

Good morning esteemed Professors, Researchers, Doctors,

I thank the organizers of this conference for inviting me. It is with great emotion and deep respect that I address you today. A detailed meeting where experiences in health care and pharmaceutical research are compared: the method of confrontation always leads to positive results, especially in the field of public and global health. Because here today you will be talking about vaccines and future challenges in this field.

In an era where threats to public health can rapidly take on global proportions, the research and development of vaccines emerge as vital components of our collective armour against diseases. Vaccines that are, and will be, life-saving. Since their discovery, they have been key tools in our arsenal against infectious diseases, reducing, and in some cases eradicating, threats that once decimated entire populations.

The trust in your, in our efforts, is immense. Optimism for future developments, anchored to your skills and dedication, is genuine and deep.

Assistance, research, and pharmaceutical solutions are all present here today: each actor must do their part. And so let me say a few words regarding the great value chain of our activities. Care, research, and pharmaceutical remedies must be aware that the dignity of the person, which is at the center of our activities, presupposes a balanced development of these three pillars.

This sector, safeguarding health and human dignity, cannot have a winner and a loser, but everyone must win and we win if we are all placed in conditions to operate serenely. Most of you will not have missed the underlying theme being discussed here is represented by sustainability that postulates the fair distribution of resources among health actors. In various sectors, the future economic model is being rethought to ensure long-term sustainability: look at banks, for example, where strong financial disintermediation by the internet has led the banking system and its regulators to review the basic economic model.

And so it must be done in all sectors: we cannot witness an imbalance of resources in favour of a few subjects, if then the accumulation of these resources can only take place thanks to the presence of the other subjects who, on the other hand, struggle to go ahead. Who knows how high the level of frustration of those who have responsibility for managing the less endowed entities is: surely paradoxical! they are fundamental, assume high risks, but they cannot extract resources adequate for their sustainability when instead the entire supply chain experiences huge rates of production and accumulation of wealth.

This, that is, the search for a balanced economic model that knows how to recognize merits and resources to the entire supply chain, respecting the level of risks taken, including financial ones, this I said is the real future challenge. Artificial intelligence and data analysis can help us in this direction, eliminating or at least trying to mitigate the negotiating approach between the actors of the vast health world to embrace instead an approach that exalts and keeps in mind the overall vision of the system, of its coherent and sustainable growth for everyone, where we can arrive at a vision no longer postponable based on the sense of community.

At this point, Menenius Agrippa's apologue in 494 BC comes to my mind. The human body, when its limbs decided to rebel against the stomach, accusing it of laziness, underwent extreme wasting. It soon became clear that the stomach, although apparently inactive, distributed vital nutrients to every member, and harmony was restored.

Thus, distinguished Scholars and Doctors, we can adapt this apologue to our sector: only by working together, valuing every single act and actor in the health world, and distributing resources and acknowledgments fairly, can we all prosper and stay healthy.

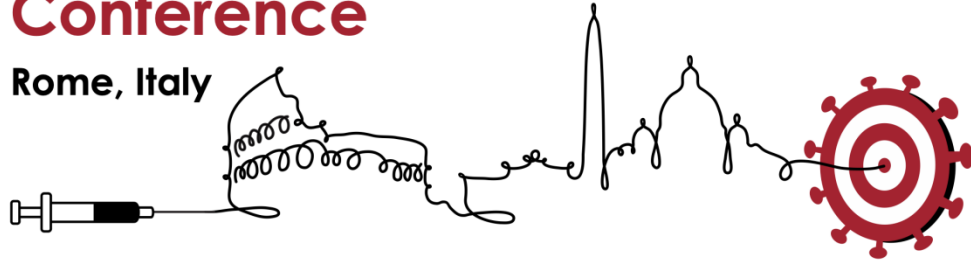
I thank you for your kind attention and, with an open heart and mind, I wish you a collaborative, stimulating, and fruitful conference.

Thank you from the bottom of my heart.

