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## Integrating predictive biomarkers in the development of targeted cancer therapies

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The regulatory approval of new drugs for marketing requires a demonstration that the drug is safe and effective in the intended patient population that is specified in the drug label. In evaluating potential anticancer agents, there is a continued interest in using predictive biomarkers to select patients likely to respond or be resistant to a particular treatment. The ability to identify the subsets of patients with molecularly defined cancers could significantly improve patient outcome. Several clinically validated biomarkers such as HER2 and K-Ras mutation status has become an essential part of the clinical use of the HER2/EGFR targeted therapies. However, the identification of clinically useful predictive biomarkers for solid tumours has proven challenging with many initially promising biomarkers failing to translate into clinical useful applications. The problem mainly lies in the inherent heterogeneity of tumor cells as being found between tumor types, individuals with the same type of tumor, and within one tumor of a patient at any given time. The complex matter also poses challenges to the regulatory review of submissions for biomarker development and drug and biomarker co-development. This presentation will introduce the recent efforts of the US Food and Drug Administration in facilitating the development of biomarkers as well as case studies to highlight the major challenges in the discovery, qualification and regulatory review of predictive cancer biomarkers.

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## To evaluate the level of oxidative stress parameters and its relationship with clinical symptoms in women with fibromyalgia syndrome

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**Objective:** In the present study we examined the involvement of oxidative stress in women with Fibromyalgia Syndrome (FMS) and also evaluated its correlation with the severity of its symptoms.

**Introduction:** FMS is a common chronic pain syndrome with an unknown etiology. Increased oxidative stress results from an imbalance between products of oxidation and antioxidant defenses. There are several clinical conditions associated with increased oxidative stress, but novel data suggest a relationship between oxidative stress and pain perception. Furthermore, there is little information available in scientific literature about oxidative stress in FMS.

**Methods:** Oxidative stress was determined by measuring the levels of Lipid Peroxides (LPO) and Protein carbonyl group in plasma in 30 female patients satisfying American College of Rheumatology (ACR) criteria for FMS and 30 healthy females without FMS. Clinical parameters of FMS were evaluated by Fibromyalgia Impact Questionnaire Revised (FIQR).

**Results:** We found increased LPO and Protein carbonyl group in FMS patients as compared to control ( $p < 0.01$ ). A significant positive correlation was found between LPO and clinical symptoms of FMS among patients group. Furthermore, a significant positive correlation was also found between Protein carbonyl group and clinical symptoms of FMS among patients group in comparison to control group.

**Conclusion:** The present results indicate that women with FMS are exposed to oxidative stress and this increased oxidative stress may play a role in the etiopathogenesis of the disease. Moreover, our results also show that increased oxidative stress parameters are more strongly associated with FMS symptoms.

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