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## Authorization to Operate Decision Memorandum

**From:** Craig Taylor, Authorizing Official  
**To:** Elaine Johanson, System Owner  
**Date:** October 12, 2018  
**Subject:** Authorization to Operate for FDA Office of the Commissioner PrecisionFDA Cloud System

Our IT infrastructure, network, systems, and applications face constant cybersecurity threats, vulnerabilities, and risks. Both external and internal threats leverage computer access to exploit sensitive information that can negatively impact our mission, as well as U.S. National and Economic Security. We must reduce risk and/or minimize the potential impact on our computing resources, sensitive data, funds, productivity, and public health reputation.

An assessment of the FDA OC PrecisionFDA Cloud System and its system-level components has been conducted in accordance with the Office of Management and Budget Circular A-130, Appendix III, National Institute of Standards and Technology guidelines, and the FDA Security Authorization Program. After reviewing the security controls that have been implemented and planned and weighing the enterprise risks against the operational requirements and FDA mission, the FDA OC PrecisionFDA Cloud system is granted an Authorization to Operate at the moderate impact level.

The Authorization to Operate will remain in effect as long as the following conditions are met:

- The required security reports are submitted in accordance with Office of Management and Budget Circular A-130, Department of Health and Human Services and National Institute of Standards and Technology guidance.
- New vulnerabilities are mitigated and do not change the system's security posture.
- No significant changes are made within or to the authorization boundary without approval from the Authorizing Official.
- The authorization does not exceed the maximum allowable time period of 3 years.

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Craig Taylor  
Chief Information Officer (CIO) (Acting)  
Authorizing Official (AO)  
U.S. Food and Drug Administration

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Date Signed