Enabling the Evaluation of COVID-19 Vaccines with Correlates of Protection

Vaccinopolis, University of Antwerp, Belgium

February 16 -17, 2023

Scientific Committee

Cristina Cassetti
National Institute of Allergy and Infectious Diseases, NIH, U.S.A.
Jakob Cramer
Coalition for Epidemic Preparedness Innovations (CEPI), United Kingdom
Marion Gruber
International AIDS Vaccine Initiative (IAVI), U.S.A.
Adam Hacker
Coalition for Epidemic Preparedness Innovations (CEPI), United Kingdom
Deborah King
Wellcome Trust, United Kingdom
Arnaud Marchant
European Plotkin Institute for Vaccinology (EPIV), Université Libre de Bruxelles (ULB), Belgium
Pieter Neels
Vaccine Advice, Belgium
Stanley Plotkin
University of Pennsylvania, U.S.A.
Pierre Van Damme
European Plotkin Institute for Vaccinology (EPIV); Vaccine & Infectious Disease Institute, University of Antwerp, Belgium
Joris Vandeputte
International Alliance for Biological Standardization (IABS), Belgium

The aim of the workshop is to review current evidence regarding correlates of protection against COVID-19, identify gaps in knowledge and define research strategies to advance vaccine-induced protection against beta coronaviruses. The meeting will also discuss the role of controlled human infection model studies for the identification of correlates of protection and evaluation of novel vaccines. A multidisciplinary panel of experts will participate in the meeting. Ample time will be given to discussions to generate a common understanding of the topic and define guidelines for the way forward.

Agenda

Day 1 - February 16, 2023
8.00 – 17.50

8.00-9:00	**Registration**
9.00-9.25	**Opening**: welcome by **Pierre Van Damme** and **Stanley Plotkin** IABS, NIH, CEPI and WT to introduce the importance of the topic for their institution.

SESSION 1

9.25-10.25	**Introduction**: Why do we need correlates of protection against SARS-CoV-2? *Chair*: **Stanley Plotkin,** Department of Pediatrics, University of Pennsylvania, U.S.A.
9.25-9.45	Immune effectors controlling SARS-CoV-2 infection, disease and transmission. **Dan Barouch,** Beth Israel Deaconess Medical Center, U.S.A. (Remote)
9.45-10.00	Using CoP to license future SARS-COV-2 vaccines. **Marion Gruber,** IAVI, U.S.A.
10.00-10.15	Using CoP to guide the use of current SARS-COV-2 vaccines. **Hanna Nohynek,** Finnish Institute for Health and Welfare, Finland
10.15-10.35	Break

SESSION 2

10.35-12.30	Serum antibodies. *Chair*: **David Goldblatt,** Great Ormond Street Institute of Child Health University College London, United Kingdom
10:35-10:50	Measurement of serum antibodies **David Montefiori,** Duke University, U.S.A (Remote)
10:50- 11:05	Antibody correlates I **Miles Davenport**, Kirby Institute, Australia
11:05-11:20	Antibody correlates II **Merryn Voysey,** Oxford Vaccine Group, Department of Paediatrics, University of Oxford
11.20-11:35	Knowledge gaps and future research for antibody CoP **Peter Gilbert,** Fred Hutchinson Cancer Research Center, University of Washington, U.S.A.

11.35-12.30 Panel discussion sessions 1 and 2: Do we have a consensus on the purpose of correlates of protection for COVID-19 vaccines? Do we make the best use of available antibody data? Do we need additional data and for which purpose? Can we define correlates of protection against infection/shedding?

Discussants

Margaret Ackerman, Dartmouth College, U.S.A.
Cristina Cassetti, NIAID, U.S.A.
Marco Cavaleri, EMA, The Netherlands
Adam Hacker, CEPI, United Kingdom
Liz Miller, London School of Hygiene & Tropical Medicine, United Kingdom
Pieter Neels, Vaccine Advice, Belgium
Dean Smith, Health Canada
Jerry Weir, CBER-FDA, U.S.A.

12.30-13.15 Lunch

SESSION 3

13.15-14.45 Circulating T lymphocytes.
Chair: **Arnaud Marchant,** Institute for Medical Immunology (IMI) Université Libre de Bruxelles

13.15-13.35 The role of T lymphocytes in COVID-19
John Wherry, University of Pennsylvania Institute for Immunology, U.S.A.

13.35-13.55 T cell correlates of protection against SARS-CoV-2
Arnaud Marchant, Institute for Medical Immunology (IMI) Université Libre de Bruxelles

13.55-14.15 How to measure T lymphocyte response to SARS-CoV-2 and what performance to expect?
Robbert van der Most, BioNTech SE, Germany

14.15-14.45 Panel discussion: Are T cells important to protection against diverse clinical outcomes? Link with Ab? What do available data tell us? Can we use them? What other data do we need and for which purpose? How can other vaccine-preventable disease models inform identification of COVID CoP?

All Speakers

Discussants

Miles Davenport, Kirby Institute, Australia
Martina Sester, Universität des Saarlande, Germany
John Tsang, Yale Center for Systems and Engineering Immunology (CSEI), U.S.A.

SESSION 4

14.45-16.10 Mucosal immunity
Chair: **Cristina Cassetti**, NIAID, U.S.A.

14.45-15.05 What are the components of mucosal immunity to SARS-CoV-2
Yongjun Sui, National Cancer Institute, U.S.A.

15.05-15.25 Mucosal correlates of protection against SARS-CoV-2
Ryan Thwaites, Imperial College, United Kingdom (Remote)

15.25-15.50 How to induce mucosal immunity to SARS-CoV-2
Mark Connors, NIAID / Laboratory of Immunoregulation *(*LIR*)*, U.S.A.

15.50-16.20 Panel discussion: Can we use available data? What other data do we need and for which purpose?
All Speakers
Discussant
Peter Wright, Dartmouth College, U.S.A.

16.20-16.40 Break

SESSION 5

16.40-17.50 T and B Cell Memory.
Chair: **Jakob Cramer**, CEPI, United Kingdom

16.40-17.00 Cellular basis for immunological memory to SARS-CoV-2
Mehul Suthar, Emory University, U.S.A.

17.00-17.20 How to measure immunological memory to SARS-CoV-2?
Alessandro Sette, LaJolla Institute for Immunology, U.S.A.

