

Table of Contents

- 1) Insite HALOPV User Manual
- 2) Preface
- 3) Introduction
- 4) Aggregate Reporting

1) HALO PV

User Manual - Release 3.0 (JUNE 2021)

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2) Preface

Where to Find More Information

The latest product information including release notes for HALOPV is available at

<https://www.halopv.com/>

Insife Support

Insife Support team can be reached out at Support@insife.com

3) Introduction

3.1) Purpose

This User Manual describes the process workflow for aggregate reporting in HALO PV.

HALO PV **Aggregate Reporting** allows for creating various types of aggregate reporting from clinical to post-market. Users of HALO PV can review, approve, manage schedules, and workflow progress of reports. HALO PV offers seamless data integration with auto-generated documents using word-based templates.

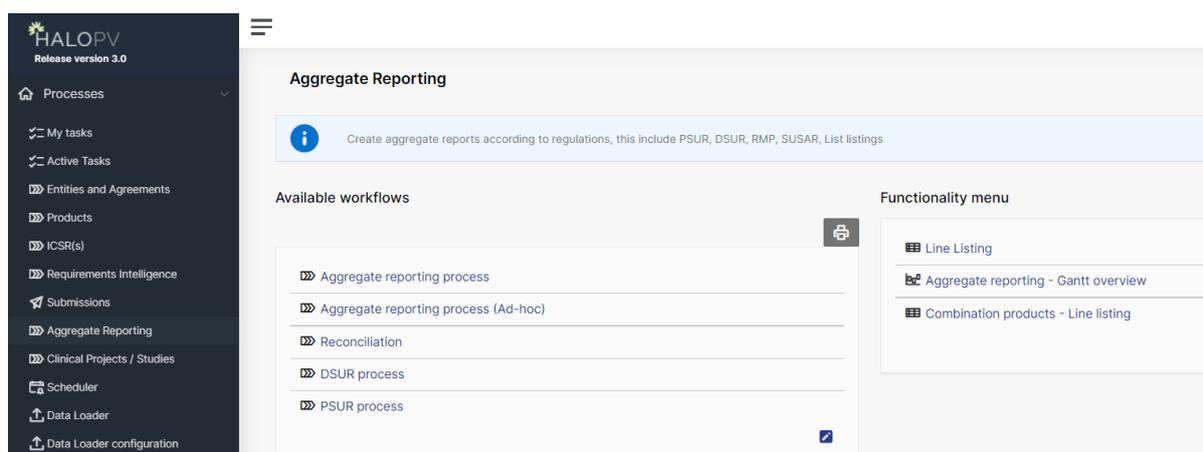
4) Aggregate Reporting

Aggregate Reporting Management includes all available process workflows concerning creation and management aggregate reports, including line listings and tabulations.

4.1) Aggregate Reporting Workflow

On the left menu, you will find a list of Processes available for your user profile. Please select **Aggregate Reporting**.

Once clicking **Aggregate Reporting**, you will find the **Available workflows** of aggregate reporting.



In this example let's select **Aggregate reporting process**. By clicking on the **Aggregate reporting process**, you will have an overview of all the ongoing and completed aggregate reports. Click a **Record ID** to proceed. When clicking on a **Record ID**, a new window will open, showing the process workflow and the steps to follow.

4.2) Create a New Record: Example: Aggregate reporting process

On the left menu Processes, click on **Aggregate Reporting**, then select **Aggregate reporting process** and then **Create new**.

4.2.1) First Step Initiate/configure aggregate report

The first step Initiate/configure aggregate report will help configure the first report and/or set up the next reporting deadline (in case it is version 2). The timeline of the task is configured on the system as a default timeline (days allocated for a task).

To start the first task action, go to the section **Task activities**, as shown below and select the corresponding task to your role, in this case, select **Aggregate report configuration details** to proceed.

