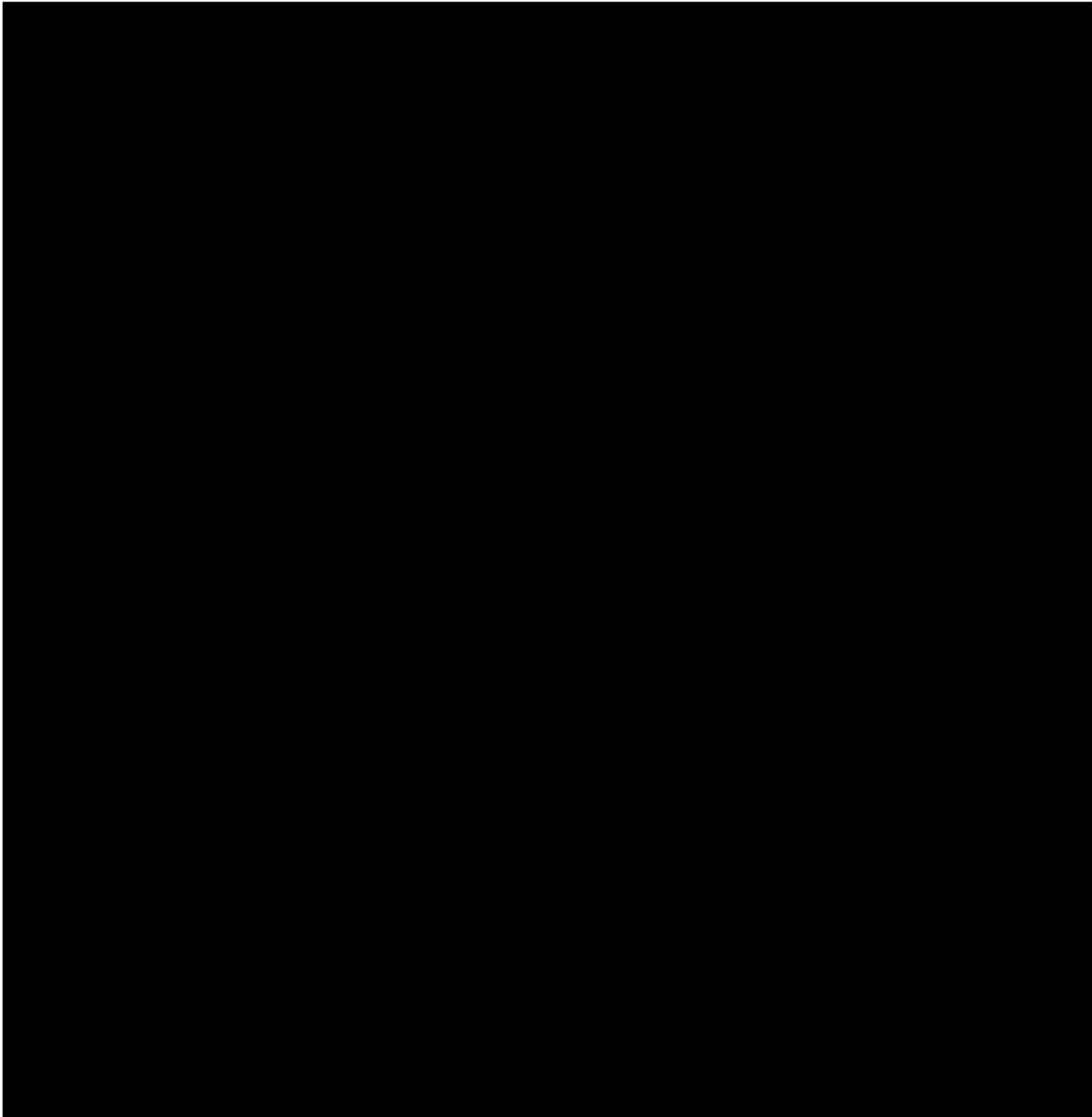
