



# Defining Patient Populations for Clinical Studies in Multiple Myeloma

An FDA/IMS Joint Workshop



Oncology Center of Excellence

## February 22, 2024 | Hyatt Regency Bethesda

**7:00 – 8:00 AM**      **NETWORKING BREAKFAST**

**8:00 – 8:30 AM**      **SESSION 1: WELCOME**

8:00 - 8:15 AM      Nikhil Munshi, International Myeloma Society Workshop Co-Chair, Dana Farber Institute  
 8:15 - 8:30 AM      Bindu Kanapuru, FDA Workshop Co-Chair, U.S. Food and Drug Administration

**8:30 - 11:00 AM**      **SESSION 2: RELAPSED OR REFRACTORY MULTIPLE MYELOMA**

8:30 - 8:45 AM	Relapsed or refractory multiple myeloma	Kenneth Anderson
8:45 - 9:00 AM	Regulatory Considerations for approval in RRMM	Andrea Baines
9:00 - 11:00 AM	Panel Discussion <i>Moderator: Nikhil Munshi</i>	Kenneth Anderson, Andrea Baines, Yelak Biru, Faith Davies, Rod Humerickhouse, Bindu Kanapuru, Odoardo Olimpieri, Sham Mailankody, Jesus San Miguel

**11:00 - 11:15 AM**      **BREAK**

**11:15 - 12:15 PM**      **SESSION 3: BIOMARKER CONSIDERATIONS**

11:15 - 11:30 AM	MRD and biomarker considerations	Deepti Telaraja
11:30 - 12:15 PM	Panel Discussion <i>Moderator: Shaji Kumar</i>	Jesus Berdeja, Yelak Biru, Orlando Bueno, Ajai Chari, Pierre Demolis, Nicole Gormley, Sundar Jagannath, Marivi Mateos, Deepti Telaraja

**12:15 - 1:15 PM**      **LUNCH**

**1:15 PM - 3:00 PM**

**SESSION 4: NEWLY DIAGNOSED MM**

1:15 - 1:30 PM

Newly diagnosed MM

Vincent Rajkumar

1:30 - 3:00 PM

Panel Discussion

*Moderator: Vincent Rajkumar*

Natalie Callander, Bindu Kanapuru,  
Sagar Lonial, Tom Martin,  
David Mitchell, Jordan Schecter,  
Alex Schwarsin, Michal Zwiewka

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**3:00 - 3:15 PM**

**BREAK**

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**3:15 - 4:15 PM**

**SESSION 5: CONSOLIDATION AND MAINTENANCE**

3:15 - 3:30 PM

Consolidation and maintenance

Philippe Moreau

3:30 - 4:15 PM

Panel Discussion

*Moderator: Noopur Raje*

Rachel Ershler, Nicole Gormley,  
Zandra Klippel, Edward Laane,  
Suzanne Lentzsch, David Mitchell,  
Philippe Moreau, Krina Patel,  
Saad Usmani

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**4:15 - 4:30 PM**

**WRAP - UP**

Nikhil Munshi and Nicole Gormley

**Special Thanks**

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