

LINKS TO USEFUL PHARMACOVIGILANCE SITES

- EMA – Pharmacovigilance:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000258.jsp&mid=WC0b01ac05800241de
- EMA - Good Pharmacovigilance Practices (GVP):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp
- EMA – Risk Management Plans (RMP):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000360.jsp&mid=WC0b01ac058067a113
- EMA – European public assessment reports (including public RMP summaries):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124
- CMDh- Risk Management Plans (RMP) and List of safety concerns per approved RMP of active substances per product
<http://www.hma.eu/464.html>
- EMA – Signal Management : For list of Designated Medical Events (DMEs)
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000587.jsp
- EMA – PRAC recommendations on safety signals
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000375.jsp&mid=WC0b01ac0580727d1c#section1
- EMA – Periodic Safety Update Report (PSUR):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000361.jsp&mid=WC0b01ac058066f910

- EMA- Periodic safety update report single assessments
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/psusa_search.jsp&mid=WC0b01ac0580902b8d
- ICH – Periodic Benefit-Risk Evaluation Report (PBRER):
<http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>
- CMDh- MRI product index (Public Assessment Reports for products authorised via MRP/DCP procedures)
<http://www.hma.eu/mriproductindex.html>
- ICH – Development Safety Update Report (DSUR):
<http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/development-safety-update-report.html>
- EMA – ICH guideline E2F on DSUR:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/09/WC500097061.pdf
- CIOMS- Pharmacovigilance
<https://cioms.ch/pharmacovigilance/>
- Reports of CIOMS Working Groups: Pharmacovigilance
<https://cioms.ch/shop/?filterby=pharmacovigilance>
- ENCePP- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
<http://www.encepp.eu/>
- The European Union electronic Register of Post-Authorisation Studies (EU PAS Register)
http://www.encepp.eu/encepp_studies/indexRegister.shtml
- ENCePP Guide on Methodological Standards in Pharmacoepidemiology.
http://www.encepp.eu/standards_and_guidances/methodologicalGuide.shtml