

109MS301 Advisory Committee
Friday, 2 February 2007

DISTRIBUTION / ATTENDEES

Committee Members

[REDACTED]

Biogen Idec

[REDACTED]
Kate Dawson
Phill Gallacher
[REDACTED]

Names in **BOLD** attended this meeting

[REDACTED]



INEC Assessment Documentation Review

- The INEC assessment documentation was shared with the Advisory Committee.
- [REDACTED] has been hired to serve as the administrator and monitor of the INEC.
- The Advisory Committee was asked if the information provided would be enough for an INEC member to confirm if a patient has had a relapse.
 - Consistency is the goal; the clinical team wants the decision to be made using the same body of information.
 - Of the data we are already capturing, what would an independent body need to make an assessment?
- It was suggested the clinical team speak to neurologists who have been on this type of committee before.
 - [REDACTED] were suggested as possible contacts.

Study Update

- [REDACTED] provided the committee with a high-level summary of study status:
 - 119 sites have been approved to participate. One site in Slovakia declined after being approved.

- The clinical team would like to add 41 more sites to the study to meet timelines.
- The timeline will be amended to reflect study start-up challenges.

