U.S. FOOD & DRUG ADMINISTRATION

Oncology Center of Excellence

Diversity Plans - Oncology

Project Equity is a public health initiative established by the U.S. FDA Oncology Center of Excellence, to ensure that the data supporting approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended.

Voluntary Submission of Diversity Plans to Oncology Review Divisions

Year One Experience: April 2022 – April 2023

Lola. A. Fashoyin-Aje,[1,2] Jessica Boehmer,[1] Ramya Antony,[1] Asma Dilawari,[2] Kelie Reece,[2] Tamy Kim,[1,2] Richard Pazdur[1,2]

[1]Oncology Center of Excellence, [2]Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Diversity Plan Submissions Following FDA Recommendations in Draft Guidance

In April 2022, FDA issued a draft guidance (*https://www.fda.gov/media/157635/download*) recommending that sponsors of certain drugs, biological products, and devices (medical products), submit Diversity Plans (DPs) that describe their plan to enroll racially and ethnically representative populations in clinical trials intended to support the approval or licensing of these medical products.

This measure was taken to improve the enrollment of racial and ethnic populations that have been historically underrepresented in biomedical research, including in clinical trials.

The draft guidance recommends that a DP includes:

- An overview of the disease or condition under investigation in the clinical trial as it is distributed across racial and ethnic groups,
- The sponsor's enrollment goals for each racial and ethnic population, and,
- A description of the measures that the sponsor plans to implement achieve the stated enrollment goals.

Herein, we report on DP submissions in the oncology divisions in CDER during the first year following publication of the draft guidance.

Methods and Analysis Plan

Diversity Plan submissions to investigational new drug (IND) applications occurring between April 13, 2022, and April 13, 2023, were identified using the FDA's Document Archiving Reporting, and Regulatory Tracking System (DARRTS). The Plans were analyzed in the following manner:

- Information was manually abstracted from individual initial and amended DP submissions and were pooled for analysis.
- DPs were assessed for information on the following five elements of a DP described in FDA's draft guidance: "Overview of disease or condition," "Scope of Development Program", "Enrollment goals," "Measures to achieve enrollment goals", and "Status of Meeting Enrollment Goals."
- Information from correspondence sent to Sponsors between April 13, 2022, and May 30, 2023, regarding FDA feedback on the DP was also analyzed.

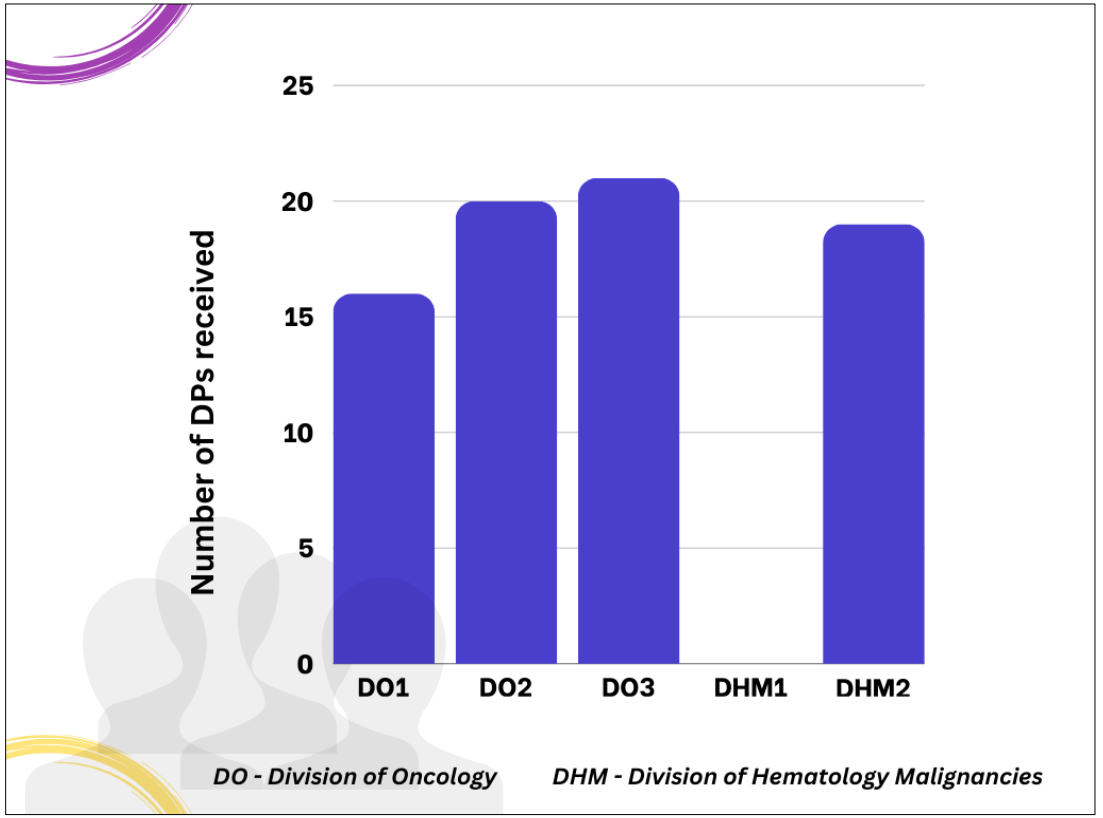
Diversity Plans (DPs) Received Between 4/13/2022 – 4/13/2023

