11th European and Global Summit for Clinical Nanomedicine, Targeted Delivery and Precision Medicine

The Building Blocks to Personalized Medicine

Conference and Exhibition — September 2 - 5, 2018

PROGRAMME: Status June 2018
Submission for Talks until May 30 and Posters until July 8

CLINAM Foundation
The goal of the CLINAM Foundation is to contribute to the benefit of patients and society by exploring and translating leading edge technologies towards clinical application, with an emphasis on nanomedicine, targeted medicine, precision medicine and personalization. The summit keeps its tradition to build bridges from the enabling technologies to clinical application for major and neglected diseases. There is broad support for this summit by many collaborating institutions.
Introduction

The CLINAM Summit is a globally unique event that brings together all stakeholders in nanomedicine, targeted medicine and precision medicine. It builds on the principle that fundamental scientists, developers and professionals in clinical application and all to nanomedicine related persons can mutually learn from each other to find better solutions for the medicine of the future. Based on recent groundbreaking achievements, the meeting will be a highlight that will explore the pathways to personalized medicine in diagnosis, therapy and development of materials and tools for the discipline. CLINAM is also the initiative to become an international highlight meeting forum for interdisciplinary fields of cutting edge medicine every year. CLINAM will again welcome the participants from the community of nanomedicine, targeted drug delivery and precision medicine and bring together the pioneers and worldwide opinion leaders, not only to learn and discuss but also to develop new ideas, create new collaborative projects and shape the future of medicine. Senior scientists enlighten young researchers with their long experience and expertise. The summit has more than 500 participants from more than 35 countries that make use of the role of the CLINAM Foundation as the nonprofit service provider for novel nanomedicine, targeted delivery and precision medicine. CLINAM BASEL welcomes you and wishes you three days of great science, great contacts and high level wellbeing with cultural elements in the evenings.

Target Audience

The faculty includes the pioneers and opinion leaders in the fields of medicine, nanoscience and targeted medicine, who share experience in an interdisciplinary and interactive manner that widens mutual understanding for both sides. The summit and the exhibition are aimed at physicians, as well as nonscientists with a background in pharmacology, biology, physics, chemistry, biophysics, medicine, materials science and engineering. The meeting is a particularly useful source of knowledge for the targeted medicine and delivery community. The conference is also of interest for members of the regulatory authorities as well as policymakers, experts from industry in the field of life sciences, developers of new tools and materials for nanomedicine, and all those investigating the potential of emerging technologies in the field of healthcare. Experts from venture companies can acquire knowledge on existing and upcoming developments and novel products in the emerging field of nanomedicine and knowledge based medicine. Government authorities can profit from the regulator’s international sessions. CLINAM is the worldwide melting pot for experts and a high-level communication platform where you meet those striving for the development in all fields of renewing medicine.
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.00</td>
<td>Special Lecture for Young Researchers and Students</td>
</tr>
<tr>
<td>15.30</td>
<td>General Assembly of the European Society for Nanomedicine</td>
</tr>
<tr>
<td>16.45</td>
<td>General Assembly of the International Society for Nanomedicine</td>
</tr>
<tr>
<td>18.00</td>
<td>Editorial Board Meeting, CLINAM Journal of Nanomedicine</td>
</tr>
<tr>
<td>19.45</td>
<td>First Meeting for all Speakers: Dinner at the Swissôtel Le Plaza, 1st Floor, Hall Helvetica</td>
</tr>
<tr>
<td>Mon.</td>
<td></td>
</tr>
<tr>
<td>08.00</td>
<td>Welcome Coffee</td>
</tr>
<tr>
<td>08.30</td>
<td>1. Opening Addresses</td>
</tr>
<tr>
<td>09.00</td>
<td>2. Scientific Introduction to CLINAM 11/2018: Nanomedicine in the Precision Principles</td>
</tr>
<tr>
<td></td>
<td>to Personalization of Medicine, Prof Dr. med. Patrick Hunziker</td>
</tr>
<tr>
<td>09.15</td>
<td>3. Activation of Innate Immunity: Toll-like Receptors and other Receptors of the Innate Immune System, Prof. Dr. Jules Hoffmann</td>
</tr>
<tr>
<td>10.05</td>
<td>Break</td>
</tr>
<tr>
<td>10.35</td>
<td>4. Linking the Global Threat of Resistance to Parasitic and Infectious Diseases and</td>
</tr>
<tr>
<td></td>
<td>Ribosomes: Next Generation of Antibiotics and Antiparasites, Prof. Dr. Ada Yonath</td>
</tr>
<tr>
<td>11.30</td>
<td>5. Topic 2018: The Scope of Precision Medicine</td>
</tr>
<tr>
<td>13.15</td>
<td>Lunch</td>
</tr>
<tr>
<td>14.15</td>
<td>6. Polymeric Materials for Cancer Therapy</td>
</tr>
<tr>
<td></td>
<td>7. Small Speeches on submitted Posters and University Village Posters</td>
</tr>
<tr>
<td></td>
<td>8. Understanding of the Mechanisms of Nano Interacting with Life</td>
</tr>
<tr>
<td></td>
<td>10. Risk Management for Nanomedical Products and Devices</td>
</tr>
<tr>
<td>14.45</td>
<td>Satellite 1</td>
</tr>
<tr>
<td></td>
<td>11. Education, Workforce and Regulatory Matters in Novel Nano- and Precision Drugs</td>
</tr>
<tr>
<td>16.00</td>
<td></td>
</tr>
<tr>
<td>16.30</td>
<td>12. Nanomedicine and Precision Medicine – Going to the Future</td>
</tr>
<tr>
<td>19.00</td>
<td>End of Day 1</td>
</tr>
<tr>
<td>19.40</td>
<td>Meeting in front of the Congress Center, Tram to Dinner</td>
</tr>
<tr>
<td></td>
<td>20.00 CLINAM Brokerage Dinner with Cultural Events and CLINAM Nano Award 2018 at</td>
</tr>
<tr>
<td></td>
<td>Landgasthof Riehen</td>
</tr>
<tr>
<td>Tue.</td>
<td></td>
</tr>
<tr>
<td>08.00</td>
<td>Welcome Coffee</td>
</tr>
<tr>
<td>08.20</td>
<td>13. Overcoming Barriers – Pharmaceutical Development and Manufacturing (APV Session)</td>
</tr>
<tr>
<td></td>
<td>14. Nano-Immunotherapy</td>
</tr>
<tr>
<td></td>
<td>15. Extracellular Vesicles in Nanomedicine – Exosomes</td>
</tr>
<tr>
<td></td>
<td>16. Clinical Experience with NICEs and their Follow-On Versions: Are we Closer to</td>
</tr>
<tr>
<td></td>
<td>Regulatory Alignment</td>
</tr>
<tr>
<td></td>
<td>Satellite 2</td>
</tr>
<tr>
<td></td>
<td>17. Part I Sizing of Nanoparticles: From Regulatory and Metrology Aspects to Application</td>
</tr>
<tr>
<td></td>
<td>and Analysis – Joint Workshop</td>
</tr>
<tr>
<td>10.20</td>
<td></td>
</tr>
<tr>
<td>10.50</td>
<td>18. Cancer Vaccination and Redefining Cancer: From Papillomavirus Discovery to</td>
</tr>
<tr>
<td></td>
<td>Cancer Vaccination, Prof. Dr. med. Dr. h.c. mult. Harald zur Hausen</td>
</tr>
<tr>
<td></td>
<td>* Redefining Cancer with Integrative Tumor Immunology: Novel Cutting Edge</td>
</tr>
<tr>
<td></td>
<td>Immunotherapies for Patients, Prof. Dr. Jerome Galon</td>
</tr>
<tr>
<td>13.00</td>
<td>Lunch</td>
</tr>
<tr>
<td>14.00</td>
<td>20. Diagnostic and Theranostic Concepts for Personalized Cancer Immunotherapy</td>
</tr>
<tr>
<td></td>
<td>21. Nanomedicine in Infection and Inflammation</td>
</tr>
<tr>
<td></td>
<td>22. Targeting and Drug Delivery in Nanomedicine and Precision Medicine</td>
</tr>
<tr>
<td></td>
<td>23. Novel Approaches in Material Sciences and Smart Materials in Nanomedicine</td>
</tr>
<tr>
<td></td>
<td>Satellite 3</td>
</tr>
<tr>
<td></td>
<td>19. (Closed Session) Reg. Authorities</td>
</tr>
<tr>
<td></td>
<td>17. Part II Continuation of the Workshop</td>
</tr>
<tr>
<td>16.00</td>
<td></td>
</tr>
<tr>
<td>16.30</td>
<td>24. The Regulatory Authorities’ Voice 2018</td>
</tr>
<tr>
<td>18.00</td>
<td>25. Ethical Matters</td>
</tr>
<tr>
<td>18.50</td>
<td>End of Day 2, Aperitif offered by the Canton of Basel</td>
</tr>
<tr>
<td>19.40</td>
<td>Speakers meet in front of the revolving doors of the Congress Center and leave for the</td>
</tr>
<tr>
<td></td>
<td>Speaker’s Dinner at Merian-Spitz (20.00 Aperitif on the Terrace, 20.15 Dinner)</td>
</tr>
<tr>
<td>Wed.</td>
<td></td>
</tr>
<tr>
<td>08.00</td>
<td>Welcome Coffee</td>
</tr>
<tr>
<td>08.20</td>
<td></td>
</tr>
<tr>
<td>08.30</td>
<td>26. Cardiology and Atherosclerosis Nanomedicine</td>
</tr>
<tr>
<td></td>
<td>27. Clinical Imaging in Nanomedicine and Precision Medicine</td>
</tr>
<tr>
<td></td>
<td>28. New Findings and Procedures for Clinical Therapy in Cancer Nanomedicine</td>
</tr>
<tr>
<td></td>
<td>29. Computational Modelling, Virtual Patient in Affordable Precision Medicine</td>
</tr>
<tr>
<td></td>
<td>Satellite 4</td>
</tr>
<tr>
<td></td>
<td>30. Part I Swiss Excellence in Science: SAMS/SPHN Workshop on Personalized Health</td>
</tr>
<tr>
<td>09.40</td>
<td></td>
</tr>
<tr>
<td>10.10</td>
<td>31. New Aspects of Physics in Nanomedicine Relating to Clinic</td>
</tr>
<tr>
<td></td>
<td>32. Degenerative Diseases Nanomedicine</td>
</tr>
<tr>
<td></td>
<td>33. Regenerative Medicine and Biomedical Engineering</td>
</tr>
<tr>
<td></td>
<td>34. EU-NCL European Nanomedicine Characterization Lab – Lessons learned</td>
</tr>
<tr>
<td></td>
<td>30. Part II Continuation of the Session</td>
</tr>
<tr>
<td>11.15</td>
<td>Change to Plenary Hall Montreal</td>
</tr>
<tr>
<td>11.30</td>
<td>35. New Nano-pharmacological Concepts for the Treatment of Cancer</td>
</tr>
<tr>
<td>12.40</td>
<td>Lunch and Awarding Poster Prizes</td>
</tr>
<tr>
<td>13.45</td>
<td>36. Novel Preclinical Approaches to Nanomedicine and Targeted Therapies</td>
</tr>
<tr>
<td></td>
<td>37. Rare and Neglected Diseases</td>
</tr>
<tr>
<td></td>
<td>38. Safety of Nanomedicine by Design &amp; Testing for Toxicity</td>
</tr>
<tr>
<td></td>
<td>39. Nanomedicine Applications in Delivery and Precision Medicine</td>
</tr>
<tr>
<td></td>
<td>Satellite 5</td>
</tr>
<tr>
<td></td>
<td>40. EU-US Nanomed Community of Research</td>
</tr>
<tr>
<td>15.00</td>
<td></td>
</tr>
<tr>
<td>15.30</td>
<td>41. Nanomedicine and Targeted Delivery – Late Breaking and Ongoing Trials</td>
</tr>
<tr>
<td>17.25</td>
<td>Closing Words</td>
</tr>
<tr>
<td>17.30</td>
<td>End of CLINAM 11/2018</td>
</tr>
<tr>
<td>18.00</td>
<td>Meeting in front of the Congress Center, leaving for a light Farewell Dinner at Brauei</td>
</tr>
<tr>
<td></td>
<td>(18.15)</td>
</tr>
</tbody>
</table>
Programme: Status June 2018

Sunday, September 2, 2018
All Sunday events on 2nd Floor, Hall Osaka/Samarkand. The Sunday of this Summit is reserved for official and unofficial gatherings.

