

Cancer Clinical Trial Worksheet

Name: _____

Controlled trials have for decades been considered essential for proving a drug's value before it can go to market. Defenders of controlled trials say they are crucial in determining whether a drug really does extend life more than competing treatments. PLX4032 is a potential new superpill drug treatment for Melanoma (skin cancer) which shrinks tumors in the right patients, for a limited time. But will those who take it live longer? No one knows for sure.

Three pairs of siblings are available for the study. The doctors would like to treat each pair of siblings as a block assigning 1 sibling to take PLX4032 and the other sibling to chemotherapy, the standard cancer treatment for the last 30 years. The pairs are as follows:

Pair 1	Pair 2	Pair 3
James	Kyle	Cory
Sarah	John	Amy

1. Use the random number table on the back to randomly assign one sibling to the PLX4032 treatment and the other sibling to the Chemotherapy treatment.
(*hint: assign numbers 0-4 to be PLX4032 and numbers 5-9 to be Chemotherapy.*)

PLX4032 Group Members:

Chemotherapy Group Members:

2. Why would Chemotherapy be considered a “control” treatment in this case?
3. Each pair of siblings is a “block” in this design. Why?
4. Chemotherapy is an intravenous treatment (not a pill) with many obvious side effects. Would chemotherapy also be considered a Placebo? Yes No
5. “Control” groups are an essential part of any clinical trial. In this case the control group received chemotherapy, a notoriously ineffective treatment for melanoma. To discourage control group dropouts, any subject randomly assigned the control group is put on a global “blacklist” which prevents them from joining any other cancer study. Does this seem unethical? Explain why or why not.

6. Consider for a moment that one sibling has just received an experimental treatment that is believed to extend the life of the patient while it is known that Chemotherapy is very ineffective at combating Melanoma. This means that it is very likely one sibling will survive longer. Does using blocking in this design seem unethical? Explain.

7. The counter arguments are that (1) controlled clinical trials can prove that drugs like PLX4032 may be so much more effective than their predecessors. This drug will then be able to help thousands of people suffering from melanoma. (2) Utilizing a blocking design reduces variability in the response which means fewer subjects are needed. And, (3) the subjects assigned to the control group are receiving the best FDA approved treatment. Which parts of the design still seem unethical? Explain.

APPENDIX E Tables

Row	TABLE OF RANDOM DIGITS					
1	96299	07196	98642	20639	23185	56282
2	71622	35940	81807	59225	18192	08710
3	03272	41230	81739	74797	70406	18564
4	46376	58596	14365	63685	56555	42974
5	47352	42853	42903	97504	56655	70355
6	20064	04266	74017	79319	70170	96572
7	73184	95907	05179	51002	83374	52297
8	72753	36216	07230	35793	71907	65571
9	03939	30763	06138	80062	02537	23561