July 26-28, 2023 | Boston, MA

Register by May 19 & Save Up To $950

3rd Annual

mRNA-Based Therapeutics Summit

Supercharging the Next Wave of Efficacious mRNA Therapeutics & Vaccines

Unlock mRNA Platforms for Next Generation Therapeutics & Vaccines from Concept to Clinical Validation & Commercialization for Patients in Need Across All Disease Indications

Peter Marks
Director – Center for Biologics Evaluation & Research (CBER)
U.S. Food & Drug Administration (FDA)

Sonia Stoszek
Executive Director & Program Lead – RSV Vaccines
Moderna

Aleksandra Pastrak
CMO
Providence Therapeutics

Michael Wenger
VP - Clinical Development
BioNTech SE

Vira Bitko
VP & Head of Vaccines
RVAC Medicines

Frank DeRosa
CTO & Global Head of Research, mRNA Center of Excellence
Sanofi

Kathleen Francissen
Global Head of Regulatory PT Cell & Gene Therapies
Roche

Yusuf Erkul
CEO
Kernal Bio

Annette Bak
Head of Advanced Drug Delivery
AstraZeneca

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+1 617 455 4188 | info@hansonwade.com | www.mrnabased-therapeutics.com | RNA Therapeutics & Vaccines | Preview the Event

hansonwade

JOIN 500+ mRNA EXPERTS

REGISTER NOW

WELCOME TO THE 3RD mRNA-BASED THERAPEUTICS SUMMIT!

To our global mRNA community,

The **mRNA revolution** is here! Stretching beyond COVID-19 vaccines, the field has exploded with 800+ mRNA drugs currently in development and the accelaration of novel mRNA platforms into unchartered disease areas.

The hotly anticipated annual **mRNA-Based Therapeutics Summit** returns to Boston in July for the **3rd year**, as the industry's premier, definitive, and most comprehensive forum bringing you a forum to discover and develop first-in-class clinically validated mRNA-based therapeutics, and best-in-class safe and effectine mRNA-based vaccines that can be delivered to patients faster.

100+ world-class speakers will be showcasing brand-new pivotal data from discovery to clinical proof-of-concept, development and commercialization, to ensure a pathway of success for regulatory approval of mRNA drugs and to unleash their potential in areas of oncology, infectious and rare diseases, and beyond.

3 days of carefully curated sessions will gather **400+ mRNA trailblazers** across **5 dedicated tracks** of content spanning **Discovery**, **Translation**, **Clinical Development**, **Chemistry, Manufacturing & Controls (CMC)** and **Logistics** to overcome the industry's largest bottlenecks from optimized dosing, targeted delivery, safety and scalability.

Developed with expert insights from the mRNA community including the **FDA, Pfizer, BioNTech SE**, **Moderna**, **Sanofi**, **Beam Therapeutics** and many more, this is your unmissable opportunity to collaborate with **key stakeholders** across pharma, biotech, regulatory bodies and solution providers.

Join the **world's only end-to-end forum** focused on the discovery and development of emerging mRNA therapeutics and vaccines to drive the next wave of clinical adoptions, leading to widespread application, positively impacting patients in need.

I look forward to welcoming you to Boston this July to deliver the promise of mRNA medicines.

Huzefa Rupawala, Ph.D.
Senior Program Director – World RNA Series
Hanson Wade

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3rd Annual mRNA-Based Therapeutics Summit

WHAT'S NEW FOR 2023?

- **400+ Attendees**
- **100+ Thought Leading Speakers**
- **10+ Hours of Dedicated Networking**
- **5 Interactive Panel Discussions**
- **80% BRAND NEW Speakers for 2023**
- **NEW 5 Track Agenda**
- **Biopharma Leaders' Fireside Chat**

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AGENDA HIGHLIGHTS
TESTIMONIALS
100+ EXPERT SPEAKERS
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PRE-CONFERENCE FOCUS DAY
PRE-CONFERENCE WORKSHOP DAY
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NEW TO THE AGENDA FOR 2023:

AGENDA HIGHLIGHTS

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PRE-CONFERENCE FOCUS DAY: NEXT GENERATION mRNA- MEDIATED TECHNOLOGIES

BRAND NEW

- Harness the power of mRNA for use in gene editing and cell therapy to expand disease targets and maximize therapeutic potential
- Discover the future of programmable and switchable RNA tools, taking mRNA therapeutics to new heights
- Insights from **Exacis Biotherapeutics**, **Cartesian Therapeutics**, **Turn Biotechnologies**, **Strand Therapeutics** and more

PRE-CONFERENCE WORKSHOP DAY

- Elucidate your understanding into novel LNP formulations and beyond for next generation mRNA therapeutic and vaccine delivery
- Explore the potential of circular RNA with improved design and and stability to overcome immunogenicity
- Expand your analytical toolbox to include an arsenal of tests to ensure your mRNA products' quality and consistency can meet the future regulatory standards
- Insights from **Tessera Therapeutics**, **Seqirus**, **Orbital Therapeutics**, and more

DISCOVERY

- Unlock next generation mRNA sequence optimization, from capping to poly-A tails to enhance chemical stability and protein expression
- Unleash novel payload carriers from LNPs and beyond to enable successful tissue targeting and selectivity
- Insights from **ReCode Therapeutics**, **AstraZeneca**, **Nava Therapeutics**, **pHion Therapeutics** and more

TRANSLATION

- Optimize your mRNA medicines using the most relevant *in vitro* and *in vivo* models for improved safety and efficacy
- Explore the latest mRNA preclinical investigations into infectious diseases, oncology, lung and protein replacement therapies
- Insights from **Kernal Bio**, **Ethris**, **Elastrin Therapeutics**, **ARV Technologies** and more

CLINICAL DEVELOPMENT

NEW DATA

- Delve into the latest mRNA-based vaccine early phase clinical trials for global infectious diseases and oncological indications
- Utilise your platforms and explore the potential of advancing mRNA-based therapeutics for rare diseases
- Insights from **Moderna, Vertex Pharmaceuticals, Gritstone Bio, RVAC Medicines** and more

CHEMISTRY, MANUFACTURING & CONTROLS (CMC)

- Discover new tools for mRNA product development and analytical characterization to create the ultimate therapeutic
- Elevate your mRNA drug product CMC processes at scale to accelerate drugs to market
- Insights from **BioNTech SE**, **Genentech, Omega Therapeutics, GeneLeap Biotech** and more

LOGISTICS

NEW TRACK

- Combat mRNA raw material sourcing, cold chain storage and bioproduction for an efficient supply chain
- Expand mRNA vaccine and therapeutic global supply chains with equity, sustainability and cost effectiveness to LMICs

Insights from **Sanofi, CEPI**, **PATH** and more

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HEAR WHAT LEADERS IN THE FIELD ARE LOOKING FORWARD TO:

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"The 3rd mRNA-Based Therapeutics Summit is an excellent event to take the pulse of a fast-moving field"

John Ramunas
CEO
Rejuvenation Technologies

"The meeting is one of the most important events to bring scientists from academia and industry together for exchange and networking in the field of mRNA therapeutics"

Heinrich Haas
VP – RNA Formulation & Drug Delivery
BioNTech SE

"The 3rd mRNA-Based Therapeutics Summit presents a wonderful opportunity to hear the latest innovations in the field and to ask questions of the field's leaders. The presentations also inspire creative thinking and help to identify potential collaborations"

Theresa Goletz
Global Head, Analytical Immunology & Cellular Platform
GlaxoSmithKline

"I look forward to interacting with mRNA and LNP experts from multiple perspectives ranging from discovery and research, preclinical and clinical development, and regulatory authorities"

Tao Niu
Associate Director – Clinical & Quantitative Pharmacology
Vertex Pharmaceuticals

"The value added for this meeting participation is to leverage the innovation expected from the movers and shakers in the mRNA vaccine field on the process and analytical technologies that could be amenable for LMIC use"

Lakshmi Khandke
Senior Program Advisor
PATH

"The use of mRNA therapeutics is expanding so rapidly that frequent meetings are necessary to keep up with the latest data and technologies available. We've seen that mRNA can be used as a drug product, and this meeting is a way to discuss - what's next?"

