

Devon R. Kuehn, MD, FAAP
Curriculum Vitae

Chief Medical Officer
Paidion Research, Inc.
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Durham, NC 27707
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SUMMARY

Board certified neonatologist and pediatrician with over 15 years of research experience and 5 years of managing all aspect of clinical research operations, fiscal performance, and strategic development. I have been responsible for the successful execution of over approximately 20 Phase II-IV clinical trials at a single US academic site with \$2M in funding. I have also designed and conducted over 20 basic and clinical trials supported by over \$0.5M in funding and mentored 10 trainees through clinical research projects.

EXPERIENCE

MEDICAL MONITOR, PAIDION RESEARCH
DURHAM, NC

SEPT 18 - PRESENT

- Provides medical expertise and medical support including, but not limited to: clinical feasibility assessments for trials, medical training for clinical operations and study staff, medical review of data collection forms and subsequent medical coding
- Serves as medical monitor for clinical trials, ensuring and monitoring the safety of enrolled subjects for assigned clinical trials/projects; function as medical representative on the project team; provide medical consultation as required or requested to client
- Provides medical input into the design of clinical protocols (in coordination with Clinical Operations with emphasis on medical/scientific and safety matters) and clinical development plans
- Contributes medical input and review of regulatory documents such as IND filings, IND annual reports, NDAs, PIPs, PSPs, and EU regulatory submissions
- Represents Paidion Research to outside medical/scientific experts in the development of the clinical protocols, solicitation of input and opinion, recruitment of investigators for clinical trials, and presentation of abstracts
- Keeps abreast of current medical/scientific progress and actively develops and maintains relationships with outside experts aligned with the scientific/medical objectives

CLINICAL PROJECT MANAGER, PAIDION RESEARCH
DURHAM, NC

SEPT 18 - PRESENT

- Successfully plan, implement and execute the contracted activities for the clinical trial through start-up activities, monitoring activities including on-site and in-house activities and assess protocol, regulatory and SOP compliance
- Build cross-functional project teams and lead their efforts to support milestone achievement and to manage study issues and obstacles
- Maintain accountability for the execution of the clinical studies per contract while optimizing speed, quality and cost of delivery
- Ensuring consistent use of study tools and training materials in compliance with standard policies and procedures
- Manage risk and contingencies proactively and lead problem solving and resolution efforts

VICE CHAIR FOR RESEARCH, DEPARTMENT OF PEDIATRICS, EAST CAROLINA UNIVERSITY
GREENVILLE, NC

NOV 16 - PRESENT

- Advisor of strategic development, management and financial performance for the department's research portfolio
- Develop annual reports and programmatic targets
- Built and restructured a team of 20 research staff, including 2 directors, 2 managers and 16 study coordinators
- Serve as an alternate member of the University and Medical Center Institutional Review Board
- Clinically active in neonatology through overnight call coverage and attending academic seminars

DIRECTOR OF RESEARCH, DEPARTMENT OF PEDIATRICS, EAST CAROLINA UNIVERSITY
GREENVILLE, NC

NOV 16 - JUL 18

- Developed the first 5-year plan for the Department of Pediatrics research portfolio incorporating strategies for growth, management, regulatory compliance, and external funding development
- Responsible for the daily operations, financial performance, regulatory compliance, and strategic development for approximately 35 clinical trials
- Managed 10-15 study coordinators, providing necessary training and professional development, strategic hiring, and effort management
- Implement process improvements to enhance productivity, efficiency and regulatory compliance
- Mentored 5 pediatric staff through project design, regulatory approval and study execution
- Serve as an alternate member of the University and Medical Center Institutional Review Board
- Clinically active in neonatology through overnight call coverage and attending academic seminars

DIRECTOR OF NEONATAL RESEARCH, DEPARTMENT OF PEDIATRICS, EAST CAROLINA UNIVERSITY
GREENVILLE, NC JAN 13 - NOV 16

- Initiated a clinical trials program, growing the program from no ongoing clinical trials to 10 funded pharmaceutical trials
- Mentored 7 trainees through successful design and execution of clinical research projects
- Grew the research support staff from one study coordinator to five study coordinators
- Continued clinical neonatology through overnight call coverage and participating in academic seminars

CLINICAL NEONATOLOGIST, WALTER REED NATIONAL MILITARY MEDICAL CENTER
BETHESDA, MD JULY 11 - SEPT 12

- Mentored 3 trainees through successful design and execution of clinical research projects
- Vice Chair for the Institutional Review Board
- Provided intensive medical care to premature and term infants to include ventilator management, vasopressor support and life saving measures
- Develop a third-year medical student experience and education session in the Neonatal Intensive Care Unit

POST-DOTORAL FELLOWSHIP, NIH JULY 09 - OCT 12
DEPARTMENT OF EPIDEMIOLOGY, STATISTICS, AND PREVENTION RESEARCH, *EUNICE KENNEDY SHRIVER* NICHD
BETHESDA, MD

- Designed methodology and conducted statistical analysis on genomic changes in infants with birth defects
- Formulated approach and conducted analysis of data of infants exposed to alcohol during pregnancy

