

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

2017				2018	Post ISO IDMP Implementation
6-17 February 2017 EudraVigilance Audit	26 June 2017 New EudraVigilance TEST environment (XCOMP) released	4 October 2017 EV/EVDAS system go live plan	22 November 2017 New EV system launched EV start accepting R3 format messages	Q1 2018 post go-live maintenance release	EV stop accepting R2 format messages
Announcement of successful audit Announcement of successful EudraVigilance Audit		Implement ICSR routing changes Implement EV Access Policy Implement new EVDAS/eRMR functionalities			