17.20-18.00 Panel discussion: Could we use immunological memory as a correlate of protection against SARS-CoV-2?
All speakers
Discussants
Antonio Bertoletti, Duke University, Singapore
Merryn Voysey, Oxford Vaccine Group, Department of Paediatrics, University of Oxford

Day 2 – February 17, 2023
8:30-12.00

8:30-9:00	**Registration**
SESSION 6	
9.00-10.30	What are the correlates of protection against beta coronavirus/sarbecovirus vaccines? *Chair*: **Deborah King,** Wellcome Trust, United Kingdom
9.00-9.20	Engineered immunogens to elicit antibodies with broad reactivity against coronaviruses **Mihai Azoitei**, Duke Human Vaccine Institute, U.S.A.
9.20-9.40	Shall we induce a broad T cell response **Antonio Bertoletti**, Duke University, Singapore
9.40-10:00	Towards a COVID-19 vaccine to protect against SARS-CoV-2 variants and animal sarbecoviruses without updating **Pamela Bjorkman**, California Institute of Technology, U.S.A.
10.00-10.30	Panel discussion: What is the path to broadly protective beta coronavirus vaccines? Imprinting and diversity of T and B cell repertoires. All speakers Discussant **Christian Gaebler**, Charité – Universitätsmedizin Berlin, Germany
10.30-10.50	Break
SESSION 7	
10.50-12.30	SARS-CoV-2 human challenge studies *Chair* **Andrew Pollard**, University of Oxford, United Kingdom
10.50-11.10	Current experience **Chris Chiu,** Imperial College London, United Kingdom
11.10-11.30	Establishing a SARS CoV2 human challenge model in previously infected subjects to identify immune correlates of protection **Helen McShane**, University of Oxford, United Kingdom
11.30-11.50	Access to SARS-CoV-2 strains **Chris Chiu**, Imperial College London, United Kingdom

11.50-12.30	Panel discussion: Using human challenge studies for identification and of correlates of protection. Creating a network for COVID-19 human challenge studies (objectives of a network, sites, lab, standardization, agencies, …). All Speakers Discussants **Gagandeep Kang**, Christian Medical College, Vellore, India (Remote) **Pierre Van Damme,** Vaccine & Infectious Disease Institute, University of Antwerp, Belgium
12.30-13.15	Lunch
13.15-14.00	Closing remarks, Conclusions and the Way Forward.

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Dr. Stanley A. Plotkin is Emeritus Prof essor of the University of Pennsylvania. Until 1991, he was Professor of Pediatrics and Microbiology at the University of Pennsylvania, Professor of Virology at the Wistar Institute and at the same time, Director of Infectious Diseases and Senior Physician at the Children's Hospital of Philadelphia. For seven years he was Medical and Scientific Director of Sanofi Pasteur, based at Marnes-la-Coquette, outside Paris. He is now consultant to vaccine developers and non-profit research organizations.

He is a member of the Institute of Medicine of the National Academy of Sciences and the French Academy of Medicine. His bibliography includes over 800 articles and he has edited several books including a textbook on vaccines. Dr. Plotkin has received honorary doctoral degrees from the University of Pennsylvania, the University of Rouen. The Université Libre de Bruxelles and the Complutense University of Madrid, He also has received the French Legion of Honor and membership in the American Academy of Arts and Sciences. Dr. Plotkin developed the rubella vaccine now in standard use throughout the world, is codeveloper of the pentavalent rotavirus vaccine, and has worked extensively on the development and application of other vaccines including anthrax, oral polio, rabies, varicella, and cytomegalovirus.

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Pierre Van Damme, MD, PhD
Full professor, University of Antwerp

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Prof. Dr. Pierre Van Damme obtained his PhD in epidemiology and public health in 1994. He was for more than 35 years active in vaccine, clinical trial and infectious disease research. Since 2000 he is full professor in Vaccinology at the University of Antwerp, Faculty of Medicine and Health Sciences, and teaches vaccinology in national and international courses. Pierre Van Damme is director of the Centre for the Evaluation of Vaccination (CEV, University of Antwerp), which he founded in 1994. The CEV is a WHO Collaborating Centre for the WHO European Region for the control and prevention of infectious diseases. With Arnaud Marchant he set up the recently founded European Plotkin Institute for Vaccinology, an initiative to accelerate the evaluation of vaccines for pandemic and endemic pathogens. Pierre Van Damme has been for more than 25 years a regular advisor for national and international organizations, including the National Immunization Technical Advisory Group, and the World Health Organization (European Regional Office and Headquarters). He has been appointed as chairman of the European Technical Advisory Group of Experts on communicable diseases and vaccines for the WHO European Region (ETAGE) (2005-2015). Pierre Van Damme obtained several awards: the Research Award of

the University of Antwerp, the Belgian Social Medicine Award 'Jean Van Beneden' for his work on the introduction of universal hepatitis B immunization programs; the prestigious Bill Marshall award of the ESPID society (2014); the ACRP (Association of Clinical Research Professionals) with the European Outstanding Leadership Award (2017); the prestigious Paul Harris Fellowship by the Rotary Foundation 2017); the Balmis distinction Award (Almeria, Spain, 2017), the AHA Antwerp Innovation award (2019) and the science communication award UAntwerpen (2021). He is a member of the Belgian Royal Academy of Medicine since 2008.

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Arnaud Marchant

Director

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Arnaud Marchant, MD, PhD, is Director of the Institute for Medical Immunology, Professor of Immunology at the Université libre de Bruxelles, Belgium, and Co-Director of the recently founded European Plotkin Institute for Vaccinology, an initiative of the University of Antwerp and the Université libre de Bruxelles to accelerate the evaluation of vaccines for pandemic and endemic pathogens. He was a post-doctoral researcher at the Medical Research Council Laboratories, The Gambia, and at the Weatherall Institute for Molecular Medicine, Oxford. He was founder and CSO of ImmuneHealth, a research center dedicated to the evaluation of vaccines. His research is focused on immunity to infections and vaccines in vulnerable populations. He is teaching vaccinology in several national and international courses.

Joris VANDEPUTTE

Dr. Veterinary Medicine, virologist, global experience and network in human and animal health, *vaccines and diagnostics, global disease control*, *one health,* public affairs with EU, WHO, Asian and African authorities.
Experienced in translational development, translating proof of concept into products (quality, regulatory, profiling, logistics and market access).
Main achievements in virology and global vaccine development:

- Discovery of H1N1 in the late 70's, proof of swine in the zoonotic chain of flu University Research)
- Development, production, flu vaccines (Rhône Mérieux, Merial)
- Global vaccine development, production, successful marketing vaccines for viral and bacterial diseases in animals Rhône Mérieux, Merial)
- Development of TB vaccines for humans (TBVI)
- COVID-19: virology and vaccination, focus on platform technologies and pre-clinical experiments
- Platform technologies for human and animal vaccines and antibodies (mRNA, DNA, viral vectors, Scaffold particles): research, development, CMC, production and regulatory (Vaccines by design)
- In vitro testing for batch release (quality control by design)

Main achievements in global networking and with EU institutions:

- GAVI Alliance and the Vaccine Fund: successful EU support for GAVI
- GALVMED: successful funding for African vaccine development for livestock
- Tuberculosis vaccines: EU support for TBVI (resolution of the EU Parliament)
- Vaccine and antibody platform technologies: regulatory adaptation in the regulation for veterinary medicines (2019/06), particularly for surge production and pandemic preparedness
- IMI (Innovative Medicines Initiative) EU and HORIZON EUROPE projects: work package leader in Zoonosis Anticipation Preparedness Initiative (ZAPI) and VAC2VAC (Vaccine batch to batch comparison by consistency testing); participant in IMI projects DRIVE (Influenza Vaccine Effectiveness) and Inno4Vacc (Controlled Human Challenges), Work package leader in HORIZON 2020 project MANCO (Monoclonal antibody development against SARS-CoV-2)

President of IABS (International Alliance for Biological Standardization) 2016-2022.
Quadrilingual: Dutch, French, English, German

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Adam Hacker PhD

Director and Head of Global Regulatory Affairs

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Adam Hacker is the Director and Head of Global Regulatory Affairs, Coalition of Epidemic Preparedness Innovations (CEPI). As part of his role at CEPI, Adam co-chairs the COVAX Regulatory Advisory Group, consisting of thirteen regulatory authorities, where regulatory issues related to COVID-19 vaccine development are discussed. Adam also leads all CEPI's regulatory activities around the 100-days initiative. He has more than 20 years of pharmaceutical industry experience in leadership roles extending from Regulatory Affairs to Quality and Medical Affairs, including 10 years at Janssen.

