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Abstract Book

ICVRD-2024

2nd International Conference on

VACCINE RESEARCH AND DEVELOPMENT

Dates : April 22-23, 2024

Venue : Munich, Germany

FOREWORD

Dear Colleagues,

2nd International conference on Vaccine Research and Development (ICVRD-2024) has been scheduled on April 22-23, 2024 at Munich, Germany. The two-day conference will include plenary and keynote lectures by experienced experts and Oral talks, Poster presentations, Workshops and Exhibitions.

The main objective of the meeting is to promote contacts between scientists working in Vaccine Research and Development, in order to share experiences, to spread the latest information on progress in their specialties and related fields, to gain visibility for their research, to put young researchers interacting with their peers and seniors, and to develop professionally.

We sincerely hope that ICVRD-2024 will serve as an international platform for meeting researchers from around the world, establishing new collaborations, and broadening professional contact.

We look forward to welcoming you to Munich for this inspiring congress in 2024!

COMMITTEE

Organizing Committee Members

- De-chu Christopher Tang — CEO OF VaxDome, USA
- Daniel Salmon — Johns Hopkins University, USA
- Lyudmila Stojanovich — Belgrade University, Serbia
- Luisa Maria Arvide Cambra — University of Almeria, Spain
- Petro Terblanche — CEO of Afrigen Biologics, South Africa

Virus/Mutation-Agnostic Vaccines

De-chu Christopher Tang
CEO OF VaxDome, USA

Abstract:

Respiratory RNA viruses often mutate into new variants with subsets ravaging public health as escape mutants that render contemporary vaccines and antivirals ineffective from time to time. We have serendipitously developed an innovative approach to vaccine development against respiratory viruses. Our initial research demonstrated that a virulent influenza virus (IFV) could be easily transformed into an influenza vaccine by incubating IFV with zanamivir at a specific ratio in vitro. This new approach has the advantage that the vaccine also acts as a virus/mutation-agnostic antiviral as well as a vaccine potentiator in one package. We demonstrated that intranasal administration of the zanamivir-crippled IFV A/Puerto Rico/8/34 (PR8) dubbed zPR8 elicited adaptive immune responses against PR8 as a safe influenza vaccine. In addition, zPR8 conferred rapid but transient protection of mice against lethal challenges by the mouse coronavirus (CoV) MHV1 in an adaptive immunity-independent manner as a virus/mutation-agnostic antiviral. No appreciable production of interferon-a within the lung was induced by zPR8 itself post-administration; however, zPR8 inexplicably amplified CoV-induced interferon-a response as an interferon multiplier. zPR8 also converted a lethal dose of CoV into a safe vaccine against repeat CoV infections as a vaccine potentiator. It is conceivable that the development of a modular system with a variety of influenza viruses disabled by a variety of neuraminidase inhibitors (NAI-IFV) capable of converting a myriad of villain viruses into safe vaccines as vaccine potentiators may enable rapid generation of vaccines in response to a surge of unknown viruses away from a Sisyphean cycle that requires characterization of unknown viral mutations.

Biography:

Dr. De-chu Chris Tang is the Founder CEO of VaxDome Inc. He and his associates were the first to have developed DNA vaccines, skin-patch vaccines, antiviral/vaccine hybrids, and in vivo cytotoxicity assay, etc. Dr. Tang obtained his PhD degree from Indiana University. He founded Vaxin Inc. when he was an assistant professor at University of Alabama at Birmingham. VaxDome Inc. is located on University of North Texas Health Science Center campus, with a focus on the development of an antiviral/vaccine/vaccine potentiator package without constraints imposed by viral mutations; as well as a tissue resident cellular immunity assay with missing-in-action T cells excluded.

Research and Development of Vaccines for Future Pandemic Preparedness

Chil-Yong Kang
The University of Western Ontario, Canada

Abstract:

As part of pandemic preparedness planning, we apply to establish comprehensive, cooperative basic and translational research to advance scientific knowledge needed to develop vaccines for prototype viral pathogens within virus families that have pandemic potential for the prototype pathogens on select virus families from Coronaviridae, Orthomyxoviridae, Arenaviridae, Hantaviridae, Nairoviridae, Phenuiviridae, Peribunyaviridae, Paramyxoviridae, Flaviviridae, and Togaviridae using our well established recombinant vesicular stomatitis virus (rVSV) vector platform technology.

Viruses that cause major pandemic most likely be transmitted by air. Vector mediated transmission of viruses such as Nairoviridae, Phenuiviridae, Peribunyaviridae, Falviviridae, and Togaviridae or viruses transmitted by body fluids of infected person such as some Arenaviridae and Filoviridae will be easier to contain. Thus, unforeseen future pandemic most likely be caused by viruses belong to Coronaviridae, Orthomyxoviridae, some Arenaviridae,Hantaviridae, and Paramyxoviridae. Thus, we need to prepare for these virus groups for future pandemic preparedness.

The major goal of our research will be to develop vaccines for prototype pathogens belong to Coronaviridae and Orthomyxoviridae that can be applied to other closely related family members based on shared functional and structural properties (ie. enveloped RNA viruses). We will perform basic research to expand foundational knowledge of virology, pathology, and immunology. Towards these goals, we will encompass a multi-project multidisciplinary research program that employs innovative virology, structural biology, and immunology to identify strategies for vaccine design.

Biography:

Chil-Yong Kang, PhD, DSc, FRSC, is a molecular virologist and Professor of Virology in the Department of Microbiology and Immunology, Schulich School of Medicine and Dentistry at the University of Western Ontario in Canada. He served as a Professor of Microbiology at the University of Texas, Southwestern Medical School in Dallas, Texas, Professor and Chairman of the Department of Microbiology and Immunology at University of Ottawa, Faculty of Medicine, and Dean of Science at the University of Western Ontario. Dr. Kang's research in molecular virology includes the development of viral-specific antiviral therapeutic agents and efficacious vaccines against various human viral diseases. Dr. Kang is an elected Life-time Fellow of the Royal Society of Canada, Academy of Science and an elected Life-time Member of Korean Academy of Science and Technology.