Dahyana Arias Escayola
Scientist – RNA Biology
Strand Therapeutics

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YOUR EXPERT SPEAKERS

PHARMA, BIOTECH & INDUSTRY LEADERS

Michiel Lodder
CEO
20Med Therapeutics

Walter Schmidt
Director – mRNA Division
ADvantage Therapeutics

Renhuan Xu
CEO & Co-Founder
ARV Technologies

Petro Terblanche
Managing Director
Afrigen Biologics

Amin Khan
Chief Scientific Advisor
Afrigen Biologics

Daryl Drummond
CSO & Co-Founder
Akagera Medicines

Annette Bak
Head of Advanced Drug Delivery
AstraZeneca

Manmohan Singh
CTO
Beam Therapeutics

Constanze Blume
SVP - Global Regulatory Affairs
BioNTech SE

Andreas Kuhn
SVP – RNA Biochemistry & Manufacturing
BioNTech SE

Pawel Widomski
Senior Director - Global Regulatory Affairs CMC
BioNTech SE

Michael Wenger
VP - Clinical Development
BioNTech SE

June Kim
CMC Lead
CEPI

Arun Kumar
Preclinical Vaccines Development Lead
CEPI

Linda Marban
CEO
Capricor Therapeutics

AJ Bergmann
CFO
Capricor Therapeutics

Metin Kurtoglu
COO
Cartesian Therapeutics

Sonia Golombek
Senior R&D Manager
Elastrin Therapeutics

Carsten Rudolph
CEO
Ethris

Marco Cavaleri
Head of Office, Health Threats & Vaccines Strategy
European Medicines Agency (EMA)

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Gregory Fiore
CEO
Exacis Biotherapeutics

Lusheng Fan
Investigator
GeneLeap Biotech

Elaine Peters
Director – Analytical – Individualized Cell & Gene Therapies
Genentech

Matthew Hawryluk
Executive VP & CBO
Gritstone Bio

Tamar Grossman
VP – Global Head of RNA & Targeted Therapeutics
Johnson & Johnson

Yusuf Erkul
CEO
Kernal Bio

Manfred Kraus
VP – R&D
Kernal Bio

Francis Poulin
VP – eRNA Sciences
Laronde

Yu He
Director – Analytical Research & Development
Merck & Co

Mike Zimmer
Director - Rare Diseases; Rare Research & Preclinical Development
Moderna

Sonia Stoszek
Executive Director & Program Lead – RSV Vaccines
Moderna

Anne Aunins
Executive Director & Program Lead - COVID-19 Vaccines
Moderna

Antonella Lozito
Executive Director - Infectious Disease, Global Regulatory Strategy
Moderna

Curtis Dobrowolski
Co-Founder
Nava Therapeutics

Bill Grier
Associate Director – Drug Substance Process Development
Omega Therapeutics

Gilles Besin
CSO
Orbital Therapeutics

Daniel Tondera
Head of Biology
Pantherna Therapeutics

Lakshmi Khandke
Senior Program Advisor
PATH

John Androsavich
Global Head - RNA Medicine Lead, Emerging Science & Innovation
Pfizer

Helen McCarthy
CEO
pHion Therapeutics

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CMO
Providence Therapeutics

Jason Zhang
CSO
RVAC Medicines

Mohamed ElSayed
EVP & CTO
RVAC Medicines

Vira Bitko
VP & Head of Vaccines
RVAC Medicines

Arunan Kaliyaperumal
VP – Preclinical Biology
ReCode Therapeutics

Daniella Ishimaru
Principal Scientist
ReCode Therapeutics

REGENERON

Kathir Muthusamy
Associate Director
Regeneron Pharmaceuticals

Yue Fu
Principal Scientist
Regeneron Pharmaceuticals

John Ramunas
CEO
Rejuvenation Technologies

Nathaniel Wang
CEO & Co-Founder
Replicate Bioscience

Kathleen Francissen
Global Head of Regulatory PT Cell & Gene Therapies
Roche

Daniel Shores
Partner
Rothwell Figg

Frank DeRosa
CTO & Global Head of Research - mRNA Center of Excellence
Sanofi

Gregory Troiano
Head of cGMP Strategic Supply & Operations - mRNA Center of Excellence
Sanofi

Joshua DiNapoli
Global Project Head - mRNA Platform Development
Sanofi Pasteur

Jianmei Kochling
Senior Director – Analytical Development - mRNA Center of Excellence
Sanofi

Vikram Agarwal
Head of mRNA Platform Design Data Science - mRNA Center of Excellence
Sanofi

Pierre Cote
Head of Strategic Partnerships & Innovation Management - mRNA Center of Excellence
Sanofi

Nicholas Manzo
Director – CMC RNA Vaccines
Seqirus

Mohammad Safari
Head of Analytical Biochemistry
Seqirus

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PHARMA, BIOTECH & INDUSTRY LEADERS

Dahyana Arias Escayola
Scientist – RNA Biology
Strand Therapeutics

Apiwat Wangweerawong
Associate Director – LNP Chemistry
Tessera Therapeutics

Jasdave Chahal
Founder & Chief Scientist
Tiba Biotech

Mustafa Turkoz
Head of Immunology
Turn Biotechnologies

Jan Komrska
Contracts Manager – Supply Division
UNICEF

Peter Marks
Director – Center for Biologics Evaluation & Research (CBER)
U.S. Food & Drug Administration (FDA)

Diane McCarthy
Senior Scientific Director - Global Biologics
US Pharmacopeia

Tao Niu
Associate Director – Clinical & Quantitative Pharmacology
Vertex Pharmaceuticals

ACADEMIC LEADERS

Philip John Santangelo
Assistant Professor
Emory University School of Medicine

Toni Celià-Terrassa
Principal Investigator
Hospital del Mar Medical Research Institute (IMIM)

Prashant Yadav
Professor & Senior Fellow
INSEAD & Centre for Global Development

Hirohide Saito
Professor
Kyoto University

Simone Spuler
Professor
Max Delbrück Center for Molecular Medicine & Charité – Universitätsmedizin Berlin; Co-founder, MyoPax

Xiaoyuan (Shawn) Chen
Professor
National University of Singapore

Gal Cafri
Immunotherapy & Genetic Engineering Group Leader
Sheba Medical Center

Becki Yi Kuang
Assistant Professor
The Hong Kong University of Science & Technology

Anna Blakney
Assistant Professor
The University of British Columbia

Chantal Pichon
Professor
University of Orleans

Bowen Li
Assistant Professor
University of Toronto

Heinrich Haas
Johannes Gutenberg-Universität Mainz

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LEADING SOLUTION PARTNERS

Venkata Indurthi
CSO
Aldevron

Diana Marcantonio
Director - Biology
Applied BioMath

May Guo
VP – Nucleic Acids
Arranta Bio

Ioana Panait
Lead Analyst – RNA
Beacon Targeted Therapies

Scott Alderucci
Director - mRNA Process Development & GMP
Curia Global

David Sokolowski
Global Workflow Manager - Nucleic Acid Therapeutics
Cytiva

Marco Blanchette
VP - R&D
Eclipse Bioinnovations

Jiancun (Larry) Zhang
CEO
Henovcom

Senthil Ramaswamy
Executive Director – R&D; CGT
Lonza

Sudhakar Voruganti
Business Development Director
Pfanstiehl

Aaron Larsen
Senior Director & Technical Head - Nucleic Acid Franchise
Resilience

Pierre Catignol
EVP & Head of Manufacturing
Samsung Biologics

Aleš Štrancar
Executive Managing Director
Sartorius BIA Separations

Zhichang Yang
Senior Scientist
Sciex

Darwin Asa
Global Market Development Manager - Nucleic Acid Therapeutics
Thermo Fisher Scientific

Aditi Mehta
Associate Director; Head of mRNA Process & Delivery
MilliporeSigma

Joshua Bell
Senior Director - Enterprise Strategy
Tempus

Cory Smith
Senior Product Manager - Nucleic Acid Services
TriLink BioTechnologies

> "The exchange of thoughts and ideas in the rapidly developing mRNA medicine space is elemental to the field and is made possible by the meeting"
>
> **Carsten Rudolph**, CEO, **Ethris**

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AGENDA AT A GLANCE

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3rd Annual mRNA-Based Therapeutics Summit

Pre-Conference Day
Wednesday, July 26

NEW FOR 2023

Pre-Conference Focus Day: Next Generation mRNA-Mediated Technologies	Pre-Conference Workshop Day
Focus Day	Workshop A

Morning Break & Networking

Focus Day	Workshop B

Lunch Break & Networking

Focus Day	Workshop C

End of Pre-Conference Day

Day One | Thursday, July 27

Opening Plenary: Emergence of mRNA-Based Therapeutics & Vaccines — NEW DATA

Biopharma Leaders' Fireside Chat

Morning Break & Speed Networking

Discovery	Translation	Clinical Development (NEW TRACK)	Chemistry, Manufacturing & Controls	Logistics (NEW TRACK)

Lunch Break & Networking

Discovery	Translation	Clinical Development	Chemistry, Manufacturing & Controls	Logistics

Tech Slam

Afternoon Plenary: Unraveling the Complex mRNA Landscape: Exploring Opportunities for Future Collaborations

End of Day One

Day Two | Friday, July 28

Morning Plenary: Driving the Vision of the mRNA Regulatory Environment for First-in-Class Therapeutics & Best-in-Class Vaccines

Morning Networking Break & Poster Session

Discovery	Translation	Clinical Development (NEW TRACK)	Chemistry, Manufacturing & Controls	Logistics (NEW TRACK)

Lunch Break & Networking

Discovery	Translation	Clinical Development	Chemistry, Manufacturing & Controls	Logistics

Afternoon Break & Networking

Closing Plenary: Harnessing Innovations & Expertise to Grow Your mRNA Company & Progress Therapies to Market

End of 3rd Annual mRNA-Based Therapeutics Summit

3rd Annual
mRNA-Based Therapeutics Summit
Supercharging the Next Wave of Efficacious mRNA Therapeutics & Vaccines

PRE-CONFERENCE FOCUS DAY: NEXT GENERATION mRNA-MEDIATED TECHNOLOGIES

WEDNESDAY, JULY 26

Key Sessions:

- Unlocking Novel mRNA Applications for Gene Editing to Uncover New Disease Targets & Improve Therapeutic Efficacy
- Advancing Next Generation Precise RNA Cell Engineering to Enable Durable Therapeutic Impact
- Modifying mRNA for Synthetic Biology Applications

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PRE-CONFERENCE FOCUS DAY: NEXT GENERATION mRNA-MEDIATED TECHNOLOGIES | WEDNESDAY, JULY 26

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mRNA's exceptional features such as easy manipulation, rapid and transient expression, and adaptive convertibility, coupled with the mRNA industry now entering an explosive age, mean there is a greater need to find real applications and tools to unlock hard-to-treat diseases. The **Next Generation mRNA-Mediated Technologies Focus Day** will delve into the latest avenues where mRNA application is driving the next wave of innovations including gene therapy, cell therapy and synthetic biology!

