Predicting Biomarker success: a new toolkit

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Background & Aims: Increased resources have been spent on cancer biomarker (BM) discovery, for both prognostic and diagnostic purposes, but very few of these BMs have been clinically adopted. Therefore, in an attempt to bridge the gap between BM discovery and clinical use, this study aims to generate a BM assesment toolkit based on literature-reported attributes associated with successful BM implementation.

Methods: A checklist of BM attributes was created using Medline and Embase databases according to PRISMA guidelines. Retrospective validation of the checklist was achieved by six independent systematic literature searches using keywords/subheadings related to successfully implemented (n=2) and stalled (n=5) breast cancer BMs. Composite aggregated scores were generated for each selected publication based on the presence/absence of a characteristic listed in the BM checklist. Subsequently, logistic regression was performed to assess the relationship of each BM attribute/total average scores and the clinical implementation status.

Results: Attributes retrieved from literature and guidelines (n=125) were included in the BM toolkit. Average total % scores generated based on these attributes were significantly higher in the successfully implemented BM group (P<0.0001). The logistic regression model between the average total % score and BM clinical implementation status reached significance with sensitivity and specificity of 97.5% and 95.4%, respectively.

Conclusions: This study generated a validated checklist with literature-reported attributes linked with successful BM implementation. Upon future work and prospective validation, this toolkit could be used i) to detect BMs with the highest potential of being clinically implemented and ii) to shape how BM studies are designed and performed.

Keywords
Biomarkers, Clinical Implementation, Checklist