EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

A new way of managing procedures - Pilot for Orphan Medicine designation activities

S-REPS: Scientific and Regulatory Evaluation Procedure Support

Industry stakeholder platform on research and development support, 15.11.2017

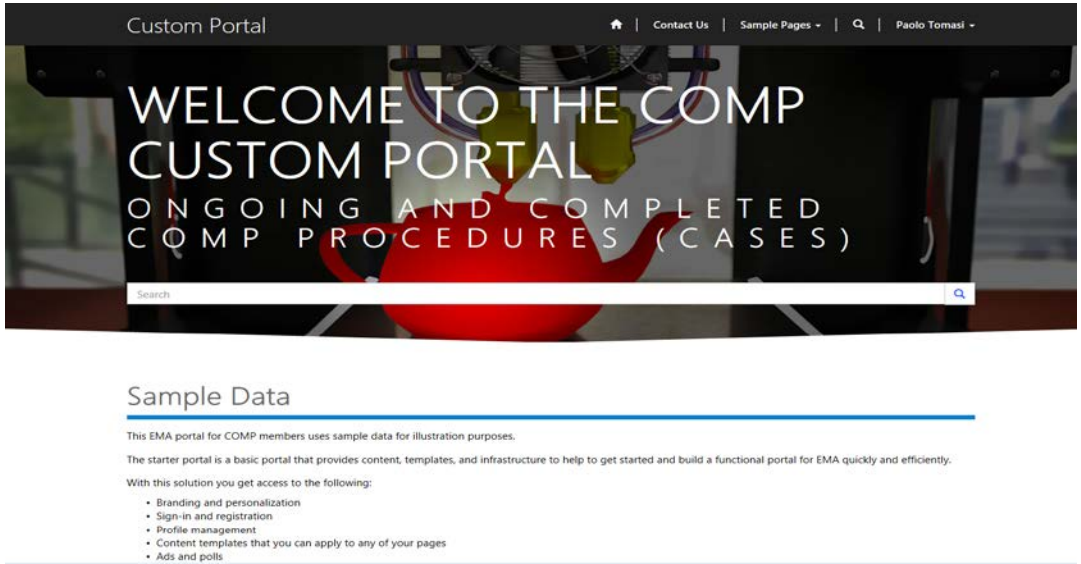
Presented by Valerie Johnson and Paolo Tomasi, Product Development Support Department

What is new?

Portal - web interface (Edge, Explorer, Chrome, Safari, Firefox...)

Can be accessed from PC, laptop, tablet, phone

The implementation of new software and improvements to the processes for the designation of orphan drugs



What are the aims?

This project has the following objectives

Enables a cloud-based technology as a pilot for future Agency-wide platform for procedure management

Implements a comprehensive procedural and scientific support system for orphan designation and allied procedures

What are expected benefits?

Key features	Impact
Implementing an Agency wide platform for process management	To improve the processes across the Agency for executing procedures and managing process related data.
Streamlining the flows of information	Increase efficiency of business operations
Providing a modern and user friendly solution for industry	Improve user experience for applicants and sponsors
Improving support for scientific decision making	Improve visibility to scientific data and foster information-sharing throughout the network.

What does this mean practically?

- ✓ Access to all Orphan applications and procedures in one portal
- ✓ Available on multiple devices
- ✓ If application has not been validated, a new application can be submitted using relevant previously submitted data.
- ✓ Real-time access to EMA/COMP output - you will be 'alerted' and can log-in and view or download documents.
- ✓ The process will be more efficient and streamlined
- ✓ Can see 'status updates' in one view - easier to track progress of applications
- ✓ Pre-registration of organisation, substance(s), and Research Product Identifier (RPI) needed (This is related to SPOR)
- ✓ 'Go Live' scheduled for late Spring- Early Summer 2018

From an applicant's perspective…….

- The system will give you guidance and online prompts on how to fill in the online form.

- More details will be sent out closer to 'go live'

How can prospective Orphan Sponsors get involved?

What? Volunteers to develop and test the system from an applicant/sponsor perspective

When?

- First phase: December 2017: Requirements gathering and analysis.
- Second-phase: mid- Feb to mid-March 2018: Design, iteration and testing (UAT)
- Third phase : Early implementation: Late Spring/ Early Summer 2018: using system and testing.

How? Participate in webinars and tele-conferences
(on average once a fortnight lasting one hour per session)

Where? All online or conducted 'virtually'

Who? Applicants/ Sponsors applying for orphan designation.

- Regulatory Project Managers- not IT Project!
- Also seeking volunteers through Trade Associations

Deadline for nominations: 30th November 2017

Take home messages

What?

- ✓ Changes are coming for Orphan Designation Process.
- ✓ Pilot may be extended to other scientific regulatory processes.
- ✓ New system will make full use of a group of controlled terms lists (SPOR)
- ✓ Pre-registration of sponsor (organisation), substance(s), and a “research product identifier” (RPI) will be a requisite before being able to draft and submit applications.
- ✓ Web-portal application plus attachments will replace current PDF and Word forms–based submission (for Orphan medicines)
- ✓ The new system should be easier for you.

Any questions?

Further information

Contact the Project Team on: SREPS@ema.europa.eu

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