7.30 **Registration & Morning Coffee**

Mohamed ElSayed
EVP & CTO
RVAC Medicines

8.25 **Chair's Opening Remarks**

Unlocking Novel mRNA Applications for Gene Editing to Uncover New Disease Targets & Improve Therapeutic Efficacy

Bowen Li
Assistant Professor
University of Toronto

8.30 **Combinatorial Design of Lipid Nanoparticles for Pulmonary mRNA Delivery & Genome Editing**

- Discover combinatorial LNP design
- Explore pulmonary mRNA delivery
- Discuss gene editing in the lung

Simone Spuler
Professor
Max Delbrück Center for Molecular Medicine & Charité – Universitätsmedizin Berlin; Co-founder, MyoPax

9.00 **mRNA-Mediated Delivery of CRISPR/Cas9 Tools to Human Muscle Stem Cells in Muscular Dystrophy**

- Monogenic muscular dystrophies
- Highly effective and safe mutation corrections by base editing and by classical Cas9
- First-in-human clinical trial in advanced planning (bASKet-trial)

9.30 **Panel Discussion – Delving into Innovative mRNA Technologies for Gene Editing for Powerful mRNA-Based Treatments**

- Leveraging the developments of mRNA-based gene editing to outline the roadmap for future therapeutic avenues
- Discussing key technologies and their relative advantages and drawbacks for gene delivery

Host: Senthil Ramaswamy
Executive Director – R&D, CGT
Lonza

Manmohan Singh
CTO
Beam Therapeutics

Bowen Li
Assistant Professor
University of Toronto

Gregory Fiore
CEO
Exacis Biotherapeutics

Simone Spuler
Professor
Max Delbrück Center for Molecular Medicine & Charité

10.30 **Morning Break & Networking**

Advancing Next Generation Precise RNA Cell Engineering to Enable Durable Therapeutic Impact

11.30 **Transient Epigenetic Reprogramming Rejuvenates T cells & Improves Functionality**

- Turn Biotechnologies is evaluating their novel mRNA-based Epigenetic Reprogramming of Aging (ERA™) technology and eTurna Delivery Platform to eliminate manufacturing induced differentiation and accelerated exhaustion of CAR-T cell therapies
- ERA-treated T cells have significantly higher proliferation capacity and enhanced T-cell mediated tumor cell killing by enhancing the Tscm phenotype and reducing exhaustion, while preserving cellular identity
- These data demonstrate that ERA treatment can rejuvenate T cells and result in a more effective, safer drug product, potentially translating to superior patient outcomes, reduced costs, and increased patient accessibility

Mustafa Turkoz
Head of Immunology
Turn Biotechnologies

PRE-CONFERENCE FOCUS DAY: NEXT GENERATION mRNA-MEDIATED TECHNOLOGIES | WEDNESDAY, JULY 26

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12.00 RNA Cell Therapy in Autoimmune Diseases & Cancer

Metin Kurtoglu
COO
Cartesian Therapeutics

- RNA cell therapy harnesses the best traits of conventional RNA and DNA-based cell therapy while eliminating their worst. By engineering primary human cells with RNA, there is no concern of immunogenicity induced by RNA or its carrier. The activity of the engineered gene can be controlled by the RNA's natural half-life conferring a high level of safety over the engineered cell product
- Descartes-08 is a prime example of RNA cell therapy, comprised of autologous RNA-engineered Chimeric Antigen Receptor T-cells (CAR T-cells) that target B-cell maturation antigen on plasma cells, with Phase 1/2a trial (NCT04146051) results revealing no CAR T-cell toxicities such as Cytokine Release Syndrome or neurotoxicity
- Cartesian's proprietary RNA Armory platform can engineer primary human cells with multiple RNAs which will allow targeting a disease with multiple biologic pathways

12.30 Panel Discussion – Next Generation Cell Therapies with mRNA Technology

- Sharing recent successes and failures of mRNA-based cell therapies to indicate future directions
- Taking learnings from vaccine delivery to enhance efficiency and deliverability *in vivo* and *ex vivo*
- Elucidating the role of RNA engineering and transient vs long term effect in producing versatile therapies

Cory Smith
Senior Product Manager - Nucleic Acid Services
TriLink BioTechnologies

Metin Kurtoglu
COO
Cartesian Therapeutics

Mustafa Turkoz
Head of Immunology
Turn Biotechnologies

Daryl Drummond
CSO & Co-Founder
Akagera Medicines

1.00 Lunch Break & Networking

Modifying mRNA for Synthetic Biology Applications

2.00 Roundtable Discussion – Optimizing Targeted Delivery & Cell Specificity

- What does targeted delivery success look like?
- What will we make an mRNA therapeutic powerful?
- How can we target the most challenging organs?

Moderators:

Anna Blakney
Assistant Professor
The University of British Columbia

Jasdave Chahal
Founder & Chief Scientist
Tiba Biotech

Dahyana Arias Escayola
Scientist – RNA Biology
Strand Therapeutics

2.45 Smart mRNA: Designing & Developing the Future of Programmable & Switchable mRNA Tools

- Harnessing genetic circuits in an mRNA therapeutic
- Showcasing the therapeutic potential of mRNA circuits in oncology

Hirohide Saito
Professor
Kyoto University

3.15 Synthetic mRNA Switches & Circuits to Program Cells

- mRNA ON and OFF switch technologies can activate or repress translation of mRNA in specific cell-types
- We also designed microRNA (miRNA) and protein-responsive circRNA switches and circuits
- Synthetic RNA devices provide new insights into RNA engineering and have a potential for RNA synthetic biology and therapies

Mohamed ElSayed
EVP & CTO
RVAC Medicines

3.45 Chair's Closing Remarks

4.00 End of Pre-Conference Focus Day: Next Generation mRNA-Mediated Technologies

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PRE-CONFERENCE WORKSHOP DAY
WEDNESDAY, JULY 26

Workshop A: LNPs & Beyond – A Drug Delivery Masterclass

AstraZeneca | JGU Johannes Gutenberg University Mainz | 20Med Therapeutics | TESSERA

Workshop B: Unleashing the Potential of Circular RNA – Design, Stability & Immunogenicity

laronde | ORBITAL

Workshop C: Delving into an mRNA Analytical Toolbox – From Drug Substance to Drug Product

MERCK | REGENERON | usp | Seqirus A CSL Company

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Registration & Morning Coffee 7.30

Workshop A 8.30 - 10.30

LNPs & Beyond – A Drug Delivery Masterclass

LNPs have demonstrated high efficacy as the vaccine delivery of choice against SARS-CoV-2. The modular nature of LNP formulations and the flexibility of mRNA as a payload provide many pathways to implement these strategies. This drug delivery masterclass will delve into the innovation of LNP formulations and beyond for applications in therapeutics and implications for the success for next-generation biological therapies.

Join this Masterclass to Address the Following Questions:

- What will the next generation of LNP drug delivery systems look like?
- How can new delivery vehicles and innovative formulations enable efficient and safe targeting?

Workshop Leaders:

Annette Bak
Head of Advanced Drug Delivery
AstraZeneca

Heinrich Haas
Johannes Gutenberg-Universität Mainz

Michiel Lodder
CEO
20Med Therapeutics

Apiwat Wangweerawong
Associate Director – LNP Chemistry
Tessera Therapeutics

Morning Break & Networking 10.30

Workshop B 11.00 - 1.00

Unleashing the Potential of Circular RNA – Design, Stability & Immunogenicity

mRNA has broad potential for novel medicines, yet, one fundamental limitation to its use is the relatively short half-life in biological systems and eliciting an immunogenic response. Circular RNA is now gaining attention as a novel strategy offering a stable choice, reduced dosing and costs. This workshop will dive into circular RNA chemical and physical properties and applications as a new modality of choice.

Join this Workshop to Answer:

- What is the best way to generate circular RNA with superior quality attributes?
- What is the therapeutic potential of the circular RNA platform for vaccines and beyond?

