Release notes

June 2020

HALO PV 2.2

RELEASE NOTES

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ABOUT THIS RELEASE

HALO PV version 2.2 is a minor release (x.y.z → *major.minor.patch*)

Please contact support@insife.com for the full release notes including impact assessments.

NEW FEATURES IN HALO 2.2

Area / Process / Group	Title	Description
User administration	User deletion	A new configuration switch has been added in the user configuration screen ("Nullify user") to allow soft deletion of users. The Delete button under Organizational entities > Persons is updated to nullify rather than hard-delete light users.
Child forms	Line listings	A new child form is created to allow for configuration of inclusion criteria in aggregate reports
Attachments	PDF merging	A new feature is added to allow merging of PDF files into combined PDF files. The merging can be configured as a task action on any step in any workflow. The merging allows merging of all PDF attachments in a record including PDF attachments in child records.
Attachments	Attachments in old revisions	A new section is added on page 113 (Attachments) to show attachments across all record revisions. The list only includes attachments in the main folder (i.e. manually created subfolder objects are not included).
Reports	Assigned to column	Page 118 (Generic record overview page) is updated with a new switch to include records assigned to other users. Overall, individually assigned records are still locked for update by other users, but with the new switch these records can be included in the overview. New columns to show the assignee as well as the creator are added to the overview. On workflow task configuration the existing switch "Hide records for other users when individually assigned?" can still be used to completely hide individually assigned records from other users (i.e. for records which are personal, timesheets etc.)
Workflow configuration	Disabling workflow tasks	The ability to disable workflow tasks is added with a new configuration switch (Workflow configuration > Edit Tasks > Task details > Disabled). When the switch is enabled, the task step will no longer appear in workflows (historic records are preserved).

		This switch can be used to hide steps that cannot be deleted because historic data exist. To additionally support easy configuration of task steps, a feature to re-number steps has been added (new buttons allows to move steps up and down in order without having to manually re-number other steps). The system has been updated to allow for "holes" in the workflow step order (to allow for disabled steps to exist) - this means that the re-numbering of steps when disabling steps is not a requirement.
Workflow configuration	Saving workflow configuration updates	Cancel button re-labelled to "Close" and the save button no longer closes the window.
List value maintenance	List value maintenance improvements	List of value maintenance has been updated to allow use of code lists: Page 97: Meta data configuration - here the user can now select a code list to use for the list of value maintenance Page 26: The List of value selected in Page 97 (meta data configuration of the code list) will now show a text OR a list of value depending on the configuration made in Page 97. If an LOV is selected for the code list field, the corresponding list of value will be shown for easy selection of values. Page 25: Updated to show decode values for columns configured with code lists.
Data collection programs	Relationship between SDEA, DPCs and Partners	Jumping between SDEAs DCPs and Partner records has been improved to allow easier overview directly from the DCP (Data collection program) record
Reports	Signal notification requirement report	New periodic report on Page 86 is added to show Signal notification reporting requirements
Reports	Local qualified persons report columns	List of local qualified persons report update with a new column showing the home country of the Qualified person
Reports	Report descriptions	Tabular report content can be configured and stored as user defined reports. Therefore, hardcoded report descriptions do not make sense and have been removed. Instead the title of the report can dynamically be set by configuration of the task action linking to the report (existing feature)
Process records (data)	Navigation between parent- and child records	The main record form has been revised to show related parent- and child records in a new section (Associated Child records). The title and labels are contextual and can be configured using the following switches: Workflow configuration > Record information: - Default parent workflow - Default Parent Label - Default child workflow - Default Child Label