View/edit record

→ Initiate / configure aggregate report → Generate tabulations/listings and author report body → Review document → Approval → Prepare Submission

Complete task

Record and task information

Aggregate reporting process - HALO PV 3.0 (AGG-RPT-816)

Configure the aggregate report

Aggregate Report Medical Writer 29-NOV-2021

Task activities

Action	Status
Aggregate report configuration details	0

Description

Description

Notes and linking

Notes

URL

Aggregate report configuration details

This form can be completed with the Start, End date, the International Birth Date, the product(s) and Summary of tabulation products – including Investigational medicinal products, Placebo, and Comparator (the products are populated by the product dictionary in HALO). Once the configuration is reviewed, click Save and then Return to go back to the master record.

Aggregate reporting details form

Save Return

Data Configuration Drug-Event details Event details Reporting destination Summary tabulation products

Include invalid cases

Period - Start date Period - End date

(Report filter) (Report filter)

International Birth Date

(Report filter)

Study

Hello world study
ISO-ABC
LUMENT
My Study
My second study
OEV-128
Study - Blinded

Filter products Re-select studies for products selected below

Products

ABC Drug (ABC Drug)
Amoxicillin 500mg (AMOXICILLIN)
Amoxil (AMOXICILLIN)
DoqaqDrug

Completing a Task and Sending it Forward

Once you have finished reviewing the data and completed the assigned tasks, click on **Complete task** to send the report forward. When clicking on Complete task, the task proceeds to the second step **Generate tabulations/listings and author report body**.

4.2.2) Second Step Generate tabulation/listing and author report body

The second step step, **Generate tabulation/listing and author report body**, allows to generate the report, line listing, tabulation or other output as per the template you would like to produce the output from. If you want to work on a report externally then manage it in HALO, it can be uploaded in HALO PV by clicking the attachment icon. When generating a document from a customized template, click on **Generate document from template** seen under **Task activities**.

Generate Document from Template

By clicking on **Generate document from template**, a new window will open. **Document Template** dropdown list will display a set of templates that allows for selecting any available template. Choose a template and a Format.

Document link

Document link

Action: Assign Document Template Record Title: HALO PV 3.0

Document Template

Interactive report (Optional)

Template file (Optional)

Select a WORD file as template instead of the default document template

Output format: WORD

Upload to working folder:

Generate Return

After generating the output from the template, items become available in the repository. To see the output, click on the attachment icon at the upper menu. A new window will display the files, as shown in the example below. Click on the concerned object to download.

Documents

Upload / Drop file(s)

Drop files here (click to browse)

Upload Create folder

Type name to add folder

Documents

Go Actions Return

Object	Action	Last modified
DSUR line listing.docx_HALO PV 3.0_version1,22-Nov-2021.docx	Delete	22-NOV-2021 15:37:53
DSUR line listing.docx_HALO PV 3.0_version1,22-Nov-2021.pdf	Delete	22-NOV-2021 15:37:24

