

# **Evidence-Based Treatment Decisions In Transplantation: The Right Dose & Regimen for the Right Patient/Individualized Treatment**

*The following originally appeared on [fda.gov](http://fda.gov):*

## **Summary:**

The Food and Drug Administration is announcing the following public workshop titled “Evidence-Based Treatment Decisions In Transplantation: The Right Dose & Regimen for the Right Patient/Individualized Treatment. This public workshop is planned and presented in collaboration with the Transplant Therapeutics Consortium (TTC), a public-private partnership between the FDA, transplantation societies and members of the pharmaceutical and biotechnology industries, founded by the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and Critical Path Institute (C-Path) in March 2017. The workshop is intended to discuss potential candidate biomarkers to determine organ transplant patients’ immunologic risk for organ rejection or tolerance. The meeting will include discussion of the biomarker qualification process and how it could be used to develop biomarkers for use in clinical trials in transplantation, to develop new drugs to address unmet needs, and in clinical practice to guide patient treatment selection. Patient speakers will provide perspective on challenges of living with a transplant, managing immunosuppression and perspectives on tolerability, adherence and risk that may inform PRO and patient focused drug development.

Presentations and discussions will cover identifying potential candidate biomarkers that could

- be considered for the biomarker qualification process
- be used in identifying patients at high immunologic risk or low immunologic risk
- be used in clinical trials to develop drugs to address unmet individual needs in transplantation
- be used to make appropriate immunosuppressive regimen treatment decisions

In addition, patient speakers will provide perspectives on

- challenges of living with a transplant,
- managing immunosuppression, and
- tolerability, adherence and risk of therapy

The goal of these presentations is to inform PRO and patient focused drug development.

## **Date and Time:**

The public workshop will be held on September 27, 2018, from 8:00 a.m. to 6 p.m. and September 28, 2018, from 8 a.m. to 12:30 p.m. (Eastern Time)

## **Location:**

The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Building 31 Great Room, Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to [Public Meetings at the FDA White Oak Campus](#).

### **Registration:**

To register, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to [TransplantationWorkshop2018@fda.hhs.gov](mailto:TransplantationWorkshop2018@fda.hhs.gov) by **September 14, 2018**. Registrants will receive email confirmation when they have been accepted. Persons without access to the Internet can call 301-796-1300 to register. Onsite registration on the day of the meeting will start at 7:00 am and will be provided based on space availability.


### **Requests for Oral Presentations:**

During online registration, you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by **September 14, 2018**. All requests to make oral presentations must be received by the close of registration on **September 10, 2018**. If selected for presentation, any presentation materials must be emailed to [TransplantationWorkshop2018@fda.hhs.gov](mailto:TransplantationWorkshop2018@fda.hhs.gov) no later than **September 19, 2018**. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

### **Contact:**

If further information is needed, please contact Derek Alberding, PharmD, or Ramou Pratt, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 240-402-0963, [derek.alberding@fda.hhs.gov](mailto:derek.alberding@fda.hhs.gov) or 301-796-3928, [ramou.pratt@fda.hhs.gov](mailto:ramou.pratt@fda.hhs.gov).

### **Streaming Webcast:**

This public workshop will also be webcast at <https://collaboration.fda.gov/ebtd092018/>. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview)  disclosure icon unknown.

### **Meeting Materials:**

The agenda, speaker slides and other meeting material will be posted here a few days prior to the workshop. Please note that only printed copies of the agenda, affiliations and disclosures will be provided during the meeting. Please print/bring your own slides, as these will not be provided on the day of the meeting as printed copies.

### **Webcast Recordings:**

A recording(s) of the workshop will be posted here shortly after the completion of the workshop.

**Transcripts:**

Transcripts will be posted here approximately one month after the completion of the workshop.