4th Biennial

International Precision Vaccines Conference

Rome, Italy



05-06 October 2023

Parco dei Principi Grand Hotel & Spa
Via G. Frescobaldi, 5 – 00198 Roma, Italy

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Day 1 - 05 October 2023

8:30 - 10:00

Plenary session

8:30 - 8:40 - Welcome

Rector of University of Rome Tor Vergata **Nathan Levaldi** / President of Bambino Gesù Children's Hospital **Tiziano Onesti**

8:40 - 8:50 - Opening remarks: Drs. **Ofer Levy & Paolo Palma**

8:50 - 9:20 - *What we learned for COVID-19. How can we ensure vaccine protection of vulnerable populations in future pandemics?*

Sir. Andrew Pollard, Director, Oxford Vaccine Group, Department of Paediatrics, University of Oxford, UK

9:20 - 09:50 - *The role of Controlled Human Infection Models in defining novel correlates of vaccine protection*

Pierre Van Damme, MD, PhD, Professor, Faculty of Medicine and Health Sciences; Chair, VAXINFECTIO (Vaccine & Infectious Disease Institute), University of Antwerp, Belgium

09:50-10:10 Coffee break

10:10-11:50 - Session #1

Limitations of current vaccine schedules

Chair/Moderator: Alberto Villani

10:10 - 10:15 - Introduction - **Alberto Villani**, MD. Professor of Pediatrics at University of Rome Tor Vergata; Director of General and Emergency Pediatrics Unit at Bambino Gesù Children's Hospital, Rome, Italy

10:15 - 10:35 - *Suggestions to address immunization in elderly*

Walter Ricciardi MD, MPH, MSc. Full Professor of Hygiene at the Faculty of Medicine "A. Gemelli" of the Cattolica University, Rome, Italy

10:35 - 10:55 - *Vaccines in Pregnant women*

Claire Thorne, Phil - Professor of Infectious Disease Epidemiology, Population, Policy and Practice Research and Teaching Department, UCL Institute of Child Health, University College London, UK

10:55 - 11:15 - *Vaccines efficacy in individuals with primary or secondary immune deficiency*

Paolo Palma, MD, PhD - Head of Clinical and Research Immunology and Vaccinology Unit, Bambino Gesù Children's Hospital; Associate Professor of Pediatrics, University of Rome Tor Vergata, Rome, Italy

11:15 - 11:30 - *Vaccines in oncologic patients* - **Amy Sherman**, MD. Boston Children's Hospital

11:30- 11:50 - Q&A Panel

11:50 - 13:00 Session #2

New strategies to optimize vaccine efficacy

Chair/Moderator: Viviana Moschese

11:50 - 11:55 - Introduction: **Viviana Moschese**, MD, PhD. Professor of Pediatrics at University of Rome Tor Vergata. Head of Pediatric Immunopathology and Allergology Unit at Tor Vergata Hospital Rome, Italy

11:55 - 12:15 - *Precision Vaccines: Bringing Precision Medicine to Vaccinology*

Ofer Levy, MD, PhD. Senior Physician in Pediatrics, Boston Children's Hospital; Director, *Precision Vaccines Program*; Professor of Pediatrics, Harvard Medical School, Boston, United States

12:15 - 12:35 - *Precision Adjuvants: High throughput in vitro screening of small molecules against human leukocytes to define an adjuvant diversity library*

David Dowling, PhD - Immunologist and vaccinologist, Boston Children's Hospital; Operational

Lead, *Precision Vaccines Program*; Instructor in Pediatrics, Harvard Medical School, Boston, United States

12:35 - 12:55 - *Innate immune-based strategies to potentiate vaccine efficacy*

Ivan Zanoni, PhD - Associate Professor of Pediatrics and Immunology, Boston Children's Hospital; Assistant Professor, Harvard Medical School, Boston, United States

12:55 - 13:10 - Q&A Panel

13:10 - 14:00 Lunch break

14:00 - 14:35 Poster session

14:35 - 16:00 - Session #3

Bioinformatic approaches to define vaccine correlates of protection

Chair/Moderator: Laurent Beloeil, Bioaster

14:35 - 14:40 - Introduction: **Laurent Beloeil**, Head of Vaccine Program at Bioaster, Lyon, France

14:40 - 15:00 - *Integrated molecular biomarkers to predict neonatal vaccine responses*