12.00 Special Lecture for Young Researchers and Students
15.30 General Assembly of the European Society for Nanomedicine
16.45 General Assembly of the International Society for Nanomedicine
18.00 Editorial Board Meeting, CLINAM Journal of Precision Nanomedicine
19.45 First Meeting for all Speakers: Dinner at the Swissôtel Le Plaza**** on the 1st Floor, Hall Helvetia

Monday, September 3, 2018

Section 1: Plenary Session

Plenary Chair
Dr. med. h.c. Beat Löffler, MA, CEO, European Foundation for Clinical Nanomedicine, Basel (CH)

08.30 Opening Address from the European Foundation for Clinical Nanomedicine
Dr. med. h.c. Beat Löffler, MA, CEO, European Foundation for Clinical Nanomedicine, Basel (CH)

08.36 Opening Address from the European Commission
NN

08.42 Opening Address from the Canton of Basel-Stadt
Christoph Brutschin, Member of the Executive Council of the Canton of Basel-Stadt, Head of the Department of Economic, Social and Environmental Affairs Basel (CH)

08.48 Opening Address from the Swiss Government
Dr. Cyrille Girardin, Scientific Counselor, State Secretariat for Education, Research and Innovation SERI, Bern (CH)

Plenary Chair
Prof. Dr. med. Simo Schwartz, Jr., PhD, Director Molecular Biology and Biochemistry, Research Center for Nanomedicine (CIBBIM-Nanomedicine) University Hospital Vall d’Hebron and Vall d’Hebron Institut de Recerca (VHIR), Barcelona and President of the European Society for Nanomedicine, Basel (CH)/Barcelona (E)

About The Foundation keeps pace with the development: Nanomedicine as crucial interdisciplinary field is growing and gets in line with other fields to realize the rapid development of precision medicine. Nanomedicine is seen together with the field of genomics as a pacemaker towards the personalization of medicine.

09.00 Nanomedicine in the Precision Principles to Personalization of Medicine
Prof. Dr. med. Patrick Hunziker, President of the International Society for Nanomedicine, Basel (CH)
Monday, Hall Montreal
Opening keynote lecture 1

Plenary 3. Activation of Innate Immunity
Chair Dr. Joy Wolfram, Faculty, Mayo Clinic, Jacksonville, FL (USA); Affiliate Faculty, Houston Methodist Research Institute, Houston, TX (USA)

About Toll-like receptors-mediated activation of innate immunity controls not only host defense against pathogens but also immune disorders. The discoverer concerning the activation of innate immunity will explain how our defense system works.

09.15 Toll-like Receptors and other Receptors of the Innate Immune System
Prof. Dr. Jules Hoffmann, Nobel Laureate, Institut d’Études Avancées de l’Université de Strasbourg, Strasbourg (F)

09.55 Questions and Debate

10.05 Break

Monday, Hall Montreal
Opening keynote lecture 2

Plenary 4. Linking the Global Threat of Resistance to Parasitic and Infectious Diseases and Ribosomes
Chair Prof. Dr. Yechezkel Barenholz, Hebrew University, Hadassah Medical School, Jerusalem (IL)

About The current global escalation of resistance to parasitic infectious diseases and to ribosomes is a serious threat. It seems that the world is going towards a post-antibiotic era, in which common infections and minor injuries treated in best way for decades could become fatal again. What will be the next generation antibiotics and antiparasites?

10.35 Next Generation of Antibiotics and Antiparasites
Prof. Dr. Ada Yonath, Nobel Laureate, Weizmann Institute of Science, Structural Biology Department Rehovot (IL)

11.15 Questions and Debate

Monday, Hall Montreal

Plenary 5. Topic 2018: The Scope of Precision Medicine (12' plus 3' Questions and Debate)
Chair Prof. Dr. Yechezkel Barenholz, Hebrew University, Hadassah Medical School, Jerusalem (IL)

About Researchers and clinicians have observed during centuries inter-individual variations in clinical characteristics and therapy responses in patients. The huge importance of precision medicine has been realized only in recent years. The approach towards prevention and treatment of disease by the development of diagnostics and therapies delivering maximum effectiveness implies many disciplines. Nanomedicine has a substantial importance. The session will address different approaches to the field.

11.30 The Various Faces of Precision Medicine
Prof. Patrick Hunziker, President of the International Society for Nanomedicine, Basel (CH)

11.45 Unmet Needs in Developing Nanoparticles for Precision Medicine
Prof. Dr. med. Simo Schwartz, Jr., PhD, Director Molecular Biology and Biochemistry, Research Center for Nanomedicine (CIBBIM-Nanomedicine), University Hospital Vall d’Hebron and Vall d’Hebron Institut de Recerca (VHIR), Barcelona and President of the European Society for Nanomedicine, Basel (CH)/Barcelona (E)

12.00 Precision Therapy Based on a Molecular Platform for RNAi Therapeutics
Prof. Dr. Dan Peer, Chair, Tel Aviv University Cancer Biology Research Center, Director, Center for Translational Medicine, Director, Laboratory of Precision NanoMedicine, Dept. of Cell Research & Immunology, and Dept. of Materials Science & Engineering, Tel Aviv University, Tel-Aviv (IL)
12.15 The Importance of Precision for Controlling Assembly and Targeting of Nanomedicines  
Dr. Heinrich Haas, Vice President Drug Delivery, BioNTech RNA Pharmaceuticals GmbH, Mainz (D)

12.30 Precision Medicine in the Clinic – State of the Art  
Prof. Dr. med. Ido Wolf, Head, Oncology Division, Tel Aviv Medical Center, Tel Aviv (IL)

12.45 Virtual Self as the Basis of Truly Personalized Therapy and Prevention  
Prof. Dr. Hans Lehrach, Director, Head Department of Vertebrate Genomics, Max Planck Institute for Molecular Genetics, Berlin (D)

13.00 Precision Medicine in the Treatment of Breast Cancer of Relating Treatments to Mutation  
Dr. med. Daniela Katz, Head of Breast and Sarcoma Services at Assaf Harofeh Medical Center, Tel Aviv-Yafo (IL)

13.15 Lunch

Section 2: 4 Parallel Sessions

Monday, Hall Montreal

Parallel 1 6. Polymeric Materials for Cancer Therapy  (13' plus 2' Questions and Debate)  
Session in collaboration with the German Research Foundation (DFG) established “Collaborative Research Center on Nanodimensional Polymer Therapeutics for Tumor Therapy” (CRC 1066), Johannes Gutenberg University, Mainz (D)

Chair Prof. Dr. Rudolf Zentel, Institute of Organic Chemistry, University of Mainz (D) and Prof. Dr. Twan Lammers, Experimental Molecular Imaging, RWTH Aachen (D)

About Polymeric materials are extensively employed in cancer therapy. This session, which is organized by the CRC/SFB 1066, exemplifies the breadth and the potential of polymers and polymeric drug delivery systems for diverse therapeutic applications.

14.15 Is there More than Tumor Targeting? Nanoparticles and the Immune System  
Prof. Dr. Rudolf Zentel, Institute of Organic Chemistry, University of Mainz (D)

14.30 Self-Assembled Supramolecular Polymeric Nanosystems for Smart Diagnosis and Targeted Therapy of Intractable Diseases  
Prof. Dr. Kazunori Kataoka, Director General, Innovation Center of NanoMedicine, Kawasaki Institute of Industrial Promotion, Professor at Policy Alternatives Research Institute, University of Tokyo (J)

14.55 Polypept(o)ids: Novel Materials for Drug and Nucleic Acid Delivery  
Dr. habil. Matthias Barz, Lecturer at Institute of Organic Chemistry, Johannes Gutenberg-University of Mainz (D)

15.10 Engineering Innate and Adaptive Immunity with Polymeric Materials  
Prof. Dr. Bruno de Geest, Associate Professor, Department of Pharmaceutics, Ghent (B)

15.25 Protein Nanocapsules for Targeting and Controlled Release of Drugs  
Prof. Dr. Katharina Landfester, Director and Scientific Member, Max Planck Institute for Polymer Research, Mainz (D)

15.40 Polymeric Materials for Biomedical Applications  
Prof. Dr. Ulrich S. Schubert, Laboratory of Organic and Macromolecular Chemistry, Jena Center for Soft Matter (JCSM), School of Chemistry and Earth Sciences of the Friedrich-Schiller-University Jena, Jena (D)

15.55 Questions and Debate

16.05 Break
Parallel 2 7. Small Speeches on Submitted Posters and on University Village Posters 2018 (4’ each)
Chair Dr. Sc. nat. Ruth Schmid, Vice President Marketing, SINTEF Materials and Chemistry, Biotechnology and Nanomedicine, Polymer Particles and Surface Chemistry, Trondheim (N)

About Poster submitters, researchers and scientists at universities, participating in the University Village 2018 can apply for a small speech of 4 minutes, serving to highlight the research activities in nanotechnology/health. The speeches comprise a maximum of three slides. • Slide 1: General introduction to the topic’s future and outlook on translation of the work presented in a way that is accessible to the highly interdisciplinary audience. • Slide 2: Some of the highlights of the submitter’s work and institution’s work. • Slide 3: The prove, how the work at the university/institute fits into the area of nanomedicine and targeted delivery including showing the outlook on translation of the work.

14.15 Start of Presentations (separate programme in conference wallets)
16.00 Break

Monday, Hall Sydney
Parallel 3 8. Understanding of the Mechanisms of Nano Interacting with Life (12’ plus 3’ Questions and Debate)
Chair Prof. Dr. Kirsten Sandvig, Centre for Cancer Biomedicine, Institute for Cancer Research, Norwegian Radium Hospital, Oslo, University Hospital and University of Oslo, Oslo (N)

About This session aims to understanding of the mechanisms of nanomaterial interactions with living systems and the environment across the entire life cycle of nanomaterials.

14.15 The Behavior of Nanoparticles in Complex Environments
Prof. Dr. Barbara Rothen-Rutishauser, Co-Chair Bio Nanomaterials, Adolphe Merkle Institute University of Fribourg, Fribourg (CH) and
Prof. Dr. Alke Fink, Chair BioNanomaterials, Adolphe Merkle Institute, University of Fribourg, Fribourg (CH)

14.35 Entry of Nanoparticles into Cells: Mechanisms and Consequences
Prof. Dr. Kirsten Sandvig, Centre for Cancer Biomedicine, Institute for Cancer Research, Norwegian Radium Hospital, Oslo, University Hospital and University of Oslo, Oslo (N)

14.50 Nanomaterial – Cell Interaction: a Mechanistic Perspect
Dr. Peter Wick, Head Particles-Biology Interactions, EMPA - Swiss Federal Laboratories for Materials Science and Technology, St. Gallen (CH), Lecturer D-BAUG, ETH Zürich (CH)

15.05 Nanoparticles for Clinical Use: Importance of Degradation and Excretion
Dr. Tore Skotland, Centre for Cancer Biomedicine, Institute for Cancer Research, Oslo University, Oslo (N)

15.20 Multimodal Imaging for Evaluating the Behavior of Nanomaterials in Vivo
Keon Wook Kang, M.D., PhD, Professor, Department of Nuclear Medicine, Seoul National University College of Medicine (SNUC), Seoul

15.35 Towards Prediction of In Vivo Behavior of Nanoparticles: New Methods for Evaluation and Screening of Nanoparticles for Therapeutic Applications
Dr. Maria Giannelli, PhD, Application Specialist, Attana AB - Biosensor Technologies Stockholm (S)

15.50 Questions and Debate
16.00 Break
Monday, Hall Rio

9. Publishing and Dissemination in Nanomedicine (10’)
Chair Prof. Dr. Lajos Balogh, Editor-in-Chief, “Precision Nanomedicine” Journal, North Andover, Massachusetts (USA)

About What are the ways for integrating attempts to shape the future of nanomedicine and precision medicine and what is the role of public networks and publishing? How do we disseminate “nanomedicine” to lay public? Without knowledge in novel medical technology the acceptance is low. There are ways to raise the interest for the backgrounds of Nanomedicine.

