S10. Biomarker Development and Validation: Essential for the Future of Cancer Prevention

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A plethora of drugs, micronutrients, foodstuffs, and diet modification may delay or reverse carcinogenesis progression in common epithelial targets. Efficient, cost-effective, predictive early phase clinical translational models are limited. The costs and logistics of development and implementation of trials aimed at addressing a population based prevention hypothesis using a cancer endpoint remain overwhelming. Such barriers have limited progress towards implementing cancer preventive maneuvers in populations.

The use of biomarkers – pathologic, biological, and drug effect endpoints – permits more rapid and cost effective preliminary assessment of cancer preventive interventional efficacy in humans. Such a strategy may allow triage of interventions prior to population-based cancer endpoint trials. For example, reduction in number or recurrence of colonic adenomas supports efficacy of calcium and non-steroidal anti-inflammatory agents in preventing colorectal adenocarcinomas while not supporting the efficacy of dietary fiber.

Rapid discoveries of fundamental mechanisms of cellular transformation have identified numerous potential therapeutic targets. High throughput analytical technologies permit interrogation of biological samples for genomic and proteomic changes associated with neoplastic progression. Panels of multiple biomarkers detected and quantified using high throughput analytical tools can be used as risk assessment, early diagnostics, prognostic, and therapeutic monitoring endpoints. These new tools merit clinical translation in the form of biomarkers for early detection and for therapeutic endpoints.

Human biological diversity combined with neoplastic heterogeneity induces large variability in assayed biomarker endpoints. Useful data employing biomarker-based endpoints hinges on attention to key methodological details such as sample collection, storage, stringent analytical methods and complex data analysis. Linkage of biomarkers for early detection of neoplasias, carcinogenesis risk assessment, with preventive intervention efficacy endpoints promise to move the field of cancer prevention forward.