**Table 1. Alternative Tools Used for GCP Evaluations in FY2020 and FY2021**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Alternative Tool** | **FY2020****N (%)** | **FY2021****N (%)** | **Total** **N (%)** |
| **Remote Evaluations from FDA Locations** | 28 (72%) | 25 (66%) | 53 (69%) |
| **Remote Evaluations of Non-US Sites from US Sponsor or Agent Locations** | 10 (26%) | 6 (16%) | 16 (21%) |
| **Review of Study Records Obtained from Sponsors Through FDA’s Information Request** | 1 (2%) | 2 (5%) | 3 (4%) |
| **Review of Inspection Reports Shared by European Medicines Agency** | 0 | 5 (13%) | 5 (6%) |

**Table 2. Characteristics of GCP Evaluations Conducted Using Alternative Tools in FY2020 and FY2021**

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristics of Evaluations** | FY2020N=39 | FY2021N=38 | TotalN=77 |
| **New Drug Application (NDA)** | 23 (59%) | 32 (84%) | 55 (71%) |
| **Biologics License Application (BLA)** | 16 (41%) | 6 (16%) | 22 (29%) |
| **Original Submission**  | 33 (85%) | 29 (76%) | 62 (81%) |
| **Supplemental Submission**  | 6 (15%) | 9 (24%) | 15 (19%) |
| **Evaluations of Clinical Investigators** | 33 (85%) | 28 (74%) | 61 (79%) |
| **Evaluations of Sponsors/CROs** | 6 (15%) | 10 (26%) | 16 (21%) |
| **Sites Located Outside United States** | 33 (85%) | 27 (71%) | 60 (78%) |
| **Sites Located in the United States** | 6 (15%) | 11 (29%) | 17 (22%) |
| **Mission Critical** | 20 (51%) | 27 (71%) | 47 (61%) |
| **Non-Mission Critical** | 19 (49%) | 11 (29%) | 30 (39%) |

CRO = contract research organization

**Figure 1. The Total Number of On-site Good Clinical Practice (GCP) Inspections for Clinical Investigators, Sponsors, and Contract Research Organizations for CDER Marketing Applications in Fiscal Years 2015–2021**

This graph demonstrates the pandemic impact on on-site GCP inspections. On average, there were 481 on-site GCP inspections conducted yearly from FY2015 to FY2019. The total number of on-site GCP inspections conducted in FY2020 and FY2021 was 370 and 451, representing a 23% and 6% decrease, respectively.

**Figure 2. The Total Number of Good Clinical Practice (GCP) Activities Conducted for Clinical Investigators, Sponsors, and Contract Research Organizations for Marketing Applications in Fiscal Years 2015–2021**

GCP activities included on-site GCP inspections and GCP evaluations using alternative methods. Alternative methods contributed 10% and 8% to total GCP activities in FY2020 and FY2021, respectively.