14.15 Precision Nanomedicine and the Landscape of Nanomedicine Publications
Prof. Dr. Lajos Balogh, Editor-in-Chief, “Precision Nanomedicine” Journal, North Andover, Massachusetts (USA)

14.25 Dissemination for Lay Public in Nanomedicine and Precision Medicine
Dr. Donald Bruce, Managing Director, Edinethics Ltd., Edinburgh (UK)

14.35 Questions and Debate

Continuation Monday Hall Rio

Parallel 4 10. Risk Management for Nanomedicinal Products and Nanomedical Devices (10’)
Chair Robert E. Geertasma, M.Sc., Senior Scientist, Centre for Health Protection RIVM - National Institute for Public Health and the Environment, Belhaven (NL)

About The application of nanotechnologies in healthcare holds groundbreaking potential for innovation but simultaneously bears certain challenges with respect to assessing efficacy, quality and safety. Within the concept of a “safe innovation approach”, many questions are still open. Also regulatory requirements and related scientific guidances for nanomedical products are emerging. This session intends to show the need for risk management during the entire lifecycle of nanomedical products, in relation to patient safety and regulatory requirements.

14.45 Risk Management for Nanomedical products in Relation to Safe Innovation and Emerging Regulatory Requirements
Robert Geertasma, MSc, National Institute for Public Health and the Environment (RIVM), Bilthoven (NL)

14.55 Emerging Regulatory Guidance for Nanomedicine and the Need for Innovator-regulator Interaction During the Product Lifecycle
Dr. Katherine Tyner, PhD, Associate Director for Science (acting), Office of Pharmaceutical Quality CDER/FDA, Springfield, IL (USA)

15.05 An Improved and Integrated Strategy for Non-clinical Evaluation of Potential Immunotoxicity of Nanomedical Products
Christina Giannakou, MSc, Maastricht University (NL) and National Institute for Public Health and the Environment (RIVM) Bilthoven (NL)

15.15 Innovator’s Perspective on Understanding Regulatory Requirements for Nanomedical Products and the Benefits of Innovator-Regulator Interactions
NN

15.25 Hazards Posed by Nanomaterials to Human Health in Nanomedicine
NN

15.35 Questions and Debate

16.00 Break
**Section 3: Satellite 1 - Education and Workforce in Medicine and Regulatory Matters**

**Monday, Hall Osaka**

11. Education, Workforce and Regulatory Matters in Novel Nano- and Precision Drugs  
**Chair** Dr. Anil Patri, Chair, Nanotechnology Task Force, Director, NCTR-ORA Nanotechnology Core Facility, U.S. Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR), Jefferson, AR (USA)

**About** Emerging technologies always need training of the users. But training alone is not sufficient to support translation of new technologies and approaches into approved therapeutics. In nanomedicine and precision medicine we have critical need to provide trainees and current researchers and clinicians with educational opportunities in regulatory science, often defined as the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of regulated products. An interdisciplinary team of speakers will highlight the challenges in drug discovery, clinical trial design, medical device innovation, data analytics, and other core competencies. This meeting is of crucial importance and of critical matter for the clinicians and researchers that are the drivers towards innovation to the benefit of the patient.

14.15 Regulatory Matters in Nano- and Precision Medicine - Regulatory Clinician to Practicing Clinicians  
**Dr. med. Frank F. Weichold, PhD**, Director of Critical Path and Regulatory Science Initiatives, Office of Regulatory Science & Innovation (ORSI) and Office of the Chief Scientist/Office of the Commissioner Food and Drug Administration (FDA), Silver Spring, MD (USA)

14.25 Multi-Stakeholder Ecosystems in Rapidly Changing Educational Environments  
**Jack Barokas**, EduNano Tempus Project Local Coordinator at Tel Aviv University, Tel Aviv (IL)

14.35 Pharmaceutical Development of Nanomedicines – initial learnings & challenges  
**Dr. Marianne Ashford, PhD**, Principal Scientist Drug Targeting, Pharmaceutical Development AstraZeneca, Macclesfield, Cheshire (UK)

14.45 Enhancing Training in Regulatory Science and Translational Research  
**Dr. Scott Steele, PhD**, Director, Regulatory Science Programs, Associate Professor, Public Health Sciences University of Rochester, NY (USA) (invited)

14.55 NN

15.05 Questions and Debate

16.00 Break

**Section 4: Plenary Session**

**Monday, Hall Montreal**

12. Nanomedicine and Precision Medicine – Going to the Future (17’ plus 3’ Questions and Debate)  
**Chair** Prof. Dr. André Nel, M.B. Ch.B., PhD, Distinguished Professor of Medicine, Associate Director California NanoSystems Institute, Chief of Nanomedicine and Director of the Center for Environmental Implications of Nanotechnology, UCLA, Los Angeles, CA (USA)

**About** This session aims to give some glances into the recent revolutionary developments of medicine.

16.30 Global Collaborations in Regulatory Science and Standards Development  
**Dr. Anil Patri**, Chair, Nanotechnology Task Force, Director, NCTR-ORA Nanotechnology Core Facility, U.S. Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR), Jefferson, AR (USA)
16.50  **Engineering Enhanced Adoptive Cell Therapies against Cancer**
Prof. Dr. Darrell J. Irvine, PhD, Professor, Departments of Biological Engineering and Materials Science & Engineering, Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology, Ragon Institute of MGH, MIT, and Harvard Investigator, Howard Hughes Medical Institute, Cambridge, MA (USA)

17.10  **Long-acting Injectable Nanomedicines for Addressing Adherence Issues in Infectious Diseases**
Prof. Dr. Andrew Owen, PhD, FRSB, FBPhS, Professor of Pharmacology, Molecular and Clinical Pharmacology University of Liverpool (UK)

17.30  **Revolutionary Research in Genetic Engineering: the Method for Destruction of Cancerous Cells**
Prof. Dr. Zelig Eshhar, Marshall and Renette Ezralow Professor of Chemical and Cellular Immunology, Board Member of the European Society of Gene Therapy, Weizmann Institute, Rehovot (IL)

17.50  **Bacterial Nanoglues Targeting Wound Sites for Theranostic Applications to Read out Tissue Fiber Tensions in Health and Disease**
Prof. Dr. Dr. h.c. Viola Vogel, Head, Department of Health Sciences and Technology Laboratory of Applied Mechanobiology, ETH Zurich, Zürich (CH)

18.10  **Precision Nanomedicine by Design: Clinical Approvals Based on CNDP Engineering**
Prof. Dr. Donald Tomalia, Distinguished Visiting Professor, Columbia University, NY, Affiliate Professor, Virginia Commonwealth University, Richmond, Adjunct Professor, University of Pennsylvania, Philadelphia, CEO & Founder NanoSynthons LLC National Dendrimer & Nanotechnology Center Mt. Pleasant, MI (USA)

18.30  NN

18.50  **Questions and Debate**

19.00  **End of Day 1 and Brokerage Dinner with Cultural Events**

19.40  We meet in front of the Congress Center
19.50  Tramway leaving Messeplatz
20.00  CLINAM Brokerage Dinner with Cultural Events, CLINAM Dwarf Award 2018 at Landgasthof Riehen

---

**Tuesday, September 4, 2018**

**Section 5: 4 Parallel Sessions**

08.00  **Welcome Coffee**
Tuesday, Hall Montreal

Parallel 1  **13. Overcoming Barriers - Pharmaceutical Development & Manufacturing**
A Session in collaboration with the APV, Mainz
Chair  Dr. Bernd Riebesehl, Principal Fellow, Novartis Pharma AG, Basel (CH)
About  The International Association for Pharmaceutical Technology (APV) will feature the industrial perspective on pharmaceutical development & manufacturing of nanomedicine and precision medicine.

08.20  **CART Manufacturing**
Dr. Alexander Huber, Global CMC Head & Director, Cell & Gene Therapy Unit, Novartis Pharma AG, Basel (CH)
08.35  **CriPec® Nanomedicines the Translational Path from Preclinical to Clinical Studies**  
Dr. Cristianne JF Rijcken, Pharm.D. PhD, Founder and CSO, Cristal Therapeutics, Maastricht (NL)

08.50  **Progressing the Development of AZD2811 Nanoparticle**  
Dr. Marianne Ashford, PhD, Principal Scientist Drug Targeting, Pharmaceutical Development, AstraZeneca, Macclesfield, Cheshire (UK)

09.05  **Updates on the Development of Self-Assembling Bispecific Antibodies**  
Dr. Mark Chiu, PhD, Associate Director, Janssen Research & Development, Raritan, NJ (USA)

09.20  **Successful Design of Nano-carriers: Manipulation of the Release Rate of Drugs from Liposomal Carriers by Means of Selection of the (Phospho)lipid Composition**  
PD Dr. Peter van Hoogevest, Lipoid GmbH, Scientific Department Ludwigshafen am Rhein (D)

09.35  **Microfluidic Platform for Rapid Development and Scale-up of Nanoparticles for Genetic Medicine**  
Dr. James Taylor, PhD, CEO & Co-Founder, Precision NanoSystems, Vancouver, BC (CND)

09.55  **Questions and Debate**

10.20  **Break**

08.00  **Welcome Coffee**

Tuesday, Hall Sydney

**Parallel 2 14. Nano-immunotherapy** (13' plus 2' Questions and Debate)

*A Session in Collaboration with the German Research Foundation (DFG) established “Collaborative Research Center on Nanodimensional Polymer Therapeutics for Tumor Therapy” organized by the CRC/SFB, Johannes Gutenberg University, Mainz (D)*

**Chair**  
Prof. Dr. med. Volker Mailänder, Center for Translational Nanomedicine, University Medicine of the Johannes-Gutenberg University Mainz, Mainz (D) and  
Prof. Dr. Twan Lammers, Experimental Molecular Imaging, RWTH Aachen, Aachen (D)

08.20  **Employing the Protein Corona to Address Dendritic Cells**  
Prof. Dr. med. Volker Mailänder, Center for Translational Nanomedicine, University Medicine of the Johannes Gutenberg University Mainz, Mainz (D)

08.35  **Polymeric Nanogels for Antigen Delivery and Anticancer Vaccination Therapy**  
Prof. Dr. ir. Wim Hennink, Head of Department, Pharmaceutical Sciences, Utrecht University, Utrecht (NL)

08.50  **Plant Virus Nanoparticles for In Situ Vaccination and Treatment of Metastatic Cancer**  
Prof. Dr. Nicole Steinmetz, Professor of NanoEngineering, University of California, San Diego, La Jolla, CA (USA)

09.05  **Targeting of Antigen Presenting Cells for Tumor Immunotherapy**  
Prof. Dr. med. Stephan Grabbe, Director of the Department of Dermatology, Medical Center and Polyclinic, Speaker of the Research Center for Immunotherapy, Mainz (D)

09.20  **Engineering Immune-modulating Materials**  
Prof. Dr. Darrell J. Irvine, PhD, Professor, Departments of Biological Engineering and Materials Science & Engineering, Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology, Ragon Institute of MGH, MIT, and Harvard Investigator, Howard Hughes Medical Institute, Cambridge, MA (USA)

09.50  **Engineering Nanoparticles for a Controlled Reduction of Intratumoral cAMP Level**  
Prof. Dr. rer. nat. Tobias Bopp, Professor for Molecular Immunology, Institute for Immunology, Johannes Gutenberg University Mainz (D) and  
PD Dr. Christian Becker, Department of Dermatology, Medical Center, Johannes Gutenberg University Mainz (D)
10.05  **pH Degradable Immune Modulating Nanogels for Cancer Immunotherapy**  
*Dr. Lutz Nuhn*, Junior Group Leader, Department of Prof. Tanja Weil, Max-Planck-Institute for Polymer Research (MPIP), Mainz (D)

10.20  **Break**

08.00  **Welcome Coffee**  
*Tuesday, Hall Singapore*

**Parallel 3  ** 15. **Extracellular Vesicles in Nanomedicine – Exosomes**  
**Chair**  *Prof. Dr. med. Raymond Schiffelers*, Professor of Nanomedicine, Clinical Chemistry and Haematology, University Medical Center Utrecht UMCU, Utrecht (NL)

**About**  Extracellular vesicles contain various biomolecules and mediate short- and long-distance intercellular communication in the body. Recent work has shown that extracellular vesicles can be engineered to display therapeutic properties. This session will cover new research in extracellular vesicles with respect to their applications in nanomedicine. Exosomes and other extracellular vehicles (EVs) have recently emerged as promising biological nanoparticles for drug delivery and diagnostics. Preclinical findings have already resulted in clinical trials with EVs applications such as immunotherapy. Moreover, the first exosome-based diagnostic test was recently marketed. Nevertheless, many challenges including large-scale clinical-grade manufacturing, characterization, potential immunogenicity, and storage need to be overcome in order to exploit the full potential of EVs for therapy and diagnosis. This session will identify major hurdles and promising areas of study for extracellular vesicles in nanomedicine.

