cases imported from XML or on products added via Study selection (including changing study/arm with the replace products option).

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-604	Display Success Message on Deletion for multi-select grids	Added clear visual feedback when deleting records from multi-select grids across Case Processing forms. When single or multiple entries are successfully removed, the system now displays an immediate confirmation message: *"Selected entries deleted"*.
HPV-526	Update Field Labels and Display E2B(R3)/MIR References	**Field Label and Regulatory Reference Updates** Updated field labels across the application to improve clarity and alignment with regulatory standards. Applicable fields now display their associated E2B(R3) and/or MIR references alongside the field label, providing users with improved visibility of regulatory mappings while maintaining existing functionality and validation behaviour.
HPV-304	Auto-Assign Annex F Code (F02) for Death Cases and Backfill Missing Codes in Existing Device Records	**Automatic Annex F Code Assignment for Death Cases** Enhanced device incident auto-coding by introducing automatic assignment of Annex F code “F02” for cases classified as “Death” where no death-related Annex F code exists.
HPV-301	Clear Assignee on Follow-Up Receipt Across All Workflows	Enhanced follow-up handling by automatically clearing the Assignee field when a follow-up record is received. This update prevents reassignment to previously assigned users and supports timely reassignment and processing of updated records.
HPV-231	Suggest Substance Terms via Button Using Parsed Drug Names	**Product Coding Suggestion Enhancements** Introduced intelligent product coding suggestions within the Product(s) Information section. The system now parses reported drug names, ignoring dosage, formulation, route, and numeric values, to provide ranked coding suggestions based on confidence scoring, improving coding efficiency and accuracy.
HPV-230	“Stuck at Transfer to Signal Detection” Reports for Monitoring and Tracking Records	Enhanced handling of records stuck at the Transfer to signal detection task across Case Intake and Processing and Device Incident Processing workflows. The system now automatically reprocesses stuck records daily at 6 PM UTC, with hourly retries until 12 AM UTC where required. Reprocessing resumes at the next scheduled window.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		New Stuck at Transfer to signal detection reports have also been introduced for Case Intake and Processing and Device Incident Processing, providing visibility into stuck records, duration, last retry, and upcoming retry details, with standard search, sorting, filtering, and download capabilities.
HPV-115	Enable ASR Generation for Organizations Without Recipients with Manual Recipient Handling	Enhanced Annual Summary Report (ASR) generation for Haemovigilance custom module to support organizations without predefined recipients. For organizations without recipients, the correspondence is created as a Nil Return Letter using the configured template and remains open for user action. Users can manually add a recipient before progressing to Send Report. The system prevents report submission without a recipient and prompts the user to add one.
HPV-103	Separate NCA Reference Number and CIP Number Fields in Clinical Investigation SAE Batch Form	**Clinical Investigation SAE Batch Form Enhancements** Enhanced the Clinical Investigation SAE batch form in the Device Batch Intake workflow by introducing separate fields for CIP Number and NCA Reference Number.
HPV-99	Auto-Progress Records from Manual Validation on Misspelling Resolution	**Automatic Workflow Progression Following Product Misspelling Resolution** Workflow automation has been enhanced to automatically progress Case Incident and Processing records when all misspelled products have been successfully mapped to valid standard product terms and no validation errors remain. Eligible records now advance automatically from the Manual Validation task without requiring user intervention. If immediate progression is unsuccessful, the system automatically reprocesses eligible active records daily to ensure workflow continuity.
HPV-98	Update Notification Title and Body for INPR Received in MORE	Enhanced Industry Notification of a Public Report (INPR) notifications sent from HaloPV to external system. Notification titles now include the associated NCA Reference Number, allowing users to easily distinguish between individual reports. The notification body has also been updated with INPR-specific guidance, providing manufacturers with clearer information on their responsibilities for reviewing, investigating, and responding to reports received

