Robert W. Malone, MD, MS
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PROFESSIONAL EXPERIENCE

The original inventor of mRNA and DNA vaccination technologies (1989); including in-vitro and in-vivo RNA transfection. Dr. Malone is a specialist in clinical research, medical affairs, regulatory affairs, project management, proposal management (large grants and contracts), vaccines and biodefense. This includes writing, developing, reviewing and managing vaccine, bio-threat and biologics clinical trials and clinical development strategies. He has been involved in developing, designing, and providing oversight of approximately forty phase 1 clinical trials and twenty phase 2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on both phase 1, phase 2 and phase 3 clinical trials, including those run at a well-known vaccine-focused Clinical Contract Research Organizations. He has served as principal investigator on some of these. Examples of his infectious disease pathogen advanced (clinical phase) development oversight experience include HIV, Influenza (seasonal and pandemic), Plague, Anthrax, VEE/EEE/WEE, Tularemia, Tuberculosis, Ebola, Zika, Ricin toxin, Botulinum toxin, and Engineered pathogens. In many cases, this experience has included vaccine product development, manufacturing, regulatory compliance, and testing (manufacturing release and clinical) aspects. In most cases, his oversight responsibilities have included clinical trial design, regulatory and ethical compliance, and laboratory assay strategy, design, testing and performance.

Dr. Malone has a history of assembling and managing expert teams that focus on solving complicated biodefense challenges to meet US Government requirements. He was instrumental in enabling the PHAC/rVSV ZEBOV ("Merck Ebola") vaccine to move forward quickly towards BLA and (now recently granted) licensure. Dr. Malone got the project on track in support of DoD/DTRA and NewLink Genetics, recruited organizations to team with USAMRIID/WRAIR to develop the immunoassays, put WHO and Norwegian government philanthropic leadership in touch with Pentagon leadership to expedite the initial WRAIR clinical and ring vaccination trials, recruited a management team, recruited Merck vaccines to purchase the product candidate from NewLink, helped write and edit the clinical trials developed by the World Health Organization and lead the development of the BARDA and DTRA contracts - yielding over 200M$ in resources. Dr. Malone's early involvement in this project allowed for the Merck vaccine to be developed very rapidly.

Currently, Dr. Malone is leading a large team since January 10, 2020, focused on clinical research design, drug development, computer modeling and mechanisms of action of repurposed drugs for COVID-19 treatment. This work has included multiple manuscripts summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease, and others focused on celecoxib and famotidine are being reviewed for publication. He has developed and wrote the initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults. Another project he has been involved with is a DTRA/DOMANE-funded development and performance of a virtual outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example. He has helped open two IND for famotidine and celecoxib use for treatment and prevention of COVID19 disease including an associated

drug master file, and has enabled teaming/pharmaceutical supply arrangements with two major pharmaceutical firms.

Dr. Malone is an internationally recognized scientist and is the original inventor of mRNA Vaccination, DNA Vaccination, and multiple non-viral DNA and RNA/mRNA delivery technologies. Dr. Malone holds numerous fundamental domestic and foreign patents in the fields of gene delivery, delivery formulations, and vaccines: including DNA and RNA/mRNA vaccines. His expertise includes virology, immunology, molecular biology, pathology and pharmacology.

Scientifically trained at UC Davis, UC San Diego, and at the Salk Institute Molecular Biology and Virology laboratories, Dr. Malone received his medical training at Northwestern University (MD) and Harvard University (Clinical Research Post Graduate Fellowship) medical schools, and in Pathology at UC Davis.

He has extensive research and development experience (bench to bedside) in the areas of pre-clinical discovery research, clinical trials, vaccines, gene therapy, bio-defense, repurposing drugs for infectious diseases, high throughput screening and immunology. He has over twenty years of management and leadership experience in academia, pharmaceutical and biotechnology industries, as well as in governmental and non-governmental organizations. He often serves as study section chairperson for NIAID contract study sections relating to biodefense medical product development. He is currently a topic editor for the journal Frontiers in Pharmacology, in the area of "Treating COVID-19 With Currently Available Drugs."

Dr. Malone has approximately 100 peer-reviewed publications and published abstracts and has about 12,000 citations of his peer reviewed publications and patents, as verified by Google Scholar. His google scholar ranking is "outstanding" for impact factors. He has been an invited speaker at over 50 conferences, has chaired numerous conferences and he has sat on or served as chairperson on numerous NIAID and DoD study sections.