Of the **91** DPs submitted to CDER during the evaluation period, **76 (84%)** were submitted to the oncology divisions.

Note that this analysis is limited to the 76 DPs submitted to CDER's oncology divisions

- Oncology DP submissions were from **42** unique Sponsors comprising **40** indications (see figures)
- The median number of DPs submitted by unique sponsors was **1** (range: 1, 14)

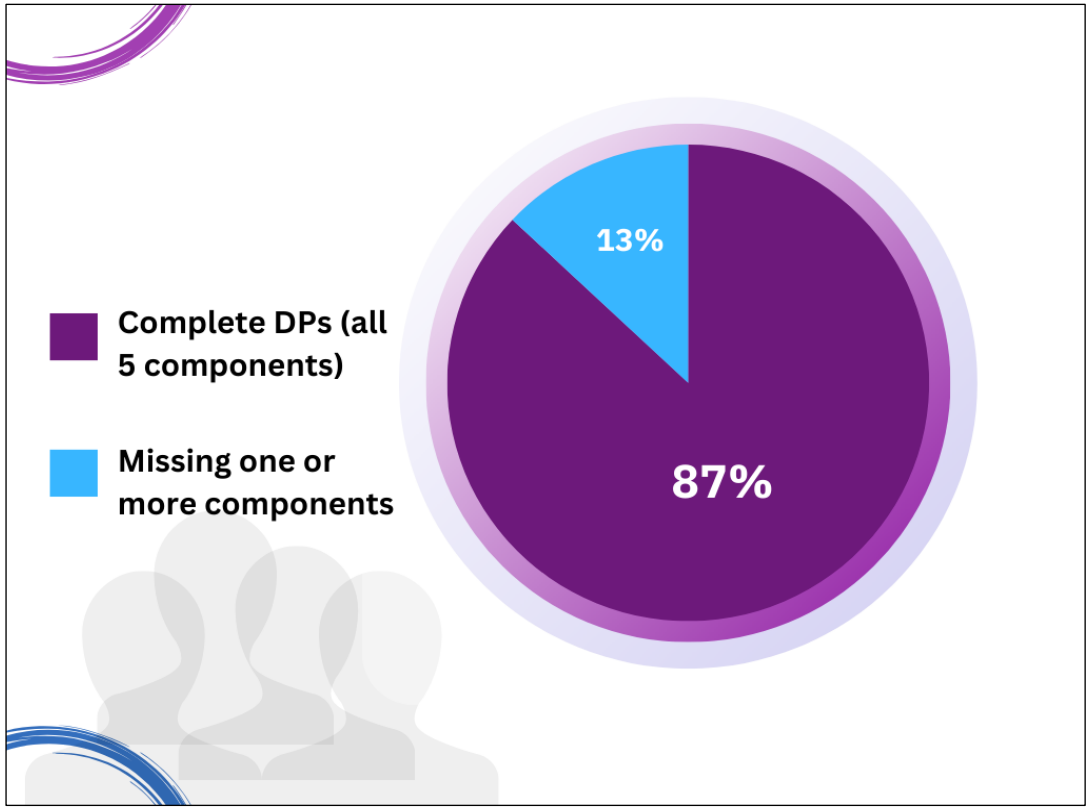
Diversity Plans Received by Oncology Division: N=76



