Beaufort®

Accelerating Medical Innovation

Industry Update
Robert Di Tullio
AMDM 2016 IVD Focus Meeting
Los Gatos, CA

October 13, 2016

Beaufort®
Accelerating Medical Innovation

Industry Update

- Looking Forward to MDUFA IV
- Common Rule Proposed Change
- Point of Care/CLIA Waiver
- Other assorted issues along the way…

Beaufort
Accelerating Medical Innovation

MDUFA IV

- What did Industry ask for?
  - Performance Improvements, including for CLIA waiver and Pre-submission process, and overall reductions to average total time to decisions, etc.
- What did we get?
  - A reasonably good deal
- What does it all mean?
  - How about almost $1 Billion over 5 years?
  - Higher User Fees

Beaufort
Accelerating Medical Innovation

Common Rule – One Year Later

- Proposed Changes to the Common Rule September 2015
- Expanding the Definition of Human Subject to Cover Research with Non-identified Biospecimens
- Proposed Changes to Obtaining, Waiving, and Documenting Informed Consent

Beaufort
Accelerating Medical Innovation

Common Rule

- Proposal to Extend the Common Rule to All Clinical Trials (with Exceptions)
- Use of Prior Collections of Biospecimens
- Strong opposition from Industry and Research community
- Awaiting Final Rule

Beaufort
Accelerating Medical Innovation

Point of Care/CLIA Waiver

- Current Landscape – What's going on?
- CLIA Waiver Coalition/AdvaMed WG Proposals and meetings with FDA
- Next Steps towards restoring requirements specified in CLIA Waiver statute and/or modifying 2008 Guidance

Beaufort
Accelerating Medical Innovation

Beaufort®

Accelerating Medical Innovation

Robert Di Tullio
Sr. VP. Global Regulatory Services
rditullio@beaufortcro.com

Beaufort®
Accelerating Medical Innovation