

Combined Industry view on Eudravigilance

Developments and access

- EFPIA, AESGP, EuropaBIO, EGA
- Delay in centralisation
 - MS should be encouraged to centralise earlier when they assess EV as functional
- Submission of non serious data.
 - What are the requirements before centralisation in the individual countries?
 - How to solve with linelistings in the PSURs
- Retrieve reports from literature and direct reporting to MS
 - requirements, format and possibilities
- Signal detection
 - Should the MAH copy the actions of the EMA on the data in EV?
- Access policy for CAP by end of 2011.
 - What are MA holder obligations
 - How many industry access points
 - License partners / generics
 - Non serious reports