Workshop Leaders:

Francis Poulin
VP – eRNA Sciences
Laronde

Gilles Besin
CSO
Orbital Therapeutics

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Afternoon Lunch Break & Networking 1.00

Workshop C 2.00 - 4.00

Delving into an mRNA Analytical Toolbox – From Drug Substance to Drug Product

With the mRNA community seeking clinical validation of their candidates, the industry continues to face challenges in overcoming analytical and bioanalytical hurdles from mRNA sequencing to drug product formulation and manufacturing. This workshop will dive deep into the importance of analytics and how to overcome these challenges creating an all-encompassing toolbox, and sparking conversation to develop safe, stable and effective mRNA therapeutics

Join this session to discuss:

- How best to develop CQAs for your mRNA platform of choice
- How can we better use analytics to assess drug substance and product attributes?
- How to trouble shoot and improve analytical value beyond typical manufacturing supports

Workshop Leaders:

Yu He
Director – Analytical Research & Development
Merck & Co

Mohammad Safari
Head of Analytical Biochemistry
Seqirus

Diane McCarthy
Senior Scientific Director - Global Biologics
US Pharmacopeia

Yue Fu
Principal Scientist
Regeneron Pharmaceuticals

End of Pre-Conference Workshop Day

> "The mRNA therapeutics field is advancing so rapidly that meetings like these are one of the best opportunities to stay on top of the developments across the industry"
>
> **Bill Grier,** Associate Director – Drug Substance Process Development, **Omega Therapeutics**

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3rd Annual
mRNA-Based Therapeutics Summit

Supercharging the Next Wave of Efficacious mRNA Therapeutics & Vaccines

DAY ONE

THURSDAY, JULY 27

NEW DATA

MORNING & AFTERNOON PLENARY SESSIONS

- Emergence of mRNA-Based Therapeutics & Vaccines 2.0
- Unraveling the Complex mRNA Landscape: Exploring Opportunities for Future Collaborations

DISCOVERY

- Engineering Next-Generation mRNA Sequences to Expand Therapeutic Protein Expression
- Evolving mRNA Drug Substance Design to Optimize Drug Effectiveness

TRANSLATION

- Optimizing *In Vivo* Characterization of Onco-Selective mRNA to Improve Tolerability & Immunogenicity
- Boosting the Development of Lung-Specific mRNA-Based Therapeutics

NEW TRACK

CLINICAL DEVELOPMENT

- Accelerating the Best-in-Class mRNA-Based Vaccines to Combat New Variants of COVID-19
- Harnessing mRNA Technology for Novel Cancer Vaccines to Improve Clinical Success

CHEMISTRY, MANUFACTURING & CONTROLS (CMC)

- Overcoming mRNA Upstream & Downstream Process Development Hurdles for Efficient Manufacturing
- Next Generation Strategies for Analytical Considerations for mRNA Drug Product Development

NEW TRACK

LOGISTICS

- Advancing Supply Chain Hurdles for Optimal Raw Material Availability & Sourcing
- Improving Cost Effectiveness of mRNA Production & Cold-Chain Storage Requirements for the Ultimate Supply Chain

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DAY ONE | THURSDAY, JULY 27

MORNING PLENARY SESSION

7.00 **Registration & Morning Coffee**

Gregory Fiore
CEO
Exacis Biotherapeutics

8.05 **Chair's Opening Remarks**

Emergence of mRNA-Based Therapeutics & Vaccines 2.0

8.15 **Biopharma Leaders' Fireside Chat – Evaluating Progress of mRNA Therapies in 2023: Where are we Succeeding & Where are the Gaps?**

- Pose your burning questions to industry pioneers as they discuss the new frontiers in mRNA technology, the hottest indications at the forefront of scientific research, for the next wave of mRNA
- What does the future look like for the next generation of mRNA-based therapeutics for clinically relevant targets?
- Where do we expect new innovations to come from, and what challenges lie ahead?

Moderator:
Metin Kurtoglu
COO
Cartesian Therapeutics

Jason Zhang
CSO
RVAC Medicines

Carsten Rudolph
CEO
Ethris

Helen McCarthy
CEO
pHion Therapeutics

Frank DeRosa
CTO & Global Head of Research - mRNA Center of Excellence
Sanofi

Gilles Besin
CSO
Orbital Therapeutics

Sonia Stoszek
Executive Director & Program Lead – RSV Vaccines
Moderna

9.00 **Moderna's mRNA-1345 Vaccine in Older Adults**

- Session Details TBC

Michael Wenger
VP - Clinical Development
BioNTech SE

9.30 **BioNTech's Update on mRNA-Based Vaccines & Other mRNA-Based Therapeutics in Clinical Development**

- Showcasing two very different mRNA-based vaccines in clinical development
- Leveraging several mRNA-based therapeutics that complement vaccines
- Understand how combinations are key

Aaron Larsen
Senior Director & Technical Head - Nucleic Acid Franchise
Resilience

10.00 **Assessing the Industry's Landscape & Preparing for the Future**

- Evaluate the current challenges the industry faces
- Consider the roadblocks we foresee in the future
- Discuss methods to overcome these challenges and what to watch for

10.30 **Morning Break & Speed Networking**

DAY ONE | THURSDAY, JULY 27

July 26-28, 2023
Boston, MA

3rd Annual mRNA-Based Therapeutics Summit

DISCOVERY | TRANSLATION | CLINICAL DEVELOPMENT | CMC | LOGISTICS

MORNING SESSION

Chair Moderator: AJ Bergmann, CFO, **Capricor Therapeutics**

Engineering Next-Generation mRNA Sequences to Expand Therapeutic Protein Expression

11.30 mRNA Sequence Optimization Effect on Protein Expression

- Applying sequence optimization for higher mRNA quality
- Utilizing modified nucleotides
- Optimization for better protein expression

Daniella Ishimaru, Principal Scientist, **ReCode Therapeutics**

12.00 A Comprehensive Approach to the Analysis of mRNA-Based Therapeutics to Assess Structure & Purity

- Quantify plasmid topological forms to ensure starting material quality
- Determine mRNA purity and sequence length with a reliable size estimation
- Reliably identify the different mRNA capping structures as well as distinguish between uncapped and capped structures
- Determine drug efficacy and safety by identifying oxidative impurities in lipid nano particle formulations

Zhichang Yang, Senior Scientist, **Sciex**

12.30 Longevity, the ADvantage Approach

- Session Details TBC

Walter Schmidt, Director – mRNA Division, **ADvantage Therapeutics**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: AJ Bergmann, CFO, **Capricor Therapeutics**

Evolving mRNA Drug Substance Design to Optimize Drug Effectiveness

2.00 Optimizing mRNA Synthesis to Enhance Effectiveness of mRNA Drugs & Vaccines

- Improving tail sequence optimization
- Elevating and prolonging protein production
- Slowing mRNA degradation

Becki Yi Kuang, Assistant Professor, **The Hong Kong University of Science & Technology**

2.30 Development of Novel mRNA Capping Agents Through Nucleoside Modifications

- Innovative and highly efficient trinucleotide capping agents were designed, synthesized and subsequently evaluated transcriptionally and translationally
- Various chemical modifications are performed on the trinucleotide-based capping agent to increase mRNA co-transcription yield, mRNA protein expression efficiency in cells and to reduce innate immunogenicity
- The 3'-N-acetylmethyl modified ribose of a trinucleotide capping agent demonstrated high transcription yield, high (>97%) mRNA capping efficiency, and mRNA with this novel capping agent showed up to 4 times higher protein expression efficiency in head-to-head comparisons with mRNAs with the current marketed trinucleotide capping agent. The novel cap structure also displayed low cytotoxicity and low innate immunogenicity profiles

Jiancun (Larry) Zhang, CEO, **Henovcom**

3.00 Machine Learning Guided mRNA Design for Vaccine Development

- Understand the importance of mRNA codon optimization – learnings from biology
- Deployment and application of multiple algorithms for codon optimization
- Active-learning based modelling for design of experiments guided by our ML

Vikram Agarwal, Head of mRNA Platform Design Data Science - mRNA Center of Excellence, **Sanofi**

3.30 Tech Slam

eTheRNA engineering RNA

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DISCOVERY | **TRANSLATION** | CLINICAL DEVELOPMENT | CMC | LOGISTICS

MORNING SESSION

Chair Moderator: Gregory Fiore, CEO, **Exacis Biotherapeutics**

Optimizing *In Vivo* Characterization of Onco-Selective mRNA to Improve Tolerability & Immunogenicity

11.30 Onco-selective mRNA LNPs Enable a Wide Therapeutic Window in Preclinical Tumor Models

- Hear how mKR-335 mRNA LNPs show high potency even at very low doses in syngeneic tumor models
- mKR-335 mRNA LNPs show high systemic tolerability even at high doses
- Onco-selective mRNA LNPs are a novel, promising modality for immuno-oncology applications


Manfred Kraus, VP – R&D, **Kernal Bio**

12.00 Multimodal Real-World Data for Accelerating Translational Research & De-Risking Drug Development: RNA Seq in Precision Oncology

