109MS301 Advisory Committee
Friday, 19 January 2007

DISTRIBUTION / ATTENDEES

Committee Members

[redacted]

Biogen Idec

[redacted]
Kate Dawson
Phill Gallacher
[redacted]

Names in **BOLD** attended this meeting

[redacted]

- [redacted] provided the committee with a high-level summary of study status:
  - 106 sites have been approved to participate in the study.
  - There have been 4 Ethics Committee submissions with one approval (Canada)
  - There have been 4 Regulatory submissions, with 2 approvals (Australia and Canada)
  - Two sites have been initiated ([redacted] in Australia and [redacted] in Canada)
  - Feasibility has begun in Romania and Bulgaria
  - We are expecting feedback from the Belgian Ethics Committee next week

[redacted]

Any Other Business

- Clinical received feedback from the FDA on the SPA submission, which included a set of stipulations on the number of MRIs to be performed in the sub-study. The team initially thought they would have to increase the number of sites in the study to meet this criteria, however, after review, neither the number of sites nor the number of patients in the sub-study will be increased. A 6-month MRI may be added in as discussed previously in the upcoming amendment. The target is for MRIs

[redacted]