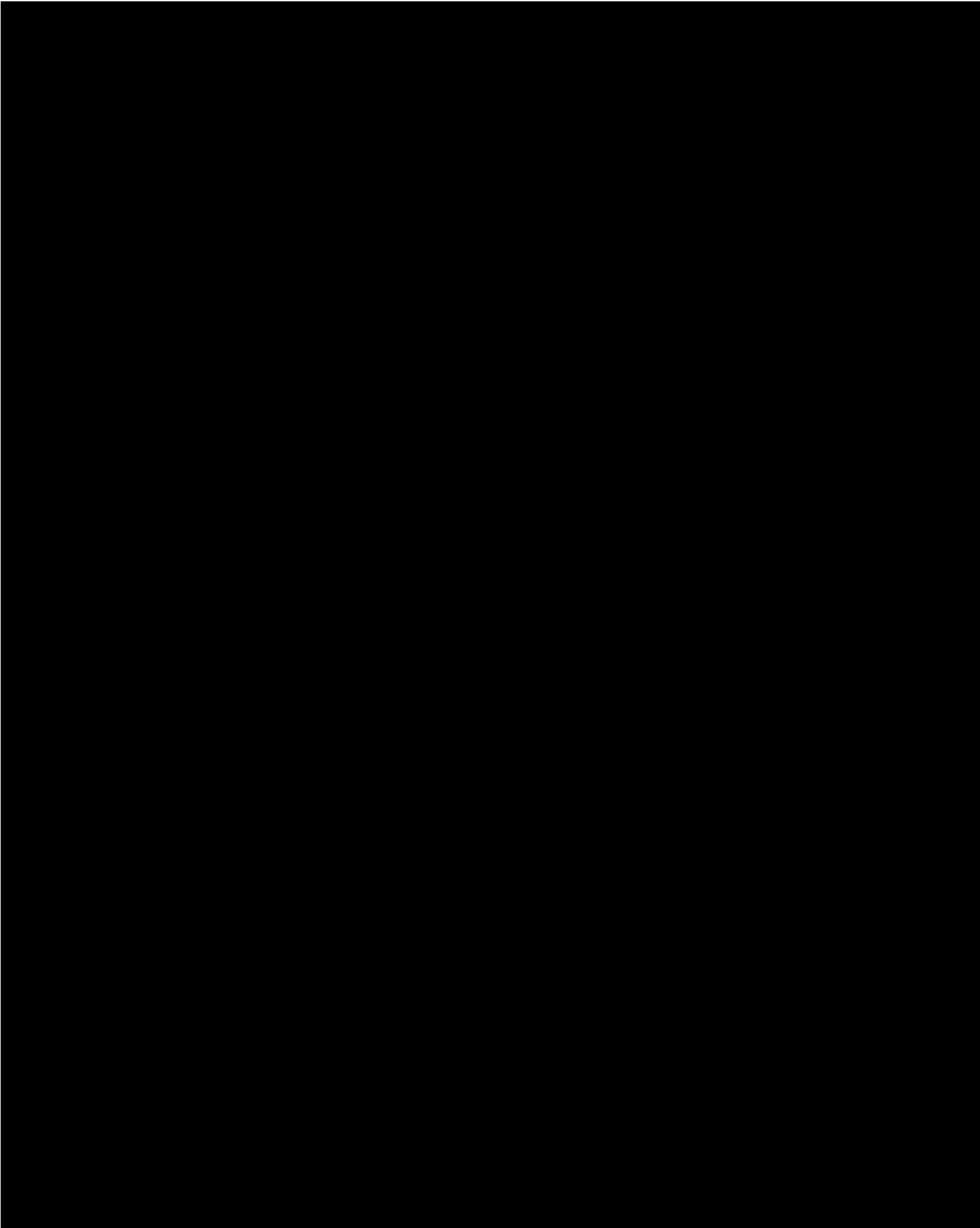


