EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific and Regulatory Evaluation Procedure Support [S-REPS]
Pilot Update / System Preview

3rd Industry Stakeholder Platform on R&D support, 18 May 2018

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An agency of the European Union

What we will cover

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Objectives

Provide an update on the S-REPS Pilot

- A brief overview of benefits; progress to date; key milestones ahead for the new platform

OD submission: what are the changes

- A brief overview of the new processes being introduced for Orphan Designation (OD)

Give a preview of the portal

- On-screen preview of how to create applications; look things up; appoint ‘Contributors’

Hear feedback from stakeholders

- Comments / thoughts on preparations for Go-Live from some of the industry stakeholder volunteers involved to date

Benefits of the new platform

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Managing OD procedures is changing

- OD Submission via web form
- User friendly interface

- Reduced the time needed to prepare and submit an OD application
- Possibility to reuse submitted data (from Go-Live date onwards)

Ability to check OD application status on-line

- More control of your own application
- Multi-device access

Link to terminology dictionaries (SPOR)

Single portal | Save time | Better visibility | Better usability | Data quality

Benefits

Progress to date

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1. Configuration and development of the new platform started in January 2018

2. Agile approach to system build: now in Iteration #3

3. Integration with EMA Account Management and Master Data Management (SPOR) systems completed

4. Engagement with external stakeholders: 3 Webinars held with Industry Volunteers (March-May 2018)

5. Test environment set up for User Acceptance Testing (UAT)

Key project milestones

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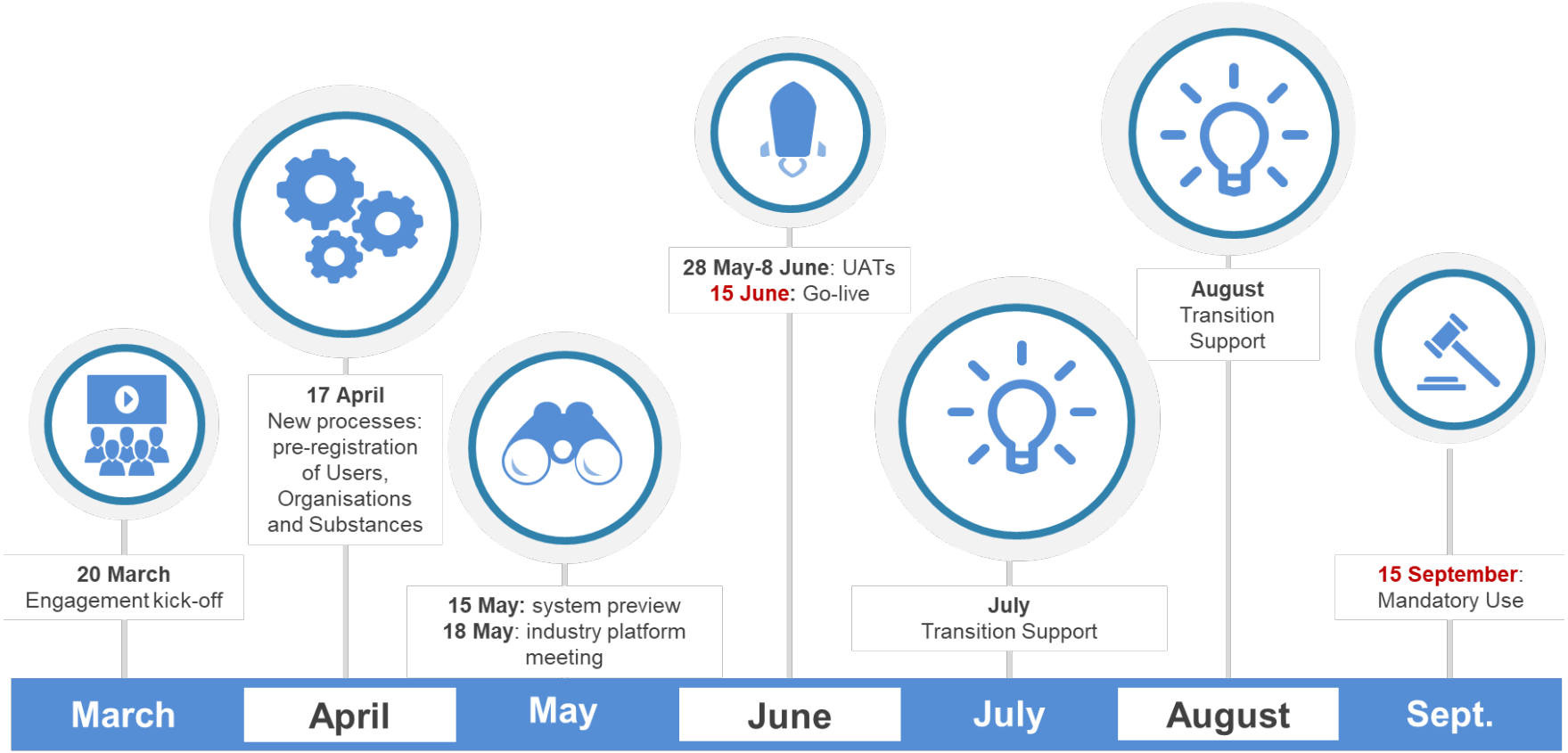

