

CURRICULUM VITAE

Luwy K. Musey, M.D.

Experienced scientist and physician with extensive academic and pharmaceutical industry expertise in microbiology, immunology, infectious diseases, and vaccine/drug development.

Led several multidisciplinary product development teams, with focus on resource efficiency, scientific excellence, scientific and leadership development of team members, strategic partnerships, efficient regulatory interactions, and speed to market from preclinical stage to product licensure.

EDUCATION

1975-83	Catholic University of Louvain, Brussels, Belgium	Doctorate in General Medicine and Surgery
1983-84	Institute of Tropical Medicine, Antwerp, Belgium	Tropical Medicine
1985-89	Institute of Tropical Medicine, Antwerp, Belgium	Microbiology
1987-88	University of Lille, Tourcoing, France	Infectious Diseases
1992-1995	University of Washington, Allergy and Infectious Diseases, Seattle, Washington, USA	Immunology and Infectious Diseases

EMPLOYMENT HISTORY

<i>Clinical Consultant, Musey Consulting Inc.</i>	2022- Present
<i>Executive Director, Clinical Research, Merck Research Laboratories</i>	2015- 2022
<i>Senior Director, Clinical Research, Merck Research Laboratories</i>	2012 - 2014
<i>Director, Clinical Research, Merck Research Laboratories</i>	2004 - 2012
<i>Associate Director, Clinical Research, Merck Research Laboratories</i>	2001- 2004
<i>Research Scientist, Department of Medicine, University of Washington, Seattle, WA</i>	1997-2001
<i>Post-doctoral Fellow, Departments of Medicine and Laboratory Medicine, University of Washington, Seattle, WA</i>	1995-1997
<i>Senior Research Fellow, International AIDS and Research Training Program (IARTP), Department of Epidemiology and Laboratory of Immunology, AIDS Vaccine Evaluation Unit, University of Washington, Seattle, WA</i>	1992-1995
<i>Research Associate, Projet Sida (Zaire), Research Laboratory of Immunology and Virology, Kinshasa, Democratic Republic of Congo</i>	1989-1992
<i>Research Associate, Department of Microbiology, Institute of Tropical Medicine, Antwerp, Belgium</i>	1988-1989
<i>Internship, Department of Infectious Diseases at Lille University, France</i>	1987-1988
<i>Research Associate, Department of Microbiology, Institute of Tropical Medicine, Belgium</i>	1984-1986

SKILLS

Vaccine Research and Development

- Led cross-functional product development teams (comprising of members from preclinical basic research, preclinical toxicology, clinical research, project management, regulatory affairs, manufacturing, commercial, value evidence functional areas) for several investigational and licensed vaccine programs.
- Led product development team for VAXNEUVANCE™ (Merck 15-valent pneumococcal conjugate vaccine) from Phase 1 to licensure, including oversight of 16 overlapping Phase 3 adult and pediatric clinical trials supporting worldwide vaccine licensure.
- Designed the strategy for the development of CAPVAXIVE™ (Merck 21-valent pneumococcal conjugate vaccine).

- Authored early-stage and late-stage clinical development strategies for pediatric and adult vaccine programs, including regulatory submissions for Investigational New Drug (IND) and New Drug Application (NDA)/Market Authorization Application (MAA) in United States, Europe, Canada, Japan, Australia, and several other countries worldwide.
- Authored numerous clinical protocols, clinical study reports, and common technical documents (CTDs) for vaccine studies and submission for licensure to regulatory agencies.
- Conducted several Phase I, Phase II, and Phase III clinical trials for bacterial and viral vaccines, including live and inactivated pediatric and adult vaccines.
- Conducted clinical trials evaluating various routes of administration and delivery methods for vaccines (i.e., oral, intramuscular, subcutaneous, intradermal, electroporation)
- Conducted and collaborated in the conduct of clinical trials in various countries worldwide, including developed, emerging, and developing countries.
- Collaborated with institutions (academia, non-governmental organizations, and pharmaceutical industry) in establishing new research laboratories and in the conduct of clinical trials in various regions of the world.
- Conducted several due diligences for vaccine and adjuvant candidates.
- Co-inventor of 9 patents by United States Patent and Trademark Office (USPTO).