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-96	Enable Filtering and Alphabetical Sorting for Events and Related Lists in Case Processing	**Enhanced Filtering and Sorting for Repeating Listings** Added enhanced filtering and sorting capabilities across repeating listings in case intake and processing workflows. Users can now organise entries by Rank and Alphabetical order, with additional category-based filtering available for Events and Product Information sections to simplify review of cases containing multiple entries.
HPV-95	Add Primary Reporter Country Column in Term-Based Coding Tool	**Primary Reporter Country Display in Term Based Coding** Added a new “Primary Reporter Country” column to the Term Based Coding tool across applicable coding and misspelling tabs. The enhancement enables users to identify reporting countries associated with coded terms using ISO-2 country codes, supporting improved visibility into country-level coding trends.
HPV-75	Notify Correspondence Creator via Email on Receipt of Reply	**Correspondence Reply Email Notifications** Introduced automated email notifications for correspondence replies within the Correspondence workflow. Correspondence creators will now receive an email notification containing a link to the related parent record whenever a response is received.
HPV-74	Enable Editing of Notes in Locked Cases Without Workflow Re-initiation	**Notes Management for Locked and Completed Cases** Enhanced case management by allowing users to add and update notes within the “Notes and Linking” section for cases locked/completed without re-initiating the workflow. This enables administrative updates, such as correspondence tracking and follow-up actions, to be recorded more efficiently while maintaining audit traceability.
HPV-72	Negative ACK Workflow Enhancements for Invalid Sender and Receiver IDs	Enhanced Case processing for cases received with an invalid Sender ID or Receiver ID. Affected records are now automatically routed to the Negative ACK workflow, with correspondence generated using the applicable Invalid Sender or Invalid Receiver template content.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		Where a sender email is available, correspondence is automatically sent and the Negative ACK record progresses to closure. Where an email is unavailable, the correspondence remains open for manual action. Responses or bounce-backs are linked to the parent record and automatically re-initiate the Negative ACK workflow for further processing.
HPV-69	Enable Multi-Select and Bulk Delete Across Repeating Sections in Medicine Intake	**Bulk Delete Enhancements for Repeating Listings** Enhanced repeating listings across Case Intake and Processing workflows with standardised bulk delete functionality. Users can now select and delete multiple entries simultaneously using selection checkboxes and a unified “Delete Selected” action. The single delete icon has been removed from applicable pages to provide a more consistent user experience.
HPV-67	Enable Multi-Select Coding for Term-Based Coding within Tabs	**Multi-Select Coding Enhancements in Term Based Coding** Enhanced the Term Based Coding tool with multi-select coding functionality across Reporter Product, Reporter Substance, and Reported Device term tabs. Users can now code multiple identical or similar terms to a single standardised term in one action, reducing repetitive manual coding effort and improving coding efficiency.
HPV-65	Improve Batch Reprocessing Performance by Loading Records on Filter Application	Enhanced the Batch Reprocessing screen to improve performance and usability when working with large record volumes. Records are no longer loaded automatically when opening the Batch screen. Users can now apply targeted filters before retrieving records, reducing loading times and improving batch processing efficiency. Existing batch actions remain available and can be performed on filtered and selected records across supported workflows.
HPV-52	Enable Bulk Hide/Unhide Functionality for Terms in Term-Based Coding Tool	**Bulk Hide and Unhide Enhancements in Term Based Coding** Added bulk hide and unhide functionality within the Term Based Coding tool for Reported Product, Substance, and Device terms. Users can now hide multiple terms and view hidden terms using the new “Show hidden terms” toggle.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-50	Enable 'AIC Initial Letter' Template Selection with Auto-Populated Correspondence Content	**AIC Initial Letter Correspondence Template Support** Added support for the 'AIC Initial Letter' correspondence template. Users can now select the template during correspondence creation to automatically populate predefined content with placeholders resolved using related device case data.
HPV-48	Enable Copy Functionality for Drug Entries	**Product Copy Functionality** Introduced the ability to copy existing product entries within the Product(s) Information section across applicable workflows. Users can now duplicate product records, including associated child forms such as Indications, Substances, and Dosages, reducing manual effort when managing similar product entries.