Orphan Designation process: what are the changes

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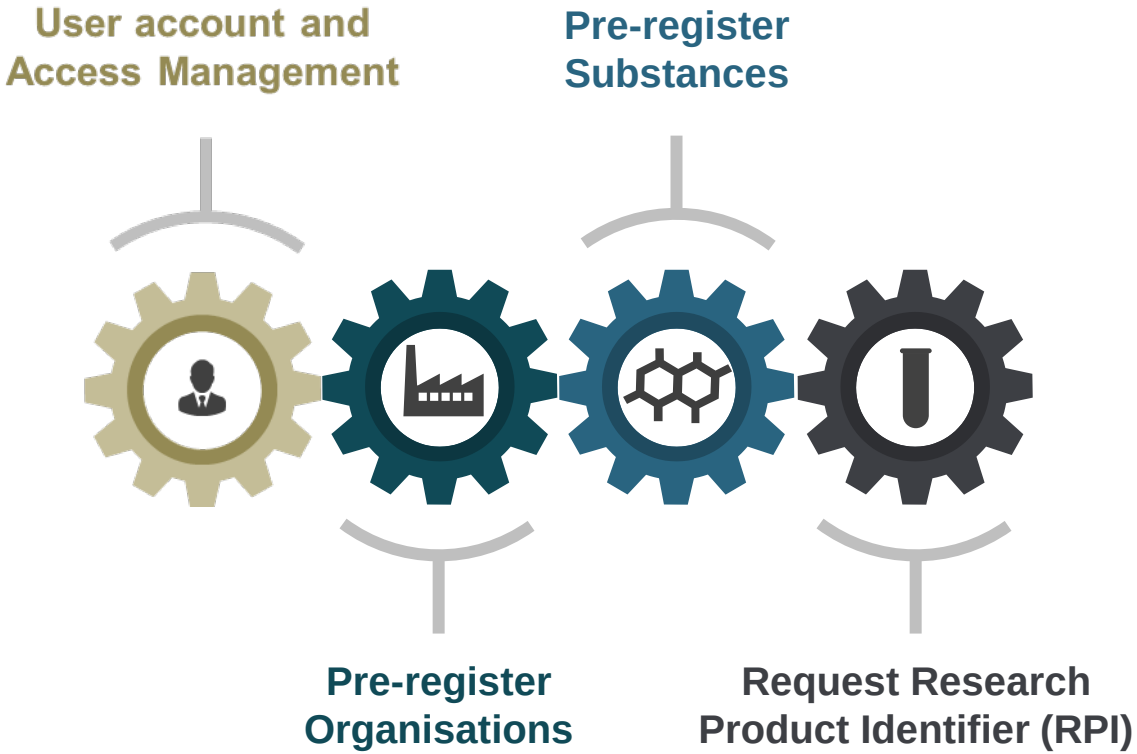

Orphan Designation process: what are the changes

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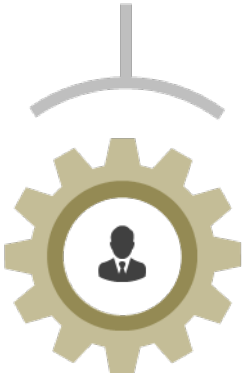
User account and Access Management



- Users must be registered in the **EMA Account Management portal** (central point to manage access to EMA systems).

