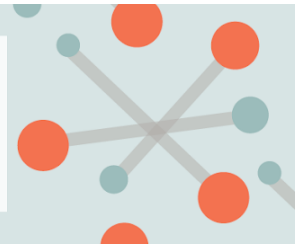


NEXTGEN THERAPIES IN SJIA, STILL'S & MAS

Focus on Clinical Trials and options for Refractory Disease

Wednesday 16 - Friday 18 February 2022 | Virtual Event Organized by Systemic JIA Foundation



NextGen Therapies in SJIA, Still's & MAS (Virtual)

Organized by: **Systemic JIA Foundation**

URL: <https://www.systemicjia.org/nextgen22/>

When: **Wed, Feb 16th - Fri, Feb 18th, 2022**

8am - 1pm EST | 1pm to 6pm UTC

Registration is Free!

[General Registration](#) | [Speaker Registration](#)

[Patients / Caregivers: Apply to Patient Ambassador Program](#)

The overall goal of the NextGen series of conferences is to advance therapies for SJIA, Still's Disease and MAS. The specific focus this year is clinical trials and therapeutic options for refractory disease. Conference will include all stakeholders: scientists, clinicians, patients & caregivers, regulators & pharmaceutical companies.

Contact Us:

- If you want to get in touch about conference program, email us at contact@systemicjia.org
- General registration enquiries can be submitted to the conference secretariat at systemicjia@mci-group.com

Agenda for NextGen Therapies in SJIA, Still's & MAS, 2022

Wednesday, Feb 16th (8am to 1pm EST / 1pm to 6pm UTC)

SESSION 1: UNMET NEEDS IN SJIA

(defining the problem, and the patient groups)

8:00am - 8:15am

Welcome

Unmet Needs in Refractory SJIA & MAS - SJIA Foundation Perspective

- *Rashmi Sinha*
- *Patients: Kari Cupp, Laura Bogg, Robyn Rivera, Ronny Bachrach*

8:15am - 8:30am

Distinct Clinical Phenotypes in Refractory SJIA & MAS

- *Alexei Grom*

8:30am - 9:15am

The elephant in the room: SJIA Diagnostic/Classification Criteria

- *Panel moderated by Peter Nigrovic | Panelists: Yuki Kimura, Bas Vastert, Fabrizio De Benedetti & Dan Lovell*
- *Discussion + Invited Comments from FDA & EMA*

9:15am - 10:00am

It is time for IL18 Driven Clinical Trials

- *Session moderated by Dan Lovell*
- *Fabrizio De Benedetti & Scott Canina*
- *Ed Behrens: Case study of patient with IL18 inhibitor usage in SJIA-LD*

- *Chris Leptak: Regulatory Perspective about Biomarkers in Drug Development*

10:00am – 10:30am **BREAK**

SESSION 2: HAEMATOPOIETIC STEM CELL TRANSPLANTATION IN SJIA-LD

(when current drugs cannot control disease)

10:30am - 12:30pm **HSCT in SJIA-Lung Disease: Recent Cases from Centers in US & Europe**

Patient Stories: Luciana Peixoto & Pauline Acevedo

Moderator: Scott Canna | Participants: Juliana Silva, Elvira Cannizzaro, Ulrike Zeihofer, Johannes Roth, Donna Wall, Susan E Prockop, Karen Onel, Bénédicte Neven, Pierre Quartier, Rolla F. Abu-Arja, Kyla Driest, Rebecca Marsh & Grant Schulert

12:30pm - 1:00pm **Working Session: SJIA/Still's Criteria and IL18 Driven Trials**

Thursday, Feb 17th (8am to 1pm EST / 1pm to 6pm UTC)

SESSION 3: CLINICAL TRIALS FOR SJIA & MAS: PROPOSALS + INVITED COMMENTS

(defining groups and overcoming barriers to clinical trials)

8:00am - 8:05am **Welcome to Day 2**

Rashmi Sinha

8:05am - 8:25am **Real World Evidence for Rare Disease Clinical Trials**

Isaac Kohane

8:25am - 9:10am **How to Overcome Barriers to MAS Clinical Trials?**

Patient Panel - Regina Minerva, Sarah Tronsdal, Robyn Rivera

- *Short Presentations: Barriers to MAS Trials: Alexei Grom & Fabrizio DeBenedetti*
- *Panel Discussion + Invited Comments from FDA & EMA*

9:10am - 10:00am **How to Include Refractory SJIA w/out Arthritis in Clinical Trials?**

Patient Panel: Zulayka Martinez, Anna Carlson, Leah Bush, Cappy Culicchia

Moderator: Hermine Brunner

- *Proposals for including this patient group: Alexei Grom*
- *Panel Discussion + Invited Comments from FDA & EMA*

10:00am – 10:30am **BREAK**

SESSION 4: DESIGNING TRIAL FOR RARE DISEASES: EXTERNAL CONTROLS & OTHER CONSIDERATIONS

(what type of trials to design)

10:30am - 10:38am **Setting the Context: MAS & Refractory SJIA - Disease & Proposed Trials**

Alexei Grom

10:35am - 10:50am **The Role of External Controls in FDA Decision Making**

Veronica Miller

10:50am - 11:05am **Proposed Design for Retrospective Natural History Study in Refractory SJIA & MAS**

Fabrizio De Benedetti + Alexei Grom

11:05am - 12:00pm **External Controls in Clinical Trials: Panel Discussion + Invited Comments**

Participants to be announced

Invited Comments from FDA & EMA

- 12:00pm - 12:30am **Searching for Historical Controls in Existing Datasets**
Grant Schulert: Yuki Kimura, Bas Vastert
- 12:30pm - 1:00pm **Working Session: External Controls: Reviewing the Options**

Friday, Feb 18th (8am to 1pm EST / 1pm to 6pm UTC)

SESSION 5: WORKING SESSIONS

- 8:00am - 8:05am **Welcome to Day 3**
- 8:05am - 9:00am **Working Sessions:**
- 8:05am - 9:00am **Part 1: Accelerate Study Planning & Coordination**
- 9:00am - 10:00am **Part 2: Retrospective Natural History Study Planning**
Moderator Grant Schulert & Alexei Grom / Participants: Scott Canna, Ed Behrens, Tiphonie.Vogel, Bryce Binstadt, Lauren Henderson, Mona Riskalla, Beth Gottlieb, Randy Cron, Bas Vastert, Claudia Bracaglia
Patients: All present patients & caregivers will join discussion
- 10:00am - 10:30am **BREAK**

SESSION 6: WHAT'S NEW WITH SJIA-LUNG DISEASE

- 10:30am - 11:10am **Cytokine Plasticity Hypothesis of SJIA-LD**
Peter Nigrovic, Bryce Binstadt + Ques/Ans
- 11:10am - 12:00pm Patient Panel: Anna Carlson, Alessandro De Bartolo, Moriah Bunker, Ronny Bachrach
- 12:00pm - 12:40pm **Final Working Session**
- 12:40pm - 12:50pm **Wrap up**

