

BG00012 Phase 3
109-MS-301 and 109-MS-302
Thursday, 2nd November 2006

DISTRIBUTION / ATTENDEES

BIIB Attendees

[REDACTED]

[REDACTED]
Kate Dawson

[REDACTED]
Minhua Yang
[REDACTED]
Ratna Lingamaneni
[REDACTED]

[REDACTED]

Names in **BOLD** attended this meeting

[REDACTED]

MINUTES

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

- 243 CDAs have been sent out, 186 returned
- 181 SRQs have been sent out, 75 returned
- about 30 sites have been approved to participate

Australia:

- EC submission for [REDACTED] and [REDACTED] pending

New Zealand:

- EC central submission scheduled for 14 Nov

Belgium:

- Approval received for coordinating site [REDACTED]
- EC submission on 20 Nov

Action: [REDACTED] to contact Imperial Graphics to get VAS for Belgium by Friday 3 Nov

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

- 195 CDAs have been sent out, 158 returned
- 158 SRQs have been sent out, 7 returned
- [REDACTED] has begun contacting sites for 302 this week

of sites that will receive approval for 109MS301 protocol version 1

- Worst case scenario: 3 Aus sites, 3 NZ, 6 Belgium
- Recommendation provided to [REDACTED]: use protocol V1 in Belgium for the first regulatory submission

Brazil Update

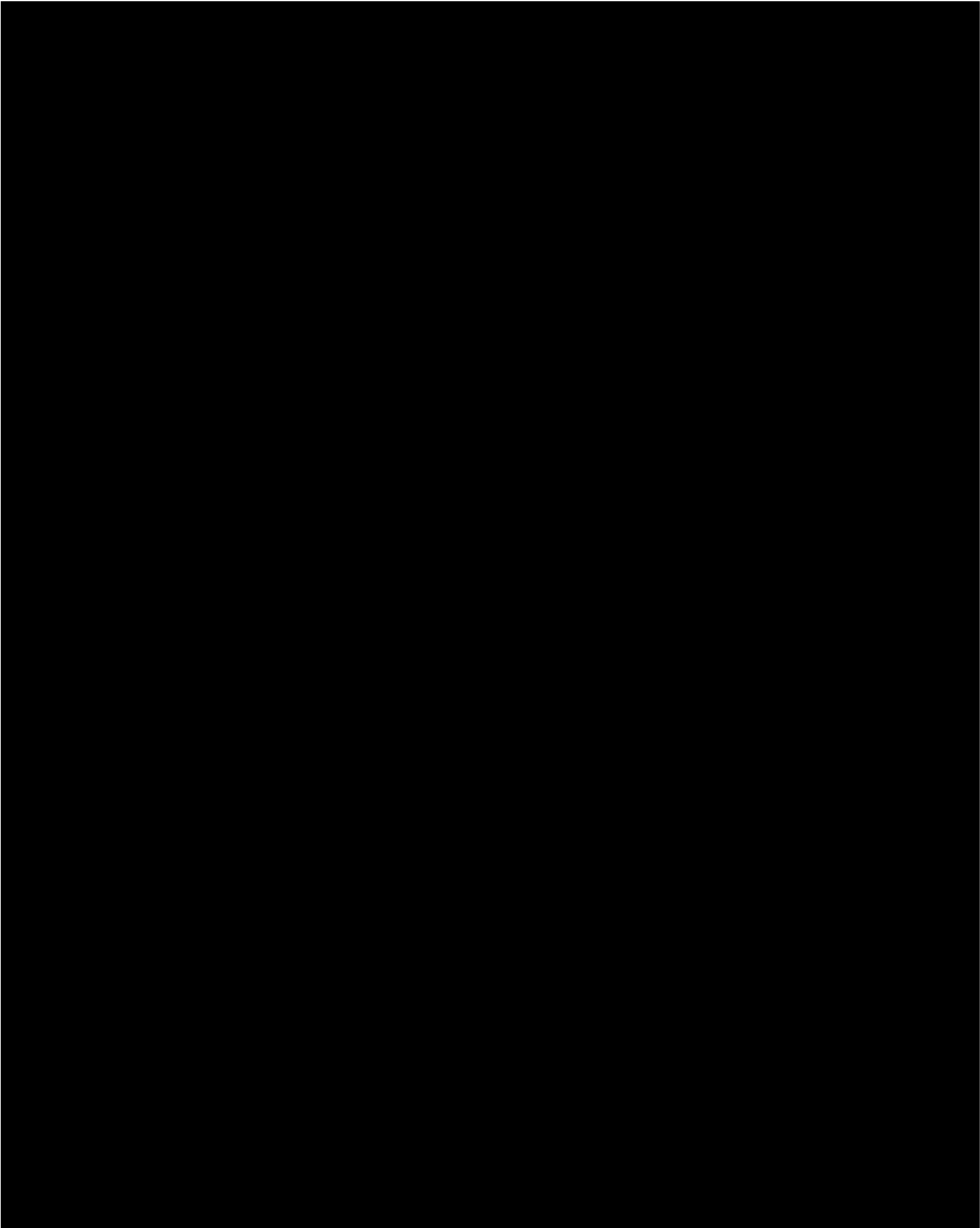
- Move Brazil from 302 to 301
- BIIB Commercial has identified a potential lead physician
- BIIB requested for [REDACTED] to begin contacting sites for 301

Action: [REDACTED] will forward [REDACTED] email/information for Brazil potential lead site and [REDACTED] will forward Brazil list to [REDACTED]

