Author’s response to reviews

Title: A prospective, non-randomized phase-II trial of Trastuzumab and Capecitabine in patients with HER2 expressing advanced pancreatic cancer

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RE: Resubmission of a previously submitted paper to BMC Surgery

Dear Sir, Dear Madame,

It is our particular pleasure to resubmit our manuscript entitled:

“A prospective, non-randomized phase II trial of Trastuzumab and Capecitabine in patients with HER2 expressing metastasized pancreatic cancer “

to BMC Surgery for peer review and possible publication in this prestigious journal. This study protocol describes a currently recruiting multicentre trial conducted in Germany. In this study pancreatic cancer patients are treated with Capecitabine and Herceptin targeting the HER2 pathway. This is the first study of its kind in which all patients undergo testing for the therapeutic target (HER2) in the German reference pathology for pancreatic cancer in Kiel. T

This study was among the very first once conducted according the new Germany law for clinical trials in accordance with EU regulations. It has not been registered in one of the clinical trial databases and we feel that retrospective trial registration is not appropriate. Therefore this trial has no ISRCTN number, but as pointed out this study is conducted according the new and very strict Germany trial regulations.

The enthusiasm for this study is based on recent studies showing that these compounds are generally effective in pancreatic cancer in the case that
pretherapeutic testing for the therapeutic target (HER2) was done.

The current study protocol is the first publication originating from this multilinstitutional clinical trial. We are convinced that this kind of trials will represent the future direction in which pancreatic cancer therapy may progress in the next few years. We speculate that this manuscript may be of interest to the readers of the BMC Surgery.

We would be thrilled to hear from you.

Kind Regards

Peter Büchler, M.D.