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Cristina Cassetti, Ph.D.

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Cristina Cassetti is the Deputy Director of the Division of Microbiology and Infectious Diseases (DMID) at the National Institutes of Allergy and Infectious Diseases (NIAID), a component of the US National Institutes of Health (NIH). Dr. Cassetti has a Ph.D. in virology from the University of Rome, Italy. She conducted research on poxviruses replication at the NIH, influenza virus biology at Rutgers University and HPV vaccine development at the Vaccine Discovery Department at Wyeth (now Pfizer). In 2003 she became a Program Officer at NIAID where she was responsible for the management and direction of extramural research programs on several emerging viral diseases of global health importance including influenza and dengue. In 2016, she was appointed to coordinate the Zika research response in extramural NIAID and to manage translational research in the Virology Branch. In 2017 she was appointed as Chief of the Virology Branch in DMID. In 2019 she become the Deputy Director of DMID where she shares responsibilities with the director for the overall scientific direction, administration and management of the largest extramural Division at NIAID.

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Dan Barouch, M.D Ph.D.

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Dr. Dan Barouch received his Ph.D. in immunology from Oxford University and his M.D. from Harvard Medical School. He is currently the William Bosworth Castle Professor of Medicine and Professor of Immunology at Harvard Medical School, Director of the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center, a member of the Ragon Institute of MGH, MIT, and Harvard, and part of the Bill & Melinda Gates Foundation Collaboration for AIDS Vaccine Discovery. His laboratory focuses on studying the immunology and pathogenesis of viral infections and developing novel vaccine and treatment strategies. His group has led the development of vaccine candidates for multiple pathogens of global significance, including HIV, Zika virus, tuberculosis, and most recently SARS-CoV-2. His recent work contributed to the development of the Johnson & Johnson COVID-19 vaccine, which is now being rolled out throughout the world. He was elected to the National Academy of Medicine in 2020.

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Marion Gruber is the Vice President for Public Health and Regulatory Science at the International AIDS Vaccine Initiative (IAVI). In this role she is leading the development and execution of IAVI's public health and regulatory science efforts to advance IAVI's product development programs in order to facilitate global access to preventive and therapeutic products critical for global public health. Prior to joining IAVI, from 1992 to 2021, she served as public health official at the US FDA where she held various research, regulatory and policy positions most recently serving as the Director, Office of Vaccines Research and Review (OVRR) (2011 to 2021). In that role she was responsible for the review, planning, development and administration of OVRR's national and international programs directing a multi-disciplinary team engaged in vaccine and related biological product development, regulation and licensure. Other key responsibilities included collaboration with top level agency officials, industry representatives, foreign government representatives, other national regulatory authorities as well as global organizations such as WHO and CEPI to advice on regulatory policy, programs and licensure strategies for preventive vaccines to facilitate access of these products critical to global public health.

Marion Gruber received her PhD degree in Microbiology from the Christian Albrecht University, Kiel, Germany and a MS in Biology from the University of Ulm, Germany .

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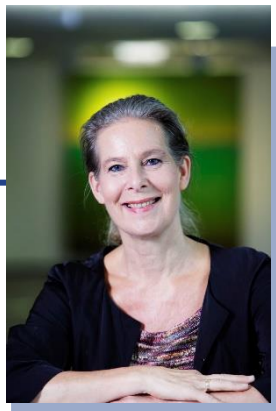

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Hanna Nohynek is MD PhD Chief Physician with special competences in international and travel health. She works in the Infectious Diseases Control and Vaccines Unit, Dept Health Security at the Finnish Institute for Health and Welfare (THL). She serves as secretary of Finnish NITAG and chair of the WHO SAGE. After coordinating several Phase II trials and major Phase III trial on 11PCV against childhood pneumonia in the Philippines until 2010, Nohynek joined THL, where her research responsibilities are in register-based vaccine impact studies, evidence-based policy/decision making, vaccine safety, acceptance, SARS-CoV-2, RSV, influenza, pneumococcus. She co-leads IMI funded PROMISE consortium´s WP Preparation for future RSV product assessment (www.imi-promise.eu). She authored >170 original articles, lectures, guides elective, graduate, PhD students. She belongs to Scientific Faculty ADVAC (2000-), initiated EPIET vaccine module (1997), Finnish Diploma Course Global Health (2000-). She initiated THL Finnish Vaccinators Manual and Finnish Travel Health Advisory. She has served expert national and international committees evaluating vaccines, and is advisor to many international organizations, incl International Vaccine Institute, Korea and icddr.b, Bangladesh.

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David Goldblatt, Ph.D.

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Great Ormond Street Institute of Child Health, University College London
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David Goldblatt is Professor of Vaccinology and Immunology and Deputy Director of the Great Ormond Street Institute of Child Health, University College London (UCL). He is a Consultant Paediatric Immunologist and Director of Clinical Research and Development at the Great Ormond Street Hospital for Children NHS Foundation Trust. He obtained his medical degree from the University of Cape Town, South Africa, a PhD in Immunology from the University of London, United Kingdom and is a Fellow of the Royal College of Paediatrics and Child Health, the Royal College of Physicians and Academia Europae. He is an Emeritus National Institute for Health Research (NIHR) Senior Investigator.

He has a long-standing interest in the immune response to vaccines and infectious diseases. He has active research programmes exploring immunity to colonisation/ carriage and infection, correlates of protection and assessing alternative vaccines schedules. His laboratory (a WHO Reference Laboratory for Pneumococcal Serology) interests include *Streptococcus Pneumoniae*, *Klebsiella Pneumonia*, Group A and B *Streptococcus* and SARS-CoV-2. He is an advisor to the World Health Organisation (WHO) on vaccines including COVID and Co-chairs the recently formed WHO Technical Advisory Group on Group B *Streptococcus*. He serves on subcommittees of the United Kingdom Department of Health Joint Committee on Vaccines and Immunisation (JCVI) has advised the US FDA and EMA on vaccine evaluation and the MHRA on COVID Vaccine licensure via membership of the Commission on Human Medicines COVID-19 Vaccines Benefit Risk Expert Working Group. He chairs several Scientific Advisory Boards including the International SAB advising the Malawi-Liverpool-Wellcome Trust Clinical Research Programme in Blantyre and the Immunisation HPRU at the London School of Hygiene. He is currently President of the International Society of Pneumonia and Pneumococcal Disease.