The Power of Cultural Validation in Immunization Equity

Julissa Soto
CEO and Founder of Julissa Soto Latino Health Equity Consulting, USA

Abstract:

Description of Presentation: Cultural Validation is a critical tool for bridging gaps between public health agencies and the communities they serve. At the onset of the COVID-19 Pandemic, policymakers and public health officials often cited "vaccine hesitancy" as a key challenge to reaching vulnerable populations, including immigrants, Spanish-speaking communities, Latino communities, and others who have been marginalized. Yet, community-based programs utilizing "Cultural Validation" techniques quickly demonstrated that barriers to access – not hesitancy – were the true culprits. In fact, public health partnerships, laws, policies and funding that support the full integration of Cultural Validation techniques can ensure vaccine equity across the board.
Cultural Validation can be applied to any community, and its success is made possible by four (4) key factors:

1) Researching and getting to know people in the community through genuine and authentic relationship-building prior to engagements;
2) Developing culturally relevant materials and marketing strategies;
3) Hosting events at places that are familiar to the community; and
4) Providing genuine, authentic care in service delivery.

The model was proven highly effective during the COVID-19 Pandemic. While Latino and immigrant communities had been described as "vaccine hesitant", events using the Cultural Validation method provided immediate results. The first event saw more than 1297 vaccines administered in what had been described as "vaccine hesitant" communities, and over the last few years, Cultural Validation techniques have resulted in more than 30,000 vaccinations and the distribution of more than 130,000 testing kits and 80,000 masks. As importantly, the results of Cultural Validation not only include increased vaccinations and access to care, but also long-term changes in the community. Positive engagements increase trust in public health

and vaccines for recipients of direct engagements who in turn promote trust and vaccinations among their friends, families, neighborhoods and communities. This training provides real-world, successful examples of Cultural Validation in practice, as well as key steps for implementation that can be duplicated in any community.

FINAL SUBMISSION DUE TO CHARACTER LIMITS

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Biography:

For more than twenty years, Soto has dedicated her career to being a leading advocate for Latino immigrant equality, inclusion and health equity in Colorado and throughout the nation. From working with teen parent programs and serving on the Colorado Vaccine Equity Task Force, to promoting health equity at the American Diabetes Association, Soto has pioneered a wide range of programming designed to empower marginalized communities. Her advocacy efforts have appeared in publications throughout Colorado, as well as NPR, Time magazine, the American Public Health Association Public Health, Religion and Spirituality Bulletin, and a new documentary from the Colorado Cross-Disability Coalition. Today, Soto is proud to continue to provide consulting and education services to partners and agencies throughout Colorado and the United States as CEO and founder of Julissa Soto Latino Health Equity Consulting.

The Perils & Pitfalls of Vaccine Safety Monitoring

Graeme Ladds
Director of PharSafer, United Kingdom

Abstract:

Unlike conventional medicines and clinical programmes designed to treat disease where improvement in patients is seen quickly as a demonstration of efficacy and safety, vaccines present a unique set of problems that require application of the well-known phrase 'Primum Non Nocere' simply because our vaccines will be largely administered to healthy individuals - usually with large numbers where we are measuring prevention as efficacy rather than improvement and what is tolerable for 'risk' when the patient has not been ill.

For centuries when the first vaccines were produced there has been many misconceptions concerning the safety of a medicine that prevents rather than cures.

To allay these fears, it is vital to demonstrate a simple, effective mechanism of pharmacovigilance/safety monitoring that can identify real safety issues, quickly and where appropriate implement risk minimisation activities to ensure maximum patient benefit and reduced and contained risk. All of this may need to be performed against a backdrop of mass vaccinations covering many geographies over a short period of time where high levels of patient exposures.

The aim of this talk is to look at innovative and practical methods of capturing adverse event data from vaccines allowing prompt and critical decision making in assessing potential safety problems to ensure patient safety and maximising benefits to the patient populations.

Biography:

Graeme Ladds, Director of PharSafer, has over 30 years experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1989 as Head of Drug Safety & Medical Information, he went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. He then set up his consultancy and specialist CRO company, PharSafer Associates Ltd, where he has been involved in establishing pharmacovigilance in companies, performing audits across Europe and the USA, SOP writing, acting as QP for companies, and helping with regulatory inspections.

A Novel Pd1-Enahced DNA Vaccine for Therapeutic Use in People Living with Hiv-1 Infection

Xia JIN
CEO of Immuno Cure, Hong Kong

Abstract:

Combination antiretroviral therapy (cART) has successfully changed the clinical course of HIV-1 disease progression, resulting in saving of millions of lives. The cART, however, is unable to cure HIV-1 infection, and its long-term use is associated with notable side-effects including cardiovascular diseases and metabolic disorders. To explore methods for cART-free virological control, we have developed a third generation DNA vaccine which incorporates DC-targeting strategy and conserved HIV-1 mosaic Gag antigens. In preclinical non-human primate studies, such DNA vaccine conferred completed suppression of viral replication, and enabled significantly extended survival of vaccinated rhesus monkeys, whereas all control monkeys died within one and half year after pathogenic SHIV challenge. In a follow-up phase I human clinical trial, 45 HIV-1-infected, cART treated individuals who have achieved sustained viral load suppression were enrolled and randomized 4:1 to receive three different dosage of vaccine or the same volume of placebo control via intramuscular injection, followed by a short-pulse electroporation with a proprietary device at the same site. Preliminary data indicate that the DNA vaccine is safe, with no vaccine-related severe adverse events (SAE), and that most vaccine recipients generated potent T cell immune responses as detected by the ELISPOT assay. These data suggest that further clinical investigation of such vaccine is warranted.

