



Curriculum Vitae

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Education and Specialized Training:

1997	Residency Arkansas Children's Hospital Little Rock, Arkansas
1995	Internship Arkansas Children's Hospital Little Rock, Arkansas
1994	Doctor of Medicine University of Alabama School of Medicine Birmingham, Alabama
1990	Bachelor of Science University of South Alabama Mobile, Alabama

Work Experience:

2005-Present	Investigator Alabama Clinical Therapeutics Birmingham, Alabama
1997-Present	Private Practice Birmingham Pediatric Associates Birmingham, Alabama
1995-1997	Transport Physician, Angel Flight Critical Care Transport Arkansas Children's Hospital Little Rock, Arkansas

Work Experience (continued):

1997 Sports Medicine Physician
Arkansas Children's Hospital Sports Medicine Plus
Little Rock, Arkansas

Credentials

Medical License State of Alabama, #20670
Certification American Board of Pediatrics

Research Experience:

1. XXX PK for the Prevention of HUS in Children
2. Safety and Efficacy of XXX (G1, G2, G3, G4, and P1) Human-Bovine Rotavirus Reassortant Vaccine in Healthy Infants
3. A Double-Blind, Randomized, Placebo-Controlled Surveillance Study of Asthma Event Outcomes in Subjects Receiving Either Usual Pharmacotherapy of Asthma or Usual Pharmacotherapy Plus XXX 42mcg (XXX) Twice Daily
4. The Effects of a Soy Based Infant Formula Supplemented with Long Chain Polyunsaturated Fatty Acids on Growth and Development in Term Infants
5. Long Term Follow-up on the Effects of a Soy Based Infant Formula Supplemented with Long Chain Polyunsaturated Fatty Acids on Growth and Development in Term Infants
6. A Randomized, Third Party Blind, Multicenter Trial Comparing the Efficacy and Safety of XXX (XXX) for 3 Weeks Versus XXX for 6 Weeks Versus XXX (XXX) for 6 Weeks Given once Daily to Pediatric Patients with Tinea Capitis
7. A Multicenter, Randomized, Comparative Study to Evaluate the Efficacy and Safety of XXX in The Treatment of Children who have Recurrent and/or Persistent Acute Otitis Media (XXX)
8. A Multicenter, Long-Term, Active-Surveillance Study of Musculoskeletal Disorders That Occur After Initiation A Course of XXX (XXX) or Non-Fluoroquinolone Therapy for Acute Infectious Diseases in Children who were enrolled in Phase 3 Clinical Trials Involving XXX Therapy
9. An Open-Label, Multi-Center Study to Assess Tolerability, Effectiveness and Quality of Life Associated with the Use of XXX (XXX) in Children with Attention Deficit Hyperactivity Disorder (ADHD) in a Community Practice Setting
10. Effects of Different Formula DNA Levels on RBC DHA Concentration of Term Infants
11. A Randomized, Evaluator-Blinded Comparison of the Efficacy and Safety of XXX with XXX and XXX and XXX and XXX in the Treatment of Acute Diffuse Otitis Externa in Children, Adolescents, and Adults
12. The Effects of an Infant Formula Supplemented with XXX of Growth and Tolerance in Term Infants

Research Experience (continued):

