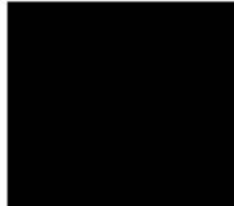
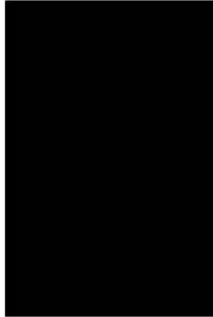


BG00012 Phase 3
109-MS-301 and 109-MS-302
Thursday, 8th February 2007

DISTRIBUTION / ATTENDEES

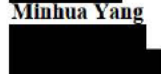
BIIB Attendees



Kate Dawson



Minhua Yang



Phill 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

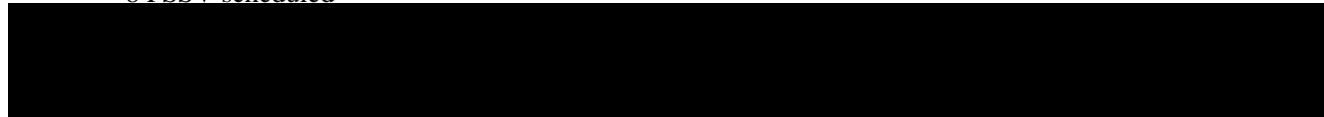
New Zealand:

- [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

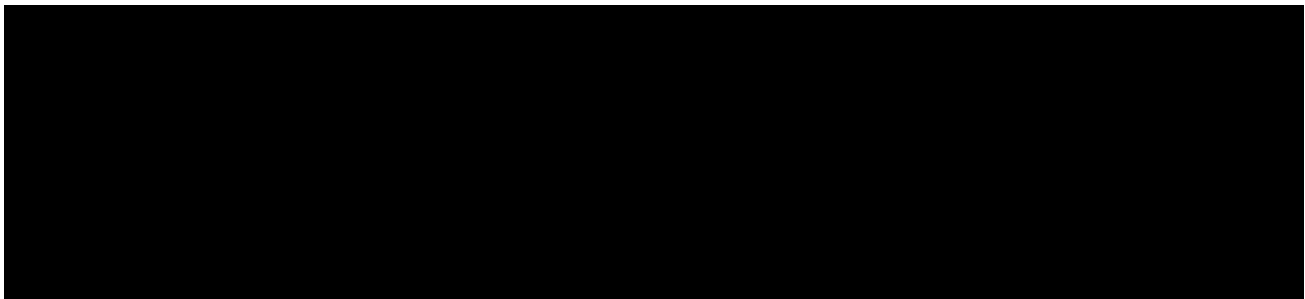
- 301 & 302 CRFs including the questionnaires will be in the warehouse by 14th Feb
- CRFs can be ordered by [REDACTED]
- [REDACTED] to contact [REDACTED] for the addresses
- Regulatory to share info with DM regarding which CRF version is being submitted for each country
- [REDACTED]:
 - Version 2 of 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

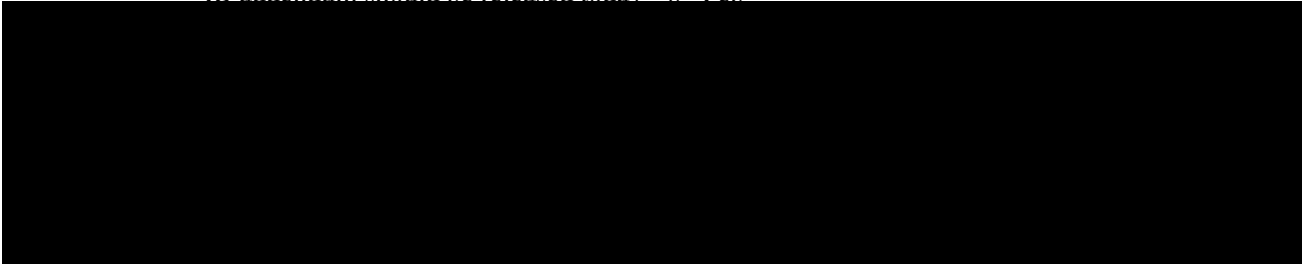
- Copaxone label requirements: label is required stating “for clinical trial use”
- Clinical operations to set up a meeting with regulatory to discuss and clarify regulatory requirements for the new backup countries
- Clinical operations need details of backup countries in order to ensure sufficient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

