



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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

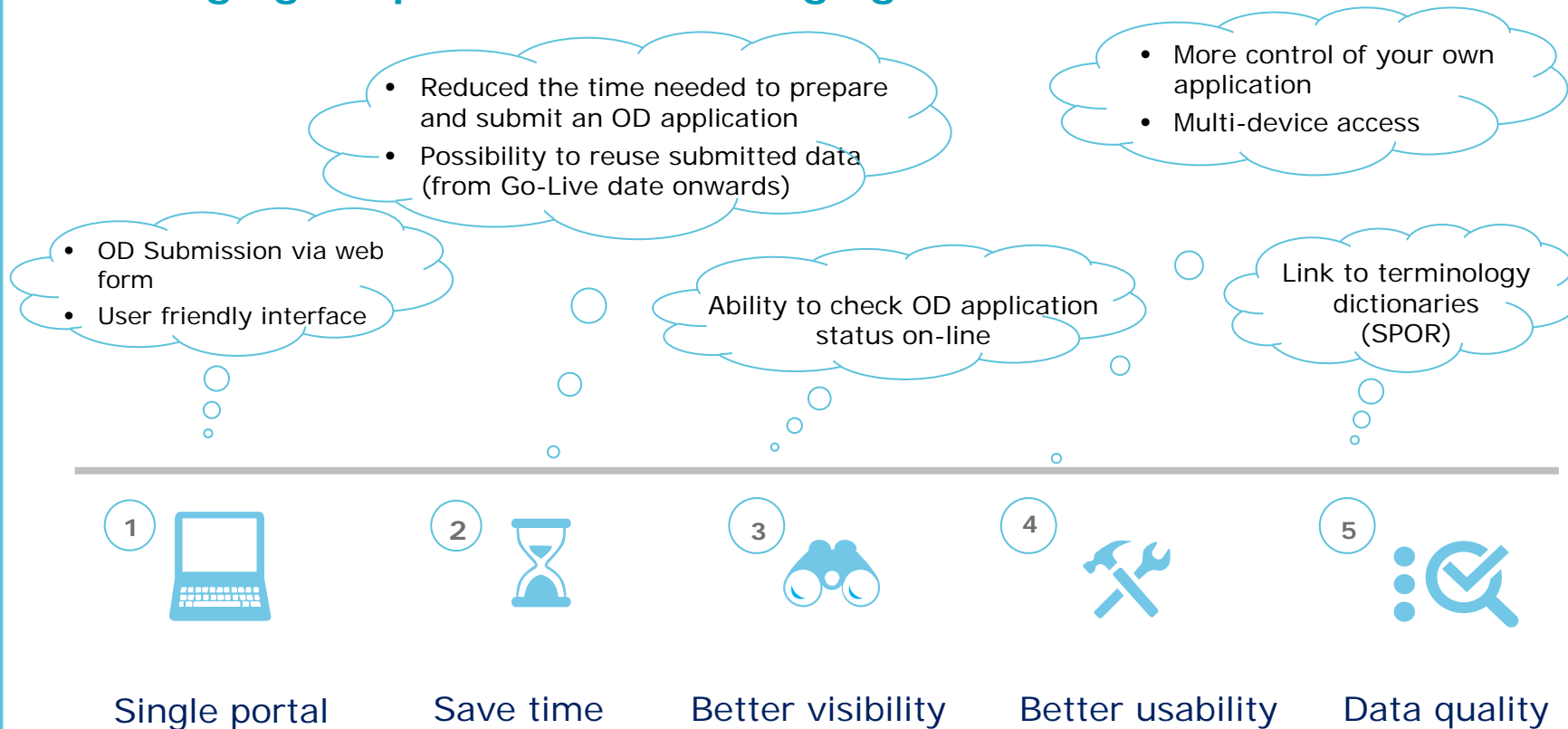
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3rd Industry Stakeholder Platform on R&D support, 18 May 2018