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Dr. Montefiori's major research interests are viral immunology and HIV and COVID-19 vaccine development, with a special emphasis on neutralizing antibodies. He directs a large vaccine immune monitoring program funded by the NIH and the Bill & Melinda Gates Foundation that operates in compliance with Good Clinical Laboratory Practices and has served as a national and international resource for standardized assessments of neutralizing antibody responses in preclinical and clinical trials of candidate HIV vaccines since 1988. More recently he turned his attention to SARS-CoV-2, with a special interest in emerging variants and how they might impact transmission, vaccines and immunotherapeutics. His laboratory also utilizes FDA approved validated neutralizing antibody assay criteria to facilitate regulatory approvals of COVID-19 vaccines. He has published over 700 original research papers that have helped shape the scientific rationale for antibody-based vaccines.

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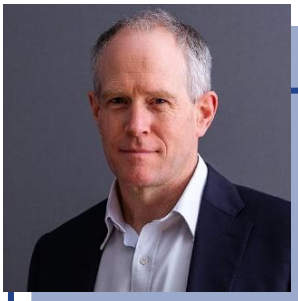

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Miles Davenport leads the Infection Analytics Program at the Kirby Institute at UNSW Sydney. His team of applied mathematicians incorporate statistical and computational approaches to understand infection and immunity. His research focus is on using modelling to analyse host-pathogen interactions in infections including SARS-CoV-2, HIV, and malaria. He has a wide variety of clinical and experimental collaborations both within Australia and overseas and his work aims to integrate experimental data and modeling. He is a past-President of the Australasian Society for Immunology, past Section Editor at *Journal of Immunology*, and current Senior Editor at *eLife*. His seminal work defining the correlates of protection from SARS-CoV-2 infection has helped inform vaccine policy for COVID-19 and understand immunity to viral variants.

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Merryn Voysey, DPhil
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Merryn Voysey is Associate Professor of Statistics in Vaccinology at the Oxford Vaccine Group. She has extensive experience in vaccines research including clinical trials and observational studies, and was the lead methodologist for the Oxford-AstraZeneca vaccine trials. Her current research interests include maternal antibody interference, vaccine correlates of protection, and the seroepidemiology of bacterial infections

She is the Principal Investigator on a large individual participant data meta-analyses of serological data from vaccine clinical trials funded through the NIHR HTA, and PI of three studies funded by the Bill and Melinda Gates Foundation: a multi-country study of maternal measles seroprevalence in infants, a clinical trial of the timing of measles vaccination in Ugandan infants, and a study of the contribution of T-cell immunity in protection against SARS-CoV-2.

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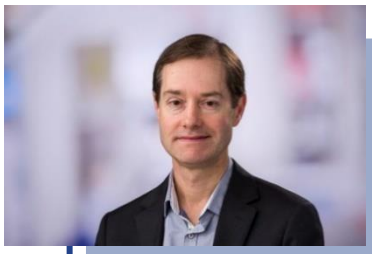

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Dr. Peter Gilbert, Professor of Biostatistics at the Fred Hutch and University of Washington, focuses on the statistical design and analysis of randomized clinical trials of candidate vaccines for HIV, SARS-CoV-2, malaria, and other infectious pathogens. He specializes in statistical methods and data analyses of these trials to pursue understanding of how immune responses to vaccination and genotypic/ immunotypic features of infectious pathogens impact the protective level of the vaccine, so-called "immune correlates of protection analyses" and "sieve analyses." Dr. Gilbert is Principal Investigator of the Statistical Data Management Center for the National Institute of Allergy and Infectious Diseases (NIAID)-sponsored HIV Vaccine Trials Network and provides statistical science leadership for the US Government's COVID-19 Vaccine Correlates of Protection Program.

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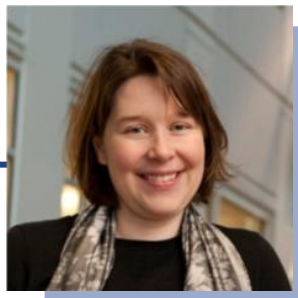

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The Ackerman laboratory conducts interdisciplinary research developing high throughput tools to evaluate the antibody response in disease states ranging from infection to cancer with the goal of advancing therapeutic antibodies and vaccine design and development. Grounded in fundamental engineering principles, we use approaches such as protein engineering and machine learning to understand and optimize the protective mechanisms of antibodies *in vivo*.

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Marco Cavaleri is Head of Office, Health Threats and Vaccines Strategy. He is the Chair of EMA COVID-19 Task Force (ETF) and responsible for EMA activities for emergent pathogens, vaccines and AMR.
He serves in different advisory groups at WHO, including PDVAC and R&D Blueprint SAG and clinical trials working groups.
Marco Cavaleri is a Pharmacologist who spent several years in industry in R&D mainly in the area of anti-infectives covering different positions in preclinical and clinical development.
In 2005 he joined the EMEA in the Scientific Advice Sector, specifically being in charge of anti-infectives and vaccines scientific advice procedures.
In 2009 he was appointed as Head of Section for Anti-infectives and vaccines in the Safety & Efficacy Sector, Human Medicines Development and Evaluation Unit.

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Elizabeth (Liz) Miller BSc, MBBS, FRCPath, FmedSci

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Professor Elizabeth Miller is an infectious disease epidemiologist who has worked on vaccines and immunisation programmes for over 40 years. She was the former Head of Immunisation at Public Health England and is now a professor in the department of Infectious Disease Epidemiology at the London School of Hygiene and a visiting professor at the School of Public Health a Tel Aviv University. She has considerable experience in evaluating vaccine safety and effectiveness and served as a member of the WHO Strategic Advisory Group of Experts (SAGE) on Immunisation and was a founder member of the WHO Global Advisory Committee on Vaccine Safety (GACVS). In response to the SARS-CoV-2 pandemic she lead the PHE (now UKHSA) studies of household transmission of the virus and the effect of vaccination in the household setting and is currently working with UKHSA colleagues on various studies of COVID-19 vaccine safety. She is also working for the WHO in assessing COVID-19 vaccines that are candidates for inclusion in the WHO efficacy trials (SOLIDARITY) that are being conducted in low and middle income countries.

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Dean Smith, Ph.D.

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Immunologist and A/Manager of a Vaccine Quality Division and Advisor in the Center for Vaccines, Clinical Trials and Biostatistics at Health Canada. Dr. Smith has over 20-years of experience in regulatory science in support of innovation in vaccine development, manufacturing and quality control. He has a wide range of biologics-based scientific and regulatory experience from his Senior Scientific Evaluator and management roles in Centre Divisions including Viral and Bacterial Vaccines, as well Hemostatic Agents and Blood Substitutes.

