



The Common European Single Submission Portal (CESSP)

Essentials

Background

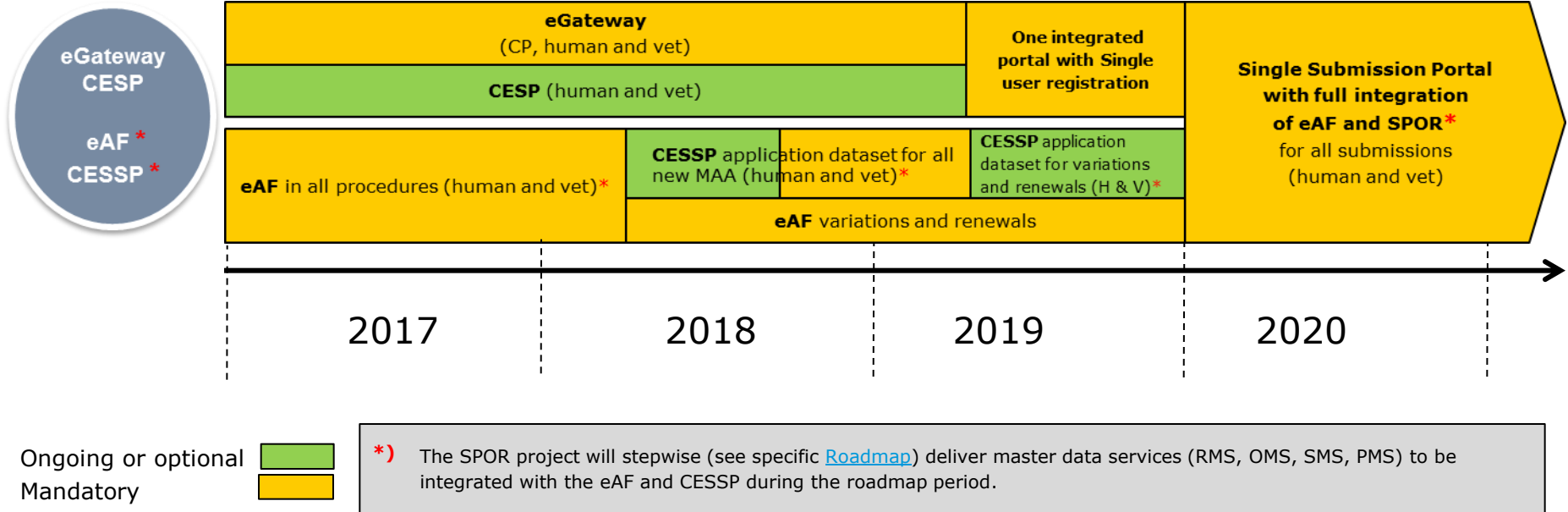
CESSP is a programme to implement an online authoring tool for application forms and to enhance the current PDF based electronic application forms. The first phase of this programme called “CESSP Phase 1” will deliver a new format for creation of Marketing Authorisation Applications with the goal to replace the relevant PDF forms with a web based interface. This will cover both, human and veterinary application forms for new marketing authorisations and extension applications.

The programme is part of the eSubmission Roadmap which also describes the concept of a Single Submission Portal which will provide online service for stakeholders and will integrate the current [Common European Submission Platform \(CESP\)](#) and the [EMA eSubmission Gateway](#). The EU Telematics Management Board has agreed that this single portal shall be built using the current CESP portal. During the development project this system has been referred to as the **CESSP** but will be implemented within the current CESP as a new module called “CESP Application Dataset Management Module (CESP Dataset Module).

As detailed in the eSubmission Roadmap but independent of the integration of EMA Gateway and CESP, the CESP Dataset Module integrates the current content of the eAFs. The application form content will be integrated into this new web based solution with a stepwise approach.