Scott Tebbutt, PhD - Professor, Department of Medicine (Respiratory Division), University of British Columbia; Principal Investigator and Director of Education, Centre for Heart Lung Innovation, St. Paul's Hospital, Vancouver, Canada

15:00 - 15:15 - *Collaborative Data Approaches for Multi-Institutional Vaccines and Infectious Diseases Research*

Joan Arce, PhD - Instructor, Harvard Medical School; Lead of the Data Management and Analysis Core (DMAC), *Precision Vaccines Program*, Boston Children's Hospital, Boston, United States

15:15 - 15:30 - *Precision medicine approaches with multiomic data*

Jessica Lasky-SU, ScD - Associate Professor in Medicine, Associate Statistician, Harvard Medical School and Brigham and Women's Hospital, Boston, United States

15.30 -15.45 - Abstract Presentation: *A systems immunology study to assess the impact of early-life antibiotic exposure on infant vaccine immune responses*

David Lynn Professor, BA MSc PhD. Professor of Systems Immunology, South Australian Health and Medical Research Institute (SAHMRI) and Flinders University College of Medicine and Public Health, Adelaide, Australia.

15:45 - 16:00 - Q&A Panel

16:00 - 16:20 - Coffee break

16:20 - 17:45 - Session #4

Vaccine safety

Chair/Moderator: Karina Top

16:20-16:25 - Introduction: **Paolo Palma** MD, PhD - Head of Clinical and Research Immunology and Vaccinology Unit, Bambino Gesù Children's Hospital; Associate Professor of Pediatrics, University of Rome Tor Vergata, Rome, Italy

16:25 - 16:45 - *International Network of Special Immunization Services (INSIS): A global network to advance vaccine safety*

Karina Top, MD, MSc, FRCPC - Associate Professor of Pediatrics and Community Health & Epidemiology, Dalhousie University, Halifax, Nova Scotia; Principal Investigator, INSIS

16:45- 17:05 - *mRNA vaccine-related myocarditis: The OPBG experience*

Donato Amodio, MD, PhD - Research fellow, Bambino Gesù Children's Hospital, Rome, Italy

17:05-17:20 - Abstract Presentation: *Melbourne Children's COVID-19 biobanking platform: biomarkers for vaccine response and adversomics*

Nigel Crawford, MD. Director, SAEFVIC (Surveillance of Adverse Events Following Vaccination In the Community), Murdoch Children's Research Institute; Head of Immunisation Services, Royal Children's Hospital; Professor, Department of Paediatrics, University of Melbourne

17:20 - 17:35 - Q&A Panel

17:35 - 17:45 - Day 1 Closing Remarks

Paolo Palma

Day 2 - 06 October 2023

8:45 - 9:50

Plenary session

8:45 - 8:50 - Opening remarks, **Paolo Palma** MD, PhD - Head of Clinical and Research Immunology and Vaccinology Unit, Bambino Gesù Children's Hospital; Associate Professor of Pediatrics, University of Rome Tor Vergata, Rome, Italy

8:50 - 9:20 - *Novel gene-based vaccine design*

Rino Rappuoli, PhD - Scientific Director, Fondazione Biotechnopolo di Siena, Siena, Italy

9:20 - 9:50 - *Impact of immune sex differences on responses to infections and vaccines: lessons from HIV*

Philip Goulder, MA, FRCPC, DPhil, FMedSci - Pediatrician and Professor of Immunology, Oxford University, UK

9:50 - 11:35 - Session #5

Host-related mechanisms of suboptimal immune responses to vaccines

Chair/Moderator: Joann Arce

9:50-9:55 - Introduction: **Joann Arce**, PhD - Instructor, Harvard Medical School; Lead of the Data Management and Analysis Core (DMAC), *Precision Vaccines Program*, Boston Children's Hospital, Boston, United States

9:55- 10:15- *A novel sample-sparing high-throughput plasma proteomics platform to study the immune state in health and disease*

Hanno Steen, PhD. Associate Professor of Pathology, Harvard Medical School, Boston Children's Hospital.