If you already have access to a EMA-hosted websites or online applications (e.g.: SPOR, Eudralink, EudraCT Secure, service desk portal, EUTCT, EVDAS, EUDRAGMDP, EPITT or PSUR repository), this means that **you already have an EMA account** and you should **use the same credentials** but still connect to Account Management portal **to set up your Account security questions**

- **EMA** will **approve the first "Orphan - Industry Admin User"**.
- Any subsequent Admin User or other Orphan Industry user access requests will be approved by an Admin User from the organisation for which S-REPS portal access has been requested

Orphan Designation process: what are the changes

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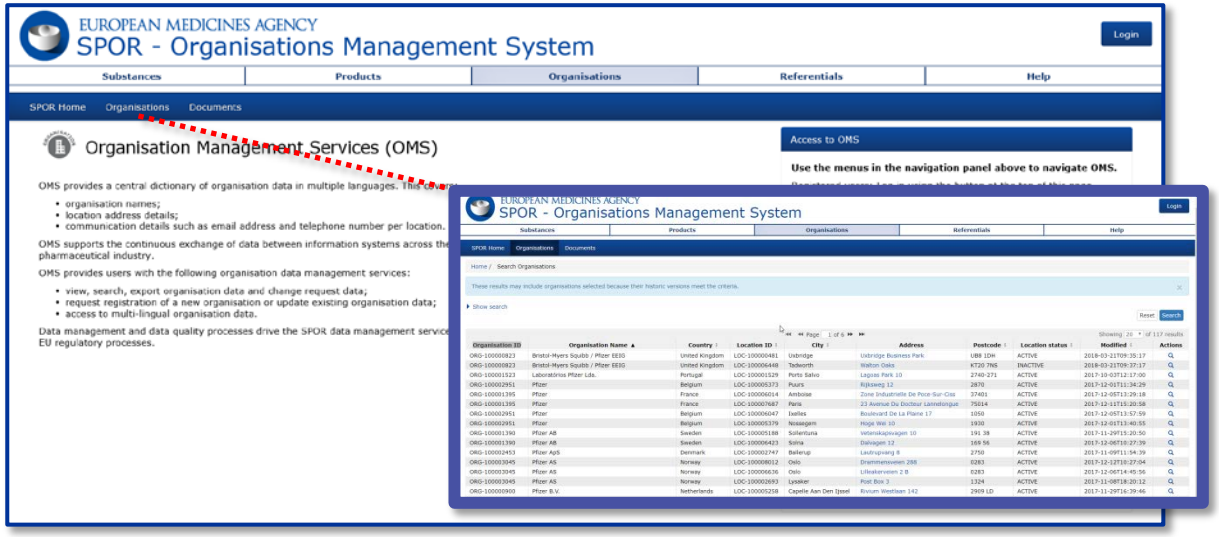
Pre-register Organisations

- **All Organisations** need to be registered in OMS (found in the **SPOR web portal**), or as a **contact detail** (Sponsor or Applicant), so that each **User can select their organisation when requesting a role for accessing the portal**.