Biography:

Dr. Xia JIN, MD PhD was Chief Scientific Officer and Vice President of Serum Bio Technology in Shanghai. Prior to that, he was Professor and Principal Investigator of Shanghai Public Health Clinical Center and the Director of Vaccine and Immunology Research Center of Fudan University. He was also Distinguished Professor of Chinese Academy of Sciences and Principal Investigator and Executive Director of Vaccine Center at Institute Pasteur of Shanghai. He had been a tenure-track Assistant and Associated Professor at Rochester University, New York, USA. He is an Academic Editor of PLoS ONE and Editorial Board Member of JAIDS. His laboratory work focuses on HIV and dengue virus immunology and vaccine development. He has published over 140 SCI papers in Science, J Exp Med, J Clin Inv, J Immunology, J Virol, J Inf Dis, AIDS, Retro virology, Vaccine.

Viral Gene Drive Spread During Herpes Simplex Virus 1 Infection in Mice

Keith R Jerome
University of Washington, USA

Abstract:

Gene drives are genetic modifications designed to propagate efficiently through a population. Most applications rely on homologous recombination during sexual reproduction in diploid organisms such as insects, but we recently developed a gene drive in herpes viruses that relies on co-infection of cells by wild-type and engineered viruses. Here, we developed a viral gene drive against human herpes simplex virus 1 (HSV-1) and showed that it propagated efficiently in vitro and during HSV-1 infection in mice. We observed high levels of co-infection and gene drive-mediated recombination in neuronal tissues during herpes encephalitis as the infection progressed from the site of inoculation to the peripheral and central nervous systems. In addition, we found evidence that a super infecting gene drive virus could recombine with wild-type viruses during latent infection. These findings indicated that HSV-1 achieves high rates of co-infection and recombination during viral infection, a phenomenon that is currently under appreciated. Overall, this study showed that a viral gene drive could spread in vivo during HSV-1 infection, paving the way toward therapeutic applications.

Biography:

Dr. Keith Jerome is a renowned virologist whose research focuses on viruses such as herpes simplex, HIV and hepatitis B that persist in their hosts. He studies the ways in which these viruses evade the immune system and potential therapies for these infections. Dr. Jerome and his colleagues are studying the uses of precision gene-editing tools like CRISPR/Cas9 to remove damaging viral genes that have tucked themselves into a personas genetic code or to insert genes that can protect cells from invading viruses. He and his colleagues are exploring this approach in combination with blood stem cell transplants as a means of curing HIV. Dr. Jerome also studies the corona virus that causes COVID-19. He and his University of Washington colleagues developed a diagnostic test for infection with the corona virus that expanded local testing capacity, and his Fred Hutch laboratory aims to validate and deliver COVID-19 tests that could diagnose infection within minutes.

Controlling Chronic Viral Infections Where Lesions Are Mainly Caused by the Host Response

Barry T Rouse
University of Tennessee, USA

Abstract:

We discuss a variety of immune modulating approaches that could be used to counteract tissue damaging viral immune inflammatory lesions which typify many chronic viral infections. We make the point that in several viral infections the lesions can be largely the result of one or more aspects of the host response mediating the cell and tissue damage rather than the virus itself being directly responsible. However, within the reactive inflammatory lesions along with the pro inflammatory components there are also other aspects of the host response that may be acting to constrain the activity of the damaging components and are contributing to resolution. This scenario should provide the prospect of rebalancing the contributions of different host responses and hence diminish or even fully control the virus induced lesions. We identify several aspects of the host reactions that influence the pattern of immune responsiveness and describe approaches that have been used successfully, mainly in model systems, to modulate the activity of damaging participants and which have led to lesion control. We emphasize examples where such therapies are, or could be, translated for practical use in the clinic to control inflammatory lesions caused by viral infections.

Biography:

Prof. Rouse is a native of England where he completed his education through a BVSc honors degree. Graduate education in Canada with MSc in Virology and PhD in immunology Post-doctoral fellowship at Walter and Eliza Hall of Medical Research in Melbourne Australia in Cellular Immunology 1970-72.Established research Program at University of Saskatchewan on Viral immunology supported by Medical Research Council of Canada. Moved to College of Veterinary Medicine University of Tennessee in 1977 where he remains as the Lindsay Young Distinguished Professor. Took several mainly sabbaticals, including one with Peter Doherty (another veterinarian) in Canberra and Hermann Wagner for one year in Mainz, Germany Worked on the immunology of herpes virus infections supported continuously by multiple NIH grants until the lad was closed in Dec 2022.Published >470 research articles and reviews with and h index 91 and won several Research Achievement awards. Trained 80 PhD and postdoctoral fellows most of whom he stays in contact and occasionally writes reviews on topics in Viral Immunology.

Turkovac:Interim Results of Phase 1 and 2 Trials for a Safe and Effective Covid-19 Vaccine

Aykut Ozdarendeli
Erciyes University, Turkey

Abstract:

In the global battle against the COVID-19 pandemic, the development of vaccines holds immense significance. These vaccines serve as a vital tool in preventing the transmission of the virus, mitigating severe illness, and ultimately saving lives. Furthermore, vaccines pave the way towards attaining herd immunity, safeguarding vulnerable populations, and reinstating a sense of normality in societies across the globe.
The development of safe and effective vaccines is crucial in the fight against the COVID-19 pandemic. In this study, we have reported the interim findings of the phase 1 and 2 trials of Turkovac, an inactivated whole virion SARS-CoV-2 vaccine.The trials were conducted on healthy adults aged 18-55 years (18-64 in phase 2) who did not have antibodies against SARS-CoV-2. The participants were randomly assigned to receive two doses of Turkovac (3 µg or 6 µg) or a placebo, with a 21-day interval (28 days in phase 2) between doses. The trials were double-blind and conducted at a single center.

