



## Joint Summit of International Bladder Cancer Group (IBCG) & the Global Society of Rare Genitourinary Tumors (GSRGT)

**DECEMBER 14<sup>th</sup>, 2024**

**Sala Convegni - HOTEL NH Milano 2 - SEGRATE [MI]**

### **DEFINING NEW ENDPOINTS AND DESIGN OF NEXT-GENERATION TRIALS OF PERIOPERATIVE THERAPIES IN MUSCLE-INVASIVE BLADDER CANCER**

half a day (13.00-17.30)

- 13.00 - 13.15 **Welcome and Introduction**  
*Andrea Necchi, Matthew D. Galsky (virtual), Ashish M. Kamat, Philippe E. Spiess*
- 13.15 - 13.25 **Fresh updates on neoadjuvant therapy trials in MIBC: local vs systemic therapy**  
*Andrea Necchi*
- 13.25 - 13.35 **Contextualizing the use of clinical response to neoadjuvant therapy in MIBC:  
framework of the available data**  
*Matthew D. Galsky (virtual)*
- 13.35 - 13.45 **The urologist's perspective: when, how and why shall we avoid radical cystectomy**  
*Sarah P. Psutka (virtual)*
- 13.45 - 13.55 **The radiologist's perspective: how can we improve the accuracy of cross sectional imaging**  
*Lawrence H. Schwartz*
- 13.55 - 14.05 **The patient perspective: a vision on a novel therapeutic journey**  
*Rick Bangs (virtual)*

14.05 - 14.15 **The radiation oncologist perspective: defining unfitnes to radical radiotherapy**  
*Jason A. Efstathiou*

14.15 - 14.35 **The regulatory perspective: European Medicines Agency**  
*Olli Tenhunen*

14.35 - 14.55 **The regulatory perspective: U.S. Food and Drug Administration**  
*Elaine Chang (virtual)*

14.55 – 15.30 *Coffee Break*

15.30 - 17.10 **Roundtable discussion and consensus development:  
using clinical complete response in modern perioperative therapy trials**

Facilitators: *Andrea Necchi, Matthew D. Galsky (virtual), Ashish M. Kamat, Philippe E. Spiess*

Discussants:

**Medical oncologists:** *Neeraj Agarwal, Petros Grivas, Sumanta K. Pal, Yohann Loriot, Shilpa Gupta, Begoña Pérez-Valderrama (virtual), Fernando Maluf, Andrea Apolo (virtual), Jonathan Rosenberg (virtual), Daniel M. Geynisman (virtual), Elizabeth Plimack (virtual), Guru P. Sonpavde (virtual), Sarmad Sadeghi*

**Urologists:** *Francesco Montorsi, Alberto Briganti, Ashish M. Kamat, Philippe E. Spiess, Maurizio Brausi, Marco Moschini, Sarah P. Psutka (virtual), Dingwei Ye (virtual), Bogdana Schmidt (virtual), Gagan Prakash (virtual), Seth Lerner (virtual), Siamak Daneshmand (virtual), Peter C. Black (virtual), Savino di Stasi*

**Radiation oncologists:** *Jason A. Efstathiou, Leslie Ballas (virtual), Nick D. James (virtual)*

**Radiologists:** *Lawrence H. Schwartz, Giorgio Brembilla*

**Nuclear medicine physicians:** *Arturo Chiti*

**Pathologists:** *Hikmat Al-Ahmadie (virtual), Maurizio Colecchia, Liang Cheng (virtual), Alessia Cimadamore (virtual)*

**FDA representatives:** *Jaleh Fallah (virtual), Daniel Suzman (virtual), Sundeep Agrawal (virtual), Elaine Chang (virtual), Chana Weinstock (virtual)*

**EMA representatives:** *Francesco Pignatti, Elias Pean, Olli Tenhunen*

**Biostatisticians:** *Alexia Iasonos (virtual), Irina Ostrovnaya (virtual)*

**Patient advocates:** *Rick Bangs (virtual), Lydia E. Makaroff (virtual)*

- 15.30 - 15.40 **Presentation of the results of the IBCG virtual poll**  
*Andrea Necchi*
- 15.40 - 15.50 **Discussion**  
*Ashish M. Kamat*
- 15.50 - 16.00 **Update from RETAIN: type of relapses, treatment patterns and outcomes**  
*Daniel M. Geynisman (virtual)*
- 16.00 - 16.05 **Discussion – Facilitators**
- 16.05 - 16.15 **Update from HCRN GU16-257: type of relapses, treatment patterns and outcomes**  
*Matthew D. Galsky (virtual)*
- 16.15 – 16.20 **Discussion – Facilitators**
- 16.20 - 16.30 **Outline of the type of relapses, treatment patterns and outcomes after standard chemoradiation protocols**  
*Nick D. James (virtual)*
- 16.30 - 16.40 **Emerging data on liquid biomarkers associated with complete response to neoadjuvant therapy: ctDNA – Petros Grivas;  
utDNA – Liang Cheng (virtual)**
- 16.40 - 16.50 **Statistical considerations for the design of a randomized trial incorporating a response-based approach**  
*Alexia Iasonos (virtual) / Irina Ostrovnaya (virtual)*
- 16.50 - 17.10 **Final Roundtable Discussion and Conclusions – All Faculty**