SUMMARY OF ACCOMPLISHMENTS / SKILLS

- Inventor of mRNA and DNA vaccination.
- Inventor of lipid mediated and naked mRNA delivery (transfection).
- Inventor of in-vivo electroporation (particularly for skin delivery).
- A senior executive and scientist with a highly successful track record of leading bench and discovery research through FDA Phase I, II, and III clinical trials, protocol development and submission, and related regulatory submissions including pIND and IND.
- Significant expertise in drug development and delivery.
- Specialist in Medical Affairs.
- Special in Regulatory Affairs.
- Domestically trained, Maryland Licensed Physician/Scientist.
- Experienced capturing and managing large federal contracts (including BARDA) with over 9 billion in ID/IQ awards and almost a billion USD in government contracts won and/or managed in the last decade.
- Expertise in pathology, infectious disease, pandemic clinical trials, influenza, regulatory affairs, project management, biodefense, HIV and Ebola. A verified list of capture is available upon request.
- Significant expertise with federal contracting, grants, international NGO health related research and development coupled with professional relationships at CDC, DoD, HHS (BARDA, CDC, FDA and NIAID).
- Prior and current service on many federal study sections and oversight boards involving infectious disease, vaccine, and biodefense.
- Experienced and formally trained as a Business Development Professional, project manager, capture/proposal manager, color team reviewer and editor for projects valued from 10M$ up to 1B$ US, with experience managing processes and teams in a wide variety of non-profit and for-profit corporate cultures including both matrix and traditional environments.
- Highly skilled in fostering a culture of innovative problem solving within project teams.
- DoD Secret Clearance authorized.
- Expert witness experience, with extensive training from some of the top attorneys/law firms in the USA.
- Rated outstanding for impact factors, by Google scholar.
- Graduated from the Harvard Medical School Global Clinical Scholars Research Training Program with distinction, a year-long program focused on international clinical research. This program combines on-site (London & Boston) as well as distance learning, with an average of 15h per week lecture and practicum exercises.

RW Malone MD, LLC
CEO and Principal Consultant: 2001-Present

Dr. Malone has been involved in developing, designing, and providing oversight of approximately forty phase-1 clinical trials and twenty phase-2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on approximately forty phase-1 clinical trials, and on twenty phase-2 clinical trials, including those run at vaccine-focused Clinical Research Organizations. He has served as principal investigator on some of these. Providing business development, proposal management, clinical trials development, expert witness, regulatory and medical affairs support for pharmaceutical, vaccines-related and biologics companies as well as related regulatory submissions including pIND and IND.

Projects include:

- Led a large team since January 10, 2020, focused on drug development, computer modeling and mechanisms of action for COVID-19 and is now preparing a manuscript summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease.
- Accelerated COVID-19 Therapeutic Interventions and Vaccines:
  ACTIV Therapeutics Clinical Working Group, NIH. Invited Participant. June, 2020-present.
- Clinical trials protocol development: Developed and wrote initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults.
- Proposed is a DOMANE/WRAIR joint development and performance of outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example.
- Opening IND for famotidine use for treatment and prevention of COVID19 disease with associated drug master file.
- Principal Regulatory Consultant, Clinical Network Services (CNS)/Novotech, 2018-2019. Regulatory, clinical and business development support.
- Served as an expert witness with specialized training, 2017 - present.
- Ebola vaccine project for NewLink/Bioprotection Systems (rVSVdG ZEBOV Ebola vaccine project), resulting in well over 100M USD non-dilutive capital to NL/BPS. This also included working with the World Health Organization as well as initial set up of the licensing deal to Merck Vaccines of the Ebola vaccine.
- Served as Medical Director, Beardsworth, half time position on retainer, 2010 – 2013.
- Service on federal biotechnology/vaccines proposal study sections (multiple).
- Served as Editor-In-Chief of Journal of Immune Based Therapies and Vaccines 2007-2012
- Service on Safety Monitoring Committee, Phase 1 safety/immunogenicity of novel Influenza vaccine
- Consulting support for multiple vaccine-focused clinical sites in US and Latin America.
- Served as Medical Director, Vaccines with Accelovance, Inc. (2008 – 2009).
- Served as medical monitor for multiple seasonal and pandemic (H1N1) studies.
- Review and edit clinical protocols.

