

Development Safety Update Report [DSUR]

The Development Safety Update Report is an annual review of safety information during clinical trials of a medicine under investigation – whether or not it is marketed. The main objectives of a Development Safety Update Report is to:

1. Summarise the current understanding and management of identified and potential risks.
2. Describe new safety issues that could have an impact on the protection of clinical trial participants.
3. Examine whether any new safety information is in line with previous knowledge of the product's safety.
4. Provide an update on the status of the clinical investigation/development programme and study results.