08.20  **Exosomes and Naturally Occurring Vesicles**  
*Prof. Dr. med. Raymond Schiffelers*, Professor of Nanomedicine, Clinical Chemistry and Haematology, University Medical Center Utrecht UMCU, Utrecht (NL)

08.30  **Engineered Extracellular Vesicles for Drug Delivery to the Brain**  
*Dr. Joy Wolfram*, Faculty, Mayo Clinic, Jacksonville, FL (USA); Affiliate Faculty, Houston Methodist Research Institute, Houston, TX (USA)

08.40  **Nanostructure and the Formation Mechanism of Extracellular Vesicles (EVs) Studied by State-of-the-art cryo-SEM and cryo-TEM**  
*Prof. Dr. Yeshayahu (Ishi) Talmon*, Ph.D, Prof. em. of Chemical Engineering, Department of Chemical Engineering and the Russell Berrie Nanotechnology Institute (RBNI), Technion-Israel Institute of Technology, Haifa (IL)

08.55  **From Basic Science Exosome Research to Listing on Stock Exchange – Two Journeys: Myocardial Ischemia and Wound Care**  
*Prof. Dr. Lee Chuen Neng*, MBBS, MMed, FRCS (Glasgow), FRCS (Edinburgh), FRACS, FAMS (Cardiothoracic Surgery), Senior Consultant Department of Cardiac Thoracic and Vascular Surgery, Head, Department of Surgery, Yong Loo Lin School of Medicine, National University Heart Centre, National University of Singapore, Singapore (SGP)

09.10  **Exosome-Hydrogels as Machinery for Anti-inflammatory Therapeutics Synthesis**  
*Dr. Gregor Fuhrmann*, Junior Research Group Leader, Helmholtz-Centre for Infection Research, Saarbrücken (D)

09.20  **The First Extracellular Vesicle-made Supported Lipid Bilayer Biosensor**  
*Sara Busatto*, MSc., Ph.D. Student, Colloidal Clinical Chemistry Laboratory, University Brescia (I), visiting Pre-doctoral Student, Nanomedicine and Extracellular Vesicles Group at Mayo Clinic, Florida (USA)
09.30 Optical Tracking of siRNA Encapsulated Exosomes in Cancer Models in Vitro and in Vivo  
Dr. Lizhou Xu, Marie-Curie Postdoc research Fellow, Institute of Pharmaceutical Science, Faculty of Life Sciences & Medicine, King's College London, London (UK)

09.50 Questions and Debate

10.20 Break

08.00 Welcome Coffee  
Tuesday, Hall Rio

Parallel 4  
16. Global Clinical Experience with Non-Biological Complex Drugs (NBCDs) and their Follow-on Versions: Are we Closer to Regulatory Alignment?

Chair  
Prof. Dr. Daan J. A. Crommelin, Emeritus Professor at the Department of Pharmaceutics, Utrecht University (NL), Adjunct Professor at the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah (USA), Co-founder of Octoplus, Leiden (NL) and  
Prof. Dr. Stefan Mühlebach, Chief Scientific Officer, Vifor Pharma Ltd, Villars-sur-Glâne, and Professor of Pharmaceutical Sciences, University of Basel, Basel (CH)

About  
Assessment of therapeutic equivalence of Non-Biological Complex Drugs (NBCDs) and their follow-on versions poses significant challenges to the scientific community. The family of NBCDs consists of products such as liposomes, glatiramoids, iron carbohydrate complexes and ocular emulsions. Regulatory agencies across the globe have approved follow-on versions of NBCDs based on different approaches. Some agencies have applied the generic drug approval paradigm, whilst others followed the biosimilar approach or a hybrid application route. As a consequence, the scope of studies required for marketing authorization of follow-on products depends on the countries where the product is planned to be launched. This regulatory uncertainty underlines the need for science-based evaluation criteria to ensure safe, effective and equivalent or similar follow-on versions of NBCDs. The questions to be answered in this session are: 1) What can we learn from recent experiences in this field, and 2) Which steps are being taken to globally align the regulatory processes?

08.20 Introduction  
Dr. Jon de Vlieger, Secretary of the Non-Biological Complex Drug Working Group, Lygature, Utrecht (NL)

Regulatory Considerations for Drug Products Containing Nanomaterials: US FDA Perspective  
Dr. Katherine Tyner, Associate Director for Science (acting), Office of Pharmaceutical Quality CDER/FDA, Springfield, IL (USA)

NBCD: Trends and Current EU Regulatory Approach  
Prof. Dr. med. Marisa Papaluca, Senior Scientific Adviser, Scientific Committees Regulatory Science Strategy, European Medicine Agency (EMA), London (UK)

Follow-on NBCDs at Health Canada: Current Perspectives and Future Considerations  
Dr. Michael Johnston, PhD, Research Scientist, Centre for Biologics Evaluation and Genetic Therapies Directorate, Health Canada, Ottawa (CND)

Title to be announced  
Prof. Dr. Henning Blume, Chairman of Steering Committee of the Network of Biopharmaceutics and Bioavailability of the European Federation for Pharmaceutical Sciences – EUFEPS and, SocraTec C&S GmbH, Oberursel (D)

Title to be announced  
Dr. Scott E. McNeil, Director, Nanotechnology Characterization Laboratory, National Cancer Institute, Vice-President, Leidos Biomedical Research Inc., Frederick, MD (USA)

...and further speakers

09.45 Questions and Debate

10.20 Break
### Section 6:  **Satellite 2 - Workshop of the Nanomedicine Alliance, ETPN and the US National Characterization Lab**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.00</td>
<td>Welcome Coffee</td>
</tr>
<tr>
<td><strong>Part 1</strong></td>
<td>Tuesday, Hall Samarkand</td>
</tr>
<tr>
<td></td>
<td><strong>17. Sizing of Nanoparticles: From Regulatory and Metrology Aspects to Application and Analysis</strong></td>
</tr>
<tr>
<td>Chair</td>
<td>Dr. Jeffrey D. Clogston, Principal Scientist, Section Head, Physicochemical Characterization, Nanotechnology Characterization Lab National Cancer Institute, Frederick, MD (USA)</td>
</tr>
<tr>
<td>About</td>
<td>This session will focus on representatives from regulatory, government and industry view on the various aspects of particle sizing relating to nanomedicine/nanotechnology.</td>
</tr>
<tr>
<td>08.20</td>
<td><strong>Experiences of work within the European Nanomedicine Characterization Laboratory (EU-NCL)</strong></td>
</tr>
<tr>
<td></td>
<td>Prof. Dr. Adriele Prina-Mello, PhD, Ussher Assistant Professor/LBCAM Director Trinity Translational Medicine Institute (TTMI)/Department of Clinical Medicine, School of Medicine and AMBER/CRANN, Trinity College Dublin, the University of Dublin (IRL)</td>
</tr>
<tr>
<td>08.35</td>
<td><strong>Physico-chemical Characterization and Standardization of Nanoparticles Intended in Therapeutics and Diagnostics</strong></td>
</tr>
<tr>
<td></td>
<td>Dr. Jeffrey D. Clogston, Principal Scientist, Section Head, Physicochemical Characterization, Nanotechnology Characterization Lab National Cancer Institute, Frederick, MD (USA)</td>
</tr>
<tr>
<td>08.50</td>
<td><strong>Product and Process Optimization to Improve Liposome/LNP Characteristics</strong></td>
</tr>
<tr>
<td></td>
<td>Dr. Andreas Wagner, Head Liposome Technology, Polymun Scientific, Immunobiologische Forschung GmbH, Klosterneuburg (A)</td>
</tr>
<tr>
<td>09.05</td>
<td><strong>Clinical Needs for Nanomedicine: Characterization as Key for Product Development</strong></td>
</tr>
<tr>
<td></td>
<td>Dr. med. Frank F. Weichold, Ph.D., Director of Critical Path and Regulatory Science Initiatives, Office of Regulatory Science &amp; Innovation (ORSI) and Office of the Chief Scientist / Office of the Commissioner Food and Drug Administration (FDA), Silver Spring, MD (USA)</td>
</tr>
<tr>
<td>09.20</td>
<td>NN</td>
</tr>
<tr>
<td>09.40</td>
<td>Questions and Debate</td>
</tr>
<tr>
<td>10.20</td>
<td>Break</td>
</tr>
<tr>
<td>10.50</td>
<td>Plenary Hall Session 18 and Lunch</td>
</tr>
<tr>
<td><strong>Continuation</strong></td>
<td>Tuesday, Hall Samarkand</td>
</tr>
<tr>
<td><strong>Part 2</strong></td>
<td>17. Presentations on Nanoparticles – Analytics and Methods and Technologies</td>
</tr>
<tr>
<td>Chair</td>
<td>Prof. Dr. Adriele Prina-Mello, PhD, Ussher Assistant Professor / LBCAM Director Trinity Translational Medicine Institute (TTMI) / Department of Clinical Medicine, School of Medicine and AMBER / CRANN, Trinity College Dublin, the University of Dublin (IRL)</td>
</tr>
<tr>
<td>14.00</td>
<td><strong>Nanoparticles, Liposomes, Extracellular Vesicles and Viruses</strong></td>
</tr>
<tr>
<td></td>
<td>Dr. Clemens Helmbrecht, Director R&amp;D, Particle Metrix GmbH, Inning a. Ammersee (D)</td>
</tr>
<tr>
<td>14.15</td>
<td><strong>Single Particle Measurement of Number, Size and Charge is Required for Confidence in Nanomedicine Engineering and Development</strong></td>
</tr>
<tr>
<td></td>
<td>Hans van der Voorn, BE (Hons), CEO, IZON SCIENCE Ltd, Christchurch (NZL)</td>
</tr>
<tr>
<td>14.30</td>
<td>...further speakers to be announced</td>
</tr>
<tr>
<td>15.15</td>
<td>Questions and Debate</td>
</tr>
<tr>
<td>16.00</td>
<td>Break</td>
</tr>
</tbody>
</table>
Section 7: Plenary Session

Tuesday, Hall Montreal

18. Cancer Vaccination and Redefining Cancer
Chair: Prof. Dr. Dan Peer, Chair, Tel Aviv University Cancer Biology Research Center, Director, Center for Translational Medicine, Director, Laboratory of Precision Nanomedicine, Dept. of Cell Research & Immunology, and Dept. of Materials Science & Engineering, Tel Aviv University, Tel-Aviv (IL)

10.50 From Papillomavirus Discovery to Cancer Vaccination
Prof. Dr. med. Dr. h.c. mult. Harald zur Hausen, Professor emeritus, Nobel Laureate, German Cancer Research Center (DKFZ), Heidelberg (D)

11.40 Questions and Debate

12.00 Redefining Cancer with Integrative Tumor Immunology: Novel Cutting Edge Immunotherapies for Patients
Prof. Dr. Jerome Galon, Research Director, Chief French National Institute of the Health and Medical Research (INSERM) laboratory of Integrative Cancer Immunology, Cordeliers Research Center, Paris (F)

12.40 Questions and Debate

13.00 Lunch

Section 8: Satellite 3 - Closed Session IPRF Regulatory Authorities

Tuesday, Hall Mexico

19. Closed Session IPRF Regulatory Authorities Satellite
Chair: Dr. Michael Johnston, PhD, Research Scientist, Centre for Biologics Evaluation and Genetic Therapies Directorate, Health Canada, Ottawa (CND)

13.00 Group Lunch

Tuesday, Hall Osaka

13.45 IPRF Meeting

About
The International Pharmaceutical Regulators Forum (IPRF) holds its Nanomedicines Working Group meeting 2018 in Basel at the neutral CLINAM-Platform to discuss nanotechnology and specifically nanomedicine related issues relevant to regulated products. (The agenda of this meeting will be handed out to all invited participants.)