- Harmonized multimodal data sources can help researchers uncover actionable biomarkers and signatures of response or resistance
- Whole transcriptome RNA sequencing unlocks a range of insights beyond the reach of traditional DNA-based methods, facilitating novel fusion detection, alternative splicing events, disease subtyping, and prognostic/ predictive signatures
- Leveraging RNA sequencing data at scale to accelerate development and improve the probability of success of the next class of precision medicines


Joshua Bell, Senior Director - Enterprise Strategy, **Tempus**

12.30 LCOR mRNA Therapy for Breast Immuno-Oncology

- Showcasing LCOR mRNA therapy delivery
- Unravelling its application as a specific therapy for antigen presentation stimulation and tumor immunogenicity
- Evaluate the radical benefit in combination with immunotherapy in preclinical models


Toni Celià-Terrassa, Principal Investigator, **Hospital del Mar Medical Research Institute (IMIM)**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Gregory Fiore, CEO, **Exacis Biotherapeutics**

Boosting the Development of Lung-Specific mRNA-Based Therapeutics

2.00 The Therapeutic Potential of mRNA in the Restoration of Endothelial Cell Function

- Exploring Next-generation PTX_LNP formulations for delivering PTXmRNA to various tissues and cell types
- Reviewing PTXcLNP enabling target protein expression in the vascular endothelium of the lung via the intravenous delivery
- Case Study: mRNA therapy to prevent lung oedema in Acute Respiratory Distress Syndrome


Daniel Tondera, Head of Biology, **Pantherna Therapeutics**

2.30 Novel PCR-Based mRNA Drug Substance Manufacturing

- The key factors in mRNA manufacturing and analytics
- Our unique PCR based template generation approach for mRNA synthesis
- Accelerated mRNA development and manufacturing using our approach


Aditi Mehta, Associate Director; Head of mRNA Process & Delivery, **MilliporeSigma**

3.00 mRNA-Based Therapeutics for the Lung

- Screening platforms greatly improve the ability to find delivery platforms for the lung
- Combinatorial chemistry approaches can generate lots of new formulations for screening
- Many therapeutic molecules can be expressed in the lung opening the door to many new therapies


Philip John Santangelo, Assistant Professor, **Emory University School of Medicine**

3.30 Tech Slam

eTheRNA engineering RNA

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MORNING SESSION

Chair Moderator: Jason Zhang, CSO, **RVAC Medicines**

Accelerating the Best-in-Class mRNA-Based Vaccines to Combat New Variants of COVID-19

11.30 COVID-19 mRNA Vaccine Candidate Development at Moderna

- Consistent safety and immunogenicity has been observed with variant-containing bivalent vaccines in both adults and children
- The Omicron BA.4/BA.5 bivalent vaccine showed cross-neutralization of emerging variants of concern
- Booster doses with variant-containing bivalent vaccines protect against infection and severe disease/ hospitalizations, as demonstrated in real-world studies

Anne Aunins, Executive Director & Program Lead - COVID-19 Vaccines, **Moderna**

12.00 Session Reserved for Combined Therapeutics

COMBINED THERAPEUTICS

12.30 PTX-COVID19-B mRNA Vaccine: Phase 2 Immunobridging Study vs. Comirnaty® - Topline Results

- PTX-COVID19-B was generally well-tolerated, with a safety and tolerability profile similar to Comirnaty®
- PTX-COVID19-B demonstrated non-inferiority compared to Comirnaty®, Pfizer's and BioNTech's U.S. FDA-approved mRNA vaccine, with respect to the geometric mean titer (GMT) ratio of neutralizing antibodies observed two weeks after the second of two intramuscular injections
- Based on the positive safety and immunogenicity results from the immunobridging Phase 2 study, Providence plans to initiate a Phase 3 trial in a booster setting

Aleksandra Pastrak, CMO, **Providence Therapeutics**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Jason Zhang, CSO, **RVAC Medicines**

Harnessing mRNA Technology for Novel Cancer Vaccines to Improve Clinical Success

2.00 Neoantigen Immunotherapy for Solid Tumors: Molecular Responses & Clinical Benefit in End-stage Patients

- Neoantigens can be delivered to solid tumor patients on an individualized or "off-the-shelf" immunotherapy product basis
- Phase 1/2 data in advanced disease shows clear evidence of immune response and associated clinical benefit
- Neoantigen immunotherapy is likely to drive even greater benefit in earlier-stage patients – these trials are starting

Matthew Hawryluk, Executive VP & CBO, **Gritstone Bio**

2.30 Insights From the Development of mRNA Vaccine Targeting Tumor Mutations

- Development of a personalized mRNA vaccine
- Sharing clinical data from an mRNA vaccine trial
- Discussing future applications of personalized mRNA vaccines

Gal Cafri, Immunotherapy & Genetic Engineering Group Leader, **Sheba Medical Center**

3.00 Panel Q&A – Ask Speakers Your Burning Questions

Matthew Hawryluk, Executive VP & CBO, **Gritstone Bio**

Gal Cafri, Immunotherapy & Genetic Engineering Group Leader, **Sheba Medical Center**

3.30 Tech Slam

eTheRNA

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MORNING SESSION

Chair Moderator: Amin Khan, Chief Science Advisor, **Afrigen Biologics**

Overcoming mRNA Upstream & Downstream Process Development Hurdles for Efficient Manufacturing

11.30 Harnessing Plasmid DNA Manufacturing to Improve Quality & Impact on mRNA Drug Substance in the *In Vitro* Transcription Reaction

- Linearized plasmid quality is critical for mRNA production through *in vitro* transcription
- Plasmid linearization condition needs to be optimized sequence by sequence
- Optimized *in vitro* transcription can improve mRNA quality

Lusheng Fan, Investigator, **GeneLeap Biotech**

12.00 Overcoming Bottlenecks in mRNA Manufacturing

- Addressing challenges in the mRNA ecosystem: Key considerations for plasmid supply chain issues, IVT difficulties, purification practicalities, encapsulation, cold chain, and more
- Advancing mRNA molecules from the clinic to commercialization amidst rising expectations for mRNA vaccines and therapeutics
- Applying the Power of One to successfully and optimally manufacture mRNA therapeutics

Pierre Catignol, EVP & Head of Manufacturing, **Samsung Biologics**

12.30 Overcoming Scale-Up & Tech Transfer Hurdles in mRNA Manufacturing

- Delving into key considerations when moving from the lab to the suite
- Processing intermediate stability studies
- Implementing process controls

Bill Grier, Associate Director – Drug Substance Process Development, **Omega Therapeutics**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Amin Khan, Chief Science Advisor, **Afrigen Biologics**

Next Generation Strategies for Analytical Considerations for mRNA Drug Product Development

2.00 Analytical Characterization of mRNA-based Therapeutics & Vaccines

- As a still-new technology for therapeutics and vaccines, the critical quality attributes for mRNA need further refinement
- For this, it is important to characterize mRNA as well as possible, and correlate this to its functionality
- Here, a set of assays for the characterization of mRNA will be presented

Andreas Kuhn, SVP – RNA Biochemistry & Manufacturing, **BioNTech SE**

2.30 Key Considerations for mRNA Process Optimization to Accelerate Path to Clinic

- An overview of the role of template DNA and its design
- Assessing key parameters
- Understanding the importance of analytical development

Venkata Indurthi, CSO, **Aldevron**

3.00 Harnessing the Power of Capillary Electrophoresis for the Analytical Characterization of mRNA

- Determining purity utilizing Liquid Chromatography (LC) and Capillary Electrophoresis (CE) based platforms
- Assessing the viability of multiple CE-based instruments for the analytical characterization of mRNA
- Challenges and considerations related to the development of analytical electrophoretic methods

Kathir Muthusamy, Associate Director, **Regeneron Pharmaceuticals**

3.30 Tech Slam

eTheRNA

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MORNING SESSION

Chair Moderator: Petro Terblanche, Managing Director, **Afrigen Biologics**

Advancing Supply Chain Hurdles for Optimal Raw Material Availability & Sourcing

11.30 Opportunities for mRNA Supply Chain

- Progression in formulations and thermostability
- Commercializing the raw material supply chain
- Evaluating process innovations

Gregory Troiano, Head of cGMP Strategic Supply & Operations - mRNA Center of Excellence, **Sanofi**

12.00 Session Reserved for Ziccum

12.15 Round Table Discussion – Revolutionizing Pandemic Response: Harnessing the Power of mRNA Innovations to Achieve 100 days Mission of Vaccines Development

- How can mRNA platform technology be leveraged to further accelerate vaccine development and compress timelines?
- What unique innovations are needed to address current challenges of mRNA technology?
- What kind of global collaborations, ecosystem, partnerships are needed to achieve the 100-day mission of vaccine development?

Arun Kumar, Preclinical Vaccines Development Lead, **CEPI**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Petro Terblanche, Managing Director, **Afrigen Biologics**

Improving Cost Effectiveness of mRNA Production & Cold-Chain Storage Requirements for the Ultimate Supply Chain

2.00 Messenger RNA Bioproduction

- How can we reduce the supply chain for a cost-effective process?
- How can we maintain quality in the bio process?
- What are the main challenges to overcome?