Orphan Designation process: what are the changes

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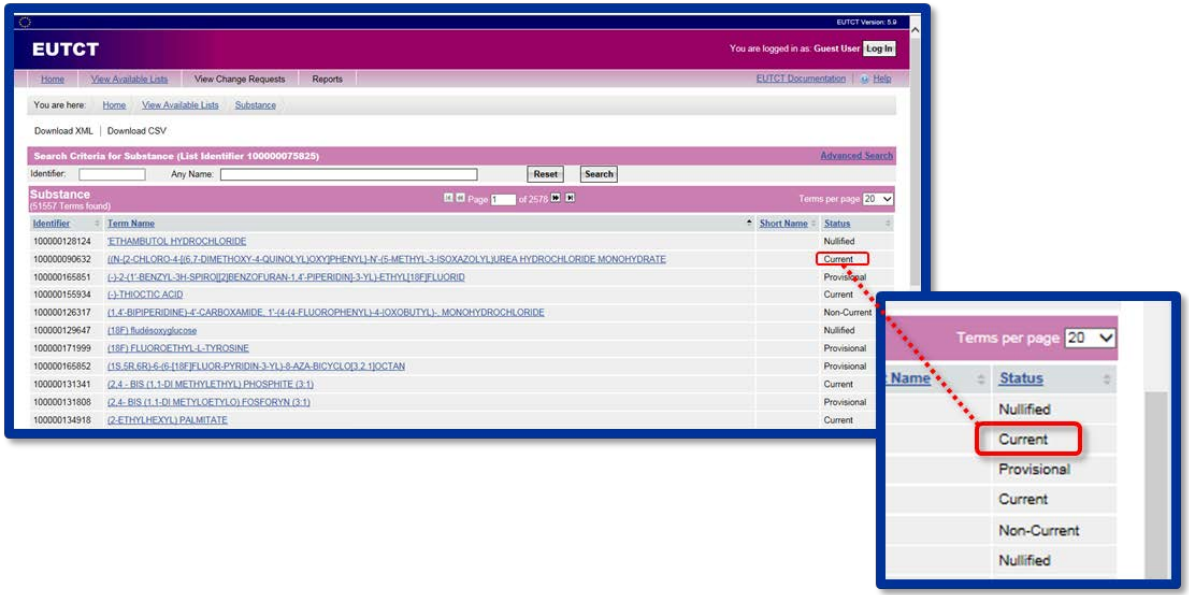
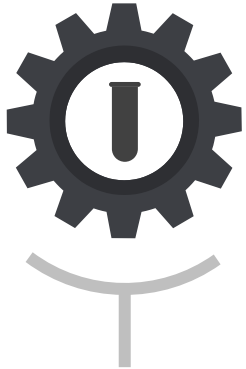
Pre-register Substances

- If each active **substance** is ***not*** listed as "**Current**" in the **EUTCT list**, it will need to be registered through the EMA ServiceDesk.



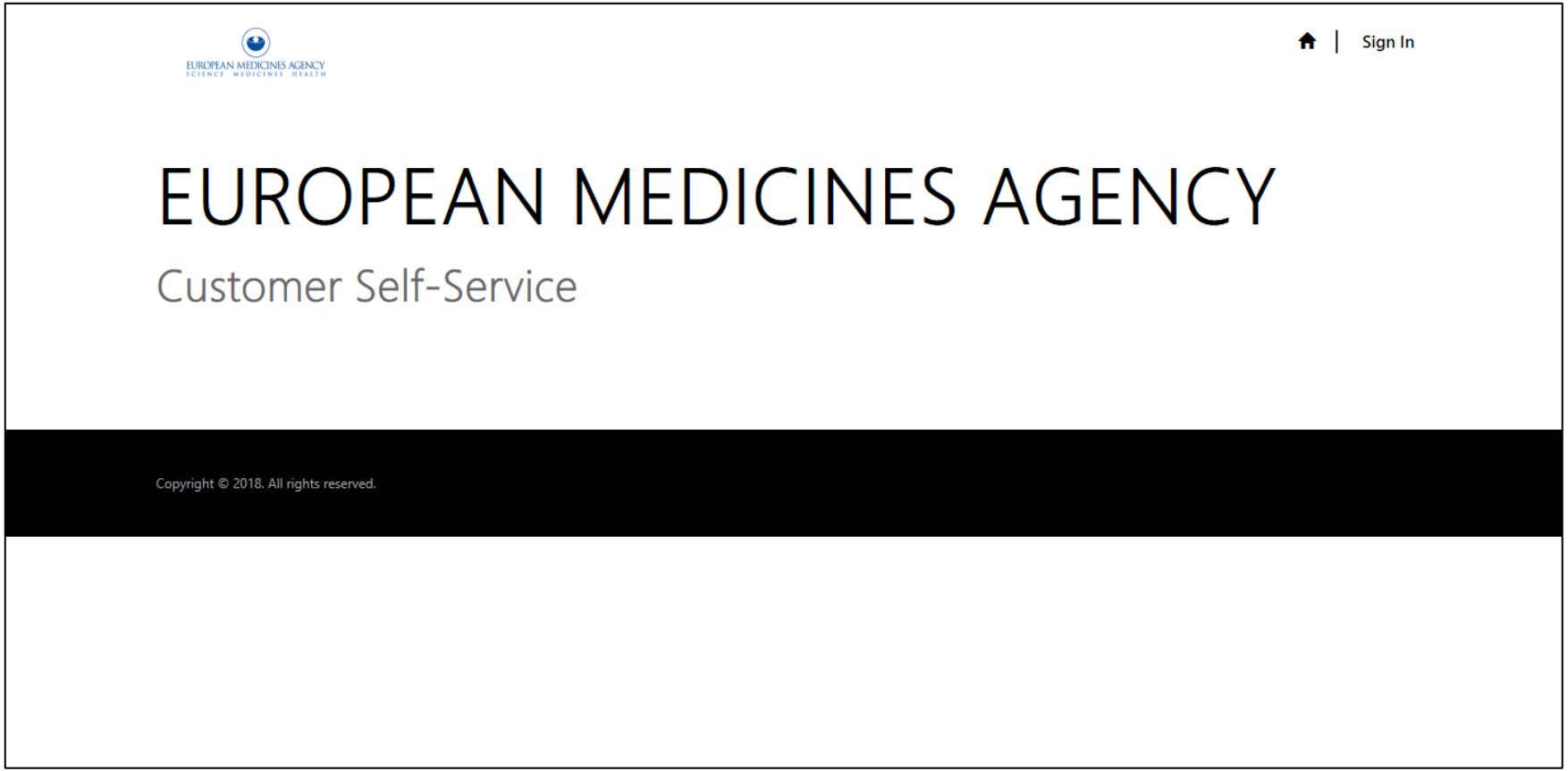
Orphan Designation process: what are the changes