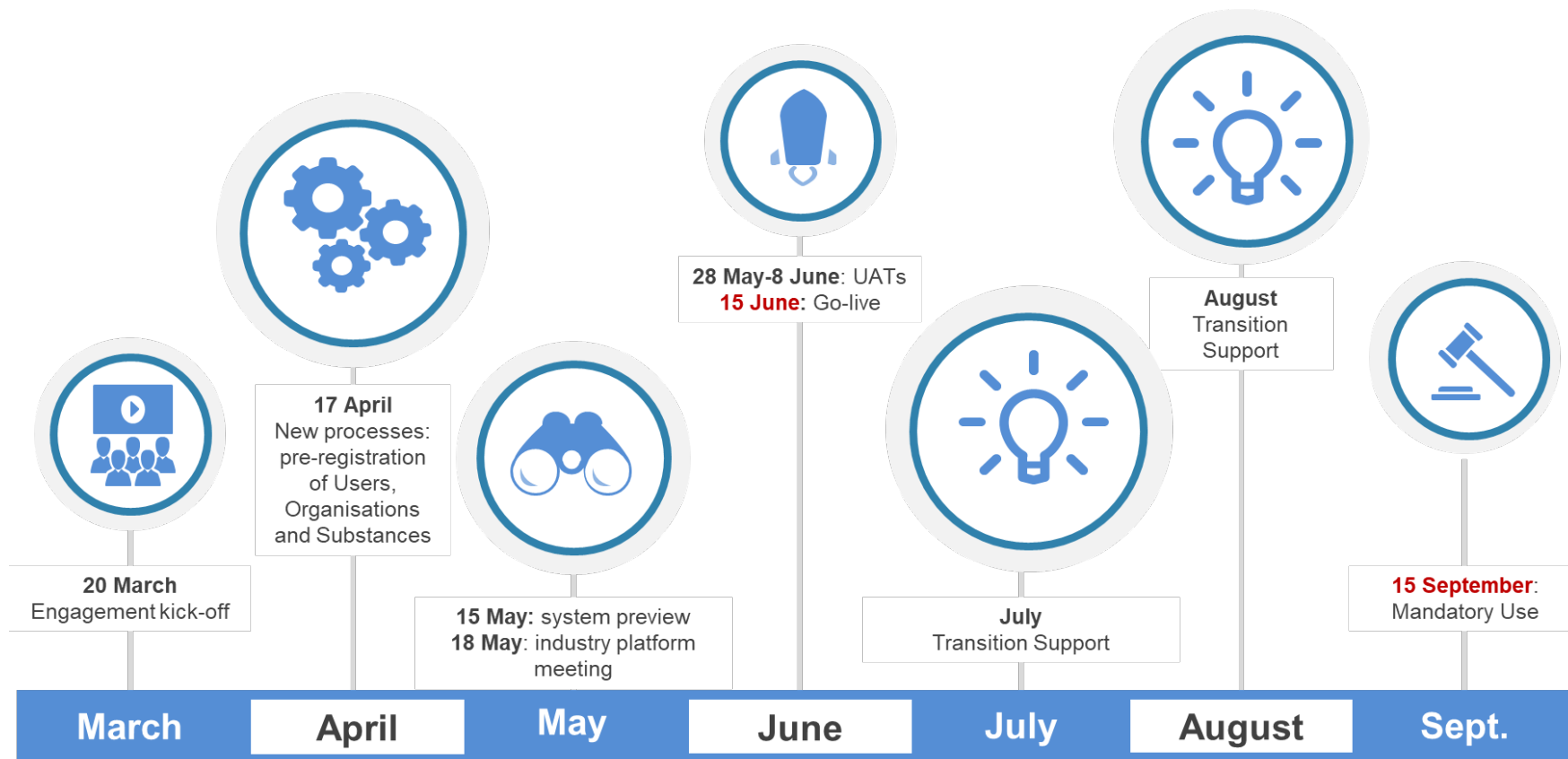
## Managing OD procedures is changing



## Benefits

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)

