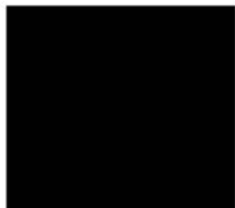
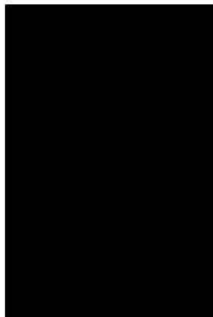


BG00012 Phase 3
109-MS-301 and 109-MS-302
Thursday, 8th February 2007

DISTRIBUTION / ATTENDEES

BIIB Attendees



Kate Dawson



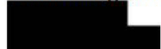
Minhua Yang



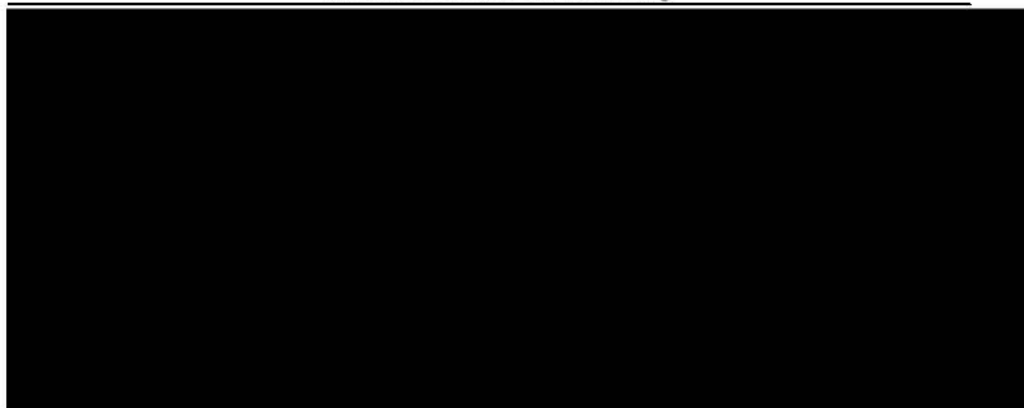
Phil Gallacher



Ratna Lingamaneni



Names in **BOLD** attended this meeting





Clinical Update:

109MS301 Study Status Update

- 120 sites Sponsor approved
- 150 PSSV completed – currently following up with US, Romania & Bulgaria to give 160 sites

Australia:

-  SIV date 20th March
-  update: 6 patients identified:
 - 1 Rejected – dosing schedule
 - 3 currently reviewing ICF – Site to follow up
 - 2 currently reviewing medical history

BG12 SMT Meeting Minutes

Belgium:

- SIV dates for Belgium have been targeted for between 15th – 28th Feb

Post meeting note - Confirmed SIV dates [REDACTED] 19th Feb, [REDACTED] 20th Feb, [REDACTED] 13th March & [REDACTED] 23rd March

- Awaiting Regulatory approval – 15th March final date (60 days) for approval, however should receive approval before this date

