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Surrogate end points for overall survival. *Festina lente* (more haste, less speed)

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disclosure

The author has declared no conflicts of interest.

references

1. Maeda H, Kurokawa T. Acceptance of surrogate endpoints in clinical trials supporting approval of drugs for cancer treatment by the Japanese regulatory agency. Ann Oncol 2015; 26: 211–216.
2. Mauguen A, Pignon JP, Burdett S et al. Surrogate endpoints for overall survival in chemotherapy and radiotherapy trials in operable and locally advanced lung cancer: a re-analysis of meta-analyses of individual patients' data. Lancet Oncol 2013; 14: 619–626.
3. Johnson JR, Ning YM, Farrell A et al. Accelerated approval of oncology products: the food and drug administration experience. J Natl Cancer Inst 2011; 103: 636–644.
4. Ridker PM, Torres J. Reported outcomes in major cardiovascular clinical trials funded by for-profit and not-for-profit organizations: 2000–2005. JAMA 2006; 295: 2270–2274.
5. Braillon A. Vinflunine for non-small cell lung cancer: realistic hopes? J Thorac Oncol 2011; 6: 1777.
6. Braillon A. The many moral responsibilities of independent data-monitoring committees. Am J Bioeth 2011; 11: 16–17.

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Reply to the letter to the editor 'Surrogate end points for overall survival. *Festina lente* (more haste, less speed)' by Braillon

In the letter to the editor, Dr Braillon has made critical comments on using surrogate end points in clinical trials in oncology for drug approval from several viewpoints [1]. First of all, we would like to express our respect to him for giving thoughtful comments on our paper. There are some parts we agree with and some parts we don't.

First, taking lung cancer which has a poor prognosis, he pointed out that the time gain was limited by using progression-free survival (PFS) instead of survival as the end point. The time gain with PFS generally depends on estimated median survival post-progression time of each cancer type. Although it is difficult to validate PFS as the surrogate end point, the time gain