

2014 Pre-Submissions Workshop Meeting Agenda

Wednesday

April 9, 2014

8:15 a.m. – 10:30 a.m.

7:30 – 8:15 a.m.

Registration / Breakfast

Room:
White Flint

8:15 – 8:20

Welcome

Jean Cooper, OIR

8:20 – 8:50

Pre-Submission Draft Guidance Review

Danielle Turley, OIR

8:50 – 9:45

**Effective Use of the Pre-Submissions Process:
An Industry View**

Christopher Bentsen, Bio-Rad Laboratories

9:45 – 10:15

Key Statistical Aspects of a Clinical Trial

Marina Kondratovich, OIR

10:15 – 10:30

Panel Discussion / Q&A
