Dear Sir or Madam

I have been asked to send through Biogen Idec's comments on the public consultation document ' Draft Detailed Guidance on the Collection, Verification and Presentation of Adverse Reports Arising from Clinical Trials on Medicinal Products for Human Use'.

Please find these below. Should you require any additional information please do not hesitate to let me know. Many thanks,

Best Wishes

Richard

45. In the absence of information on the expectedness by the reporting investigator, the sponsor should consult the reporting investigator and encourage him to express an opinion on this aspect. The expectedness assessment given by the investigator should not be downgraded by the sponsor. If the sponsor disagrees with the investigator's expectedness assessment, both, the opinion of the investigator and the sponsor should be provided with the report.

The company respectfully submits that this point should *not* be included in the finalized version of this document. Inherent in this point, there is potential disagreement with Point 34 ("The unexpectedness of an adverse reaction is determined by the sponsor according to the reference safety information")and Point 42 ("The sponsor is responsible for ensuring that only unexpected adverse reactions are reported"). The company disagrees that sponsor should not downgrade an expectedness assessment provided by an investigator if such assessment is not in agreement with the IB/SmPC. This would lead to sponsor improperly expediting cases due to investigator error. In sum, the sponsor is unable to ensure that only unexpected reactions are reported if investigator must also make an expectedness assessment and assesses incorrectly.

91. If appropriate, the information on SUSARs should be aggregated in a line listing of SUSARs in periods as warranted by the nature of the clinical development project and the volume of SUSARs generated. This line listing should be accompanied by a concise summary of the evolving safety profile of the IMP.

The company fully supports such a change to investigator reporting and strongly hope that this point will be included in the finalized document. It is our perspective that aggregated data accompanied by sponsor summaries provides a clearer picture of the evolving safety profile of an IMP than isolated individual case reports. The data can be more easily evaluated in context when provided via periodic line listings.