- Examples of multi-year contract clients include Accelovance, Alchem Laboratories, Avancer, Beardsworth, Chesapeake Perl, Corium, DOAR, ITS, ITT-Exelis, EpiVax, Jean Brown Research, Opgen, Quest Diagnostics (Focus), PaxVax, SAI, Soligenix, TASC, Univ of MA.
- Commercial intelligence work for two of the largest pharmaceutical companies in the world (sub-contractor).
- Partnering with Galloway and Associates (Darrell Galloway) 2012-2014.
- Acting as *Managing Director, Clinical Development and Government Affairs* for the Avancer Group. April 2012 – 2016.
- Proposal development (patch-based vaccine delivery, Tularemia vaccine, CDC contract for clinical trials site development, international government and NGO contract and grant solicitations) – Aeras Global TB Vaccine Foundation 2003-2005.
- Proposal development (plague vaccine- HHS), Technical diligence – VaxGen Corporation.
- Consulting services for EpiVax, 2005-2018 (member, Scientific Advisory Board), 2020.
- Consulting services for Aldevron, LLC.
  2001-2005 (operating as Gene Delivery Alliance).
- Business and proposal development in the areas of Bioinformatics and Life Sciences (including telemedicine) and research at the University of Bern, Switzerland.
- Consulting services for Molecular Histology, Inc. with the title of Medical Director.
- Collaboration with Inovio, including incorporation of company in the USA.
- Consulting services for MSD, Inc. for business/ technology development planning.

Alchem Laboratories
Chief Medical Officer

This position was as a consultant, but then full time FTE. Consulting for Alchem and/or its CEO: 2012 – 2019. CMO 11/2019 to 4/2020.

- Led a high through-put screening and research team for drug development 2019-2020.
- Dr. Malone began modeling and focusing on the Plpro (papain-like protease) and Mpro (main protease) of then novel coronavirus (now SARS-CoV-2) using computational tools including Modeller to generate homology-modeled crystal structures for the SARS-CoV-2 Plpro and Mpro. Which generated a candidate list for COVID-19, which was reduced to a few candidates, based on binding sites, safety, licensure, efficacy, bioavailability of drug candidates.
- Lead the discovery and development of famotidine for the Treatment of COVID-19.
- Technical Lead/writer for funded full proposal under BAA-18-100-SOL-00003 Amendment 15 entitled: "A Multi-site, Randomized, Double-Blind, Multi-Arm Historical Control, Comparative Trial of the Safety and Efficacy of Hydroxychloroquine, and the Combination of Hydroxychloroquine and Famotidine for the Treatment of COVID-19 in Hospitalized Adults."
- Developed and wrote initial clinical trial design for a comparative trial of the safety and efficacy of hydroxychloroquine, and the combination of hydroxychloroquine and famotidine for the treatment of COVID-19 in hospitalized adults.

Atheric Pharmaceutical, LLC
CEO, and Co-founder.

Feb 2016-Dec 2017. Atheric™ Pharmaceutical LLC was a biopharmaceutical company focused on the rapid development and commercialization of re-purposed drugs to prevent and treat Zika and other Flavivirus disease. Optimization of high through-put screening techniques for anti-viral drug development.

Kennesaw State University
Adjunct Associate Professor 2009-2013

Beardsworth Consulting Group, Inc
Medical Director, Vaccines (RW Malone MD, LLC under contract to Beardsworth)
2010-2013
Dr. Malone functioned as the in-house medical vaccine expert for medical monitoring and Scientific Liaison

- Medical liaison to investigator sites including oversight of clinical monitoring
- Provided medical monitoring input including CRF review, 24x7 accessibility to site personnel, assess enrollment waiver requests, SAE review, etc.
- Safety Officer and Medical Representative on project teams
- Medical consultant to clients
- Business development/proposal writing/government contracting

Solvay Pharmaceuticals, Inc (currently Abbvie)
Director, Clinical Development & Medical Affairs, Influenza 2006-2008
Led an extended clinical team (both internal and CRO components), providing project and clinical trials management oversight, serving as primary author on clinical protocols, strategic documents including clinical development plans, DSMB/SMC charters, and all clinical documents required to support IND filing. Support and review of outcomes including safety data assessment
Generated and managed cost projections and budgetary oversight, providing strategic management and serving as a communication hub for clinical aspects of a $300 million USD federal contract to develop and license a cell-based influenza vaccine
Solvay's US Government contract for cell-based influenza vaccine was terminated around the end of 2007. At which point the cell-based influenza vaccine project was dissolved.