13. A Randomized, Double-Blind Trial to Assess the Safety and Relative Efficacy of XXX against XXX in Children 6-59 Months of Age
14. A Phase II, randomized, open, multicenter study to assess the safety and immunogenicity of primary vaccination with GlaxoSmithKline's Biologicals' XXX, Y-tetanus toxoid conjugate XXX administered intramuscularly as 1 or 2 doses to healthy toddlers at 9-15 months of age
15. Safety Study of XXX when Administered with Other Pediatric Vaccines to Healthy Toddlers,ž Protocol XXX.
16. XXX A Phase 3, Randomized, Observer-blind, Controlled, Multi-Center Study to Evaluate the Lot to Lot Consistency of Novartis XXX when One Dose is Administered to Healthy Adolescents 11-18 Years of Age and to Compare the Safety and Immunogenicity of XXX with that of Licensed XXX when One Dose is Administered to Healthy Subjects 11-55 Years of Age
17. XXX A Phase III, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety and Immunogenicity of XXX When Administered with Routine Infant Vaccinations to Healthy Infants
18. A Phase II randomized, observer blind, multicenter study of GlaxoSmithKline Biologicals' combined XXX according to a one dose schedule, both administered subcutaneously at 12-14 months of age, concomitantly with XXX) and XXX but at separate sites
19. A Phase III, open, randomized, controlled, multicenter study to assess the safety and immunogenicity of XXX . XXX co-administered with XXX as compared to XXX) in healthy toddlers 12-15 months of age who were primed at 2, 4 and 6 months of age with XXX, and to assess the safety and immunogenicity of XXX in healthy toddlers 15-18 months of age who were primed with XXX at 2, 4, and 6 months of age as compared to the administration of XXX alone in healthy toddlers 15-18 months of age who were primed with XXX and XXX at 2, 4 and 6 months of age.
20. XXX A Multi-center, Randomized, Double Blind, Placebo Controlled Parallel Group Study of the Safety of XXX Oral Liquid Formulation in Children Aged 6 Months to 11 Months
21. A Phase II, randomized, open, multicenter study to assess the safety and immunogenicity of primary vaccination with XXX administered intramuscularly as 1 or 2 doses to healthy toddlers at 9-15 months of age
22. A phase III, single-blind, randomized, controlled, multinational study for the evaluation of safety of XXX compared to XXX in healthy infants at 2, 4, 6, and 12 to 15 months of age."
23. A Phase III, open, randomized, controlled, multicenter study to assess the safety and immunogenicity of XXX. XXX as compared to XXX in healthy toddlers 12-15 months of age who were primed at 2, 4 and 6 months of age with XXX, and to assess the safety and immunogenicity XXX co-administered with XXX in healthy toddlers 15-18 months of age who were primed with XXX at 2, 4, and 6 months of age as compared to the administration of XXX alone in healthy toddlers 15-18 months of age who were primed with XXX at 2, 4 and 6 months of age.
24. A phase III, randomized, multinational study, double-blinded for the immunogenicity and consistency evaluation of 3 XXX lots and single-blinded and controlled for the evaluation of safety and immunogenicity of XXX compared to XXX in healthy infants at 2, 4, 6, and 12 to 15 months of age.

Research Experience (continued):

25. A phase III, single-blind, randomized, controlled, multinational study for the evaluation of safety of XXX compared to XXX control vaccine in healthy infants at 2, 4, 6, and 12 to 15 months of age
26. An Open, Randomized, Multicenter Study of the Safety, Tolerability, and Immunogenicity of XXX Given Concomitantly With XXX and XXX in Healthy Children 12 Months of Age
27. Safety Study of XXX when Administered with Other Pediatric Vaccines to Healthy Toddlers,ž XXX
28. "Safety and Immunogenicity of XXX Compared to XXX as Fifth Dose Booster in Children 4 to 6 Years of Age"
29. A Multi-Center, Double-Blind Trial To Compare The Safety And Efficacy Of XXX In Patients With Otitis Externa
30. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Parallel-Group Study of the Safety of XXX in children aged 6 months to 11 months with Symptoms of Allergic Rhinitis or Chronic Urticaria
31. A Phase III, Observer-Blind, Multi-Centre, Multi-Country, Randomized Study to Evaluate the Immunogenicity and Safety of XXX Compared to XXX Administered Intramuscularly in Children 6 to 35 Months of Age
32. A Phase 3b, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety of XXX when Administered with Routine Infant Vaccinations to Healthy Infants
33. A Phase II, Randomized, Observer Blind, Multicenter Study of XXX vs XXX according to one dose schedule, both administered subcutaneously at 12-14 months of age, concomitantly with XXX and XXX, but at separate sites
34. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Parallel-Group Study of the Safety of XXX Dosing Children aged 1 to less than 6 Years Suffering from Allergic Rhinitis or Chronic Urticria of Unknown Origin
35. A Phase 3, Open-Label, Randomized, Multi-Center Study evaluate the Safety and Immunogenicity of XXX when administered concomitantly with XXX to Healthy Toddlers
36. Safety and Immunogenicity of XXX compared to XXX as Fifth Dose Booster in Children 4 to 6 years of age
37. A Randomized, Double-Blind, Placebo-Controlled, Parallel Design, Multiple Site Study to Evaluate the Clinical Equivalence of Two XXX 0.3%, 0.1% Sterile Otic Suspensions in the Treatment of Acute Bacterial Otitis Externa
38. A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Withdrawal Study to Evaluate the Safety and Efficacy of Delayed-Release XXX in 1 to 11 Month-Old Pediatric Subjects with Symptomatic/Erosive Gastroesophageal Reflux Disease (GERD)
39. An Observational Prospective Study to Assess Respiratory Syncytial Virus (RSV) Respiratory Events Amount Premature Infants (32 to 35 Week Gestational Age) – Outcomes and Risk Tracking Study

Research Experience (continued):

