

Release notes

HALO PV 2.1.1

January 2020

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ABOUT THIS PATCH RELEASE

HALO PV version 2.1.1 is a patch release.

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

NEW FEATURES IN HALO 2.1.1

Area / Process / Group	Title	Description
Programs	CHG-2.1-10 New URL column on List of programs	<p>Add URL field to the "List of programs" standard report</p> <p><i>How to test:</i> Go to Tabular reports page. Select the "List of programs" report and inspect the available columns. The URL column should be available and populated with the value of the URL field for the selected records (if the column is not available, it can be added from Actions > Columns)</p>
Attachments	CHG-2.1-11 Amazon S3 support in region Frankfurt	<p>S3 support using API proxy instead of direct S3 REST API connection - to support AWS regions (i.e. Frankfurt) without support for the AWS R4 signature format. Using an AWS API Gateway moves the signature logic to the API instead of database and removes the need for custom AWS signature functionality.</p> <p><i>How to test:</i> 1. Open a record (any) and click the attachment icon ("Paperclip") 2. Verify that it is possible to:</p> <ul style="list-style-type: none"> - Create a subfolder - Upload file(s) - Delete a file - Delete a folder (if empty)
Tabular reports	CHG-2.1-12 New External Parties column on List of programs	<p>List of programs tabular report column "External parties" shows Data collection programs > Data collections program form > External Parties > SDEA. It would be more logic with a header called SDEA and then adding a new column called "External parties" with the actual party name. The same change applies to the External Parties form under the Data collection program child form.</p>

		<p>How to test:</p> <ol style="list-style-type: none"> 1. Open a Data collection program record 2. Go to the External Partner tab 3. Verify that the table with partners contains a column with the SDEA name as well as the name of the External Partner linked to the SDEA 4. Go to the List of Programs tabular report 5. Verify that the report contains both and SDEA column and an External Parties reference
Data Loader	CHG-2.1-13 Data loader	Generic data load capabilities for automatic load / update / deletion of records (i.e. products, studies, QMS documents). The data load feature must be available for authorized end users (as per configuration)
Attachments Document generation	CHG-2.1-14 PDF merging	Merging of multiple, uploaded PDF files into one document (in addition to Word sub-templates which allow merging of multiple Word documents and subsequent PDF rendition)
Scheduler	CHG-2.1-15 Child record scheduling	Generic Scheduler features for both single-record and dynamic workflow scheduling (workflow restart on existing records) should include an option to include child records (i.e. to cover restart of a full PSMF including child annexes)
Notifications	CHG-2.1-17 Custom notification framework	<p>It should be possible to configure custom filters (where-clauses) on all notification types, per workflow task and recipient. The mail subject and message for each notification should be configurable.</p> <p><i>How to test:</i></p> <ol style="list-style-type: none"> 1. Go to the workflow configuration and edit a task where a custom notification is desired 2. Under the Notifications and Escalation tab, add a new notification in the Custom notifications table - configure as relevant 3. Create a new record within the workflow created above and route through the workflow tasks. 4. Verify that notifications are send according to the configuration
Notifications	CHG-2.1-18 Custom notification texts	It should be possible to configure custom notification texts per workflow task notification type and recipient. See CHG-2.1.17 for details.
Child forms (Customer specific)	CHG-2.1-20 Organizational entity help texts	Addition of help texts on Organizational entities (Customer provided help text)
Field validations	CHG-2.1-23 New Form field validations	<p>Add new form validation rules for the following fields.</p> <p><i>Mandatory field validations (Data collection programs):</i></p>

