

REQUIREMENTS
to development safety update report about investigational medicinal product
(hereinafter - DSUR)

DSUR shall consist of 20 sections:

1. Introduction.
2. Worldwide authorization/registration status.
3. Actions taken in the reporting period for safety reasons.
4. Changes to reference safety information.
5. Inventory of clinical trials ongoing and completed during the reporting period.
6. Estimated cumulative exposure (overall effect):
 - 6.1. Cumulative exposure in the development program.
 - 6.2. Patient exposure (patient effect) from marketing experience.
7. Data in line listings and summary tabulations:
 - 7.1. Reference information.
 - 7.2. Line listings of serious adverse reactions during the reporting period.
 - 7.3. Cumulative/summary tabulations of serious adverse events.
8. Significant findings from clinical trials during the reporting period:
 - 8.1. Completed clinical trials.
 - 8.2. Ongoing clinical trials.
 - 8.3. Long-term control (follow-up).
 - 8.4. Other therapeutic use of investigational medicinal product.
 - 8.5. New safety data related to the combination therapies.
9. Safety findings from non-interventional studies.
10. Other clinical trial safety information.
11. Safety findings from marketing experience.
12. Non-clinical data.
13. Literature.
14. Other DSURs.
15. Lack of efficacy.
16. Region-specific information.
17. Late-breaking information.
18. Overall safety assessment:
 - 18.1. Evaluation of the risks.
 - 18.2. Benefit/risk considerations.
19. Summary of important risks.
20. Conclusions.