In the phase 1 trial, 44 participants received at least one dose of the vaccine or placebo. Until day 43, 25 adverse events were reported in 15 participants, with the majority being mild. There was no significant difference in safety events between the different doses of Turkovac. The most common adverse event was pain at the injection site. Both doses of Turkovac induced similar levels of neutralizing antibodies against the wild-type SARS-CoV-2 virus.
In the phase 2 trial, 250 participants received at least one dose of the vaccine or placebo. A total of 268 adverse events were reported in 153 participants, with the most common being pain at the injection site and headache. Pain at the injection site was more frequent in the Turkovac groups compared to the placebo group. However, the frequency of adverse events was similar between the Turkovac groups. Both doses of the vaccine induced comparable levels of neutralizing antibodies.

Overall, the two-dose regimens of Turkovac (3 µg and 6 µg) were found to be safe and well-tolerated. They also elicited strong immune responses, with neutralizing antibody seroconversion rates exceeding 95% at day 43 and 60 after the first vaccination.
These findings suggest that Turkovac has the potential to be an effective vaccine against SARS-CoV-2, providing valuable insights for the ongoing efforts to combat the COVID-19 pandemic.

Biography:

I am a Professor of Erciyes University, Medical Faculty, Department of Medical Microbiology and also director of Erciyes University Vaccine Research and Development Center (ERAGEM). I have devoted my career to advancing our understanding of viral infections and developing effective vaccines. My research initially focused on the molecular mechanisms of viral replication and subgenomic MRNA transcription on corona viruses.

From Research to Resilience: A Strategic Pipeline for mAb and Vaccine Development in Africa

Tsepo Tsekoa
Council for Scientific & Industrial Research, South Africa

Abstract:

Africa faces unique health challenges and disparities in access to medicines, especially high-cost biopharmaceuticals like monoclonal antibodies and vaccines. The presentation details our strategic work to establish a resilient pipeline for the local development and manufacturing of these critical health tools, aimed at transforming the landscape of public health across the continent. We discuss the integration of advanced biomanufacturing platforms within existing and pioneering new infrastructure to support the production of biologics from research through to clinical development. This initiative aligns with the African Union's New Public Health Order, South Africa's Decadal Plan and addresses key challenges such as high import dependence, lack of local manufacturing, and the urgent need for self-sufficiency highlighted by the recent COVID-19 pandemic. Through case studies including COVID-19 antibodies and HIV monoclonal antibodies, VLPand vaccine carrier protein production, we demonstrate the potential of diverse production systems, including plants, in meeting local needs. The presentation concludes with.

Biography:

Tsepo Tsekoa is a Chief Researcher and Research Group Leader for Biomanufacturing Technology Demonstration at CSIR's Advanced Chemistry and Life Sciences Division. He was trained at the University of London (UCL), the University of Cape Town (UCT) and the University of the Western Cape and has a PhD in Applied Biotechnology. He completed his postdoctoral training at UCT's Institute DM prior to joining CSIR Biosciences in 2007.
His work at the CSIR is in the recombinant production of biologics, including reagent proteins, vaccine candidates and antibodies for targets like Rabies, HIV and resistant microbial pathogens, among others. He has published on these topics and filed patents.

Digital Innovations Optimized to Achieve Vaccine Last-Mile Quality Control in Nigeria

Atef Fawaz
eHealth Africa, Nigeria

Background:

According to the World Health Organization (WHO), a significant challenge contributing to vaccine wastage is the compromised potency incurred during transportation and storage, particularly at the last mile, owing to suboptimal handling and storage conditions. Global estimates indicate vaccine spoilage rates ranging between 20% to 86%, with Nigeria experiencing extreme cases of 100% spoilage in remote areas attributed to inadequate monitoring of cold-chain equipment (CCE) impacts on vaccine availability at last-mile health facilities for immunization. Also in recent years, there has been a substantial increase in investments in cold-chain equipment (CCE) dedicated to vaccine storage at health facilities for service delivery. Despite this positive stride, the success of immunization efforts hinges upon the uninterrupted integrity of the cold chain infrastructure, necessitating a perpetual requirement for novel Cold Chain Equipment (CCEs). eHA's-lead Vaccine Direct Delivery (VDD) project implements innovative strategies to sustain vaccine quality up til the last mile.

Methodology:

To ensure the effectiveness and continuous monitoring of CCE performance at service delivery points for the maintenance of vaccine potency and waste prevention, we employed a combination of smart data collection technologies by enabling 5 Health Delivery Officers (HDOs) in the VDD-designated health facilities to collect CCE temperature data at the point of vaccine delivery from 2019-2023. The HDOs use the free Varo mobile application to collect 30DTR (30-Day Temperature Report) data from deployed Fridge Tags, PogoLT for aggregation of the data; thereby illuminating the performance of CCE. The data collected includes the number of CCE temperature reports received, the number of unique CCEs with alarms, and the percentage of time the CCE are performing within safe temperatures for vaccines. The unique loggers (Fridge Tags) deployed in each CCE make an alarm when the temperature is outside of the safe range (2-8 degrees centigrade). Through an on-the-go adapter, the Varo application collects and sends the temperature data to Pogo LT via email for aggregation and analysis. The five-year temperature data was exported from the email repository for further descriptive analysis.

Results: In 5 years, 9,674 CCE temperature reports were received across 351 facilities in Sokoto state, Nigeria. Annually, the average temperature report was 1935. The number of reports received in 2023 increased by 248% compared to 2019 data (961). In total, there were an average of 183 unique loggers identified per through the 30DTR data, with 40% indicating alarms. Between 2022 and 2023, temperature excursion alarms were reduced by 31%. The annual average CCE safe time was 93%. The CCE temperature performance data was found to have increased the safe period of the CCE; this enabled Sokoto SLWG (State Logistics Working Group) stakeholders with timely access to data for action. The escalation of alarms and CCE performance issues to the SLWG correlated with a decrease in CCE excursion alarms, showcasing the effectiveness of smart temperature data collection initiatives and swift resolution measures.

