

Additional response to Evaluation Report - Imatinib for the treatment of unresectable and/or metastatic gastrointestinal stromal tumours (part review of TA86)

This response is submitted by [REDACTED], RCP registrar on behalf of the following organisations:

Patient organisations

Sarcoma UK
GIST Support UK
Macmillan Cancer Support
Rarer Cancers Foundation
Beating Bowel Cancer
Bowel Cancer UK

Professional/medical organisations

Association of Cancer Physicians
The Institute of Cancer Research
NCRI Sarcoma Clinical Studies Group
Royal College of Physicians
Royal College of Radiologists
Joint Collegiate Council for Oncology

We are grateful for the opportunity to respond and would like to make comments on the following aspects of the Evaluation Report.

1. Statistical Modelling procedures

We believe that the statistical modelling procedures carried out and reported to the Committee are of a relative poor quality. The absence of high quality data challenges the rigidity of the NICE process. This is implicitly stated by the Review Group in their report, and when questioned by an expert witness at the Appraisal hearing was not denied. However, the economic evaluation continued despite the obvious resulting flaws. The uncertainty of the results is acknowledged in the Report but conclusions have been drawn on the basis that uncertainty leads to denial of treatment. This is a questionable principle and we know of no guidance applicable to this circumstance.

2. Trial data used by the modelling procedure

We would draw attention to the inadequacy of the trial data used by the modelling procedure. In rare diseases multi-national trials are the only way that statistically significant evidence can be developed. Large-scale studies conducted by multi-national study groups require consensus on study design and the use of such instruments as QoL. For a single nation to dictate design issues which carry cost and/or resource implications for every participating investigator's institution is not, we believe, a viable starting point for trial development.

3. Estimating the Quality of Life of GIST patients taking imatinib

The generic nature of the 'data' used to estimate the Quality of Life of GIST patients taking imatinib is very concerning. It appears to be taken from the literature with little or no investigation of what the patients themselves thought. In the particular case of GIST patients there are other factors to consider. Since GISTs are often asymptomatic for long periods of time, there is no 'typical patient'. Patients may present with very small (a few grams) tumours or extremely large (5kg) ones with widespread metastases. There are differing side-effects of surgery for patients with gastric tumours and those with rectal tumours. It is therefore almost impossible to assess the prognosis and life quality of such a varied set of patients. It is the opinion of our experts that the idea that the range and variety of experience and prognosis which GIST patients face can be captured by a single number is unlikely to be valid.