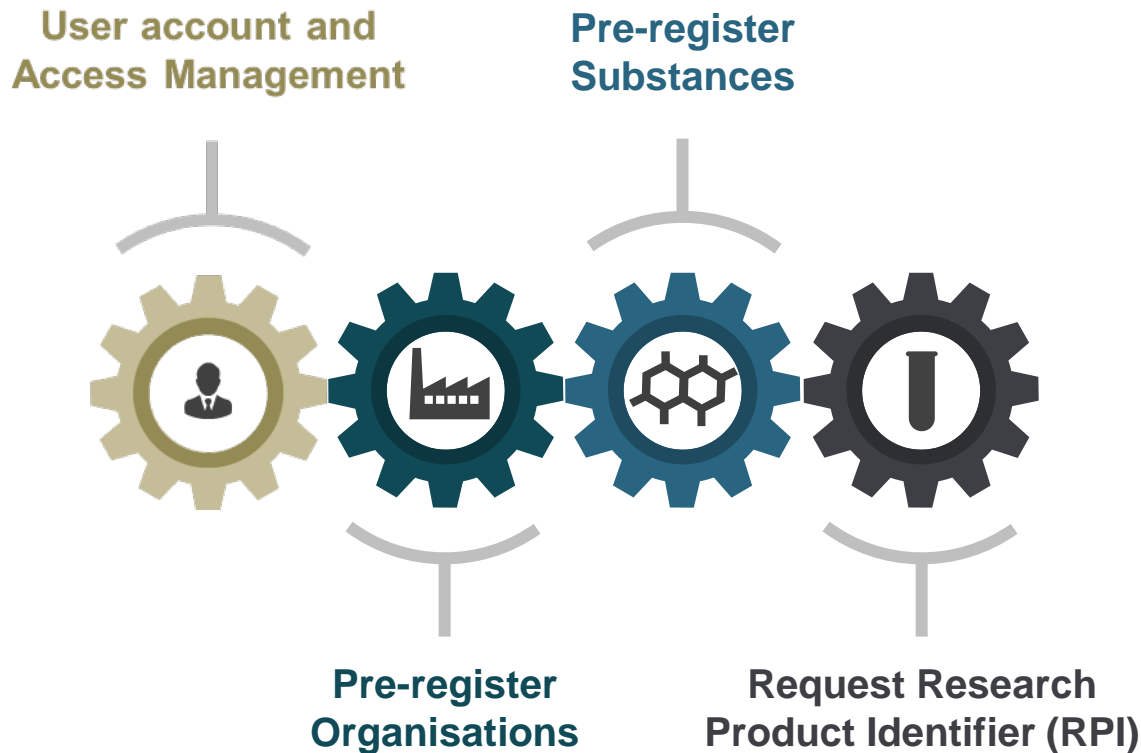
# Key project milestones



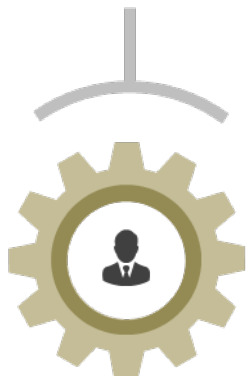
# Orphan Designation process: what are the changes



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## User account and Access Management

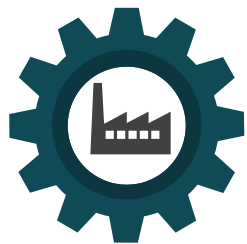


- Users must be registered in the [EMA Account Management portal](#) (central point to manage access to EMA systems).



