

Release Notes for the eSubmission Roadmap v2.0

Main updates compared to version 1.0

eCTD v4.0

New timeline has been added for planning and preparation. The timeline for optional use was postponed and a caveat has been added explaining that the implementation timelines will be confirmed based on the outcome of the planning and preparation phase.

eCTD v.3.2 (current version)

New milestones were introduced for mandatory use in national procedures (NP);

- Q3 2018 for new MAA
- Q1 2019 for all submissions

VNeS

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- Q3 2018 for new MAA
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eSubmission Gateway, CESP, eAF and CESSP

The delivery of the mandatory, fully integrated, single submission portal has been postponed.

Timeline has been added to introduce a stepwise replacement of the eAF by CESSP.

Common Repository

A new miles stone was introduced for delivery of a Common Repository for veterinary submissions in centralised procedure.

Other updates

Other changes and updates not affecting the timelines have been added to the eSubmission Roadmap. The document has been updated to reflect already achieved milestones and number of editorial changes has been made.

A section on SPOR has been included in the Roamap.