

FDA-GRASP Workshop for Experienced Oncology Patient Advocates Wednesday March 25, 2026

OVERVIEW

This workshop will be held at the <u>FDA White Oak Campus</u> in Silver Spring, Maryland. This workshop is designed for patient advocates representing a wide variety of cancer types with advanced research advocacy experience interested in enhancing their knowledge regarding the FDA's role in cancer drug development.

Applicants must be U.S. citizens or lawful permanent residents (i.e. green card holders).

APPLICATION DEADLINES

<u>Application Opens</u>: Wednesday Oct 1, 2025 <u>Deadline to Apply</u>: Friday Nov 7, 2025 <u>Acceptance Decision</u>: By December 5, 2025

Apply here*

*If you are unable to apply online, please contact us at FDAworkshop@graspcancer.org

SCHEDULE OF EVENTS

Tuesday, March 24, 2026: Welcome dinner and reception

Wednesday, March 25, 2026: Day-long intensive workshop

TIME COMMITMENT REQUIREMENTS

- Participants must attend the in-person workshop on March 25, 2026; The welcome dinner and reception will be held the evening before and are highly recommended to attend, though not required.
- Approximately **10 hours of virtual engagement** including:
 - o 6–7 hours of online coursework prior to the workshop.
 - o Two 1.5-hour Zoom training sessions prior to the workshop.
- Applicants may also be requested to do a brief interview.

PARTICIPATION CRITERIA

This advanced-level workshop is designed for experienced advocates. Participants with <u>three (3) or more</u> of the following criteria will be given preference for selection:

- Patient, caregiver, or advocate associated with a rare cancer defined as one with fewer than 15 cases per 100,000 people annually. See a comprehensive list from the American Cancer Society.
- Completed a cancer research advocacy training program.
- Served as a patient advocate on a cancer research grant.
- Served as a patient advocate reviewer for entities that fund cancer research (e.g. Department of Defense (DoD), National Cancer Institute, American Society of Clinical Oncology (ASCO), Conquer Cancer®, etc.).
- Served as a steering committee or advisory board member for entities that conduct cancer research.
- Served as a patient advocate representative for a cancer clinical trial cooperative group.
- Served as a panelist for a cancer research event, conference or an FDA event (internal or public).
- Co-authored a peer-reviewed scientific publication in cancer research.

COMPENSATION

• All expenses related to meals, accommodation, and travel are included for accepted participants.

WORKSHOP OBJECTIVES

This workshop aims to create a new collaboration between well-trained patient research advocates and the entities that drive clinical trial standards in the United States, including the FDA, pharmaceutical companies, and other similar entities. Patient advocates who have successfully completed the day-long intensive workshop and case-based training in coordination with FDA oncologists will have a basic knowledge of:

- Oncology drug regulation (the role of the FDA, globalization of drug development).
- The Investigational New Drug (IND) process (what an IND is, when an IND is required, and what criteria are used by the FDA to decide if a research study may proceed).
- Expanded access programs (single patient INDs/compassionate use, emergency INDs, expanded access protocols).
- Disease-specific considerations (e.g., novel endpoints in specific diseases, biomarker development).
- Expedited development programs (e.g., breakthrough therapy designation, fast track designation, priority review, accelerated approval).
- Clinical trial design (eligibility criteria, endpoint selection, comparator arms, dose optimization, non-inferiority vs. superiority vs. equivalence, statistical methods)
- Common errors in oncology drug development.
- Biomarker and companion diagnostics.
- The role of the advocate in patient-focused drug development.