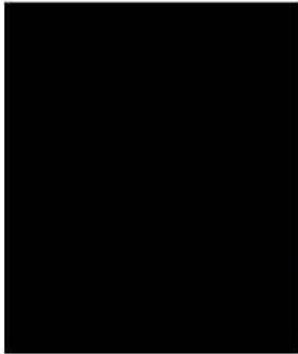


BG00012 Phase 3
109-MS-301 and 109-MS-302
Thursday, 9th November 2006

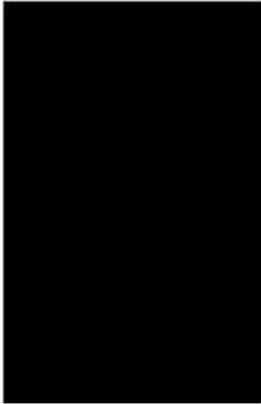
DISTRIBUTION / ATTENDEES

BIIB Attendees



[Redacted]
[Redacted]
[Redacted]
[Redacted]
Kate Dawson
[Redacted]
Minhua Yang

[Redacted]
Phil Gallacher
[Redacted]
Ratna Lingamaneni
[Redacted]
[Redacted]



109MS301: Study Start-up Update - [REDACTED]

- 245 CDAs have been sent out, 196 returned
- 192 SRQs have been sent out, 101 returned
- 68 SRQs reviewed by BIIB, 46 sites have been approved to participate

Australia:

- [REDACTED] has not yet confirmed initiation visit date
- Other potential Australian sites are reviewing the budget
- EC submission dates for [REDACTED] and [REDACTED] are pending

New Zealand:

- [REDACTED] EC central submission is scheduled for 14 Nov

Action: [REDACTED] to contact Imperial Graphics to check if there is a specific VAS for NZ

Canada:

- CTA submission completed 7 Nov

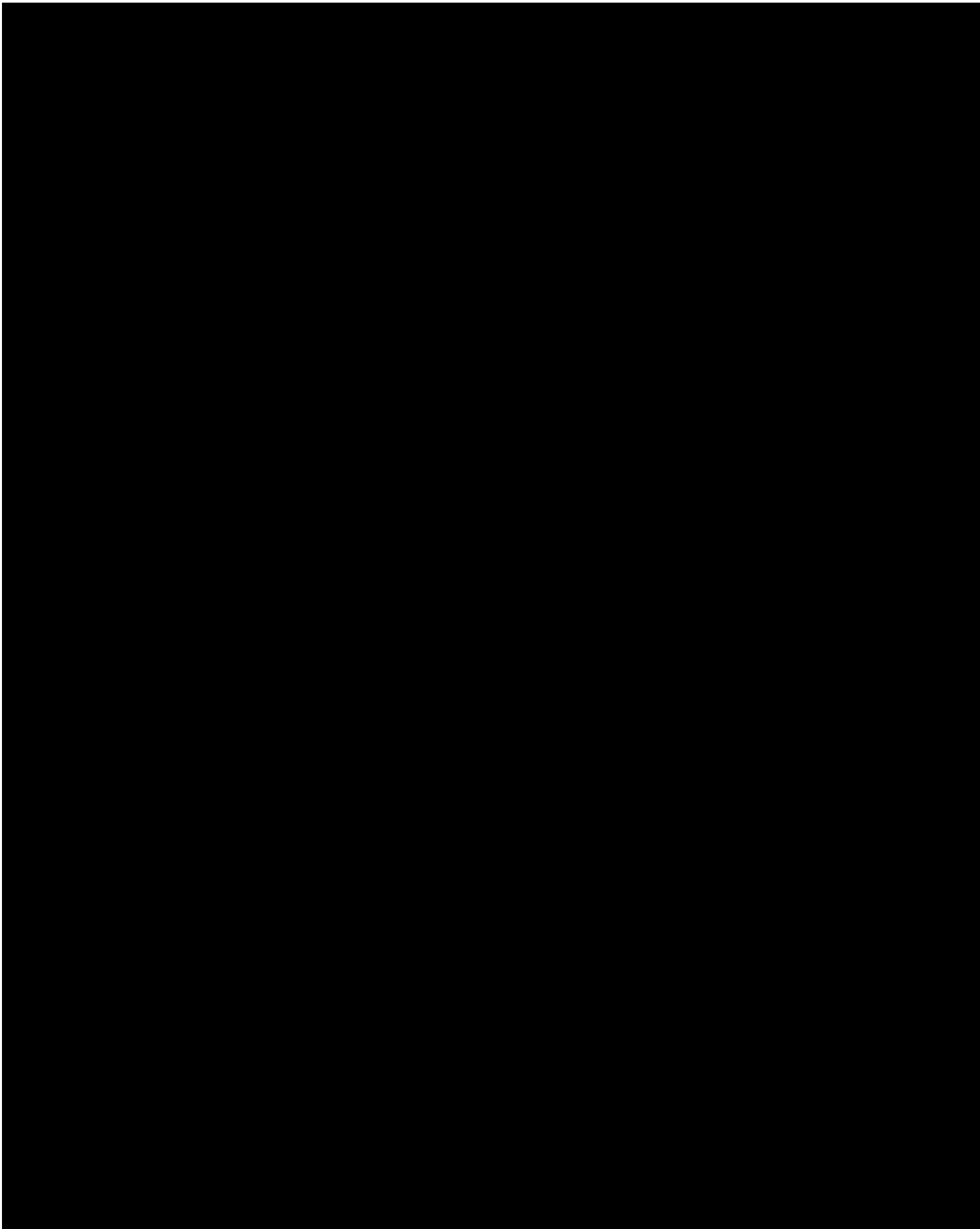
South Africa

- There are particular ethics committees in South Africa that will not accept the 1996 Dec of Helsinki, only the 2000 version. If we ask sites to use other ethics committees that we are not familiar with, we run the risk they will not accept the 1996 version.