40. A Randomized, Double-Blind, Double Dummy, Comparative, Multicenter Study to Assess the Safety and Efficacy of Topical XXX Ointment, 1% versus Oral XXX in the Treatment of Secondarily-Infected Traumatic Lesions and Impetigo Due to Methicillin-Resistant *Staphylococcus aureus*
41. The Evaluation of Cow Milk-Based Formulas-Functional Proteins
42. A Phase III, Observer-Blind, Randomized Study to Evaluate the Immunogenicity and Safety of XXX Compared with XXX Administered Intramuscularly in Children 3 to 17 Years of Age in the US
43. A Multicenter, Double-Blind Study of the Safety, Tolerability, and Immunogenicity of XXX Compared to XXX in Healthy Infants
44. A Phase III, Randomized, Open-Label, Active Comparator Controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of XXX in Infants When Given at 2, 4, and 6 Months Concomitantly with Pneumococcal Conjugate Vaccine and XXX
45. An Open-Label, Multi-Center Study to Evaluate the Persistence of Antibody Responses Among Adolescents Who Previously Received XXX or XXX
46. A Phase IIIb, Open-Label, Controlled, Multi-Center Study to Evaluate the Persistence of Antibody Responses Among Children who Previously Received XXX
47. A Phase 3, Open-Label, Randomized, Multi-Center Study to Evaluate the Safety and Immunogenicity of XXX When Administered Concomitantly with XXX to Healthy Toddlers
48. A Phase 3, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety of XXX When Administered with Routine Infant Vaccinations to Healthy Infants
49. A Phase 3b, Randomized, Open-Label, Multi-Center Study to Evaluate the Safety and Immunogenicity of 2 or 3 Doses of XXX in Healthy Infants and Effects of a Booster Dose of XXX Administered in the Second Year of Life
50. Phase 2, Observer Blinded, Controlled, Randomized, Multi-Center Study in Adolescents to Evaluate Safety and Immunogenicity of Two Different XXX Vaccination Formulations
51. Safety and Immunogenicity Among Children Administered XXX Vaccine
52. Safety and Immunogenicity of XXX Administered in Infants and Toddlers
53. Safety and Immunogenicity of XXX Vaccine Absorbed Combined to XXX as the Fifth Dose in Children 4 to 6 Years of Age
54. Safety and Immunogenicity of XXX Compared to XXX as Fifth Dose Booster in Children 4 to 6 Years of Age
55. A Multicenter, Randomized, Double-Blind Clinical Trial to Assess the Efficacy and Safety of XXX plus XXX Compared to XXX and to XXX in the Treatment of Acute Otitis Media with Tympanostomy Tubes (AOMT) in Pediatric Patients

Research Experience (continued):

56. A Phase 3b, Randomized, Open-Label, Multi-Center Study to Evaluate the Safety and Immunogenicity of 2 or 3 Doses of XXX Conjugate Vaccine in Healthy Infants and the Effects of a Booster Dose of XXX Administered in the Second Year of Life
57. A Phase 4, Placebo-Controlled, Randomized Study to Evaluate the Immunogenicity and Safety of a Combined Tetanus, XXX, XXX Vaccine and XXX Human Papillomavirus [Types 6, 11, 16, 18] Recombinant Vaccine XXX in Healthy Adolescents when Administered with Men ACWY Conjugate Vaccine
58. A Phase III, Randomized, Open-Label, Active-Comparator Controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of XXX in Infants When Given at 2, 4, and 6 Months Concomitantly with XXX and XXX
59. The Effects on Growth and Tolerance of a Hydrolyzed Infant Formula Fed to Term Infants
60. Phase 2, Observer Blinded, Controlled, Randomized Multi-Center Study in Adolescents and Young Adults to Evaluate Safety and Immunogenicity of Two Different XXX Combination Vaccination Formulations
61. A Multicenter, Double-Blind Study of the Safety, Tolerability, and Immunogenicity of Pneumococcal Conjugate Vaccine Compared to XXX in Healthy Infants
62. A Phase III, Randomized, Open-Label, Active-Comparator Controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of XXX in Infants When Given at 2, 4, and 6 Months Concomitantly with XXX and XXX
63. A Phase III, Randomized, Partially Double-Blind, Active-Comparator-Controlled, Lot-to-Lot Consistency Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of XXX in Healthy Infants When Given at 2, 4, and 6 Months Concomitantly with XXX and XXX
64. An Immunogenicity and Safety Evaluation of XXX When Administered to Healthy Subjects at 9 Months and Concomitantly with XXX at 15 to 18 Months of Age
65. A Double-Blind, Randomized, Controlled, Multicenter Study to Evaluate the Safety, Tolerability, and Immunogenicity of a new Formulation of XXX
66. A phase IIIA, randomized, observer-blind, controlled, multinational study to evaluate the immunogenicity and safety of XXX at an end of shelf-life potency compared to XXX when both are co-administered with XXX, XXX, and XXX (subset of children), and given on a two-dose schedule to healthy children in their second year of life.
67. Assessment of Growth of Infants Fed an Amino Acid Based Formula
68. Growth and Tolerance of Young Infants Fed Infant Formulas
69. Safety and Immunogenicity of XXX Compared to XXX as the Fifth Dose in Children 4 to 6 Years of Age
70. A phase IIIb, open, randomized, controlled, multicenter study to assess the co-administration of XXX with XXX at 2 and 4 months of age, XXX with the co-administration of XXX at 2, 4, and 6 months of age and the co-administration of XXX with XXX at 12 to 15 months of age

