CESSP Phase 1

Essential project information

EUROPEAN MEDICINES AGENCY

Background

CESSP Phase 1 is the first project towards the implementation of the Common European Single Submission Portal (CESSP).

This project will deliver a new implementation for creation of Marketing Authorisation Application forms with the goal to replace the relevant PDF forms with a web based interface. This will cover human and veterinary application forms for new marketing authorisations and extension applications. The system was earlier 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). However, the project is referred to as CESSP Phase 1.

The main objective of CESSP Phase 1 is to provide a modern user interface with a flexible technical platform for the future. This step will enable future enhancements which would not be possible using the current PDF technology.

CESSP Phase 1 is planned to be followed by the addition of the Variation and Renewal forms to the CESP Dataset Module.

EUROPEAN MEDICINES AGENCY

CESSP Phase 1 - implementation

The first implementation project step, CESSP Phase 1, will deliver an online web-user interface to make use of integrated human and veterinary Marketing Authorisation Application datasets for new marketing authorisation and extension applications.

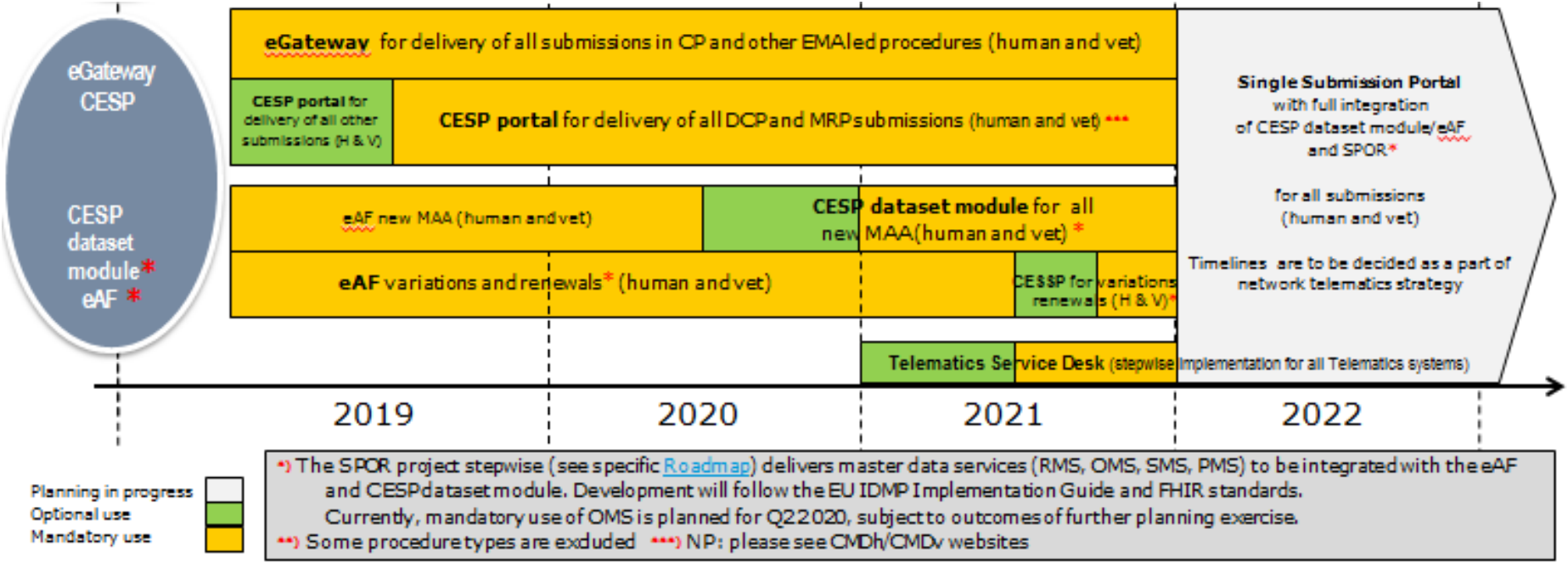
The system will provide data from SPOR (OMS, RMS and Substances). The CESP Dataset Module will make it possible to re-use the application form content.