HPV-47	Derive Product Type for Unlinked Substance Variants from Parent Substance Term	**Product Type Derivation Enhancements for Substances and Variants** Enhanced Product Dictionary product type derivation logic for substances and substance variants that are not linked to products. The system now derives Product Type from associated substances or variants where appropriate, ensuring consistent classification across the dictionary. When multiple product types exist, Medicinal Product / Drug takes precedence over other types, while Vaccine is assigned when all related records are classified as Vaccines. Existing derivation behaviour for variants linked to products remains unchanged.
HPV-79	Audit Improvement - Templates and Placeholders	**Audit history added for Templates and Placeholders** Changes to Document Templates and Template Placeholders are now captured in the Audit Log, providing improved visibility and traceability of template configuration changes.
HPV-64	Audit change request for a record having multiple revisions - Add revision	**Revision column added to Audit Logs** Audit Logs now show the record revision for each entry and support filtering by revision, making it easier to review changes across multiple revisions.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-56	Audit Log Table populated but Audit No. starts at 2.	**Removed Audit Log Number from Audit Log view** The Audit Log Number (sequence) column has been removed from the Audit Log UI to prevent confusion caused by system-generated sequence numbering. The Audit Log table no longer displays the internal sequence/audit number column.
HPV-227	Data Collection Programs Form Updates	**Data Collection Programs Form Updates** The Data Collection Programs form has been restructured: • to support ICH E2D R1 requirements for non-protocol Organised Data Collection Scheme (ODCS) activities fields for Collection Process, Data Review Method, Mechanism of Data Collection, Respondent Types, and Digital Platforms, plus Lookback Period start/end dates were added • Territories has been moved from the main details tab into its own dedicated tab; no fields or data have changed.
HPV-226	ODCS Report Type Picklist Update — ICH E2D R1 Alignment	**ODCS Report Type Picklist Update — ICH E2D R1 Alignment** The Master Type codelist used for the Report Type field in the Data Collection Programs module has been updated to include the six ICH E2D R1-mandated values for C.5.4 (Study Type Where Reaction(s)/Event(s) Were Observed): • Three new values added: Individual patient use, Other studies, ODCS with source data from digital platform • Three existing ICH-aligned values renumbered to the ICH-mandated IDs: Clinical Trial (1), Patient Support Programme (4), Market Research Programme (5)
HPV-233	Switch in List of values to mark disabled values	**Enable or Disable List Values** Application Managers can now enable or disable individual List of Value (LOV) entries without deleting them. Disabled values remain available for reference in configuration but are excluded from system processing and user selection.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-7	Page 119 Validation Rules Switch to be Manually Executed - Buttons	**Manual Validation Execution** A new configurable Validate action allows users to run validation checks on demand rather than automatically during routine saves. Users can review validation results before progressing a case, while hard validation failures continue to prevent workflow transitions when required.
HPV-6	Page 119 Validation Rules Switch to be Manually/ Auto Executed - WF Configuration	**On-Demand Validation Configuration** Validation execution can now be configured at the workflow level within Application Manager. When enabled in the workflow configuration, real-time validation during data entry is turned off, allowing users to run validation checks on demand by clicking a new Validate button. By default, this setting is Enabled (ON) in the Case Intake and Processing module, meaning on-demand validation is active out of the box. While this functionality is disabled as default configuration for other modules.
HPV-4	Page 119 Validation Rules Update - To be as per Authority	**Authority-Based Validation Rules** Validation rules can now be configured for specific regulatory authorities (such as FDA, EMA, or ICH).
HPV-530	Redesign Generation MedDRA Impact Assessment report and MQ flattenings	**Redesigned MedDRA Impact Assessment & MQ Flattening Workflow** PV and data operations teams can now run MedDRA Impact Assessments and query flattenings (SMQ/CMQ) independently from the dictionary upgrade — with background processing, conditional task configuration, and automated audit logging for full governance readiness.
HPV-286	C.5.4 Study Type Field — Add New ICH E2B(R3) Picklist Values	**C.5.4 Study Type field updated with new ICH E2B(R3) picklist values**