Chantal Pichon, Professor, **University of Orleans**

2.30 Building Ultra-Low Cold chain Capacity in Developing Countries

- Ultra-low storage capacity for mRNA vaccine was inexistent in majority of countries outside global north at the beginning of 2021
- UNICEF procured, delivered and installed over 900 ultralow freezers in over 70 countries during 6 months period (July – Dec 2021) with a capacity to store over 200 million doses of mRNA vaccines
- The effort continued throughout 2022 with training additional capacity building and maintenance training for MoH staff. Our focus is to maintain the capacity and to stay prepared for the next pandemic

Jan Komrska, Contracts Manager – Supply Division, **UNICEF**

3.00 Panel Q&A – Ask Speakers Your Burning Questions

Chantal Pichon, Professor, **University of Orleans**

Jan Komrska, Contracts Manager – Supply Division, **UNICEF**

3.30 Tech Slam

eTheRNA

DAY ONE | THURSDAY, JULY 27

AFTERNOON PLENARY SESSION

Tamar Grossman
VP - Global Head of RNA & Targeted Therapeutics
Johnson & Johnson

Afternoon Chair Moderator

Unraveling the Complex mRNA Landscape: Exploring Opportunities for Future Collaborations

4.00 **Biopharma Partnerships Panel – Exploring the Future of mRNA Investment & Collaborations**

The biopharmaceutical sector is considering mRNA-based drugs as a vital component. This community thrives on strategic alliances, which allow for cross-functional sharing of knowledge, skills, and experience across different disciplines to truly advance mRNA technologies to accelerate drug development to patients faster. This session is your ideal opportunity to ask your burning questions to a leading biopharma panel in pursuit of sharing their business insights on partnerships in this space.

- Exploring the complexities, risk, and decision-making strategies for developing, acquiring, and advancing innovative approaches
- Where are the gaps in using mRNA approaches, that can be filled by the biotechnology sector?
- Developing successful expertise in house vs asset acquisition partnering strategies

Moderator:
AJ Bergmann
CFO
Capricor Therapeutics

Matthew Hawryluk
Executive VP & CBO
Gritstone Bio

Nathaniel Wang
CEO & Co-Founder
Replicate Bioscience

June Kim
CMC Lead
CEPI

Pierre Cote
Head of Strategic Partnerships & Innovation Management - mRNA Center of Excellence
Sanofi

Tamar Grossman
VP - Global Head of RNA & Targeted Therapeutics
Johnson & Johnson

John Androsavich
Global Head, RNA Medicine Lead - Emerging Science & Innovation
Pfizer

David Sokolowski
Global Workflow Manager - Nucleic Acid Therapeutics
Cytiva

4.45 **When Molecules Grow Up: Adaptations & Considerations for Your Manufacturing Strategies**

- mRNA technology has changed the way therapies are developed. The overall potential of mRNA is clear, with mRNA therapeutic development in many research areas. Investing in innovation brings uncertainties - much of the current equipment used in manufacturing is repurposed from the biotech industry, and designed for much larger scales than is required for mRNA
- Considering manufacturability and scale-up from the beginning will help to deliver process efficiency and scalability along the spectrum of mRNA products
- Consider strategies to future proof your mRNA manufacturing, from vaccines to therapeutics and beyond

Ioana Panait
Lead Analyst – RNA
Beacon

5.15 **A Look at the Past, Present & Future of mRNA Therapeutics**

- Reviewing the progress of the RNA Landscape
- Sharing an analysis of the current mRNA therapeutic and clinical space
- Discussing the future of mRNA therapies

Tamar Grossman
VP - Global Head of RNA & Targeted Therapeutics
Johnson & Johnson

5.45 **Chair's Closing Remarks**

5.50 **End of Day One**

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Supercharging the Next Wave of Efficacious mRNA Therapeutics & Vaccines

DAY TWO
FRIDAY, JULY 28

MORNING & AFTERNOON PLENARY SESSIONS
- Driving the Vision of the mRNA Regulatory Environment for First-in-Class Therapeutics & Best-in-Class Vaccines
- Harnessing Innovations & Expertise to Grow Your mRNA Company & Progress Therapies to Market

DISCOVERY
- Unravelling Novel LNP Screening & Formulation for Delivery of mRNA-Based Therapeutics 2.0
- Unleashing Novel Delivery Vehicles Beyond LNP's to Enable Tissue Selectively & Specificity

TRANSLATION
- Harnessing the Best *In Vitro* & *In Vivo* Models for Improved Safety & Efficacy Studies for Vaccine Success
- Translating Preclinical to Clinical Success for Protein Replacement mRNA-Based Therapeutics

NEW TRACK

CLINICAL DEVELOPMENT
- Advancing Strategies for Preclinical to Clinical Development Success in mRNA-Based Therapeutics for Rare Diseases
- Clinical Development of the Next Wave of mRNA-Based Vaccines To Tackle Global Infectious Diseases & Future Pandemics

CHEMISTRY, MANUFACTURING & CONTROLS (CMC)
- Translational & Scalable Manufacturing of mRNA-Based Vaccines & Therapeutics Through to Commercialization
- Overcoming CMC Challenges to Accelerate Production & Development of mRNA Drugs at Scale

NEW TRACK

LOGISTICS
- Plan, Source, Make & Deliver – Enhancing mRNA Drug Sustainability & Equity on a Global Scale
- Scaling Up Supply – From Bench-to-Bench Side for a Sustainable mRNA Industry

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MORNING PLENARY SESSION

7.30 **Morning Coffee**

Elaine Peters
Director – Analytical – Individualized Cell & Gene Therapies
Genentech

8.20 **Chair's Opening Remarks**

Driving the Vision of the mRNA Regulatory Environment for First-in-Class Therapeutics & Best-in-Class Vaccines

Peter Marks
Director – Center for Biologics Evaluation & Research (CBER)
U.S. Food & Drug Administration (FDA)

8.30 **Regulation of the Next Generation of mRNA Vaccines Targeting Infectious Diseases**

9.00 **Panel Discussion: An Industry Perspective into the mRNA Regulatory Landscape for Next Generation mRNA Vaccines & Therapeutics**

- Overview of the regulatory environment and regulatory strategy for mRNA vaccines
- The differences in regulatory requirements for the various mRNA products – Vaccines vs therapeutic drugs

Moderator:
Antonella Lozito
Executive Director - Infectious Disease, Global Regulatory Strategy
Moderna

Peter Marks
Director – Center for Biologics Evaluation & Research (CBER)
U.S. Food & Drug Administration (FDA)

Marco Cavaleri
Head of Office, Health Threats & Vaccines Strategy
European Medicines Agency (EMA) (Virtual)

Constanze Blume
SVP - Global Regulatory Affairs
BioNTech SE

Pawel Widomski
Senior Director - Global Regulatory Affairs CMC
BioNTech SE

Kathleen Francissen
Global Head of Regulatory PT Cell & Gene Therapies
Roche

Darwin Asa
Global Market Development Manager - Nucleic Acid Therapeutics
Thermo Fisher Scientific

9.45 **Is "GMP Grade" Good Enough? Choosing Materials for Producing mRNA Therapeutics**

- Session Details TBC

10.15 **Late Breaking Abstracts**
3 posters will be selected to take part in 5-minute rapid fire presentations to showcase their late breaking abstracts in front of the mRNA community

Aleš Štrancar
Executive Managing Director
Sartorius BIA Separation

10.30 **Speeding mRNA Process Development & Securing Robust Manufacturing by Using Fast in-Process Analytics**

- Overview of chromatographic toolbox for in-process analytics of mRNA process development and manufacturing
- Enabling continuous IVT by using PATfix analytics
- New analytical tools for characterization and optimization of mRNA LNP formation

11.00 **Morning Break & Networking Poster Session**
As the landscape of innovation is supercharging the next wave of efficacious mRNA vaccines and therapeutics, it is more important than ever to collaborate and learn to facilitate the growth of this field. Join our dedicated poster session to share your latest data and have first look into your peers' work!