Participants from Europe, Japan, USA, India, Australia, Mexico, South Korea, Africa, China and India will be announced

14.50 Video Conference

16.00 Break

Section 9: 4 Parallel Sessions

Tuesday, Hall Montreal

Parallel 1

20. Diagnostic and Theranostic Concepts for Personalized Cancer Immunotherapy (13' plus 2' Question/Debate)
Chair: Prof. Dr. med. Stephan Grabbe, Director of the Department of Dermatology, Medical Center and Polyclinic, Speaker of the Research Center for Immunotherapy, Mainz (D) and Prof. Dr. Twan Lammers, Experimental Molecular Imaging, RWTH Aachen, Aachen (D)

14.00 Immune Checkpoint Blokkers (ICB) Drive Current Revolution in Immunotherapy from Melanoma across Multiple Tumor Types
Prof. Alexander Eggermont, Professor of Oncological Surgery General Director of Gustave Roussy, University Paris-Sud (F) and Professor of Oncological Surgery at the Erasmus University of Rotterdam (NL)
The Future of Clinical (cancer) Diagnosis and its Role in Precision Therapy  
Prof. Dr. med. Fabian Kiessling, University Hospital Aachen, Director of the Department for Experimental Molecular Imaging (ExMI) RWTH Aachen University, Director of the Helmholtz Institute for Biomedical Engineering, Aachen (D)

Monitoring and Modulating Innate Immunity Using Nanomaterials  
Prof. Dr. Willem Mulder, Professor of Radiology at Icahn School of Medicine at Mount Sinai, NY (USA), Professor of Radiology, ISMMS Professor of Cardiovascular Nanomedicine, Director, Nanomedicine Program, AMC, Amsterdam (NL)

Ultrasound-based Approaches to Boost Cancer Immunotherapy  
Dr. Heleen Dewitte, Laboratory for General Biochemistry and Physical Pharmacy, Ghent Research Group on Nanomedicines, Department of Pharmaceutics, Ghent University, Ghent (B)

Imaging Biomarkers to Predict the Efficacy of Cancer Immunotherapy  
PD Dr. med. Matthias Miederer, Deputy Director, Department of Nuclear Medicine, University Medical Center Mainz, Mainz (D)

The Role of PET and Radionuclide Therapy in Cancer Immunotherapy  
Prof. Dr. med. Andreas Kjær, PhD, DMSc, Chief Physician, Dept. of Clinical Physiology, Nuclear Medicine & PET, Rigshospitalet, Copenhagen (DK)

Questions and Debate

Break

Tuesday, Hall Sydney

Parallel 2  
21. Nanomedicine in Infection and Inflammation (12' plus 3' Questions and Debate)  
Chair  
Prof. Dr. Gert Storm, Institute for Pharmaceutical Sciences, Utrecht University (NL)

Nanoparticles as Antivirals  
Prof. Dr. Francesco Stellacci, Supramolecular Nanomaterials and Interfaces Laboratory, Constellium Chair, EPFL, Lausanne (CH)

Clarithromycin–PLGA Nanocapsules: a Promising Strategy to Target Intracellular Staphylococcus Aureus and Mycobacterium Abscessus Infections  
Dr. Cristiane de Souza Carvalho Wodarz, Department of Drug Delivery (DDEL) Helmholtz-Institute for Pharmaceutical Research Saarland, Saarbrücken (D)

…further speakers to be announced

Break

Tuesday, Hall Singapore

Parallel 3  
22. Targeting and Drug Delivery in Nanomedicine and Precision Medicine (12’ minutes plus 3’ for questions)  
Chair  
Dr. Marieluise Wippermann, CEO, TecoMedical Ltd, Sissach (CH)

Precise Endovascular Drug Delivery for Optimal Efficacy and Minimal Toxicity in Oncology  
Dr. med. Eldad Elnekave, Director Interventional Oncology Clinic, Davidoff Cancer Institute & Radiology Department, Rabin Medical Center, Chief Medical Officer, Zebra Medical Vision, LTD., Tel Aviv (IL)

Targeted Nano-therapeutics Aiming at the Resolution of Liver Diseases  
Dr. Ruchi Bansal, PhD, Assistant Professor, Biomaterials Science and Technology (BST), MIRA Institute, University of Twente (NL)
14.30 **Precision Cancer Nanomedicine with Tumor Homing Peptides and Peptidomimetics**
Prof. Dr. Tambet Teesalu, Head of the Lab of Cancer Biology, Institute of Biomedicine and Translational Medicine, University of Tartu (EST); Adjunct Assistant Professor Cancer Research Center, Sanford Burnham, Prebys Medical Discovery Institute, La Jolla, CA (USA)

14.45 **Nanomedicines Targeting the Multiple Myeloma-Stroma Alliance**
Prof. Dr. Gert Storm, Institute for Pharmaceutical Sciences, Utrecht University (NL)

15.00 **Development of Biohybrid Multistage Nanovaccines for Melanoma**
Flavia Fontana, MSc. Pharm., Drug Research Program, Faculty of Pharmacy, University of Helsinki (FIN)

15.15 **Redefining Therapeutic Agents Bioavailability by Transient Nanoparticle Liver Saturation**
Dr. Matthieu Germain, Senior Manager, chemistry team, Nanobiotix, Paris (F)

15.30 **Delivery of siRNA in Vivo to the Liver Using Redox Sensitive and Ionizable Lipids**
Dr. Daniel Zucker, Business Development Manager for Drug Delivery Systems NOF Europe GmbH, Frankfurt (D)

15.45 **Barcoded Nanoparticles for Amplifying the Personalized Response to Immunotherapy**
Prof. Dr. Avi Schroeder, Ph.D, Assistant Professor of Chemical Engineering Laboratory for Targeted Drug Delivery and Personalized Medicine Technologies, Technion - Israel Institute of Technology, Haifa (IL)

16.00 **Break**

Tuesday, Hall Rio

Parallel 4

23. **Novel Approaches in Material Sciences and Smart Materials in Nanomedicine** (9’ plus 1’ Questions/Debate)
Chair
Prof. Dr. Paolo Decuzzi, Senior Researcher and Professor, Director of the Laboratory of Nanotechnology for Precision Medicine, Italian Institute of Technology, Genova (I)

14.00 **Modulating Cell Sequestration, Blood Longevity and Biodistribution by Tuning Nanoconstruct Rigidity**
Prof. Dr. Paolo Decuzzi, Senior Researcher and Professor, Director of the Laboratory of Nanotechnology for Precision Medicine, Italian Institute of Technology, Genova (I)

14.10 **Nano Cell Vesicle Technologies (nCVTs): exploiting Biomimicry for Nanomedicine**
Prof. Dr. Giorgia Pastorin, Associate Professor and Deputy Head (Research), Pharmacy Department, National University of Singapore, Singapore (SGP)

14.20 **Sugar Based Surfactants for Biotherapeutics Permeability-enhancement**
Prof. Dr. Luca Casettari, Associate Professor in Pharmaceutical Technology, University of Urbino Carlo Bo, Department of Biomolecular Sciences, Urbino (I)

14.30 **Nano-structured and Nano-sized Shape-memory Polymers for Biomedical Applications**
Prof. Andreas Lendlein, Director of the Helmholtz Zentrum Geesthacht - Zentrum für Material und Küstenforschung, Hamburg (D)

14.40 **Mechano-responsive Nano-Medicines**
Prof. Dr. Netanel Korin, PhD, Assistant Professor of Biomedical Engineering, Technion - Israel Institute of Technology, Haifa (IL)

14.50 **Cellularized Scaffolds for the Treatment of Myocardial Infarction: from Bench to Bedside**
Dr. Beatriz Pelacho Samper, Scientist at the Centro de Investigación Médica Aplicada (CIMA) Pamplona (E)
15.00  **Tumor Microenvironment Targeting Nanorobots: a Promise for a Cure of Cancer**  
Prof. Dr. Guangjun Nie, PhD, Professor, CAS Key Laboratory for Biomedical Effects of Nanomaterials & Nanosafety, National Center for Nanoscience and Technology of China, Beijing (CHN)

15.10  **Nanogap-enhanced Raman Nanoprobe for Single Particle Tracking Imaging inside a Live Cell, Composed of Gold and DNA**  
Prof. Dr. Yung Doug Suh, Director, Korea Research Institute of Chemical Technology (KRICT); Associate Professor, Sungkyunkwan University (SKKU), Suwon (ROK)

15.20  **Photothermally Activated Magnetoliposomes for Cancer Therapy and Imaging**  
Dr. Wafa Al-Jamal, Reader in Nanomedicine and Drug Delivery, Prostate Cancer Fellow, School of Pharmacy, Queen's University Belfast (UK)

15.30  **Questions and Debate**

16.00  **Break**

**Section 10: Plenary Session**

**Plenary**  
Tuesday, Hall Montreal

**Chair**  
24. The Regulatory Authorities’ Voice 2018

16.30 – 18.00

**Europe**  
Prof. Dr. med. Marisa Papaluca, Senior Scientific Adviser, Scientific Committees Regulatory Science Strategy, European Medicine Agency (EMA), London (UK)

**Japan**  
Dr. Yuki Takechi-Haraya, PhD, Research Scientist, Division of Drugs, National Institute of Health Sciences, Kawasaki (JPN)

**Canada**  
Dr. Michael Johnston, Research Scientist, Principal Investigator, Health Canada, Ottawa (CND)

**China**  
Prof. Dr. Guangjun Nie, PhD, Professor, CAS Key Laboratory for Biomedical Effects of Nanomaterials & Nanosafety, National Center for Nanoscience and Technology of China, Beijing (CHN)

**USA**  
Dr. med. Frank F. Weichold, PhD, Director of Critical Path and Regulatory Science Initiatives, Office of Regulatory Science & Innovation (ORSI) and Office of the Chief Scientist / Office of the Commissioner Food and Drug Administration (FDA), Silver Spring, MD (USA)

**USA**  
Dr. Katherine Tyner, Associate Director for Science (acting), Office of Pharmaceutical Quality CDER/FDA, Springfield, IL (USA)

**India**  
Prof. Amit Dinda, MD PhD, Professor of Department of Pathology, All India Institute of Medical Sciences, and General Secretary for the Indian Society for Nanomedicine, Delhi (IND)

**Switzerland**  
Dr. Lada Leyens, MSc, Clinical Study Reviewer, Division Clinical Trials, Swiss Agency for Therapeutic Products (Swissmedic), Bern (CH)

**Africa**  
Prof. Dr. Hulda Shaidi Swai, Extraordinary Professor at University of Pretoria, School of Life Science and Bio-engineering, The Nelson Mandela African Institution of Science and Technology, Pretoria (ZA)

**Australia**  
NN, Therapeutic Goods Administration, Department of Health, Woden - Australian Capital Territory (AUS)
Section 11: Plenary Session

Plenary Chair
25. Ethical Matters
Dr. med. hc. Beat Lößfler, MA, CEO of the European Foundation for Clinical Nanomedicine, Basel (CH)

18.00 How has it Ever Come to This? A Fresh Look at Healthcare
Peter Kapitein, President and Patient Advocate of Inspire2Live, Amsterdam (NL)

18.35 Questions and Debate

18.50 End of Day 2

18.50 Aperitif offered by the Canton of Basel-Stadt

19.40 Speakers Leaving in front of the revolving doors of Congress Center to Hotel Merian-Spitz

20.00 Speakers’ Welcome Aperitif on the Terrace

20.15 Speakers’ Dinner at Hall Merian-Spitz

Wednesday, September 5, 2018

Section 12: 4 Parallel Sessions

08.00 Welcome Coffee
Wednesday, Hall Montreal

Parallel 1 26. Cardiology and Atherosclerosis Nanomedicine (9’ plus 1’ Questions and Debate)
Chair Prof. Dr. Harald Mangge, Interim Head, Clinical Institute for Medical and Chemical Laboratory Diagnosis (CIMCL) Medical University of Graz, Graz (A)