		The new sections provide a list of child records and buttons to add new child records, jump to the parent and re-select the parent record.
Access	Record locking / read-only	All forms are updated to check the lock status of the record. If the record is locked, fields will be visually marked as read-only to make it clear to the user that they cannot be modified
Workflow configuration	Workflow task completion	A new switch now controls whether to show the detailed task completion screen where routing notes can be entered. When routing back or routing late tasks, the page is still mandatory. The switch is personal and is configured per user (My settings Notifications and Workflow > Enables notes on task completion). Per default, routing comments are not shown on forwarding tasks non-late tasks.
Data collection programs	SDEA dropdown list	When assigning an SDEA to a data collection program, the drop-down is updated to show active SDEAs only (SDEAs with blank or future Agreement stop date)
Field configuration	Configuration of displayed fields	A new code list (LV_REFID = 1000) has been introduced to allow hiding of fields (per default, all fields are shown). Currently the code list is implemented in the pages: - 128 (org. entities) - 45 (Data collection programs) - 31 (Product details) - 33 (Product family details) - 34 (Product license details) To hide a field, the new code list (Field configuration (Show/Hide)) must be updated with an entry like the example below (in this example the field "Open for two-way communication?" in the Data collection program child form is hidden): Page ID: PAGE 45 Workflow ID: Data collection programs Config (1=Show, 0=Hide): Hide Field label: Open for two-way communication?
ICSR requirement intelligence	Causality default values for spontaneous rules	The form has been updated to set all causality options as checked per default for spontaneous rules. This default setting applies when saving the form. It will not impact existing records (i.e. to update existing records, a data correction is required)
Reports	Current workflow task in reports	All regulatory intelligence reports (tabular reports) are updated to show the "Current task" of the record in a new column to give a easy overview of the workflow state of the rules listed in the reports
Reports	Created by column in reports	"Created by" added in My tasks, Active tasks, The generic process overview (Page 118) and in all reports under page 86

		(Tabular reports). In addition, the record Assignee is added in the Active tasks and The generic process overview (Page 118) (in My tasks the assignee is always the current user (or blank))
Search	Free-text search	A new free-text search field is added on the front-page. This search feature currently supports free-text search in the record title field using any number of search terms
User interface	Configuration of widgets shown on front-page	New Show/Hide widget buttons added on the front-page to allow users to decide on the widgets they want to see. To re-add removed widgets the user can use the Add widget at the bottom of the front-page.
Child forms	Findings detail child form	New child form added to capture details of Audit findings
Child forms	Audit details child form	New child form added to capture details of Audits
Child forms	New Data collection program fields	New fields added to the Data collection programs child form: Open for two-way communication? Administrator (if different than owner) Global Brand Responsible International Business Analyst responsible The fields are shown per default but can be configured to be hidden
Process records (data)	Tree views	A new generic "Tree view" page is added (page 6) which can be called with the Workflow ID of the top-level records. The page will automatically render the underlying tree taking all child relations underneath the selected top-level Workflow
Audit log	Main audit log	The master audit log (Full audit log) has been updated to include a Workflow column (showing the workflow of the listed records). This column is only populated for audit records related to process records (i.e. configuration updates are not linked to a specific workflow). Date search criteria are added to make it easier to limit the data retrieved. The date field is limited per default to speed up the page loading.
Reports	Tabular reports	New reports added to Page 86: PSMF annex G.1 Audit details Submissions overview DSUR Line listing PSMF annex G - Findings PSMF annex C.3 - Studies
Child forms	Submissions detail form	New child form added to capture Submission details
Data loader	Data loader	The data loader has been updated with new features including: - Updated indication of the match between loaded data and existing data (icons displaying Match, New and Update scenarios)

		- New switch to complete the workflow of loaded data - New switch to delete records which are not in the loaded data set - New filter to select the Organization in scope of the data load (only data within this organization will be deleted if they are not in the data set and the switch above is active) - Support of multi-select lists (i.e. multiple countries separated by ", " and multi-select fields in child forms) - Support of the following date formats in date fields: yyyy-mm-dd and dd-Mon-yyyy - Support of both ISO code and ISO value for import of countries (i.e. both DK and Denmark will be allowed for import into the master country lookup table)
Process records (data)	General improvements of the main record page	Major rework of the user interface on page 119 including: - Child/parent relations improved (see separate change) - Fields re-arranged to make the main fields more visible (title, type, due date) - Buttons updated to dynamically adjust to the current state (i.e. ensuring the workflow forward- and backward buttons are only shown if it is in fact allowed to route) - Dynamic "Go back" buttons added for easier navigation between process records (per default the "Close" buttons send the user back to the process overview, but the button can be dynamically configured to go back to other records)
Child forms	General improvements of the child forms	Backend updates to allow linking of child records (i.e. allowing a 1:many relationship between different child record types
Child forms	KPI data details form	New child form added to capture KPI data
Child forms	QMS document details form	New child form added to capture QMS document details
Access	Burn links (one-time login for light users)	Addition of burn link feature: This feature allows Light users to log into the system using a one-time use "burn link". The burn is sent to users when: - The user is configured as light user - The user has email notifications enabled When the systems sends the notification email, it will normally send a direct link to the receiver. For users fulfilling the requirements above, this link will be a one-time burn link instead of the normal direct application link.

