Title of Research
Survival Modelling of Yervoy in Melanoma

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Data Sharing Agreement Date
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Summary of Research
The objective of this analysis is to assess:

1) The relationship between prognostic models built using pre-treatment data and how they correlate to early changes in imaging (e.g., percentage change in [sum of longest diameters], etc.)

2) Whether a parametric survival model using changes in imaging dynamics can be achieved (similar to what the FDA has done for non-small-cell lung cancer: http://www.ncbi.nlm.nih.gov/pubmed/19440187)

The methods for objective 1 will involve a classical multivariate Cox regression analysis against baseline measures with tests performed to assess the proportionality assumption for significant covariates. A forward selection approach will be used. The methods for objective 2 will follow the work of the following paper: http://www.ncbi.nlm.nih.gov/pubmed/19440187.

Melanoma is a severe type of skin cancer, which can spread to other parts of the body and can prove fatal. Patients with advanced melanoma can undergo surgery to have the cancer removed but there are many patients whose melanoma advances to a degree that cannot be treated with surgery. Many such patients alternatively get chemotherapy; however, many fail to respond adequately to chemotherapy as well. Yervoy (ipiluminab) is a novel chemotherapy agent approved for treating melanoma. In this analysis from a previous trial of Yervoy conducted in melanoma patients who had disease which had already failed chemotherapy and could not be treated with surgery, we will assess the accuracy of computer models designed to predict patient survival. In this analysis we will compare how well the models, which use patient characteristics before they start treatment, assess survival in these patients by assessing the tumor's response to treatment. How the cancer responds will be assessed using imaging studies such as CAT Scans, for example by seeing reductions in tumor size after treatment. The study will also analyze if the changes in tumor size and characteristics can be used to predict patients' risk of dying from the disease. Such analyses have previously been performed for lung cancer but not for melanoma.

Study Design
Given that this is an overall analysis of all the study data, a study design is not overly relevant.

Study Population
All patients in the analysis will be used, with no subgroups being analyzed.

Funding Source of Research
University of Manchester

Conflicts of Interests
Hitesh Mistry was formerly employed by AstraZeneca and is a consultant for Physiomics, SEDA, and Systems Forecasting. None of these associations will affect how the research is conducted, as this work is fully funded by the University and will be published.

Requested Study
CA184-002 (NCT00094653): A Randomized, Double-Blind, Multicenter Study Comparing MDX-010 Monotherapy, MDX-010 in Combination With a Melanoma Peptide Vaccine, and Melanoma Vaccine Monotherapy in HLA-A2*0201-Positive Patients With Previously Treated Unresectable Stage III or IV Melanoma