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Session 2: Cancer prevention: The scientific–epidemiological base

S6. The scientific basis of chemoprevention in humans: What's important?

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A large amount of experimental data indicates that the carcinogenic process can be blocked or interrupted. An equally abundant lexicon of epidemiologic observations suggests that dietary factors are associated with a lowered risk of cancer, either in general or related to a specific organ site cancer. However, except for the prevention of breast cancer the data in humans remains unconvincing, despite many phase III randomized trials. Among the major reasons, at least two this investigator, include:

- Incorrect or overenthusiastic extrapolation of epidemiologic data to clinical trials.
 - Poorly constructed phase II biomarker trials that do not usefully inform the design of phase III trials.
 - Failure to select doses of intervention agents bases on modulation of relevant markers in organ of interest.
 - Failure to develop a dose of drug that modulates relevant biomarkers without producing limiting toxicity.
- Alternative approaches to these conundrums and dilemmas will be proposed.