EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU PAS Register upgrade July 2016 – What's new?

Rebranding

- References to the former ‘ENCePP E-Register of Studies’ which de facto acts as the EU PAS Register referred to in GVP VIII since 2012 have been removed from the ENCePP website and related documentation:
  - The **EU PAS Register** tab is the landing page to enter, edit or search studies in the EU PAS Register;
  - The former tab ‘E-Register of Studies’ has been removed;

Performance enhancements

- **New size limit for file upload:** increased from 2 to 10 MB (applies to all document fields)
- **Confirmation email** including study reference number and login details is sent to PLI on registration and with each update of a **draft entry**

Study data management

- New format of the unique **EU PAS reference number**: e.g. EUPAS123456
  (Searchable & displayed on screen and on printouts)
- **Static hyperlink** to study record (URL no longer changes with each update to the record)
- *New* data field: '**RMP study category**' (mandatory, searchable)
  - *Not applicable*
  - *EU RMP category 1 (imposed as condition of marketing authorisation)*
  - *EU RMP category 2 (specific obligation of marketing authorisation)*
  - *EU RMP category 3 (required)*
  - *Non-EU RMP only*
- *New* data field: '**Other study registration identification number(s)**' (free text, searchable)

Compliance monitoring

- Searching *new* data fields allows to **monitor compliance** with legislative requirements for non-interventional PASS and GVP transparency recommendations for PAS:
  - RMP study categories 1-3 (for PAS initiated, managed or financed by MAHs)
  - Studies requested by (selected) regulator(s)
  - Other study registration identification number(s)

How do these changes affect studies registered prior to the upgrade of the database?

- ✓ The prefix of the **study identification number** will automatically be replaced with ‘EUPAS’; however, the numerical value of the study identifier will remain unchanged (e.g. ENCEPP/SDPP/12345 will become EUPAS12345).
- ✓ For existing studies the new mandatory **RMP category** field will remain blank until it has been populated; requests to populate the field will be sent to all primary lead investigators.

Further information

- Frequently asked questions – EU PAS Register
- EU PAS Register Guide
- Good pharmacovigilance practices (GVP) Module VIII

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