

## **21<sup>st</sup> Century Cures Act Report Regarding the Qualification Process under Section 507 of the Federal Food, Drug, and Cosmetic Act.**

Section 3011(c)(2) of the 21<sup>st</sup> Century Cures Act (Cures) requires that, not later than 5 years after the date of enactment of Cures, FDA make publicly available on the Agency's website a report. The report shall include the following information regarding the drug development tool qualification program under section 507 of the Food, Drug, and Cosmetic Act:

- (A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool;
- (B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package, respectively;
- (C) the number of such requests for which external scientific experts were utilized in the development of a qualification plan or review of a full qualification package;
- (D) the number of qualification plans and full qualification packages, respectively, submitted to FDA; and
- (E) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment.

This report is intended to satisfy this requirement.

### **Reporting Period: December 13, 2016 – December 13, 2021**

- (A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool: **118**
- (B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package, respectively: **63**
- (C) the number of such requests for which external scientific experts were utilized in the development of a plan or review of a full qualification: **3**
- (D) the number of qualification plans and full qualification packages, respectively, submitted to FDA:
  - **51 Qualification Plans**
  - **7 Full Qualification Packages**
- (E) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment:
  - **2 Qualified Biomarkers**
    - DDT BMQ 000044, Monitoring biomarker informs initiation of treatment with anti-malarial drug following controlled human malaria infection (CHMI) with *P. falciparum* sporozoites in healthy subjects in clinical studies for vaccine and/or drug development

- DDT BMQ 000014, Safety biomarker panel to aid in the detection of kidney tubular injury in phase 1 trials in healthy volunteers
- **4 Qualified Clinical Outcome Assessments**
  - DDT COA 000008: Symptoms of Major Depressive Disorder Scale (SMDDS)
  - DDT COA 000009: Non-Small Cell Lung Cancer Symptom Assessment Questionnaire
  - DDT COA 000006: Asthma Daytime Symptom Diary (ADSD); Asthma Nighttime Symptom Diary (ASNSD)
  - DDT COA 000005: Diary for Irritable Bowel Syndrome Symptoms-Constipation (DIBSS-C)