08.20 New Facets of Cardiovascular Disease in Persons Lacking Conventional Risk Factors
Prof. Dr. Harald Mangge, Interim Head, Clinical Institute for Medical and Chemical Laboratory Diagnosis (CIMCL) Medical University of Graz, Graz (A)

08.30 Eradication of Atherosclerosis – new Steps
Prof. Dr. med Patrick Hunziker, President of the International Society for Nanomedicine, Basel (CH)

08.40 The European NanoAthero Project: From the Design to the Clinical Trials
Prof. Dr. Didier Letourneur, Director of Cardiovascular Bioengineering, Laboratory for Translational Vascular Science, INSERM, Paris (F)

08.50 Targeted Delivery of Berberine via Liposomes Protects Heart Function in Myocardial Infarction
Dr. Jiong-Wei Wang, PhD, Department of Surgery, Yong Loo Lin School of Medicine, NUS Department of Physiology, NUS, Cardiovascular Research Institute (CVRI), National University Heart Centre (NUHCS), Singapore (SGS)

09.00 Multifunctional Nanomedicines for Targeted Drug Delivery and Imaging for Ischemic Myocardial Injury
Prof. Dr. Hélder A. Santos, Associate Professor (tenure track) in Pharmaceutical Nanotechnology, Head, Division of Pharmaceutical Chemistry and Technology, Head, Preclinical Drug Formulation and Analysis Group, Director, Doctoral Program in Drug Research, Faculty of Pharmacy and Helsinki Institute of Life Science, University of Helsinki (FIN)

09.10 High-Throughput Screening of New Lipid Markers for Coronary Artery Disease
Prof. Dr. med. Reijo Laaksonen, PhD, FESC, Chief Medical Officer, Zora Biosciences Oy, Tampere (FIN)

09.20 Questions and Debate

09.40 Break
08.00 Welcome Coffee
Wednesday, Hall Sidney

Parallel 2
27. Clinical Imaging in Nanomedicine and Precision Medicine (9’ plus 1’ Questions and Debate)
Chair Prof. Dr. med. Christoph Alexiou, Department of Otorhinolaryngology, Head and Neck Surgery, Head Section of Experimental Oncology and Nanomedicine (SEON), Else Kröner-Fresenius-Stiftungs-Professorship, University Hospital Erlangen, Erlangen (D)

About Precision medicine has a big recognition by clinicians, patients, and pharmaceutical companies, healthcare responsible and economic healthcare governmental boards. Imaging plays a critical role in precision medicine and includes screening, early diagnosis, guiding treatment, getting response to therapy, and assessing likelihood ratio of disease re-eruption. This session gives insight in different fields of imaging.

08.20 Upscaling of Nanopharmaceuticals for Biomedical Applications
Prof. Dr. med. Christoph Alexiou, Department of Otorhinolaryngology, Head and Neck Surgery, Head Section of Experimental Oncology and Nanomedicine (SEON), Else Kröner-Fresenius-Stiftungs-Professorship, University Hospital Erlangen, Erlangen (D)

08.30 Live-cell Fluorescence Imaging Platform to Characterize Internalization of Nanomedicines by Human Cells
Dr. Natalia Vtyurina, Groningen Research Institute of Pharmacy, University of Groningen (NL)

08.40 Radionanomedicine
Prof. Dr. med. Dong Soo Lee, PhD, Chairman, Department of Nuclear Medicine Seoul National University Seoul (ROK)

08.50 Intersection of Machine Learning and Complex Neural Networks with Medical Imaging
Dr. med. Eldad Elnekave, Director Interventional Oncology Clinic, Davidoff Cancer Institute & Radiology Department, Rabin Medical Center, Chief Medical Officer, Zebra Medical Vision, LTD., Tel Aviv (IL)

09.00 Protein-sized and Ultrabright Dye-loaded Polymer Nanoparticles for Intracellular Imaging
Dr. Andreas Reisch, Assistant Professor (Maître de conferences), Laboratory of Biophotonics and Pharmacology, UMR 7213 CNRS, Faculty of Pharmacy, University of Strasbourg, Illkirch (F)

09.10 Imaging Carbon Nanotubes: Journey from Basic Understanding of the Carrier Biodistribution to Alzheimer’s disease Monitoring
Dr. Julie (Tzu-Wen) Wang, Senior Research and Teaching Fellow in Nanomedicine, School of Cancer and Pharmaceutical Sciences, King’s College London (UK)

09.20 Questions and Debate

09.40 Break

08.00 Welcome Coffee
Wednesday, Hall Singapore

Parallel 3
28. New Findings and Procedures for Clinical Therapy in Cancer Nanomedicine (12’ plus 3’ Questions/Debate)
Chair NN

08.20 Breaking new Ground for the Future of Cancer Immunotherapy: Tumor-associated Macrophages, Nanomedicine and Imaging
Dr. Saeid Zanganeh, PhD, Sloan Kettering Institute for Cancer Research, New York (USA)
08.35  Links Between Bacterial Composition and Breast Cancer Tissue  
Stephen R. Grobmyer, MD, FACS, Professor of Surgery, Lerner College of Medicine, Director, Surgical Oncology Co-Leader, Cleveland Clinic Comprehensive Breast Cancer Program, Cleveland Clinic, Cleveland, Ohio (USA)

08.50  Fluorescent Polymeric Nanoparticles for Ultrasensitive Detection of Nucleic acid Cancer Markers  
Dr. Andrey S. Klymchenko, Director of Research, Laboratory of Biophotonics and Pharmacology, UMR 7213 CNRS, Faculty of Pharmacy, University of Strasbourg, Illkirch (F)

09.05  Shedding Lights on Cancer Cells and their Microenvironment: a 3D Model to Mimic Pancreatic Tumor Barriers  
Prof. Dr. Simona Mura, Junior Member of the Institut Universitaire de France, Institut Galien Paris-Sud, UMR CNRS 8612, Châtenay-Malabry (F)

09.20  NN

09.35  Questions and Debate

09.40  Break

08.00  Welcome Coffee  
Wednesday, Hall Rio

Parallel 4  29. Computational Modelling, Virtual Patient in Affordable Precision Medicine
Chair  Prof. Dr. Giacinto Scoles, Department of Medical and Biological Sciences, University Hospital, University of Udine, Udine (I) and Biology Department, Temple University, Philadelphia, PA (USA)

08.20  Introduction  
Prof. Dr. Giacinto Scoles, Department of Medical and Biological Sciences, University Hospital, University of Udine, Udine (I) and Biology Department, Temple University, Philadelphia, PA (USA)

08.35  The Role of Digital Transformation in the Quest for Affordable Innovation  
Dr. Steliyan Tinkov, MBA, PMP, Senior Pilot Plant Manager, Novartis Pharma AG, Basel (CH)

08.50  A Virtual Patient Model for Personalised Drug Response Predictions in Oncology  
Dr. Christoph Wierling, Head of Bioinformatics and Modelling, ALACRIs Theranostics Germany GmbH, Berlin (D)

09.05  Bone Remodeling by Two Stage System of Liposomal Cytokine Embedded in Hydrogel  
Prof. Dr. Yechezkel Barenholz, Hebrew University, Hadassah Medical School, Jerusalem (IL)

09.20  Questions and Debate

09.40  Break

Section 13: Satellite 4  SAMS (SAMW) Personalized Health

A special session for SAMW-registrars and all CLINAM-registered participants

Wednesday, Hall Osaka

30. Swiss Excellence in Science: SAMS/SPHN Workshop on Personalized Health
Chair  Prof. Dr. Torsten Schwede, Director of the SPHN Data Coordination Center and chair of the SPHN Executive Board, Biozentrum, University of Basel & SIB Swiss Institute of Bioinformatics, Basel (CH)

About  The Swiss Academy of Medical Sciences (SAMS) was mandated 2016 by the State Secretariat for Education, Research, and Innovation (SERI) and by the Federal Office of Public Health (FOPH) to
develop a Swiss Personalized Health Network (SPHN). During the period 2017–2020, priority is given to the development of a nationally coordinated data infrastructure, for which the SIB Swiss Institute of Bioinformatics has been mandated to coordinate and organize through the Data Coordination Center and the BioMedIT project. The aim is to ensure data interoperability of local and regional information systems with special emphasis on clinical data management systems enabling effective exchange of patient data (e.g. disease phenotypes).

08.30 **Overview of Swiss Personalized Health Network SPHN**
Prof. Dr. med, Peter Meier-Abt, Chairman of the National Steering board of Swiss Personalized Health Network (SPHN), Bern/Zürich (CH)

08.50 **Building an Interoperable Data Ecosystem for Personalized Health Research in Switzerland**
Prof. Dr. Torsten Schwede, Director of the SPHN Data Coordination Center and chair of the SPHN Executive Board, Biozentrum University of Basel & SIB Swiss Institute of Bioinformatics, Basel (CH)

09.10 **Computational Oncology & Molecular Modeling – the Development of Novel Strategies**
Dr. med. Krisztian Homicsko, Head of Clinic, Service of Medical Oncology, CHUV – Department of Oncology, Research Scientist, EPFL, Lausanne (CH)

09.30 **Questions and Debate**

09.40 **Break**

10.10 **The Personalized Swiss Sepsis Study**
PD Dr. med. Adrian Egli, Department of Biomedicine University Hospital Basel, Basel (CH)

10.30 **Report on Swiss Electronic Informed Consent (eConsent)**
Prof. Dr. Christiane Pauli-Magnus, Head of Department Clinical Research, University of Basel (CH)

10.50 **Questions and Debate**

11.15 **SHORT BREAK TO CHANGE TO PLENARY HALL MONTREAL**

12.40 **Lunch**

**SAMW-registrars have free access to the CLINAM-Summit for the rest of the day**

**Section 14: 4 Parallel Sessions**

**Parallel 1**

**31. New Aspects of Physics in Nanomedicine Relating to Clinic**
Chair  
Prof. Dr. Wolfgang J. Parak, CHYN - Physics Department Center for Hybrid Nanostructures, University of Hamburg (D)

10.10 **Towards Detecting the Protein Corona in Vivo**
Prof. Dr. Wolfgang J. Parak, Physics Department, CHYN - Center for Hybrid Nanostructures, University of Hamburg (D)

10.25 **Gold Nanoparticle-based Artificial Antibody Created by Conformational Engineering**
Prof. Dr. Aoneng Cao, PhD, Professor at the Institute of Nanochemistry and Nanobiology Shanghai University, Shanghai (CHN)

10.40 **Magnetic Drug Targeting: Preclinical in Vivo Studies, Mathematical Modelling, and Extrapolation to Human**
Prof. Dr. Khuloud T. Al-Jamal, Chair of Drug Delivery & Nanomedicine, King’s College London (London)
10.55  Questions and Debate

11.15  SHORT BREAK: STAY IN PLENARY HALL MONTREAL

Wednesday, Hall Sydney

Parallel 2

32. Degenerative Diseases Nanomedicine (12' plus 3' Questions and Debate)
Chair  
Dr. Zahraa Al-Ahmad, BSc. MSc. PhD, Division of Pharmacy and Optometry, Faculty of Biology, Medicine, and Health, Stopford Building, Manchester (UK)

10.10  Novel Neuronanopharmaceuticals for Alzheimer Disease
Prof. Dr. Moein Moghimi, Professor of Pharmaceutics and Nanomedicine, School of Pharmacy, Newcastle University, Institute of Cellular Medicine, School of Medicine, Newcastle University (UK) and Adjoint Professor, University of Colorado Medical Center, Boulder, CO (USA)

10.25  Prions: Deadly Self-replicating Nanomachines
Prof. Dr. med. Adriano Aguzzi, PhD h.c., DVM h.c. FRCP, FRCPath, Director of the Institute of Neuropathology, University Hospital of Zurich, Zürich (CH)

10.40  Selective drug Delivery Approaches to Lesioned Brain through Blood Brain Barrier Disruption
Dr. Zahraa Al-Ahmad, BSc. MSc. PhD, Division of Pharmacy and Optometry, Faculty of Biology, Medicine, and Health, Stopford Building, Manchester (UK)

