

The Foundation for the National Institutes of Health  
National Cancer Institute and FDA Oncology Center of Excellence

**Public Meeting on Development of a Public Private Partnership  
Developing Anti-Cancer Therapies for Ultra-Rare Tumor Indications**

August 24, 2023

Zoom: <https://fnih.zoom.us/j/83722291582?pwd=dWNVbGJldi90VU0zd0dCd1BTQT11UT09>

Passcode: 183993

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|-------------------------|---|
| <b>11:00-11:15 am</b>   | Introduction, Agenda Review, and Meeting Objectives<br><i>Stacey Adam, FNIH</i>                                 |
| <b>11:15-11:30 am</b>   | Opening Remarks<br><i>Monica Bertagnolli, NCI</i><br><i>Marc Theoret, OCE FDA</i>                               |
| <b>11:30-11:45 am</b>   | The Challenge of Drug Development for Ultra-Rare Cancers<br><i>Karlyne Reilly, NCI</i>                          |
| <b>11:45am-12:00 pm</b> | FDA Engagement in the Proposed Public-Private Partnership for Ultra-Rare Cancers<br><i>Martha Donoghue, FDA</i> |
| <b>Break – 10 min</b>   |   |
| <b>12:10-12:20 pm</b>   | Compound Screening to Lead Compound<br><i>Jay Schneekloth, NCI CCR</i>  |
| <b>12:20-12:40 pm</b>   | Preclinical Testing Models for Rare Tumors<br><i>Malcolm Smith and Alice Chen, NCI CTEP</i>                     |
| <b>12:40-12:50 pm</b>   | Preclinical IND Enabling Studies at NIH<br><i>Liz Ottinger, NCATS</i>   |
| <b>12:50-1:00 pm</b>    | NCI SBIR Funding Mechanisms For Ultra-Rare Cancer Drug Development<br><i>William Bozza, NCI SBIR</i>            |
| <b>1:00-1:10 pm</b>     | Incentives and Challenges for Participation with Large Pharma<br><i>David Weinstock, Merck</i>                  |
| <b>1:10-1:20 pm</b>     | Patient Advocate Perspective on Need for Partnership<br><i>Jim Palma, TargetCancer Foundation</i>               |
| <b>1:20-1:30pm</b>      | Summarized Strawman for PPP<br><i>Stacey Adam, FNIH</i>   |
| <b>1:30-2:00 pm</b>     | Discussion and Q&A<br><i>Roundtable Participants</i>  |

- 2:00-2:50 pm**            Questions from Virtual Audience for Roundtable  
*Roundtable Participants*
- 2:50-3:00 pm**            Closing Remarks/Wrap up  
*Stacey Adam, FNIH*

### **Round Table Participants**

- *David Drewry, UNC, SGC*
- *Sarah Glass, N-Lorem*
- *Rachel Harding, University of Toronto, SGC*
- *Lyn Jones, Dana-Farber Cancer Institute, Harvard Medical School*
- *Andrew Lo, MIT*
- *Peter Marks, FDA CBER*
- *Anne Pariser, Alltrna*
- *Jimmy Rosen, READDI*
- *Angela Shen, Massachusetts General Brigham*
- *Louis Stancato, Eli Lilly*
- *Brigitte Widemann, NCI*
- *John Zhang, AACR*