

BG00012 Phase 3
109-MS-301 and 109-MS-302
Thursday, 07th December 2006

DISTRIBUTION / ATTENDEES

BIIB Attendees

[REDACTED]

[REDACTED]
Kate Dawson

Minhua Yang
[REDACTED]
Phill Gallacher
[REDACTED]
Ratna Lingamaneni
[REDACTED]

[REDACTED]

Names in **BOLD** attended this meeting

[REDACTED]



109MS301 Study Status Update – P. Gallacher

Australia:

- Site Initiation Visit (SIV) at [REDACTED] site scheduled for 14 Dec to be confirmed
- [REDACTED] (BIIB Lead CRA) will be the only individual in direct contact with the site
- [REDACTED] identified as back-up site for FPI
- [REDACTED] (BIIB Australia) said she would approve us to ship drug after TGA completed provided [REDACTED] is ready to enroll

Action: P Gallacher will follow-up with [REDACTED] to make sure that is in accordance with [REDACTED] SOP (we will submit a deviation if it is not)

Canada:

- Response from Health Canada: had some CMC questions only, responses to questions are going in today (07 Dec), and regulatory is waiting to see if they have any clinical questions

Austria:

- Potentially able to bring submission date forward

Belgium:

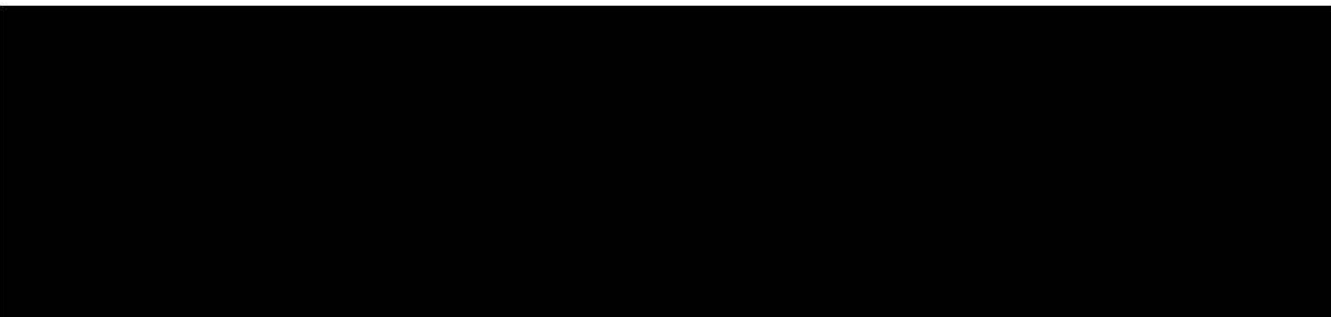
- EC submission due to go in today, submission deadline is 11 December

Germany:

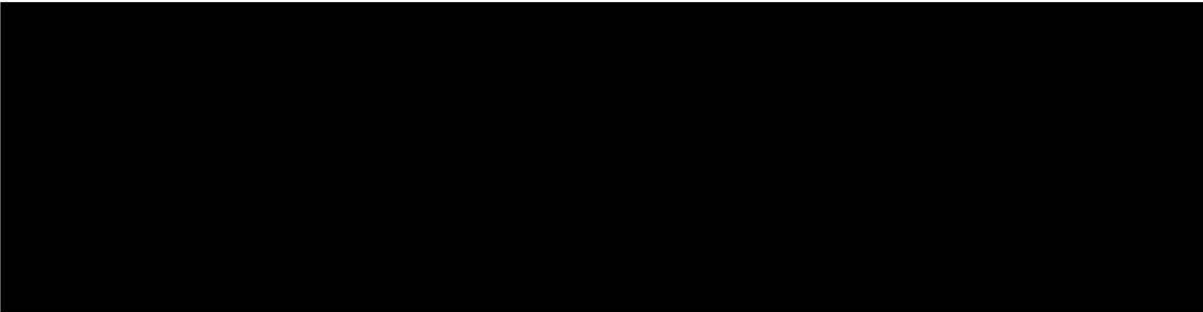
- Have had good response, there are a lot of PSSV to be done there

Action: By next Friday (15 Dec) the team to make the decision to go forward with current sites selected to make the submission deadline, then add other sites as they are identified

Site Selection:

- The team is working with [REDACTED] and Commercial to add sites in Bulgaria, Romania and Serbia if Avonex and Copaxone are confirmed as approved therapies. **Post Meeting Note:** Serbia does not have Avonex or Copaxone approved
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109MS302 MRI Vendor Update – [REDACTED]

- MRI center Administrator has issued letter of intent and is working on the contract
 - A few administrative documents are being finalized and will be ready before Christmas
 - The Scope of Work (SOW) is in progress and should be finished by end of next week
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[REDACTED]

Announce Advisory Committee Member List - [REDACTED] K.Dawson

- 301 advisory committee list announced, 302 list pending
- MP agreed in principle and wants to add extra members so there is an odd number
- Internally, [REDACTED] P Gallacher and K Dawson will be on the committees

Continue DSMC Charter Review/Discussion – [REDACTED]

- The team reviewed the charter and comments
 - [REDACTED] is external independent non-voting statistician and is un-blinded
 - [REDACTED] is the voting statistician, but he has not formally committed to be on the DSMC
 - Taking MRI data out
 - Committee duration: have commitment end after last patient visit
 - Looking into adding cardiologist
 - Following the teams' discussion, [REDACTED] will incorporate the comments into the DSMC Charter, such charter will be presented as is to the DSMC Members, following their review/comment the charter will be finalized
- [REDACTED]

