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| Annex 30 to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during the Validity Period of Registration Certificate (item 4 section IV) |

**Clinical study report**

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| 1. Name of medicinal product (registration certificate №, if available ) |  |
| 2. Applicant |  |
| 3. Manufacturer |  |
| 4. Studies conducted: | yes      no       if no, please justify |
| 1) type of medicinal product, which has been or will be registered |  |
| 5. Title of clinical trial, code number of clinical trial |  |
| 6. Phase of clinical trial |  |
| 7. Period of clinical trial | from \_\_\_\_ \_\_\_\_ \_\_\_\_ till \_\_\_\_ \_\_\_\_ \_\_\_\_ |
| 8. Countries, where clinical trial has been conducted |  |
| 9. Number of trial subjects | planned:  actual: |
| 10. Objective and secondary endpoints of clinical trial |  |
| 11. Clinical trial design |  |
| 12. Main inclusion criteria |  |
| 13. Investigational medicinal product, mode of administration and strength |  |
| 14. Reference product, dose, mode of administration and strength |  |
| 15. Concomitant therapy |  |
| 16. Criteria for evaluation efficacy |  |
| 17. Criteria for evaluation safety |  |
| 18. Statistical methods |  |
| 19. Demographic indices of studied population (sex, age, race, etc.) |  |
| 20. Efficacy results |  |
| 21. Safety results |  |
| 22. Conclusion (summary) |  |
| Applicant (registration certificate holder) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (full name) |

{Procedure amended by new annex 30 according to MoH Ukraine Order № 1528 of 27.06.2019 }