

# SOFTWARE THOUGHT-LEADERSHIP SERIES



Tuesday, February 7  
4:00 PM to 5:15 PM



## FDA REGULATION OF CLINICAL DECISION SUPPORT SOFTWARE & ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING (AI/ML)

### DISCUSSION

When is digital health software regulated by FDA as a medical device?

What regulatory considerations apply to product development for medical device software, including AI/ML?

### THE SPEAKERS

**Pamela Forrest**

Partner at Covington  
& Burling LLP



**Christina Kuhn**

Associate at Covington  
& Burling LLP



### REGISTRATION

[Zoom webinar link](#)

Questions:  
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