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Validating the PredicTR-OPC treatment response classifier for oropharyngeal cancer (PredicTR 2)

Principle Applicant: Hisham Mehanna

Co-Applicants: Professor Jonathan Deeks, Professor Tim Helliwell, Professor Christopher Holmes, Professor Dr Marcus Jepson, Mr Paul Nankivell, Professor Andy Ness, Mr Stuart Winter, Dr Miranda Pring, Dr Max Robinson, Professor Steven Thomas, Dr Rachel Spruce, Professor Nasir Rajpoot

Scientific Outline

Summary

Oropharyngeal cancer (OPC) is one of the most rapidly rising cancers in the West, mainly due to increased human papillomavirus related incidence. Chemotherapy and radiotherapy are the standard treatment for OPC. Adding surgery may improve outcomes for patients most at risk of recurrence, but can result in increased complications, poorer function and increased cost. We developed a 'biomarker-based test' to predict which OPC patients will benefit most from additional surgery; this could guide treatment decision-making. We intend to complete clinical validation of our biomarker test and convert it into a standardised assay which may be adopted into clinical practice. We will do this by:

1. Replacing one of the antibodies used to detect the biomarker Survivin with a CE marked product. We will demonstrate equivalence with the research use only reagent by staining samples from a previously tested cohort.
2. Investigating the potential to replace manual scoring by pathologists of the biomarker tumour infiltrating lymphocytes (TILs) with a computer based automated algorithm. This has the potential to improve reproducibility and time taken to score.
3. Testing the reproducibility of the biomarker-based test on whole tissue sections. If poorly reproducible, a qualitative study and further experiments will be done to address causes.
4. Validating the biomarker-based test in a prospective, independent external cohort under routine clinical conditions. OPC samples, already collected prospectively, will be stained and scored at 6 NHS laboratories. The performance and prediction accuracy of the test will then be evaluated.

Key words: Oropharyngeal cancer, biomarker-based test, clinical validation