CLINICAL STUDY REPORT

FULL

FINAL

Study Number: 109MS301

Study Title: A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis

Name of Study Treatment:	BG00012
Indication:	Relapsing-Remitting Multiple Sclerosis
Development Phase:	3
Date of First Treatment:	14 March 2007
End of Study Date:	23 February 2011

Sponsor:	Biogen Idec Inc. 14 Cambridge Center Cambridge, MA 02142 United States	Biogen Idec Ltd. Innovation House 70 Norden Road Maidenhead Berkshire SL6 4AY United Kingdom
Name of Sponsor Signatory:	Gilmore N. O'Neill, MB, MRCPI, MMSc Vice President, Clinical Development, MS	
Sponsor's Study Medical Director:	Katherine T. Dawson, MD Senior Director, Clinical Development, MS	

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.

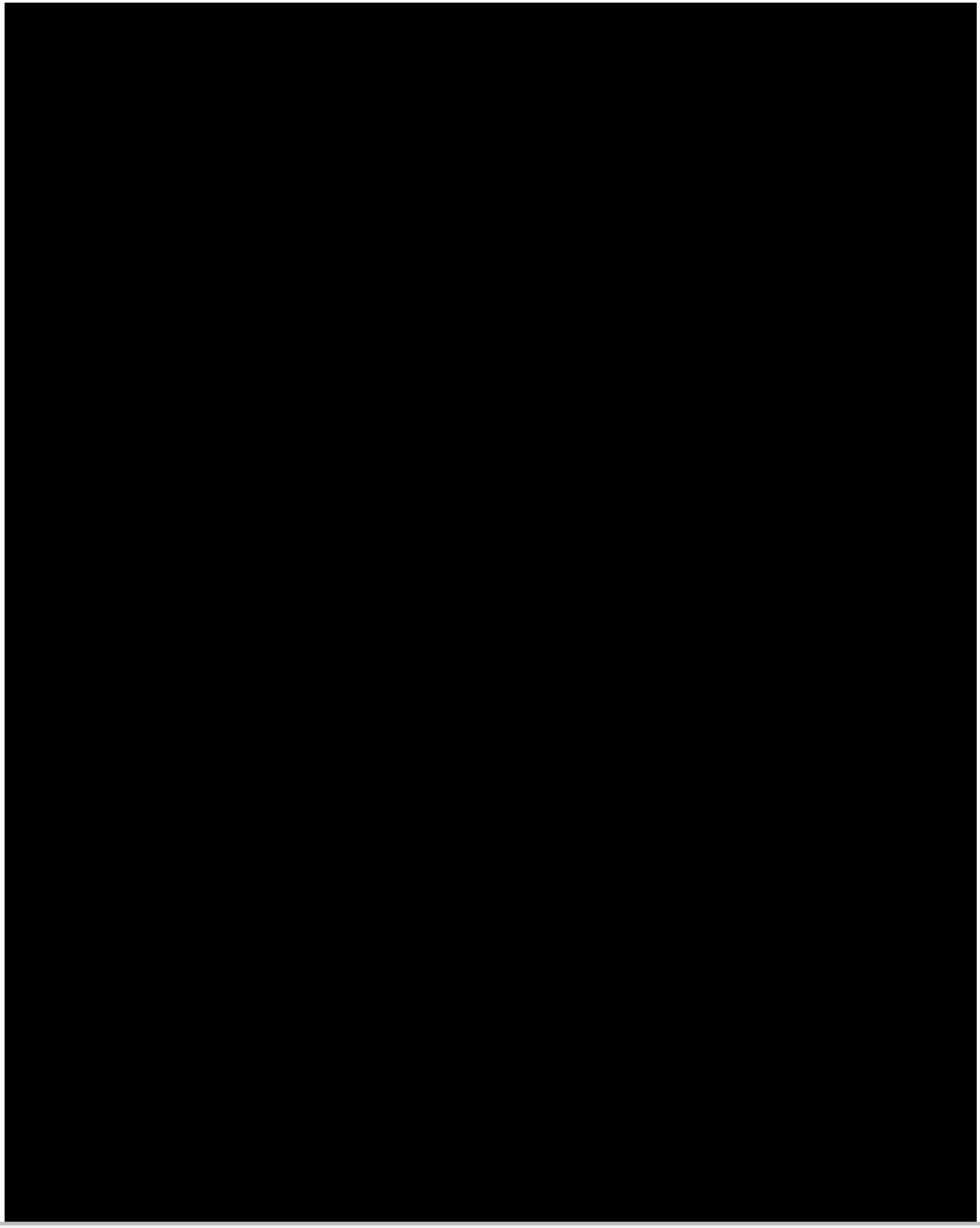
6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