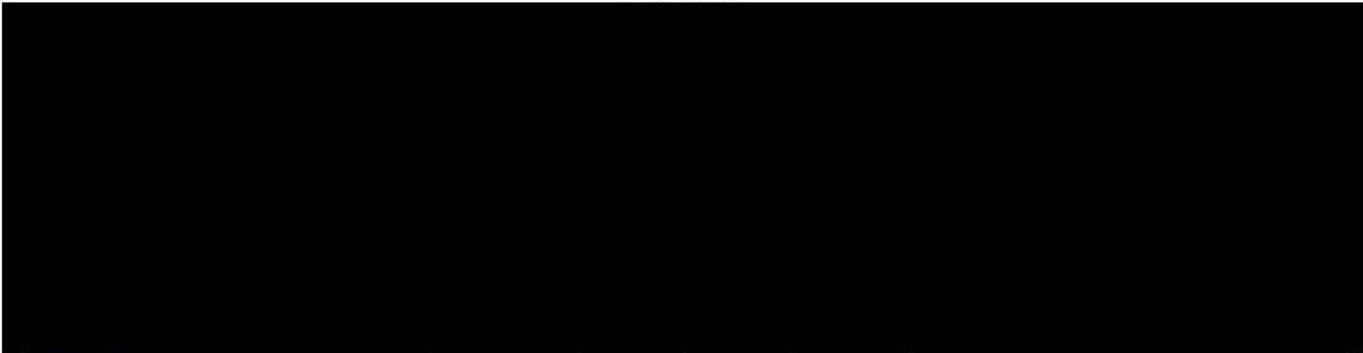
South Africa, Spain, Ireland

South Africa:

- Potentially out of both 301 and 302, however [REDACTED] is looking into regions within S. Africa that will approve the 1996 version of the Declaration of Helsinki, more info to follow from [REDACTED] next week

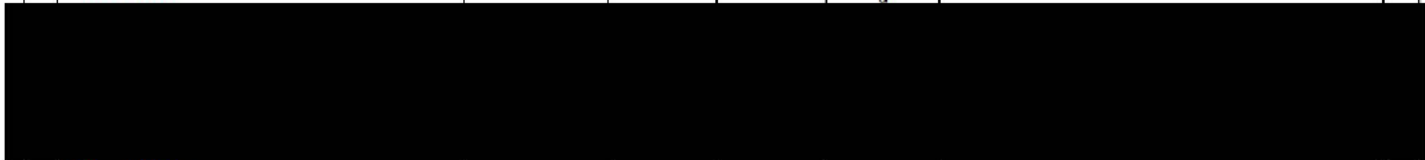


ACTION ITEMS

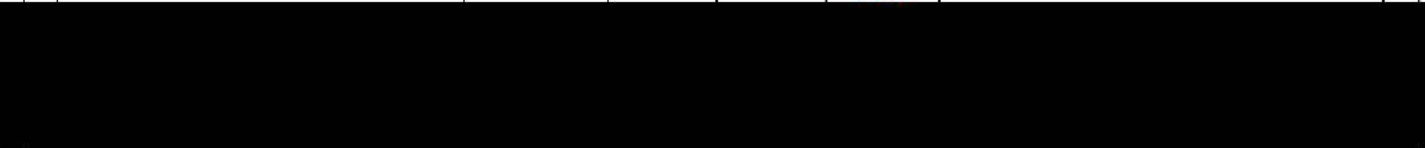


SITE SELECTION					
█ will forward █ email/information from Brazil potential lead site	█	2 nd Nov		Now	
█ to Brazil Investigator list to █	█	2 nd Nov		New	
█ to send █ the site number list	█	2 nd Nov		New	
█ to provide update on potential sites in South Africa	█	2 nd Nov		New	
█ to discuss sites with █ █ to send suggested additional sites to █	█	05 th Oct		Ongoing	
ICF					ICF to be modified due to results from EOP2 meeting
301 Sign Off of NA model ICF	RL	07 th and 21 st Sept	06 th Oct	Completed	
301 Sign Off NA model ICF	█ and KD	21 st Sept	06 th Oct	Completed	
301 Sign Off of supplemental ICFs (Dummy MRI, MRI)	█ RL, KD	28 th Sept	13 th Oct	On target	
301 Sign off of supplemental ICF (Pipedia ICF, Canadian Version of PHI)	RL, █, KD	28 th Sept	06 th Oct	Completed	
301 Sign Off of supplemental ICFs (pharmacogenomic)	█ RL,	28 th Sept	06 th Oct	Completed	
Reg to confirm date for Health Canada	Regulatory	28 th Sept			

submission date for 301			2nd Nov		
302 Sign Off of International model ICF	■	28 th Sept	Pending	Completed	
302 Sign Off of NA model ICF	■	28 th Sept	Pending	Completed	
302 Sign Off of supplemental ICF (disease progression / relapse)	■	28 th Sept	Pending	Completed	
302 Sign Off of supplemental ICF (Dummy MRI/MRI)	■	28 th Sept		Pending	
302 Sign Off of supplemental ICF (Pipedia ICF, Canadian Version of PHI)	■	28 th Sept	Pending	Completed	
302 Sign Off of supplemental ICF (PHI)	■	28 th Sept	Pending	Completed	
302 Sign Off of supplemental ICF (pharmacogenomic)	■	28 th Sept	Pending	Completed	
■ to follow up with MRI center on MRI ICF CRF	■	25 th Oct		Pending	
■ to contact Imperial Graphics to get VAS for Belgium by Friday 3 Nov	■	2 nd Nov	3 rd Nov	New	
■ to distribute 301v1 Guidelines and 302 CRFs and schedule review meetings	■	2 nd Nov		New	
■ to follow up with ■ on CRF Completion Guideline date	■	25 th Oct	2 nd Nov	Completed	



Questionnaires					
■ KD to develop telephone relapse questionnaire for 301 and 302. ■ KD and the team to consider whether to capture in	■ KD	07 th Sept	9 th Nov	Pending final review	



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