



META-ANALYSES OF CLINICAL TRIALS TO SUPPORT NEW DRUG APPROVAL.

IDDI has been involved in numerous meta-analyses to directly or indirectly support new drug applications. The purpose of these meta-analyses was to combine evidence from several trials in order to confirm efficacy and/or safety of a new drug; to explore different endpoints; to validate earlier endpoints as surrogates for later endpoints; and to look at meaningful subsets reliably (Buyse M. Contributions of meta-analyses based on individual patient data to therapeutic progress in colorectal cancer. *Int J Clin Oncol* **14**: 95-101, 2009; Buyse M. Use of meta-analysis for the validation of surrogate endpoints and biomarkers in cancer trials. *Cancer J* **15**: 421-5, 2009). Recently published meta-analyses performed with IDDI's methodology skills have ranged over an array of therapeutic areas including solid tumors (The GASTRIC (Global Advanced/Adjuvant Stomach Tumor Research International Collaboration) Group. Benefit of adjuvant chemotherapy for resectable gastric cancer: a meta-analysis. *J Am Med Assoc* **303**:1729-1737, 2010) as well as hematologic malignancies (Buyse M, Squifflet P, Lange BJ, Alonzo T, Larson RA, Kolitz JE, George SL, Bloomfield CD, Castaigne S, Chevret S, Blaise D, Lucchesi KJ, Burzykowski T. Individual patient data meta-analysis of randomized trials evaluating interleukin-2 monotherapy as remission maintenance therapy in acute myeloid leukemia. *Blood* 2011