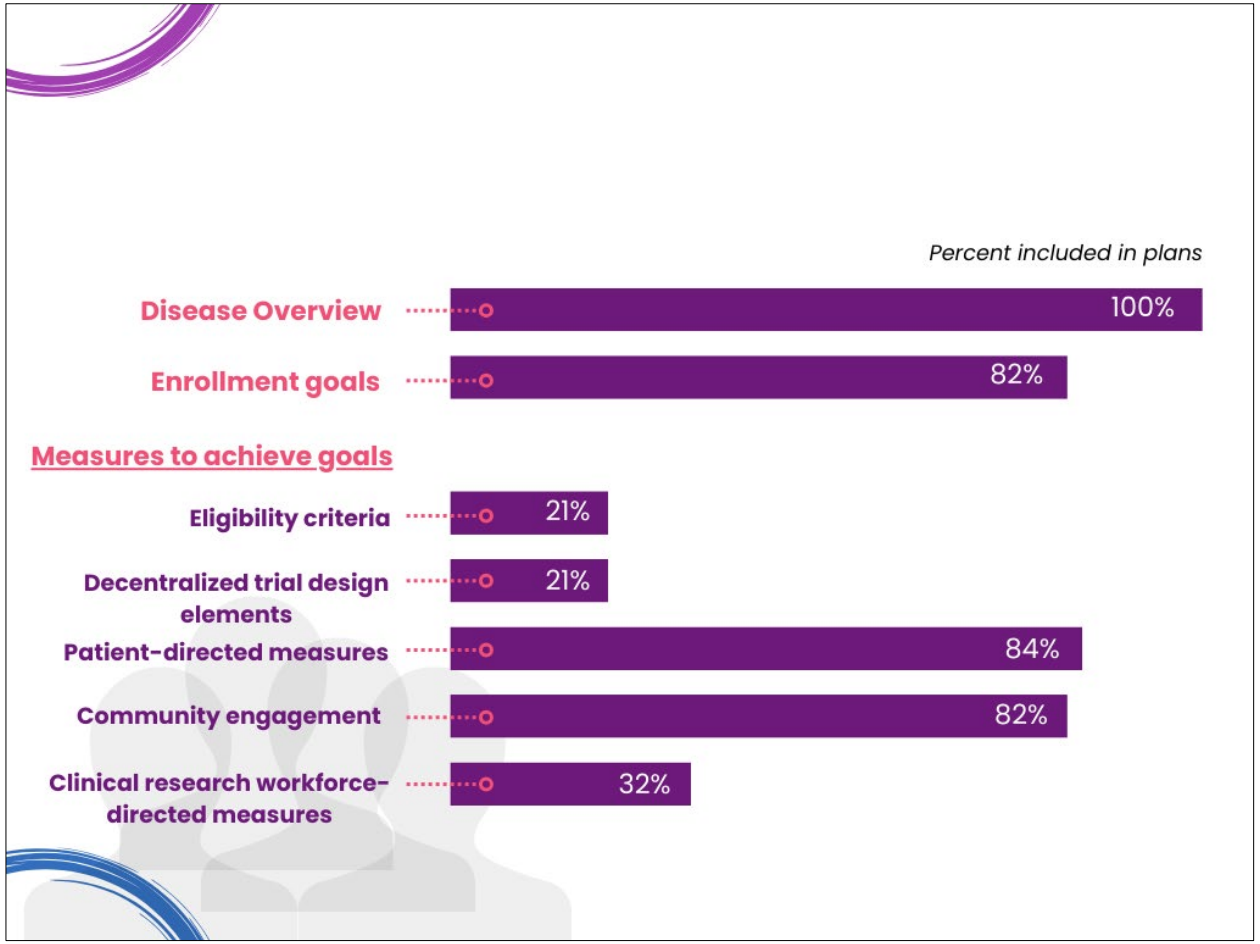
Completeness of Diversity Plans

DP content completeness was assessed based on **five** components specified.

