# FDA/OCE Public Meeting on Relevant Molecular Targets in Pediatric Cancers: Applicability to Therapeutic Investigation FDARA 2017

**FDA White Oak Campus Building 31**  
**White Oak Great Room A**  
10903 New Hampshire Avenue  
Silver Spring, Maryland  
**April 20, 2018**

## AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter/Participant Details</th>
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| 8:00 am | Introduction and Background                                             | **Gregory Reaman, MD**  
Associate Director (Acting) for Pediatric Oncology  
Oncology Center of Excellence, OC  
Associate Director, Oncology Sciences  
Office of Hematology and Oncology Products, CDER, OND  
U.S. Food and Drug Administration (FDA) |
| 8:15 am | Targeted Therapeutics and the Potential for Precision Medicine in Pediatric Oncology | **Donald W. Parsons, MD, PhD**  
Co-Director, Brain Tumor Program  
Co-Director, Cancer Genetics and Genomics Program  
Director, Pediatric Center for Personal Cancer Genomics and Therapeutics  
Texas Children’s Hospital |
| 8:45 am | Classification of Molecular Targets and Additional Considerations Related to Relevance to Pediatric Cancers | **Malcolm A. Smith, MD, PhD**  
Associate Branch Chief for Pediatrics  
Clinical Investigations Branch, CTEP, DCTD, NCI |
| 9:00 am | Panel Discussion and Public Comments on Gene Abnormality Targets        | **Scott A. Armstrong, MD, PhD, Dana-Farber Cancer/Boston Children’s**  
**Katherine A. Janeway, MD, Dana-Farber Cancer/Boston Children’s**  
**Rajen Mody, MBBS, Mott Children’s Hospital**  
**Giles W. Robinson, MD, St. Jude Children’s Research Hospital**  
**Hubert Caron, MD, PhD, Roche**  
**Ralf Herold, MD,PhD, Bayer**  
**Mark Kieran, MD, PhD, Dana-Farber/Boston Children’s**  
**Javed Khan, M.D., National Cancer Institute**  
**Danielle Leach- Patient Advocate**  
**Leslie Doros, MD, FDA**  
**Christy Osgood, MD, FDA** |
| 10:30  | **Break**                                                               |                                                                                               |
10:45 am  Panel Discussion and Public Comments on Cell Lineage Targets

**Moderators**
- E. Anders Kolb, MD, Dupont Hospital for Children
- Brenda Weigel, MD, MSc, University of Minnesota
- Malcolm A. Smith, MD, PhD, National Cancer Institute
- Darshan Wariabharaj, Janssen Research & Development, LLC
- Donna Ludwinski- Patient Advocate
- Shannon Maude, MD, PhD, Children’s Hospital of Philadelphia
- Nicholas Richardson, DO, MPH, FDA
- Lori Ehrlich, MD, PhD, FDA
- Maura O’Leary, MD, FDA
- Najat Bouchkouj, MD, FDA

12:15 pm  Lunch

1:15 pm  Panel Discussion and Public Comments on Non-cancer cell Targets

**Moderators**
- Timothy Cripe MD, PhD, Nationwide Children’s Hospital
- Mark Kieran, MD, PhD, Dana-Farber/Boston Children’s
- Elad Sharon, MD, National Cancer Institute
- David Munn, MD, Medical College of Georgia
- Karen Weiss, MD, Janssen Research & Development, LLC
- Eric Rubin, MD, Merck
- Nancy Goodman- Patient Advocate
- Amy Barone, MD, FDA
- Ashley Ward, MD, FDA

2:00 pm  Panel Discussion and Public Comments on Other Targets and Non-Relevant Targets

**Moderators**
- Brenda Weigel, MD, MSc, University of Minnesota
- Elizabeth Fox, MD, Children's Hospital of Philadelphia
- Gilles Vassal, MD, Institut Gustave Roussy
- Alice Chen, MD, National Cancer Institute
- Nita L. Seibel, MD, National Cancer Institute
- Ralf Herold, MD, Bayer
- Hubert Caron, MD, PhD, Roche
- Lucy Vereshchagina, PhD, PhRMA
- Susan Weiner- Patient Advocate
- Martha Donoghue, MD, FDA
- Diana Bradford, MD, FDA

3:15 pm  Summary  Greg Reaman, MD

3:30 pm  Adjourn