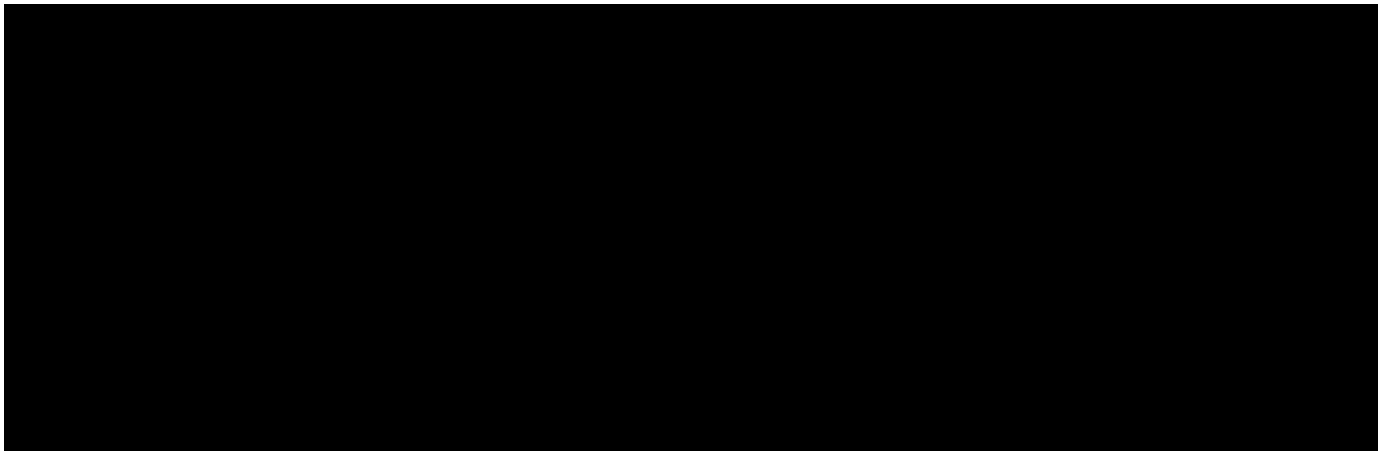
Post meeting note - Belgium approval received 13th Feb 07 – awaiting confirmation letter

Canada:

- [REDACTED] SIV date 28th Feb
- Local EC submissions have been completed, however those sites will not be initiated until March 07
- [REDACTED] update: 1 outstanding document (contract). Once received site can be activated and drug released. [REDACTED] and local affiliate have all been in contact with site. If nothing has been received from site by Friday 9th Feb – K. Dawson to call and follow up with site

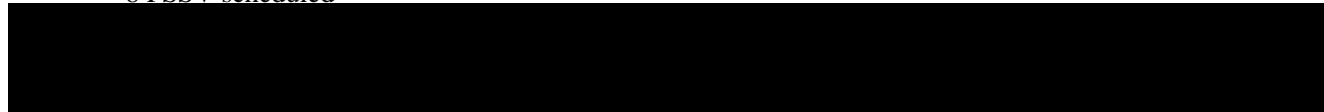
New Zealand:

- [REDACTED] SIV dates 1st – 15th March



109MS302 Study Status Update

- 100 PSSV completed
- 8 PSSV scheduled



Canada:

- [REDACTED]:
 - Local EC submitted on 7th Feb
 - Potential FPI site
 - SIV scheduled for last week March 07
- [REDACTED]:
 - Prefers 301 study
 - Has confirmed to submit to MRI committee on 20th Feb – need clarification what this means. [REDACTED] to follow up
- [REDACTED]:
 - Need site to confirm if they can meet the submission date of 20th Feb
- [REDACTED]:
 - Site will not commit to making a submission.

Russia:

- Potentially 3 sites could be initiated in April

Other:

- **Target countries:** Canada, Russia, NZ, Germany and Czech
- **Timelines:**
 - FPI – May 07
 - LPI – Q2/2008: Jun 08

INEC Members Update

- 3 members have been a few issues with contracts
- currently approaching other potential members

Data Management Update

- 301 & 302 CRFs including the questionnaires will be in the warehouse by 14th Feb
- CRFs can be ordered by [REDACTED]
- [REDACTED] to contact [REDACTED] for the addresses
- Regulatory to share info with DM regarding which CRF version is being submitted for each country
- [REDACTED]:
 - Version 2 of CRF has not been submitted. Awaiting comments as these have to be included into the submission
 - Important to submit Version 2 before Version 3 is released

Clinical Operations Update

- Copaxone label requirements: label is required stating “for clinical trial use”
- Clinical operations to set up a meeting with regulatory to discuss and clarify regulatory requirements for the new backup countries
- Clinical operations need details of backup countries in order to ensure sufficient supplies are available
- Clinical operations to clarify if current label is acceptable in India – may need to be revised

