CLINICAL STUDY REPORT

FULL

FINAL

Study Number: 109MS302

Study Title: A Randomized, Multicenter, Placebo-Controlled and Active Reference (Glatiramer Acetate) Comparison Study to Evaluate the Efficacy and Safety of BG00012 in Subjects With Relapsing-Remitting Multiple Sclerosis

Name of Study Treatment:	BG00012 (dimethyl fumarate)
Indication:	Relapsing-Remitting Multiple Sclerosis
Development Phase:	3
Date of First Treatment:	28 July 2007
End of Study Date:	24 August 2011

Sponsor:

Biogen Idec Inc.
14 Cambridge Center
Cambridge, MA 02142
United States

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Report Date: 14 January 2012

This study was conducted in accordance with the ethical principles of Good Clinical Practice, according to the ICH Harmonized Tripartite Guideline.

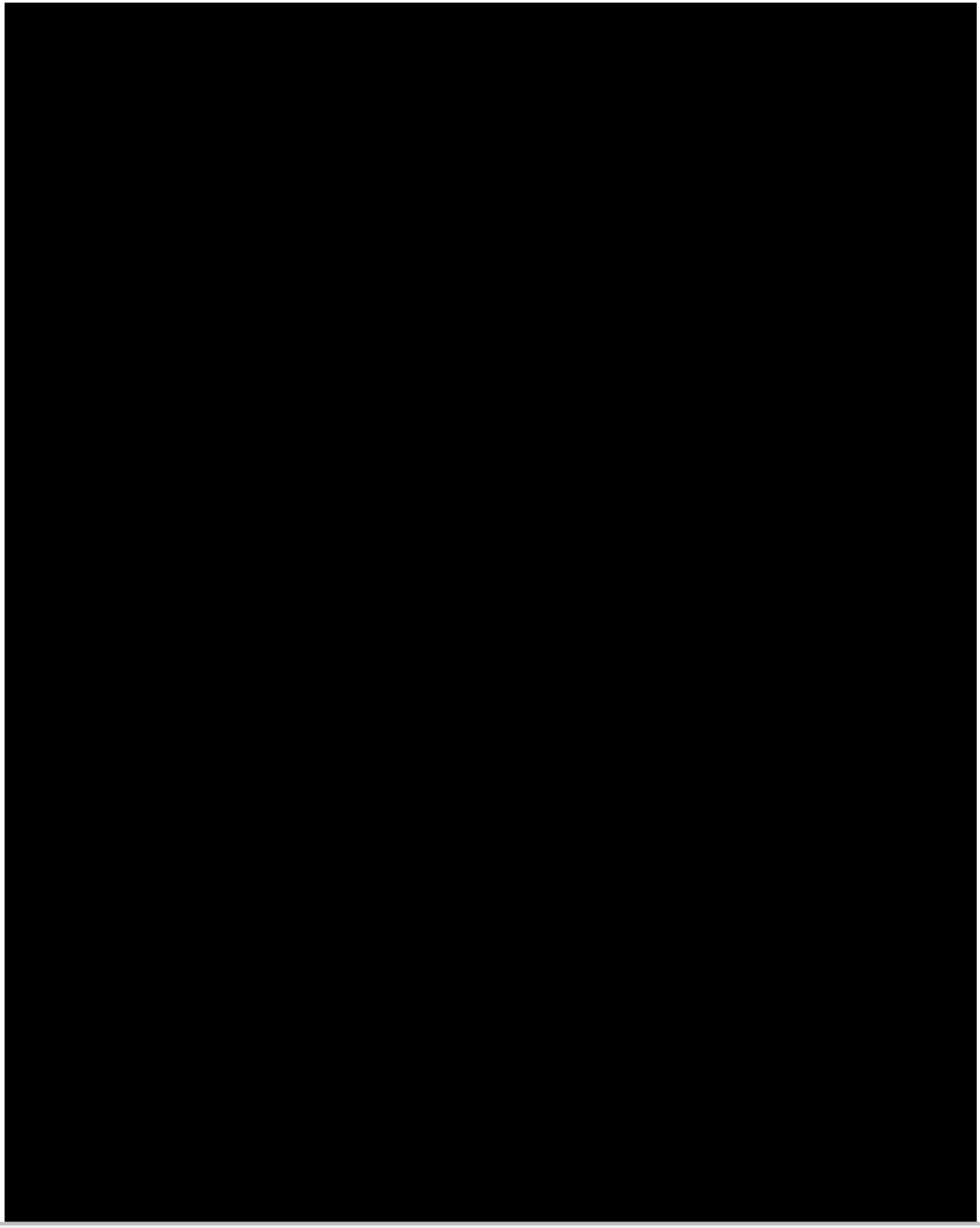
6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