From: [REDACTED]
Sent: Wed Dec 06 2006 14:35:41 EST
To: bg00012 phase 3 smt;
CC: [REDACTED]
Subject: 109MS301/302 SMT AGENDA: Thursday 7th December 8:30AM Eastern/1:30PM UK





BG00012 Phase 3
109-MS-301 and 109-MS-302
Thursday, 30th November 2006

DISTRIBUTION / ATTENDEES

BIIB Attendees

[REDACTED]

[REDACTED]
Kate Dawson
[REDACTED]
Minhua Yang

[REDACTED]
Phill Gallacher
[REDACTED]
Ratna Lingamaneni
[REDACTED]

[REDACTED]

[REDACTED]

Study Status Update – [REDACTED] /P. Gallacher

Australia:

- First EC submission completed for [REDACTED]

Canada:

- Central Regulatory Submission completed in November 2007 for [REDACTED] Site
- [REDACTED] is working with [REDACTED] site to schedule a Site Initiation Visit (SIV) for the end of December or early January 2007. [REDACTED] has requested it to be early in January 2007 rather than the end of December.

Formatted

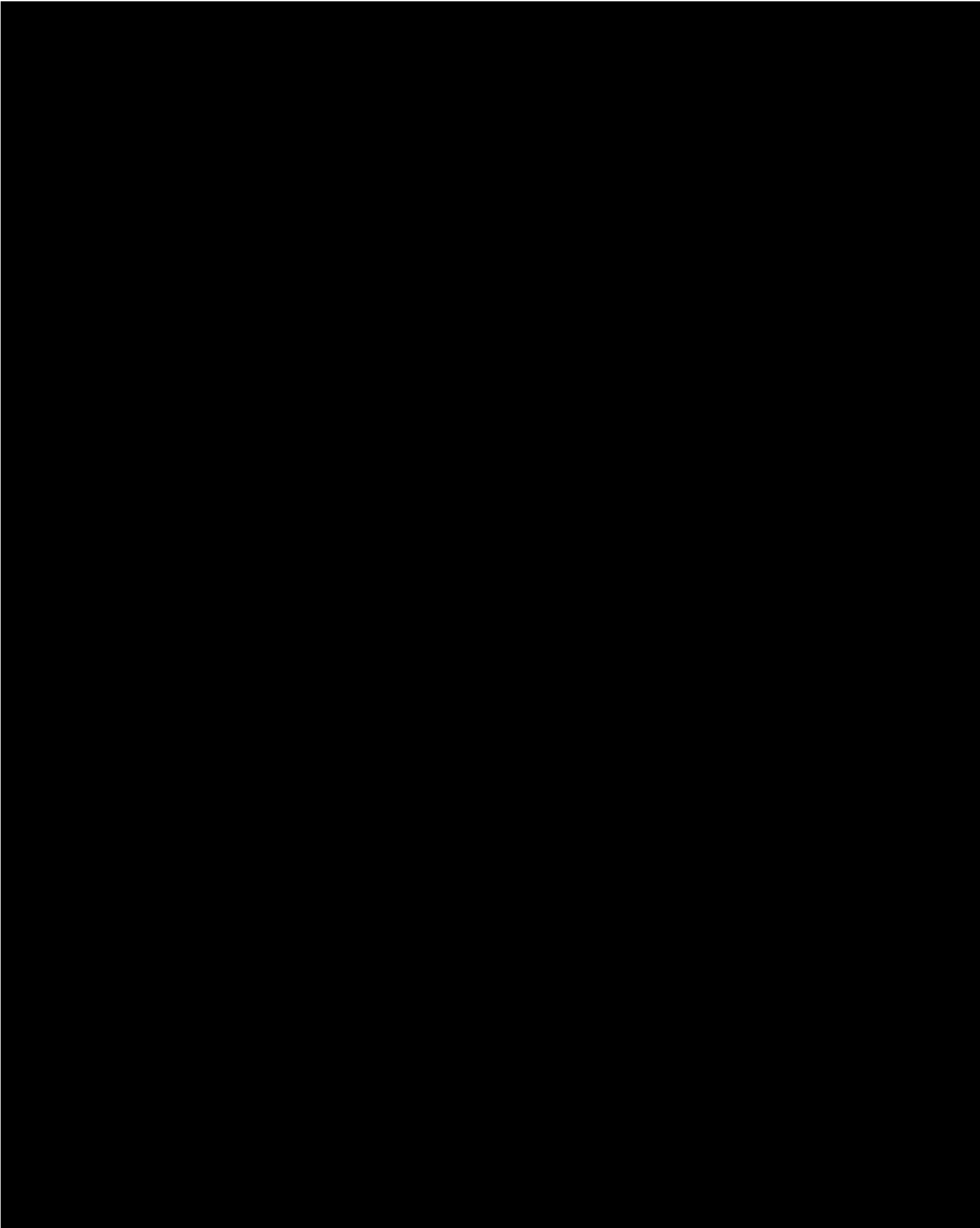


Site Selection:

- The team is discussing the addition of more sites to make up for lack of responsiveness of sites
- Bulgaria, Romania and Italy are possibilities provided that the PO&T group can accommodate such needs
- The team will also work with the commercial group to see if we can get enough sites within these countries to ensure it is worth going to these countries for both 301 and 302. At a minimum 4 sites per country are required needed, and for 301 Avonex lyo needs to be approved and for 302 both Avonex lyo and Copaxone need to be approved.

General:

- 36 sites have been approved to participate in 301, 12 approved to participate in 302
 - There are a large number of PSSVs to be completed by [REDACTED] in the next few weeks. The expectation is to have all sites selected by 15 December for 301 and 2 February 2007 for 302.
 - BIIB has requested [REDACTED] to provide the target/prospective dates of submission and SIV.
 - [REDACTED] report suggests 302 will be submitted before 301 in the UK. Clinical to discuss such rational with [REDACTED]
- 



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