



**CLINICAL STUDY REPORT
FINAL**

Study Number: 109-HV-101

**A Single-Center, Randomized, Blinded, Placebo- and Active-Controlled Study to
Evaluate the QTc Interval Prolongation Potential of BG00012 When Administered to
Healthy Volunteers**

Name of Study Treatment: BG00012 (Dimethyl fumarate)

Indication: Not applicable

Development Phase: 1

Date of First Treatment: 10 September 2006
Date of Study Completion: 16 November 2006

Sponsor: Biogen Idec Inc.
14 Cambridge Center
Cambridge, MA 02142

Name of Sponsor Signatory: [REDACTED]
VP, Chief Medical Officer
[REDACTED]

Sponsor's Study Medical Director: Katherine Dawson, MD
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Report Date: 16 April 2007

To the best of the sponsor's knowledge, this study was conducted in compliance with the requirements of the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), United States 21 Code of Federal Regulations (CFR) Parts 50, 56, and 312, and other applicable standards for the protection of human subjects and integrity of clinical data. It has been monitored by the sponsor or by the sponsor's representative. There were no deviations from the above-referenced standards that, in the view of the sponsor, were likely to have compromised the integrity or quality of the study, the interpretation of the results, subject safety, or ethical standards. Essential documents, as described in ICH E6, have been archived in Central Clinical Files and in an electronic study file.