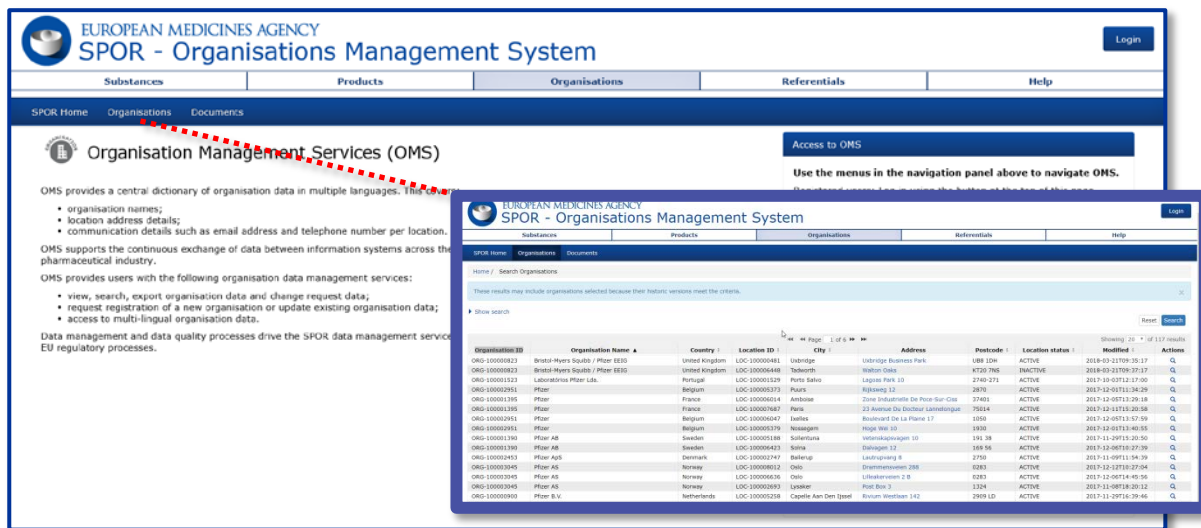
If you already have access to a EMA-hosted websites or online applications (e.g.: SPOR, Eudralink, EudraCT Secure, service desk portal, EUTCT, EVDAS, EUDRAGMDP, EPITT or PSUR repository), this means that **you already have an EMA account** and you should **use the same credentials** but still connect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



## 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.



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SPOR - Organisations Management System

Substances Products **Organisations** Referentials Help

SPOR Home Organisations Documents

**Organisation Management Services (OMS)**

OMS provides a central dictionary of organisation data in multiple languages. The system:

- organisation names;
- location address details;
- communication details such as email address and telephone number per location.

OMS supports the continuous exchange of data between information systems across the pharmaceutical industry.

OMS provides users with the following organisation data management services:

- view, search, export organisation data and change request data;
- request registration of a new organisation or update existing organisation data;
- access to multi-lingual organisation data.

Data management and data quality processes drive the SPOR data management service EU regulatory processes.

Access to OMS

Use the menus in the navigation panel above to navigate OMS.

SPOR Home / Search Organisations

These results may include organisations selected because their historic version meet the criteria.