EDUCATION

PERINATAL NEONATAL FELLOWSHIP JUNE 2011
WALTER REED NATIONAL MILITARY MEDICAL CENTER, BETHESDA, MD

PEDIATRIC RESIDENCY JUNE 2008
WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC

MEDICAL DOCTORATE MAY 2005
UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, BETHESDA, MD

BACHELOR OF ARTS (BIOLOGY) MAY 2001
UNIVERSITY OF VIRGINIA, CHARLOTTESVILLE, VA

CONTINUING EDUCATION

Masters in Clinical Research, (12 credit hours) Duke University/NIH Clinical Research Training Program

Statistics I and II (6 credit hours) NIH, Foundation for Advanced Education in the Sciences

LICENSURE AND PROFESSIONAL AFFILIATIONS

Board Certified Neonatologist, American Board of Pediatrics

Board Certified Pediatrician, American Board of Pediatrics

Licensed Physician, North Carolina and Virginia

Fellow, American Academy of Pediatrics

AWARDS AND HONORS

Alpha Omega Alpha Honor Medical Society, Uniformed Services University of the Health Sciences

Southern Society for Pediatric Research Young Investigator Award

Outstanding Fellow Award, National Capital Consortium

Major General Lewis A. Mologne Award, Walter Reed Army Medical Center

PUBLICATIONS

Novonty WE, Ledoux MR, Keel CP, and **Kuehn D**. Can profound hypernatremia ever be a good thing? 2017. 4(1):93-96.

Stokes TA, **Kuehn D**, Hood M, Biko DM, Pavey A, Olsen C, and Hunt CE. *The clinical utility of anthropometric measures to assess adiposity in a cohort of prematurely born infants: Correlations with MRI fat quantification.* J Neonatal Perinatal Med. 2017. 10(2):133-138. PMID: 28409754

Guest JF, Moya F, Sisk PM, Hidak ML, and **Kuehn D**. *Relative cost-effectiveness of using a liquid human milk fortifier in preterm infants in the US.* ClinicoEconomic and Outcomes Research. 2017. 9:49-57. PMID: 28115859

Ravisankar S, **Kuehn D**, Clark RH, Greenberg RG, Smith PB, Hornik CP. *Antihypertensive drug exposure in premature infants from 1997 to 2013.* Cardiol Young. October 2016. 1-7. PMID: 27748228

Lozada LE, Nylund CM, Gorman GH, Hisle-Gorman E, Erdie-Lalena CR, **Kuehn D**. *Association of Autism Spectrum Disorders with Neonatal Hyperbilirubinemia.* Global Pediatric Health. 2015. 2:1-5. PMID: 27335973

Juanita A Yerry, **Devon Kuehn**, and Alan G Finkel. *Onabotulinum Toxin A for the Treatment of Headache in Service Members with a History of Mild Traumatic Brain Injury: A Cohort Study.* Headache. 2015. 55(3):395-406. PMID: 25644249

Ashleigh R Pavey, Gregory H Gorman, **Devon Kuehn**, MD, Theophil A Stokes, Elizabeth Hisle-Gorman. *Intimate Partner Violence Increases Adverse Outcomes at Birth and in Early Infancy.* J Pediatr. 2014. 165(5):1034-1039. PMID: 25128162

Nicole R Dobson, Ravi M Patel, P Brian Smith, **Devon R Kuehn**, Jennifer Clark, Shilpa Vyas-Read, Amy Herring, Matthew M Laughon, David Carlton, and Carl E Hunt. *Trends in Caffeine Use and Association between Clinical Outcomes and Timing of Therapy in Very Low Birth Weight Infants*. J Pediatr. 2014. 164(5):992-998. PMID: 24461786

Hickey PW, **Kuehn DR**, Aviles R, Yu C, Watson CM, Medina R, Lopez M. *Knowledge, Attitudes, and Practice Regarding HIV Testing among Female Military Family Members of Child-Bearing Age in Honduras*. Military Medicine. 2013. 178(10): 1126-1132. PMID: 24083927

Plunkett A, **Kuehn D**, Lenart M, Wilkinson I. *Opioid maintenance, weaning and detoxification techniques: where we have been, where we are now and what the future holds*. Pain Manage. 2013. 3(4): 277-83. PMID: 24654813

Carter TC, Kay DM, Browne, ML, Liu A, Romitti PA, **Kuehn D**, Conley MR, Caggana M, Druschel CM, Brody LC, Mills JL. *Anorectal atresia and Variants at Predicted Regulatory Sites in Candidate Genes*. Ann Hum Genet. 2012. 77(1):31-46. PMID: 23127126

Browne ML, Carter TC, Kay DM, **Kuehn D**, Brody LC, Romitti PA, Liu A, Caggana M, Druschel CM, and Mills JL. *Evaluation of genes involved in limb development, angiogenesis, and coagulation as risk factors for congenital limb deficiencies*. American Journal of Medical Genetics. 2012. 158A(10):2463-72. PMID: 22965740