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		The "Study Type Where Reaction(s)/Event(s) Were Observed" (C.5.4) field in the Case Intake and Processing module has been updated to display the six valid ICH E2B(R3) values: 1 – Clinical trials, 2 – Individual patient use, 3 – Other studies, 4 – Patient Support Program, 5 – Market Research Program, 6 – Organised Data Collection System with source data from a digital platform. Three new values (Individual patient use, Other studies, and Organised Data Collection System with source data from a digital platform) have been added.
HPV-420	Aggregate Reporting — Study Case Types: Report Generation for New C.5.4 Values	**Aggregate Reporting – Support for New ICH E2B(R3) Study Case Types (HaloPV 6.3.0)** HaloPV now supports three additional study case types as defined by the updated ICH E2B(R3) standard: • Patient Support Programme – cases collected through manufacturer-sponsored patient support or disease management programmes • Market Research Programme – cases identified during structured market research activities • Organised Data Collection System with source data from a digital platform – cases originating from organised data collection schemes that use a digital platform as their primary data source When any of these new categories is selected in the Data Query Configuration form, aggregate reports — including PBRER, DSUR, PADER, CIOMS II, Reconciliation, Compliance/Submissions, Productivity/Worklist Management, and Expert Reporting — will correctly retrieve and count only the cases that belong to the selected study type(s). Multiple study types can be selected together, and the report will include cases matching any of the chosen options.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		Please note: These three new options are not yet visible in the user interface in this release. Regulatory agencies have not yet updated their systems to accept the new codes, so the options are temporarily hidden to prevent submission errors. The underlying functionality is fully implemented and will be made available in the UI once the relevant authorities confirm support. All existing study case type options — Clinical Trials, Individual Patient Use, and Other Studies — continue to work exactly as before, with no change to existing report outputs.
HPV-419	Aggregate Reporting — Study Case Types UI: Add New Checkboxes	**Study Case Types – new C.5.4 checkboxes added to Aggregate report configuration** The "Study case types" checkbox group in the Data query configuration form has been extended with three new options to align with the ICH E2B(R3) Information Paper (adopted Dec 2025): Patient Support Programme (C.5.4 = 4), Market Research Programme (C.5.4 = 5), and Organised Data Collection System with source data from a digital platform (C.5.4 = 6). Please note: These three new options are not yet visible in the user interface in this release. Regulatory agencies have not yet updated their systems to accept the new codes, so the options are temporarily hidden to prevent submission errors. The underlying functionality is fully implemented and will be made available in the UI once the relevant authorities confirm support. All existing study case type options — Clinical Trials, Individual Patient Use, and Other Studies — continue to work exactly as before, with no change to existing report outputs.
HPV-639	EU MIR 7.3.1 - Review of the validation rule for the 'Applicable legislation unknown' field [JIM-3207]	Updated Device Incident validation rules to correctly recognise Applicable Legislation Unknown (2.4.a) as satisfying the device classification requirement in accordance with EU MIR 7.3.1. Device Class validation is now satisfied when an applicable classification field is populated, preventing valid cases from being incorrectly blocked. A validation error will continue to be raised where no applicable device classification information is provided.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Patch 6.3.1 Addition