CESSP Phase 1 - implementation

- The first implementation project step, CESSP Phase 1, will deliver a user interface to make use of integrated human and veterinary Marketing Authorisation Application datasets for new marketing authorisation and extension applications. It is expected that the first version of the system will be available for use by end of 2018. This will be followed by the integration of the Variation and Renewal form into the CESP Dataset Module. The current eAFs will be withdrawn after a transitional period and the use of the new CESP Dataset Module will become mandatory at a future date which will be communicated right in advance but at a later stage.
- The CESP Dataset Module will make it possible to reuse the application form content. Applicants will also be able to use pre-registered organisation data and controlled vocabulary terms provided by EMA SPOR (Substances, Products, Organisations, Referentials) data services.



Source: <http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html>

- Marketing Authorisation Application form (human)
- Marketing Authorisation Application form (veterinary)
- Renewal form (human and veterinary)
- Variation form (human and veterinary)

for decentralised, mutual recognition, national and centralised procedures

Word form

- Free text only
- Copy/paste only (error prone)
- No validation rules
- No data export / import

eAF - PDF

- Higher data quality
 - Free text reduced to minimum
 - Controlled terms are mandatory
 - Context-dependent structured layout with built-in business rules
 - Built-in form validation
- Data export / import

CESP Dataset Module – web based application

- Improved usability and performance
- Fundamental change of data collection concept
- Use of SPOR master data



replaced
2012-2016



stepwise
replacement
planned for 2018-2020



Overview of the CESSP Programme and ongoing Phase 1

Project CESSP Phase 1.0 is ongoing for replacement of the eAF MAA Human and Vet

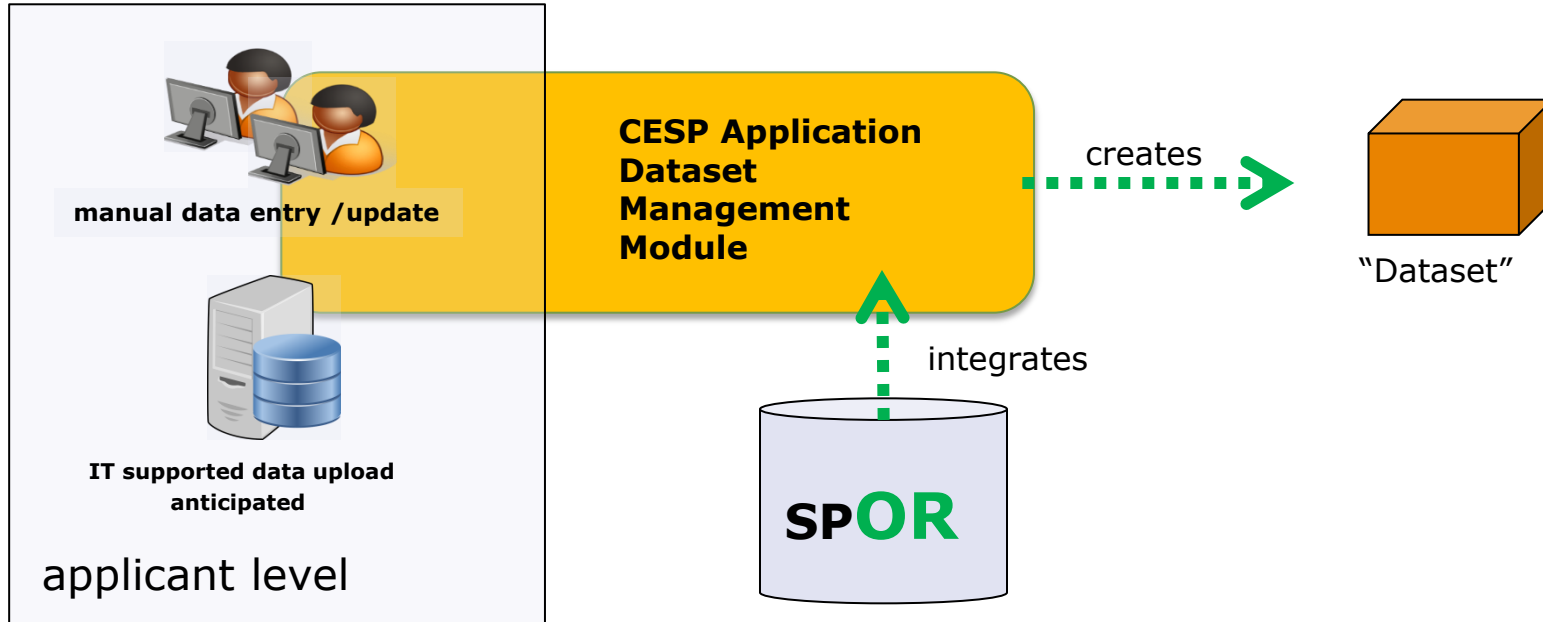
Online application dataset module available by end of 2018