Communication

- Fluent in English and French.
- Excellent writing and communication skills in both English and French.
- Experience in presentation at national and international scientific meetings
- Experience with regulatory agencies for discussions related to early-stage and late-stage vaccine research and development strategies.
- Experience collaborating with physicians and other scientists to communicate scientific and medical information related to conduct of clinical trials.
- Ability to communicate with groups of different scientific and cultural backgrounds and to handle difficult situations with tact and sensitivity.

Planning/Organization

- Lead several multifunctional teams in vaccine development, including initiation and conduct of clinical trials as well as submission of several biological licensing applications.
- Demonstrate creativity and innovation when designing vaccine development strategy.

- Plan and coordinate conduct of multiple and overlapping Phase 3 adult and pediatric clinical trials.
- Supervise several junior members in academia and pharmaceutical industry.
- Demonstrate and promote flexibility in the workplace.

Teamwork

- Understand the need to listen and participate in team discussions.
- Enable development of strong scientific and leadership skills of junior team members.

KEY PUBLICATIONS

1. **Musey K**, Van Dyck E, Vervoort T, Taylor D, Hoge C, Piot P. Detection of serum IgG antibodies to *Haemophilus ducreyi* in an enzyme immune assay. *J Infect Dis* 1988; 157:1039-43
2. **K. L. Musey**, C. Chidiac, G. Beaucaire, S. Houriez, A. Fourrier. Effectiveness of Roxithromycin for Treating *Isospora belli* Infection. *J Infect Dis* 1988; 158: 646
3. C. Chidiac, G. Beaucaire, **L. Musey**, O. Leroy, A. Prat, S. Houriez, C. Beuscart, Y. Mouton. Septicémies itératives et prothèse aortique sous-rénale : Le diagnostic difficile d'une fistule entero-paraprothétique. A propos d'un cas -- [*Multiple bacteremia and abdominal aortic graft: The difficult diagnosis of an enteroparaprosthetic fistula. One case report*]. *Médecine Maladies Infectieuses* 1988; 18: 290-292
4. **KL Musey KL, K** Akafomo, C Beuscart, C Santre, G Beaucaire, O Leroy, C Chidiac, S Houriez, et Y Mouton. Autocontrôle de l'antibiothérapie. Evaluation d'un système de suivi informatisé. *Médecine Maladies Infectieuses* 1990; 20: 25-32.
5. Stanley S, Kessler S, Justement J, Schnittman S, Greenhouse J, Brown C, Musongela L, **Musey K**, Kapita B, Fauci A. CD34+ bone marrow cells are infected with the human immunodeficiency virus in a subset of seropositive individuals. *J Immunol* 1992; 149:689-97.
6. KE. Potts, ML. Kalish, CI. Bandea, GM Orloff, M. Saint-Louis, C. Brown, M. Nsuami, **K. Musey**, G. Schochetman, C-Y Ou, and WL Heyward. Genetic Diversity of Human Immunodeficiency Virus Type 1 Strains in Kinshasa, Zaire. *AIDS Research and Human Retroviruses* 1993;9(7):613-618
7. Brown CC, Poli G, Lubaki N, St Louis M, Davachi F, **Musey L**, Manzila T, Kovacs A, Quinn TC, Fauci AS. Elevated levels of tumor necrosis factor-alpha in Zairian neonate plasmas: implications for perinatal infection with the human immunodeficiency virus. *J Infect Dis*. 1994 May;169:975-80.