Representing Health Canada, Dr. Smith contributes to WHO's vaccine and vaccine stability guidance development initiatives and supports WHO's recent efforts with COVID-19 and Monkeypox vaccine responses. He is Health Canada's representative to the European Directorate of Quality of Medicines (EDQM), Group 15 (Vaccines and Sera) in support of the European Pharmacopeia, the Regulatory Advisory Committee to the WHO/Collation for Emergency Preparedness and Innovation (CEPI) and served on the Science and Ethics Advisory Committee for VAC2VAC under the European Vaccines Initiative.

Dr. Smith's Ph.D. in Immunology is from the University of Alberta, Canada, where his research dealt with vaccine antigen discovery, autoimmunity and viral vector-based gene therapy. He was a Research Associate at the National Research Council's Institute of Biological Science, Vaccine Design Group in Ottawa prior to joining Health Canada.

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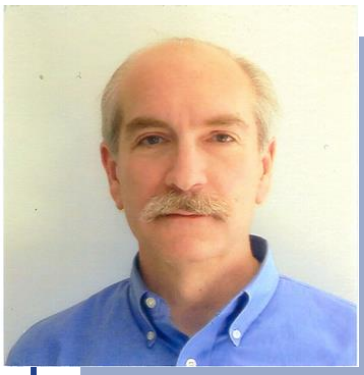

Jerry P Weir, PhD

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Dr. Jerry P. Weir is the Director of the Division of Viral Products (DVP), Office of Vaccines Research and Review with the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER). He received his PhD in Biochemistry from Vanderbilt University and did postdoctoral research in virology at the National Institutes of Health. He joined the Food and Drug Administration in 1994. In his position as Director of DVP, Dr. Weir manages the regulatory activities and research programs of the Division. As a Senior Investigator at CBER, he directs a research program pertaining to diverse viruses, including SARS-CoV-2, influenza, herpesviruses, and poxviruses. Dr. Weir frequently serves as an advisor to the World Health Organization on issues relating to influenza virus vaccines activities and vaccine standards.

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E. John Wherry, Ph.D.
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Dr. E. John Wherry is the Barbara and Richard Schiffrin President's Distinguished Professor, Chair of the Department of Systems Pharmacology and Translational Therapeutics in the Perelman School of Medicine and Director of the UPenn Institute for Immunology. Dr. Wherry received his Ph.D. at Thomas Jefferson University in 2000 and performed postdoctoral research at Emory University from 2000-2004. Dr. Wherry has received numerous honors including the Distinguished Alumni award from the Thomas Jefferson University, the Cancer Research Institute's Frederick W. Alt Award for New Discoveries in Immunology, the Stanley N. Cohen Biomedical Research Award from the University of Pennsylvania Perelman School of Medicine and was inducted as an AAAS Fellow in 2021. As of November 2022, Dr. Wherry has over 300 publications, an H-Index of 126, and his publications have been cited over 86,000 times.

Dr. Wherry helped pioneered the field of T cell exhaustion, the mechanisms by which T cell responses are attenuated during chronic infections and cancer. He helped identify the role of the "checkpoint" molecule PD-1and others for reinvigoration of exhausted T cells in cancer. Dr. Wherry's work has defined the underlying molecular and epigenetic mechanisms of exhausted T cells. His laboratory has also recently focused on applying systems immunology approaches to define Immune Health patients across a spectrum of diseases. in 2020-2021, Dr. Wherry's laboratory focused considerable efforts on the immunology of COVID-19and SARS-CoV-2 vaccination including establishing a new Immune Health Project to interrogate and use immune features to identify novel treatment opportunities.

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After obtaining his PhD at Leiden University (NL) in 1994 on coronavirus RNA replication, Robbert joined Dr Rafi Ahmed's lab at UCLA (USA) to conduct postdoctoral research on the immunology of (chronic) viral infection. Following postdoctoral work at Caltech, the then went to Dr Ahmed's laboratory at Emory University. Returning to the Netherlands in 2000, he worked on RSV vaccines and enhanced disease models. In 2004, he joined the Tumour Immunoloigy Group at the University of Western Australia, working on mesothelioma. He made the change to industry by joining GSK Vaccines in Belgium in 2008, I roles of increasing responsibility. In 2021, he left GSK to join CEPI, followed by a change to BioNTech in 2022, in the currently held position of VP Translational Science, located in Germany and being responsible for biomarker strategy across infectious disease projects. Robbert has published ~100 peer-reviewed articles.

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Martina Sester, PhD

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Martina Sester, PhD, is a professor of immunology and director of the department of transplant and infection immunology at Saarland University, Germany. She specialized in T-cell immunology with relevance to graft rejection and clinically relevant pathogens with specific interest on immunology towards cytomegalovirus, other herpesviruses, BK polyomavirus, Mycobacterium tuberculosis, and more recently SARS-CoV-2. Her research focuses on basic understanding of antigen-specific immune regulation in immunocompromised patients, and on translational aspects of immunomonitoring of infectious complications and graft rejection. Her recent research on SARS-CoV-2 immunology focusses on specific immunity after infection and vaccination in immunocompetent individuals as well as in immunocompromized risk groups. She is a member of national and international transplant societies and participated in national and international consensus conferences and guideline committees.

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John Tsang, PhD

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John Tsang is a systems immunologist, computational biologist, and engineer. Tsang earned his PhD in biophysics and systems biology from Harvard University and trained in computer engineering (BASc) and computer science (MMath) at the University of Waterloo, Canada.

He is currently Professor of Immunobiology and Biomedical Engineering at Yale University; he is also the founding Director of the Yale Center for Systems and Engineering Immunology (CSEI), which serves as a cross-departmental home, enabler, and center of collaborative research for systems, quantitative, and synthetic immunology at Yale.

Prior to joining Yale, he was a tenured Senior Investigator in the National Institutes of Health's Intramural Research Program and led a laboratory focusing on systems and quantitative immunology at the National Institute of Allergy and Infectious Diseases (NIAID). He also co-directed the Trans-NIH Center for Human Immunology and led its research program in systems human immunology. He remains an Adjunct Investigator at NIAID.

He has won multiple awards for his research, including NIAID Merit Awards recognizing his scientific leadership in systems immunology, COVID-19, and human immunology research. His work on human immune variability, systems immunology, and prediction of vaccination responses was selected as a Top NIAID Research Advance of 2014. Tsang has served as an advisor on systems immunology and computational biology for numerous programs and organizations, including the Allen Institute, Human Vaccines Project (Human Immunome Project), World Allergy Organization, National Cancer Institute, National Institute of Allergy and Infectious Diseases, and the Fred Hutchinson Cancer Center. He currently serves on the Editorial Board of PLOS Biology and the Scientific Advisory Board of NIAID ImmPort, the NIAID Influenza IMPRINT Program, the NIH Common Fund Cellular Senescence Network (SenNet), the Human Immunome Project, the Vaccine and Immunology Statistical Center of the Gates Foundation, and CytoReason.

