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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Scholastic Assessment for Trialists (SAT): Answers

1. Only those sites in multicenter studies having contact with study participants require IRB review and approval?
. . . . . ( )$_T$ ( )$_F$
False *Review and approval necessary for all centers whether or not participant contact.*

2. A breakdown in randomization is an assignment scheme that fails to yield comparable treatment groups?
. . . . . ( )$_T$ ( )$_F$
False *Comparable with regard to what? It is foolish to believe that randomization is capable of producing comparable treatment groups with regard to the host of baseline characteristics that are of concern to a trialist. If you want comparability you should not trust to luck to achieve it.*

3. Why are British sailors called limeys?
Because of James Lind's scurvy trial showing the value of lime as a preventative for scurvy, though it was 50 years after the experiment before the British navy stocked ships with fresh limes and fruits.

4. Which of the following are possible stratification variables in a multicenter trial? (check all that apply)
( ) Age on entry
( ) Gender
( ) Clinic
( ) Compliance to assigned treatment
( ) All of the above
Age on entry, gender, and clinic*. Compliance cannot be used for stratification since it is not known at the time of randomization.*

5. The Tuskegee Syphilis Study was a trial involving poor black males?
. . . . . ( )$_T$ ( )$_F$
False *A trick question! The operative word is trial. The study, indeed, involved poor black males, but it was not a trial. It was an observational study.*

6. What was the issue that created the firestorm of concern over the Tuskegee Syphilis Study?
The fact that subjects in the study were not offered treatment for their syphilis once a treatment became available (penicillin).

7. The phrase "randomization worked" means that the treatment groups were comparable?
. . . . . ( )$_T$ ( )$_F$
True. *However, no self respecting trialist would talk that way. Randomization "works" if the assignments are the product of a random process properly administered. Hence, it "works" even if the product is not what one desires.*

8. Where was Ronald Fisher employed when he published his work on analysis of variance?
Rothamsted Experimental Station (an agricultural research station).

9. The modern day father of clinical trials?
Widely regarded as Bradford Hill.

10. Any assignment scheme lacking pattern is random?
. . . . . ( )$_T$ ( )$_F$
False *Though random and haphazard tend to be used interchangeably in everyday language they are different. The lack of pattern or of predictability does not mean that the underlying process is random in the scientific sense of usage.*

11. For a trial to be valid, people enrolled must be representative of the general population?
. . . . . ( )$_T$ ( )$_F$
False *Validity derives from the design and execution of the study, not from who is studied. In any case, all trials involve nonrepresentative populations. If for no reason, than for the fact that only those who consent can be studied.*

12. What do Henry Kissinger and the University Group Diabetes Program have in common?
Both requests under the freedom of information act (for Kissinger's telephone log and for raw data from the UGDP) wound their way through U.S. court systems to be heard together by the U.S. Supreme Court.

13 What does HIPAA stand for?
Health Insurance Portability and Accountability Act

14. What is an ITT analysis?
Intention to treat; jargon meaning all persons enrolled are counted to the treatment groups to which assigned regardless of treatment received.

15. When did IRBs come into existence?. 1974
( ) 1947
( ) 1952
( ) 1974
( ) 1981
1974

16. A person is enrolled in a trial but does not receive the assigned treatment. Where should the person be counted in analyses?
( ) In the control-assigned group
( ) In the group to which assigned
( ) Not counted
In the group to which assigned!

17. Who coined the phrase "Pigs is pigs and data is data"?
Jerry Cornfield

18. Define the following terms
Baseline data
An observation or set of observations made or recorded on a person just prior to or in conjunction with treatment assignment that serves as a basis for gauging change after enrollment.

Time window *The time interval for performing a specified activity or procedure; in trials the window for performing a specified examination or type of data collection; purpose to provide time limits beyond which an examination or data collection is counted as missed.*

Treatment failure
1: The failure of a treatment in a person to produce a desired effect or result. 2: Such a failure as observed, inferred, or declared by a study physician or other study personnel from measurements, evaluations, or observations on the person in question and resulting in cessation of the treatment or a treatment switch. 3: A person no longer receiving the assigned treatment; especially cessation of treatment occurring because of concerns regarding the safety or efficacy of the treatment. Usage note: The term should be used with caution because of the implied conclusion regarding treatment. Its use should be limited to settings where there is supporting evidence indicating failure. It should not be used simply as a synonym for treatment cessation.

Endpoint
A primary or secondary outcome measure, especially one recorded as an event such as death or a nonfatal morbid event, that results in termination or alteration of treatment or followup of the person. Best avoided because of misuse and potential for confusion. Most "endpoints" are not "ends" in regard to treatment or followup. Most protocols call for followup, and often treatment as well, over a defined period of time even in the presence of and following intercurrent events. As a rule, there are no endpoints in this operational sense of usage, except death. Use of the term can cause personnel at clinics to stop treatment and followup if they regard the term as having operational meaning.

Type I error
The probability of rejecting the null hypothesis when it is true, usually denoted by α.

19. A dropout is one who stops taking the assigned treatment?
. . . . . ( )$_T$ ( )$_F$
False *Broadly, a person who terminates involvement in a trial. Dropping out means treatment stops if administered during clinic visits, but may not have any impact on treatment if the treatment process was finished when the person dropped out (e.g., as in surgery trials).*

20. Consents were required by the NIH as a condition for funding in:
( ) 1947
( ) 1952
( ) 1954
( ) 1966
1966

21. Registration of trials became reality with the launch of ClinicalTrials.gov in:
( ) 1995
( ) 2000
( ) 2005
( ) 2010
2000

22. Blocked randomization is another name for stratification?
. . . . . ( )$_T$ ( )$_F$
False *Blocking is done to ensure the assignment ratio is satisfied after a specified number of assignments. Stratification involves randomization within defined strata, e.g., males and females with separate randomization schemes for the two strata.*

23 The first modern day trial is widely regarded as having been done by:
( ) Ambroise Paré during the battle to capture the castle of Villaine; 1537
( ) Lady Mary Wortley-Montague and Charles Maitland at the Newgate prison in London; 1721
( ) James Lind onboard the Salisbury; 1747
( ) John Snow at the site of the Broad Street pump in London; 1854
James Lind onboard the Salisbury; 1747

24. What is the meaning of the saying "*the way to cure a disease is to start a trial*"?
A comment on the impact of eligibility criteria on ability to find people eligible for enrollment.

25. The three basic principles outlined in the Belmont Report:

1. *Respect for persons*

2. *Beneficence*

3. *Justice*