Show Search

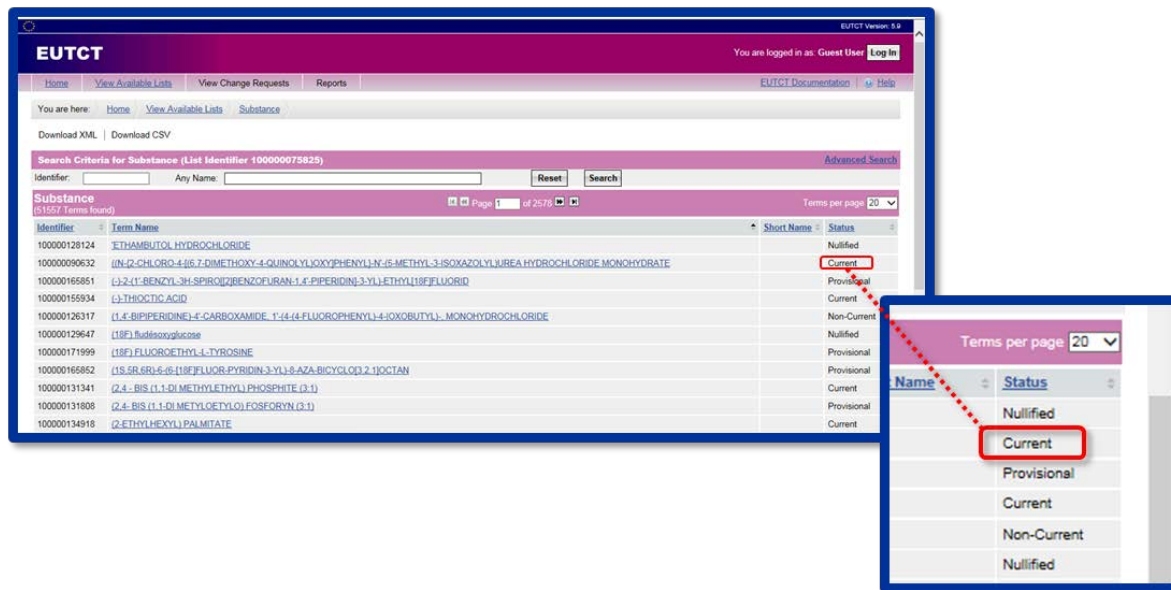
Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-10000823	Bristol Myers Squibb / Pfizer EES	United Kingdom	LOC-100000481	Uxbridge	Uxbridge Business Park	UB8 3DH	ACTIVE	2018-02-21T09:20:17	Q
ORG-10000053	Bristol Myers Squibb / Pfizer EES	United Kingdom	LOC-100000488	Totterdell	Woburn Gate	KT20 7NE	INACTIVE	2018-02-21T09:20:17	Q
ORG-10000123	Laboratoire Pfizer Ltd.	Portugal	LOC-100000529	Porto Salvo	Lagoa Park 10	2740-271	ACTIVE	2017-10-03T12:17:00	Q
ORG-10002951	Pfizer	Belgium	LOC-100000373	Puurs	Rijksweg 12	2870	ACTIVE	2017-12-01T11:34:29	Q
ORG-10001195	Pfizer	France	LOC-100000514	Antenne	Zone Industrielle De Pese-Bar-Cla	27401	ACTIVE	2017-12-01T11:34:29	Q
ORG-10001395	Pfizer	France	LOC-100000687	Paris	23 Avenue Du Docteur Lavoisier	75014	ACTIVE	2017-12-13T15:20:58	Q
ORG-10002941	Pfizer	Belgium	LOC-100000547	Enfesa	Boulevard De La Plaine 17	1050	ACTIVE	2017-12-01T11:34:29	Q
ORG-10002951	Pfizer	Belgium	LOC-100000579	Nieuwegein	Nieuwegein 10	1930	ACTIVE	2017-12-01T11:34:29	Q
ORG-10001190	Pfizer AB	Sweden	LOC-100000188	Sollersuna	Industriparkgatan 10	191 38	ACTIVE	2017-11-29T15:20:50	Q
ORG-10001190	Pfizer AB	Sweden	LOC-100000423	Sollersuna	Industripark 12	191 38	ACTIVE	2017-12-01T11:34:29	Q
ORG-10002453	Pfizer Aps	Denmark	LOC-100002747	Ballerup	Lundsgaard 8	2750	ACTIVE	2017-11-09T11:54:39	Q
ORG-10000395	Pfizer AB	Norway	LOC-100000612	Oslo	Enghaveveien 208	0381	ACTIVE	2017-12-13T15:20:58	Q
ORG-10000395	Pfizer AB	Norway	LOC-100000626	Oslo	Lillestrømsveien 2 B	0283	ACTIVE	2017-12-01T11:34:29	Q
ORG-10000395	Pfizer AB	Norway	LOC-100000393	Lysaker	Prest Raa 3	1324	ACTIVE	2017-11-08T18:20:12	Q
ORG-10000395	Pfizer B.V.	Netherlands	LOC-100000258	Capelle Aan Den IJssel	Erasmusplein 142	2669 LD	ACTIVE	2017-11-29T15:20:58	Q



## 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.



**EUTCT** Version: 5.8

You are logged in as: Guest User [Log in](#)

Home View Available Lists View Change Requests Reports EUTCT Documentation Help

You are here: Home View Available Lists Substance

Download XML Download CSV

Search Criteria for Substance (List Identifier: 100000075825) [Advanced Search](#)

