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Industry Update
Robert Di Tullio
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Industry Update

- Significant Changes in FDA
- Common Rule Proposed Change
- CLIA Waiver
- Semantic Interoperability – Effects on Industry

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Changes

- Significant Changes in FDA

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Common Rule

- Scope of Proposed Changes and Applicability of the Regulations.
- Effects on IVD's Specifically
- Expanding the Definition of Human Subject to Cover Research with Non-identified Biospecimens
- Proposed Changes to Obtaining, Waiving, and Documenting Informed Consent

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Common Rule

- Proposed Changes to Protect Information and Biospecimens
- Proposal to Extend the Common Rule to All Clinical Trials (with Exceptions)
- Effective and Compliance Dates of New Rule
- Use of Prior Collections of Biospecimens

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CLIA Waiver

- Current Landscape
- AdvaMed Dx CLIA Waiver WG Proposals
- CLIA Waiver Coalition Proposals
- Next Steps towards restoring requirements specified in CLIA Waiver statute and/or modifying 2008 Guidance

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Lab Interoperability

- What this means
- Semantic interoperability Standards, e.g. LOINC
- How this affects Dx Companies

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