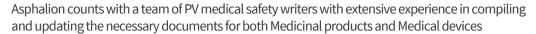
SAFETY WRITING THROUGH PRODUCT LIFECYCLE











Drug Safety Plan

DSUR Development Safety Update Report

authorisation

Post

Marketing

phase

RMP Risk Management Plan



Periodic Safety Update Report Periodic Risk Benefit Evaluation Report

ACO

Addendum to the Clinical Overview Clinical Expert Statement

Signal detection report

Any Update of RMP

Any other safety report requested by authorities

