EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

User Testing of the Clinical Data Publication Website Prototype

Clinical Data Publication Policy 0070

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An agency of the European Union

Clinical Data Publication Policy 0070

Scope of Policy 0070: publication of clinical reports in a marketing authorisation application (MAA) submitted to EMA on or after 1.1.2015 for initial MAAs & article 58 applications

1.7.2015 for extension of indication applications & line extension applications relating to existing centrally authorised products (CAPs). An effective date is not yet established for post authorisation procedures.

Publication, after the Commission Decision granting/refusing the marketing authorisation, or other regulatory decision, or the withdrawal of the application by the company.

Specific benefits of Policy 0070 are:

Proactive publication enables public scrutiny -> establishing trust and confidence in the system.

Public access enables application of new knowledge in future research -> increasing efficiency of medicine development learning from experience.

Avoid duplication of clinical trials, limiting unnecessary patient exposure

User Test for the Clinical Data Publication Website Prototype

- The Agency is designing a website that will provide access to redacted clinical data published by the Agency
- A prototype of the main pages of the website is currently being created and will provide a "click-through" user experience during a User Test
- User Testing of the prototype is scheduled for **2 days**, between **01.02.16 and 03.02.16** at the EMA office, Canary Wharf
- Attendees: 5 x patient representatives (maximum) and 5 x healthcare professionals (maximum) are required for the User Test. Participation is reimbursable
- The deadline for the nomination of participants of the User Test is **18 December 2015**
- Please send nominations to Isabelle Moulon, Head of the Patients and Healthcare Professionals Department, at isabelle.moulon@ema.europa.eu

Thank you for your attention

Further information

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