General question: In this randomized study, what is the effect of the drug on elevated potassium levels (i.e. hyperkalemia)?

Data sets:

1. t05xc: Adverse event data
2. t016: Lab test data
3. master\_data: Master database for clinical trial

Notes:

1. Hyperkalemia is defined as any potassium value >=5.5
2. Potassium values are recorded in the column labeled “k” in both the adverse event data set and the lab test data set.
3. Each patient may have multiple potassium values recorded. We are interested in whether each patient EVER experienced hyperkalemia. Assume that if no potassium values are available, then hyperkalemia was not present.
4. Patients are identified by “master\_id” in each of the data sets.
5. Each patient’s treatment assignment is identified by “treat” (0 for placebo; 1 for drug) in the master data set.
6. Geographic region is identified by “region” in the master data set.

Questions:

1. Is there evidence that the drug is associated with hyperkalemia?
2. Does the drug effect depend on geographic region?