CESSP Phase 1 is planned to be followed by the addition of the Variation and Renewal forms to the CESP Dataset Module.

The current eAFs will be withdrawn after transitional periods and the use of the new CESP Dataset Module will become mandatory at a future date which will be communicated in advance.

eSubmission Roadmap - Version 2.2 (21.06.2019)

EUROPEAN MEDICINES AGENCY



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

Application Form – Past and Future

EUROPEAN MEDICINES AGENCY

- 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**

→ **replaced 2012-2016**

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**

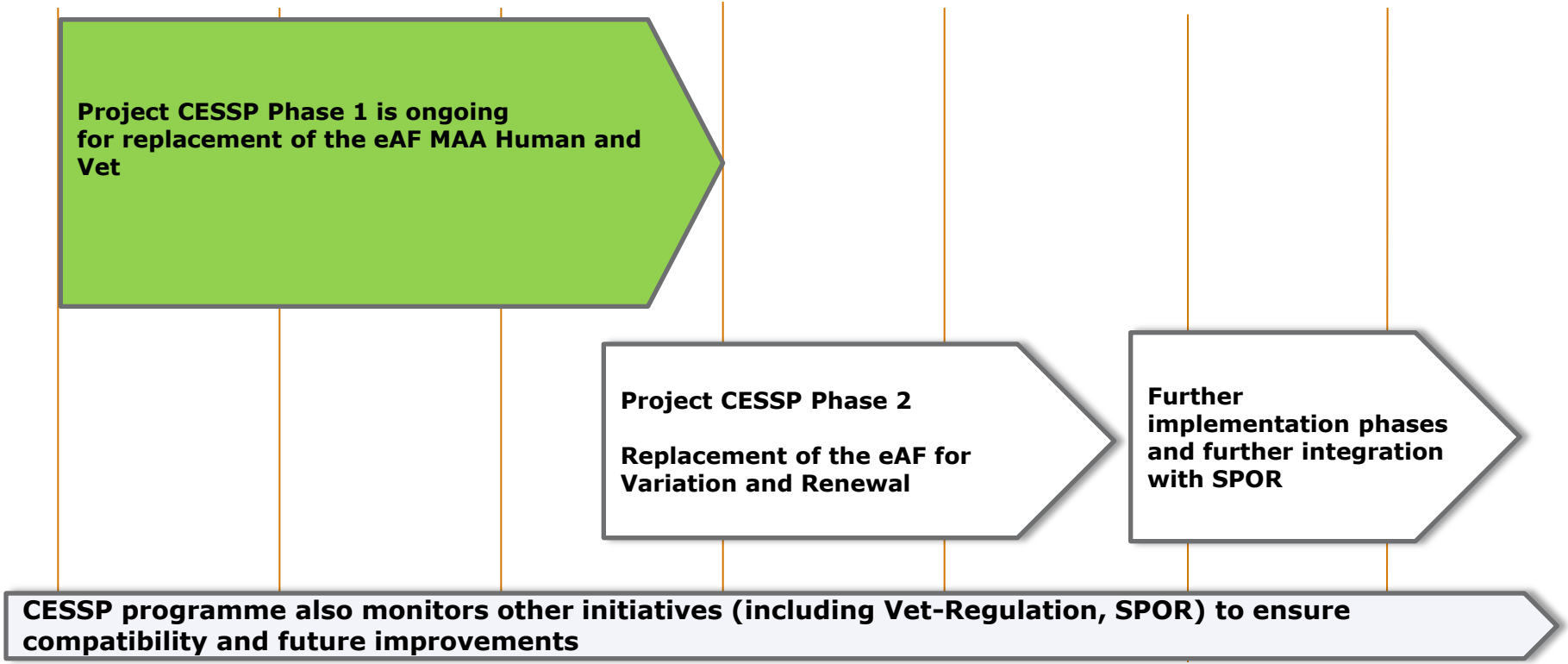
→ **stepwise replacement planned from 2020**

