

Pivotal Phase 2 Clinical Trial in Malignant Pleural Mesothelioma: Understanding of the Patient Pathway as a Critical Step in Developing a Robust Recruitment Campaign

Background

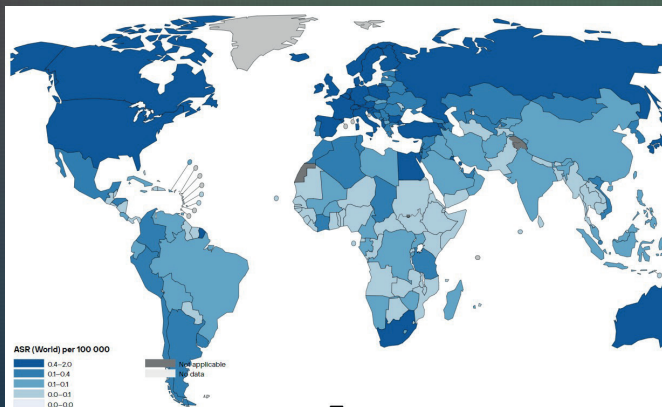
Malignant pleural mesothelioma (MPM) is a rare and among the most aggressive and lethal cancers. It is found in the lining of the lung which is often caused by exposure to asbestos. Tumours usually arise 30 years or more after exposure and 80% occur in men.

The incidence of mesothelioma in the United States is about 3,000 new mesothelioma cases per year, making it more rare than other cancers. The UK has the highest prevalence of mesothelioma cases in the world, with approximately 2,700 people diagnosed with the cancer each year. The incidence of MPM is rising worldwide and expected to peak in another 10-20 years.

Due to the aggressive nature of mesothelioma, treatment options are limited.

Age-Standardized Rate (World) per 100 000, Incidence, Both sexes, in 2022

Mesothelioma



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<https://gco.iarc.who.int/today>
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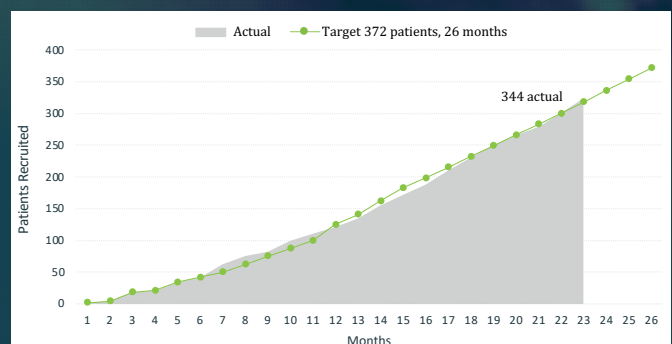
Objectives

TMC was requested by a US-based Biotech company to support patient enrollment in their pivotal registration Phase 2 clinical trial in treatment of patients with MPM. We successfully completed patient enrollment, by recruiting patients over a 24-month period, enabling 344 patients to participate across 74 sites globally.

Study design	A Phase 2 randomized, double-blind, placebo-controlled, multicenter study in subjects with malignant pleural mesothelioma
Purpose of study	To assess efficacy of the study drug in treatment of subjects with MPM who have been previously treated with cytotoxic chemotherapy
Number of patients	372
Number of sites	74 sites globally (16 countries across 4 regions: US, EU, UK, APAC)

Outcomes

Recruitment Projections Vs Actual (Study stopped early owing to futility)



Challenges & Solutions

Understanding the importance of a meaningful **patient pathway*** is a critical step in developing a robust recruitment campaign to meet the study targets.

Considering the potential patient population, TMC's solution is to generate and streamline the process of study recruitment by addressing the following issues:

- Who are the primary HCPs that are most likely in a position to be a source of subjects (identifying and referring them and/or providing them information about the trial opportunities)?
- Where are all the touch points and times the patient and HCP might learn about the trial opportunities?

Education and collaboration with the study site teams has been essential:

- TMC worked with the study sites to review each sites' pathway for mesothelioma patients presenting with a pleural effusion to ensure each relevant site department has an awareness of the clinical trial and so understands the impact of starting pleurodesis ahead of discussions around trial entry with the patient.

***Patient pathway** means a visual representation of how a patient (i.e. prospective study subject) navigates through the healthcare system and the touch points where they might learn about and encounter opportunities to get involved in the clinical trial.

It is estimated that up to 50% of patients with metastatic malignancy will develop a pleural effusion, either at the time of diagnosis, or during the evolution of their cancer [Kastelik 2013, Bennett 2005]. The most common etiologies for MPE are lung, breast, gastric, ovarian, and other cancers, in order of decreasing frequency. The four most frequent malignancies account for over 70% of all malignant pleural effusion (MPE). [Taghizadeh 2017, Roberts 2010]. Malignant mesothelioma is the most common primary pleural malignancy associated with a pleural effusion [Psallidas 2016].

Patient Pathway & Referral Network

