The Common European Single Submission Portal (CESSP)

Essentials

Statement of Intent

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Background

As outlined in the eSubmission Roadmap, the current Common European Submission Platform (CESP) and the EMA eSubmission Gateway will eventually be integrated into a Single Submission Portal. The EU Telematics Management Board have agreed that this single portal shall be built on the current CESP. This future system is meanwhile referred to as the Common European Single Submission Portal (CESSP).

As detailed in the eSubmission Roadmap but independent of the integration of EMA Gateway and CESP, CESSP is also envisaged to integrate the current content of the eAFs. The application content (further on referred to as the application datasets) 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 Q1 2018. This will be followed by the delivery of the Variation and Renewal form datasets into the CESSP. The current eAFs will be withdrawn after a transitional period and the use of the new, integrated application dataset within the portal will become mandatory at a future date which will be communicated right in advance but at a later stage.

The CESSP will make it possible to reuse the application datasets. Applicants will also be able to use preregistered organisation data and controlled vocabulary terms provided by EMA SPOR (Substances, Products, Organisations, Referentials) data services.

eSubmission Roadmap - Version 2.0 (24.02.2017)

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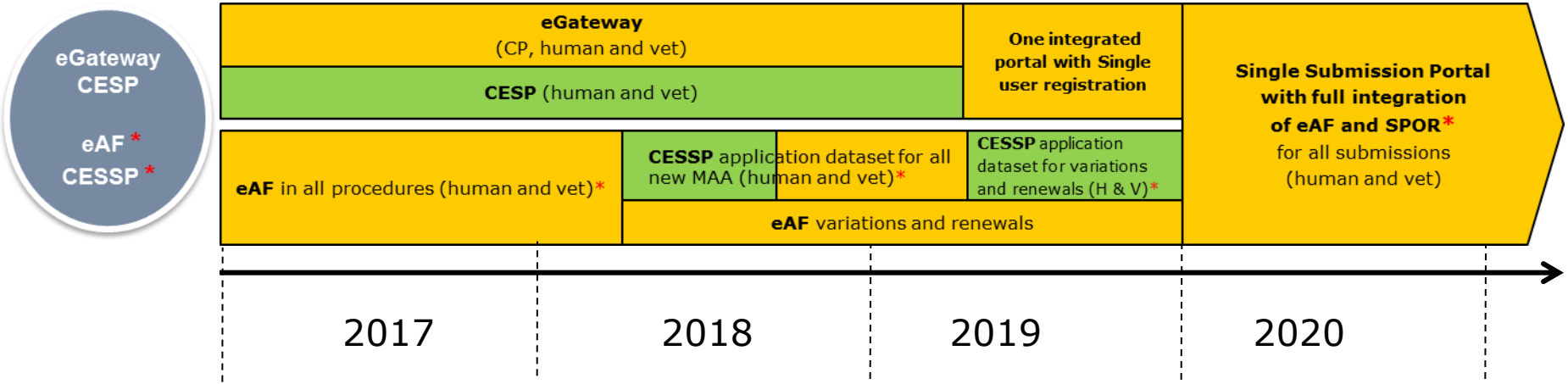

Ongoing or optional

Mandatory

*) The SPOR project will stepwise (see specific Roadmap) deliver master data services (RMS, OMS, SMS, PMS) to be integrated with the eAF and CESSP during the roadmap period.

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

Application Form – Past and Future

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- 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**

