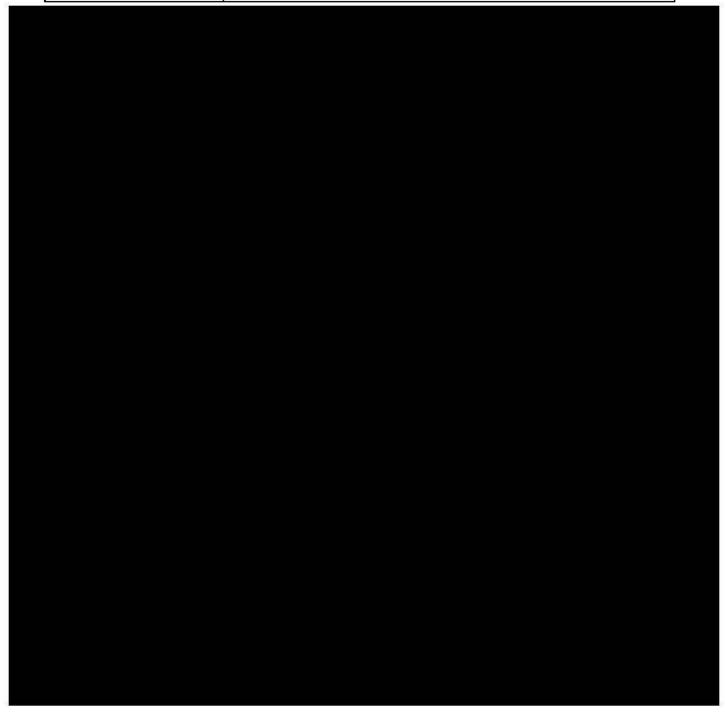
BG-12 Program Team Meeting Minutes 25 May 2006			
То	Program Team		
PT Attendees	Sarnelli,	Cara Lansden, Tammy	
Other Attendees		. .	
Next Meeting	Thursday, June 1; 1100-1200 ET/800-900 PT/1600-1700 UK		





Topic/Presenter	Summary	
3. Scenario planning for regulatory feedback	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 Spain meeting to be in July, could be used for validating contingency plan if trial design needs to be changed France could be added if additional fallback guidance is needed Four key issues that we should expect to receive feedback: 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 If we receive consistent feedback from EU agencies we should change plan accordingly prior to receiving advice from FDA Need to revisit discussion at next week's Program Team meeting to finalize recommendation on our approach to mixed feedback from EU agencies	
Planning for FDA EOP2 meeting	 Plan to request End of Phase II meeting with FDA in mid-June, targeting mid-August for actual meeting Timeline to complete draft of FDA Briefing document by June 13, then iterate and review for mid-July submission Timeline could be impacted if we make changes based on EU agency feedback Need contingency plan with clear decision point to make changes to clinical development Cara and Tammy will review clinical and regulatory timelines, to revisit at next week's Program Team meeting 	