Summit Drug Development Services
Senior Medical Director 2005-2006
Directed due diligence assessments and strategic drug development planning and prepared regulatory submissions and implemented, monitored, and analyzed clinical trials for clients (oncology, vaccines, biologicals, cell/stem cell therapies). Primary author of three pIND, two IND, an Appendix M submission. Served as proposal manager and primary author for a 129M USD federal contract submission focused on pandemic influenza.

AERAS Global TB Vaccine Foundation
Director, Business Development and Program Management 2004-2005
Initially serving as consultant, provided leadership primarily focused on tuberculosis vaccine development and proposal development to NGO (B&M Gates), USG (CDC, NIH, DoD).

Dynport Vaccine Company, LLC

Associate Director, Clinical Research 2002-2003

- Served as liaison between product development teams and clinical research support groups.
- Prepared planning documents and product development plans.
- Participated in and supported safety review and assessment of smallpox vaccine product.
- Identified new technologies relevant to product development teams, facilitating integration of same in product development plans.
- Created documents for clinical trials including investigator brochures. Prepared proposal solicitations, technical review of subcontractor proposals. Performed technical review of potential subcontractors, new technologies.
- Assisted business development group in strategic evaluation and planning concerning new business opportunities and managed in-house Publication.

Intradigm, Corp

Co-Founder (one of three co-founders), CSO, Board of Director Member 2000-2001

Intradigm was a biotechnology company that develops gene therapeutic technology based on RNA interference. Intradigm merged with Silence Technologies in 2009 and the merged company is now publicly traded. Silence Technologies is involved in developmental research of targeted RNAi therapeutics for the treatment of serious diseases.

Dr. Malone co-founded and helped to secure $2.3 million in V.C. funding, including monies from the Novartis Venture Fund, ETP Venture Capital Fund and the State of Maryland. Performed facilities set-up, infrastructure set-up and Intellectual Property Development. Business and technology development planning, including in-depth business and scientific plan.

Uniformed Services University of the Health Sciences

Dept of Surgery, Clinical Breast Care Program (CBCP) through the Henry M. Jackson Foundation
Adjunct Associate Professor

Chief of Laboratory Science and Director of Tissue Banking 2000-2001

- Worked closely with architect firm to design space, set-up laboratory facilities for the Clinical Breast Care Project, including new facilities design (tissue banking facilities, laboratory, animal rooms, animal surgical suite, office suites) at USUHS and Windber Medical Center, PA
- Hired faculty, technicians, staff for CBCP at both sites, including writing and initiating job descriptions, job interviews, hiring decisions, set-up for re-locations
- Laboratory Supervisor: Tissue banking immunology, cell culture, gene transfer, genetic vaccination research, animal research.

University of Maryland, Baltimore School of Medicine, Dept. of Pathology

Assistant Professor 1997-2000

Set-up and ran successful research laboratory in immunology (genetic vaccination) and gene transfer.

University of California, Davis Department of Medical Pathology

1991-1997

Assistant Professor 1993-1997

Director and Founder, Gene Therapy Program (pulmonary, dermal, heart, liver, mucosal and parenteral vaccines).

Research Fellow, Pathology Resident 1991-1993

Vical, Inc
Research Scientist 1989

- Set up Vical's molecular biology laboratory.
- Initiated and carried out research in non-viral gene therapy and DNA vaccination.
- Inventor of "naked DNA" gene therapy. (see issued patents for details).
- Inventor of DNA vaccination (see issued patents for details).
- Inventor of "mRNA" gene therapy. Salk institute.
- Inventor of mRNA vaccination. Salk institute.
- Inventor of "mRNA as a drug" or "transient gene therapy", terms both coined by Dr. Malone. Salk Institute.

LICENSURE / CERTIFICATIONS
Physician and Surgeon, State of Maryland License 1997-present. #DOO55466

BOARD OF DIRECTOR POSITIONS:
Discovery Cure, Inc. Founding Board of Director. 2018-2020
Epivax, Scientific Advisory Board, 2012-2019.