		<p>Program name, Type, program objective, Will an external party be involved who may receive safety information?, Program contact, Start date, either expected or actual end date (but not both), External party information (see below)</p> <p><i>Other mandatory validations (Data collection programs)</i> Start & end date of program: It must not be possible to select an expected end date prior to the start date; It should not be possible to enter an actual end date without first deleting the expected end date</p> <p><i>External partner:</i> If creator of form has indicated, in the DCP details form, that an external partner will be used, it should not be possible to save/continue with form until the External parties tab has been completed with partner + SDEA Mandatory requirement intelligence fields: Reporting required (yes/No) (OBS: The field has different labels depending on the Requirement type)</p> <p><i>Mandatory Entities and agreements fields:</i> Roles must be mandatory (only available on External Partners)</p> <p><i>Other validations / default values</i> Auto-populate the Reviewed by field in the child form for Review comments (Manual override is possible). The Review comments action is available on the Data Collection Program - QC workflow.</p>
<p>Regulatory intelligence child form</p>	<p>CHG-2.1-25 ICSR reporting rule child form Field label update</p>	<p>Devices, ICSRs: When choosing "local format", it should be "followed up by CIOMS (drugs) or MIR (Devices)?" and not "followed up by CIOMS" as this is not possible for device cases (the label should be dynamically adjusted based on the type)</p> <p><i>How to test:</i></p> <ol style="list-style-type: none"> 1. Create a new ICSR requirement record 2. In the Details form, select Local format in the format drop-down 3. Verify that the "Follow up by .." field has a dynamic label depending on the record type: <p>- For Device rules, the label is "Follow up by MIR report"</p>

		- For Drug rules, the label is "Follow up by CIOMS I report"
Tabular reports (Requirement intelligence)	CHG-2.1-26 Tabular reports default entity filters	The Entity filter should - per default - be set to the current user's organization. It should be possible to change the default / remove the filter manually. <i>How to test:</i> 1. Go to Tabular reports page 2. Verify that the organizational entity filter is preset to the current user's organization when entering the following reports: Non-expedited reporting requirements overview and Audit Partner Report / All organizational entities and agreements 3. Verify that the filter can be cleared / overwritten
Workflow	CHG-2.1-27 Workflow task default timeline configuration	It should be possible to disable timelines on workflows (specific enquiry to remove this on the reg. Intelligence workflow) - i.e. when not specifying timelines on a workflow task step, no due date should be set

BUGS RESOLVED IN HALO PV 2.1.1

Area / Process / Group	Title	Description
Audit log	2.1.0.4-03 Cross table audit	Role of External Party (in Program) (cross table) is not audited (the role is audited correctly on the SDEA form itself, but should also be captured as part of Program forms where the SDEA is selected - together with the selected SDEA reference) <i>How to reproduce/test:</i> 1. Create a new Data collection program record 2. Open the child form and select that External parties are involved 3. Select or change an external party in the table <i>Expected:</i> the selected party is added to the audit log of the program record
Audit log	2.1.0.4-06 Audit of current revision label and value	The audit logging of the Current revision record property is not intuitive - i.e. it should be made more obvious in the audit log when a record goes from current to non-current.

Child forms	2.1.0.4-09 ICSR rule child form header	<p>Header in ICSR detail records show incorrect seriousness- and type information (child form). The header should be updated to correctly reflect the content of the Regulatory rule child form</p> <p><i>How to reproduce/test:</i></p> <ol style="list-style-type: none"> 1. Create a new Regulatory requirement record (ICSR) 2. Open the child form and populate various seriousness- and type data <p><i>Expected:</i> The header correctly reflects the seriousness- and type criteria in the child form</p>
Scheduler	2.1.0.4-14 Nullified records enabled when scheduling workflow restart	<p>Using the Dynamic HALO scheduler to restart workflows on existing records may result in nullified records to be re-activated.</p> <p><i>How to reproduce/test:</i></p> <ol style="list-style-type: none"> 1. Use the record scheduler to restart records in a workflow where nullified records are present <p><i>Expected:</i> Nullified records in scope of the scheduler are not restarted (activated)</p>
Core forms	2.1.0.4-16 Page 51 (Review form) hangs in IE 11	<p>Counter on Page 51 (Review comments) causes the page to hang in IE 11</p> <p><i>How to reproduce/test:</i></p> <ol style="list-style-type: none"> 1. Open a record in HALO where the Review comments action is available (i.e. Data collection programs > Data collection program - QC) 2. Click on the Review comments task and enter text in the review field <p><i>Expected:</i> There is no delay / page do not "hang" when typing the review comment field</p>

BACKEND / TECHNICAL IMPROVEMENTS

Area / Process / Group	Title	Description
Database	2.1.0.4-13 Database sequence numbers for cross-tables	Sequence numbers for cross tables use default values for New process records. These may conflict with alternative sequence roll for systems with migrated data. To avoid having to manually increase sequence numbers, the cross tables should use dedicated sequence numbers.