The MGTX experience: challenges in planning and executing an international, multicenter clinical trial.

Submitted by caban on Mon, 09/08/2014 - 2:45pm

Title
The MGTX experience: challenges in planning and executing an international, multicenter clinical trial.

Publication Type
Journal Article

Year of Publication
2008

Authors
Aban, IB, Wolfe, GI, Cutter, GR, Kaminski, HJ, Jaretzki, A, Minisman, G, Conwit, R, Newsom-Davis, J

Corporate Authors
Mgtx Advisory Committee

Journal
J Neuroimmunol

Volume
201-202

Pagination
80-4

Date Published
2008 Sep 15

ISSN
0165-5728

Keywords
Clinical Trials as Topic, Ethics Committees, Research, Humans, International Cooperation, Myasthenia Gravis, Retrospective Studies, Thymectomy

Abstract
We present our experience planning and launching a multinational, NIH/NINDS funded study of thymectomy in myasthenia gravis. We highlight the additional steps required for international sites and analyze and contrast the time investment required to bring U.S. and non-U.S. sites into full regulatory compliance. Results show the mean time for non-U.S. centers to achieve regulatory approval was significantly longer (mean 13.4+/0.96 [corrected] months) than for U.S. sites (9.67+/0.74 [corrected] months; p=0.003, [corrected] t-test). The delay for non-U.S. sites was mainly attributable to Federalwide Assurance certification and State Department clearance.

DOI
10.1016/j.jneuroim.2008.05.031

Alternate Journal
J. Neuroimmunol.

PubMed ID
18675464

PubMed Central ID
PMC2654214

Grant List
5U01NS42685-03 / NS / NINDS NIH HHS / United States
U01 NS042685-03 / NS / NINDS NIH HHS / United States