



Industry Update
Robert Di Tullio
AMDM 2017 IVD Focus Meeting
Los Gatos, CA

October 5, 2017

Industry Update

- FDA - Changes at the top....what's next?
- Common Rule Change - A good resolution!
- 21st Century Cures
- Other assorted issues along the way...

FDA Leadership Changes

- Liz Mansfield
- Scott Gottlieb
- Alberto Gutierrez

Common Rule - Two Years Later

- Proposed changes to the Common Rule
September 2015
- Expanding the definition of human subject to cover research with non-identified biospecimens
- Endangered our left-over deidentified samples
- Strong opposition from industry and research community

21st Century Cures

- Exemptions, Exemptions, Exemptions...
- Waiver of Informed Consent for low risk studies
- Cancer Moonshot
- Speed up development and review of novel medical products



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