Reviewer’s report

Title: The trans-DATA study: Aims and Design of a Translational Breast Cancer Prognostic Marker Identification Study

Version: 0 Date: 23 May 2019

Reviewer: William Barlow

Reviewer's report:

This is a very good description of what is intended in trans-DATA. The manuscript is clear and well written.

It can be difficult to get such papers published without data, but there is value in establishing the plan in advance.

I only have a few minor comments about the plan.

The plan is to compare cases to matched controls. The controls are described as not having distant recurrence within six years, but they could have been censored within the follow-up period. They should still be eligible as controls. Please consider matching the case to a control whose follow-up time is at least the same as the case which could be less than six years. This is described as a time-matched case control study. Secondly only 60 controls are used in the discovery cohort, but 661 are used in the validation cohort. It would be more efficient to increase the number of controls in the discovery cohort (e.g. 1 case to 3 controls) as controls are overrepresented in the validation cohort.

Lastly consider a case-cohort approach instead of case control. The analytic work is more difficult, but the case-cohort design can accommodate different endpoints (such as DFS) and additional outcomes that occur with continued follow-up.

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