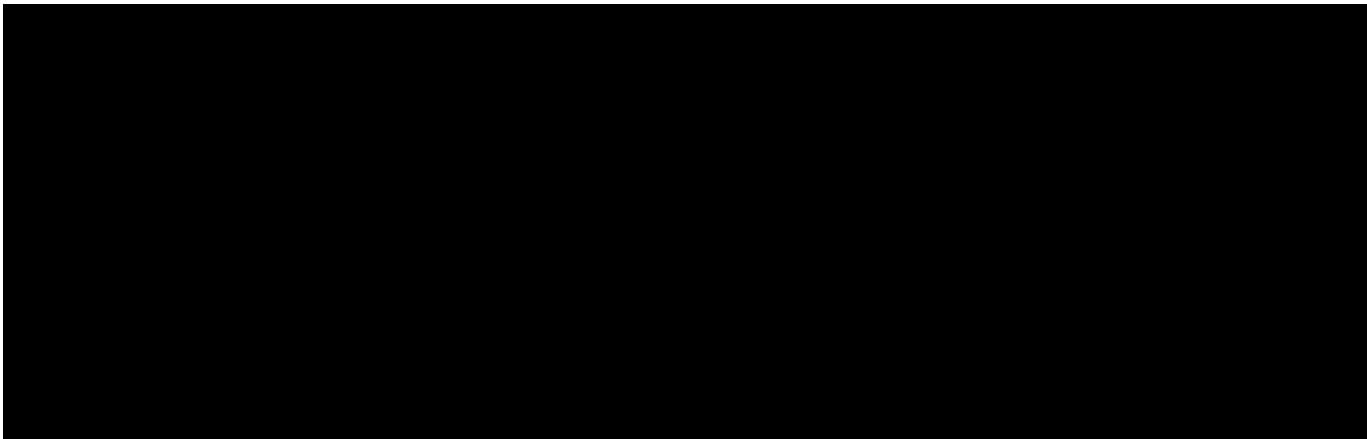
Protocol Amendment update

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

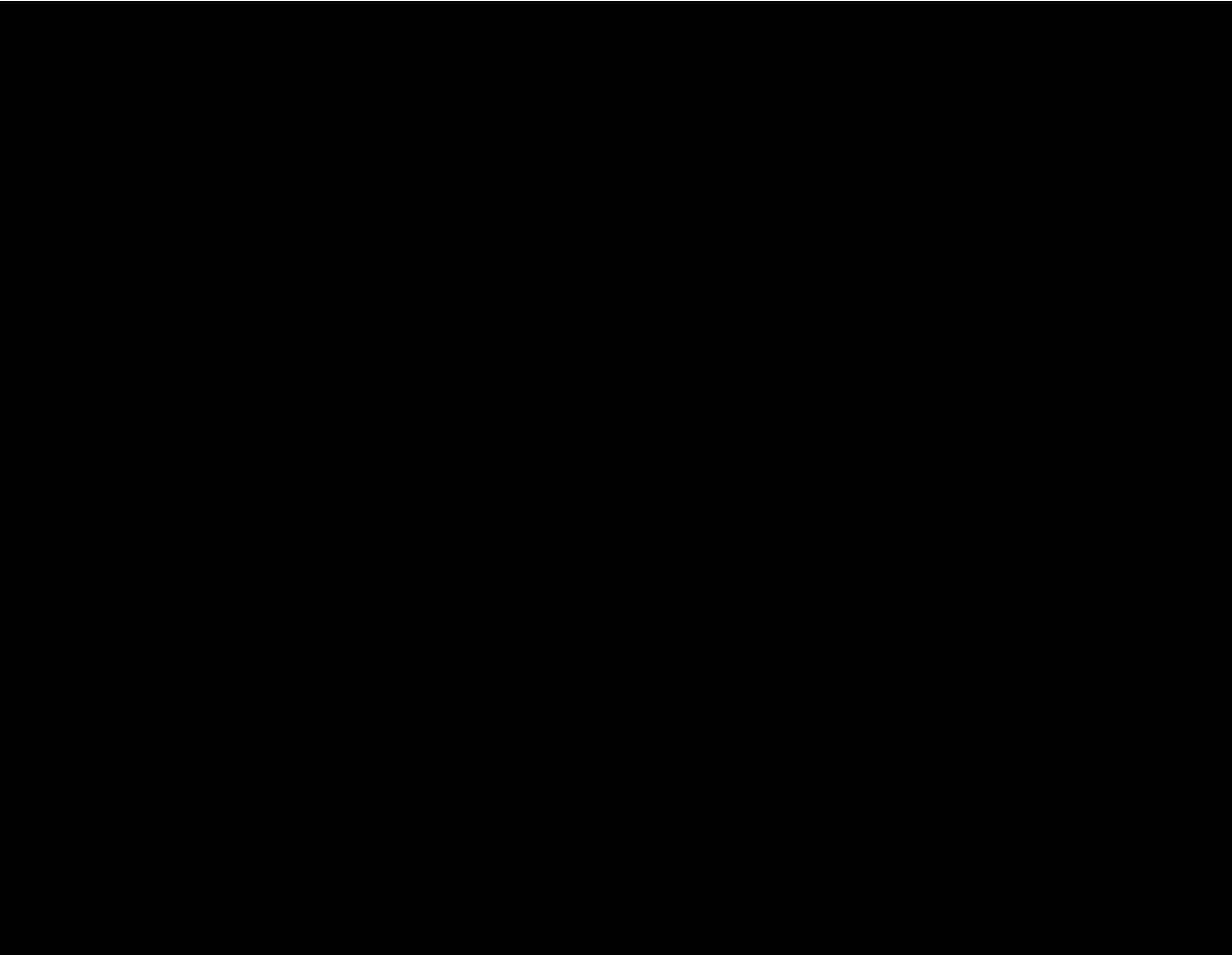


- **Regulatory update:**
 - IMPD has now been finalized
 - IB addendum should be released today - 8th Feb





BG12 SMT Meeting Minutes



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.