Research Experience (continued):

71. A Phase 3, Randomized, Active-Controlled, Observer-Blinded Trial to Assess the Lot Consistency, Safety, Tolerability, and Immunogenicity of XXX in Healthy Subjects Aged ≥ 10 to ≥ 19 Years
72. A Randomized, Double-Blind, Parallel Design, Multiple-Site Study to Evaluate the Clinical Equivalence of XXX Compared to XXX in the Treatment of Acute Bacterial Otitis Media in Children with Patent Tympanostomy Tubes
73. Phase 2, Observer-Blind, Placebo-Controlled, Randomized, Multi-Center Extension Study to Evaluate the Safety and Immunogenicity of a Booster Dose of XXX Vaccine Administered 24 Months Following the Primary Series to Adolescents and Young Adults Who Participated in XXX
74. A Phase III, Stratified, Randomized, Observer Blind, Controlled, Multicenter Clinical Study to Evaluate the Safety, Immunogenicity and Efficacy of an Adjuvanted Quadrivalent Subunit Influenza Virus Vaccine Compared to Non-Adjuvanted Comparator Influenza Vaccine in Children ≥ 6 to <72 Months of Age
75. The Effects on Growth and Tolerance of a Routine Infant Formula Fed to Term Infants
76. A phase IIIA, randomized, observer-blind, controlled, multinational study to evaluate the safety and immunogenicity of XXX compared to XXX as a first dose, both co-administered with XXX, XXX and XXX in healthy children 12 to 15 months of age
77. A Phase 3, Randomized, Double-Blind, Active-Controlled, Parallel-Group Study of the Comparative Efficacy and Safety of XXX in Subjects with Acute Otitis Externa
78. A Phase II Study of the Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Healthy Adolescents
79. A Phase I-II, Randomized, Double-Blind, Study to Evaluate the Safety, Tolerability, and Immunogenicity of XXX in Healthy Adults and Infants
80. A Phase III, observer-blind, randomised, controlled, multi-centre study to evaluate the immunogenicity and safety of GSK Biologicals' quadrivalent influenza vaccine candidate, XXX, compared to Sanofi Pasteur's quadrivalent influenza vaccine XX, administered intramuscularly to children 6 to 35 months of age
81. Nutritive Effects of Prebiotics on Early Postnatal Behavioral Measures of Tolerance
82. A Phase I-II, Randomized, Double-Blind, Study to Evaluate the Safety, Tolerability and Immunogenicity of Different Formulations of XXX in Healthy Adults and Infants
83. A Phase II, Double-Blind, Randomized, Multicenter Trial to Evaluate the Safety, Tolerability, and Immunogenicity of XXX Compared to XXX in healthy Infants
84. A Phase 3, randomized, active-controlled, observer-blinded study to assess the immunogenicity, safety, and tolerability of XXX when administered as a 2-dose regimen and a first-in-human study to describe the immunogenicity, safety, and tolerability of a bivalent XXX containing pentavalent vaccine XXX in healthy subjects ≥ 10 to <26 years of age

Research Experience (continued):

