BG-12 Program Team Meeting Minutes 25 May 2006	
To	Program Team
PT Attendees	[redacted] Cara Lansden, Tammy Sarnelli,
Other Attendees	[redacted]
Next Meeting	**Thursday, June 1; 1100-1200 ET/800-900 PT/1600-1700 UK**

[redacted]

Topic/Presenter	Summary
	[redacted]

3. Scenario planning for regulatory feedback	o The three EU scientific agencies with meeting in June (Sweden 6/12, Netherlands 6/21, UK 6/27) will all receive the same briefing document, no time to change between them
	  o Spain meeting to be in July, could be used for validating contingency plan if trial design needs to be changed
	  o France could be added if additional fallback guidance is needed
	o Four key issues that we should expect to receive feedback:
	  o Choice of endpoint, no direct comparison between active comparator and BG-12, choice of Copaxone as comparator (including lack of double dummy placebo) and using subset of patients for MRI
	o If we receive consistent feedback from EU agencies we should change plan accordingly prior to receiving advice from FDA
	o Need to revisit discussion at next week's Program Team meeting to finalize recommendation on our approach to mixed feedback from EU agencies
	[redacted]

4. Planning for FDA EOP2 meeting	o Plan to request End of Phase II meeting with FDA in mid-June, targeting mid-August for actual meeting o Timeline to complete draft of FDA Briefing document by June 13, then iterate and review for mid-July submission o Timeline could be impacted if we make changes based on EU agency feedback o Need contingency plan with clear decision point to make changes to clinical development o [redacted], Cara and Tammy will review clinical and regulatory timelines, to revisit at next week's Program Team meeting [redacted]
[redacted]	[redacted]

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