

# 2015 Pre-Submissions Workshop

## Meeting Agenda

**Meeting materials online:** [www.amdm.org/2015-presub-presentations.html](http://www.amdm.org/2015-presub-presentations.html)

Evaluation at: [www.amdm.org/preevaluation.html](http://www.amdm.org/preevaluation.html)

Password: AMDM2015

Wednesday

April 22, 2015

8:15 a.m. – 10:30 a.m.

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7:30 – 8:15 a.m.

**Registration / Breakfast**

Room:  
White Flint

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8:15 – 8:20

**Welcome**  
Allen Webb, OIR

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8:20 – 8:50

8:50- 9:00 (Q&A)

**Pre-Submission Guidance Review**  
Danielle Turley, OIR

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9:00– 9:40

**Effective Use of the Pre-Submissions Process:  
An Industry View**  
Judi Smith, Precision for Medicine

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9:40 – 10:10

**Analytical and Clinical Studies Design Considerations for IVD Devices**  
Marina Kondratovich, OIR

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10:10 – 10:30

**Panel Discussion / Q&A**

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