At the twelfth PDUFA Negotiation meeting, FDA and Industry discussed draft DHT commitment language and alignment of key priority areas for Data/IT Modernization language.

The parties continued exploring alignment on appropriate usage and reporting of data from DHTs trials, including proper measurement and detection. FDA and Industry discussed FDA progress reporting options on the IT modernization strategy, as well as the feasibility of specific deadlines proposed by Industry. The group discussed FDA’s progress on implementing cloud-based technology in the Agency. FDA and Industry agreed to further consider commitments and to continue discussion at the next meeting.

There were no other substantive proposals or significant controversies.