

## **2019 Accelerating Anticancer Agent Development and Validation Workshop (AAADV)**

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Every spring, the Food and Drug Administration (FDA), Duke University, American Association for Cancer Research (AACR) and American Society of Clinical Oncology (ASCO) sponsor the AAADV Workshop to bring together scientists, pharmaceutical companies, regulatory agencies and patient advocates involved in drug development. Discussions include urgent issues and new approaches for treatment and clinical trial design as well as case studies of recent drug approvals to help identify ways to bring safe and effective cancer treatments to patients more quickly.

The sessions and dialogue I found most interesting included efforts to Decentralize Clinical Trials, efforts to capture Real World Evidence and incorporate Patient Reported Outcomes (PROs) into more clinical trials, and ongoing work needed to develop and validate liquid biopsy.

Patient Advocates are included on every panel. I was the patient advocate on the External Controls in Clinical Trials in Rare Diseases: Opportunities and Challenges panel. Use of external controls means that historical data is used as the control arm avoiding the need for randomization. This can be helpful in rare cancers and rare subtypes when there are not as many patients available to participate in clinical trials. I shared with the attendees that many patients do not want to be randomized and use of external controls may increase participation. I also shared that patients want to engage with researchers and that a recent study by the [Clinical Trials Transformation Initiative \(CTTI\)](#) showed that trials with early patient engagement accrued faster and needed fewer amendments, saving both time and money.

There is also a Patient Advocate Workshop for patient advocates to learn about the regulatory agencies and help prepare them to engage and network during the full AAADV Workshop.

Scholarships are available and information to apply for the 2020 meeting will be available in January.

The 2019 AAADV Agenda can be found here:  
<https://aaadv.org/2019/05/08/2019-aaadv-agenda/>

For more information about AAADV, please see:  
<https://aaadv.org/>

For more information about Patient Engagement with the FDA, please see:  
<https://www.fda.gov/patients/learn-about-fda-patient-engagement>

For more information about ovarian cancer research advocacy with OCRA, please see:  
<https://ocrahope.org/advocacy/research-advocacy/>