**Phase II study review**

You will need to read/review the following:

[HurvitzJCO2013protocol.pdf](http://people.musc.edu/~elg26/teaching/MCCR2015/ProtocolAssignments/HurvitzJCO2013.protocol.pdf)

[HurvitzJCO2013.pdf](http://people.musc.edu/~elg26/teaching/MCCR2015/ProtocolAssignments/HurvitzJCO2013.pdf)

[WilksBCR2015.pdf](http://people.musc.edu/~elg26/teaching/MCCR2015/ProtocolAssignments/WilksBCR2015.pdf)

The Wilks study was recently published and is a single arm phase II study.

The Hurvitz study is a randomized Phase II study that was published in 2013 with a protocol summary included.

1. *What were the primary objectives and the primary outcomes for each study?*
2. *For the Hurvitz study, does the published paper follow the protocol defined study plan? That is, are the results presented in the way that is consistent with the protocol?*
3. *The Wilks paper relies on the Hurvitz study for its baseline response rate. Please discuss. Include comments regarding the appropriateness of relying on the response rate from Hurvitz and why it may be an over- or under-estimate of a control response rate that would be expected in the Wilks study. Consider “Table 1” in each study where the patient characteristics are described.*
4. *Does that Wilks paper do a good job supporting that there results are comparable to other treatments for the same patient population? Discuss.*
5. *Based on the review of the two papers and the protocol, do you feel convinced that Eribulin Mesylate + Trastuzumab has a comparable response rate as compared to Docetaxel + Trastuzumab in this patient population? How do you think your response would change had Wilks et al. performed a randomized phase II study of Eribulin Mesylate + Trastuzumab versus Docetaxel + Trastuzumab?*