CESSP – 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

CESSP programme

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

Online application dataset available by Q1/2018

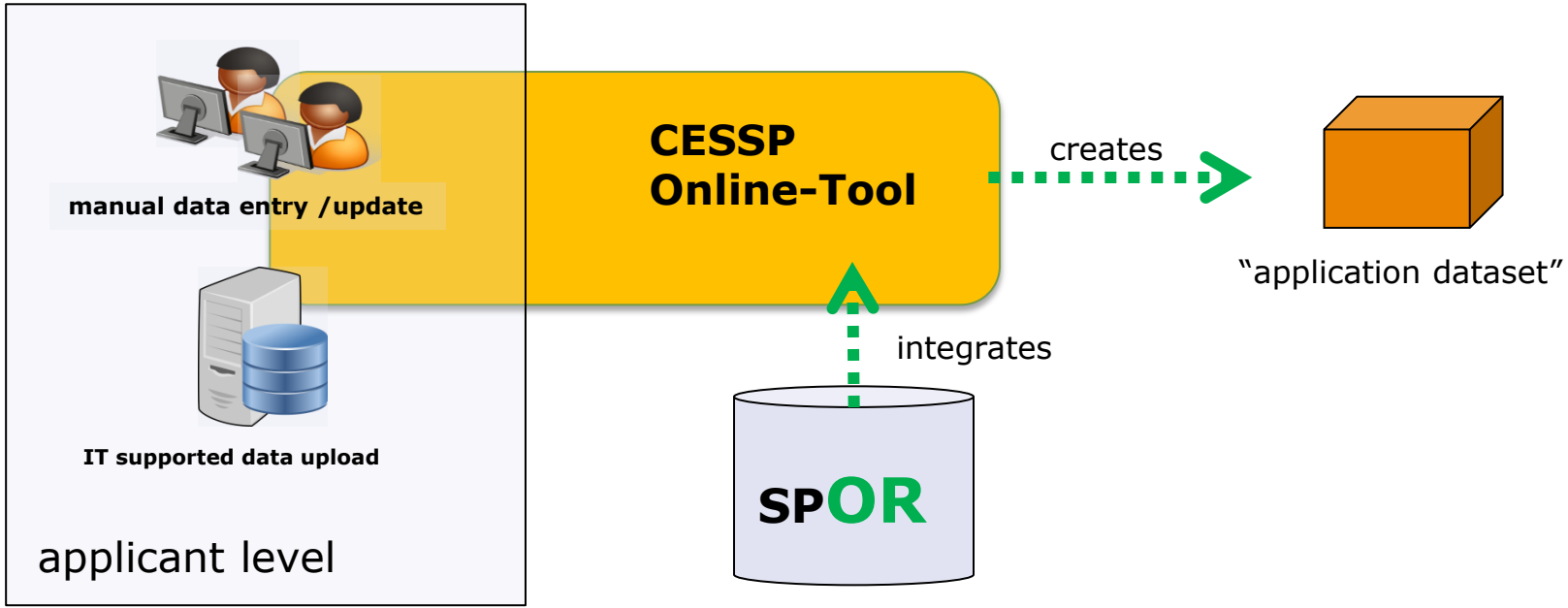
Project CESSP Phase 2 – not yet started

Replacement of the eAF for Variation and Renewal

Further implementation phases – not yet started

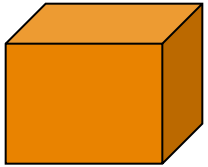
CESSP programme also monitors other initiatives (including Vet-Regulation, SPOR) to ensure compatibility and future improvements

CESSP - Process flow



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.

CESSP – Concept of the application dataset



"application dataset"
(= eAF and even MORE)

contains information 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

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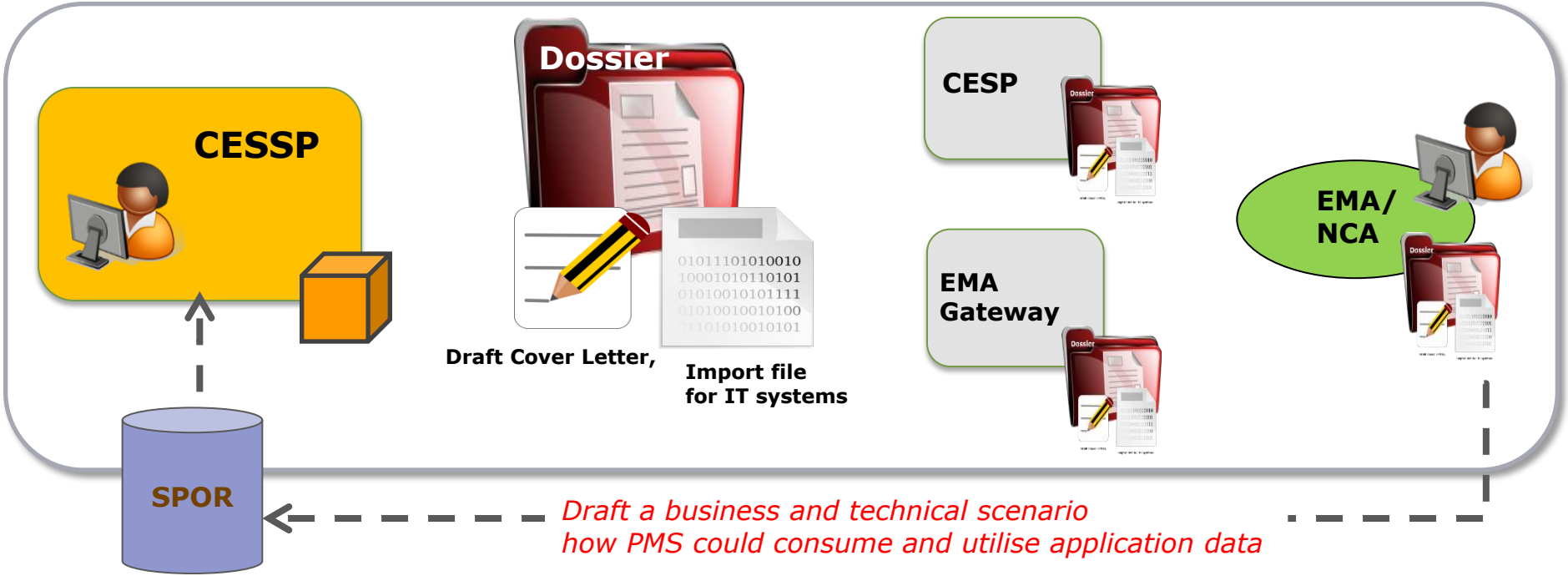

