# BG00012 Phase 3 109-MS-301 and 109-MS-302 Thursday, 22nd February 2007

# BIIB Attendees Final Attendees Kate Dawson Minhua Yang

Names in BOLD attended this meeting

### <u>Clinical Update:</u> 109MS301 - Study Status Update

- 129 sites Sponsor approved
- 155 PSSV completed (13 sites in recruitment and 43 in follow up)
- US site number has been increased from 17 to 24 to reduce overlap

BG12 SMT Meeting Minutes

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Find authenticated court documents without watermarks at docketalarm.com.

### Australia:

update: 2 patients have been screened.

Post-meeting note: FPI within the next few weeks (8th March possibly)

### **Belgium**:

- Regulatory approval received
- SIV dates confirmed for: 5th March, 6th March, : 8th March, : 8th March, : 8th March, : 30th March

Awaiting Central Ethics approval - expected by 28th Feb

Post-meeting note - Central Ethics approval received Friday 2nd March

### New Zealand:

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SIV dates Mid to End March

### Other:

- UK Regulatory approval received
- Submissions made in: Czech Republic, Slovakia, Austria & Germany
- Contining to do feasibility in backup countries
- Canada & Russia Potential SIV dates in April

# 109MS302 Study Status Update

- 101 sites Sponsor approved
- 137 PSSV completed (45 in recruitment, 87 in feasibility)

### Canada:

: Potential FPI site

### **Russia**:

- Regulatory Submission made
- Have received Central ethics and Pharmacological committee approval
- Potential SIV dates in April dependant on approval

### Other:

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- Regulatory Submission: Canada, Czech Republic, Spain have been completed
- · Belgium & Hungary submission are currently being submitted

# **INEC Members Update**

• 3 members; 1 outstanding contract

INEC high-level timeline & update -

- Weekly meeting with (Scheduled on Wednesdays at 11.00am EST)
  - Status update including system development, communications with INEC etc
- Review of portal meeting (Scheduled for 22nd Feb at 1.00pm EST), portal should be available after meeting
- representative will be presenting at the Investigator meeting; Training will include:
   Communication process with INEC and how is involved
- Sites currently have instructions on how to send information to INEC when there is a relapse. Currently this states information is to be sent to the sent to the

# Data Management Update

- 301 & 302 CRFs including the questionnaires are available at the warehouse
- V2 for 301 and V1 for 302

# **DSMC update & Charter**

- First meeting was held on 21st February 2007
- Minor changes will need to be made to DSMC charter
- DSMC are interested in seeing efficacy data they requested additional tables

Action: to send DSMC Charter out to team within the next couple of weeks

## **Investigator meeting reminder**

- First Investigator meeting to be held 26th & 27th February in Dublin
- Meeting planners are coordinating all details
- Presentations are currently being finalized
- April meeting invites to be sent in the next couple of weeks
- Boston meeting to be held in June. Currently discussing possible location due to AAN also being held in Boston

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**BG12 SMT Meeting Minutes** 

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