At the second PDUFA Negotiation meeting on 10/07, FDA provided Industry with an overview of its IT governance structure and Information Management (IM) program and roadmap. FDA and Industry then engaged in a fruitful discussion of Digital Health Technologies (DHT), identifying points of alignment and areas for particular focus.

1. **FDA Governance Structure.** FDA described its IT governance structure, discussing with Industry how IT strategic decision-making occurs across Agency and Centers to meet both Program and enterprise needs effectively. FDA confirmed that while Programs have unique needs, the governance model is geared towards taking an enterprise approach.

2. **Information Management Roadmap.** FDA described its IM program and roadmap, informing Industry that the primary objective is to create a user-centric advanced analytics ecosystem to answer regulatory questions. While sponsored by CDER, the initiative is being developed in close collaboration with CBER and the Agency for broader use.
3. **Digital Health Technologies.** FDA and Industry agreed that a program focused on continually improving the ability to utilize DHTs in drug development and oversight would be mutually beneficial. FDA and Industry identified two key themes, including additional guidance to industry on the use of DHTs in drug development and oversight, and consistency within and across Centers where appropriate. FDA and Industry will continue discussion on this topic at subsequent negotiation sessions.