8. **Musey L**, Hu X-Y, Eckert L, Christensen M, Karchmer T, McElrath MJ. HIV-1 induces specific cytotoxic T lymphocytes in the cervix of infected women. *J Exp Med* 1997; 185:293-303.
9. Liu SL, Schacker T, **Musey L**, Shriner D, McElrath MJ, Corey L, Mullins JI. Divergent patterns of progression to AIDS after infection from the same source: human immunodeficiency virus type 1 evolution and antiviral responses. *J Virol* 1997; 71:4284-95
10. **Musey L**, Hughes J, Schacker T, Shea T, Corey L, McElrath MJ. Cytotoxic T cell responses, viral load, and disease progression in early HIV-1 infection. *N Engl J Med* 1997; 337:1267-74
11. Goh WC, Markee J, Akridge RE, Meldorf M, **Musey L**, Karchmer T, Krone M, Collier A, Corey L, Emerman M, McElrath MJ. Protection against human immunodeficiency virus type 1 infection in persons with repeated exposure: evidence for T cell immunity in the absence of inherited CCR5 coreceptor defects. *J Infect Dis* 1999; 179: 548-57
12. **Musey LK**, Krieger JN, Hughes JP, Schacker TW, Corey L, and McElrath MJ. Early and persistent human immunodeficiency virus type 1 (HIV-1)-specific T helper dysfunction in blood and lymph nodes following acute HIV-1 infection. *J Infect Dis* 1999; 180:278-84.
13. Malhotra U, Berrey MM, Huang Y, Markee J, Brown DJ, Ap S, **Musey L**, Schacker T, Corey L, McElrath MJ. Effect of combination antiretroviral therapy on T-cell immunity in acute human immunodeficiency virus type 1 infection. *J Infect Dis* 2000; 181: 121-31
14. White HD, **Musey LK**, Andrews MM, Yeaman GR, DeMars LR, Manganiello PD, Howell AL, Wira CR, Green WR, McElrath MJ. Human immunodeficiency virus-specific and CD3-redirected cytotoxic T lymphocyte activity in the human female reproductive tract: lack of correlation between mucosa and peripheral blood. *J Infect Dis*. 2001 Mar 15;183:977-83.
15. **Musey L**, Ding Y, Cao J, Lee J, Galloway C, Yuen A, Jerome KR, and McElrath MJ. Ontogeny and specificities of mucosal and blood human immunodeficiency virus type 1-specific CD8(+) cytotoxic T lymphocytes. *J Virol* 2003; 77:291-300

16. **Musey L**, Ding Y, Elizaga M, Ha R, Celum C., and McElrath MJ. HIV-1 vaccination administered intramuscularly can induce both systemic and mucosal T cell immunity in HIV-1-uninfected individuals. *J Immunol* 2003; 171:1094-101
17. C. Morishima, **L. Musey**, M. Elizaga, K. Gaba, M. Allison, R.L. Carithers, D. Gretch, and J.M. McElrath Hepatitis C virus-specific cytolytic T cell responses after antiviral therapy. *Clinical Immunology* 2003; 108:211-220
18. Kashamuka M, Nzila N, **Mussey L**, Lubaki N, Quinn TC, Bollinger R, Kumar N. Analysis of anti-malaria immune response during human immunodeficiency virus infection in adults in Kinshasa, Democratic Republic of the Congo. *Am J Trop Med Hyg.* 2003 Mar;68(3):376-8.
19. N. N. Zheng, N. B. Kiviat, P. S. Sow, S. E. Hawes, A. Wilson, H. Diallo-Agne, C. W. Critchlow, G. S. Gottlieb, **L. Musey**, and M. J. McElrath. Comparison of Human Immunodeficiency Virus (HIV)-Specific T-Cell Responses in HIV-1- and HIV-2-Infected Individuals in Senegal. *J. Virol* 2004; 78:13934-13942
20. Wallace M, Evans B, Woods S, Mogg R, Zhang L, Finnefrock AC, Rabussay D, Fons M, Mallee J, Mehrotra D, Schödel F, and **Musey L**. Tolerability of Two Sequential Electroporation Treatments Using MedPulser DNA Delivery System (DDS) in Healthy Adults. *Mol Ther.* 2009; 17: 922-8.
21. Grabenstein JD, **Musey LK**. Differences in serious clinical outcomes of infection caused by specific pneumococcal serotypes among adults. *Vaccine* 2014; 32: 2399-2405.
22. Sobanjo-ter Meulen A, Vesikari T, Malacaman EA, Shapiro SA, Dallas MJ, Hoover PA, McFetridge R, Stek JE, Marchese RD, Hartzel J, Watson WJ, Musey **LK**. Safety, Tolerability, and Immunogenicity of 15-Valent Pneumococcal Conjugate Vaccine in Toddlers Previously Vaccinated with 7-Valent Pneumococcal Conjugate Vaccine. *Ped Infect Dis J* 2015; 34: 186-194.
23. Wiedman RT, Reisinger KS, Hartzel J, Malacaman E, Senders SD, Giacoletti KED, Shaw E, Kuter B, Schodel F, **Musey LK**. M-M-R_{II} manufactured using recombinant human albumin (rHA) and M-M-R_{II} manufactured using human serum albumin (HSA) exhibit similar safety and immunogenicity profiles when administered as a 2-dose regimen to healthy children. *Vaccine* 2015; 33: 2132-2140.