Identifier: Any Name: Reset Search

Substance (51557 Terms found) Page 1 of 257 Terms per page: 20

Identifier	Term Name	Short Name	Status
100000128124	1-THAMBITOL HYDROCHLORIDE		Nullified
100000090632	(IN-2-CHLORO-4-(6,7-DIMETHOXY-4-QUINOLYLOXY)PHENYL)-N-(5-METHYL-3-ISOXAZOLYL)UREA HYDROCHLORIDE MONOHYDRATE		Current
100000165851	(1-2-(1-BENZYL-3H-SPIRO[2]BENZOFURAN-1,4-PIPERIDIN-3-YL)ETHYL)BIFLUORIDE		Provisional
100000155934	(3-THIOCTIC ACID		Current
100000126317	(1,4-BIPERIDINE)-4-CARBOXAMIDE, 1-(4-(4-FLUOROPHENYL)-4-ISOXYBUTYL)-, MONOHYDROCHLORIDE		Non-Current
100000129647	(1S)-Budesonolone		Nullified
100000171999	(1S)-FLUOROETHYL-L-TYROSINE		Provisional
100000165852	(1S,5R,6R,6S,6E)-18-FLUORO-2-PYRIDIN-3-YL-8-AZA-BICYCLO[2.2.1]OCTAN		Provisional
100000131341	(2,4-BIS (1,1-DI METHYLETHYL) PHOSPHITE (3:1)		Current
100000131808	(2,4-BIS (1,1-DI METHYLETHYL) O) FOSFORYN (3:1)		Provisional
100000134918	(2-ETHYLHEXYL) PALMITATE		Current