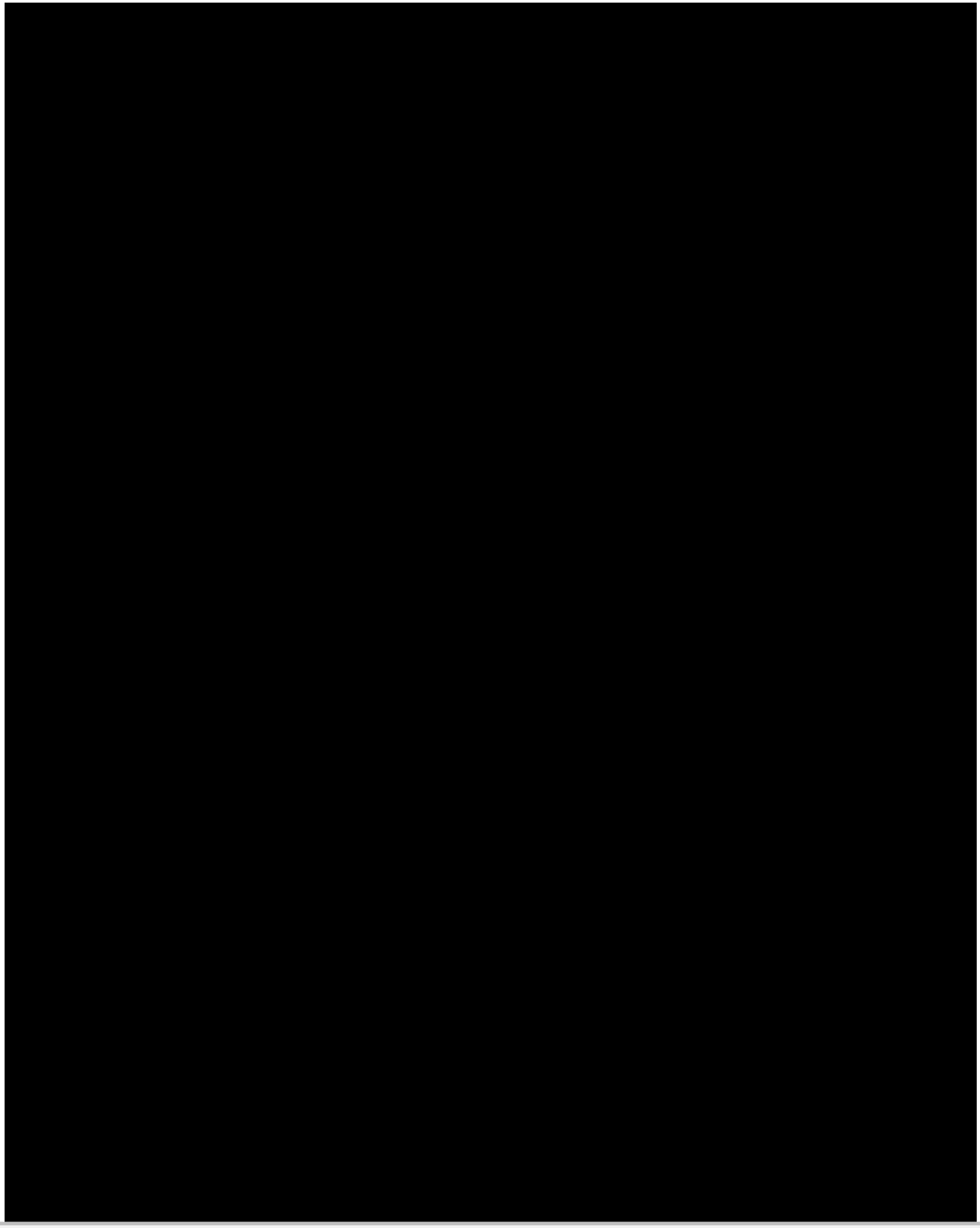
6.1. Investigators

[redacted]

Investigator meetings 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. The 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). Additionally, a live meeting webcast for Investigators in the US was held (December 2007). Training was also provided at site initiation visits that occurred before the start of the study. 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 6-1.

Table 6-1: Central Laboratories Used in Study 109MS301

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 Gd, under the direction of [redacted], MD. The Imaging Review Charter is provided in Appendix 16.1.10. MRI assessments are described in Section 9.5.2.2.

[redacted]

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