24. Richard McFetridge R, Sobanjo-ter Meulen A, Folkerth SD, Hoekstra AA, Raad GL, Dallas M, Hoover PA, Marchese RD, Zacholski D, Watson W, Stek JE, Hartzel JS, **Musey L**. Safety, Tolerability, and Immunogenicity of 15-Valent Pneumococcal Conjugate Vaccine in Healthy Adults. *Vaccine* 2015; 33: 2793-2799.
25. Ciprero KL, Marchese RD, Richard P, Baudin M, Sterling TM, Manoff SB, Radley D, Stek J, Soubeyrand B, Grabenstein JD, Samson SI, **Musey LK**. Vaccination of adults with 23-valent pneumococcal polysaccharide vaccination induces robust antibody responses against pneumococcal serotypes associated with serious clinical outcomes. *Human Vaccine and Immunotherapeutics* 2016; 12: 2135-2141
26. Ciprero KL, Zykov KA, Briko NI, Shekar T, Sterling TM, Bitieva E, Stek JE, and **Musey L**. Safety and Immunogenicity of 23-Valent Pneumococcal Polysaccharide Vaccine in Russian Subjects. *Human Vaccine and Immunotherapeutics* 2016; 12: 2142-2147
27. Kawakami K, Kishino H, Kanazu S, Toshimizu N, Takahashi K, Sterling T, Wang M, and **Musey L**. Revaccination with 23-valent pneumococcal polysaccharide vaccine in the Japanese elderly is well tolerated and elicits immune responses. *Vaccine* 2016; 34: 3875-81
28. Kuter BJ, Brown M, Wiedmann RT, Hartzel J, and **Musey L**. Safety and Immunogenicity of M-M-RII (Combination Measles-Mumps-Rubella Vaccine) in Clinical Trials of Healthy Children Conducted Between 1988 and 2009. *Pediatr Infect Dis J* 2016; 35: 1011-20
29. Ermlich SJ, Andrews CP, Folkerth S, Rupp R, Greenberg D, McFetridge RD, Hartzel J, Marchese RD, Stek JE, Abeygunawardana C, **Musey LK**. Safety and Immunogenicity of 15-Valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults ≥50 Years of Age. *Vaccine* 2018; 36: 6875-6882
30. Greenberg D, Hoover PA, Vesikari T, Peltier C, Hurley DC, McFetridge R, Dallas M, Hartzel J, Marchese RD, Griswold-Coller BA, Stek JE, Abeygunawardana C, Winters MA, MacNair JE, Pujar NS, and **Musey L**. Safety and Immunogenicity of 15-Valent Pneumococcal Conjugate Vaccine (PCV15) in Healthy Infants. *Vaccine* 2018; 36: 6883-6891

