

EXPECTED TIMELINE* SNSA

(*max. days)



Submission of the Application to the Coordination Unit (PEI, AEMPS and FAGG-AFMPS) using the following email address:

snsa@fagg-afmps.be

PEI, AEMPS or FAGG-AFMPS will send the FINAL meeting date to the NCAs involved and confirm to the Applicant the NCAs involved, the lead NCA, their contact point and meeting date.

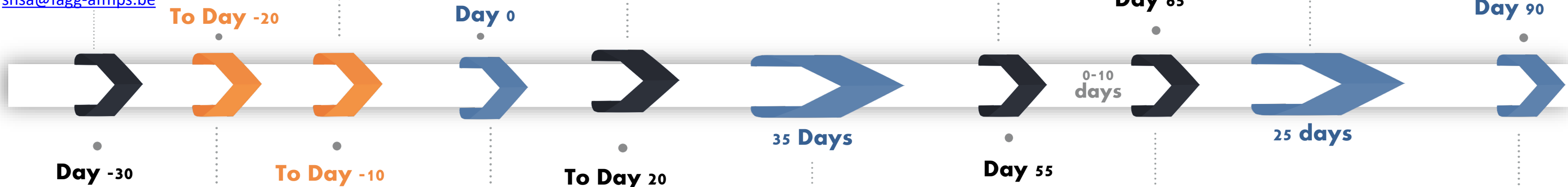
DEADLINE for the Applicant to submit any missing information in order to provide the complete application to the NCAs. The fees to the lead and participating NCA must be paid according to their national fee regulations. NCAs will check the documentation and the lead NCA will contact the Applicant asking for any missing documentation if needed.

- Role of PEI (Paul-Ehrlich-Institut), AEMPS (Spanish Agency of Medicines and Medical Devices) and FAGG-AFMPS (Belgium federal Agency for medicines and health products) as Coordination Unit
- Role of the Applicant
- Roles of the Lead National Competent Authority (NCA), the participating NCA(s) and the Observer



NCAs and Applicant SNSA MEETING

Review of the meeting minutes by Lead and participating NCAs. The Observer NCA will only check the participants list and include only information about National legal requirements if needed.



VALIDATION OF SNSA by the Coordination Unit (PEI, AEMPS or FAGG-AFMPS). One of them will contact the NCAs proposed by the Applicant and confirm with them their participation and the proposed dates for the TC (by doodle)

START OF THE PROCEDURE Submission of the complete application by the Applicant. The lead NCA will send the link for the meeting between the NCAs and the Applicant and the template for the minutes to the participating NCAs and to the Applicant.

Evaluation of the information by the lead and participating NCAs

The Applicant will send the minutes to the lead NCA using the predefined template, who will share it with the participating NCAs.

END OF THE PROCEDURE The lead NCA will send the final advice report to the Applicant together with the feedback survey for completion. The final advice report will also be sent to the involved NCAs

