

AIMIC

Key AI Concepts

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Introduction



- The Artificial Intelligence in Medical Imaging Coalition (AIMIC) is a group of leading medical imaging companies
 - Dedicated to advancing patient care
 - Supports innovative and effective use of artificial intelligence (AI).
 - Believes AI in medical imaging can provide substantial patient benefit in a cost-effective manner.
- Ralph F. Hall – Principal – Leavitt Partners
 - Professor of Practice – University of Minnesota Law School



Avoid AI Exceptionalism



- AI should not automatically trigger new or additional regulatory oversight
- Locked AI has many similarities to existing software products
 - Past use of “training data” for product development
 - ICDs
 - Imaging devices
 - Neuromodulators
 - Complex “black box” algorithms also exist
 - Similar need for unbiased data inputs
 - Same transparency questions
- Existing regulatory systems provide oversight framework for locked AI
 - Avoid special rules for locked AI
 - Unlocked AI may require some unique regulatory approaches



FDA Should Focus on Intended Use



- Intended use is the basis for FDA jurisdiction and requirements
- Premarket review should focus on intended use
 - Data needs
 - Benefit/risk assessment
 - Premarket process
- Data robustness, bias and transparency needs to be framed by intended use
- Post market data collection also should focus on intended use
- Looking outside of the intended use framework may not be supported by statute



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Smart on Value

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