31. Kawakami K, Kishino H, Kanazu S, Takahashi K, Ino T, Sawata M, **Musey L**. Time Interval of revaccination with 23-valent pneumococcal polysaccharide vaccine more than 5 years does not affect the immunogenicity and safety in the Japanese elderly. *Human Vaccine and Immunotherapeutics* 2018; 14: 1931-1938
32. Stacey HL, Rosen J, Peterson JT, Williams-Diaz A, Gakhar V, Sterling TM, Acosta CJ, Nolan KM, Li J, Pedley A, Benner P, Abeygunawardana C, Kosinski M, Smith WJ, Pujar H, **Musey LK**. Safety and immunogenicity of 15-valent pneumococcal conjugate vaccine (PCV-15) compared to PCV-13 in healthy older adults. *Human Vaccine and Immunotherapeutics* 2019; 15: 530-539
33. Peterson JT, Stacey HL, MacNair JE, Li J, Hartzel JS, Sterling TM, Benner P, Tamms GM, **Musey LK**. Safety and immunogenicity of 15-valent pneumococcal conjugate vaccine compared to 13-valent pneumococcal conjugate vaccine in adults >65 years of age previously vaccinated with 23-valent pneumococcal polysaccharide vaccine. *Human Vaccine and Immunotherapeutics* 2019; 15: 540-548
34. Rupp R, Hurley D, Grayson S, Li J, Nolan K, McFetridge RD, Hartzel J, Abeygunawardana C, Winters M, Pujar H, Benner P, **Musey L**. A dose ranging study of 2 different formulations of 15-valent pneumococcal conjugate vaccine (PCV15) in healthy infants. *Human Vaccine and Immunotherapeutics* 2019; 15: 549-559
35. Suart P Adler, Nicole Lewis, Anthony Conlon, Mark P Christiansen, Mohamed Al-Ibrahim, Richard Rupp, Tong Ming Fu, Oliver Bautista, Huaping Tand, Dai Wang, Alison Fisher, Timothy Culp, Rituparna Das, Karen Beck, Gretchen Tamms, **Luwy Musey**, and the V160-001 Study Group. Phase 1 Clinical Trial of a Conditionally Replication-Defective Human Cytomegalovirus (CMV) Vaccine in CMV-Seronegative Subjects. *Journal of Infectious Diseases* 2019; 220: 411-419
36. Liu Y, Freed DC, Li L, Tang A, Li F, Murray EM, Adler SP, McVoy MA, Rupp RE, Barrett D, Ye X, Zhang N, Beck K, Culp T, Das R, Song L, Vora K, Zhu H, Wang D, Espeseth AS, An Z, **Musey L**, Fu TM. A Replication Defective Human Cytomegalovirus Vaccine Elicits Humoral Immune Responses Analogous to Those with Natural Infection. *J Virol*. 2019 Sep 11. pii: JVI.00747-19. doi: 10.1128/JVI.00747-19.

37. Xie J, Zhang Y, Caro-Aguilar I, Indrawati L, Smith WJ, Giovarelli C, Winters MA, MacNair J, He J, Abeygunawardana C, **Musey L**, Kosinski M, Skinner JM. Immunogenicity Comparison of a Next Generation Pneumococcal Conjugate Vaccine in Animal Models and Human Infants. *Pediatr Infect Dis J*. 2020 Jan;39(1):70-77. doi: 10.1097/INF.0000000000002522.PMID: 31725555
38. Platt HL, Greenberg D, Tapiero B, Clifford RA, Klein NP, Hurley DC, Shekar T, Li J, Hurtado K, Su SC, Nolan KM, Acosta CJ, McFetridge RD, Bickham K, **Musey LK**; V114-008 Study Group. A Phase II Trial of Safety, Tolerability, and Immunogenicity of V114, a 15-Valent Pneumococcal Conjugate Vaccine, Compared With 13-Valent Pneumococcal Conjugate Vaccine in Healthy Infants. *Pediatr Infect Dis J*. 2020 Aug;39(8):763-770. doi: 10.1097/INF.0000000000002765.PMID: 32639460
39. Song JY, Chang CJ, Andrews C, Diez-Domingo J, Oh MD, Dagan R, Hartzel J, Pedley A, Li J, Sterling T, Tamms G, Chiarappa JA, Lutkiewicz J, **Musey L**, Tu Y, Buchwald UK; V114-016 (PNEU-PATH) study group. Safety, tolerability, and immunogenicity of V114, a 15-valent pneumococcal conjugate vaccine, followed by sequential PPSV23 vaccination in healthy adults aged ≥50 years: A randomized phase III trial (PNEU-PATH). *Vaccine*. 2021 Oct 15;39(43):6422-6436. doi: 10.1016/j.vaccine.2021.08.038. Epub 2021 Sep 4. PMID: 34489128
40. Mt-Isa S, Abderhalden LA, **Musey L**, Weiss T. Matching-adjusted indirect comparison of pneumococcal vaccines V114 and PCV20. *Expert Rev Vaccines*. 2022 Jan;21(1):115-123. doi: 10.1080/14760584.2021.1994858. Epub 2021 Oct 27. PMID: 34672224
41. McGuinness D, Kaufhold RM, McHugh PM, Winters MA, Smith WJ, Giovarelli C, He J, Zhang Y, **Musey L**, Skinner JM. Immunogenicity of PCV24, an expanded pneumococcal conjugate vaccine, in adult monkeys and protection in mice. *Vaccine*. 2021 Jul 5;39(30):4231-4237. doi: 10.1016/j.vaccine.2021.04.067. Epub 2021 May 29. PMID: 3407454.
42. Niederman MS, Folaranmi T, Buchwald UK, **Musey L**, Cripps AW, Johnson KD. Efficacy and effectiveness of a 23-valent polysaccharide vaccine against invasive and noninvasive pneumococcal disease and related outcomes: a review of available evidence. *Expert Rev Vaccines*. 2021 Mar;20(3):243-256. doi: 10.1080/14760584.2021.1880328. Epub 2021 Feb 20. PMID: 33478306
43. Cripps AW, Folaranmi T, Johnson KD, **Musey L**, Niederman MS, Buchwald UK. Immunogenicity following revaccination or sequential vaccination with 23-valent pneumococcal polysaccharide vaccine (PPSV23) in older adults and those at increased risk of pneumococcal disease: a review of the literature. *Expert Rev Vaccines*. 2021 Mar;20(3):257-267. doi: 10.1080/14760584.2021.1889374. Epub 2021 Mar 2. PMID: 33567914

