

### Study Description

Study drug plus platinum-based chemotherapy in treatment of squamous cell carcinoma of the head and neck (SCCHN)

### Study Objective

Compare overall survival time of patients receiving chemotherapy with patients receiving the same chemotherapy plus study drug.

### Study Compound

Study Drug

### Patient Population

Patients with metastatic and/or recurrent SCCHN

### Treatment Period

As required – maximum 6 chemotherapy cycles

### Primary Efficacy Parameter

Survival time from randomization to death

### Participating Countries

Austria, Belgium, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Portugal, Russia, Slovakia, Spain, Sweden, Switzerland, United Kingdom, Ukraine

### Study Specifics

- Active sites: 89
- Patients: 420 (target)
- Recruitment period: November 2004 – June 2006
- Database lock: October 2007

### Quintiles Services

Project Management, Clinical Monitoring, Pharmacovigilance, IVRS, Data Management, Clinical Trials Supplies

### Overview

Communication is crucial in the management of clinical studies with multiple sites around the globe. In this worldwide trial, Quintiles established the working relationships needed to facilitate communication and ensure effective project monitoring. These efforts enabled the project to exceed its recruitment scheduling goals.

### Key Challenges

- Protracted study start-up due to problems with site contracts (United Kingdom and Germany).
- Lab logistics, calibrators and the lab contract.
- Provision of in-line filters to the sites.
- Ensuring resources and supplies were sufficient to keep ahead of the recruitment curve.
- Drug Safety Monitoring Board review occurred halfway through study.

### How Were These Challenges Met?

- The majority of sites recruited well and made up for the lengthy start-up. Continuous motivation was provided to encourage enrollment at inactive sites.
- Close communication with the lab and follow-up with the CRAs and sites.
- Continuous monitoring of the resource situation in each country was implemented to ensure that additional resource requirements were identified quickly and brought in at the appropriate time to ensure that work was not held up.
- Good working relationships with the customer and a close working partnership with Quintiles Global Data Management team led to mutual agreement on the data to be collected as well as timelines for database lock.

### Outcome

The original timeline called for 420 patients to be randomized between November 2004 and the end of June 2006. The actual first patient in was December 2004; 442 patients were randomized by December 30, 2005. Quintiles achieved the recruitment target six months ahead of schedule.