Phase III, Randomized, Double-Blind Study of Sulfasalazine versus Placebo in the Prevention of Acute Diarrhea in Patients Receiving Pelvic Radiation Therapy

**Purpose of Study:**

1) The primary objective of this study is to determine whether sulfasalazine is effective in reducing the acute treatment-related diarrhea in patients receiving pelvic radiation therapy as measured by CTC, in patients receiving pelvic external-beam radiation therapy (EBRT) as adjuvant or primary treatment for malignancy.

2) The second goal will be to determine circulating levels of serum IL-6 are correlated with severity of acute enteritis and if sulfasalazine reduces the average level of serum IL-6 during radiotherapy.

3) The third goal will be to determine whether sulfasalazine can reduce chronic treatment-related bowel dysfunction following completion of therapy.

4) The fourth objective is to determine whether sulfasalazine causes any toxicity in this situation.

**Schema:**

Randomize
Sulfasalazine
Placebo