Key	Summary	Release Note
HPV-944	**Update (C.1.5) Population for ICSR Submission Files**	**Configuration for element 'Date of most recent information for this report (C.1.5)' Population Enhancement for EMA E2B(R3) Submissions** Added a customer-specific configuration to the generation of EMA E2B(R3) submissions, enabling the 'Date of most recent information for this report (C.1.5)' field to be populated using the latest case revision date for applicable ICSR submissions. Existing behaviour for amendment and nullification reports remains unchanged.
HPV-1148	**Performance improvement for WHO DD load**	**Improved Performance for WHO Drug Dictionary (WHO DD) Loading** WHO Drug Dictionary load speed and background processing have been significantly improved. Updates and dictionary refreshes now complete much faster with minimal system impact, ensuring day-to-day business operations and case processing continue smoothly without disruption.

4. Bugs

Key	Summary	Release Note
HPV-318	Backport 6.1.4 The case is an AE. Not reported on Medwatch(HLP-16156)	**FDA MedWatch Form "Type of Report" Mapping Fix** Resolved an issue where cases categorized as an Adverse Event did not reflect the corresponding selection in the "Type of Report" section on the generated FDA MedWatch form.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV-221	If D.1 is NI blinded XML R3 will create data for D.1 information	The system now correctly distinguishes between a genuine null flavor selection (via the "Is Patient (name or initials) (D.1) null flavoured?" indicator) and free-text patient initials.
HPV-209	Invalid sorting of Products for FDA, resulting negative ACK	The FDA E2B(R3) XML now uses the same rank-based product ordering as the UI, resolving an issue where products were generated in a different order than displayed, which could lead to negative acknowledgements.
HPV-157	ARM - Not possible to save report as public report on page 1042	Users can now save reports as public reports on the ICSR Product-Event Line Listing page as expected.
HPV-124	Resolve regulatory discrepancy for the frequency field	**Resolved regulatory discrepancy for the dosage frequency field in E2B R2 export** The dosage frequency field in the E2B R2 export has been updated to correctly map standard frequency dropdown values (e.g., qd, bid, tid) to the required numeric code list fields (B.4.k.5.3, B.4.k.5.4, B.4.k.5.5). Frequencies that cannot be numerically mapped (e.g., cyclic, prn, single) leave these fields blank as per regulatory requirements. When no frequency is selected, the export falls back to G.k.4.r.2 and G.k.4.r.3 values where available.
HPV-17	WHO Drug builder is showing unapproved/unactivated versions of CDG in the list of Drug groupings	**Product Term Collection - WHO Drug Builder filters out unapproved drug groupings** In the Term Collection module, when navigating to the Product Term Collection workflow and opening the WHO Drug Builder, the list under the Drug Groupings tab now displays only approved and activated Custom Drug Groupings (CDGs). Draft, unapproved, or deactivated term collections are hidden, ensuring that users can only select finalized and approved drug groupings when creating or updating product term collections.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		This ensures data integrity when building product term collections. No user action is required, as the system automatically filters out unapproved and draft term collections from the selection list.
HPV-15	Product Term Collection Content Report not possible to scroll down report bar Scroll bar horizontal scroll bar missing	**Product Term Collection Content Report** Resolved an issue that prevented users from scrolling through the Product Term Collection Content Report. The report now displays the required vertical and horizontal scroll bars, improving navigation and usability for large reports.
HPV-14	Blank values shown in the “Read only” column when downloading user roles	**Read Only user role displays correctly in exported Excel** The system has been updated to ensure user role exports clearly display read-only permissions for all user groups, improving report accuracy and audit visibility.
HLP-15324	For Medicinal Products form > Pharmaceutical Product(s) > Ingredient list the dropdown concentration type is blank	**Concentration Type Selection Fix** The Concentration Type dropdown in the Medicinal Products ingredient list now displays the configured values, allowing users to select the correct concentration type when creating or updating product ingredient details.
HLP-15328	QC Check is skipped on reinitiation	The QC Check step now runs as expected when a case is sent back and reprocessed, helping ensure quality review is not skipped.
HLP-15374	Incorrect Display of “Personal Identifiable Data Hidden” Message	The “Personal Identifiable Data Hidden” message now displays only when relevant PII fields are hidden based on user access.
HLP-15325	File Annotated using HaloPV Edit Online feature gets corrupted	Files annotated using the HaloPV Edit Online feature can now be opened correctly without corruption.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HLP-15406	Datasheet listedness for product licenses need to be updated	Users can now select datasheets linked to the product family, not only those linked directly to the medicinal product.
HLP-15662	Medicinal Products Linked Parent Title Display issue	Fixed a display issue in the Medicinal Products and Product License worklists where the "Linked Parent Title" was appearing multiple times for a single record. The parent title now correctly displays only once, regardless of how many revisions the record has. This ensures your worklist remains easy to read and accurately reflects the linked parent information.
HLP-15324	For Medicinal Products form > Pharmaceutical Product(s) > Ingredient list the dropdown concentration type is blank	The Concentration Type dropdown now displays configured values when adding product ingredient details.
CUST-2315	Audit log does not decode some code list values.	Audit logs now show decoded values for additional fields, improving readability while keeping stored data unchanged.
CUST-2329	Submission scheduling rule analysis > Eligible products showing blank licenses	Product license information now displays correctly in Submission Scheduling Rule Analysis for eligible products.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Patch 6.3.1 Addition

