Design and analysis of window and neoadjuvant trials

Synopsis

The development of novel therapeutics in setting of patients with non-metastatic disease most often uses the setting of preoperative systemic therapy, including neoadjuvant trials with therapeutic intent and window of opportunity trials with translational intent. We’ll discuss issues of the design of such trials to meet the objectives, including the endpoints, statistical designs, safety considerations, as well as issues that arise in their analysis.