EDUCATION

- **HARVARD MEDICAL SCHOOL** *Global Clinical Scholars Research Training Program (fellowship)* A year-long comprehensive program that combines on-site (London, Boston) and distance learning, with an average of 15h per week lecture and practicum exercises. 2015-2016. Graduation with distinction (top 5% of graduating class).

- **UNIVERSITY OF CALIFORNIA, DAVIS:** RESEARCH FELLOWSHIP, 1992 – 1993
  Postgraduate Fellowship Award

- **UNIVERSITY OF CALIFORNIA, DAVIS MEDICAL CENTER**: 1992
  Clinical Pathology Internship

- **NORTHWESTERN UNIVERSITY MEDICAL SCHOOL**: 1991
  Doctor of Medicine

- **UNIVERSITY OF CALIFORNIA, SAN DIEGO**: 1988
  Master of Science, Biology

- **UNIVERSITY OF CALIFORNIA, DAVIS**: 1984
  Bachelor of Science, Biochemistry

TEACHING EXPERIENCE

Kennesaw State University
Associate Professor:
BTEC 4490 Experimental Design and Analysis (2009): Survey course focused on advanced product development and regulatory aspects of biotechnology and vaccines products.

University of Maryland, Medical School
Assistant Professor:
Fundamentals of Molecular Biology (Graduate Course, Winter 2000)
Host defenses and Infectious Diseases, small group instructor Year 2 Medical School core curriculum. 1998, 1999

University of California, Davis
Assistant Professor:
MD 410A/410B. General Systemic Pathology (1992, 1993, 1994, 1995, 1996)
PTX 202. Principles of Pharmacology and Toxicology-Lecturer (1995, 1996)
BCM 214-414. Molecular Medicine-Lecturer (1995, 1996)
IM 295 Cytokines-Lecturer (1996), IDI 280. Molecular Basis of Disease-Lecturer (1996)

University of California, San Diego
Biology 111. Cell Biology (Fall 1988). Teaching Assistant under Dr. M. Montal
Biology 123. Embryology laboratory (Spring 1988). Teaching Assistant under Dr. C.Holt

Santa Barbara City College
Computer Laboratory (Spring 1981) Teaching Assistant

PROFESSIONAL OFFICES AND MEMBERSHIPS

- Royal Society of Medicine, Fellow 2021-Present.
- Harvard Medical School Alumni, 2016- present.
- American Society of Tropical Medicine and Hygiene Member (ASTMH): 2016-2018.
- Virginia Bio: 2016-2018
- IEEE Genomics and Bioinformatics Working Group Member: 2002
- Northern Virginia Technology Council BioMedTech Committee: Co-chair: 2002 – 2003
- Intradigm, Corp. – a new start-up from Novartis, Inc.: Scientific Advisory Board: 2000 – 2001
- Novartis, Inc. (GTI/Systemix & Pharmacokinetics): Scientific Advisory Board and External Portfolio Reviewer: 1999 – 2001
- University of Maryland, Medical School: Pathology Education Policy Committee: 1999 – 2000
- UC Davis:
  - Education Policy Committee Graduate Group in Comparative Pathology: 1996 – 1/1997
  - Member, Biochemistry and Molecular Biology Graduate Group: 1993 – 1/1997
  - Member, Comparative Pathology Graduate Group: 1995 – 1/1997
- Boehringer Mannheim: Scientific Advisory Board: 1992 – 1993

EDITORIAL BOARDS

- Topic Editor, Frontiers in Pharmacology (Respiratory Pharmacology): "Treating COVID-19 with Currently Available Drugs," 2020-2021.
- Editor-In-Chief, Journal of Immune Based Therapies and Vaccines. 2009 – 2012, Editor: 2012.
- Gene Therapy/Molecular Biology International Society. 1997 – 2014.
- Reviewer for: Numerous peer-reviewed journals on infectious disease, public health 2016 to present.
- Nucleic Acids Research: 2001 – 2002.
- Molecular Therapy: 1999 – 2001.