CESP Dataset Module – web based application

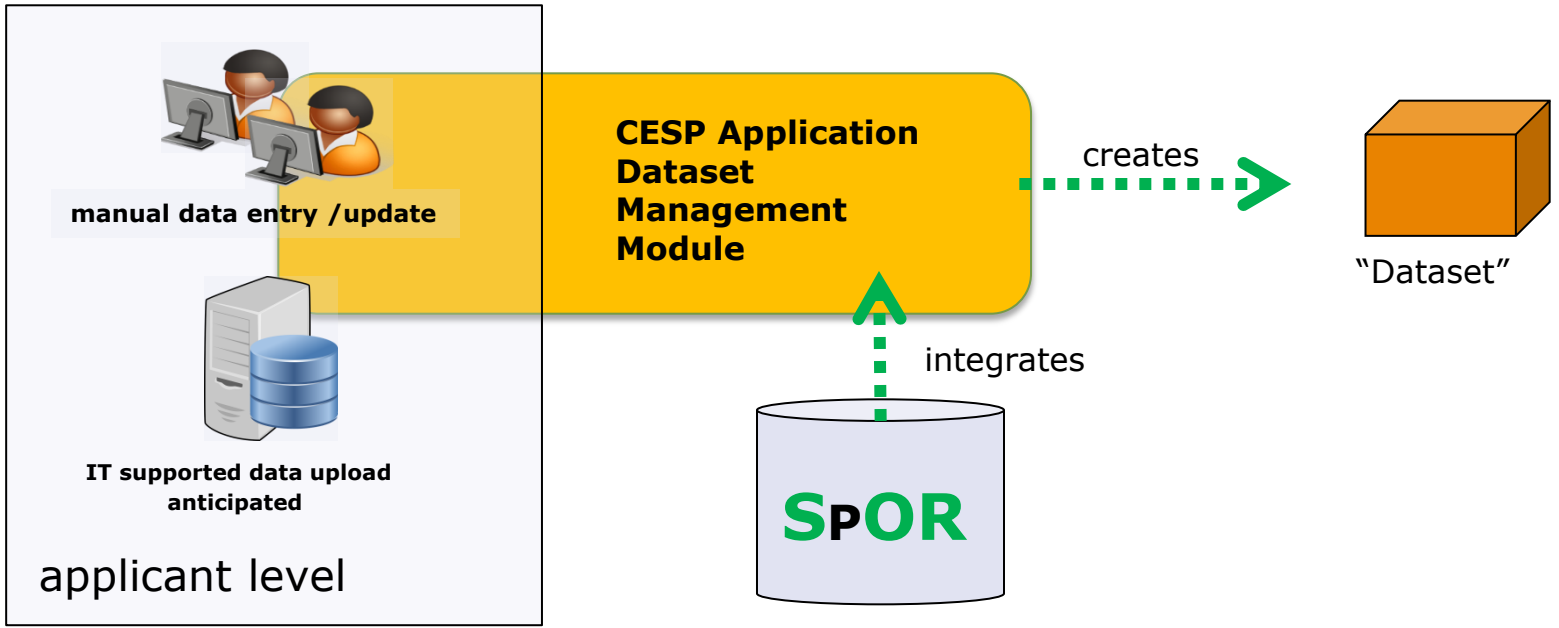
- **Improved usability and performance**
- **Fundamental change of data collection concept**
- **Use of SPOR master data**

Overview of the CESSP Programme and ongoing Phase 1

CESSP programme

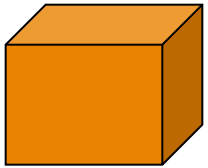


CESSP - Process flow



CESSP phase 1 will use data from O, R and S in SPOR.