1 - 2

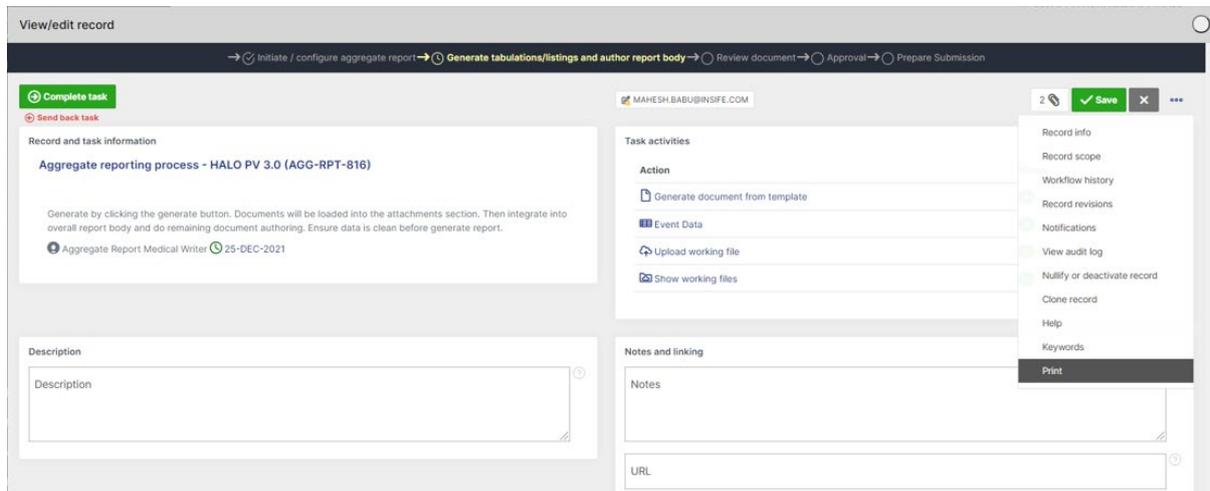
All revisions

Object	Last modified
REV1	-

1 - 1

Once the authoring of the documentation is completed, the documents are filed back to the section Attachments. This section allows to add any relevant documentation or create folders for your record storage. E.g., background documentation, final rendition documents. The storage area makes it easier for the user to organize or retrieve information at a later point.

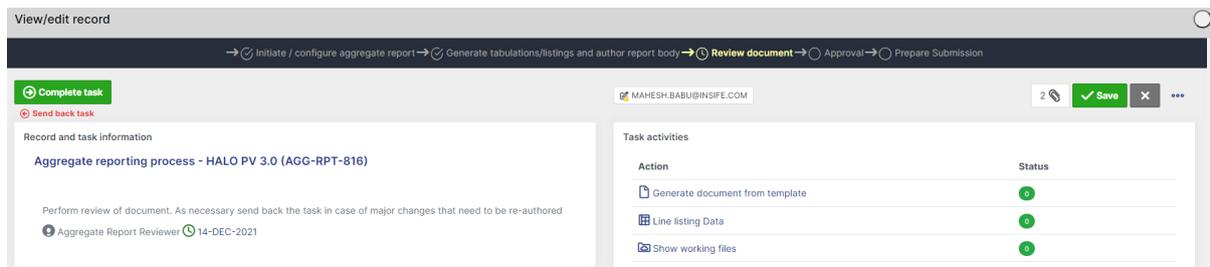
Another option to preview outputs without necessarily save them as attachments in HALO, but seeing locally on computer, is option **Print**.



To forward the task, select **Complete task**

4.2.3) Third Step Review document

Review document allows the designated reviewer(s) to check the documentation. Documents can be downloaded in this step, and marked with track changes etc.



Once review is completed, the task can be forwarded. Or, In the event of major changes that need to be re-authored, the task can be sent back to the previous step in the workflow.

4.2.4) Fourth step Approval

Fourth step, approval, allows the approver to revise, edit, and approve the documentation. In case the report cannot be approved and needs to be updated or corrected, the approver can send it back to the previous author.

View/edit record

→ Initiate / configure aggregate report → Generate tabulations/listings and author report body → Review document → **Approval** → Prepare Submission

Complete task | MAHESH.BABU@INSIFE.COM | 2 | Save | X | ...

Record and task information

Aggregate reporting process - HALO PV 3.0 (AGG-RPT-816)

Ensure the report is forwarded for submission. Send the case back in case the report cannot be considered final and needs to be updated.

Aggregate Report Approval 30-DEC-2021

Task activities

Action	Status
Generate document from template	0
Line listing Data	0

4.2.5) Fifth step Prepare Submission

In this scenario, once the document is ready and task **Create Aggregate Submission Record** is completed; it can be prepared for submission to the corresponding authorities.

View/edit record

→ Initiate / configure aggregate report → Generate tabulations/listings and author report body → Review document → Approval → **Prepare Submission**

Complete task | MAHESH.BABU@INSIFE.COM | 2 | Save | X | ...

Record and task information

Aggregate reporting process - HALO PV 3.0 (AGG-RPT-816)

Prepare Submission using the create submission record on Task activities section.

Aggregate Report Medical Writer 14-JAN-2022

Task activities

Action	Status
Create Aggregate Submission Record	0

Clicking the **Complete task** button concludes the activities. The revision is closed and can no longer be changed.