ACADEMIC HONORS

- Harvard Medical School, Global Clinical Scholar Post Graduate: graduation with distinction (top 5% of graduating class).
- "DNA Vaccine" Recognizes Robert W. Malone, MD, MS, 2013.
- Trainee Investigator Award, American Federation for Clinical Research: 1993.
- Bank of America – Giannini Foundation Medical Research Fellow: 1992 – 1993.
- Henry Christian Award for Excellence in Research, American Federation for Clinical Research: 1992.
- UCDMC Medical Scholars Grant: 1992 – 1993.
- DNA and RNA Transfection and Vaccination (Abstract). First Place, Northwestern AOA Research Symposium Competition for Medical Students: 1989.
- USPHS Pre-Doctoral Fellowship: 1986 – 1988.
- San Diego Supercomputer Grant for RNA Structure Modeling: 1988.
- Northwestern University MD/ PhD Scholarship: 1984 – 1986.
- Dean's List, UC Davis: 1982 – 1984.
- President's Undergraduate Fellowship Grant for Investigation of Oncogene Expression in Breast Tumor Tissue: 1983 – 1984.
- Edmonson Summer Fellowship, Department of Pathology, UC Davis Medical School: 1984.

PATENTS ISSUED:

1. Lipid-mediated polynucleotide administration to deliver a biologically active peptide and to induce a cellular immune response. Assigned to Vical, Inc and licensed to Merck. No. 7,250,404, date of issue: 7/31/07. Priority date 3/21/1989. **Cited in 105 articles.**
2. Lipid-mediated polynucleotide administration to reduce likelihood of subject's becoming infected. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,867,195 B1, date of issue: 3/15/05. Priority date 3/21/1989.
3. Generation of an immune response to a pathogen. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,710,035, date of issue: 3/23/04. Priority date 3/21/1989. **Citations: 37 articles.**
4. Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,673,776, date of issue: 1/6/04. Priority date 3/21/1989.

5. Methods of delivering a physiologically active polypeptide to a mammal. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6.413.942, date of issue: 7/2/02. Priority date 3/21/1989. **(cited in 150 articles).**
6. Induction of a protective immune response in a mammal by injecting a DNA sequence (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,214,804, date of issue: 4/10/01. Priority date 3/21/1989. **Cited in 359 articles.**
7. DNA vaccines for eliciting a mucosal immune response (includes mRNA). US Pat. Ser. No. 6,110,898, date of issue: 8/29/00. Priority date 1996. **Cited in 40 articles.**
8. Formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,925,623 7/20/99.
9. Cationic Transport Reagents. US Pat. Ser. No. 5,892,071 issued 4/06/99.
10. Polyfunctional cationic cytofectins, formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,824,812 issued 10/20/98.
11. Cationic Transport Reagents. US Pat. Ser. No. 5,744,625 issued 4/28/98.
12. Generation of antibodies through lipid mediated DNA delivery. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,703,055, date of issue: 12/30/97. Priority date 3/21/1989. **Cited in 463 articles.**
13. Induction of a protective immune response in a mammal by injecting a DNA sequence (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,589,466, date of issue: 12/31/96. Priority date 3/21/1989. **Cited in 889 articles.**
14. Delivery of exogenous DNA sequences in a mammal (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,580,859, date of issue: 12/3/96. Priority date 3/21/1989. **Cited in 1234 articles.**
15. Cationic Transport Reagents. US Pat. Ser. No. 5,527,928, date of issue: 6/18/96.

Of note: Cationic Lipid-Mediated RNA and DNA Transfection ("RNA as a Drug). 1988 patent application, Salk institute assignee, patent abandoned without inventor permission or knowledge. Inventor: Robert Malone. Available upon request.

PUBLICATIONS (selected)

Famotidine and Celecoxib COVID-19 Treatment Without and With Dexamethasone; Retrospective Comparison of Sequential Continuous Cohorts, Submitted to Nature, Scientific Reports, May 2021. Robert W Malone, Kevin M Tomera, Leo Egbujiobi, Joseph K Kittah
Preprint at Research Square https://www.researchsquare.com/article/rs-526394/v1

More Than Just Heartburn: Does Famotidine Effectively Treat Patients with COVID-19? Malone RW. Dig Dis Sci. 2021 Feb 24:1–2. doi: 10.1007/s10620-021-06875-w. PMID: 33625612; PMCID: PMC7903029.

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.
Malone RW, et. al. Frontiers in Pharmacololgy, 23 March 2021. https://doi.org/10.3389/fphar.2021.633680
Cited in 32 articles.

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.