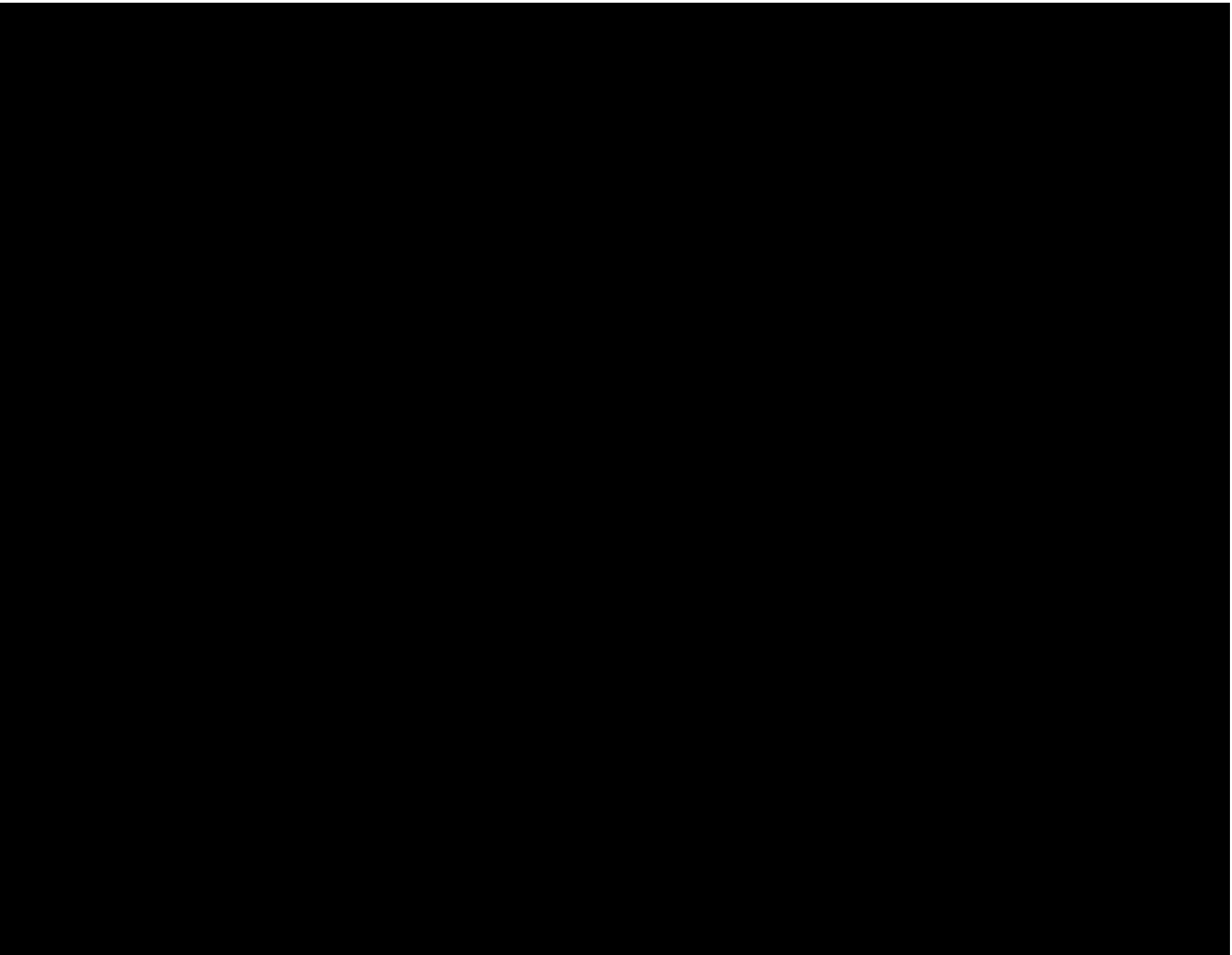
Protocol Amendment update

- Sign off of amendments – 22nd Feb
- Version 1 of draft has been reviewed. Version 2 to be reviewed 9th Feb

- **Regulatory update:**
 - IMPD has now been finalized
 - IB addendum should be released today - 8th Feb



BG12 SMT Meeting Minutes



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