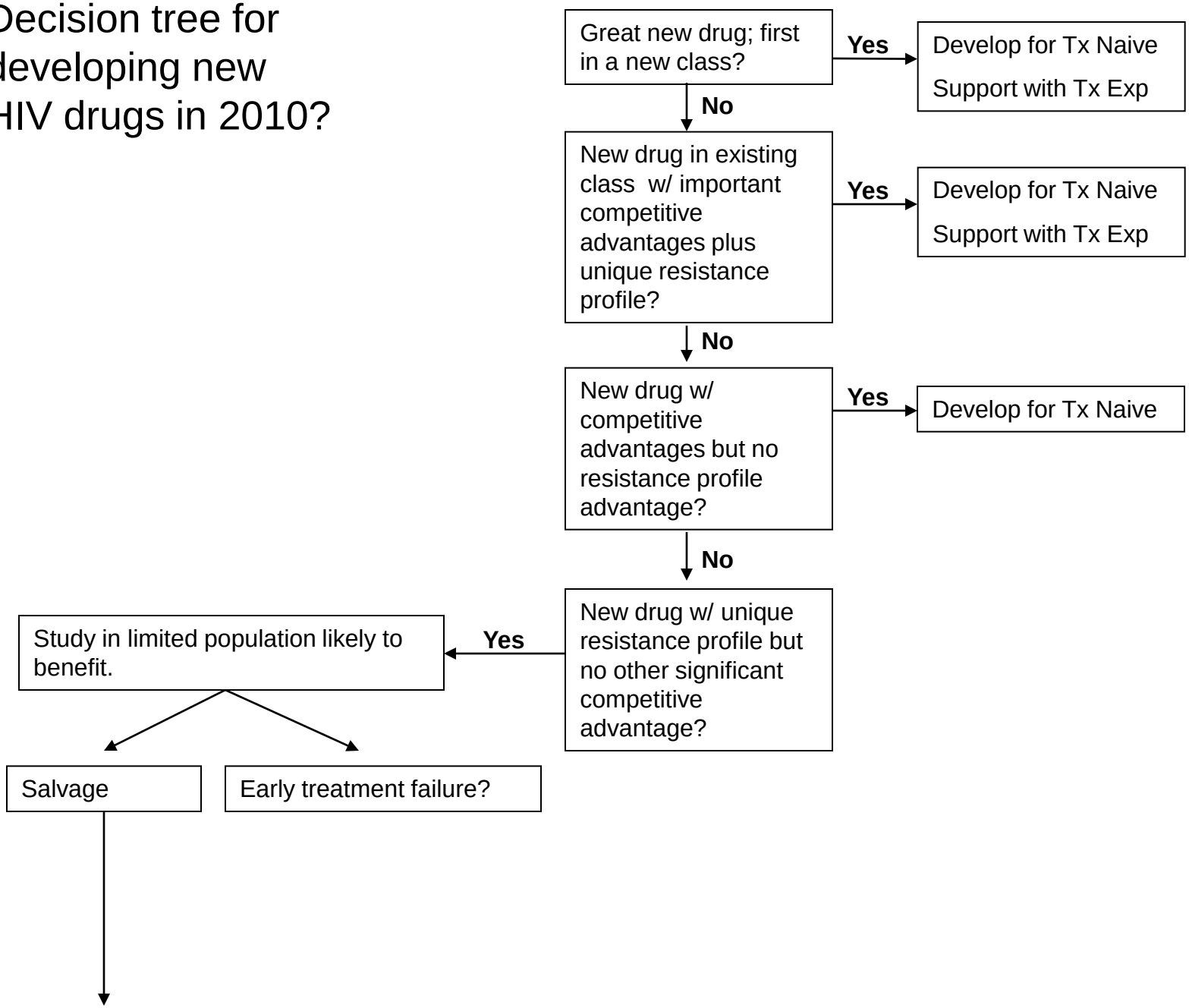
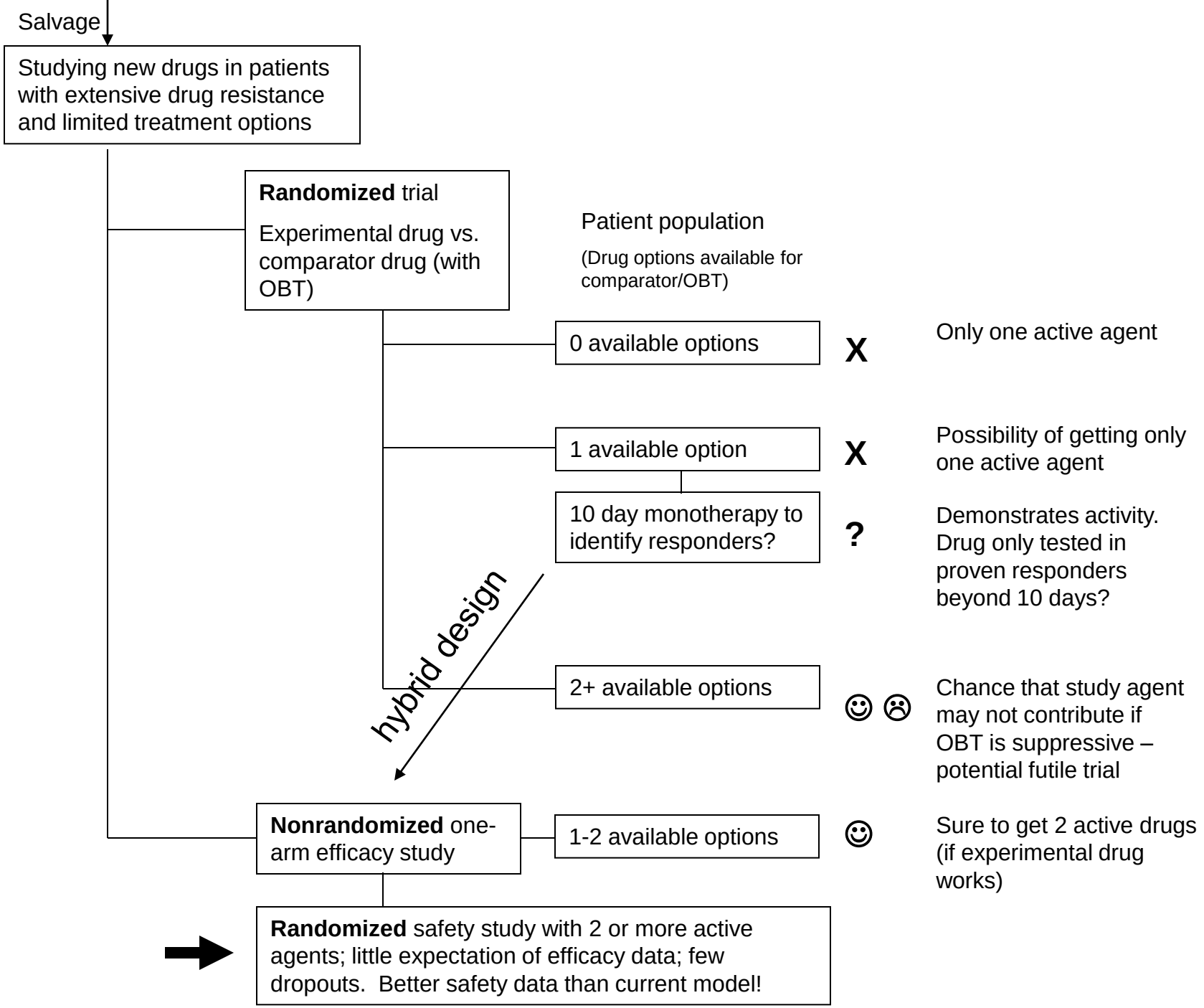
Decision tree for developing new HIV drugs in 2010?




Salvage
Studying new drugs in patients with extensive drug resistance and limited treatment options
Randomized trial
Experimental drug vs. comparator drug (with OBT)
Patient population
(Drug options available for comparator/OBT)
0 available options
X
Only one active agent
1 available option
X
Possibility of getting only one active agent
10 day monotherapy to identify responders?
?
Demonstrates activity. Drug only tested in proven responders beyond 10 days?
hybrid design
2+ available options
☺ ☹
Chance that study agent may not contribute if OBT is suppressive – potential futile trial
Nonrandomized one-arm efficacy study
1-2 available options
☺
Sure to get 2 active drugs (if experimental drug works)
Randomized safety study with 2 or more active agents; little expectation of efficacy data; few dropouts. Better safety data than current model!

From Avexa press release on closing its ATC program:

•“an inability to determine the level of activity of ATC when used in combination with a number of new active drugs on the market (which mask the level of activity).”

Is it possible/allowable to develop drugs for the small “salvage market?”

- What is scientifically and statistically possible/acceptable?
    - Keep temporal challenges apart for now...
        - size of subject population
        - willingness of investigators to participate

If we can stake out what is possible and what is acceptable to regulators, then motivated parties may find creative solutions to the other challenges