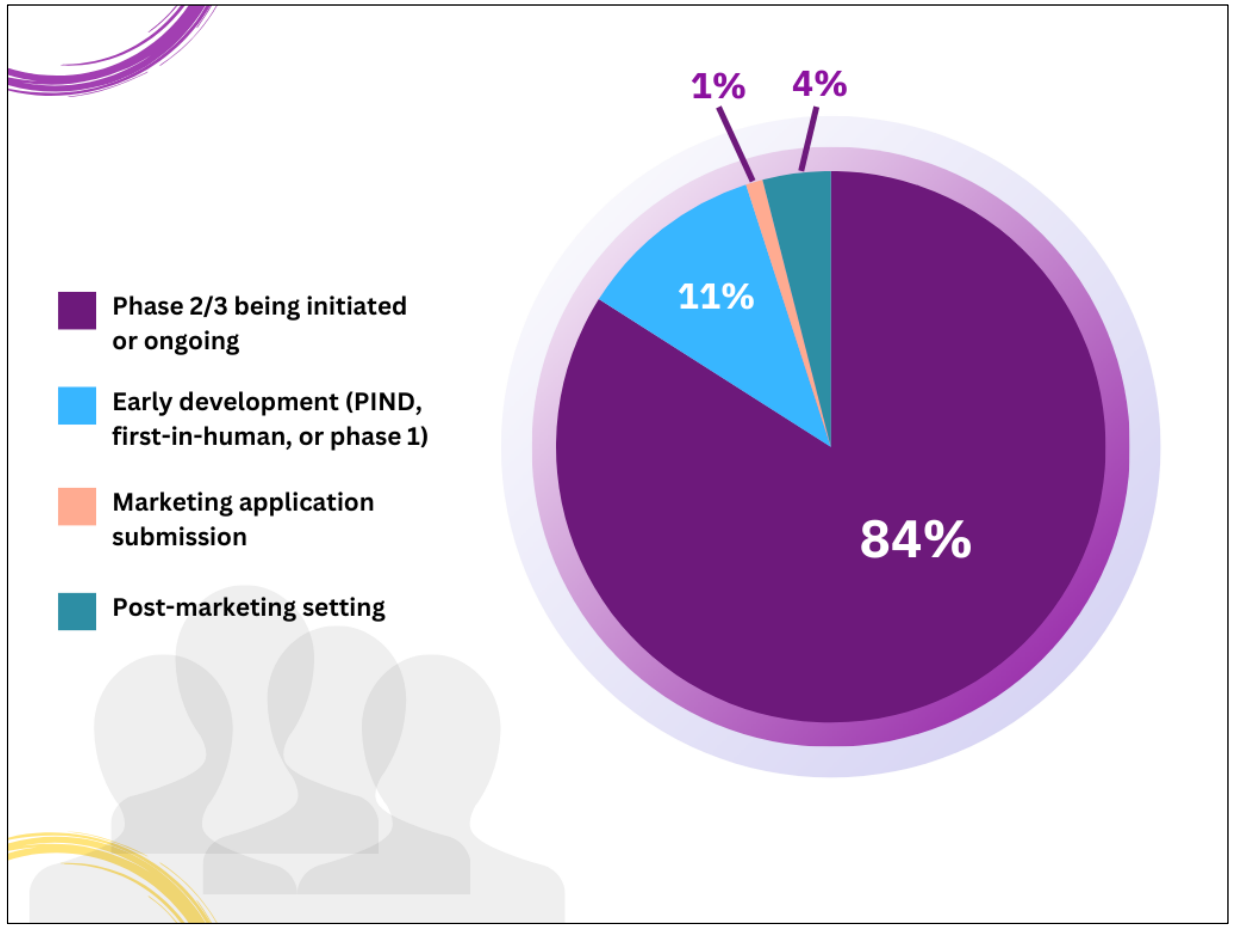
DP Content- Five Recommended Components