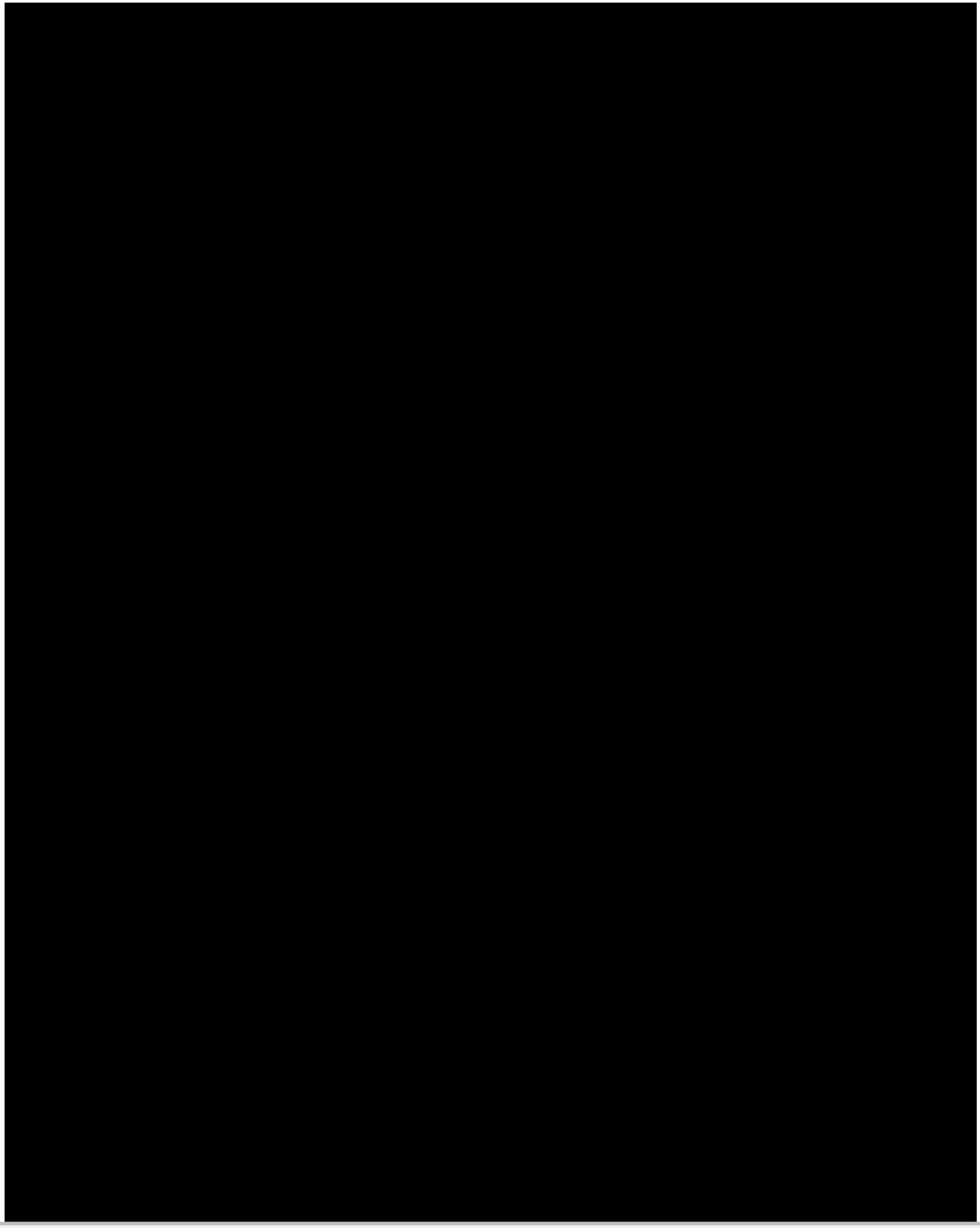
6.1. Investigators

[redacted]

Investigator meetings and/or site initiation visits were held for the purpose of training the Investigators, examining and treating neurologists, study coordinators, and other team members on the procedures, tests, and evaluations to be used in the study. Investigator meetings occurred in Dublin, Ireland (February and April 2007); Boston, Massachusetts, US (June 2007); Cancun, Mexico (January 2008); Budapest, Hungary (January 2008); and Istanbul, Turkey (November 2008). Training for site personnel who did not attend an Investigator meeting was also provided at site initiation visits that occurred before the start of the study. Additionally, a live meeting webcast for Investigators in the US was held (December 2007), and additional mid-study meetings were held to provide ongoing training to site personnel. Subjects were not enrolled at a given investigational site until after the study staff training had occurred. See Section 9.6 for additional information on training.

[redacted]





[redacted]

6.3. Laboratories

The central laboratories contracted to acquire and evaluate MRI scans, analyze clinical laboratory samples, and evaluate electrocardiograms (ECGs) collected in this study are listed in Table 1.

Table 1: Central Laboratories Used in Study 109MS302

Central Laboratory	Responsibilities
[redacted]	Analysis of clinical samples and sample management. The laboratory manual, documentation of accreditation, and reference ranges are provided in Appendix 16.1.10.
	Evaluation of ECGs collected for this study. The ECG Procedures Manual is provided in Appendix 16.1.10.
	Acquisition and evaluation of MRI scans with and without gadolinium, was performed under the direction of [redacted]. The Imaging Review Charter and site acquisition guidelines are provided in Appendix 16.1.10. MRI assessments are described in Section 9.5.2.2.

[redacted]

6.4. Contractors and/or Vendors

Contract research organizations and vendors that performed services in this study are listed in Table 2 with their respective responsibilities.

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