Key	Summary	Release Note
HPV - 140	"Complete Task" Button Displayed for Nullified Records	**Hide "Complete Task" Button for Nullified Records** Resolved an issue where the Complete Task button remained visible on records that had been nullified using batch actions. The button is now properly hidden for nullified records.
HPV - 141	Missing "Return to Stock" and "Modify Stock Workflow" Buttons in Process Workflows	**Application Management update for workflow configuration modification** Resolved an issue where the Return to Stock and Modify Stock Workflow action buttons did not appear in process workflow configurations. Users can now view and access these action buttons as expected.
HPV - 150	Review mapping of G.k.6.a/G.k.6b and D.2.2.1a/D.2.2.1b elements	**Resolved Gestation Period Field Mapping Issue in E2B(R3) Processing** Resolved an issue affecting the mapping of Gestation Period When Reaction/Event Was Observed in the Foetus (D.2.2.1a/D.2.2.1b) values during E2B(R3) processing. The update ensures these fields are populated using the correct source data, preventing incorrect values from being returned during ICSR message processing and improving the accuracy of regulatory submissions.
HPV -1176	Error message is showing for initial report when neither similarIncImdrfCodesAnnexA or similarIncOtherReportingCodes is populated. One field is only mandatory for Final and Initial Final report types.	**Resolved Validation Error for Similar Device Reporting Codes in EU MIR 7.3.1**

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
		Resolved an issue where the validation message "IMDRF or Other Reporting Codes is required" was displayed incorrectly in EU MIR records. Validation now correctly applies only to report types where Similar Device reporting codes are required, preventing unnecessary validation errors for applicable Initial, Follow-up, and Final Non-Reportable incident submissions.
HPV - 990	Audit Log and Workflow History Are Not Captured for Batch Actions in Negative ACK / Failed Medicine Incident and Annual Summary Report for HV Organisations Workflows	**Audit log for Bulk Actions in customer specific workflows** When performing bulk or batch actions on records, the system now immediately captures and displays full audit trail entries and workflow history on each individual record.
HPV- 1006	Device Product is not getting coded in Term Based Coding	**Automated Term Based Coding** Resolved an issue where adding or mapping misspellings for reporter device terms in Term-Based Coding failed to code device products or update linked records. Device terms now code properly on the first attempt, allowing device incident records to advance smoothly through the workflow without getting stuck in manual validation.
HPV -1010	An unexpected error message is displayed when opening certain pages.	