Conclusions: Our CCE performance checks, aligned with Gavi's Cold Chain Equipment Optimization Platform Guideline, are crucial for maintaining vaccine efficacy and potency especially at the last mile. The combination of the freely available Varo mobile application, PogoLT and Berlinger FridgeTags were instrumental in improving visibility of CCE performance in low resource setting, thereby positively impacting the overall maintenance and response times for deployed CCEs. The success of this strategy highlights its contributory impact on immunization coverage and equity in Sokoto state, reinforcing the importance of systematic cold-chain equipment performance data for maintenance management.

Biography:

Atef Fawaz is a distinguished leader in healthcare management, currently serving as the Executive Director at eHealth Africa (eHA). With over a decade of experience, Atef has honed his skills in operations management, beginning his journey as Operations Manager and COO at Electronic Connections Ltd. in Kano. Since joining eHA in November 2012, he has played a pivotal role in improving healthcare accessibility and quality in underserved regions. Notable achievements include establishing Polio Emergency Operations Centers in Nigeria, leading Ebola response efforts, and expanding Polio control rooms across Africa. Atef's humanitarian contributions have earned him recognition, including a service award from Rotary International and a nomination to the Kano State COVID-19 Task Force. With over a decade of experience in operations management, he excels in strategic planning and program success.

Personalized and Precision Medicine (PPM) as a Unique Healthcare Model to be Set Up via Biodesign-Driven Biotech and Upgraded Biomarketing to Secure the Human Healthcare and Biosafety

Sergey Suchkov
The Russian University of Medicine and Russian Academy of Natural Sciences, Russia

Abstract:

Traditionally a disease has been defined by its clinical presentation and observable characteristics, not by the underlying molecular mechanisms, pathways and systems biology-related processes specific to a particular patient (ignoring persons-at-risk). A new systems approach to subclinical and/or diseased states and wellness resulted in a new trend in the healthcare services, namely, personalized and precision medicine (PPM).

To achieve the implementation of PPM concept, it is necessary to create a fundamentally new strategy based upon the biomarkers and targets to have a unique impact for the implementation of PPM model into the daily clinical practice and pharma. In this sense, despite breakthroughs in research that have led to an increased understanding of PPM-based human disease, the translation of discoveries into therapies for patients has not kept pace with medical need. It would be extremely useful to integrate data harvesting from different databanks for applications such as prediction and personalization of further treatment to thus provide more tailored measures for the patients and persons-at-risk resulting in improved outcomes and more cost effective use of the latest health care resources including diagnostic (companion ones), preventive and therapeutic (targeted molecular and cellular) etc.

Translational researchers, bio-designers and manufacturers are beginning to realize the promise of PPM, translating to direct benefit to patients or persons-at-risk. And thus both PPM and nanobiotechnologies are being integrated into diagnostic and therapeutic tools to manage an array of PPM-guided conditions to customize therapeutic management. Novel nanomedicines have been employed in PPM-driven treatment of several diseases, which can be adapted to each patient-specific case according to their genetic profiles. So, partnering and forming stra-

tegic alliances between researchers, bio-designers, clinicians, business, regulatory bodies and government can help ensure an optimal development program that leverages the Academia and industry experience and FDA's new and evolving toolkit to speed our way to getting new tools into the innovative markets.

Healthcare is undergoing a transformation, and it is imperative to leverage new technologies to support the advent of PPM. And it is urgently needed to to discover, to develop and to create new (targeted and/or smart/intelligent) drugs. And with the support of nanotechnology, new targeted therapeutic agents and biomaterials, or aid the development of assays for disease biomarkers and identification of potential biomarker-target-ligand (drug) tandems to be used for the targeting, PPM is making phenomenal steps in the future to come. This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM and design-driven translational medicine to elicit the content of the new trend. The latter would provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and disease and patient advocacy with an interest in improving the system of healthcare delivery on one hand and drug discovery, development, and translation, on the other one, whilst educating the policy community about issues where biomedical science and policy intersect. So, the Grand Change and Challenge to secure our Health and Wellness are rooted not in Medicine, and not even in Science! Just imagine WHERE?!In the upgraded Hi-Tech Culture!

Biography:

Dr. Sergey Suchkov was born in the City of Astrakhan, Russia, in a family of dynasty medical doctors. In 1980, graduated from Astrakhan State Medical University and was awarded with MD. In 1985, Suchkov maintained his PhD as a PhD student of the I.M. Sechenov Moscow Medical Academy and Institute of Medical Enzymology. In 2001, Suchkov maintained his Doctor Degree at the National Institute of Immunology, Russia. From 1989 through 1995, Dr. Suchkov was being a Head of the Lab of Clinical Immunology, Helmholtz Eye Research Institute in Moscow. From 1995 through 2004 - a Chair of the Dept for Clinical Immunology, Moscow Clinical Research Institute (MONIKI). In 1993-1996, Dr. Suchkov was a Secretary-in-Chief of the Editorial Board, Biomedical Science, an international journal published jointly by the USSR Academy of Sciences and the Royal Society of Chemistry, UK. He is also a Member of the Editorial Boards of "Open Journal of Immunology", EPMA J., American J. of Cardiovascular Research and "Personalized Medicine Universe".