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Dr. Sui received her Ph.D. in pathology from Beijing Institute of Basic Medical Sciences and completed her postdoctoral training in Dr. Opendra Narayan's lab at the Department of Pathology and Microbiology in the University of Kansas Medical Center, and Dr. Todd Reinhart's lab at the Department of Infectious Diseases and Microbiology in the University of Pittsburgh. She joined Vaccine Branch, NCI, as a staff scientist in 2008. Dr. Sui's research interests focus on the development of mucosal HIV and SARS-CoV-2 vaccine using non-human primate and rodent models. She is interested in identifying innate and adaptive immune correlates of protection against HIV and SARS-Cov-2 infections, as well as exploring trained innate immunity mediated by myeloid cells.

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Ryan Thwaites, PhD

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Dr Ryan Thwaites is a Lecturer in Respiratory Immunology within the National Heart and Lung Institute, Imperial College London.

Dr Thwaites' postdoctoral research focused on the immune system of the human respiratory tract, incorporating studies of natural viral infections and 'challenge' studies in healthy adults. These challenge studies included non-infectious human models of innate immune activation (such as Toll-like receptor agonists), allergens and experimental human infection models with respiratory viruses such as Respiratory Syncytial Virus (RSV) and SARS-CoV-2 (the cause of COVID-19). These studies furthered the development of non-invasive techniques for sampling the airways, including the development of nasosorption as a tool for studying respiratory viral infections in children. This postdoctoral work challenged the existing dogmas of viral disease severity in children, developed the minimally-invasive endophenotyping of chronic respiratory diseases, and identified the role of neutrophils in governing susceptibility to respiratory viral infections.

During the COVID-19 pandemic Dr Thwaites worked within the ISARIC4C consortium to profile the immunopathogenic response to SARS-CoV-2 infection in cases of severe disease. These studies continued into monitoring the nature and longevity of immunity to SARS-CoV-2 after natural infection and vaccination. These studies sought to identify

the elements of the immune response to infection that contributed to disease severity, versus those that contribute to clearing infection.

In October 2021 Dr Thwaites established an independent research group at the NHLI. This group continues to study the immune response to respiratory viral infections, with particular interests in the drivers of disease severity and the factors governing susceptibility to viral infections.

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I have 34 years of experience in studying virus-specific immunity to HIV,RSV, and Influenza virus. I did my fellowship training under Robert Chanock and Brian Murphy examining the immune response to respiratory virus vaccines. As Chief of the HIV-Specific Immunity Section of the Laboratory of Immunoregulation, NIAID, I direct research in understanding the mechanistic basis of an effective humoral and cellular response to HIV. Our laboratory seeks to take the best available examples of immunologic control of HIV or neutralizing antibodies to HIV in nature and systematically dissect the underlying mechanisms of these responses. Most important, our work on the cellular and humoral immune response to HIV has had a major impact on our current understanding of the basis of an effective immune response to HIV and other viruses and has suggested possible routes to use that information in strategies for immunization or immunotherapy. More recently we have used this information to examine the components (replication, route, valency, adjuvants, innate immunity response) of vaccines that contribute to an effective immune response to HIV, influenza virus, or SARS-CoV-2. This work includes basic immunology in humans and experimental animals, and the completion of 4 clinical trials of Ad4 recombinant vaccines for HIV and Influenza virus.

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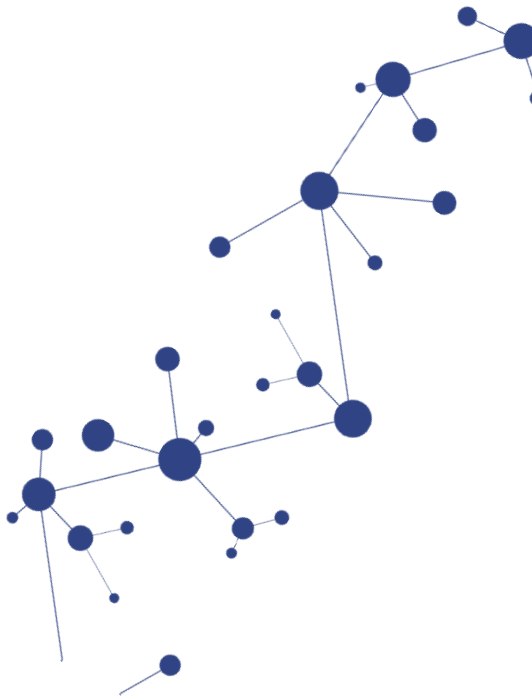
I have worked with vaccines since the initiation of my research career at the NIH. One particular focus has been on vaccines for the prevention of viral respiratory disease. RSV has been an abiding interest since starting at NIH where we initiated work on temperature-sensitive mutants as potential live-attenuated vaccine candidates. These progressed to a series of trials in infants and young children that defined the significant protection afforded by prior infection, the optimal level of attenuation, and the importance of genetic stability. Using cohorts of children at Vanderbilt and Dartmouth we defined the clinical impact of RSV in normal, otherwise healthy children. We have demonstrated that primary epithelial cells derived from adenoids are a surrogate for predicting attenuation and replication in young children and shared in the demonstration of the human pathology associated with RSV.

Another interest grew out of a sabbatical year at the World Health Organization establishing the capacity within the Expanded Programme on Immunization to assess the introduction of new vaccines into the EPI, a precursor of the GAVI effort. During that year I looked at the performance of polio vaccine in the developing country setting, and I assessed the impact of the effort to eradicate polio. I more recently served as chair of the Polio Research Committee for WHO and in that capacity directed the research supportive of the eradication effort.

Both of these interests have coalesced into in-depth studies of the mucosal immune system. With support from the Gates Foundation we have successfully developed a mucosal neutralization test for polio that predicts inhibition of recovery of virus and influences the thinking about choices of inactivated or live, oral vaccine.

The nature of this protection is clearly IgA and an immune system can be defined that is separate and distinct from humoral immunity. Working with Dr. Ackerman's group we are taking this interest in mucosal immunity into the field of COVID-19 in documenting the height and duration of mucosal responses to natural infection and vaccines.



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Mehul S. Suthar

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Mehul S. Suthar is an Associate Professor in the Department of Pediatrics-Infectious Disease at the Emory University School of Medicine. He is also a member of the Emory Vaccine Center and the Emory National Primate Research Center. Dr. Suthar's lab is focused on understanding the molecular and immunological mechanisms by which emerging viral infections are controlled by the host. His lab uses a multidisciplinary approach to understand virus-host interactions that regulate innate immune signaling and viral control, understand how CD8+ T cells mediate viral control and clearance, and understand the antibody response to virus infection. More recently, Dr. Suthar has been involved in a major effort to study the antibody response to SARS-CoV-2 infection and vaccination. His group is focused on identifying, characterizing, and assessing the risk of SARS-CoV-2 variants on vaccines currently in use.

