



EudraVigilance high level plan

Changes to legislation of:

- Post-authorisation
- Clinical trials

Results in changes to:

- EudraVigilance system
- Reporting of ICSRs and SUSARs

Change Management Plan to detail **IT & business changes** which affect EMA, NCAs, MAHs and Clinical Trials Sponsors

Stakeholders to develop individual internal detailed plans to manage the changes.

High level plan of changes