		When accessing the system through burn-links, the user is sent directly to the relevant record and will see a simplified form. Once the task is completed, the user is automatically logged out and cannot log back into the system The feature is implemented using a new login page (Page 141) with a dedicated authentication scheme (HALO_LIGHT_AUTHENTICATION). Encryption / Decryption of the one-time link codes are handled by existing functions in HALO. The encryption ensures that
List of values	Limitation of drop-down list values	The core access functions in HALO are updated including the list of values which limit the users responsibilities. Subscribed LOVs (list of values which limit the visible values to the ones allowed by the users organizational filters) are updated to be contextual. Before they always followed the users responsibilities - after the change they follow the users responsibilities only when they are not used in a specific record - i.e.: When a user opens a process record (Page 119), the available countries on that form will follow the organization of the form itself and not the organization of the user (often the organization will be the same, but the record could also be assigned to a child organization of the current users organization - in that situation, the lists will show the values of the record organization).
PSMF	New PSMF annex standard templates	Standard templates loaded for: Annex G.2 - Conducted and Completed audit Annex G.1 - Audit Schedule Annex G.3 - Open Deviations from PV Procedures Annex C.3.2 - Study Sources / Completed Trials Annex C.3.1 - Ongoing Trials Annex F.2.1 Submission Compliance Annex C.3.4 - Digital Activities Overview Annex B.2.3 - Distributor contacts Annex C.3.3 - Programs Annex D - Computerized systems and Database Annex E.1 - List of Written Policies and Procedures Annex F - Performance indicators Annex G.4 - Audit notes Annex H - Products Annex B.2.4 - Licensing Partners Annex I - Document control Annex B.2.1 - Service providers Annex B.2.2 - List contact persons Main PSMF
Organizational entities / User admin	Creation of light users	Light user creation from organizational entities updated to only allow entry of the user email. The email is automatically used as the ID of the user.

		To make the email different from the user login, the user can be modified by a proper user administrator from the user admin module.
Organizational entities	Simplification of organizational entity roles	The partner role selection has been updated to include a filter/search free-text field which limits the values available for selection. The filter does not impact already selected values.
Organizational entities	SDEA template update	Technical update to the SDEA template to allow flexible update of the placeholders
ICSR	ICSR R3	New module for handling E2B R3 files. Separate specifications are created to document the details of the new module. New ICSR child form pages and fields added to capture all E2B R3 (ICH) fields Page 119 updated with new E2B R3 draft report feature for generation of E2B R3 compliant XML files
ICSR	MedDRA	A new MedDRA dictionary page has been added and integrated with the E2B R3 forms. A new page for selection and display of MedDRA terms is available.
Access	Automatic AD synchronization	This change allows retrieval of user groups from Azure AD (and other OAUTH2 enabled SSO providers). At login, the HALO users roles are automatically updated based on the groups retrieved from AD. To map the AD groups with roles in HALO, a new configuration option in the HALO user roles have been created (Page 4 > Create / edit user role / groups > Synchronize with SSO / AD?)
Organizational entities	SDEA- and Partner relationship	Page 105 (New SDEA) and Page 45 (Data collection program details) are updated to simplify the setup of new Partners and SDEAS: There is now only one button on the Data collection program details form to create a new SDEA and Partner. If the user has selected an existing partner, the popup window allows creation of a new SDEA under the selected partner. If the user leaves the Partner selector blank, the pop-up allows creation of a new Partner in the same process as the SDEA creation. The user can either provide a specific partner name or leave the Partner name field blank to use the same name as the SDEA name. The territory selector is removed and the system automatically assigns the same territory(ies) to the partner and SDEA as selected for the program.