Terms per page: 20

Name Status

Nullified

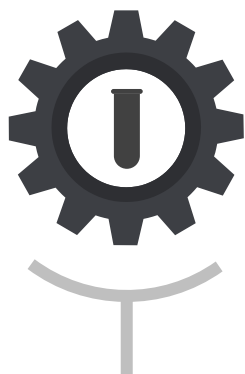
Current

Provisional

Current

Non-Current

Nullified



**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

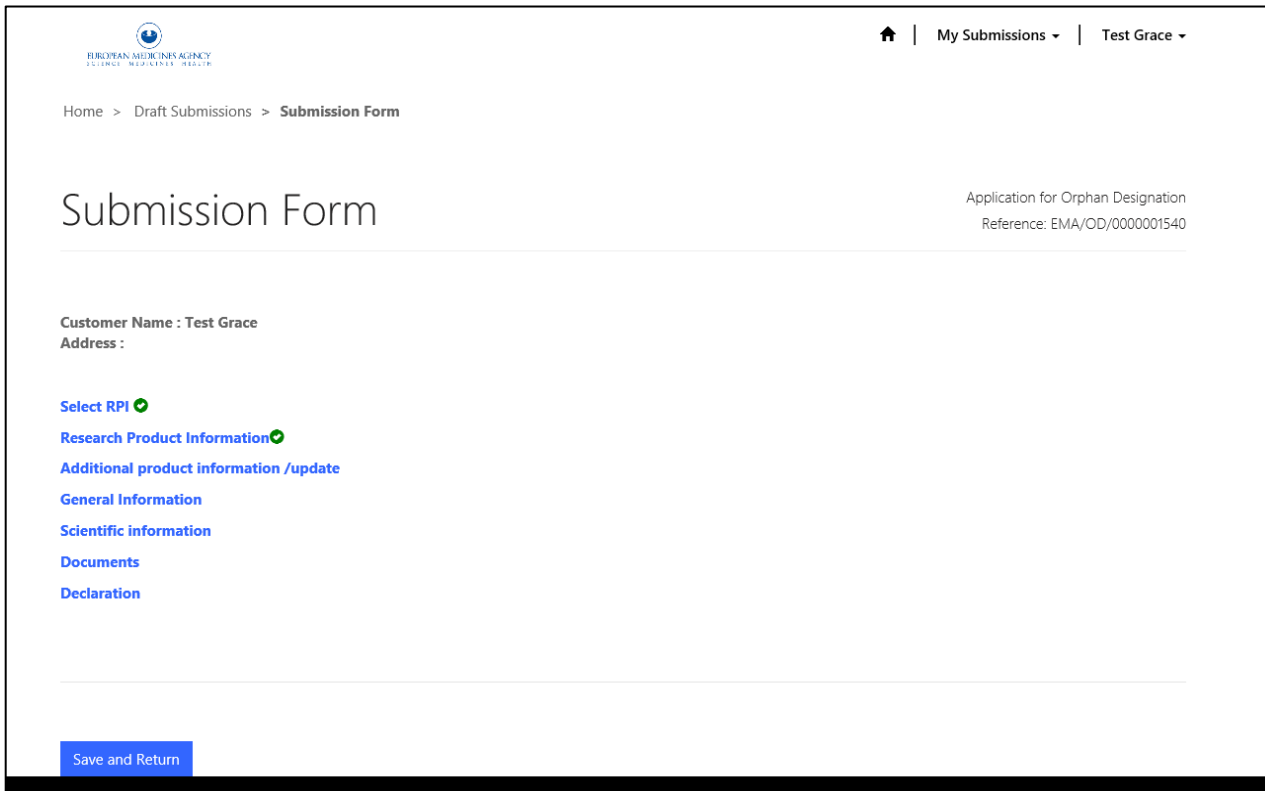


 | [Sign In](#)

# EUROPEAN MEDICINES AGENCY

Customer Self-Service


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The screenshot shows the 'Submission Form' page in the S-REPS portal. At the top left is the EMA logo and the text 'EUROPEAN MEDICINES AGENCY'. At the top right are navigation links: a home icon, 'My Submissions', and 'Test Grace'. Below the navigation is a breadcrumb trail: 'Home > Draft Submissions > Submission Form'. The main heading is 'Submission Form'. To the right of the heading, it says 'Application for Orphan Designation' and 'Reference: EMA/OD/0000001540'. Below the heading, there is a section for 'Customer Name : Test Grace' and 'Address :'. A list of links follows: 'Select RPI' (with a green checkmark), 'Research Product Information' (with a green checkmark), 'Additional product information /update', 'General Information', 'Scientific information', 'Documents', and 'Declaration'. At the bottom left is a blue button labeled 'Save and Return'.

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



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 | **My Submissions** ▾ | **Test Grace** ▾