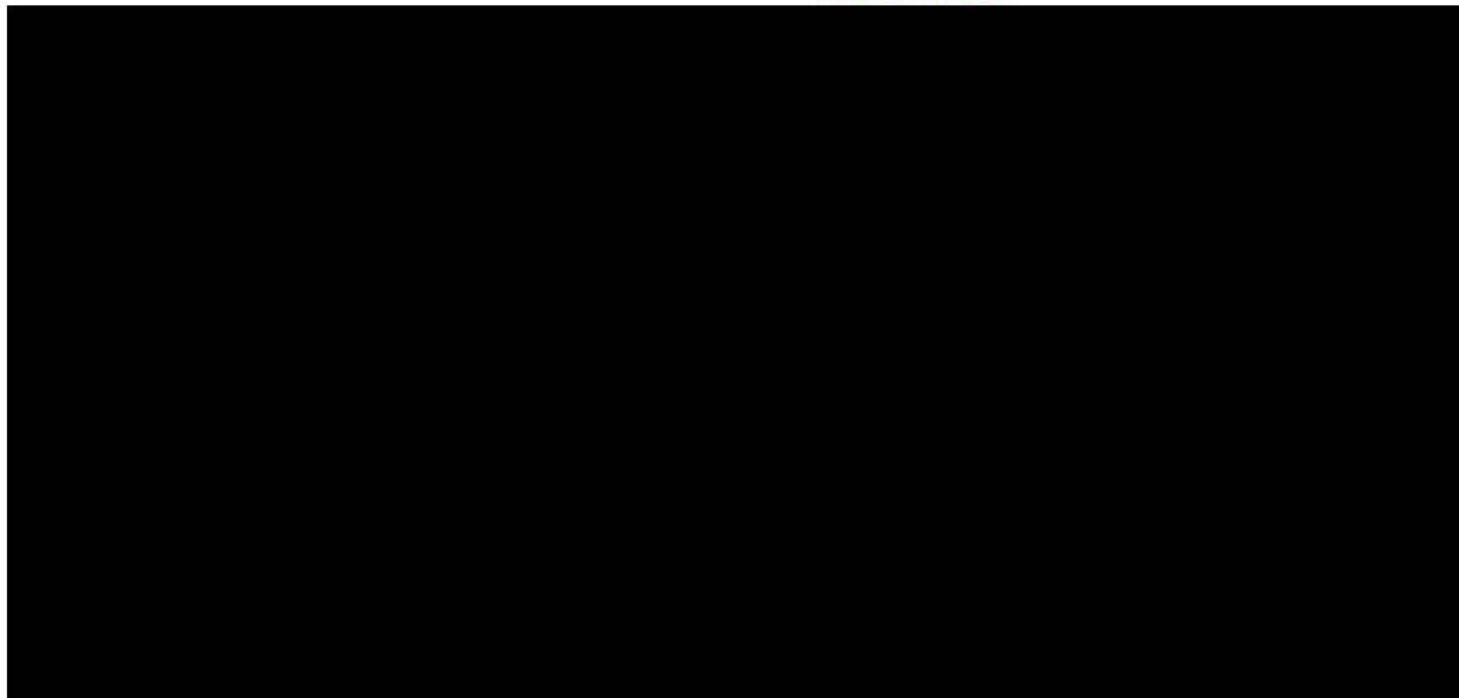
Action: BIIB clinical/commercial to discuss and provide guidance to [REDACTED]

109MS302: Study Start-up Update - [REDACTED]

- 195 CDAs have been sent out, 164 returned
- 158 SRQs have been sent out, 55 returned



ACTION ITEMS



ICF					
301 Sign Off of supplemental ICFs (Dummy MRI, MRI)	██████████ KD	28 th Sept	13 th Oct	On target	Sign off by 11/10
Reg to confirm date for Health Canada submission date for 301 & 302	Regulatory	28 th Sept	2 nd Nov	Completed	
302 Sign Off of supplemental ICF (Dummy MRI/MRI)	████	28 th Sept		On target	Sign off by 11/10
SH to follow up with MRI center on MRI ICF	████	25 th Oct		Complete	
CRF					
████ to contact Imperial Graphics to check if there is a specific VAS for NZ	████	9 Nov		New	
████ to contact Imperial Graphics to get VAS for Belgium by Friday 3 Nov	████	2 nd Nov	3 rd Nov	Completed	
████ to distribute 301v1 Guidelines and 302 CRFs and schedule review meetings	████	2 nd Nov		Completed	

BG12 SMT Meeting Minutes



Questionnaires					
█ / KD to develop telephone relapse questionnaire for 301 and 302. █ / KD and the team to consider whether to capture in the CRF.	█ / KD	07 th Sept	9 th Nov	Pending final review	On target for next week

