PILOT PROGRAMS SHOWCASE REGULATORY INNOVATION

Begun in 2018, the Real-Time Oncology Review (RTOR) and Assessment Aid (AA) pilot programs share the goal of improving the efficiency of the U.S. Food and Drug Administration (FDA) review process and speeding the delivery of safe and effective drugs and biologics to cancer patients.

RTOR:

- Allows the FDA to access key datasets before the official submission of a new drug or biologic license application.
- With earlier access to data, the FDA can begin reviewing the data earlier and communicate with the company before the formal submission.
- RTOR can drastically cut review time, typically to a few weeks after complete submission.

AA:

- AA is a template for a form that accompanies submission of a drug or biologic application in which most sections are divided into two parts: one to convey the company's position and one for the FDA's assessment.
- The goals of AA are to allow FDA reviewers to better focus on key details of an application, and to increase review efficiency through consistent formatting.