

Decentralised Procedure

Improvement of Clock-off period

Meeting with interested parties June 2010

Agence française
de sécurité sanitaire
des produits de santé



Alban Dhanani

AFSSAPS - FRANCE

Objective

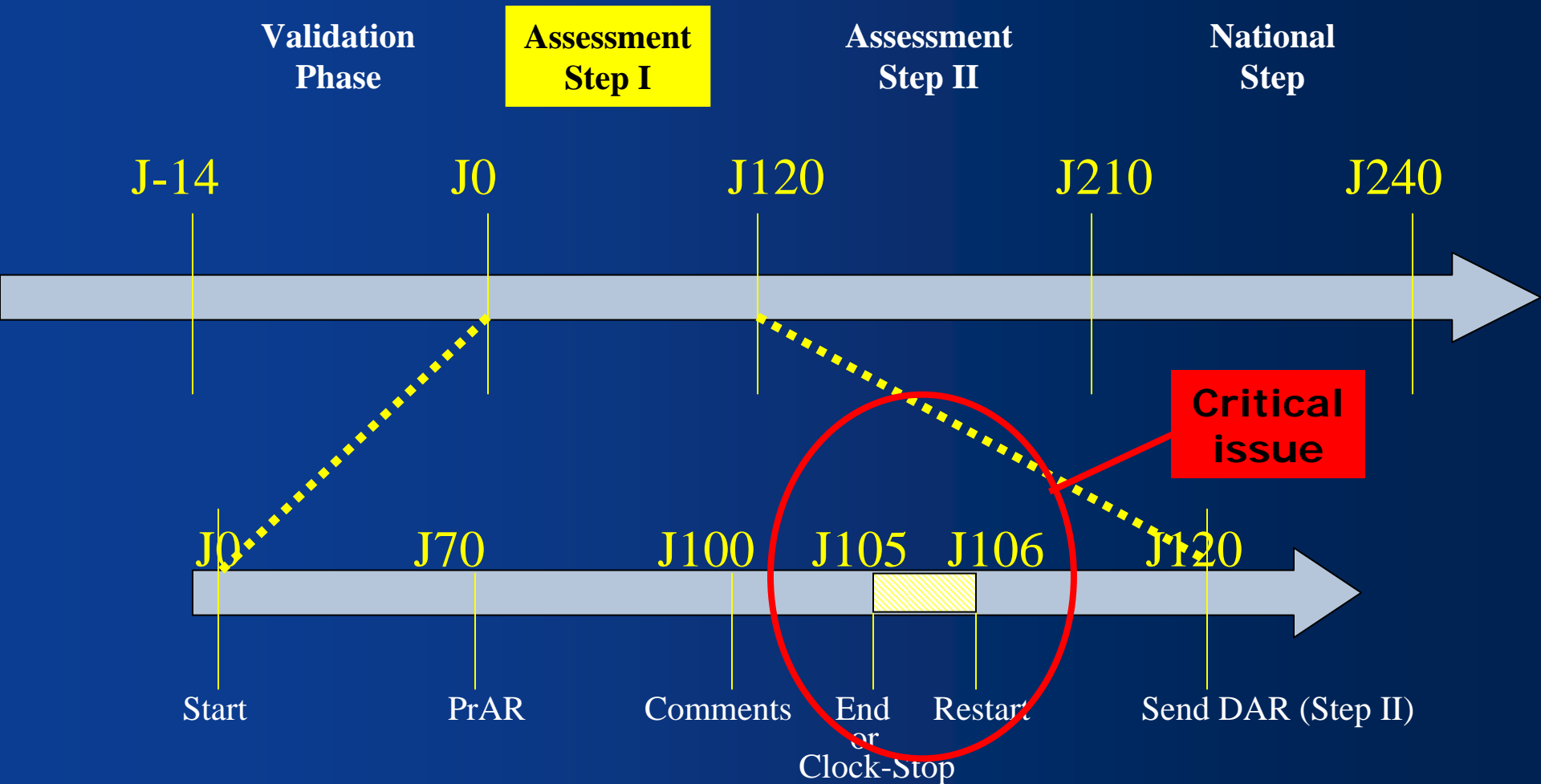
To reflect the experience gained since the creation of the procedure in 2005

To improve the functioning of the procedure
To improve the predictability of the procedure

Major improvements proposed for the management of clock-stop periods

SOP on DCP

Clock-off period



Why this step represents a critical issue ?

- There are **only 14 days for sending the DAR** after restarting the procedure at Day 106
 - Need to have sufficient time (> 14 days) to assess the applicant response document, especially when there are a lot of comments raised by the Member States
- **Important consequences** for the next step of the procedure **if the RMS maintains a negative opinion**
 - The procedure may be rejected without any CMDh referral procedure

Main reasons leading to a long delay in restarting the procedure

- Need to submit new data/to perform new studies
- Draft response document not submitted
- No final response submitted after RMS feedback
- Multiple revised versions of draft response document
- Request from applicant to validate the draft document before restarting the procedure

Main reasons leading to a long delay in restarting the procedure



- Poor quality of draft response document
- Problems about available resources in the RMS
- Need to wait for the results of inspection (GCP, GMP etc.)
- Need to wait for decision coming from other procedures which could have an important impact:
article 30 referral procedure, critical issue currently assessed by relevant WPs etc.

Need to improve this step by adopting new rules in order to avoid long delay in restarting the procedure.

2 main principles

- **For the applicant:** maximum time allowed to submit the response document.
- **For the RMS:** maximum time to provide a feedback with a proposal for the restart of the procedure.