10.55  NN

11.10  Questions and Debate

11.15  SHORT BREAK TO CHANGE TO PLENARY HALL MONTREAL

Wednesday Hall Singapore

Parallel 3

33. Regenerative Medicine and Biomedical Engineering (12' plus3' Questions and Debate)
Chair  
Dr. Nadia Benkirane-Jessel, Research Director and Head, Osteoarticular and Dental regenerative Nanomedicine Laboratory, INSERM (French National Institute for Health and Medical Research), Strasbourg (F)

10.10  Combined Advanced Therapeutic Medical Device and Stem Cells for Regenerative Nanomedicine
Dr. Nadia Benkirane-Jessel, Research Director and Head, Osteoarticular and Dental Regenerative Nanomedicine Laboratory, INSERM (French National Institute for Health and Medical Research), Strasbourg (F)

10.25  Non-destructive Three-dimensional Analysis of Repaired Peripheral Nerves using X-ray Microtomography
Dr. Georg Schulz, Postdoc PhD Physics, Biomaterials Science Center (BMC), University of Basel, Allschwil (CH)

10.40  Programmable Design of Tissue-mimetic Materials
Prof. Dr. Ronit Freeman, Associate Professor, Department of Applied Physical Sciences, University of North Carolina at Chapel Hill, Chapel Hill, NC (USA)

10.55  Approaches Towards Editing Cell Fate and Phenotype
Prof. Dr. Primo Schär, Department of Biomedicine, University of Basel, Basel (CH)

11.10  Questions and Debate

11.15  SHORT BREAK TO CHANGE TO PLENARY HALL MONTREAL
Wednesday, Hall Rio
Parallel 4 34. EU-NCL European Nanomedicine Characterization Laboratory – Lessons learned
Chair Patrick Boisseau, CEA-Léti, EUNCL infrastructure coordinator, Chairman of the ETPN, Grenoble (F)

10.10 Introduction to EUNCL
Patrick Boisseau, CEA-Léti, EUNCL infrastructure coordinator, Chairman of the ETPN, Grenoble (F)

10.20 How to Get your Nanomedicines Processed by EUNCL?
Dr. Simon Baconnier, Innovation Project Manager, CEA-Clinatec, Grenoble (F)

10.30 The Regulators’ Needs; Towards Standardization
Dr. Susanne Bremer-Hoffmann, PhD, Team Leader European Commission Directorate General Joint Research Centre Directorate F – Health, Consumers and Reference Materials Consumer Products Safety, Ispra (I)

10.40 New Frontiers in Characterizations: the Example of Liposomal Irinotecan Nanomedicine
• Dr. Sven Even Borgos, Research Scientist at SINTEF Materials and Chemistry, Department of Biotechnology and Nanomedicine, Trondheim (N) • Dr. Neil Litprott, BSc., MSc., PhD, MRSB, Tenure-track Fellow, Nano-immunotoxicology (Biocompatibility) & Immunopharmacology Nanomedicine Research Group, Dept. of Molecular and Clinical Pharmacology Institute of Translational Medicine, University of Liverpool (UK) • Patrick Boisseau, CEA-Léti, EUNCL infrastructure coordinator, Chairman of the ETPN, Grenoble (F) • Prof. Dr. Adriele Prina-Mello, PhD, Ussher Assistant Professor/LBCAM Director Trinity Translational Medicine Institute (TTMI)/Department of Clinical Medicine, School of Medicine and AMBER/CRANN, Trinity College Dublin, the University of Dublin (IRL) • Dr. Fanny Caputo, EUNCL responsible of the physical-chemical characterization, CEA Grenoble/LETI/DTBS, Grenoble (F)

11.05 Questions and Debate

11.15 SHORT BREAK TO CHANGE TO PLENARY HALL MONTREAL

Section 15: Plenary Session

Wednesday, Hall Montreal
Plenary 35. New Nano-pharmacological Concepts for the Treatment of Cancer
Chair Prof. Dr. med. Patrick Hunziker, President of the International Society for Nanomedicine and University Hospital Basel, Basel (CH)

11.30 The Squalenoylation, a Generic Approach for the Conception of New Nanomedicines
Prof. Dr. Patrick Couvreur, Membre de l’Institut Universitaire de France, UMR CNRS 8612, Université Paris-Sud- UFR de Pharmacie, Chatenay-Malabry (F)

11.55 Questions and Debate

12.05 Nano-enabled Chemo and Immunotherapy for Pancreas Cancer
Prof. Dr. André Nel, M.B. Ch.B., Ph.D., Distinguished Professor of Medicine, Associate Director California NanoSystems Institute, Chief of Nanomedicine and Director of the Center for Environmental Implications of Nanotechnology, UCLA, Los Angeles, CA (USA)

12.30 Questions and Debate

12.40 Lunch
During this lunch the poster prizes will be awarded. There will be a first, second and third prize
<table>
<thead>
<tr>
<th>Time</th>
<th>Session 36: Novel Preclinical Approaches to Nanomedicine and Targeted Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:45</td>
<td>Novel Thermosensitive Liposomes for Neoadjuvant Treatment of High-risk Soft Tissue Sarcoma; From Comparative Oncology Trials Towards Clinical Application</td>
</tr>
<tr>
<td>13:55</td>
<td>Selection Criteria during Preclinical Evaluation and Results from Integrating Targeting RS Polymer Drug Conjugates for Solid Tumors</td>
</tr>
<tr>
<td>14:05</td>
<td>The Zebrafish: A Preclinical Screening Model for the Optimization of Nanomedicine Formulations</td>
</tr>
<tr>
<td>14:15</td>
<td>2D Angiogenesis and 3D Osteosarcoma Microtissues to Improve Vascularization</td>
</tr>
<tr>
<td>14:25</td>
<td>A Nanostrategy for Dynamic Monitoring Patient Therapy Response</td>
</tr>
<tr>
<td>14:35</td>
<td>Questions and Debate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Session 37: Rare and Neglected Diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:45</td>
<td>Introduction</td>
</tr>
<tr>
<td>13:55</td>
<td>Efficacy and Safety of Bovine Lactoferrin Nanocarriers for Treatment of Placental Malaria and Pregnancy Induced Complications in Murine Model</td>
</tr>
<tr>
<td>14:05</td>
<td>...further speakers to be announced</td>
</tr>
<tr>
<td>14:35</td>
<td>Questions and Debate</td>
</tr>
<tr>
<td>15:00</td>
<td>Break</td>
</tr>
</tbody>
</table>
Parallel 3  
**38. Safety of Nanomedicine by Design & Testing for Toxicity**

**Chair**  
Prof. Dr. med. János Szebeni, Head of the Nanomedicine Research and Education Center, Semmelweis University, Budapest (H)

**13.45**  
*Roadmap and Strategies for Overcoming Infusion Reactions to Nanomedicines*  
Prof. Dr. med. János Szebeni, Head of the Nanomedicine Research and Education Center, Semmelweis University, Budapest (H)

**13.55**  
*Anti-polyethylene-glycol Antibody Response to PEGylated Nanoparticles*”  
Dr. Tatsuhiro Ishida, PhD, Department of Pharmacokinetics and Biopharmaceutics, Institute of Biomedical Sciences, Tokushima University, Tokushima (J)

**14.05**  
*Complement Activation-related Pseudoallergy (CARPA) as a Possible Reaction Behind Hypersensitivity Signs During Hemodialysis*  
PD Dr. László Dézsi, PhD, Senior Researcher, adjunct professor, Semmelweis University, Institute of Pathophysiology, Nanomedicine Research and Education Center & SeroScience Ltd., Budapest (H)

**14.15**  
*Role of Natural Antibodies and Protein Corona in Variability and Efficiency of Complement C3 Deposition on Preclinical and Clinical Nanomedicines*  
Prof. Dr. Dmitri Simberg, Assistant Professor, Skaggs School of Pharmacy and Pharmaceutical Sciences, Colorado Center for Nanomedicine and Nanosafety (CCNN), University of Colorado, Denver, CO (USA)

**14.25**  
*Nanomedicine Safety Testing in a Porcine Model: Questions Regarding Validity for Preclinical Testing and Mechanism*  
Dr. med. Rudolf Urbanics, PhD, Semmelweis University & Geoscience Ltd., Budapest (H)

**14.35**  
*Questions and Debate*

**15.00**  
*Break*

Parallel 4  
**39. Nanomedicine Applications in Delivery and Precision Medicine**

**Chair**  
NN

**13.45**  
*Novel Oral Self-nanoemulsifying Delivery Systems of Gentamicin: New Frontier against Cerebrospinal Meningitis*  
Prof. Dr. Anthony A. Attama, Drug Delivery and Nanomedicines Research Group, Department of Pharmaceutics and Pharm. Microbiology, Faculty of Pharmaceutical Sciences, University of Nigeria, Nsukka Enugu State (NGA)

**Further Speakers to be announced**

**15.00**  
*Break*

---

**Section 17: Satellite 5**

**Wednesday, Hall Osaka**

**40. EU-US Nanomed Community of Research**

**Chair**  
NN

**13.45**  
*Topics and Speakers to be announced in July*

**15.00**  
*Break*
Section 18: Plenary Session

Wednesday, Hall Singapore

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.30</td>
<td><strong>Ongoing Phase 2 Trial of Lead Candidate, SEL-212, in Development for Chronic Severe Gout</strong></td>
</tr>
<tr>
<td></td>
<td>Dr. Werner Cautreels, CEO, Selecta Biosciences Watertown/Boston, MA (USA)</td>
</tr>
<tr>
<td>15.45</td>
<td><strong>CriPec® Platform and Lead Product CriPec® Docetaxel: Principles, Preparation, Biomedical Applications and Clinical Translation</strong></td>
</tr>
<tr>
<td></td>
<td>Dr. Cristianne JF Rijcken, PharmD PhD, Founder and CSO, Cristal Therapeutics, Maastricht (NL)</td>
</tr>
<tr>
<td>16.00</td>
<td><strong>Pharmacology and Clinical Trials with nanoparticle albumin-bound rapamycin (ABI-009)</strong></td>
</tr>
<tr>
<td></td>
<td>Dr. Neil Desai, PhD, Aadi Bioscience Inc. Pacific Palisades (CA) (USA)</td>
</tr>
<tr>
<td>16.15</td>
<td>... further speakers to be announced</td>
</tr>
<tr>
<td>17.00</td>
<td><strong>Questions and Debate</strong></td>
</tr>
<tr>
<td>17.25</td>
<td><strong>Closing Words</strong></td>
</tr>
<tr>
<td>17.30</td>
<td><strong>End of CLINAM 11/2018</strong></td>
</tr>
<tr>
<td>18.00</td>
<td><strong>Leaving in front of Congress Center and walking to Restaurant Brauerei</strong></td>
</tr>
<tr>
<td>18.15</td>
<td><strong>Light Farwell Dinner</strong></td>
</tr>
</tbody>
</table>

General Information

Submissions of Abstracts for Speeches and Posters

ALL MAIL RELATED TO SUBMISSIONS GO TO submiss18@clinam.org

The CLINAM Foundation is glad that every year the amount of submissions is increasing and we hope to see a lot of new research progresses and findings. At CLINAM you have the possibility to present your work on a worldwide platform with members from more than 35 countries. Hereafter you will see the topics that relate to the Summit 2018:

1. Topics for Abstracts

- **Clinical Topics**: Nanomedicine and targeted delivery and precision medicine for cardiovascular disease, rheumatic disease, oncology, gastro-intestinal/hepatic disease, bacterial infection, viral infection, parasitic infection, implantology, inflammation, hematology, diabetes, neurology, neurosurgery, orphan diseases, eye and ear disease, tuberculosis, HIV, Ebola, tissue repair, orthopedics, etc.