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**SEGRATE [MI]**

**Neeraj Agarwal**

Division of Medical Oncology, Department of Internal Medicine, Huntsman Cancer Institute, University of Utah, Salt Lake City, USA

**Sundeep Agrawal**

Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD, USA

**Hikmat Al-Ahmadie**

Department of Pathology and Laboratory Medicine, Genitourinary Pathology Service, Memorial Sloan Kettering Cancer Center, New York, NY, USA

**Andrea B. Apolo**

Genitourinary Malignancies Branch, National Cancer Institute, Center for Cancer Research, Bethesda, MD, USA

**Leslie Ballas**

Department of Radiation Oncology, Cedars-Sinai Medical Center, Los Angeles, CA, USA

**Rick Bangs**

Bladder Cancer Advocacy Network, Bethesda, MD, USA

**Peter C. Black**

Department of Urology Sciences at the University of British Columbia (UBC), Vancouver, Canada

**Maurizio Brausi**

Department of Urology, Cure Hesperia Hospital, Modena, Italy

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Cleveland Clinic Taussig Cancer Institute, Cleveland, Ohio

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Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, USA

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Institute of Cancer Research and the Royal Marsden Hospital, London, UK

**Ashish M. Kamat**

President, International Bladder Cancer Group (IBCG) Department of Urology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

I N V I T E D F A C U L T Y



**DECEMBER 14<sup>th</sup>, 2024**  
**SEGRATE [MI]**

**Seth P. Lerner**

Baylor College of Medicine, Dan L Duncan Cancer Center, Houston, TX, USA

**Yohann Lorient**

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**Lydia E. Makaroff**

World Bladder Cancer Patient Coalition, Brussels, Belgium; Fight Bladder Cancer UK, Oxford, UK

**Fernando Maluf**

Latin American Cooperative Oncology Group - LACOG, Porto Alegre, Brazil; Hospital Beneficencia Portuguesa de São Paulo, São Paulo, SP, Brazil

**Francesco Montorsi**

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City of Hope Comprehensive Cancer Center, Duarte, CA, USA

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European Medicines Agency, Amsterdam, Netherlands

**Begoña Pérez-Valderrama**

Hospital Universitario Virgen del Rocío, Seville, Spain

**Francesco Pignatti**

European Medicines Agency, Amsterdam, Netherlands

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Fox Chase Cancer Center, Temple Health, Philadelphia, PA, USA

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**Jonathan E. Rosenberg**

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**Sarmad Sadeghi**

MD, PhD, Associate Professor of Clinical Medicine and Urology, Norris Comprehensive Cancer Center University of Southern California

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Huntsman Cancer Institute, University of Utah, Salt Lake City Veterans Administration Medical Center, Salt Lake City, Utah, USA

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Director of Genitourinary Medical Oncology & Phase I, Clinical Research Christopher K. Glanz Chair for Bladder Cancer Research, AdventHealth Cancer Institute, Professor of Medicine, University of Central Florida, Orlando, FL, USA

**Philippe E. Spiess**

President, Global Society of Rare Genitourinary Tumors (GSRGT)

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**Olli Tenhunen**

M.D., Ph.D., Vice-chair, Oncology Working Party, European Medicines Agency  
Fimea, Finnish Medicines Agency

**Chana Weinstock**

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**SEGRATE [MI]**

Meeting Chairs: **Andrea Necchi, Matthew D.Galsky**

On behalf of IBCG (*International Bladder Cancer Group*):

**Ashish M. Kamat**

On behalf of GSRGT (*Global Society of Rare Genitourinary Tumors*):

**Philippe E. Spiess**

Location: **Sala Convegni, Hotel NH Milano 2**  
**Strada di Olgia Nuova - Segrate [Milan]**

Date: Saturday December 14<sup>th</sup>, 2024

Duration: half a day (13.00-17.30)

**EVENTO NON ECM**

**SEGRETERIA ORGANIZZATIVA**

EXPOPOINT - Organizzazione Congressi Eventi



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