Carter TC, Kay DM, Browne, ML, Liu A, Romitti PA, **Kuehn D**, Conley MR, Caggana M, Druschel CM, Brody LC, Mills JL. *Hirschsprung's disease and variants in genes that regulate enteric neural crest cell proliferation, migration and differentiation*. Journal of Human Genetics. 2012. 57(8):485-93. PMID: 22648184

Kuehn D and Aros S, Cassorla F, Avaria M, Unanue N, Henriquez C, Kleinstaub K, Conca B, Avila A, Carter TC, Conley MR, Troendle J, Mills JL. *A prospective cohort study of the prevalence of growth, facial and central nervous system abnormalities in children with heavy prenatal alcohol exposure*. Alcoholism-- Clinical and Experimental Research. 2012. 36(10):1811-19. PMID: 22823161

Kuehn D, Roberts SS, Olsen C, Harvery DN, Charnock KM, Brewer BD, Maliakel PG, and Lopreiato J. *Reticulocyte Hemoglobin Content Testing for Iron Deficiency in Healthy Toddlers*. Military Medicine. 2012. 177(1): 91-95. PMID: 22338987

Cornman-Homonoff J, **Kuehn D**, Aros S, Carter TC, Conley MR, Troendle J, Cassorla F, Mills JL. *Heavy prenatal alcohol exposure and risk of stillbirth and preterm delivery*. J Matern Fetal Neonatal Med. 2012. 25(6):860-3. PMID: 21728738

Rohena L, **Kuehn D**, Marchegiani S, Higginson J. *Evidence for Autosomal Dominant Inheritance of Ablepharon Macrostomia Syndrome*. Am J Med Genet A. 2011. 155(4):850-4. PMID: 21595001

Kuehn D, May J, Bauer AJ. *Phospho-soda induced symptomatic hypocalcemia in a patient with cystic fibrosis and vitamin D malabsorption*. J Pediatr Gastroenterol Nutr. 2008. 47(5):514-6. PMID: 18852647

Kuehn D, Kunz A, Rajnik M. Resident Rounds: *A case of lyme arthritis*. Infectious Diseases in Children. 2007. 20:12. 7, 30-32.

PRESENTATIONS

Kuehn D, Kay DM, Pangilinan F, Browne ML, Carter TC, Liu A, Romitti PA, Caggana M, Druschel CM, Brody LC, Mills JL. *Vitamin A pathway genes linked to congenital diaphragmatic hernia*. Platform Presentation. Pediatric Academic Societies' Annual Meeting. Boston, MA. April 2012.

Kuehn D, Aros S, Carter T, Conley M, Troendle J, Cassorla F, Mills JL. *Heavy prenatal exposure to alcohol and the risk for growth, facial and neurologic abnormalities in children*. Platform Presentation. Pediatric Academic Societies' Annual Meeting. Denver, CO. May 2011.

Kuehn D, Aros S, Carter T, Conley M, Troendle J, Cassorla F, Mills JL. *Heavy prenatal exposure to alcohol and the risk for growth, facial and neurologic abnormalities in children*. American Academy of Pediatrics, Uniformed Services Pediatric Seminar Annual Meeting. Washington, DC. March 2011.

Kuehn D, Aros S, Carter T, Conley M, Troendle J, Cassorla F, Mills JL. *Heavy prenatal exposure to alcohol and the risk for growth, facial and neurologic abnormalities in children*. Conference on Military Perinatal Research. Austin, TX. November 2010.

Kuehn D, Aros S, Carter T, Conley M, Troendle J, Cassorla F, Mills JL. *Heavy prenatal exposure to alcohol and the risk for growth, facial and neurologic abnormalities in children*. Mid-Atlantic Conference on Perinatal Research. Hershey, PA. September 2010.

Kuehn D, Lopreiato J. *Use of Reticulocyte Hemoglobin Content to Identify the Prevalence of Iron Deficiency Among Toddlers in a General Population*. Platform Presentation. Pediatric Academic Societies' Annual Meeting. Waikiki, HI. May 2008.

Kuehn D, Lopreiato J. *Prevalence of Iron Deficiency Anemia among Toddlers in a Uniformed Services Population*. American Academy of Pediatrics, Uniformed Services Pediatric Seminar Annual Meeting. Waikiki, Hawaii. March 2008.

Kuehn D, Lopreiato J. *Use of Reticulocyte Hemoglobin Content to Identify the Prevalence of Iron Deficiency Among Toddlers in a General Population*. Academic Pediatric Association Region IV Annual Meeting. Charlottesville, VA. January 2008.

Kuehn D, Patel A, Jensen K, Bauer AJ, Vasko VV. *The role of integrin linked kinase (ILK) expression in early events of thyroid tumorigenesis*. American Academy of Pediatrics, Uniformed Pediatric Society Annual Meeting. Bethesda, MD. March 2007.

Jensen K, Kuehn D, Patel A, Bauer AJ, Vasko VV. *E-Cadherin gene promoter methylation in papillary thyroid cancer and in lymph node metastases*. American Academy of Pediatrics, Uniformed Services Pediatric Society Annual Meeting. Bethesda, MD. March 2007.

Balog E, Newton T, Kuehn D, