

BG12 Phase III SMT Minutes
Thursday 20 July 2006

Attendees:

[REDACTED] Kate Dawson (KD), [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Ratna Lingamaneni (RL), [REDACTED]
[REDACTED]

[REDACTED]

Protocol Status & Plans for Sign-off

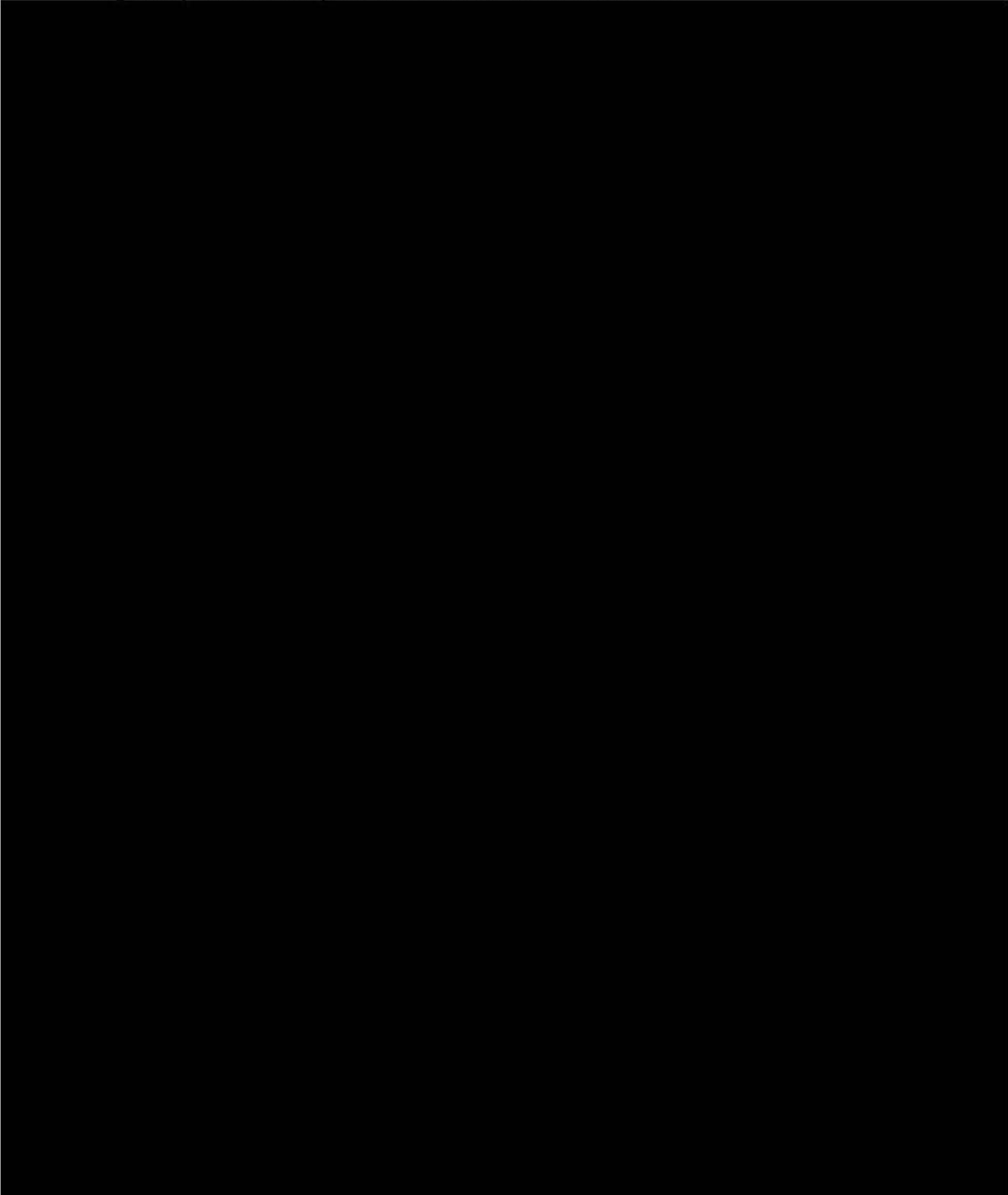
- End of Phase 2 meeting scheduled for August 30 2006. Deadline for completion of the protocols has been moved forward due to the addition of an 18-month interim analysis to both study designs/protocols (109MS301 and 109MS302). The EOP2 package including the final "approved" drafts of the phase 3 protocols will be submitted to the FDA on Friday, 28July06.

[REDACTED]



❖ **CRO selection**

- [REDACTED] and [REDACTED] informed the team that [REDACTED] has been selected to submit safety reports/documentation to regulatory agencies in Europe. [REDACTED] clarified that BIIB US Regulatory Affairs is responsible for these submissions in NA.



❖ **ICFs**

- ICFs required: Model ICF, relapse ICF, genetic ICF, HIPPA (US) and MRI ICF
- Model ICF will be finalised after the PSP and IB are approved. The IB and PSP are due to be finalized and approved by 18Aug06.

❖ **Vendor selection**

- Vendors needed for: IVRS, MRI reading center, Central Labs (CCLS), ECG reading center