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

5. Known Issues

Key	Summary	Review
HPV-972	HALOVAL 6.3: Template placeholder> 'Page ID' Field Displays Incorrect Values During Creation and Mismatched Values in Audit Log	When configuring a Template Placeholder of type Interactive Report within Application Management > Document Templates, the Page ID field could display an incorrect page name drawn from the application's list of values. As a result, the page name shown to the user during configuration did not match the value subsequently recorded in the Audit Log, creating a discrepancy between what was selected and what was tracked. Why this was deferred: Following review, this behaviour occurs only in an edge-case configuration scenario — Interactive Report templates are typically set up against standard HaloPV application pages, making this an uncommon path for most users. The root cause has been identified as a missing filter in the shared list of values component. Given the low business impact and the limited number of users likely to encounter this, the fix has been scheduled for future release.
HPV-933	Mismatch Between UI and Audit Log Values for Reporter's State or Province	When entering or selecting a value in the Reporter's State or Province (C.2.r.2.5) field on the Case Intake screen, the value displayed to the user on screen may show as a code (e.g. *130* for Abruzzo, Italy) rather than the decoded, human-readable name. This creates a confusing experience for users during day-to-day case processing, as it requires additional manual effort to verify that the correct value has been recorded. The Audit Log, by contrast, correctly displays the decoded, readable name. The root cause is that the Reporter's State or Province field currently allows both selection from the list of values and free-text manual entry. Because of this dual-entry behaviour, the system stores the internal code when a value is selected from the list of values, which is then displayed back in its coded form on the UI rather than as the user-friendly decoded name.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Review
		Why this is deferred: This issue does not block case submission or downstream regulatory reporting — cases can still be processed and submitted correctly. This is planned to be addressed as part of the broader UI/UX improvements planned for next release, where the original field requirements and display behaviour will be reviewed and aligned to provide a consistent, user-friendly experience.

Patch 6.3.1 Addition

Key	Summary	Release Note
HPV - 988	Special Characters in H.1 Case Narrative Are Not Retained Correctly After Save	**Special characters and HTML codes auto-formatted in Case Narrative (H.1)** • **Affected Area:** Case Intake & Processing H.1 Case Narrative field • **Description:** When typing special characters, codes or symbols (such as | or characters like ~, *, _, {{}}) into the H.1 Case Narrative box, the editor may automatically change them into symbols or text formatting instead of showing the exact characters you typed. Regular narrative text and standard punctuation are not affected. • **Impact:** Any technical character codes entered into the narrative will appear as the resulting symbol rather than the code itself. **Workaround / Recommendations** • When drafting narratives, enter standard characters directly rather than encoded HTML entities (e.g., enter | directly instead of |). • Enter narrative test as normal plain text without adding codes or special symbols

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Key	Summary	Release Note
HPV- 1188	Audit Log Records Changes for Date of Creation and Safety Received Date Without User Modification	**Date of Creation (C.1.2) field audit log missing timestamp** When saving changes to an ICSR record in HaloPV, the audit log may record an update to Date of Creation (C.1.2) and Safety Received Date, even if users did not edit those fields. • The actual dates are not changing. The case dates remain completely accurate and unchanged. • The audit entry is created because background system processes automatically remove the time of day (timestamp) when the record is saved. • No action is required from users. Case data integrity is fully preserved.

Docusign Envelope ID: BAB32E5D-A943-844D-8056-4799A2653A38

Document History:

Version	Date	Author	Comments
1.0	1-Sep-2026	Ritika Aggarwal	New Document for 6.3 release
1.1	09-Oct-2026	Sanchita Khanduri	Patch 6.3.1 items were added to document Certain — The rows explicitly marked as “Patch 6.3.1 Addition” are: 1 Stories • HPV-944 — Update (C.1.5) Population for ICSR Submission Files • HPV-1148 — Performance improvement for WHO DD load 2 Bugs • HPV-1140 — “Complete Task” Button Displayed for Nullified Records • HPV-1141 — Missing “Return to Stock” and “Modify Stock Workflow” Buttons • HPV-1150 — Review mapping of G.k.6.a/G.k.6b and D.2.2.1a/D.2.2.1b elements • HPV-1176 — Incorrect validation for Similar Device reporting codes • HPV-990 — Audit Log and Workflow History not captured for batch actions • HPV-1006 — Device Product not coded in Term-Based Coding • HPV-1010 — Unexpected error when opening certain pages 3 Known Issues • HPV-988 — Special Characters in H.1 Case Narrative Are Not Retained Correctly After Save • HPV-1188 - Audit Log Records Changes for Date of Creation and Safety Received Date Without User Modification