Concept of data use

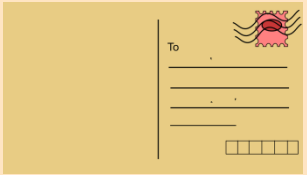


"Dataset"

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

Human readable application data

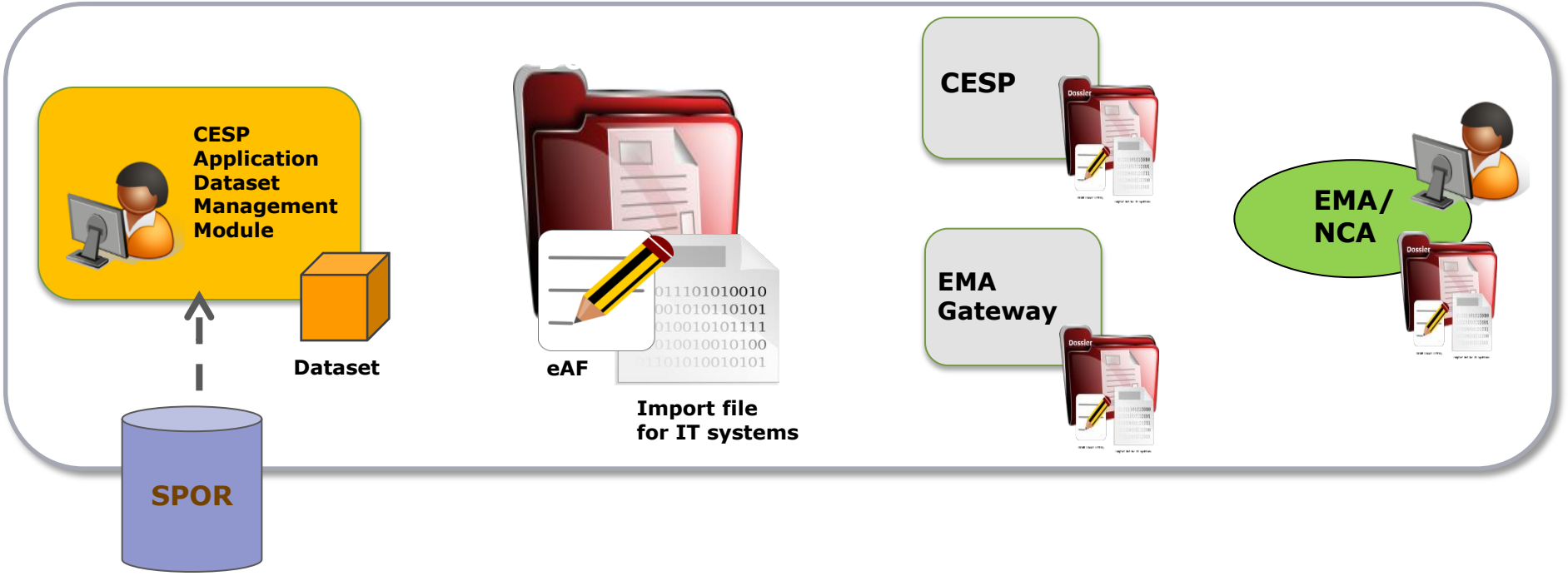
Electronic data format for automated data import



CESP delivery file

Draft cover letter

Future process after implementation of CESSP Phase 1



Start and Finalise Dataset (eAF etc.) → **Finalise dossier submission** → **Submit** → **Process submission**