Obtaining the Subunit Vaccine Candidate S. Aureus Enterotoxin B (SEB) Protein Via Conventional Methods

Hivda Ulbegi Polat
Tubitak Marmara Research Center, Turkey

Abstract:

Traditionally a disease has been defined by its clinical presentation and observable characterStaphylococcus aureus is a common gram-positive bacterium that causes many infections nowadays. This bacterium is important in both minor and serious skin infections, such as burns. Furthermore, it causes a wide range of illnesses, including lethal pneumonia and sepsis. Methicillin-resistant S. aureus (MRSA), which causes prevalent nosocomial infections worldwide, has a high morbidity and fatality rate. Common toxins secreted by S. aureus include hemolysin, enterotoxin (SE), exfoliative toxin (ET), and toxic shock syndrome toxin 1 (TSST-1). S. aureus releases toxins, which are proteins that typically result in cell death by harming the host cell's cell membranes. With its continuing evolution, S. aureus, which is involved in many illnesses around the world, has become antibiotic-resistant. This condition is a global health issue, resulting in millions of deaths each year. So far, vaccine research against many S. aureus illnesses has been conducted, although it has only reached phase I/II stage. Despite extensive research, no vaccine is currently in use.

In this investigation, SEB protein was produced conventionally from S. aureus bacteria that generate Enterotoxin B (SEB) against toxic shock syndrome (TSST-1). LD50 and humoral response experiments were carried out in mice using the live SEB toxin obtained. Our findings will inform future research on subunit vaccines using standard SEB toxins.

Biography:

Dr. Hivda Ulbeği Polat is a distinguished Doctor of Veterinary Medicine affiliated with the TUBITAK Marmara Research Center's Genetic Engineering and Biotechnology Institute. Her educational background in veterinary medicine has provided her with a robust foundation in animal health and medical practices. Dr. Polat's research interests lie at the intersection of genetic engineering and biotechnology within veterinary science.

MRNA Vaccine Research and Development for Sustainability: Process and Product Innovation Partnerships of the MRNA Technology Development and Transfer Programme

Ike James
Medicines Patent Pool, Switzerland

Abstract:

The remarkable success and impact of mRNA Covid-19 vaccines has sparked great interest and extensive R&D activities in RNA vaccine innovation 50 years after the discovery of messenger RNA. The development speed of mRNA vaccines during the pandemic demonstrated the potential value of mRNA technology platforms to not only respond to epidemics and pandemics but to contribute to the development of new vaccines or the improvement of existing vaccines. mRNA technology however requires ongoing multi-disciplinary research to fully embed the technology in vaccine R&D and translate into cost effective manufacturing. The challenges stimulating R&D includes access (complex evolving IP landscape), high cost of goods, raw material supply, durability and potency, thermostability, delivery technology and a diverse advancing product pipeline. The place for mRNA in a geo-diversified vaccine manufacturing sector is center stage to the WHO/MPP mRNA technology development and transfer program making mRNA technology accessible to 15 partners in LMICs and building end-to-end research, development and manufacturing capabilities. The more than 50 leading vaccine developers are primarily located in the USA, Europe and Asia which potentially could result in prioritizations that does not focus on neglected diseases in LMICs. The mRNA program center for vaccine development and transfer has created global R&D partnerships to contribute to the sustainability of mRNA platforms. This paper will discuss the progress, results, R&D partnerships and portfolio of the mRNA technology development and transfer program making MRNA vaccine development and manufacturing accessible to a network of partners in LMICs.

Biography:

Ike James is a distinguished professional at the Medicines Patent Pool (MPP), where he serves as the Head of Technology Transfer. He is a key member of the Senior Management Team and oversees MPP's initiatives in technology transfer, local production in low- and middle-income countries, and its role in the ACT-A/COVAX Manufacturing Workforce. Before joining MPP, Ike held technical leadership roles at Biovac, Aspen Pharmacare, and Lonza, accumulating approximately 16 years of experience in the pharmaceutical industry. His expertise includes product development, technology transfer, process validation of small molecules and biological products, and operationalizing new manufacturing facilities. Ike earned his PhD in Chemical Engineering from Stellenbosch University, South Africa.

Immunization of Patients with Autoimmune Rheumatic Disease Against Influenza: a Study of Vaccine Safety and Immunogenicity

Lyudmila Stojanovich
Belgrade University, Serbia

Abstract:

Objectives: We aim to assess the protective role of the influenza vaccine by analyzing the association between respiratory infections occurrence and humoral response to influenza A (H1N1) infection in patients with autoimmune rheumatic diseases.

Methods: Our study includes three groups of patients (99 in total) with stable underlying diseases status, suffering from: 30 patients with systemic lupus erythematosus (SLE), 37 with rheumatoid arthritis (RA) and 32 with Sjögren's Syndrome (SjS). In November 2021. 46 patients were immunized with an inactivated trivalent split vaccine (15 µg HA A/California/7/2009 (H1N1), 15 µg HA A/Pert/16/2009 (H3N2) and 15 µg / HA B Brisbane / 60/2008) whereas 52 patients did not accept the proposed vaccination. These three groups of patients were divided into two subgroups depending on vaccination: vaccinated - SLE1 (19), RA1 (15) and SjS1 (14), and unvaccinated - SLE2 (11), RA2 (22), SjS2 (18). During the following year disease activity parameters (SLEDAI for SLE), presence of viral and bacterial infections and concentration of A H1N1 antibodies were monitored in vaccinated and unvaccinated patients. We used hem agglutination inhibition test (according to the method of the Center for Disease Control and Prevention (CDC) with antigen A/California/7/2009 influenza virus (H1N1), and turkey erythrocytes for the detection of antibodies against the A H1N1. Value of seroprotective titer (ST) was defined as ≥ 32.

Results: The incidence of viral and bacterial infections among vaccinated patients (primarily influenza) was significantly lower, compared to the non-vaccinated group. Influenza occurrence was significantly associated with previous respiratory infections (p=0.001). The mean titer of antibodies was highest in SLE patients and significantly higher in all vaccinated patients (p=0.018). Mid-level antibody titer was significantly related to last vaccination in all pa-

tients (p= 0.001) and has not been proven after removal of last vaccination effects (p=0.227). Similar results were obtained for patients with SLE, while in RA and SjS these correlations were not significant. There was no significant difference between the three diseases regarding the mean ranks of antibody titer (p=0.418).