Malone RW, et al DO.Res Sq. 2020 Jun 22:rs.3.rs-30934. doi: 10.21203/rs.3.rs-30934/v2. Preprint.PMID: 32702719 https://www.researchsquare.com/article/rs-30934/v2 Cited in 26 articles.

Hospitalized COVID-19 Patients Treated With Celecoxib and High Dose Famotidine Adjuvant Therapy Show Significant Clinical Responses (July 8, 2020). Tomera, K, Malone, R and kittah, J. Available at SSRN: https://ssrn.com/abstract=3646583 or http://dx.doi.org/10.2139/ssrn.3646583 Cited in 8 articles.

Medical Countermeasures Analysis of 2019-nCoV and Vaccine Risks for Antibody-Dependent Enhancement (ADE). Ricke, D.O.; Malone, R.W. Preprints 2020, 2020030138 (doi: 10.20944/preprints202003.0138.v1). May, 2020 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3646583

Molecular evolution of Zika virus as it crossed the Pacific to the Americas. Schneider AB, Malone RW, et al. Cladistics. 2017; 12: 10.1111/cla.12178

Zika Virus: Medical Countermeasure Development Challenges. Malone RW, et al. PLoS Negl Trop Dis. 2016;10(3):e0004530. **Cited in 70 articles, viewed over 54,000 times, full PDF downloaded over 11,000 times.**

Zika Fetal Neuropathogenesis: Etiology of a Viral Syndrome. Klase ZA, Khakhina S, Schneider Ade B, Callahan MV, Glasspool-Malone J, Malone R. PLoS Negl Trop Dis. 2016;10(8):e0004877. **Cited in 51 articles, viewed over 13,000 times**.

Antibody mediated epitope mimicry in the pathogenesis of Zika virus related disease. Homan J, Malone RW, et al. BioRxiv. 2016.

Making vaccines "on demand": a potential solution for emerging pathogens and biodefense? De Groot AS, Einck L, Moise L, Chambers M, Ballantyne J, Malone RW Hum Vaccin Immunother. 2013;9(9):1877-84.

Electroporation enhances transfection efficiency in murine cutaneous wounds. Byrnes CK, Malone RW, et al. Wound Repair Regen. 2004;12(4):397-403.

DNA transfection of macaque and murine respiratory tissue is greatly enhanced by use of a nuclease inhibitor. Glasspool-Malone J, …, Malone RW. J Gene Med. 2002;4(3):323-2.

Marked enhancement of macaque respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, …, Malone RW. Gene Med. 2002;4(3):323-2.

Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields. Glasspool-Malone J, Malone RW. In Gene Therapy Methods: Methods Enzymol. 2002;346:72-91

Cutaneous transfection and immune responses to intradermal nucleic acid vaccination are significantly enhanced by in vivo electropermeabilization. Drabick JJ, Glasspool-Malone J, …, Malone RW. Mol Ther. 2001;3(2):249-55. Cited in 192 articles.

Theory and in vivo application of electroporative gene delivery. Somiari S, Glasspool-Malone J, … Malone RW. Mol Ther. 2000;2(3):178-87. Cited in 345 articles.

Nucleic acid vaccination with a single SIV can protect rhesus macaques from oral challenge with pathogenic SIVMAC239. Gary Rhodes, … Robert Malone, et al. *Journal of Medical Primatology* 29.3-4 (2000).

Efficient nonviral cutaneous transfection. Glasspool-Malone J, …, Malone RW. Mol Ther. 2000;2(2):140-6. Cited in 138 articles.

Transfer and expression of foreign genes in mammalian cells. Colosimo A, …, Malone RW, et al. Biotechniques. 2000;29(2):314-8, 20-2, 24 passim. Cited in 188 articles.

Specific inhibition of macrophage TNF-alpha expression by in vivo ribozyme treatment. Kisich KO, Malone RW, …, Erickson KL. J Immunol. 1999;163(4):2008-16. **Cited in 131 Articles**.