Essential functions implemented by CESSP Phase 1

EUROPEAN MEDICINES AGENCY

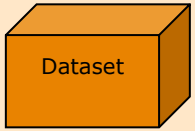
at applicant level

manual data input

or

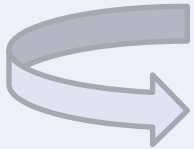
XML-upload

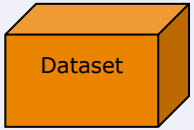
CESP Dataset Module



- Create/re-use/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

at NCA/EMA level





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

Readable representation

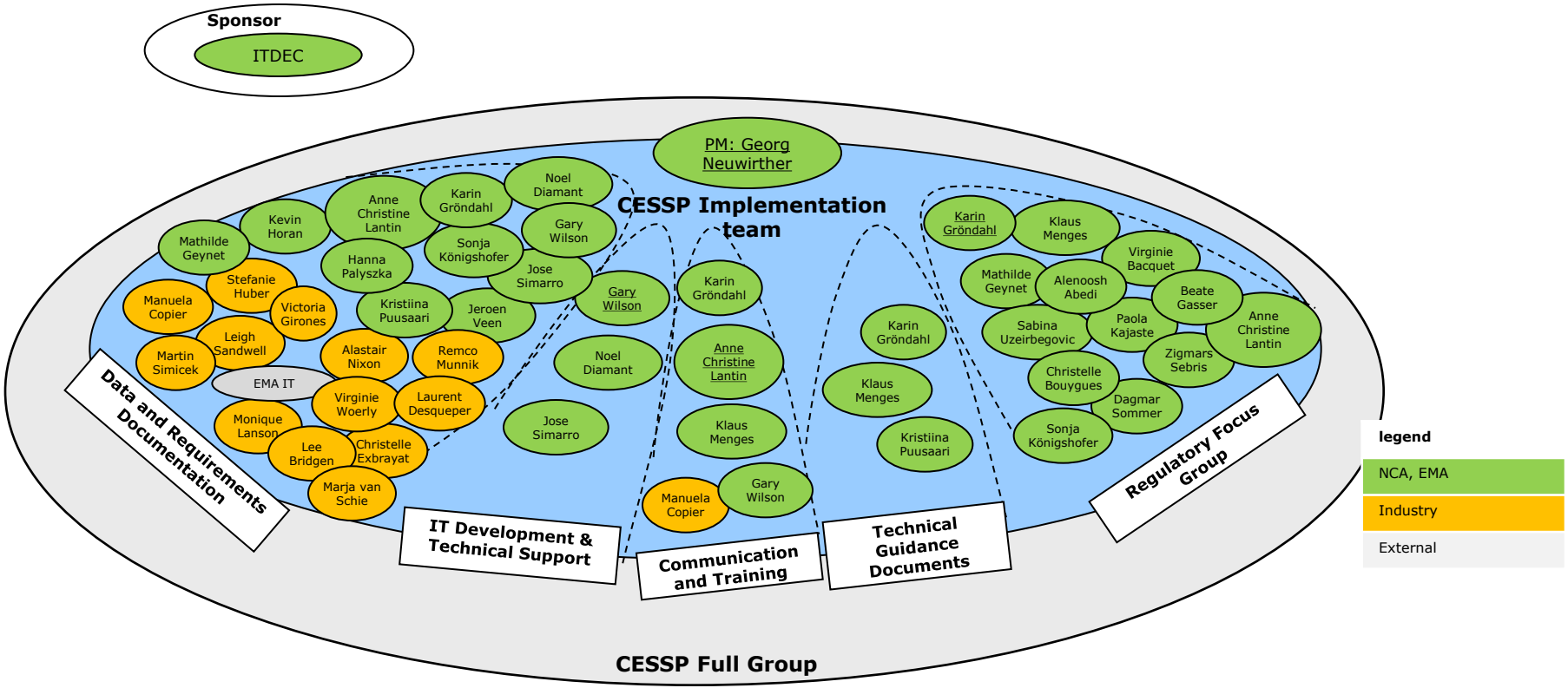
Data import

CESSP Phase 1 - Out of scope

- The CESP Dataset Module is not a long term repository for datasets
- CESSP Phase 1 does not replace variation and renewal forms
- Datasets created in the CESP Dataset Module will not be completely compatible with IDMP-standards

CESSP Phase 1 - Project Organisation & Milestones

Project Organisation



Milestones

- UAT 1 - completed 05/2017
- UAT 2 - completed 03/2018
- Draft upgraded XML DES - Done
- Publication of upgraded XML DES - Q4 2019
- UAT 3 - Q1 2020
- Go live - Q2 2020
- Mandatory use of CESP Dataset Module and terminating use of current eAF for new application - 6 months after go-live

The project has been experiencing some delays related to additional requirements to be implemented, resources having been diverted to other projects and limitations within the project budget.

Contact

For any question about the project please contact:

cesspproject@hma.eu