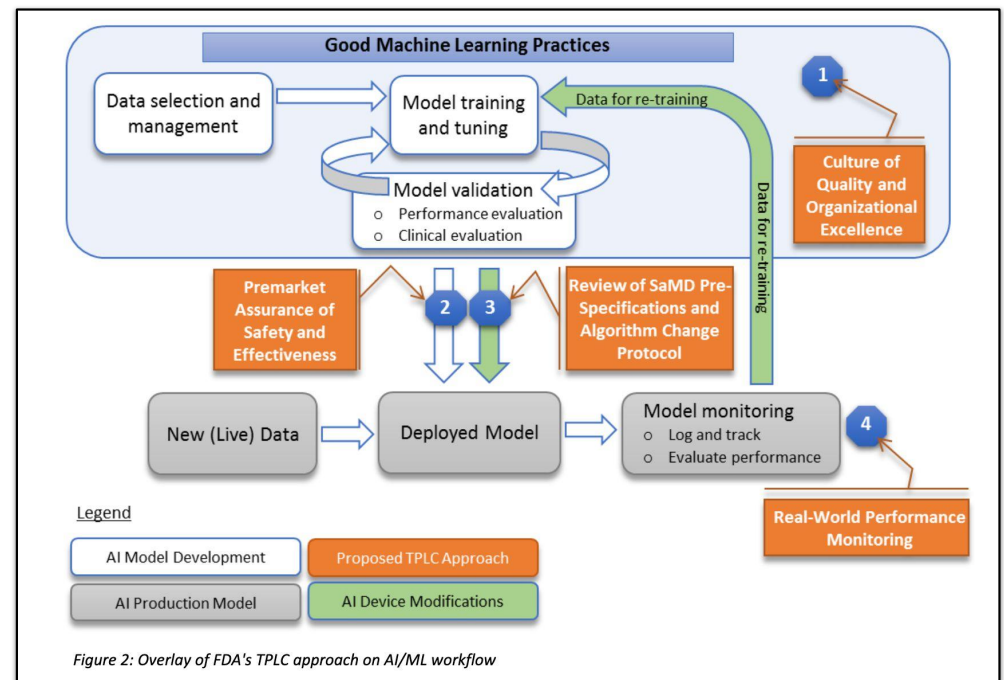# In Progress | FDA Total Product Life Cycle (TPLC) Approach

The FDA has proposed a TPLC approach for AI and ML technologies, emphasizing the importance of transparency, real-world performance monitoring and clear expectations for modifications and updates to AI/ML algorithms

The TPLC approach:

- Provides FDA staff with a holistic view, from device development through commercialization, which helps guide device premarket and postmarket decision-making

- Promotes transparency and consistency in medical device premarket and postmarket review activities, which provides predictable and clear expectations to device manufacturers

A cradle to grave approach to Generative AI models/uses would be prudent to manage ongoing risk and complexity.

Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

Access the model HERE