At the twelfth PDUFA Negotiation meeting, FDA and Industry discussed the Data/IT Modernization proposal. FDA and Industry discussed commitment language, resources, and alignment regarding key priority areas.

FDA and Industry reviewed draft Data/IT commitment language and discussed FDA’s plans related to enterprise-wide IT modernization efforts. Industry shared its interest in reporting modernization progress, and its impact on enhancing review process. FDA described its continued efforts in developing a roadmap toward modernization including milestones and phasing and clarified its expected scope. FDA outlined its plans to engage with external stakeholders in the area of cloud technologies, offering to provide quarterly reports on the progress of demonstration projects. FDA and Industry agreed to continue further discussion of the proposal at the next meeting.

There were no other substantive proposals or significant controversies.