Project CESSP Phase 2 – not yet started

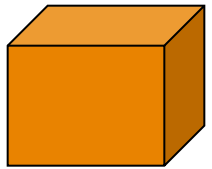
Replacement of the eAF for Variation and Renewal

Further implementation phases – not yet started

CESSP programme also monitors other initiatives (including Vet-Regulation, SPOR) to ensure compatibility and future improvements

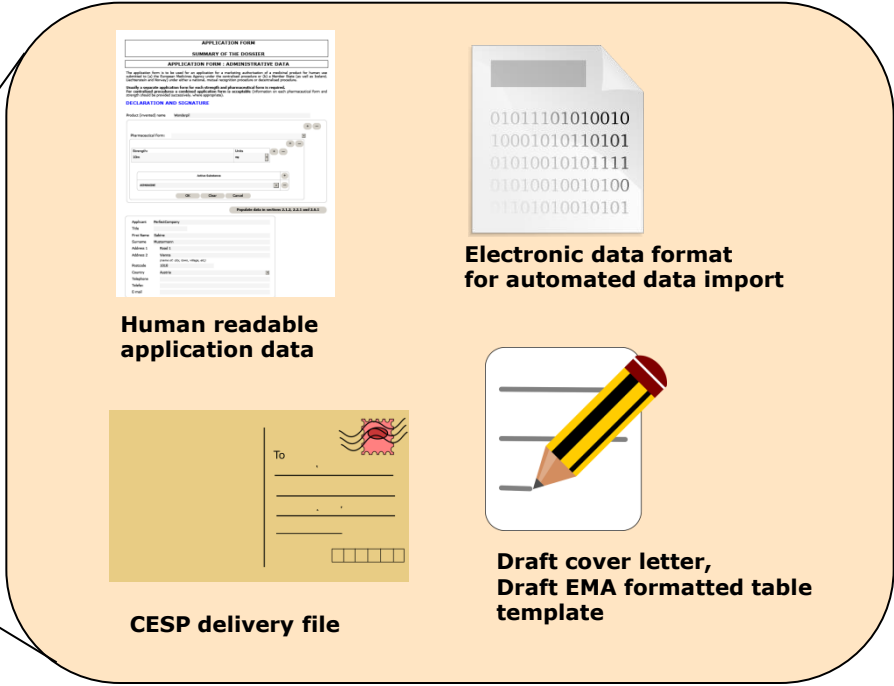


CESSP phase 1 will use data from OMS and RMS (O and R in SPOR) in a way that organisations and referentials can be selected during the authoring process.



“Dataset”

The dataset contains information to be used in the application form and can also be reused for other purposes



