

INVESTIGATOR MEETING AGENDA

STUDY 3104001002

Day 1 - Monday 21 May 2012

Time	Presentation
12.00-13.00	Lunch
13:00-13:15	Day 1 agenda and housekeeping
13:15-13:40	Introduction and Orion Pharma presentation
13:40-14:00	Introduction and ENDO Pharma presentation
14:00-14:30	Study 3104001002 design - major objectives
14:30-14:45	Study 3104001002 update
14:45-15:00	Break
15:00-15:45	[Molecule X] - phase 1 study results (general data and PK)
15:45-16:15	Study experience in France
16:15-16:45	Study experience in UK
16:45-17:30	GCP overview - responsibilities of investigator, sponsor, monitor
17:30-18:00	Q&A
20:00	Dinner

Day 2 - Tuesday 22 May 2012

Time	Presentation
8:45-9:00	Day 1 overview and Day 2 agenda
9:00-10:45	Study protocol
10:45-11:00	Break
11:00-11:30	Patient enrollment procedures
11:30-12:00	AE and SAE reporting
12:00-12:30	Study drug - packaging, distribution, storage, return
12:30-13:30	Lunch
13:30-14:15	Overview of laboratory sample process and of ECG process
14:15-15:00	CRF overview and completion (Questions and guidance)
15:00-15:30	Questions and closure