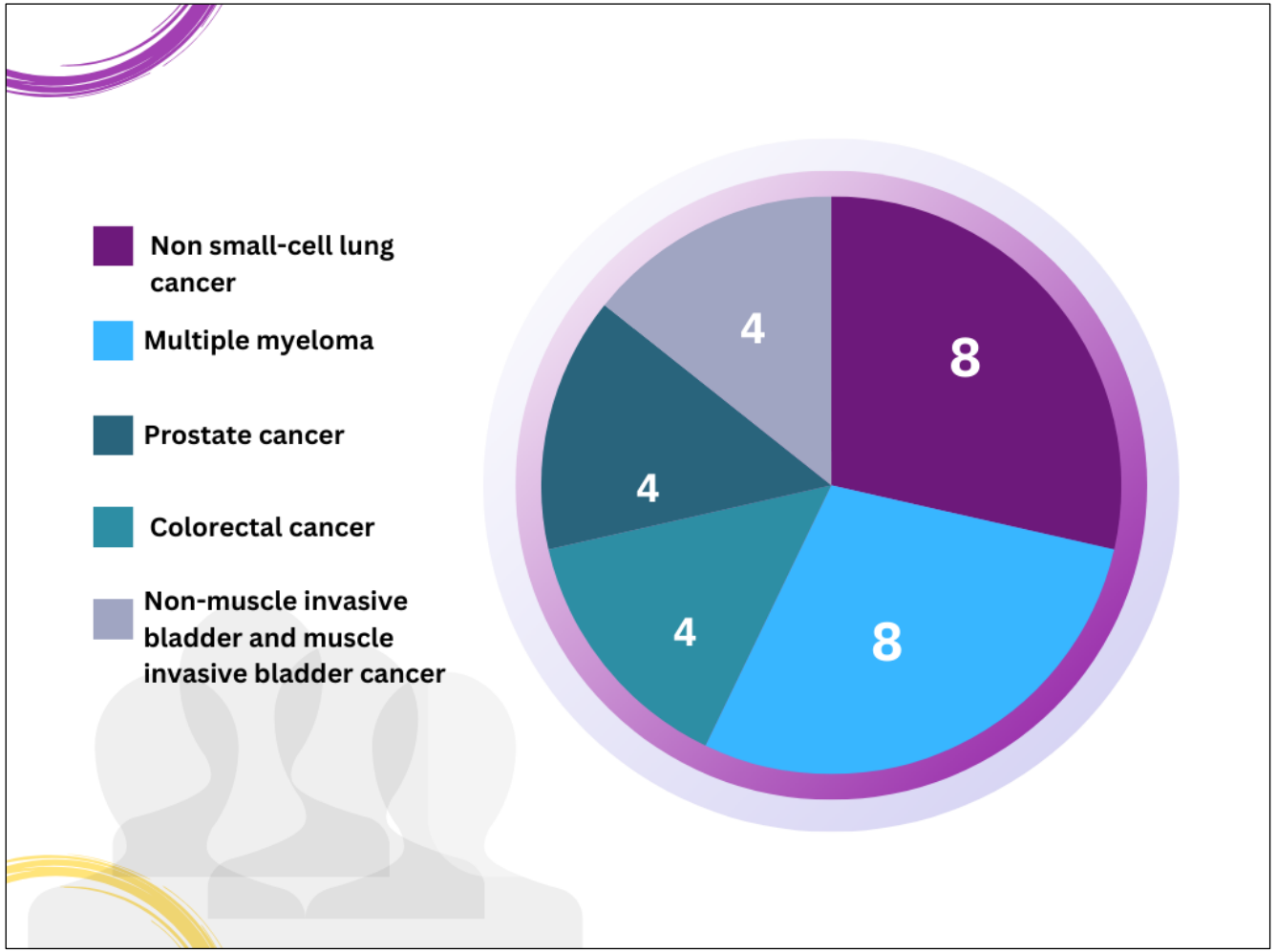
Diversity Plan Content: Planned Measures to Achieve Enrollment Goals