10:15 - 10:30 *Immunization in Early Life*

Asimena Angelidou, MD, PhD - Neonatologist, Department of Neonatology, Beth Israel Deaconess Medical Center; Clinical Lead, Precision Vaccines Program, Boston Children's Hospital; Assistant Professor in Pediatrics, Harvard Medical School, Boston, United States

10:30 -10:45 - *Pre-vaccination phenotypic and transcriptional characteristics provide signatures of immune memory response upon BNT162b2 vaccine in vulnerable populations*

Nicola Cotugno, MD, PhD - Pediatric, Ospedale Pediatrico Bambino Gesù, Rome, Italy

10:45 - 11:00 - Abstract Presentation: *Host-related genomic factors influencing vaccine mediated immunity.*

David Martino

11:00 - 11:15 - Q&A Panel

11:15-11:35 Coffee break

11:35 - 13:00 - Session #6

Updates on RSV immunization

Chair/Moderator: Carlo Giaquinto

11:35 - 11:40 - Introduction: **Carlo Giaquinto**, MD, PhD. Full Professor of Paediatrics, University of Padova, Italy; President of PENTA

11:40 - 12:00 - *Where do we stand with maternal vaccination*

Kirsten Maertens, PhD, Assistant Professor, University of Antwerp, Belgium

12:00 - 12:20 - *Where do we stand with infant immunization?*

Paul Heath - Professor of Paediatric Infectious Diseases, St. Georges University, London, UK

12:20 - 12:35 - Panel - *How do we compare these strategies?*

Kirsten Maertens / Paul Heath

12:35 - 13:00 Debate - **Carlo Giaquinto**

13:00 - 13:45 Lunch break

13:45 - 14:30 - Poster session

14:30 - 15:15 - Oral abstract Presentations

14:30 – 14:45 - *Timing and order of vaccination in the first week of life impacts hepatitis B vaccine immunogenicity in titer-negative neonates: Early BCG enhances immunogenicity of subsequent HBV.*

Casey Shannon, University of British Columbia

14:45 – 15:00 - *Ontogeny of the human plasma metabolome across the first week of life in geographically distinct cohorts*

Anmarie Hoch, Boston Children's Hospital

15:00 – 15:15 - *Ad26.COVS administered at different dose levels as a one or two dose regimen elicits humoral antibody responses in adolescents 12-17 years of age*

Veronica V Rezelij, PhD. Biomarker Lead, Janssen Vaccines and Prevention

15:15 - 15:30 - Coffee break

15:30 - 17:20 - Industry Presentations

Chair/Moderator - Paolo Rossi - Vito Di Cioccio

15:30 - 15:35 - Introduction - **Paolo Rossi**, MD, PhD. Full Professor of Pediatrics University of Rome Tor Vergata

15:35 – 15:50 - Corner Scientific - *Next generation adjuvants enhance the immunogenicity of vaccines that use protein and mRNA-encoded antigens* (**Steven Altschuler**, MD. CEO and Board Chair at Corner Scientific)

15:50 - 16:05 - Moderna - *Immune profiling of mRNA vaccines* - (**Gaby Baldeon Vaca**, MD, PhD. Sr. Scientist at Moderna)

16:05 - 16:20 - Vismederi - *Correlates of protection for influenza and other vaccines for respiratory diseases* - Vismederi (**Emanuele Montomoli**, BSc, MSc – Professor of Hygiene and Public Health, University of Siena, Italy)

16:20 - 16:35 - CRODA (**Christensen Dennis** - Head of Global Research & Development for Adjuvant Systems at CRODA)

16:35 - 16:50 - InImmune (**Jay Evans**, PhD - TLR7 agonists, Co-Founder Chief Scientific and Strategy Officer at InImmune)

16:50 - 17:05 - InSilicoTrials - *Hyper Accelerate Vaccine Development from Discovery to Market through Advanced Computational Modeling and Simulation* (**Luca Emili** Founder and CEO at InSilicoTrials)

17:05 - 17:20 - Q&A Panel

17:20 - 18:00 - Round Table

**Importance of biomarkers of vaccine safety and efficacy in pandemic preparedness:
Current status and key gaps**

17:45 - 18:00 - Concluding remarks

Drs. Ofer Levy & Paolo Palma

18:00 - Meeting adjourns