DAY TWO | FRIDAY, JULY 28

DISCOVERY | TRANSLATION | CLINICAL DEVELOPMENT | CMC | LOGISTICS

MORNING SESSION

Chair Moderator: Manmohan Singh, CTO, **Beam Therapeutics**

Unraveling Novel LNP Screening & Formulation for Delivery of mRNA-Based Therapeutics 2.0

11.30 Optimizing LNP Libraries & High-Throughput *In Vivo* Screens to Unravel Novel LNPs for mRNA Delivery

- Using Oligo-tagged LNPs to discover novel LNPs
- Harnessing scRNA sequencing of transcriptome and LNP delivery
- Understanding how these are used to discover LNPs that target hard-to-characterize cell types

Curtis Dobrowolski, Co-Founder, **Nava Therapeutics**

12.00 RNA Genomic Technologies: Accelerating RNA Therapeutics

- Advancements in SHAPE-MaP technologies: eSHAPE platform, for structure analysis of IVT RNA and transcriptome-wide data
- Highlighting alternative approaches to ribosomal profiling: eRibo platform, high throughput methods for profiling protein translation
- Providing a comprehensive target interrogation: A cross system approach to allow multidimensional view of transcripts

Marco Blanchette, VP - R&D, **Eclipse Bioinnovations**

12.30 Drug Delivery for Non-Viral Gene Therapies

- Design, make, test and analyze automated selection of nano-particle systems for RNA delivery
- Sharing a lipid nanoparticle case study
- Discussing a polymeric nano-particle case study

Annette Bak, Head of Advanced Drug Delivery, **AstraZeneca**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Manmohan Singh, CTO, **Beam Therapeutics**

Unleashing Novel Delivery Vehicles Beyond LNPs to Enable Tissue Selectively & Specificity

2.00 Delivery of a Therapeutic mRNA Vaccine for HPV Using a Peptide

- Developing mRNA vaccines utilizing RALA, a 30-mer cationic amphipathic helical peptide, for HPV-16 driven cervical cancer and squamous cell head and neck carcinomas
- Using a blend of three mRNA, the pre-clinical development plan examines the mode of action, appropriate modification of the mRNA, the immune and therapeutic responses. The chemistry and manufacturing plan determined the key quality attributes of the product, scale-up of the vaccine and a route to manufacture
- Presenting the first toxicology results of this RALA/mRNA vaccine

Helen McCarthy, CEO, **pHion Therapeutics**

2.30 Session Reserved for Mercury Bio

3.00 Polymer-Based Cancer mRNA Delivery

- Leveraging the key to design mRNA delivery vehicles
- Evaluating the pros and cons of polymer over lipid nanoparticles in mRNA delivery
- Applying mRNA nanoformulas as a cancer nanovaccine and protein replacement therapy

Xiaoyuan (Shawn) Chen, Professor, **National University of Singapore**

3.30 Engineered Exosomes to Deliver Nucleic Acids & Other Molecules for Therapeutic Development

- Harnessing exosomes as a drug delivery system
- Unlocking therapeutic development and clinical applications of exosome-based products
- Evaluating methods for loading nucleic acids into exosomes

Linda Marban, CEO, **Capricor Therapeutics**

4.00 Afternoon Break & Networking

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MORNING SESSION

Chair Moderator: Yusuf Erkul, CEO, **Kernal Bio**

Harnessing the Best *In Vitro* & In *Vivo Models* for Improved Safety & Efficacy Studies for Vaccine Success

11.30 Optimization of Novel Self-Amplifying RNA Vectors

- Historically, saRNA vectors have been derived from VEEV, SFV and Sindbis viruses despite a rich landscape of potential backbones
- Investigating novel saRNA vectors and characterize their replication and protein expression profiles both *in vitro* and *in vivo*
- Exploring the 'sweet spot' for replication, and how different vectors may be more amenable to vaccine or therapeutic applications

Anna Blakney, Assistant Professor, **The University of British Columbia**

12.00 Update in the Development of RSV mRNA Vaccine

- Despite recent successes in RSV vaccine development, there is still a need to develop an efficacious RSV vaccine for the elderly, infants, and maternal immunization
- Hear how RVAC's RSV mRNA vaccine is shown to be efficacious and safe in a preclinical model
- Showcasing current clinical development which is now underway

Vira Bitko, VP & Head of Vaccines, **RVAC Medicines**

12.30 Design & Preclinical Evaluation of a Broad HSV-2 mRNA Vaccine

- HSV-2 mRNA vaccine elicits a robust neutralizing antibody and T-cell response
- The LNP formulation of HSV-2 mRNA vaccine can be delivered *in vivo* at low doses
- This results in broad protection against HSV-2 and HSV-1 infection

Renhuan Xu, CEO & Co-Founder, **ARV Technologies**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Yusuf Erkul, CEO, **Kernal Bio**

Translating Preclinical to Clinical Success for mRNA-Based Therapeutics

2.00 Immuno-Modulation & mRNA-Based Protein Replacement Therapy for Treatment of Pulmonary Disease

- Using mRNA for immuno-modulation of lung tissue to treat infectious diseases
- The role of mRNA in replacement of missing or dysfunctional proteins in lung tissue for
- treatment of genetic lung diseases
- Addressing solutions for LNP stabilization to overcome limitations of thermostability, mechano-stability and aerosol delivery

Carsten Rudolph, CEO, **Ethris**

2.30 Applications of a QSP Model of LNP mRNA delivery for the Treatment of Crigler-Najjar Syndrome Type 1

- Crigler-Najjar syndrome type 1 (CN1) is an autosomal recessive disease caused by a marked decrease in uridine-diphosphate-glucuronosyltransferase (UGT1A1) enzyme activity with limited treatment options
- In this talk, we will discuss the application of quantitative systems pharmacology (QSP)
- modeling to the design and development of an LNP-delivered mRNA gene therapy for the treatment of CN1
- We will cover two case studies, how the "LNP-encapsulated mRNA targeting an intracellular protein in vivo" model in Applied BioMath Assess ™ was used to explore key design features for an LNP-delivered mRNA gene therapy, and how a similar QSP model was developed and calibrated to data from a Gunn rat animal model and used for preclinical-to-clinical translation and FIH dose projections

Diana Marcantonio, Director - Biology, **Applied BioMath**

3.00 Delivery of Tropoelastin mRNA for the Regeneration of Elastic Tissues

- An overview of elastin and pathogenesis
- Application of synthetic mRNA delivery for protein replacement therapies
- Sharing the results of synthetic TE mRNA delivery for regeneration of elastic tissues

Sonia Golombek, Senior R&D Manager, **Elastrin Therapeutics**

3.30 Telomerase mRNA as a Therapy for Interstitial Lung Disease

- Telomerase mRNA can reverse a decade of telomere shortening with a single dose
- Short telomeres underlie the etiology of interstitial lung disease
- Telomerase mRNA is safe and effective in preclinical animal models

John Ramunas, CEO, **Rejuvenation Technologies**

4.00 Afternoon Break & Networking

DAY TWO | FRIDAY, JULY 28

July 26-28, 2023
Boston, MA

3rd Annual mRNA-Based Therapeutics Summit

DISCOVERY | TRANSLATION | CLINICAL DEVELOPMENT | CMC | LOGISTICS

MORNING SESSION

Chair Moderator: Michael Wenger, VP - Clinical Development, **BioNTech SE**

Advancing Strategies for Preclinical to Clinical Development Success in mRNA-Based Therapeutics for Rare Diseases

11.30 Discovery to Clinic: mRNA as a Potential Treatment for Rare Disease

- Evaluating the construct selection process
- Assessing delivery options
- Setting the clinical dose

Mike Zimmer, Director - Rare Diseases; Rare Research & Preclinical Development, **Moderna**

12.00 Clinical Immunogenicity of LNP-Encapsulated RNA Therapeutics & Impact on Drug Development

- Summarizing the clinical immunogenicity of approved and investigational LNP-encapsulated RNA therapeutics
- Outlining the impact of clinical immunogenicity on the development strategy
- Delving into regulatory considerations related to immunogenicity assessment

Tao Niu, Associate Director – Clinical & Quantitative Pharmacology, **Vertex Pharmaceuticals**

12.30 Preclinical Study Considerations for mRNA-Based Therapeutics to Initiate Successful Clinical Studies

- Areas to focus in preclinical studies that will enable better translation to clinical outcome
- Evaluating the safety parameters that allow making an informed decisions for the clinical design
- Sharing good practices to include in preclinical assessments

Arunan Kaliyaperumal, VP – Preclinical Biology, **ReCode Therapeutics**

1.00 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Michael Wenger, VP - Clinical Development, **BioNTech SE**

Clinical Development of the Next Wave of mRNA-Based Vaccines To Tackle Global Infectious Diseases & Future Pandemics

2.00 Moving Towards a "Best-in-Class" Platform for mRNA-Based Vaccines & Beyond

- Showcasing key platform features for vaccines and beyond
- Presenting translational models used by Sanofi, and preclinical data supporting the current Sanofi platform
- Reviewing clinical data supporting the current Sanofi platform

Joshua DiNapoli, Global Project Head - mRNA Platform Development, **Sanofi Pasteur**

2.30 Session Reserved for Precision NanoSystems

PRECISION NANOSYSTEMS

3.00 Next Generation Self-Replicating RNA Enable Next Wave of Complex Infectious Disease Vaccines

- Next generation srRNA vectors provide enhanced durability for antibody responses and superior T cells
- srRNA enable very low doses in conventional two dose regimens as well as single dose regimens
- Low doses lead to correspondingly lower levels of molecules associated with reactogenicity

Nathaniel Wang, CEO & Co-Founder, **Replicate Bioscience**

3.30 Developing Next Generation mRNA Vaccines using Ligand-Directed Targeting to Immune Cells

- Presenting a novel approach to engineering a COVID-19 vaccine with both T-cell and antibody mRNA components
- Use of small molecule ligands as cost-effective and highly efficient targeting moieties for lipid nanoparticles (LNPs)
- Inclusion of novel ionizable cationic lipids with reduced propensity for oxidative degradation

Daryl Drummond, CSO & Co-Founder, **Akagera Medicines**

4.00 Afternoon Break & Networking

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MORNING SESSION

Chair Moderator: Jianmei Kochling, Senior Director – Analytical Development - mRNA Center of Excellence, **Sanofi**

