

Variation Type IA minor MRP Project

This procedure is used for **Variation Type IA minor Projects** in more than one **EEA Member State** in parallel using the **Reference Member State** and the **Concerned Member State(s)** concept.

Milestones are marked in dark orange, **main project activities** in avocado green, and **significant events** in regular text. Comments and explanations are given for significant events. Using **milestones**, **project activities** and **significant events** along with other features of **Enriched Email**, the progress of project realization can be monitored in real “real-time”.

Below are presented all **significant events** that can be selected by a designated **regulatory project person**, nominated **Assistant**, or **Agent** when sending or receiving **enriched email messages** during the realization of this type of **Corporate Project**. The designated **regulatory project person**, as the **designated follower** of the **enriched emails** for the specific project, also receives copies of all **enriched email messages** sent by the **Assistant** or **Agent** and is forwarded to all **enriched email messages** received by the nominated **Assistant** or **Agent**.

Automatically generated **enriched email notifications**, sent or received, cannot be selected and are presented here for illustrative purposes only.

Replies to **significant events** are not shown. If a reply message to the **significant event** is not sent as a reply, a **regular email message** can be set as a reply to a previous message using replication, one of the **Enriched Email** features.

The procedure model can be easily modified by adding, deleting, or changing **milestones**, **activities**, and **significant events** to suit particular needs/requests.

Milestones, activities, and significant events

Initiated

Initial Submission Preparation

- (auto-in) Notification - Start of the Project
- (int-out) Internal submission eCTD Request

- (int-out) Internal info Request
- (ext-out) Pre-submission Dialog with NCA(s)
- (int-out) Internal Payment Request
- (auto-in) Notif. - Technical validation started
- (auto-in) Notification of the Initial Submission to RMS and CMSs
- (ext-in/out) Related correspondence

Submitted

Automatic Content Validation by RMS and CMS(s) (5 days)

- (ext-out) List of Despatch Dates to RMS
- (ext-in) Non-receipt/Non-payment notification by CMS
- (int-out) Internal Payment Request
- (ext-out) Proof of additional payment
- (ext-in) RMS Notification of the start of the variation process (Day 0)
- (ext-in/out) Related correspondence

Validated

Review Phase (30 days)

- (ext-in) Acceptance of Notification without MA amendment
- (ext-in) Acceptance of Notification with MA amendment
- (ext-in) Non-acceptance of Notification
- (ext-in/out) Related correspondence

Notification accepted with MA amendment

MA Amendment Preparation (180 days)

- (ext-out) Documentation necessary for MA amendment
- (ext-in) Marketing Authorization with amendment
- (ext-in/out) Related correspondence

Closed - Accepted

Closed - Not-Accepted