		The window for adding new Partners / SDEAs will immediately add the Partner / SDEA to the program when saved - before the user had to manually select roles and add the created SDEA to the program). Both the SDEA and partner record can be modified directly from the program after addition / creation (links go directly to the child form and a "Go back" button takes the user back to the program).
Attachments	Attachment size limitation	The S3 storage capabilities are updated to allow transfer of files above 10MB (currently the S3 storage is not limited by any size restrictions, but the API used for transfer of files fails if files are larger than 10MB). This limitation has been removed.
E-signature	SSO task step signatures	Password field made mandatory to ensure that it is not possible to complete workflow task step signatures using single-sign-on
API	Integration	
Attachments	Locking mechanisms for attachments	The Attachment page has been updated to allow for upload of new attachments even if a record is locked. A check is added to make sure that existing, locked attachments cannot be modified or overwritten
Attachments	E-signature PDF sheet	The E-signature functionality has been updated to generate an MD5 checksum of all the signature components / data points. This checksum is generated into a PDF document which will be uploaded to the record after signature.
User interface	Help button color	Update of the underlying HALO style sheets (CSS files) to make the help text buttons and "x" buttons appear in a darker color to make sure that they are clearly visible on light background pages (i.e. Tabular reports / grids and on Popup dialogue boxes)
Child forms	Grid view edition of child records (Audit findings)	New page (153) added to allow for batch update of records. Page 119 updated with link to child records (the button is only visible if a default child workflow is configured under the workflow configuration)
Dashboards	Open tasks dashboard	New dashboard implemented on custom page (152)
Reports	Special columns for audits- and finding workflow overviews	New logic (switch) added in page 118 to allow for addition of custom views on page 118 for specified workflows
Reports	List of programs report filter	The existing organization filter is enabled for the List of programs reports
Reports	Data collection programs - Page 45 - child form update	The Switch to add an external party has been moved below the data fields to ensure that all mandatory fields are populated during entry before adding the external party. This ensures a more logical entry flow.

BUGS RESOLVED IN HALO PV 2.2

Area / Process / Group	Title	Description

Child forms	Data collection programs - Page 45 - child form update	The page has been updated to perform a submit - this ensures a full refresh which solves the issue for Internet Explorer based browsers
DSUR Line listing (2.2.4)	Update of LLT/PT meddra term mapping	Database views used by the DSUR report updated to lookup the PT term based on the LLT term stored in the form
Audit log	Audit logging details	New field added to all X tables (cross reference tables) to mark if the new records are made as part of a new revision. When the records are only updated due to a new revision, the change should not be stamped into the audit log. The new column used to track this is REVISION_ONLY. All triggers are updated to ignore entries where this field is populated with 1 AND the update is a new record. Updates/deletions are not impacted and insertions without this mark, are audited as normal.
Custom notifications	Custom notification backend job updated to include records which are not in an active workflow	Backend custom notifications should trigger on records which are not in a current workflow.

BACKEND / TECHNICAL IMPROVEMENTS in HALO 2.2

Area / Process / Group	**Title**	**Description**
Reports	Performance improvements	Filters changed to use direct match instead of wild-card search (no impact on end-user functionality) APEX LOV calls replaced with direct SQL queries in the view
Miscellaneous	Consolidation of territory and country fields	Territories are now controlled on the master table (adding a new cross table to allow for multiple territories). Child forms using territories are synchronized with the main record to ensure consistent usage of territories (i.e. there is now no difference between territory "access filters" and the territories selected on the child form. New cross table added and synchronization mechanisms between child forms and master form added
Organizational entities	Performance improvements	The user of "child organizations" has been moved into a dedicated cross-table (obsoleting the column orgentities_x_orgentities) to improve performance