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7th Edition of International Conference on

Pain Management

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8th Edition of International Conference on

Internal Medicine & Patient Care

March 25-26, 2019
Rome, Italy

Laurent Ecochard, Int J Anesth Pain Med 2019, Volume 5
DOI: 10.21767/2471-982X-C1-005

# Strategic and operational considerations in designing and executing multicenter pain trials

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**Pain is a symptom related to a heterogeneous group of disorders. Pain can be further subdivided into whether the origin of the pain is nociceptive, neuropathic, or mixed nociceptive/neuropathic origin. Peripheral neuropathic pain is a pain initiated or caused by a primary lesion or dysfunction in the nervous system. For the indication of the treatment of neuropathic pain, FDA recommends to conduct one in each of atleast three separate neuropathic conditions while EMA only recommends two separate conditions (one trial each). In this context, several investigational drugs have failed to show benefit in reducing the pain intensity in the past two decades and have led the sponsors of the same compounds to terminate their programs of development prematurely. Several design considerations are now widely recommended to improve assay sensitivity and increase the chance of success of the chronic pain therapies under investigation. Besides these study design factors, patient, study site and outcome measurement factors have to be carefully taken into consideration. Once the multi-centre pain trials are actively recruiting, the operational teams frequently deal with difficulties to identify the right candidates for enrolment and as many screened patients do not qualify due to uncontrolled co-morbid conditions and/or prescribed pain medications that are not allowed per protocol. Given the prevalence and incidence of neuropathic pain, there is a clear need for better treatment as the related conditions have such a severe impact on the patient's ability to function on a daily basis thus affecting overall quality of life, but also represent a substantial burden for family and caregivers. In this regard, innovative adaptive (enriched) study designs may have a major impact on increasing the probability of positive study results with these potential better treatments that are randomly compared to placebo as randomized placebo controlled multi center pain trials are recommended in neuropathic pain.**

### Biography

Laurent Ecochard has completed his PhD in Physiology by University of Lyon, France. He has served as a study coordinator in oncology and hematology units of Paris Public Hospital and has acted as a Clinical Research Associate in different therapeutic areas across the pharmaceutical industry in France. He has then endorsed responsibilities as Project Manager and ultimately as Clinical Study Leader in General Medicines at Novartis. He has published several papers in reputed journals and is currently working as a Clinical Development Director on the Olodanrigan Program of Development in Peripheral Neuropathic Pain at Novartis Pharma AG, Switzerland.

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