

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 and should include the following points:

- 1 History of PV inspections
- 2 Worldwide marketing approval status
- 3 Actions taken for safety reasons (i.e. 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.



Concept to Safety

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