

BG-12 MS
Clinical Development Team

Subject: Minutes from BG-12 MS CDT meeting on 27 Sept 2006

Date: October 23, 2006

From: [REDACTED]

Attendees: Kate Dawson, Tammy Sarnelli, [REDACTED] Ratna
Lingamaneni, [REDACTED], Minhua
Yang, [REDACTED]

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| 1 | Update regarding Phase 3 protocol status | <ul style="list-style-type: none">301 was signed off 21 Sept, 302 going for sign-off next week. Plan is for 302 protocol and ICFs to be available for [REDACTED] by Oct 6th. |
| 2 | Discussion regarding submission of Ph 3 protocols to FDA | <ul style="list-style-type: none">Regulatory outlines process for sending protocols in via SPA (Special Protocol Assessment). Table reviewed at meeting outlines the types of changes made to the protocol. Regulatory advises that we address FDA's specific concerns regarding primary endpoint analysis, how we handle switchers and drop-outs. We also need to develop a plan for Population Pk. |

