

Clinical study report

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 }