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45. Cox KS, Zhang L, Freed DC, Tang A, Zhang S, Zhou Y, Wang IM, Rupp RE, Adler SP, **Musey LK**, Wang D, Vora KA, Fu TM. Functional Evaluation and Genetic Evolution of Human T-Cell Responses After Vaccination With a Conditionally Replication-Defective Cytomegalovirus Vaccine. *J Infect Dis*. 2021 Jun 4;223(11):2001-2012. doi: 10.1093/infdis/jiaa631. PMID: 33031517

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Patents by Inventor Luwy Musey

Luwy Musey has filed for patents to protect the following inventions. This listing includes patent applications that are pending as well as patents that have already been granted by the United States Patent and Trademark Office (USPTO).

- **COMPOSITIONS COMPRISING STREPTOCOCCUS PNEUMONIAE POLYSACCHARIDE-PROTEIN CONJUGATES AND METHODS OF USE THEREOF**

Publication number: 20210379174

Abstract: The invention is related to multivalent immunogenic compositions comprising more than one *S. pneumoniae* polysaccharide protein conjugates, wherein each of the conjugates comprises a polysaccharide from an *S. pneumoniae* serotype conjugated to a carrier protein, wherein the serotypes of *S. pneumoniae* are as defined herein. In some embodiments, at least one of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. In further embodiments, each of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. Also provided are methods for inducing a protective immune response in a human patient comprising administering the multivalent immunogenic compositions of the invention to the patient. The multivalent immunogenic compositions are useful for providing protection against *S. pneumoniae* infection and diseases caused by *S. pneumoniae*.

Type: Application

Filed: July 13, 2021

Publication date: December 9, 2021

Applicant: Merck Sharp & Dohme Corp.

Inventors: William J. Smith, Patrick McHugh, Michael A. Winters, Julie M. Skinner, Jian He, **Luwy Musey**, Chitrananda Abeygunawardana, Yadong Adam Cui, Michael J. Kosinski

- **ENHANCING IMMUNOGENICITY OF STREPTOCOCCUS PNEUMONIAE POLYSACCHARIDE-PROTEIN CONJUGATES**

Publication number: 20210330778

Abstract: The present invention provides immunogenic compositions having one or more polysaccharide-protein conjugates in which one or more polysaccharides from *Streptococcus pneumoniae* bacterial capsules are conjugated to a carrier protein in an aprotic solvent such as dimethylsulfoxide (DMSO). The present invention also provides methods for providing an enhanced immune response to a pneumococcal polysaccharide protein conjugate vaccine comprising administering to a human subject an immunogenic composition comprising polysaccharide-protein conjugates prepared in DMSO conditions.