Timing of the DP Submissions Relative to Stage in Clinical Development



Top Five Indications in Diversity Plan Submissions



Full List of Indications in Diversity Plan Submissions

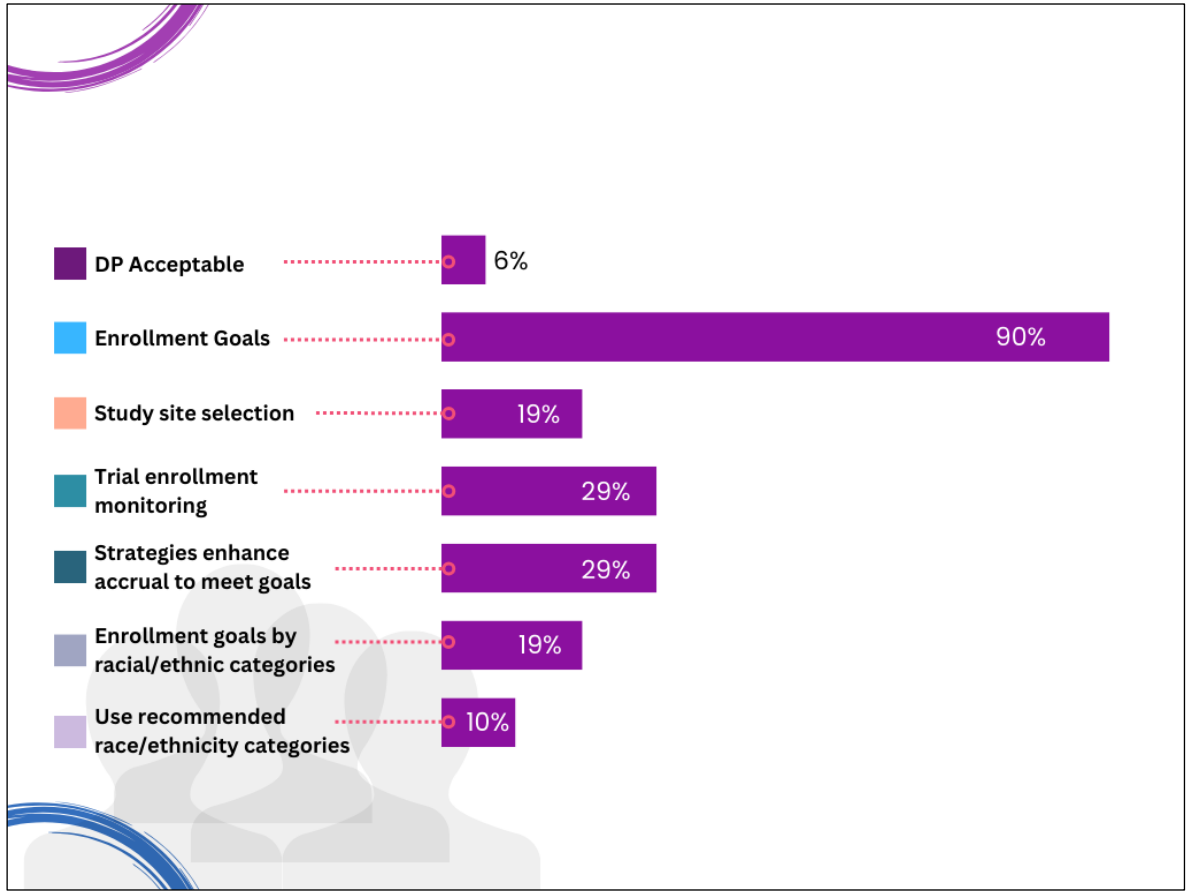
Cancer	2
Melanoma	1
Multiple myeloma	8
Prostate cancer	4
Renal Cell Carcinoma	3
Endometrial carcinoma	1
Solid Tumors with FGFR2 pathway alterations	1
Colorectal cancer	4
Hepatocellular Carcinoma	2
Lymphoma	1
NSCLC	8
B-cell malignancies	2
Ovarian cancer	2
Nasopharyngeal carcinoma	2
Solid Tumors	2
Glioma	1
Hematologic malignancies	3
Dedifferentiated liposarcoma	1
MSI-H or dMMR unresectable or mCRC	1
B-cell malignancies	1
Esophageal squamous cell carcinoma	1

