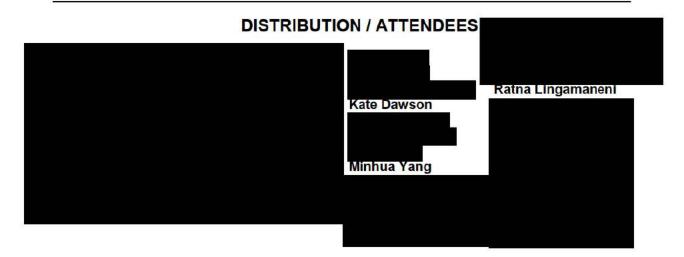
## BG00012 Phase 3 109-MS-301 and 109-MS-302 Thursday, 21<sup>st</sup> September 2006



Names in **BOLD** attended this meeting



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## MINUTES

### Protocol Status & ICF \* Development/Approval Timeline

#### 1. Protocol

Carmen Bozic to sign off today

Action: KD, MY and to also sign protocol

- Lead investigator preferably Prof. Redacte to be confirmed.
- Ongoing discussions regarding whether to use Lyophilised or Liquid (PFS) Avonex for the study, depending on availability.

Action: to confirm with regards Avonex Lyo / PFS

Action: MY to have internal discussions regarding how the relapse rates are calculated for patients on Avonex open label.

## 2. ICFs

- Draft ICFs (MRI, EDSS) reviewed, comments being incorporated by medical writing
  (
- Finalise 4 ICFs: models (Intl, NA), suspected Relapse and sustain progression for tomorrow.

Action: to sign off model ICF for EU, Ratna to sign off NA model ICF on Friday 22<sup>nd</sup> September.

Action: and KD to also sign off model ICFs.

Action: to send comments on ICF to

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## CRO Kick off meeting

- Finalised date and venue to 18<sup>th</sup> and 19<sup>th</sup> October in UK office
- Action: MY to discuss with whether to attend in person

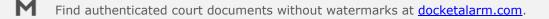
### **Investigator Meetings**

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- Australian mini investigator meeting planned in November (either week of 13<sup>th</sup> November or 20<sup>th</sup> November) details TBC.
- Large investigator meeting planned for last week in Jan / last week in Feb in Dublin. Details TBC.



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