Conclusions: Based on results to date, it is our opinion that overall, influenza vaccination for patients suffering from SLE, RA and Sjögren's Syndrome is safe, efficient, and sufficiently immunogenic.

Biography:

Dr. Ljudmila Stojanovich received her Ph.D. in Medicine, with the thesis Neuropsychiatric manifestations in patients with Systemic Lupus Erythematosus in 1999. She is the scientific director in the Bezhanijska Kosa, University Medical Center of Belgrade University, where she is currently a Full Research Professor. Dr. Stojanovich research focuses on Systemic Lupus Erythematosus, Antiphospholipid Syndrome, and Vaccination in patients with Autoimmune Rheumatic diseases. She is an author of three monographs and of about 250 articles on various aspects of Autoimmune Rheumatic disorders, published in international and domestic journals and in conference proceedings.

Translating Veterinary Medicines from Development to Scale: A Case Study for plant Produced Vaccine Candidate Against Bluetongue Disease

Nobalanda Mokoena
Onderstepoort Biological Products, South Africa

Abstract:

The concept of plant-produced vaccines and related pharmaceuticals was first established about 3 decades ago. To date, though only a few plant-made vaccines have been approved by regulatory authorities, many recombinant pharmaceutical proteins made in plants have been granted emergency approval. Despite the extensive research in plants, a knowledge gap still exists between the ability to create plant-based products in the laboratory, and commercialisation of the products. Bluetongue (BT) disease remains a major health and trade problem for the sheep and cattle industries. Vaccination using conventional live attenuated vaccines or the inactivated products is the most effective control method. This research further advances the commercialisation of BT multivalent plant made vaccines. The multivalent virus-like particle vaccine candidate against BT disease was produced in Nicotiana benthamiana leaves. Chimaeric VLPs BT3/8 and BT4/8 designed from BTV8 inner core (VP3/VP7) and outer core (VP2/VP5) from BT3 and BT4, were successfully expressed and assembly of VLPs achieved for three serotypes, including homologous BTV8. Stability of multivalent and monovalent vaccine antigens was determined at 11 months following assessment and optimisation of different stabilizers. Antigens were formulated with proprietary adjuvant and safety and the efficacy was evaluated in a virulent virus challenge using merino sheep. The vaccine was safe and did not induce temperature reactions or BTV clinical signs. Furthermore, the vaccine protected animals against challenge with different BTV serotypes. The results demonstrated that the plant made chimeric VLP vaccine candidate is safe and efficacious in sheep and can be used for prophylactic immunisation against BT disease.

Biography:

Dr. Nobalanda Mokoena is a Senior Researcher at Onderstepoort Biological Products LTD SOC, a veterinary vaccines manufacturer in South Africa. Her research interests are on Vaccinology with special focus on development of veterinary medicines against viral pathogens. Dr Mokoena works on various projects towards viral Vaccine development up scaling and commercialization of this veterinary therapeutics. She conducts research in translating the early-stage technology developments to scale and ensures compliance with regulatory framework both in South Africa and other countries internationally. Dr. Mokoena is the author of a peer reviewed papers; product technology packages and patents. She collaborates with research institutions and universities for research and postgraduate students 'supervision.

Immunization of Patients with Autoimmune Rheumatic Disease Against Influenza: a Study of Vaccine Safety and Immunogenicity

Essa Suleman
Council for Scientific & Industrial Research, South Africa

Abstract:

Aquaculture and terrestrial agricultural production are increasing globally to meet the demands of the world's population. While hazards such as climate change, politics, socio-economic affect aquaculture and agriculture, disease outbreaks remain one of the most challenging hazards. This is exacerbated by availability of vaccines, diagnostics, therapeutics, surveillance and epidemiological capabilities for many infectious diseases. In Africa, Tilapia lake virus (TiLV) and Infectious Spleen and Kidney Necrosis Virus (ISKNV) are major threats to aquaculture due to lack of diagnostics, vaccines and therapeutics resulting in significant socio-economic impacts and millions of dollars in financial losses annually. Additionally, the cattle and dairy sector sare plagued by numerous outbreaks of transboundary animal diseases (TADs) such as Foot and Mouth Disease (FMD), Rift Valley Fever (RVF), Lumpy Skin Disease (LSD), among other diseases. Currently available vaccines for livestock diseases are often limited in terms of availability and effectiveness against emerging strains. There are also significant limitations in vaccine manufacturing capability and availability across the African continent. These challenges emphasize the need for vaccine and diagnostics development targeting infectious diseases affecting aquaculture and agriculture across the African continent. The recently established mRNA vaccine technology transfer hub in South Africa aims to develop local manufacturing capability and capacity for production of mRNA vaccines that are relevant to the African continent with an initial focus on vaccines for human health. The Council for Scientific and Industrial Research (CSIR) in South Africa also has a well-established vaccines program focused on development of recombinant vaccines in bacterial, yeast and plant-based expression systems. However, the COVID-19 pandemic has highlighted the potential of mRNA-based vaccines in terms of efficacy, reliability, safety, speed and cost-effectiveness. Furthermore, mRNA technologies have significant potential to address challenges associated with currently available

vaccines for infectious diseases affecting agriculture and aquaculture. Therefore, the CSIR has expanded its focus and established the Next Generation mRNA Vaccines program integrating innovative bioinformatics and immune informatics technologies for design and development of mRNA vaccines for diseases affecting aquaculture and agriculture.

Biography:

Dr. Essa Suleman is a Principal Researcher and the Research Group Leader of the Aquaculture and Veterinary Diagnostics and Vaccines group at the Council for Scientific and Industrial Research (CSIR) in South Africa. He holds an undergraduate degree in microbiology and biotechnology from the University of Cape Town (UCT) and a PhD in microbiology from Nelson Mandela University (NMU), and is a Visiting Researcher in the Protein-Structure Function Research Unit (PSFRU), in the school of Molecular and Cellular Biology at the University of Witwatersrand (WITS).