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Education:

Humanistic studies at Liceo Classico "T. Tasso" in Rome (1974-1979); Enrolled in the Department of Biological Sciences of the University of Rome (1980-1984); Graduated in Biological Sciences (*maximum cum laude*) with an experimental thesis, realized under the supervision of Prof. G. Doria, on "Age-related changes in radiosensitivity of the immune system." (July 1984); Graduated from 6-month intensive program on Leadership and Management (LAMP) at the University of California San Diego (UCSD, July 1994)

Professional Positions:

1988-1996	Various positions; Staff Scientist-Director of Immunology, Cytel Corp, San Diego, CA
1996-2002	Chief Scientific Officer, Epimmune Inc., San Diego, CA
2002-Present	Adjunct Professor, The Scripps Research Institute, San Diego, CA
2002-Present	Fully Tenured Member, La Jolla Institute for Immunology, San Diego, CA
2003-Present	Head of the Division of Translational Immunology/Vaccine Discovery, La Jolla Institute for Immunology, San Diego, CA
2017-Present	Adjunct Professor, University of California, San Diego, CA (Past: 2003-2009)
2019-Present	Professor, Center for Infectious Disease and Vaccine Research, Center for Autoimmunity and Inflammation, La Jolla Institute for Immunology, San Diego, CA

Editorial Board, Peer Review Responsibilities and Translational Science impact:
Past and Current Editorial Positions: The Journal of Immunology, Immunome research, Nature Vaccines NPJ, Human Immunology, Current Pharmaceutical Biotechnology; Current Drugs, Tissue Antigens, Immunogenetics, Expert Review of Vaccines.

Standing Study Section Memberships: National Arthritis Foundation (1994-1997), HIV Vaccines (NIH) (1998-1999), Allergy Immunology and Transplantation Committee (NIAID) (2007-2013) and Cancer Prevention Research Institute of Texas (CPRIT) (2014-), Vaccine Microbial Diseases (NIAID) (2017-), Swiss National Science Foundation (2020-)
Ad hoc Reviewer and Panelist: for over 20 NIH NIAID panels, study sections and programs, and for 20 different organizations, including the Bill & Melinda Gates Foundation, Instituto Superiore di Sanita', The Rome Foundation, and the European Research Council.
*Translational Science impact:*_Consultant and Scientific Advisory Board Member for over 70 different biotech and large pharma companies. Inventor on 45 issued U.S., 6 International and 18 European Patents.

Honors and Awards:
51st Oregon State University Biological Colloquium Award (1990); American Association of Immunologists Investigator Award (1995); Member of the Kriegler Lecture and Award Selection Committee (1998); American Liver Foundation Award for Biotechnology Companies (2000); Board of Directors, Member of the American Liver Foundation, San Diego Chapter (2001-2006); Vice-President, American Liver Foundation, San Diego Chapter (2002-2005); International Immunomics and Immmunogenics Society Award (2006); 10th Annual ViE Vaccine Industry Excellence Award (2017); Elected Fellow of the AAAS (2020); Elected Honorary Member of the Accademia Medica di Roma (2021); 2021 Gold Medal from the Italian Society of Internal Medicine (SIMI), Fellow of Sigma Xi The Scientific Research Honor Society (2021-); Boulle-SEI International Award (Alicante, Spain 2021); Member of the Scientific Committee of CISI (Centro Interdipartimentale Scienze Immunologiche) of Università di Napoli Federico II (2021-), Faculty member of Dottorato in Immunologia Clinica e Sperimentale, Università di Genova (2022-), Member of the Instituto Spallanzani (Roma) International Advisory Board (2022-)

Over 980 publications in peer-reviewed journals with over 113,000 citations and an h-index of 180
2001 ISI highly cited investigator (top 100 in the Immunology category over the (1981- 2000 period); Named as one of the top 400 influential researchers in the last 15 years (out of 15 million worldwide) (Boyack et al. PMID: 24134636); Ranked 4th amongst Italian Scientist in Biomedical Sciences. (hwww.topitalianscientists.org; 2022); Ranked amongst the Top 1% Thomson Reuters Highly Researchers in the last decade for several years in a row (2018-2022). (https://www.ncbi.nlm.nih.gov/sites/myncbi/alessandro.sette.1/bibliography/40968398/public/?sort=date&direction=ascending)

Media outreach:
Over 300 interviews since the beginning of the COVID-19 pandemic, including the New York Times, Washington Post, Wall Street Journal, Scientific American, National Geographic, CNN, BBC Radio, La Repubblica, Paziente zero/podcast, WIRED.it, Corriere della sera, La Gazzetta del Mezzogiorno.it, and RAI.

Contributions to Science:

Early work. I devoted more than 36 years to understanding basic mechanisms of antigen recognition and immune responses, measuring and predicting immune activity, and developing disease intervention strategies against cancer, infectious diseases, autoimmune diseases and allergies.

My early work, in the mid-80s to mid-90s, demonstrated that the main biological function of MHC is to bind epitopes. From those studies, we further developed the notion that different MHCs have distinct binding specificities that can be used to predict epitopes. Our group has defined motifs for over one hundred different class I and class II MHC variants expressed from humans, and several other species.

Our group also discovered and characterized how MHC variants can be grouped according to broad functional specificities (MHC supertypes), greatly facilitating epitope classification, characterization and understanding the basic rules of epitope-MHC interactions. Over the last 36 years, I have been continuously involved in hundreds of epitope identification studies, in cancer, autoimmunity, allergy, and infectious disease. A recent focus of my laboratory has been the study of SARS-CoV-2 adaptive immunity, as describe in more detail below.

The study of SARS-CoV-2 adaptive immunity. Our group was first to define successful adaptive response to SARS CoV2, by studying mild convalescent samples, and defined durability of immune memory in natural infection and vaccination. We reported the phenomenon of SARS CoV2 preexisting immune memory in unexposed donors, and demonstrated its influence on vaccination outcomes. We also demonstrated that T cell responses are largely preserved in terms of recognition of SARS CoV2 variants, including Omicron and Delta. Overall, my work in the SARS CoV2 resulted in over 100 peer reviewed publications. The epitope pools developed by the group are used to measure responses; they have been provided to over 187 labs, in 34 different countries in 6 continents. Last, but not least, since the start of the pandemic advocated a fact-based approach to informing the general public, though publications, social media and media interviews This resulted in over 600 interviews which were published and/or aired in over 100 different countries.

The Immune Epitope Database and Analysis Resource (IEDB). Over the last 17 years, I designed, directed, developed and managed the IEDB, (http://www.iedb.org), a freely available bioinformatics resource funded by the NIAID. The database catalogs all epitopes for humans, non-human primates, rodents, and other vertebrates, from allergens, infectious diseases, autoantigens, and transplantation epitopes. Currently, almost one million epitopes derived from almost 20,700 different literature reports are included. The IEDB can also access the Analysis Resource, a suite of bioinformatics tools to analyze epitope data and predict epitopes. The user can predict epitopes with the tools contained in the Analysis Resource (http://tools.iedb.org). The IEDB receives about 15,400 visits/month on the main website and an additional 18,300 visits/month on the tools website.