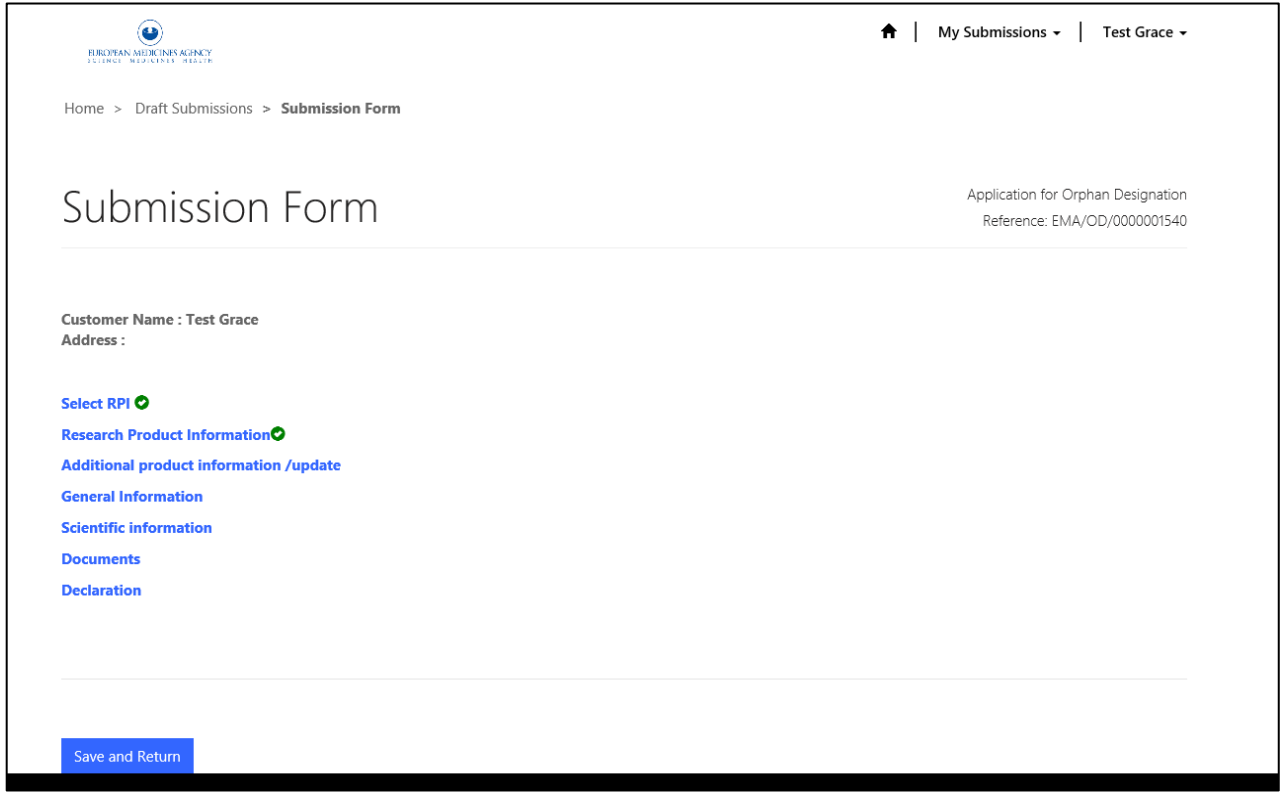
Request Research Product Identifier (RPI)