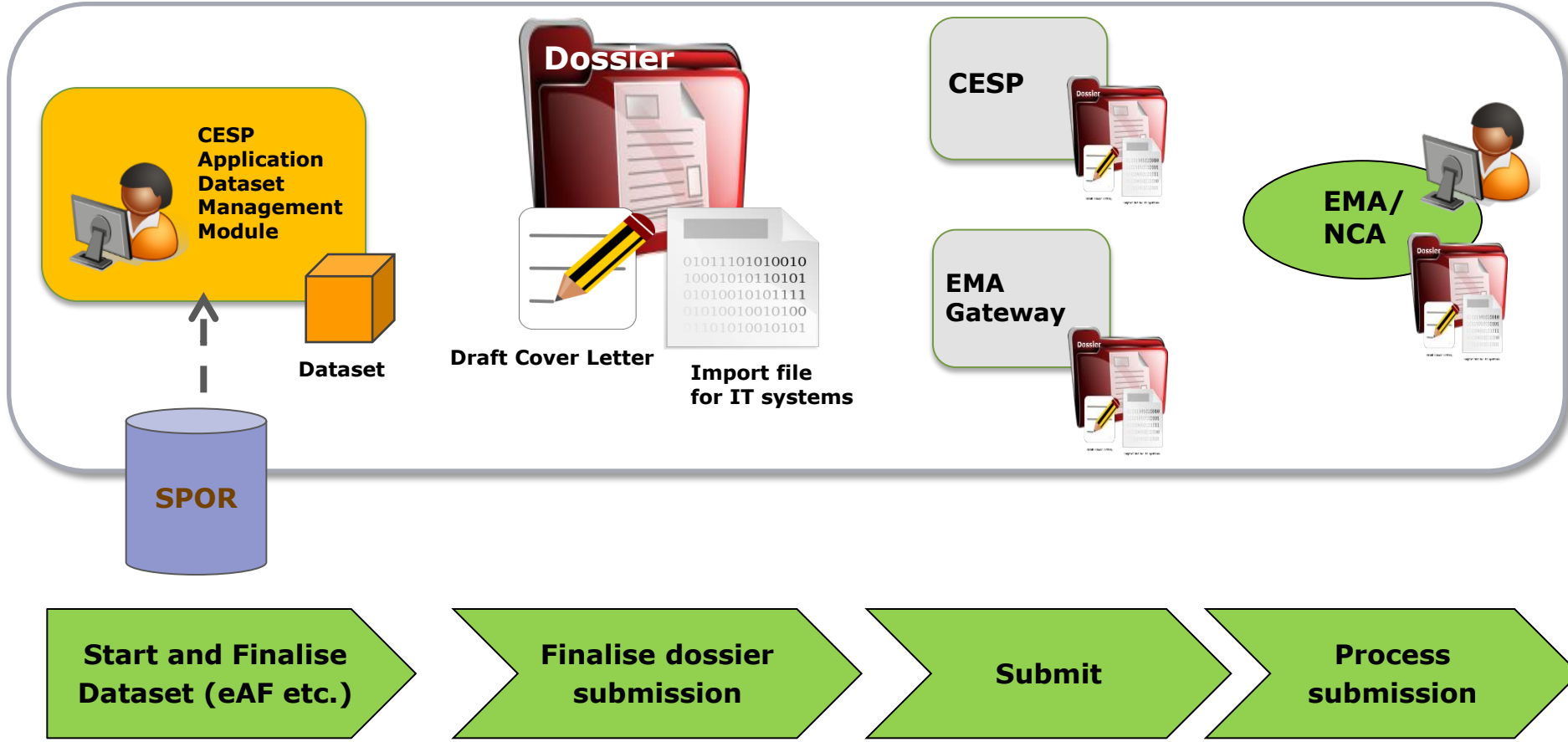
Human readable application data

Electronic data format for automated data import

CESP delivery file

Draft cover letter, Draft EMA formatted table template

Future process after implementation of CESSP Phase 1



at applicant level

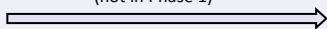


manual data input

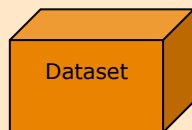


XML-upload

(not in Phase 1)

