

C B G

M E B

Common European Submission Platform

CESP

- Develop a single EU submission platform
 - **that can be used by both industry and agency**
 - **for both Human and veterinary medicinal products**
 - **using current and future standards (eCTD, NeeS, eAF) and controlled terms.**
- This platform will provide:
 - **a mechanism to submit /create and validate eCTD compliant dossiers for MRP, DCP and National procedures;**
 - **structured information for incorporation into national and European databases**
 - **a tracking system for submissions and product status in each agency**
 - **a solution that builds-on EU telematics initiatives in respect of CTS , EUTCT, EudraCT, EudraPharm, EudraGMP etc.**
 - **agencies with the functionality to download submissions to national repositories and upload approved product information**
- Converging with EMA portal in the long term
- Commitment of all NCA to use CESP

Activity or result	By
Feasibility Study Common European Submission Platform (CESP)	March 2009
TSG mandated by the HMA to perform the Feasibility Study	April 2009
Project plan agreed in TSG and drafting group ¹ defined	November 2009
Execution Feasibility Study	Jan-May 2010
Adoption of FS Report by TSG	June 2010
Consultation of First draft FS Report with MS, EMA and industry	Aug-Sept 2010
Update to HMA and proposal for progress	October 2010

1. Drafting Group: DE, FR, UK, ESP, AT, PO, IE, NL, FI and HU

Activity or result	By
Meeting with industry and EMA on next steps	March 2011
Endorsement from HMA to start a <u>POC</u> , including agreement EMA role	April 2011
Preparing, running and evaluating the POC system	May-Oct 2011
Update to HMA and proposal for progress	Nov 2011

Member States	Present: DE, FR, UK, ESP, AT, PO, IE, NL and HU (original group), plus new members BE, MT, PT, DK, HR and SI (NL-UK: Chair/Co-Chair) + EMA
Industry	Present: AESGP, EFPIA, EGA, IFAH-Europe and EGGVP

- The EMA confirmed that:
 - the initiative on CESP was welcomed,
 - that the Proof of Concept as a next step is logical and can be supported
 - that at this time developments of EMA gateway and CESP can run in parallel.
- Arguments for the last point are:
 - EMA initiative is a *gateway* targeted for multiple submission types, however, the concept of a gateway differs from a portal
 - At this stage CESP will deal with MRP/DCP not the centralized procedure
 - CESP PoC can deliver important information relevant for further development within EMA
- There is general agreement that activities around CESP and EMA gateway should be aligned as much as possible for the moment, longer term converging of the gateway and portal is foreseen.

Difference between PoC and Pilot?

- **The timing of the technical decision**
- **Speed to get a test system in place**
- **Implication that this is not immediately scalable to a final solution (“throw away”)**