- If a UPI has not been assigned previously, a **Research Product Identifier (RPI)** will need to be requested
- To do this, complete the web form stating:
  - First developer of product
  - Name of Active Substance(s)
  - Enabling Technologies
- The RPI can be used to submit an Orphan Designation

Preview of the S-REPS portal



Preview of the S-REPS portal



- The current application form (PDF file) is replaced by the online portal
- The scientific document (Word template) is uploaded in the “Documents” section

Preview of the S-REPS portal

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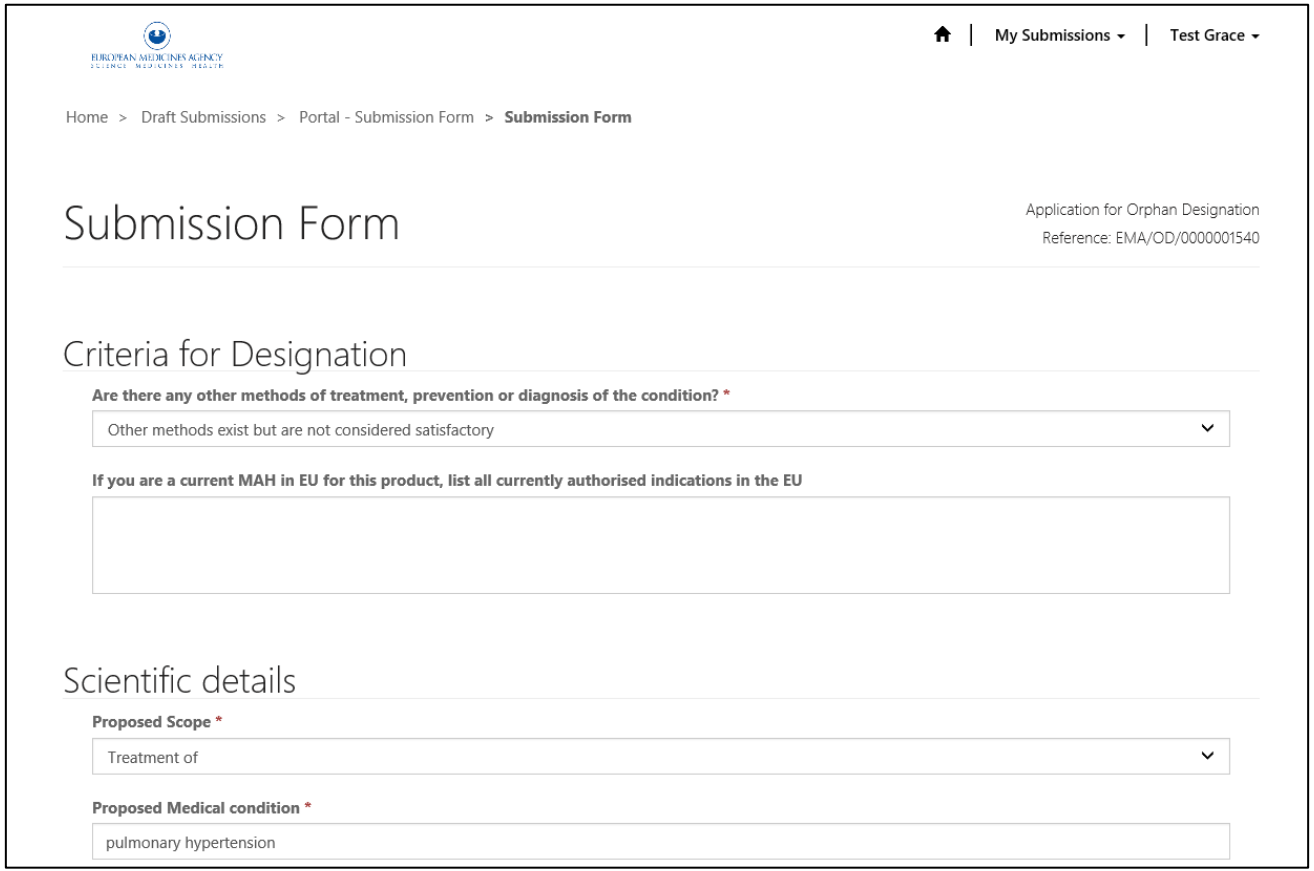
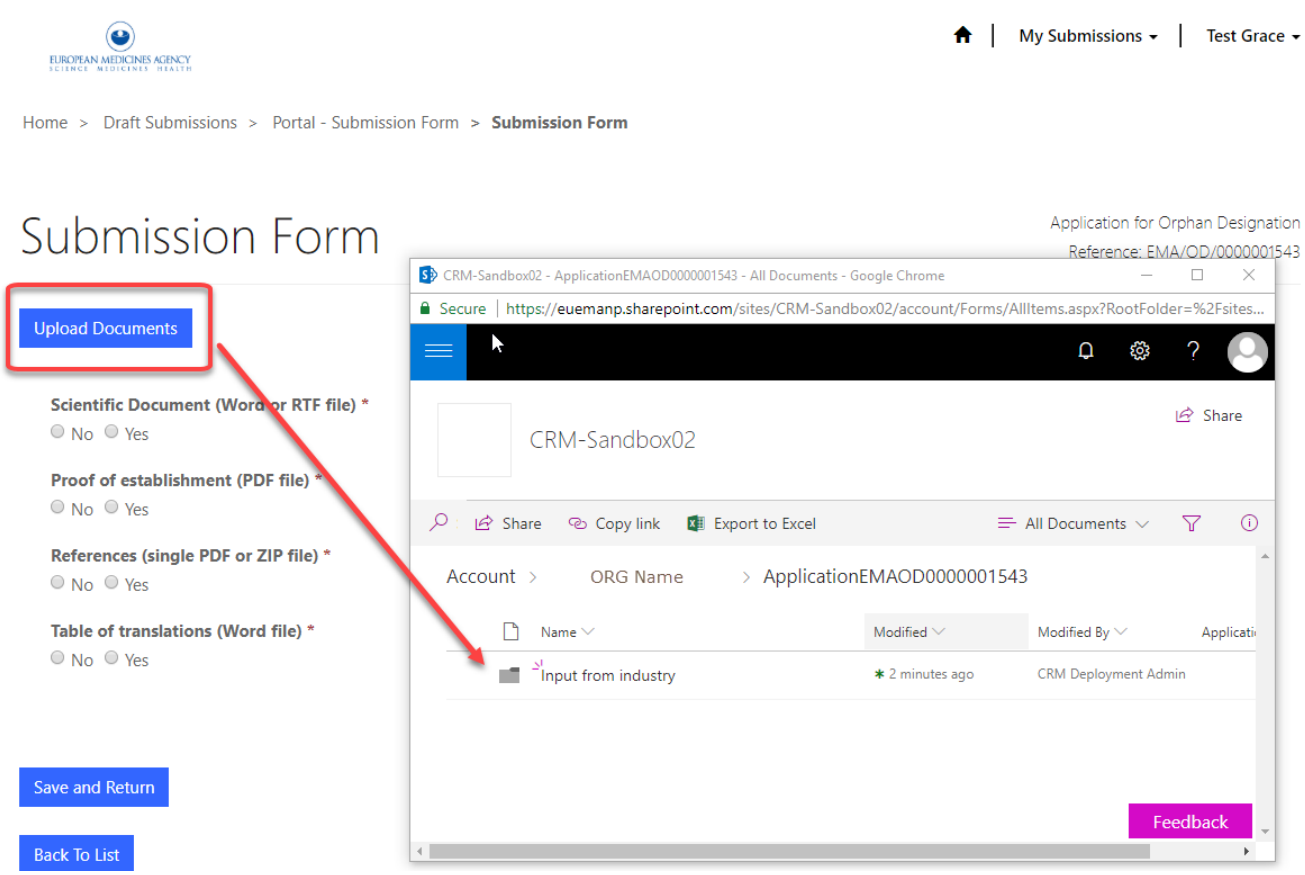