Type: Application

Filed: July 7, 2021

Publication date: October 28, 2021

Applicant: Merck Sharp & Dohme Corp.

Inventors: Jian He, John E. MacNair, William J. Smith, Michael A. Winters, Joseph G. Joyce, Chitrananda Abeygunawardana, **Luwy Musey**, Hari Pujar

- [**ENHANCING IMMUNOGENICITY OF STREPTOCOCCUS PNEUMONIAE POLYSACCHARIDE-PROTEIN CONJUGATES**](#)

Publication number: 20210330777

Abstract: The present invention provides immunogenic compositions having one or more polysaccharide-protein conjugates in which one or more polysaccharides from Streptococcus pneumoniae bacterial capsules are conjugated to a carrier protein in an aprotic solvent such as dimethylsulfoxide (DMSO). The present invention also provides methods for providing an enhanced immune response to a pneumococcal polysaccharide protein conjugate vaccine comprising administering to a human subject an immunogenic composition comprising polysaccharide-protein conjugates prepared in DMSO conditions.

Type: Application

Filed: July 7, 2021

Publication date: October 28, 2021

Applicant: Merck Sharp & Dohme Corp.

Inventors: Jian He, John E. MacNair, William J. Smith, Michael A. Winters, Joseph G. Joyce, Chitrananda Abeygunawardana, [**Luwy Musey**](#), Hari Pujar, Julie M. Skinner, Patrick McHugh

- [**Compositions comprising polysaccharide-protein conjugates and methods of use thereof**](#)

Patent number: 11116828

Abstract: The invention is related to multivalent immunogenic compositions comprising more than one S. pneumoniae polysaccharide protein conjugates, wherein each of the conjugates comprises a polysaccharide from an S. pneumoniae serotype conjugated to a carrier protein, wherein the serotypes of S. pneumoniae are as defined herein. In some embodiments, at least one of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. In further embodiments, each of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. Also provided are methods for inducing a protective immune response in a human patient comprising administering the multivalent immunogenic compositions of the invention to the patient. The multivalent immunogenic compositions are useful for providing protection against S. pneumoniae infection and diseases caused by S. pneumoniae.

Type: Grant

Filed: December 4, 2018

Date of Patent: September 14, 2021

Assignee: Merck Sharp & Dohme Corp.

Inventors: William J. Smith, Patrick McHugh, Michael Albert Winters, Julie M. Skinner, Jian He, [**Luwy Musey**](#), Chitrananda Abeygunawardana, Yadong Adam Cui, Michael J. Kosinski

- [**Enhancing immunogenicity of polysaccharide-protein conjugates**](#)

Patent number: 11090374

Abstract: The present invention provides immunogenic compositions having one or more polysaccharide-protein conjugates in which one or more polysaccharides from Streptococcus pneumoniae bacterial capsules are conjugated to a carrier protein in an aprotic solvent such as dimethylsulfoxide (DMSO). The present invention also provides methods for providing an enhanced immune response to a pneumococcal polysaccharide protein conjugate vaccine comprising

administering to a human subject an immunogenic composition comprising polysaccharide-protein conjugates prepared in DMSO conditions.

Type: Grant

Filed: February 20, 2018

Date of Patent: August 17, 2021

Assignee: Merck Sharp & Dohme Corp.

Inventors: Jian He, John E. MacNair, William J. Smith, Michael A. Winters, Joseph G. Joyce, Chitrananda Abeygunawardana, Luwy Musey, Hari Pujar, Julie M. Skinner, Emily Wen, Patrick McHugh, John Michael Williams, Catherine Lancaster

- [COMPOSITIONS COMPRISING STREPTOCOCCUS PNEUMONIAE POLYSACCHARIDE-PROTEIN CONJUGATES AND METHODS OF USE THEREOF](#)

Publication number: 20210177957

Abstract: The invention is related to multivalent immunogenic compositions comprising more than one S. pneumoniae polysaccharide protein conjugates, wherein each of the conjugates comprises a polysaccharide from an S. pneumoniae serotype conjugated to a carrier protein, wherein the serotypes of S. pneumoniae are as defined herein. In some embodiments, at least one of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. In further embodiments, each of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. Also provided are methods for inducing a protective immune response in a human patient comprising administering the multivalent immunogenic compositions of the invention to the patient. The multivalent immunogenic compositions are useful for providing protection against S. pneumoniae infection and diseases caused by S. pneumoniae.