Marked enhancement of direct respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, Malone RW. Hum Gene Ther. 1999;10(10):1703-13

Developing dendritic cell polynucleotide vaccination for prostate cancer immunotherapy. Berlyn KA, …, Malone RW J Biotechnol. 1999;73(2-3):155-79

Models of Cationic Liposome Mediated Transfection. Gene Therapy and Molecular Biology. Ahearn A, Malone RW. Vol 4. Gene Therapy and Molecular Biology 1999;4

Feline dendritic-like cells: Isolation, culture, and genetic modification using monocytic precursors. Malone, J. G., Watts, T. L., Hale, A., & Malone, R. W. (1998, January). In *JOURNAL OF LEUKOCYTE BIOLOGY* (pp. 63-63): FEDERATION AMER SOC EXP BIOL.

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PUBLISHED ABSTRACTS: Over 50 published

CHAIRPERSON/ORAL PRESENTATIONS BY INVITATION: **Over 40 Invitations**
(Only the most recent events listed)

- Vaccines R&D, 2019. Keynote Speaker, Panel Moderator: Boston, MA. 18-20 November, 2019.
- Repurposing drugs for Infectious Disease Outbreaks. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017 (Chairperson)
- Accelerated Discovery and Development of re-purposed licensed drugs for Zika virus outbreak antiviral prophylaxis and therapy. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017. (Oral Presentation)
- Zika Virus: Accelerating Development of Medical Countermeasures by Re-purposing Licensed Drugs. Bridging the Sciences: Zika Virus. Emery, Atlanta, GA 1-3 May, 2016. (Oral Presentation)
- Speaker/Round table- Zika virus: Challenges for Medical Countermeasure Development. World Vaccine Conference. Washington, DC. 29-31 March, 2016.
- The World Health Organization (WHO) Consultation for Zika Virus: Research and Development. Presentation of Drug Development TPP. Geneva, Switzerland. 12-14 March, 2016. (Oral Presentation)
- Keynote Speaker: Ebola Vaccine in 12 months, Global Village, and the Need for Speed. Vaccines R&D, Baltimore, MD. 2-4 November, 2015. (Keynote Speaker)

- Current USG contracting Opportunities and Initiatives from the point of View of Vaccine Developers. World Vaccine Conference, Washington, DC. 24-26 March, 2014. (Oral Presentation)

- World Vaccine Conference, Washington, DC. 24-26 March, 2014 Preclinical and Clinical Vaccine Research. (Session Chair)

- PHEMCE Modeling Workshop "Operational Decision Making using Innovative Modeling, Analysis, and Visualization Tools", Sponsored by Deloitte. 2013 (Conference Co-Organizer and Coordinator/Oral Presentation)

- "Vaccine Production Strategies: Ensuring Alignment and Sustainability" The World Health Organization (WHO) Global Action Plan for Influenza Vaccines. Geneva, Switzerland. 12-14 July 2011 (Oral Presentation)

RECENT STUDY SECTIONS (selected):

- Accelerated COVID-19 Therapeutic Interventions and Vaccines:
  ACTIV Therapeutics Clinical Working Group, NIH. Invited Participant. June, 2020-present.
- Chairperson, NIH/NIAID/DMID Special Emphasis Panel, Development of Vaccines to Combat Antibiotic Resistant Bacteria September 2019.
- Chairperson, NIH/NIAID Special Emphasis Panel, December 2018.
- Reviewer, NIH/NIAID Special Emphasis Panel, December 2017.
- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, for "Congressionally Directed Medical Research Programs (DMRDP), 2012.
- Committee member and reviewer for NIH/NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines. 2011
- Chair and reviewer for NIH/NIAID: Partnerships in Biodefense Immunotherapeutics. 2011
- NIH/NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel. 2010
- Chairperson and scientific reviewer for NIH/NIAID Omnibus BAA 2017-1: Research Area 5 (N01) ZAI1-KP- M-C6 (Topic 5: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases), September 2017.
- Scientific reviewer for NIH/NIAID Special Emphasis Panel/Scientific Review Group 2017/08 ZRG1 IMM-R (12) B (Non-HIV Microbial vaccines), June 2017.
- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, "CDMRP: Defense Medical Research & Development Program (DMRDP), 2012.
- Chairperson and scientific reviewer for NIH/NIAID Committee on Partnerships in Biodefense Immunotherapeutics, Fall 2011.
- Committee member and reviewer for NIH/ NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines, Fall 2011.
- NIH/ NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel, 2010.
- NIH Study Section K01 Breast Cancer Study Section: July 1997

- NIDDK Special Emphasis Panel Review Committee for Competing Continuation Program Project: April 1999 and April 1998
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