Translational & Scalable Manufacturing of mRNA-Based Vaccines & Therapeutics Through to Commercialization

11.30 Overcoming the Evolving Challenges in mRNA

- Process Advancements - IVT and capping reactions are not universal and must be finely tuned to each molecule based on composition, structure and size. Using the literature and experimental design, tailoring each reaction to fit the molecule
- Analytical Approaches - Baseline testing methods are not always well defined by industry or rregulatory boards, therefore creative approaches and different angles must be taken to address the importance of getting accurate data back for measuring contaminants, as well as defining your product most comprehensively
- Success Stories - Details of process changes that lead to positive results for these defined molecules including the platform approaches taken to meet each program need in a timely manner

Scott Alderucci, Director - mRNA Process Development & GMP, **Curia Global**

12.00 mRNA Therapeutics for Small Patient Populations: Overcoming Analytical & Process Development Scale-Up Challenges

- mRNA therapeutics use highly versatile technology. Changes in the RNA sequence are relatively simple to implement resulting in a versatile platform manufacturing process that can target a variety of sequences and conditions, including both small patient populations and individualized/personalized treatments
- A different approach is needed to scale up analytical and process development for clinical development and potential commercialization of these types of therapeutics
- Control system designs to overcome these challenges will be presented

Elaine Peters, Director – Analytical – Individualized Cell & Gene Therapies, **Genentech**

12.30 Trehalose & Sucrose: Essential Components of Platform Biopharma Formulations & COVID-19 applications

- An introduction to Pfanstiehl and its high quality/purity GMP components
- Analyzing essential components of a "Platform Biopharma Formulation"
- Understanding important physicochemical properties of Trehalose and Sucrose. Purity, quality, and consistency of Pfanstiehl's trehalose and sucrose
- Pfanstiehl's Biopharma Stabilization Portfolio including newly launched amino acids

Sudhakar Voruganti, Business Development Director, **Pfanstiehl**

12.45 Lunch Break & Networking

AFTERNOON SESSION

Chair Moderator: Jianmei Kochling, Senior Director – Analytical Development - mRNA Center of Excellence, **Sanofi**

Overcoming CMC Challenges to Accelerate Production & Development of mRNA Drugs at Scale

2.00 Building a Self-Amplifying mRNA Vaccine Platform for Influenza

- Harnessing opportunities of sa-mRNA against Influenza
- CMC considerations in sa-mRNA development to Influenza
- Evaluating challenges and opportunities of sa-mRNA beyond Influenza

Nicholas Manzo, Director – CMC RNA Vaccines, **Seqirus**

2.30 Overcoming mRNA Process Optimization & Scalability: Challenges for mRNA Therapeutic Development

- Process optimization and scalability of mRNA products can prove challenging.
- Discussing some of these challenges and solutions through the evaluation of factors and responses during development, scale-up, and *in-vivo* testing
- Through process optimization we can positively influence different quality attributes of an mRNA drug substance

Trilink Biotechnologies

3.00 Round Table Discussion - mRNA Platform Requirements & Development of a Scalable Production Process to Support Early Phase Clinical Trials & Advance a Commercialized Process

- How can we effectively scale mRNA-based vaccines from bench to bedside?
- How can we leverage the same or similar manufacturing process and methods for different mRNA sequences?
- What does scale mean for therapeutics and what size matters most?
- How to apply considerations for manufacture of personalized mRNA-based vaccines and therapeutics

Moderated By: Nicholas Manzo, Director – CMC RNA Vaccines, **Seqirus**

4.00 Afternoon Break & Networking

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MORNING SESSION

Plan, Source, Make & Deliver – Enhancing mRNA Drug Sustainability & Equity on a Global Scale

11.30 Improving mRNA Sustainability with Efficient & Equitable Manufacturing & Supply

- Innovation – Exploring innovative design of mRNA construct, critical reagents and novel processes to improve speed, cost and stability
- Speed - CEPI's 100 days aspiration and strategy for emergency response
- Beyond Covid – disease X and exemplary vaccines against priority pathogens

June Kim, CMC Lead, **CEPI**

12.00 mRNA Hub Technology Transfer Program: A Cost-Effective Platform for mRNA Vaccine Innovation in LMICs

- Unlocking mRNA vaccine design, development and production geared to enable LMICs to produce mRNA products
- Establishing a "green fields" mRNA end to end commercial production process
- Product innovations for effective, affordable and accessible mRNA vaccines for neglected diseases suitable for LMICs and relevance to pandemic preparedness

Petro Terblanche, Managing Director, **Afrigen Biologics**

Amin Khan, Chief Science Advisor, **Afrigen Biologics**

12.30 Challenges & Strategic Approaches in the Development of mRNA Vaccines for LMICs

- Discuss key challenges related to scale up of processes, implementation of novel analytical methods, availability of raw materials and cost
- Approaches to leverage and support cost effective new technologies and transfer to LMICs for development and regulatory approval of safe and efficacious mRNA-based therapeutics and vaccines.
- Planning for readiness to obtain WHO Pre-Qualification in a timely manner to ensure global delivery of vaccines

Lakshmi Khandke, Senior Program Advisor, **PATH**

12.45 Lunch Break & Networking

AFTERNOON SESSION

Scaling Up Supply – From Bench-to-Bench Side for a Sustainable mRNA Industry

2.00 Scaling Up Supply from Laboratory to Facility with Equipment, Tech Transfer & Consumables to Match Global Supply & Demand

- Creating GMP suppliers early in the development cycle
- Integrating multiple processes within the organization vs managing multiple vendors-pros and cons of cost vs complexity
- Collaborating to compete-Figuring out which parts to leverage industry networks, and which parts to focus for your company
- Planning supply networks to address global demand vs only high-income country demand.

Prashant Yadav, Professor & Senior Fellow, **INSEAD & Centre for Global Development**

2.30 Round Table Discussion – Streamlining Best Practices for mRNA- Based Therapeutics Across the Supply Chain

- How can we accelerate supply chain platforms using innovative technologies, and what are the applications for commercial opportunities?
- How to define a supply chain roadmap and work collaboratively?
- What role do key stakeholders play?

Moderated By: Prashant Yadav, Professor & Senior Fellow, **INSEAD & Centre for Global Development**

3.30 Afternoon Break & Networking

> "The 3rd mRNA-Based Therapeutics Summit creates a unique opportunity for socializing and exchanging of knowledge among the experts in the mRNA field"
>
> **Mohammad Safari**, Head of Analytical Biochemistry, **Seqirus**

DAY TWO | FRIDAY, JULY 28

AFTERNOON PLENARY SESSION

Yusuf Erkul
CEO
Kernal Bio

Afternoon Chair Moderator

Harnessing Innovations & Expertise to Grow Your mRNA Company & Progress Therapies to Market

May Guo
VP – Nucleic Acids
Arranta Bio

4.30 Moving mRNA from the Research Lab to Commercial Manufacturing

- Considerations for mRNA design and manufacturing
- Scaling up mRNA synthesis from tubes-in-water-bath to bioreactors
- Optimizing IVT to reduce dsRNA and improve potency

Daniel Shores
Partner
Rothwell Figg

5.00 The IP Landscape in the mRNA Space: Winning with Knowledge, Strategy & Innovation

- Providing an overview of the IP landscape in the mRNA space
- Sharing key strategies to operate, collaborate and win
- Evaluating innovation approaches and trends

Yusuf Erkul
CEO
Kernal Bio

5.30 Chair's Closing Remarks

5.40 End of 3rd Annual mRNA-Based Therapeutics Summit

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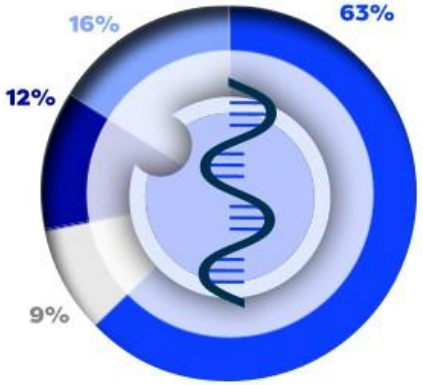
Attendees by Seniority*

- C-Level/ President/ VP: 20%
- Director/ Head: 31%
- Team Leader/Manager/ Scientist: 29%
- Other: 20%

Attendees by Company Type*



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EXPAND your understanding of the current challenges, strategies and solutions to translate from proof-of-concept to the clinic, manufacturing and scale-up of next generation mRNA therapeutics

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Venues

Pre-Conference Day – July 26, 2023
Boston Convention and Exhibition Center - 415 Summer Street, Boston, MA 02210, United States
www.signatureboston.com/bcec/floor-plans-and-specs/space-finder

Main Conference Days – July 27-28. 2023
The Westin Boston Seaport District - 425 Summer Street, Boston, MA 02210, United States
https://www.marriott.com/en-us/hotels/bosow-the-westin-boston-seaport-district/overview/?scid=f2ae0541-1279-4f24-b197-a979c79310b0

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