Cholangiocarcinoma	1
diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma, chronic lymphoid leukemia	1
EGFR-mutated NSCLC	3
dMMR or MSI-H rectal cancer	2
Gastric cancer or gastroesophageal junction cancer	1
Lung Cancer	1
non-muscle invasive bladder cancer and muscle invasive bladder cancer	4
Esophageal carcinoma	1
HER2-positive Gastroesophageal Adenocarcinoma (GEA); HER2-positive Gastroesophageal Adenocarcinoma (GEA)	1
Limited-stage small cell lung cancer	1
Ovarian cancer	1
B-Cell Lymphoma	1
Solid Tumor	1
Hepatocellular carcinoma	1
Classical Hodgkin lymphoma	1
Breast cancer; NSCLC	1
HR+/HER2-breast cancer	1
NSCLC; SCCHN	1
SCLC	1

FDA Feedback on Diversity Plans

- FDA provided feedback on the sponsors' proposals for 31 of 76 DPs (41%).
- Average time from DP receipt to FDA sending comments to Sponsors was **61 days**.
- For the 31 DPs for which FDA provided feedback, the feedback focused on the topics listed in the figure.

Topics Addressed in FDA Comments by percentage - Certain DP feedback contained multiple topics.



Authorship Credit

Lola. A. Fashoyin-Aje,[1,2] Jessica Boehmer,[1] Ramya Antony,[1] Asma Dilawari,[2] Kelie Reece,[2] Tamy Kim,[1,2] Richard Pazdur.[1,2] **Voluntary Submission of Diversity Plans to Oncology Review Divisions in the Center for Drug Evaluation and Research (CDER) Following FDA Draft Guidance: Year one experience: April 2022 – April 2023**. Project Equity Website: *https://www.fda.gov/about-fda/oncology-center-excellence/project-equity* (November 2023)

Author Affiliations: [1]Oncology Center of Excellence, [2]Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Contact: OCE-Equity@fda.hhs.gov

Acknowledgements

OCE Project Equity
OCE Leadership
OOD Leadership
OOD clinical reviewers
OND-ORO-ONCOLOGY
OCE Communications Team
OCE Guidance Team
CDER-Office of Medical Policy
CDER-Office of Regulatory Policy
CDER-Office of Clinical Pharmacology
FDA Office of Minority Health and Health Equity
FDA Office of Women's Health