Type: Application

Filed: December 4, 2018

Publication date: June 17, 2021

Applicant: Merck Sharp & Dohme Corp.

Inventors: William J. Smith, Patrick McHugh, Michael Albert Winters, Julie M. Skinner, Jian He, Luwy Musey, Chitrananda Abeygunawardana, Yadong Adam Cui, Michael J. Kosinski

- [COMPOSITIONS COMPRISING STREPTOCOCCUS PNEUMONIAE POLYSACCHARIDE-PROTEIN CONJUGATES AND METHODS OF USE THEREOF](#)

Publication number: 20200197503

Abstract: The invention is related to multivalent immunogenic compositions comprising more than one S. pneumoniae polysaccharide protein conjugates, wherein each of the conjugates comprises a polysaccharide from an S. pneumoniae serotype conjugated to a carrier protein, wherein the serotypes of S. pneumoniae are as defined herein. In some embodiments, at least one of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. In further embodiments, each of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. Also provided are methods for inducing a protective immune response in a human patient comprising administering the multivalent immunogenic compositions of the invention to the patient. The multivalent immunogenic compositions are useful for providing protection against S. pneumoniae infection and/or pneumococcal diseases caused by S. pneumoniae.

Type: Application

Filed: December 17, 2019

Publication date: June 25, 2020

Applicant: Merck Sharp & Dohme Corp.

Inventors: Chitrananda Abeygunawardana, Yadong Adam Cui, Romulo Ferrero, Jian He, Luwy Musey, Tanaz Petigara, Julie M. Skinner

- **ENHANCING IMMUNOGENICITY OF STREPTOCOCCUS PNEUMONIAE POLYSACCHARIDE-PROTEIN CONJUGATES**

Publication number: 20200054733

Abstract: The present invention provides immunogenic compositions having one or more polysaccharide-protein conjugates in which one or more polysaccharides from Streptococcus pneumoniae bacterial capsules are conjugated to a carrier protein in an aprotic solvent such as dimethylsulfoxide (DMSO). The present invention also provides methods for providing an enhanced immune response to a pneumococcal polysaccharide protein conjugate vaccine comprising administering to a human subject an immunogenic composition comprising polysaccharide-protein conjugates prepared in DMSO conditions.

Type: Application

Filed: February 20, 2018

Publication date: February 20, 2020

Applicant: Merck Sharp & Dohme Corp.

Inventors: Jian He, John E. MacNair, William J. Smith, Michael A. Winters, Joseph G. Joyce, Chitrananda Abeygunawardana, Luwy Musey, Hari Pujar, Julie M. Skinner, Emily Wen, Patrick McHugh, John Michael Williams, Catherine Lancaster

- **COMPOSITIONS COMPRISING STREPTOCOCCUS PNEUMONIAE POLYSACCHARIDE-PROTEIN CONJUGATES AND METHODS OF USE THEREOF**

Publication number: 20190192648

Abstract: The invention is related to multivalent immunogenic compositions comprising more than one S. pneumoniae polysaccharide protein conjugates, wherein each of the conjugates comprises a polysaccharide from an S. pneumoniae serotype conjugated to a carrier protein, wherein the serotypes of S. pneumoniae are as defined herein. In some embodiments, at least one of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. In further embodiments, each of the polysaccharide protein conjugates is formed by a conjugation reaction comprising an aprotic solvent. Also provided are methods for inducing a protective immune response in a human patient comprising administering the multivalent immunogenic compositions of the invention to the patient. The multivalent immunogenic compositions are useful for providing protection against S. pneumoniae infection and diseases caused by S. pneumoniae.

Type: Application

Filed: December 4, 2018

Publication date: June 27, 2019

Applicant: Merck Sharp & Dohme Corp.

Inventors: William J. Smith, Patrick McHugh, Michael Albert Winters, Julie M. Skinner, Jian He, Luwy Musey, Chitrananda Abeygunawardana, Yadong Adam Cui, Michael J. Kosinski