At the third PDUFA Negotiation meeting on 10/14, FDA and Industry discussed FDA’s digital health technologies (DHT) proposal. FDA and Industry identified and agreed upon points of alignment regarding primary objectives.

FDA discussed the DHT proposal with Industry to determine Industry’s perspective. FDA proposed convening public forums focusing on DHTs in clinical trials; Industry concurred that this would enable community discussion as different groups currently are shaping the digital health ecosystem. Industry expressed interest in learning more about how CDER/CBER would interact with the Digital Health Center of Excellence (DHCoE). FDA presented its proposal to enhance consistency. FDA also proposed ensuring IT support to enable review of DHT-generated data. FDA noted that this could not be performed without a cloud capability, viewing cloud as an enterprise-wide solution to fix the issue of scalability. Industry agreed that the DHT proposal as a whole was moving in the correct direction but wanted further clarity around FDA’s proposals.

FDA and Industry began their conversation of the FDA’s cloud proposal at a high-level and potential pilot to enhance the review process and agreed to continue the conversation at the next negotiation meeting.