Task of the applicant

- During the clock-off period, the applicant supplements the dossier by responding to the questions raised by Member States and may submit a draft response document to the RMS for (pre-) assessment.
 -  Draft document should be of high quality and should properly address all the questions raised by the Member States
- Possibility for the applicant, to send directly to Member States, the response document (without sending any draft).
 -  Need to inform the RMS (14 days in advance) about the proposed submission date

- **Task of the RMS**

- To provide feedback on whether there is a need to correct deficiencies in the response document or whether the document can be submitted to the CMSs without any changes.
- Feedback from RMS given once-only and normally within 4 weeks after receipt of the response document. This RMS feedback will include a proposal for the restart of the procedure, unless an inspection is necessary.

Duration of clock-off period

- Submission of the response document within 3 months, which can be extended by a further 3 months.
- In exceptional circumstances, a further extension of this period could be accepted if the applicant can provide appropriate scientific justification.
- Any request for an extension should be submitted to the RMS at the latest one month before the end of the 3 months period/earlier agreed date.

Restart of the procedure

- If no request for an extension of the clock-off period is received, the RMS will automatically restart the procedure and distribute a Draft Assessment Report (DAR).
- If it is not expected that the response will be submitted within an acceptable time (i.e. 6 months maximum), the applicant will be suggested by the RMS to withdraw the application in all involved Member States.

If the applicant has not submitted a response within 3 months/extended period, or withdrawn the application
→ the RMS will continue the procedure by restarting the clock and distributing a DAR

Other important information

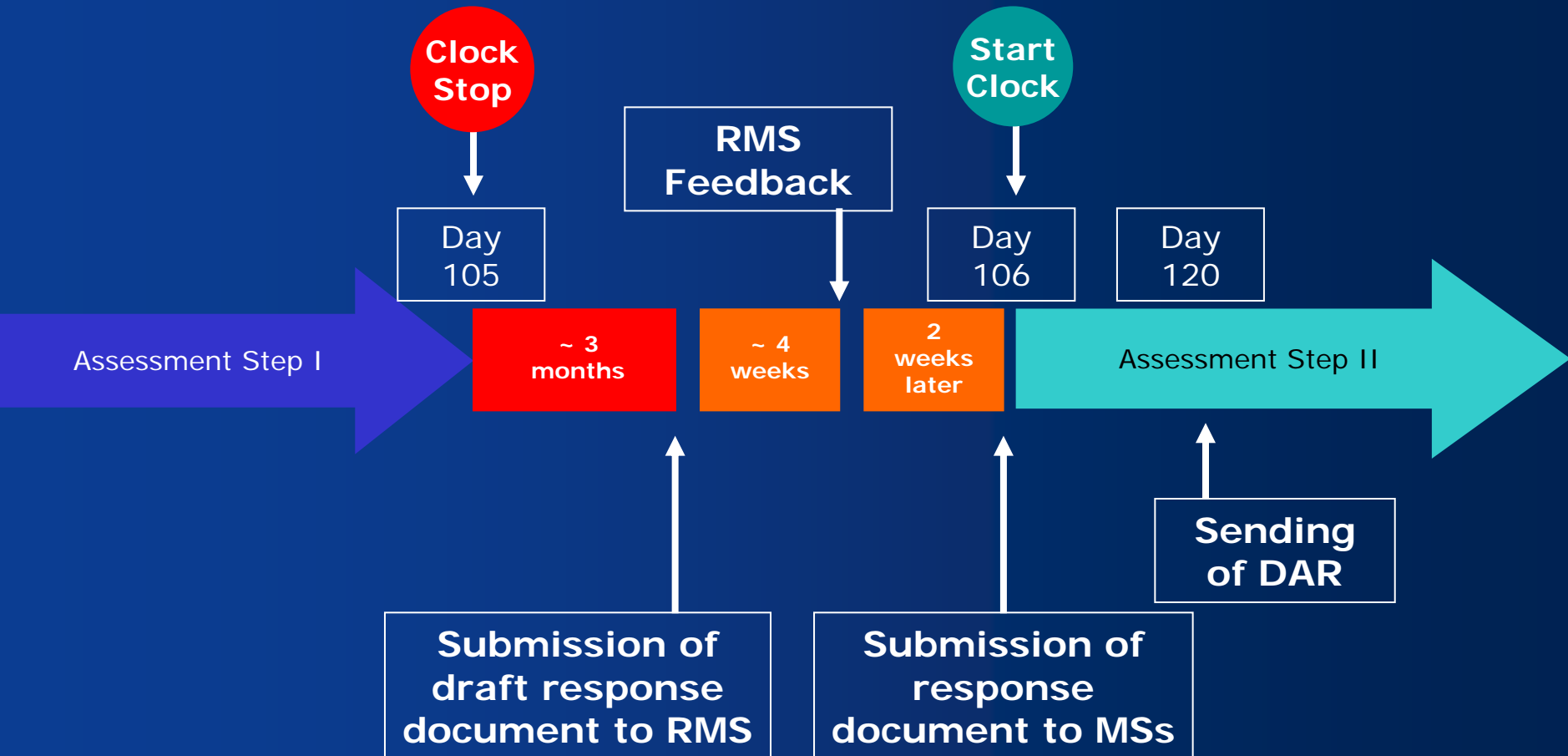
- Applicants are only allowed to submit new data during the clock-off period.
- Data derived from new studies are not accepted after Day 120 (during assessment step II), so it will not be possible to supplement a deficient dossier with new data once the clock has restarted.

Clock-off period

Example



Time period between receipt of draft response document and sending of DAR = 8 weeks



Clock-off period

New rules



- New rules adopted in January 2010
- RMS have just started the implementation of these new rules in the management of clock-off periods
 - Need to gain more experience/feedback from applicants and Member States about the effectiveness of these rules

Close monitoring (every 3 months) of procedures in clock-stop by the CMDh including feedback from RMS