Start and Finalise Application Dataset → **Finalise dossier submission** → **Submit** → **Process submission**

Essential functions implemented by CESSP Phase 1

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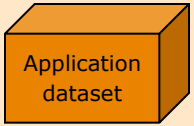
at applicant level

manual data input

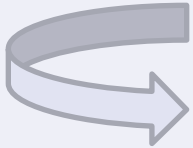
XML-upload
(not in Phase 1)

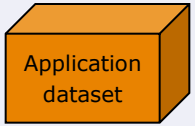
CESSP



- Create/clone/save/open datasets
- Grant access to application datasets
- Retrieve SPOR data
- Validate data completion and business rules
- View dataset in human readable layout
- Export dataset (application data) for use in submissions
- Reuse dataset for draft cover letter / EMA 'formatted table template' for usage in submissions

at NCA/EMA level





- View application dataset via stylesheets
- Import dataset into NCA databases

readable representation

Data import

CESSP Phase 1 - Out of scope

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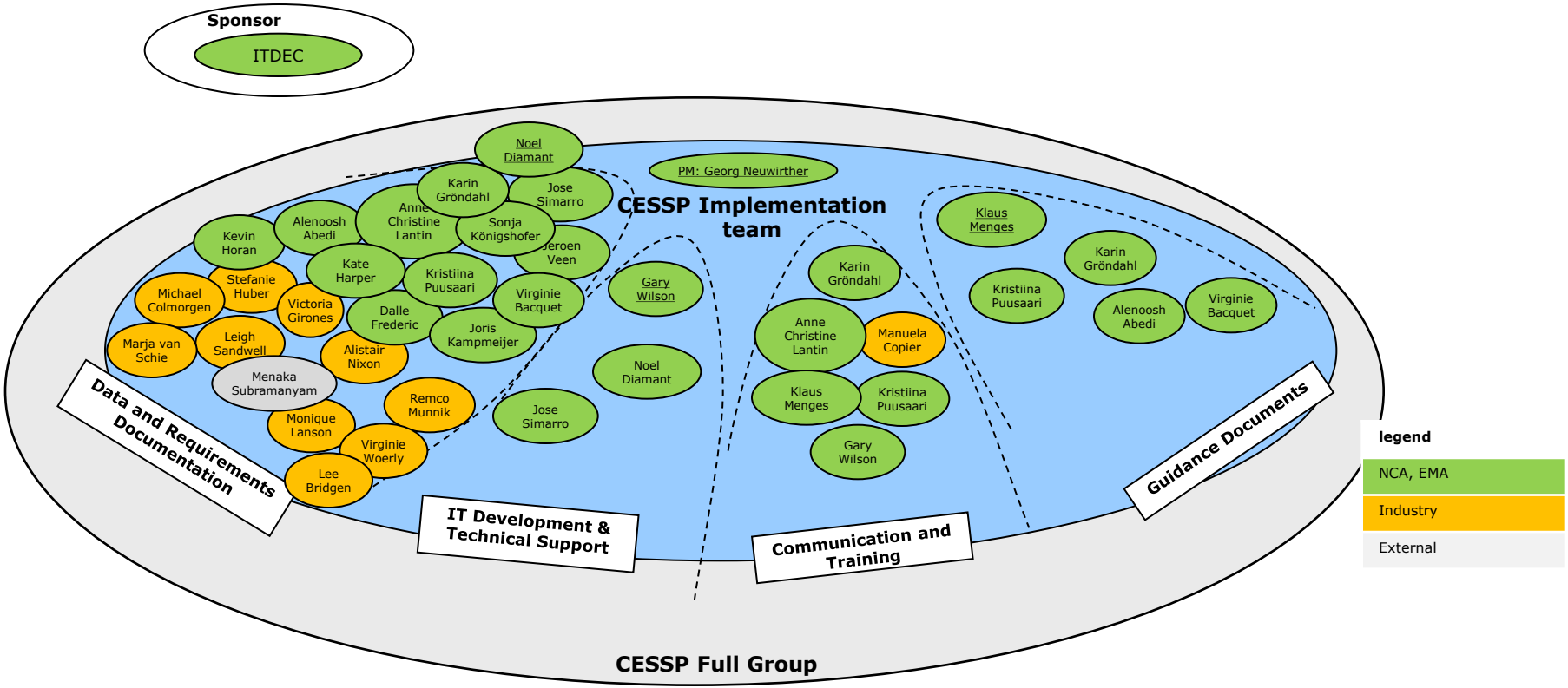
- “CESSP Phase 1” is not a long term repository for application datasets
- “CESSP Phase 1” doesn‘t replace variation and renewal forms
- Datasets created by “CESSP Phase 1” will not be completely compatible with IDMP-standards

CESSP Phase 1 - Project Organisation & Milestones

Project Organisation



Milestones

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Planned release dates:

- UAT 1 - 05/2017
- UAT 2 - 09/2017
- Final UAT - 12/2017
- Go live – 03/2018
- Mandatory use – 09/2018 (6 months after go-live)

Contact

For any question about the project please contact:

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