ELC GROUP

Addendum to Clinical Overview (ACO)

What is ACO?

ACO is a PV doc that has to be reviewed by an EU QPPV & signed by a Clinical Expert.

Addendum to Clinical Overview (ACO) to be submitted during Renewal

6 – 9 months
before the renewal date

The doc is based on the post-marketing data of the current risk/benefit balance & should include the following points:

1. History of PV inspections
2. Worldwide marketing approval status
3. Actions taken for safety reasons. (ie withdrawal / suspension / restriction)
4. Significant changes to SmPC
5. Estimated exposure (clinical trials, post-marketing sales data)
6. No. of ADRs reported
7. No. of Post-Marketed clinical trials data
8. Literature search data
9. Risk Evaluation (Analysis of ADRs reported / post-marketed clinical trials data / lit. search data)
10. Benefit Evaluation (effectiveness & lack of efficacy)
11. Benefit / Risk balance discussion
12. Late breaking information: any new info received 30 days after the DLP (data lock point)

ELC Group provides a full range of Medical Writing services and also ensure that all of the requisite Pharmacovigilance activities are duly taken into account.

For more information about ELC Group's fully compliant pharmacovigilance solutions, please visit our website or contact Fionna Tan at ftan@elc-group.com

Concept to Safety

www.elc-group.com/en/Pharmacovigilance