

**Phase II Study for Curative Intent Treatment for Patients Presenting with  
Oligometastatic Disease (UPCI #10-027)**

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## Summary

### Title: Phase II Study for Curative Intent Treatment for Patients Presenting with Oligometastatic Disease (UPCI #10-027)

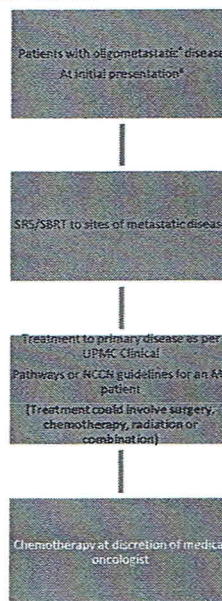
Hypothesis: Patients with oligometastatic disease (defined here as 5 or fewer sites of metastatic disease involving 3 or fewer organ systems) are potentially curable with stereotactic radiosurgery (SRS) or stereotactic radiotherapy (SRT) (collectively referred to as stereotactic body radiotherapy or SBRT) to the metastatic disease sites in combination with standard curative therapy to the primary site.

**Primary objective:** Phase II study to evaluate feasibility of this curative intent treatment approach to patients presenting with oligometastatic disease

#### Secondary objectives

1. Quality of life (as measured by FACT surveys)
2. Local control of metastatic sites
3. Local control of primary site
4. Overall survival
5. Analysis of patterns of failure post-SRS/SBRT

#### SCHEMA



\* oligometastatic disease defined as 5 or fewer sites of metastatic disease involving 3 or fewer organs

# Only patients with oligometastatic disease at presentation are eligible. Patients with recurrent disease are not eligible for this study.

#### **Patient Population:** (See Section 3.0 for Eligibility)

Patients with stage IV (M1) disease at initial presentation (newly diagnosed) who have 5 or fewer sites of metastatic disease involving 3 or fewer organ systems. Patients have not had previous therapy for disease.

**Required Sample Size:** 44 patients (See section 11.0)