Certificate Of Completion

Envelope Id: BAB32E5D-A943-844D-8056-4799A2653A38

Status: Completed

Subject: Complete with Docusign: HPV-RLN-001.1 HaloPV 6.3 Release Notes - Patch 6.3.1.pdf

Source Envelope:

Document Pages: 30

Signatures: 3

Envelope Originator:

Certificate Pages: 2

Initials: 0

Sanchita Khanduri

AutoNav: Enabled

sanchita.khanduri@qinecsa.com

EnvelopeId Stamping: Enabled

IP Address: 2a01:4b00:ab4d:

Time Zone: (UTC+05:30) Chennai, Kolkata, Mumbai, New Delhi

Record Tracking

Status: Original
10/9/2026 7:31:41 PM

Holder: Sanchita Khanduri
sanchita.khanduri@qinecsa.com

Location: DocuSign

Signer Events	Signature	Timestamp
Sanchita Khanduri sanchita.khanduri@qinecsa.com Product Manager Qinecsa Solutions Security Level: Email, Account Authentication (Required)	Signed by: Sanchita Khanduri Signer Name: Sanchita Khanduri Signing Reason: I am the author of this document Signing Time: 09-Oct-2026 | 7:33:26 PM IST EF4EBAAEBA46408683F5EDFC75B090D8 Signature Adoption: Pre-selected Style Signature ID: EF4EBAAE-BA46-4086-83F5-EDFC75B090D8 Using IP Address: 152.37.101.184 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I am the author of this document	Sent: 10/9/2026 7:33:09 PM Viewed: 10/9/2026 7:33:16 PM Signed: 10/9/2026 7:33:58 PM
Electronic Record and Signature Disclosure: Not Offered via Docusign		
Gyongyi Mezey gyongyi.mezey@qinecsa.com Senior PV Consultant Qinecsa Solutions Security Level: Email, Account Authentication (Required)	Signed by: Gyongyi Mezey Signer Name: Gyongyi Mezey Signing Reason: I have reviewed this document Signing Time: 09-Oct-2026 | 7:35:15 PM IST A8F35A243E8742B694C533627EE0D6CE Signature Adoption: Pre-selected Style Signature ID: A8F35A24-3E87-42B6-94C5-33627EE0D6CE Using IP Address: 212.132.195.138 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I have reviewed this document	Sent: 10/9/2026 7:34:01 PM Viewed: 10/9/2026 7:35:06 PM Signed: 10/9/2026 7:36:00 PM
Electronic Record and Signature Disclosure: Not Offered via Docusign		

Signer Events	Signature	Timestamp
Rishu Ranjan rishu.ranjan@qinecsa.com Qinecsa solutions Security Level: Email, Account Authentication (Required)	Signed by: Rishu Ranjan Signer Name: Rishu Ranjan Signing Reason: I approve this document Signing Time: 09-Oct-2026 | 7:47:40 PM IST BC91C600D89E4ED9915124FE94ABEF3C Signature Adoption: Pre-selected Style Signature ID: BC91C600-D89E-4ED9-9151-24FE94ABEF3C Using IP Address: 151.186.177.135 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 10/9/2026 7:36:03 PM Viewed: 10/9/2026 7:47:30 PM Signed: 10/9/2026 7:48:04 PM

Electronic Record and Signature Disclosure:
Not Offered via Docusign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	10/9/2026 7:33:09 PM
Certified Delivered	Security Checked	10/9/2026 7:47:30 PM
Signing Complete	Security Checked	10/9/2026 7:48:04 PM
Completed	Security Checked	10/9/2026 7:48:04 PM

Payment Events	Status	Timestamps