

## Study Description

A multi-center phase III randomized trial comparing Drug X in combination with prednisone to mitoxantrone and prednisone for advanced hormone refractory prostate cancer

## Study Objective

Global registration study

## Study Compound

Taxoid (in combination with prednisone)

## Patient Population

Patients with metastatic, hormone-refractory prostate cancer

## Treatment Period

Treatment until progressive disease or unacceptable toxicity to a maximum of 10 cycles of chemotherapy

## Primary Efficacy Parameter

Overall survival

## Participating Countries

Quintiles: Argentina, Austria, Belgium, Brazil, Czech Republic, Finland, Germany, Hungary, Ireland, Italy, New Zealand, Poland, Russia, Slovakia, RSA, Sweden, US  
Sponsor: Australia, Canada, France, Netherlands, Lebanon, Norway, Spain, UK

## Study Specifics

- Total number of active sites: 106
- Patients randomized: 1029 (609 by Quintiles and 420 by sponsor)
- Recruitment period: 27 months
- Recruitment dates: March 2000 – June 2002

## Quintiles Services

Project Management, Clinical Monitoring, Study-Site Coordination, Data Management, Statistics

## Key Challenges

- Because current survival data showed patients living far longer than expected, the target enrollment increased from 804 to 1000 patients for the 24-month period.
- Patient motivation and retention were challenging due to the long and intensive treatment period and the requirement to keep a diary.
- Data management was complex since data was sent from both Quintiles and sponsor CRAs.
- In addition, statistical programming and analysis were particularly challenging due to the high number of secondary endpoints. Because the study was breaking new ground in prostate cancer, there were no accepted conventions for the collection and analysis of secondary endpoints.

## How Were These Challenges Met?

- Quintiles' global reach facilitated site selection in countries with large patient populations and where access to expensive chemotherapy is usually limited. This encouraged both investigators and patients to participate as they would have access to "state-of-the-art" treatment not normally available in their area.
- Quintiles' knowledge of patient-referral patterns in the selected countries enabled quick identification of key investigators and maximization of referrals to them. Special strategies to broaden awareness of the study and create referral networks further facilitated recruitment of patients.
- In addition, local study-site coordinators assisted investigators with patient identification and retention.
- Joint workshops and training built strong, supportive relationships between the SSCs and CRAs. This partnership resulted in the timely delivery of high quality data to the Quintiles data management team.

## Outcome

Through outstanding motivation and coordination, Quintiles recruited a total of 609 patients, and the sponsor recruited 420, resulting in a total of 1029 patients in 27 months. Star recruiters were USA (202), Poland (77) and Hungary (64). Database lock was on target for both the interim and final analyses.

Patient Recruitment by Country

