**M. Pharm II sem**

**Clinical trials and PV**

**Assignment 8**

**Name:**

**Roll no:**

**MCQs – Clinical trials**

1. Which of the following are not correct on the basis of clinical trials?

a) Biomedical research studies

b) Behavioral research studies

c) Studies on human subjects

d) Study based only on animals

2. What are the different types of clinical trials according to the U.S. National Institutes of Health?
a) 6

b) 5

c) 4

d) 3

3. What do you mean by a randomized design?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Randomly assigning subjects either for placebo or active dose

d) Signed document of the recruited patient for the clinical trial procedures

4. What is meant by blind subject?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Fake treatment

d) Signed document of the recruited patient for the clinical trial procedures

5. Which one of the following describes “double dummy”?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Fake treatment

d) Signed document of the recruited patient for the clinical trial procedures

6. What is placebo?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Fake treatment

d) Signed document of the recruited patient for the clinical trial procedures

7. What is informed consent in a clinical trial?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Fake treatment

d) Signed document of the recruited patient for the clinical trial procedures

8. Which one of the following is the last step of a clinical trial process?

a) Investigator selection

b) Patient recruitment

c) Statistical Analysis

d) Data filed and registration

9. Which one of the following will perfectly fit on the marked place?


a) Investigator selection

b) Patient recruitment

c) Statistical Analysis

d) Data filed and registration

10. Which one of the following will perfectly fit on the marked place?

a) Investigator selection

b) Patient recruitment

c) Statistical Analysis

d) Data filed and registration

11. Which one of the following will perfectly fit on the marked place?

a) Investigator selection

b) Patient recruitment

c) Statistical Analysis

d) Data filed and registration

12. How many people will be selected for phase I trial?

a) The whole market will be under surveillance

b) 300-3000 people

c) 20-300 people

d) 20-50 people

13. How many people will be selected for phase II trial?

a) The whole market will be under surveillance

b) 300-3000 people

c) 20-300 people

d) 20-50 people

14. How many people will be selected for phase III trial?

a) The whole market will be under surveillance

b) 300-3000 people

c) 20-300 people

d) 20-50 people

15. Which one of the following will be checked under phase IV surveillance?

a) The whole market will be under surveillance

b) 300-3000 people

c) 20-300 people

d) 20-50 people

**MCqs ICH GCP Responsibilities**

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| 16. Who is responsible for destruction of unused IMP? |
| a. The SponsorB. The InvestigatorC. The SubjectD. The Pharmacist17. Who is responsible for communicating with the Ethics Committee- |
| a. The SponsorB. The InvestigatorC. The Sponsor and the investigatorD. The Regulatory authority  |
| 18. According to ICH GCP the sponsor is responsible for appointing monitors. These monitors should be appropriately trained, and should have what else?a. documented evidence of GCP trainingb. monitor/CRA certificationc. scientific and /or clinical knowledge needed to monitor the trial adequately.d. experience in the specific therapeutic area of the trial. |
| 19. According to ICH GCP who should be responsible for the medical care of trial subjects at site?a. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trialb. the Investigatorc. The investigator or sub-investigatord. a Qualified physician20. What is missing: The sponsor should develop a systematic, prioritized, xxxxxx approach to monitoring clinical trials.a. approvedb. pragmaticc. auditedd. risk based21. According to ICH GCP (R2) results of monitoring activities should be documented in sufficient detail to allow verification of what?a. compliance with the monitoring planb. compliance with GCPc. trial progressd. compliance with the protocol22. What are the three main purposed of monitoring?a. Subject protection, data quality, protocol and GCP complianceb. Subject protection, management of project protocol and GCP compliancec. Data quality, subject recruitment, protocol and GCP complianced. Subject protection, data quality, compliance with project timelines23. According to ICH GCP (R2) who should review and follow up a monitoring report?a. the monitorb. the project managerc. the investigatord. the sponsor’s designated representative

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| 24. According to ICH GCP who can obtain consenta. only the investifgatorb. only the investigator or another physicianc. only the investigator or another healthcare professionald. only the investigator or a person designated by the investigator. |
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| 25. According to the Declaration of Helsinki (1996) who can obtain consenta. The investigator or a person designated by the investigator b. The investigator or another physicianc. The investigator or another healthcare professionald. Only the investigator |

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