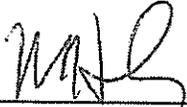
85. A Phase 3, Double-Blind, Randomized, Multicenter, Controlled Study to Evaluate the Immunogenicity, Safety, and Tolerability of XXX Process Administered Concomitantly with XXX
86. Growth and Tolerance of Young Infants Fed Amino Acid-Based Formulas
87. A phase IIIA, randomized, single-blind, multi-centric study to evaluate the immunogenicity, reactogenicity and safety of three doses of XXX, XXX and XXXX when co-administered with two doses of the PCV-free liquid formulation of XXX oral live attenuated HRV vaccine as compared to the currently licensed lyophilized formulation of the HRV vaccine in healthy infants 6-12 weeks of age.
88. A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Pivotal Study to Evaluate the Safety and Efficacy of XXX in Subjects (2 years and older) with *Molluscum Contagiosum*
89. Growth and Safety Study of an Infant Formula for Health Term Infants
90. A Phase IIIB, Observer-Blind, Randomized, Placebo-Controlled, Multi-Center Study to Assess the Safety and Immunogenicity of XXX Meningococcal Group B Vaccine and 13-valent Pneumococcal Vaccine when Administered Concomitantly with Routine Vaccines to Healthy Infants.
91. Effects of Addition to Infant Formula of XXX on Growth, Fecal Bacterial Populations, and Safety
92. Double-Blind, Randomized, Placebo-Controlled Phase 2b, Multi-center Study to Evaluate the Safety, Tolerability, Efficacy and Immunogenicity of a 2-Dose and a 3-Dose Regimen of XXX in Healthy Seronegative Women, 16 to 35 Years of Age
93. A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Interchangeability of XXX and XXX with Respect to Safety, Tolerability, and Immunogenicity in Healthy Infants
94. A Randomized Study to Describe the Safety of an Investigational XXX Vaccine Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers -Phase III
95. Immunogenicity and Safety Study of an Investigational XXX Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers -Phase III
96. Immunogenicity and Safety Study of an Investigational XXX Vaccine Administered in Healthy Infants and Toddlers
97. Gastrointestinal tract microbiome in healthy terms infants receiving mother's-own breast milk or cow's milk-based infant formulas
98. Evaluation of Preterm Infants Fed Post-Discharge Preterm Infant Formula with Added Human Milk XXX
99. Immunogenicity and Safety of a Booster Dose of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Adolescents and Adults
100. Evaluation of growth, safety, and efficacy of an infant formula for healthy term infants

Research Experience (continued):

101. A phase 3, randomized, active-controlled, observer-blinded trial to assess the safety, tolerability, and immunogenicity of MenACWY in healthy participants ≥ 10 to <26 years of age
102. A Phase 3, Multicenter, Randomized, Double-blind, Active-Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 4-dose Regimen of V114 in Healthy Infants (PNEU-PED)
103. Phase 3 International, Multi-center, Open-label Study to Evaluate the Tolerability and Immunogenicity of XXX Vaccine Administered as 2-dose Regimen with Extended Dosing Intervals in 9 to 14 Year-Old Boys and Girls Compared with a Standard 3-dose Regimen in 16 to 26 Year-Old Women
104. A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of XXX, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants
105. A Phase 2b Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of XXX, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants
106. A phase III, observer-blind, randomized, multi-country study to assess the reactogenicity and safety of the XXX free liquid formulation of GSK's oral live attenuated human rotavirus (HRV) vaccine as compared to the lyophilized formulation of the GSK's HRV vaccine, when administered as a 2-dose vaccination in infants starting at age 6-12 weeks.
107. Growth and Tolerance of a Partially Hydrolyzed Cow's Milk Protein (PHP) Infant Formula
108. A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Interchangeability of XXX and XXX with Respect to Safety, Tolerability, and Immunogenicity in Healthy Infants (PNEU-DIRECTION)
109. Growth and Safety Study of an Infant Formula for Health Term Infants
110. Evaluation of growth, safety, and efficacy of an infant formula for healthy term infants
111. A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with XXX Adjuvant in Adult Participants ≥ 18 Years with a Pediatric Expansion in Adolescents (12-17 Years)
112. Immunogenicity and Safety Study of an Investigational XXX Meningococcal Conjugate Vaccine Administered in Healthy Infants and Toddlers
113. Prospective Collection of Biological Samples from Pediatric Subjects for Research (Birth-17 Years)
114. A randomized, controlled, double-blind study to demonstrate that an infant formula supports normal physical growth in healthy term infants
115. Immunogenicity and Safety of XXX Recombinant Influenza Vaccine Compared with Egg-Based Standard-Dose XXX Influenza Vaccine in Children 3 to 8 Years of Age.

Research Experience (continued):

116. Immunogenicity and Safety of XXX Recombinant Influenza Vaccine (XXX) in Children and Adolescents Aged 9 to 17 Years and Adults Aged 18 to 49 Years.
117. A Phase II, single-blind, randomized, controlled study to evaluate the immunogenicity and safety of a measles, mumps, rubella, varicella vaccine compared with XXX, administered in healthy children 4 to 6 years of age.



Max Howard Hale, MD

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Date

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