Preview of the S-REPS portal



- Supporting documents will be uploaded directly into a document folder
- It is possible to upload a template file (e.g. for Scientific Document) and edit it directly within the folder, with Word online directly in the browser or with Word installed in the device (including from a phone/tablet)

Feedback from Industry Stakeholder Volunteers

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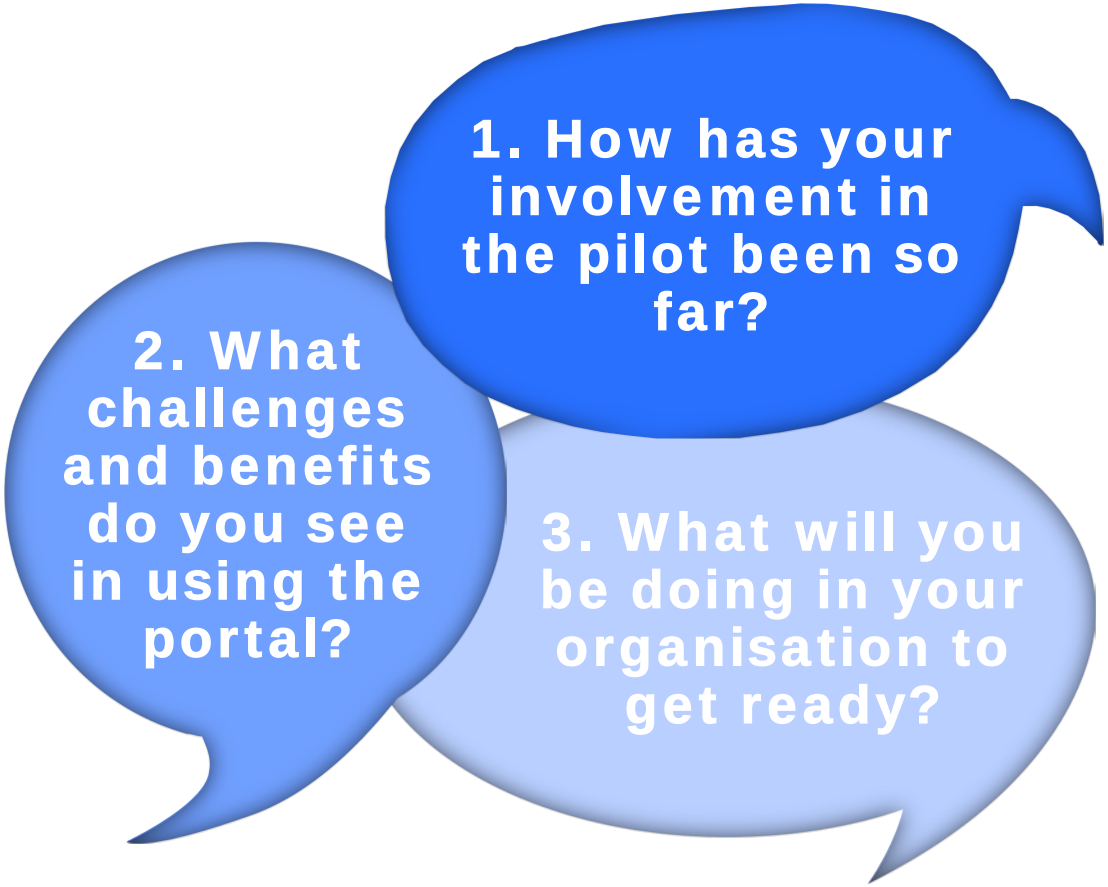

Thank You

Any questions?

Further information

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