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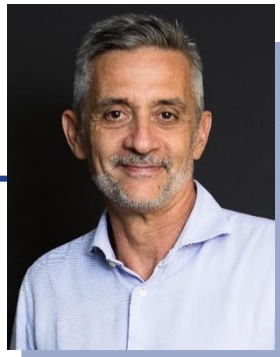

Antonio Bertoletti, M.D.
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Antonio Bertoletti, MD is an expert in the field of viral hepatitis, with a specific interest in the immunopathogenesis of HBV infection and is a Professor at the Emerging Viral Disease Program at Duke-NUS Medical School, Singapore. His current research is focus on the development of new immunological based therapies (TCR-redirected T cells) for the treatment of HBV chronic infection and Hepatocellular carcinoma. In 2020, after the start of the COVID-19 pandemic, his laboratory has been actively involved in the characterization of SARS-COV2 specific T cell immune response in infected and vaccinated individuals. (*Le Bert N, Tan A et al, Nature 2020, 584: 457-62, Swandling et al, Nature 2021, doi:10.1038/s41586-021-04186-8, Tan et al, 2021 J Clin Invest 131(17)*, Schwarz M et al, Nat Biotech 2022 https://doi.org/10.1038/s41587-022-01347-6).

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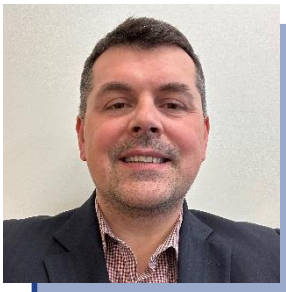

Mihai L. Azoitei, PhD

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Dr. Azoitei obtained a BA in Biochemistry and Computer Science from Middlebury College (Middlebury, VT) and a PhD in Biochemistry from the University of Washington (Seattle, WA), where he worked in the group of Dr. William Schief. He then completed postdoctoral studies in the lab of Dr. Klaus Hahn in the Department of Pharmacology at the University of North Carolina at Chapel Hill before joining Duke University and the Duke Human Vaccine Institute as an Assistant Professor in 2018. Proteins are the building blocks of life and manipulating their function holds immense promise to both uncover fundamental biological processes as well as to develop novel therapeutics. The Azoitei group aims to harness recent advances in protein engineering methods to develop vaccines against pathogens that pose a serious threat to human health.

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Pamela Bjorkman received a B.A. in Chemistry from the University of Oregon and a PhD in Biochemistry and Molecular Biology from Harvard University. As a graduate student and postdoctoral fellow with Don Wiley at Harvard, she solved the first 3-D structure of a major histocompatibility complex (MHC) molecule, which functions to present pieces of potentially dangerous pathogens to T lymphocytes during immune recognition of infected cells. Dr. Bjorkman continued her postdoctoral training at Stanford with Mark Davis, where she worked on T cell receptors, joining the faculty at the California Institute of Technology (Caltech) in 1989.

Dr. Bjorkman's laboratory studies the structural basis of the host immune response to viruses such as HIV-1 and coronaviruses. They use structural studies of antibody recognition of viral fusion proteins to design improved antibody therapeutics and immunogens to elicit broad and potent antibodies for vaccines. In particular, they have used protein nanoparticles presenting HIV-1 or SARS-like betacoronavirus (sarbecovirus) antigens to elicit cross-reactive neutralizing antibody responses. For example, they have shown that a mosaic nanoparticle that co-displays multiple sarbecovirus spike receptor-binding domains elicits cross-reactive immune responses that are protective against SARS-CoV-2 and SARS-CoV challenges in animal models, demonstrating the potential for a protective pan-sarbecovirus vaccine against future SARS-CoV-2 variants and sarbecoviruses that could spillover into humans from animal reservoirs to cause another epidemic or pandemic.

Dr. Bjorkman is a member of the US National Academy of Sciences, the American Academy of Arts and Sciences, and the American Philosophical Society. She has received the William B. Coley Award for Distinguished Research in Fundamental Immunology (1993), the Gairdner Foundation International Award (1994), the Paul Ehrlich and Ludwig Darmstaedter Award (1996), the Max Planck Research Award (2002), the University of Oregon Department of Chemistry Alumni Achievement Award (2003), was the L'OREAL-UNESCO Women in Science North American Laureate in 2006, received an NIH Director's Pioneer Award in 2010, the Ceppellini Award (European Federation for Immunogenetics) in 2019, was a Citation Laureate in Physiology or Medicine (2020), and received the Delphine Parrott award and the Pearl Meister Greengard prize in 2021.

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Vaccinopolis
University of Antwerp, Belgium
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Dr. Christian Gaebler is a physician-scientist specializing in immunity and immunotherapy of viral infections. He earned his MD from the Charité – Universitätsmedizin Berlin before joining the Laboratory of Molecular Immunology at Rockefeller University in 2018. At Rockefeller, he studied HIV and SARS-CoV-2 immune responses and developed antibody-based immunotherapies. Dr. Gaebler served as Associate Physician at the Rockefeller University Hospital, where he earned a Master's in Clinical and Translational Science, before being promoted to Assistant Professor of Clinical Investigation in 2021. In January 2023, he returned to the Charité Berlin to lead the Laboratory of Translational Immunology of Viral Infections in the Department of Infectious Diseases.

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Professor Chris Chiu is an Infectious Diseases physician and Immunologist. He trained as a clinician at Cambridge and Oxford Universities, followed by a PhD supported by a Wellcome Trust Clinical Research Training fellowship and then an MRC Clinician Scientist fellowship, during which he worked in Rafi Ahmed's group at Emory Vaccine Center. His research focuses on mucosal pathogenesis and protective immunity in human respiratory viral infections, including respiratory syncytial virus (RSV), influenza and SARS-CoV-2. To understand why some people suffer life-threatening illness while others have only mild/asymptomatic infection, he has developed a set of unique experimental medicine techniques using infection and vaccination. This is exemplified by his recent role as Chief Investigator of the first SARS-CoV-2 human challenge study, which together with his other programmes aims to enhance our understanding of how respiratory viral illnesses may be better prevented and accelerate the development of more effective vaccines.

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Helen McShane is currently Professor of Vaccinology at the University of Oxford, Director of the NIHR Oxford Biomedical Research Centre, Deputy Head, Medical Sciences Division and an Honorary Consultant in Infectious Diseases.

Since 2001, Helen has lead a TB vaccine research group at the University of Oxford. She led the development of MVA85A, the first new TB vaccine candidate to enter efficacy testing. She collaborates with several research groups across Africa in TB vaccine clinical trials. For the last 10 years, Helen has been developing a controlled human infection model using BCG as a surrogate mycobacterial challenge agent. These studies initially delivered BCG intradermally, and more recently have delivered BCG by aerosol direct to the respiratory mucosa.

Most recently, Helen is leading a programme to establish a controlled human infection model with SARS CoV2 which will allow the evaluation of protective immunity.