Monitoring Memory B Cells by Next Generation Immunospot® Provides Insights into Humoral Immunity That Measurements of Circulating Antibodies Do Not Reveal

Greg A. Kirchenbaum
Cellular Technology Limited, USA

Abstract:

Memory B cells (Bmem) provide the second wall of adaptive humoral host defense upon specific antigen rechallenge when the first wall, consisting of pre-formed antibodies originating from a preceding antibody response, fails. This is the case, as recently experienced with SARS-CoV-2 infections and previously with seasonal influenza, when levels of neutralizing antibodies decline or when variant viruses arise that evade such. While in these instances reinfection can occur, in both scenarios, the rapid engagement of preexisting Bmem into the recall response can still confer immune protection. Bmem are known to play a critical role in host defense, yet their assessment has not become part of the standard immune monitoring repertoire. Here we describe a new generation of B cell ELISPOT/FluoroSpot (collectively ImmunoSpot®) approaches suited to dissect, at single-cell resolution, the Bmem repertoire ex vivo, revealing its immunoglobulin class/subclass utilization, and its affinity distribution for the original, and for variant viruses/antigens. Because such comprehensive B cell ImmunoSpot® tests can be performed with minimal cell material, are scalable, and robust, they promise to be well-suited for routine immune monitoring.

Biography:

I have a long-standing fascination with the immune system, and specifically the development and maintenance of immunological memory in the context of natural infection or prophylactic vaccination. Since joining CTL, I have been exploring the utility of the ImmunoSpot (ELISPOT/FluoroSpot) assay platform for performing detailed characterization of rare antigen-specific B cell populations. In particular, my research group is leveraging the ImmunoSpot assay approach to evidence affinity maturation of the adaptive B cell response elicited by SARS-CoV-2 infection and/or COVID-19 vaccination.

Development of Epitope-Based Diva Vaccines for Senecavirus A

Fandan Meng
Harbin Veterinary Research Institute, China

Abstract:

Seneca virus A (SVA) is an important emerging swine pathogen that causes vesicular lesions in swine and acute death in newborn piglets. It has been prevalent in many countries and SVA-associated vesicular diseases have caused economic losses to the pig industry. As picornaviruses, their capsid proteins have good immunogenicity, so inactivated vaccines can provide good protection against SVA. However, it is difficult to distinguish vaccinated and naturally infected animals. Therefore, the development of epitope-based SVA marker vaccines will be beneficial to SVA prevention and control. Currently, we identified a series of non-neutralizing SVA Linear B cell epitopes by monoclonal antibodies (mAbs) and peptide scanning. One linear epitope with a high continuity in key amino acids showed potential for developing SVA maker vaccine. We found that this linear epitope was fully exposed on the VP2 surface and located at the EF loop. In addition, combined mutations within this epitope blocked the interaction of the mutant virus with antibody in vitro, and the serum obtained from recombinant virus-immunized mice cannot recognize the deleted linear epitope but does not affect the level of neutralizing antibodies in vivo. Furthermore, we successfully obtained the peptide for epitope-based differential diagnosis and developed the diagnostics methods. In summary, we developed an epitope-based SVA marker vaccine candidate, and evaluated the difference in antibody levels between epitope deletion mutant and wild type strain, which promote the development of diagnostics tools and DIVA vaccines for SVA.

Biography:

Dr. Fandan Meng, Harbin Veterinary Research Institute of Chinese Academy of Agricultural Sciences, China. She obtained Ph.D in 2015 from University of Veterinary Medicine Hannover, Germany. Currently, she is working in the field of Virology and development of vaccines.

Ribavirin-Resistant Porcine Reproductive and Respiratory Syndrome Virus Decreases Recombination Frequency and Pathogenicity

Tongqing An
Harbin Veterinary Research Institute, China

Abstract:

Porcine reproductive and respiratory syndrome (PRRS) is one of the most important economic diseases affecting the global pig industry. PRRS virus (PRRSV) has a high degree of genetic diversity due to viral genomic mutation and recombination. Notably, recent evidence highlights recombination between circulating strains and modified live vaccines (MLV) caused severe outbreaks. To explore possible approaches for reducing the risk of recombination of PRRSV, in the present study, two representative PRRSV strains (HeB108 from Lineage 1, HuN4 from Lineage 8) were serially passaged in the presence of ribavirin, and the ribavirin-resistant-associated amino acid substitutions in viral RdRp and helicase were identified. Based on the infectious clones of PRRSV HeB108 and HuN4, ribavirin-resistant viruses with single or multiple amino acid substitutions were generated, which were used to investigate the recombination ratio between PRRSVs HeB108 and HuN4 via a co-infection recombination assay. The results showed that the combinatorial mutated viruses have reduced recombination frequency. Notably, the combined mutated viruses showed higher fidelity and lower pathogenicity in infected piglets than their parental PRRSVs, respectively. The findings reveal that recombination associates the RdRp fidelity and provides a practical approach to generate a safer modified live vaccine.

Biography:

Dr. Tongqing An obtained his doctorate in 2007 from the Chinese Academy of Agricultural Sciences (CAAS) and subsequently conducted research at the State Key Laboratory of Veterinary Biotechnology, Harbin Veterinary Research Institute, CAAS. His research focused on the porcine reproductive and respiratory syndrome virus (PRRSV) and pseudorabies virus (PRV), including molecular epidemiology, viral pathogenicity, and vaccine development. Dr.

An has authored over 130 peer-reviewed papers, 5 book chapters and 4 patents. Furthermore, a modified live vaccine developed in his group, targeting highly pathogenic PRRS, has been licensed and commercially utilized in China. Currently, a DIVA and low-recombination-risk MLV against PRRS was in preclinical study in his lab.

Upcoming Event

3rd International Conference on VACCINES RESEARCH AND DEVELOPMENT

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