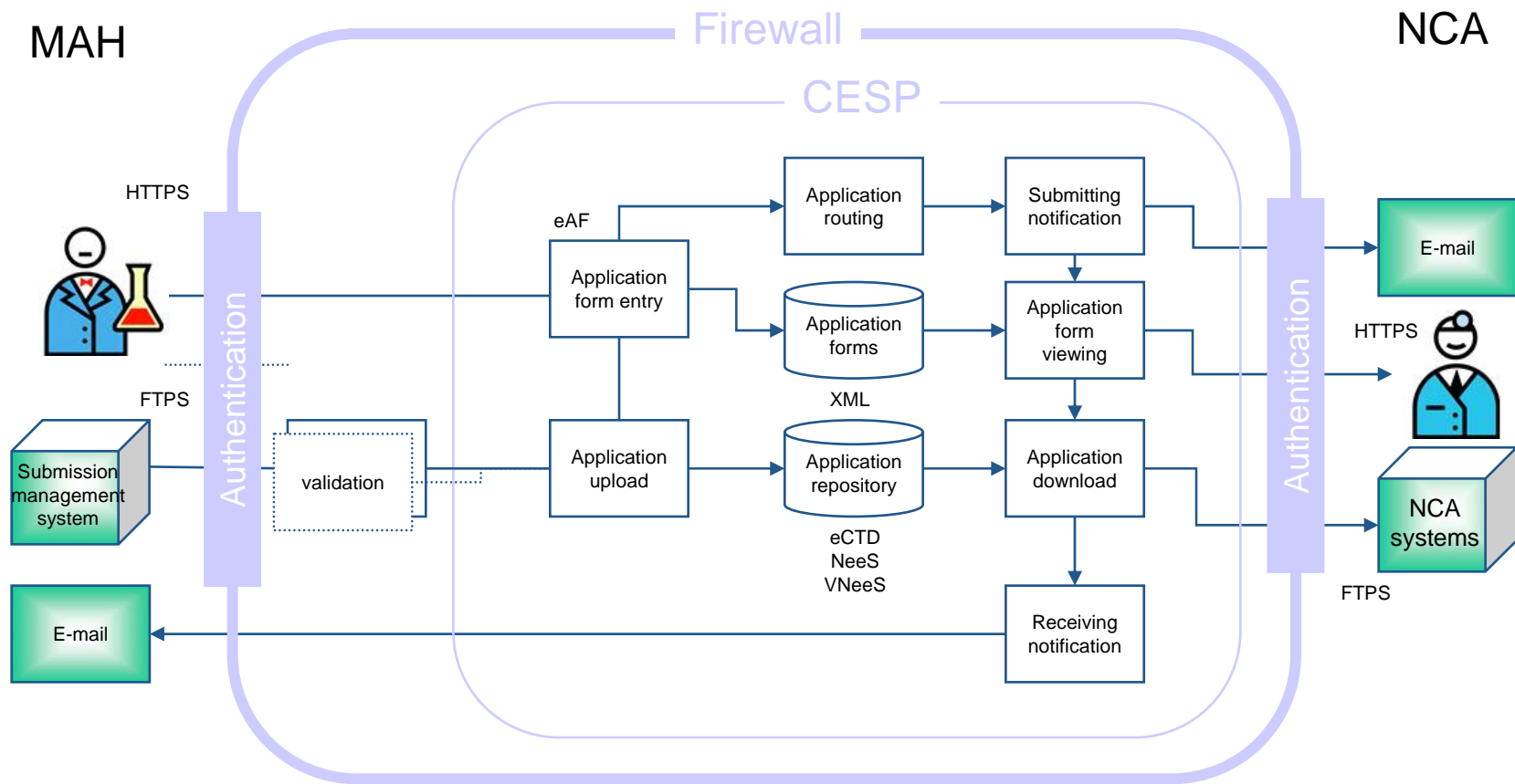
General agreement regulators and industry: Proof of Concept

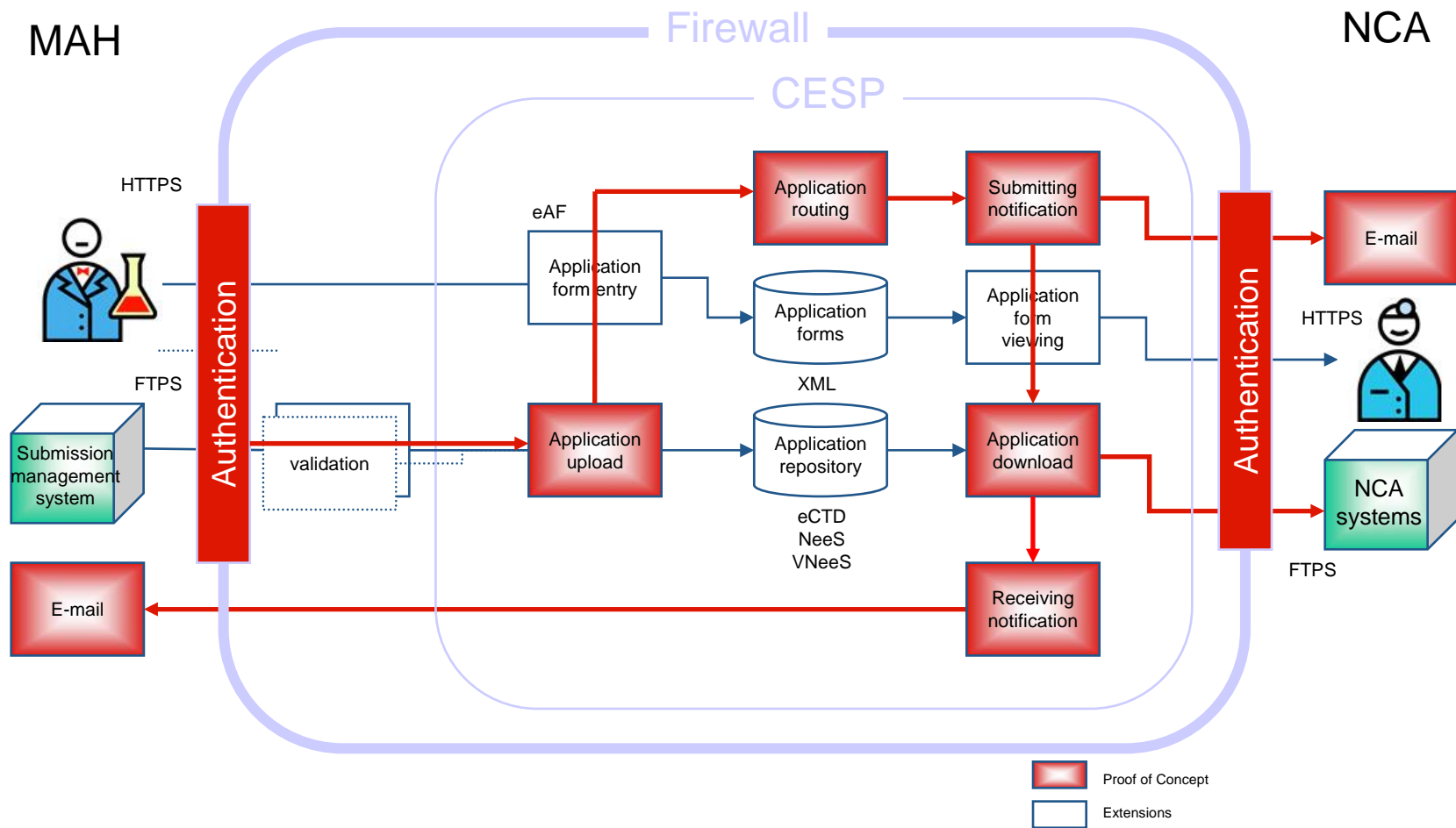
Establish that the concept of CESP can:

- **deliver a system capable of handling submissions of varying sizes**
- **manage one submission being received by various Agencies (human or vet)**
- **minimize the effort for handling CD/DVD applications**

- A simple and secure mechanism for exchange of submission information, covering the following:
 - **Both human and veterinary products**
 - **MRP and DCP application types**
 - **Both initial and variation submissions**
 - **all aspects of the submission including a mechanism for resubmitting updated information**
- One-way, from Industry to Regulator, with simple notification systems
- Is not dependent on submission standards, i.e. will accept eAF, eCTD etc but is not built around these
- Excludes dictionaries or validation
- Will use copies of live cases establishing the potential for a working system, while continuing with 'business as usual'
- Must be seen as a 'throw-away' solution

- Technical implementation: IE
- Technical assistance: AT
- Project oversight: NL and UK
- High level planning:
 - **April: tender for FTP software & decision**
 - **May: configuration**
 - **May: workshop drafting Group and industry**
 - **June-August: final set-up and identity management**
 - **September: Proof of Concept**
- **Costs: 100k€ (equal share Drafting Group members confirmed, no fee for industry)**





Number of participating companies	22
Number of participating regulators	14
Number of packages submitted in two testing weeks	500+
Packages sizes	50, 100 and 500MB
Performance	50MB 2.5 mins 100MB, 7 mins 500MB, 11 mins
Average size of a submission (new applications)	ca 650MB
Average size of a submission (variation)	ca 100MB

- Feedback on the PoC was positive
 - Industry liked its simplicity
 - Generally found the speed good
 - Was a good replacement to submitting CDs/DVDs
- Feedback from Agencies
 - PoC worked effectively
 - Early problems were rectified
 - Broadly achieved aims
- Everyone keen to move forward

- The results of the PoC confirm that the primary goals are achieved
- All stakeholders involved are unanimously positive and want to continue developing the CESP solution
- Next Steps:
 - Continue with an extended PoC using real life submissions
 - Prepare for a pilot through creating two project teams:
 - for the governance and financing of full solution
 - focusing on the full solution
- EMA will continue to be involved with the group

- Request approval to proceed with the next steps
 - Continue with an extended PoC using real life submissions – starting Jan/Feb 2012 until a full solution is available
 - Prepare for a pilot through creating two project teams:
 - for the governance and financing of full solution
 - focusing on the full solution
 - Target for completion of activities June 2012

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