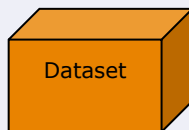


CESSP Dataset Module



- Create/clone/save/modify/export/import datasets
- Retrieve OMS and RMS (SPOR data)
- Validate data completion and business rules
- View dataset in human readable layout
- Export the eAF for use in submissions
- Reuse dataset for CESP delivery file, draft cover letter / EMA 'formatted table template' for usage in submissions

at NCA/EMA level



- View the eAF via PDF and stylesheets
- Import dataset into NCA databases

readable
representation



Data import

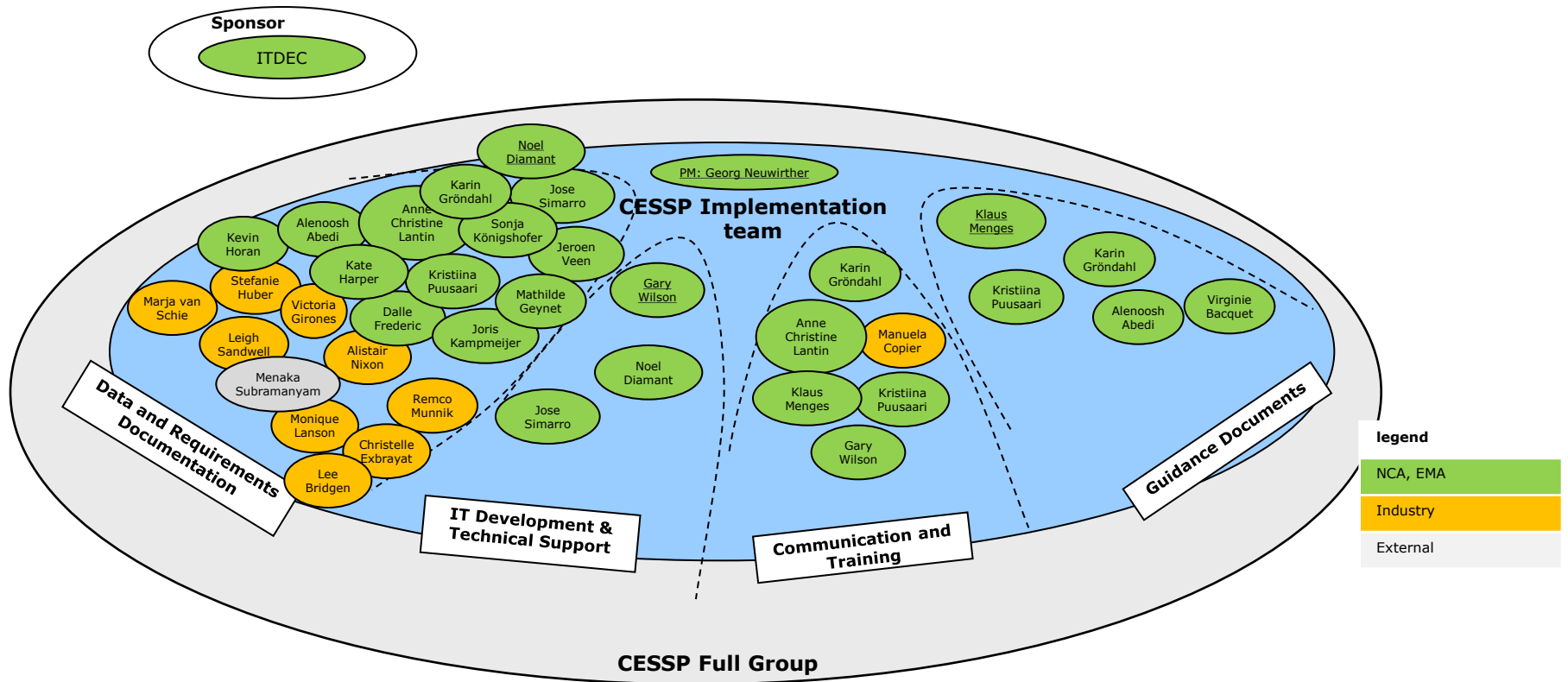




- “CESSP Phase 1” is not a long term repository for datasets
- “CESSP Phase 1” doesn’t replace variation and renewal forms
- Datasets created by “CESSP Phase 1” will not be completely compatible with IDMP-standards



CESSP Phase 1 - Project Organisation & Milestones



Planned release dates:

- UAT 1 - 05/2017
- UAT 2 - 12/2017 to be confirmed
- Final UAT - 06/2018
- Go live - by end of 2018
- Mandatory use - 6 months after go-live



Contact



For any question about the project please contact:

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