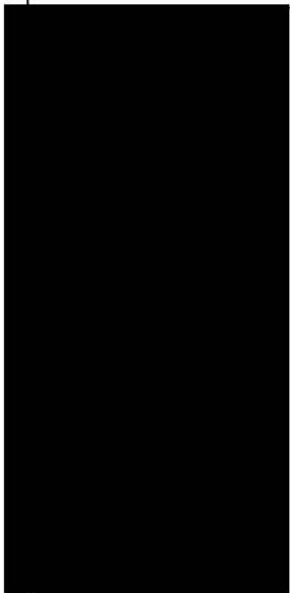




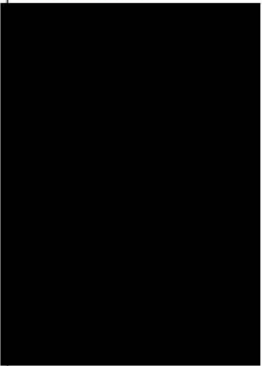


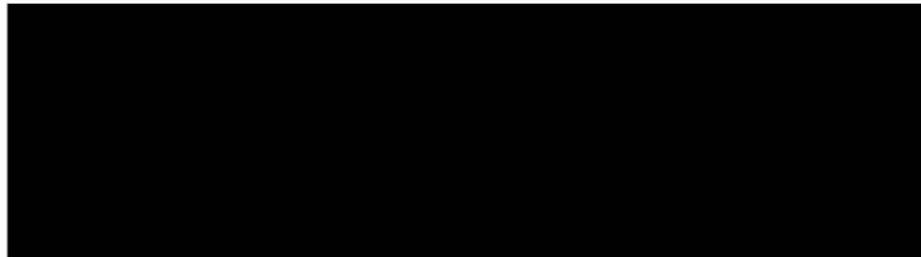


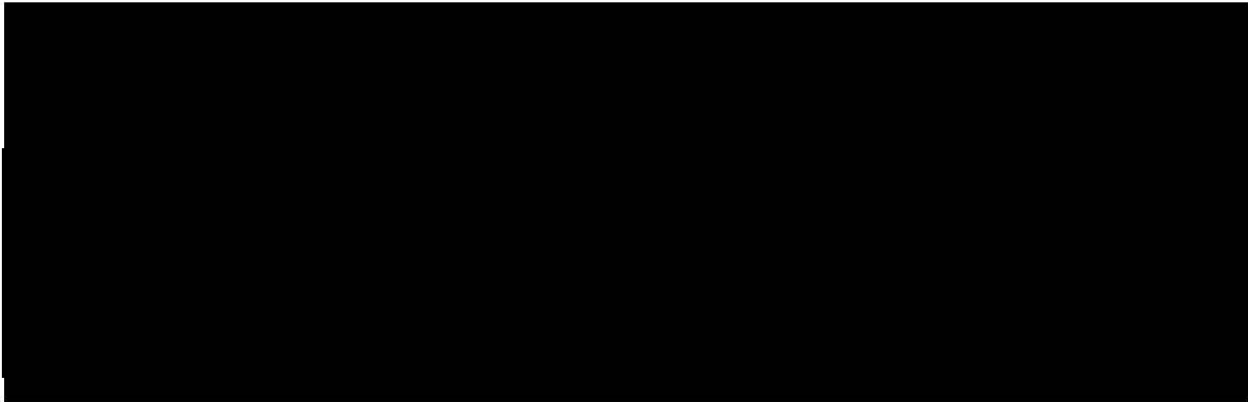
BG00012 Phase 3
109MS301, 109MS302 & 109MS303
Tuesday 18 January 2011
DM SMT Meeting Minutes

DISTRIBUTION / ATTENDEES

BIIB Attendees		
		
	John O'Gorman	Minhua Yang
		
	Kate Dawson	Phill Gallacher
		
		Tammy Sarnelli
		

Names in **BOLD** attended this meeting





301/302/303 Timelines

██████████ distributed the updated Final DBL timelines to the SMT. The 302 Final DBL timelines were revised to account for the new LPLV date of 06Jun11 (previous LPLV was 20May2011). The Timeline remains 6 weeks from LPLV to DBL, however, many of the activities and durations have shifted from the previous timelines. ██████████ explained that she needed to add additional days to some activities and remove days from other activities and thus these do not match up with the predecessors and durations of the 301 Final DBL timelines. ██████████ confirmed the differences between 301 and 302 timelines are not due to errors, but expected to have differences given the 301 DBL is 7 weeks and 302 DBL is 6 weeks. Minhua asked to add in activities related to reconciliation of 303 data listings against both 301 and 302 data listings as well as adding in an additional 3rd review prior to the Data Audit. ACTION: ██████████ to update the timelines and redistribute to the SMT for final review.

Trend of increased re-query rate

Re ██████████ will present on the query trend for 301/302/303 and revisit the Quality Management Plan/Gap Analysis for BG12 at the SMT on 01 February.
POST MEETING NOTE: ██████████ to still provide an update on the increased re-query rate trend as this is a separate topic from ██████████ query trending (region/county/site).

Unblinding after Database lock – Informing Sites of treatment arm

In follow up to an EC annual renewal report, the question arose if and when would we notify sites and pts of their treatment arm on 301 and 302. Per the 303 protocol, if a favorable dose is determined from 301/302 then all pts would then be switched to that dose in 303. ██████████