Home > Draft Submissions > Portal - Submission Form > **Submission Form**

## Submission Form

Application for Orphan Designation  
Reference: EMA/OD/0000001540

### Criteria for Designation

**Are there any other methods of treatment, prevention or diagnosis of the condition? \***

Other methods exist but are not considered satisfactory ▾

**If you are a current MAH in EU for this product, list all currently authorised indications in the EU**

### Scientific details

**Proposed Scope \***

Treatment of ▾

**Proposed Medical condition \***

pulmonary hypertension

## Submission Form

Upload Documents

Scientific Document (Word or RTF file) \*

☐ No ☐ Yes

Proof of establishment (PDF file) \*

☐ No ☐ Yes

References (single PDF or ZIP file) \*

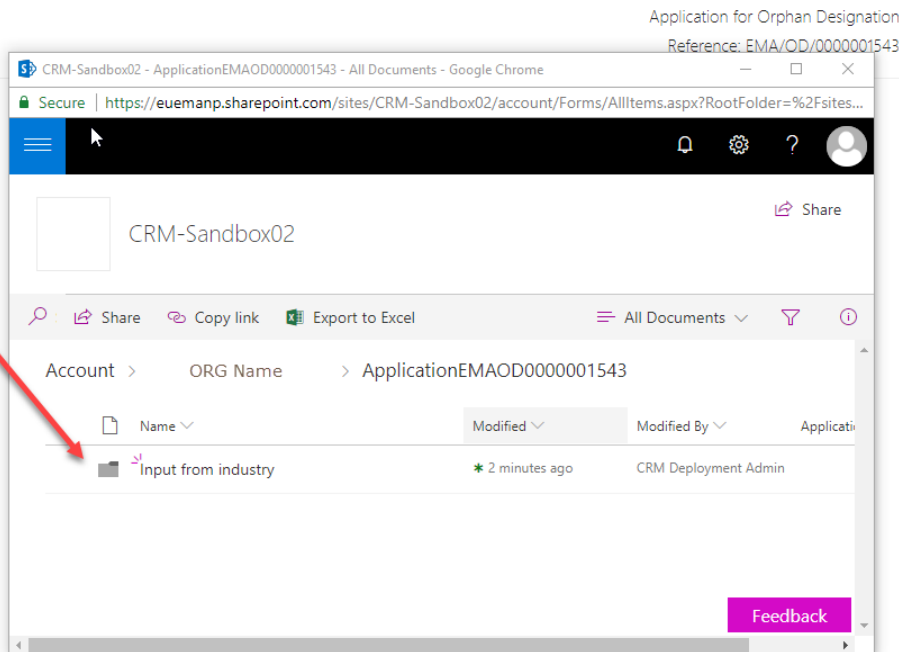
☐ No ☐ Yes

Table of translations (Word file) \*

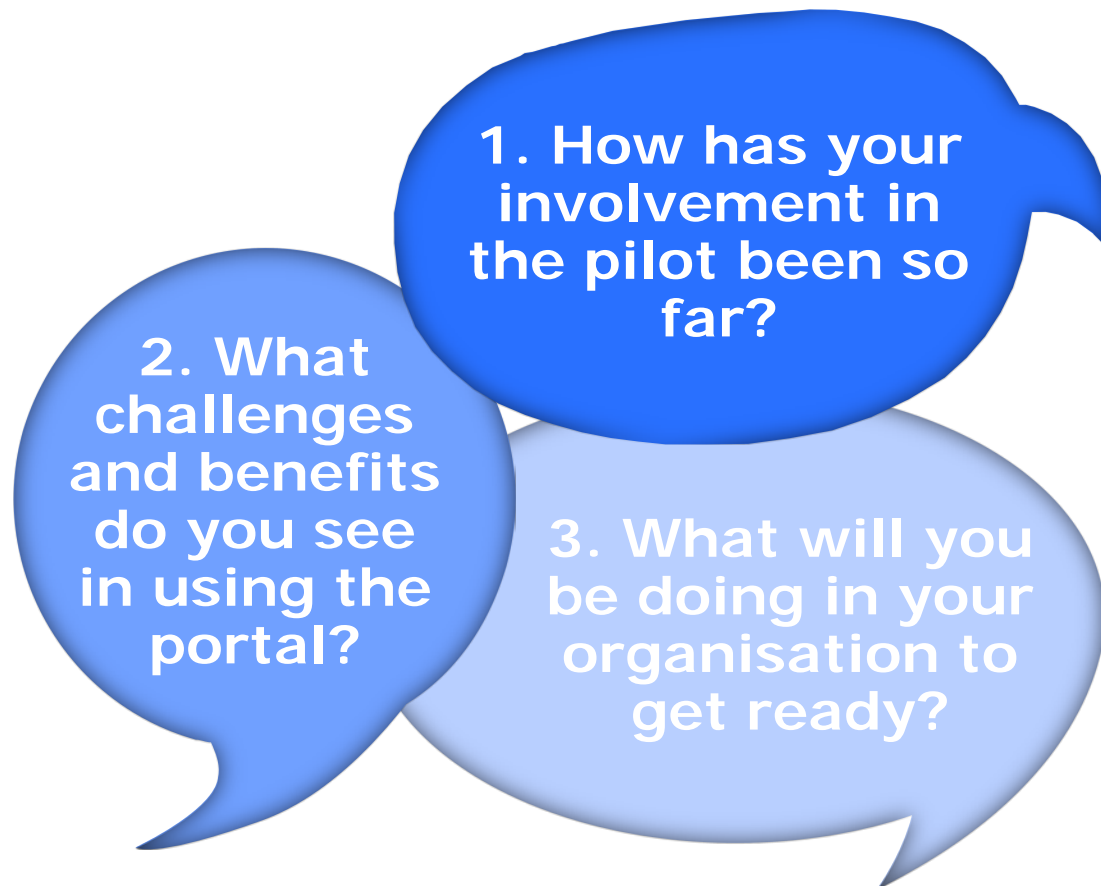
☐ No ☐ Yes

Save and Return

Back To List



- 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)





# Thank You

## Any questions?

### Further information

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Send a question to [SREPS@ema.europa.eu](mailto:SREPS@ema.europa.eu)

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