- **Technology Topics**: Nanosystems, nanoparticles, nanoanalytics and diagnostics, toxicology, nano-imaging, targeted drug delivery, using nanoparticles, GMP and quality assurance, propositions for solving a medical problem in a novel way by the use of nanotechnology, novel concepts and ideas if they can be supported by thorough reasoning and could lead to novel research and solutions. Materials for use in nanotechnology and targeted medicine, concepts, diagnosis and therapy in the field of personalized medicine: clinical diagnosis and management on the individual patient's clinical signs and symptoms, medical and family history, and data from laboratory and imaging evaluation to diagnose and treat illnesses, genetic testing leading to more personalized treatments. In addition, relevant novel tools for translational research and diagnostics, etc.

- **Implications Topics**: Implications of nanomedicine for society, developing countries, environment, risks and benefits, public health finance, health economics, other subjects, etc.

- **Strategy, Government and Political Topics**: Strategy building and policy processes in nanomedicine. Strategic approaches towards establishing a unified funding area for nanotechnologies for medical research. Policy processes to foster leadership in nanomedicine, regulatory authority topics as well as financial and marketing matter.
Industry Topics: Industry projects and solutions in nanomedicine and targeted medicine, tools related to Nanomedicine and targeted medicine. Industry models for the future large-scale production, good manufacturing practice, etc.

Regulatory and Societal Affairs, Networking and Financing Topics: Regulatory issues in nanomedicine, strategy and policy, the patient’s perspective, ethical Issues in nanomedicine, University Village presentations, cutting-edge EU-project presentations, networking for international consortium formation, venture funding, fund investment and business-angel-investment.

Exhibitors Topics: Integrated interventions of exhibitors that are of high scientific or technical relevance and do not have the solely purpose of promoting the trademark.

2. Canon of CLINAM 2018
All abstracts must cover original research aimed at future or current applications of nanoscience and targeted medicine including clinical trial designs, reports of ongoing and completed clinical trials, preclinical work, and technology papers with clinical long-term vision. All fields leading to the development of personalized medicine (precision-medicine) are also issues of great interest.

3. Deadline for Submissions of Abstracts
Send your abstracts as soon as possible. We regularly have meetings of the committee and make choices. A submission until end of May is the best choice. Until then we accept applications for oral presentations. However all those who cannot make it, have still chance to submit a poster until July 8, 2018. Later submissions of posters can be sent until 3 weeks before the summit but will not be included into the proceedings of the summit. These submitters must therefore bring 20 handouts of their abstracts with them.

4. Submission Procedure (Sending Paper Abstract / Poster Abstract)
Abstract: Send us your poster-abstract or oral presentation-abstract (Microsoft Word, RTF or Open document file format, using Times New Roman, font size 11, single spacing, NO PDF). The submission must not be longer than three pages, including metadata and figures (one figure is obligatory). All illustrations, figures, and tables must be placed within the text at the appropriate points. Index your file as follows: Last name.First name.abstract18.docx (or RTF etc.). You may send besides a word document a PDF for the purpose of control at the printer’s office.

Biography: Please add in your mail as separate document with your NARRATIVE CV, max. one page. No more than 5 titles of recent publications can be included. Index your file as follows: Last name. First name.CV18.docx (or RTF etc.).

Portrait Photo: Send us a head picture in gif or jpg, minimum 300 dpi. DO NOT COPY PASTE THE PICTURE BUT SEND IT AS AN ATTACHMENT. Index your file as follows: Last name.First.Name.Picture18.jpg (or gif).

All correspondence and abstracts relating to the Submission 2018 have to be sent to submiss18@clinam.org

5. Decision Regarding Acceptance
Decision for acceptance or declination will be given as soon as possible but at latest within 3 weeks after submission. You will then receive a decision E-Mail, regarding the acceptance or declination of your work. Submissions for oral presentations that are declined can be eligible for a poster presentation. In this case you will be informed. Decisions of the Committee cannot be discussed.

6. Presentation Times, Size of Posters, Installation of Posters
Posters will be located in the Foyer visible for all conference attendees. The meeting breaks and lunches will be the preferred time to study the posters. During lunch and breaks, the authors are asked to be present close to their poster. Posters are to be presented in the size of 1.40 meter high and 1.00 meter wide. Best posters will be awarded with a prize. Poster installation is September 3, 2018 from 6.30 until 8.00 am latest and the posters can be removed on September 5, after 3.00 pm and latest until 6.00 pm.

7. University Village and Small Speeches
The University Village is an exquisite forum for universities and research institutes, giving them opportunity to present themselves as well as novel approaches, new research projects and initial outcomes of research, and patents. Researchers and engineers can use the foyer to install exhibition tables as one-stop-shops for the large spectrum of conference participants.
Poster presenters and University Village members can apply for presentations in a special session of Small Speeches, 4 minutes in length and serving to highlight the research activities in Nanotechnology, Targeted Delivery and Precision Medicine. They must comprise three slides. • Slide 1: General introduction to the topic • Slide 2: Some of the highlights of submitter’s work and institution’s work • Slide 3: The proof as to how the work fits into the area of nanomedicine or precision medicine, including a glimpse into the future. Application for a small speech is only possible after your poster has been accepted. The selection is done by Dr. Schmid. Apply at Ruth.B.Schmid@sintef.no. A University table costs 500.00 Euro and includes one registration. Address for booking this is by an E-mail to clinam@clinam.org and as reference UNIVERSITY TABLE. We will contact you then.

8. VISA FOR SWITZERLAND – Embassy Appointment 9 weeks before travelling!
Before registering, check Visa-Regulations for Switzerland: Participants with visa-need for entering Switzerland have to make their appointment with the Swiss Embassy 10 weeks before the Summit in their country in order to make an application and to acquire a visa. All concerned will register and then ask us in a mail to send an official invitation letter, which you will have to present at the embassy.

9. Registration for the Summit under www.clinam.org

<table>
<thead>
<tr>
<th>Currency is EURO</th>
<th>ONLINE REGISTRATION ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Payment by Credit Card (MasterCard or VISA) is the regular procedure. Bill in exceptional cases possible.</td>
</tr>
<tr>
<td>Category</td>
<td>Early until 15.6.2018</td>
</tr>
<tr>
<td>Academy</td>
<td>700.00</td>
</tr>
<tr>
<td>Industry/Government</td>
<td>1'300.00</td>
</tr>
<tr>
<td>Students</td>
<td>450.00</td>
</tr>
<tr>
<td>Exhibitors multi-user-badge</td>
<td>800.00</td>
</tr>
<tr>
<td>Invited Speakers</td>
<td>Registration according your Invitation letter</td>
</tr>
<tr>
<td>Submitted Talk acadamy</td>
<td>700.00</td>
</tr>
<tr>
<td>Submitted Poster academy</td>
<td>700.00</td>
</tr>
<tr>
<td>Submitted Talk Student</td>
<td>450.00</td>
</tr>
<tr>
<td>Submitted Poster Student</td>
<td>450.00</td>
</tr>
<tr>
<td>Fellowship 1</td>
<td>400.00</td>
</tr>
<tr>
<td>Fellowship 2</td>
<td>Waived and/or accommodation</td>
</tr>
</tbody>
</table>

Cancellation: until 31.5.18 80.00 €; after that 50%; after 1.7. Full Fee

In order to apply for a fellowship read the rules below.

Brokerage Cultural Event Monday 3.9. is not included in Registration. Your share is 40.00 €.

All ESNAM members, speakers, submitters and fellowshippers are invited for the farewell dinner. All other participants pay 45.00 €.

University Table incl. 1 registration: 500 €. Please contact clinam@clinam.org for booking

10. Fellowship Applications (until July 15, 2018)
Fellowship 1: Fellowship includes the summit ticket, the Brokerage Cultural Event and the Farewell Dinner. Submission of abstract of proposed poster or talk is as first act mandatory. Then write a letter and apply for the fellowship and give reasons for this.

Fellowship 2: First a submission of abstract of poster or talk is mandatory. Only for people with small means. Address a letter with your request (waived registration and / or accommodation), why the foundation should support you. Add a reference letter by a superior of your organization stating the motivation.

Send your application to Fellow18@clinam.org. Fellowship- Decisions of the Committee cannot be disputed. Fellowships are given away on a “first come first served” model since the funds are limited.

Decision on Fellowship: Applicants receive a decision by email within 4-6 weeks. Registration then has to be done within 7 days after notice of successful submission with the link provided in the decision letter.
11. CLINAM Exhibition

Profit of Exhibiting
Exhibitors at the CLINAM Summit profit from meeting their potential clients in one spot since CLINAM is presently the world’s largest Summit in Clinical Nanomedicine with 500+ participants in need of toolmakers findings, knowledge and their devices. SMEs and small Start-up companies have the chance to showcase their skills at an affordable price and to meet ALL STAKEHOLDERS in in the field of nanomedicine, targeted delivery and precision medicine. This is a Foyer exhibition at low exhibitor’s rate. All breaks and catering for lunches take place in midst of the CLINAM Marketplace. Start-up booths are given to companies that are less than 3 years in active development.

Regular Fees and Star-up Fees
Booking online [https://www.clinam.org/exhibition.html](https://www.clinam.org/exhibition.html)
Floor space (350 €/m²)
6 m² (minimum) 2’100.00 €
8 m² 2’800.00 €
12 m² 4’000.00 €
(Maximum is 36 m²)
• Company name A3 on pillar 100.00 €
• 1 table, 2 chairs, 1 pin board for poster & power connection 200.00 €
• Exhibitors ticket for conference exhibitors multi-user-badge 800.00 €
• Booth construction on demand
• **Special Start-up Booth:** 4 m², 1 table, 2 chairs, pillar, power connection and 1 registration
(upon application, company less than 3 years active) 1’650.00 €

Liability for the exhibits:
Herewith the exhibitors are notified that the Congress Organizers do not take liability for the exhibits. Goods that have to be sent by mail or freight to the Congress Center have to be insured for transportation and loss.

For all questions please address the organizers at addresses below:

<table>
<thead>
<tr>
<th>Summit Venue</th>
<th>Registration Office</th>
<th>Organizers Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congress Center Basel</td>
<td>Viva Management GmbH</td>
<td>European Foundation for Clinical Nanomedicine</td>
</tr>
<tr>
<td>Messeplatz 21</td>
<td>Kramgassee 16</td>
<td>Alemannengasse 12</td>
</tr>
<tr>
<td>CH-4058 Basel</td>
<td>CH-3011 Bern</td>
<td>CH-4058 Basel, Switzerland</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Switzerland</td>
<td>Phone +41 61 695 93 95</td>
</tr>
<tr>
<td>Phone +41 58 206 28 28</td>
<td>Phone +41 31 311 74 34</td>
<td><a href="mailto:clinam@clinam.org">clinam@clinam.org</a></td>
</tr>
<tr>
<td><a href="mailto:info@congress.ch">info@congress.ch</a></td>
<td><a href="mailto:clinam@viva-management.ch">clinam@viva-management.ch</a></td>
<td></td>
</tr>
</tbody>
</table>

This Programme is subject to changes and under the responsibility, ownership and copyright of the European Foundation for Clinical Nanomedicine in Basel, Switzerland.
Some exhibitors at CLINAM 11 / 2018

Lipoid AG, Steinhausen, Switzerland
www.lipoid.com

...and further exhibitors

How to get to Basel Congress Center, Swissôtel Le Plaza and Hotel du Commerce

Coming by train:
You will arrive at the Swiss Train Station Basel (SBB). From there you take Tram number 2. You will after five stations within 10 minutes be at the conference center. The station is called “Messeplatz” and is announced. Coming from the German Station it is only 2 stops, also with tram number 2 (or also 6) in opposite direction. The costs for a cab from SBB are about 20.-- CHF.

Coming by flight to Basel-Mulhouse-Freiburg Airport: This is a 15 minutes’ drive to the Congress Center Basel. There is an easy connection from Euro-Airport to the exhibition center downtown Basel by public transport (Bus Nr. 50), via the central Swiss railway station (Bahnhof SBB). From Bahnhof SBB the tram line no. 2 (see above) serves Basel Exhibition square directly. The costs for a cab are about 40.-- CHF

Coming from Zürich Airport: There are frequent trains between Basel SBB station and Zurich Airport taking less than an hour. You arrive in Basel at the Swiss Train Station and take as described above.
Sponsors of the 11th European and Global Summit for Clinical Nanomedicine, Targeted Delivery and Precision Medicine

The Building Blocks to Personalized Medicine

... and further sponsors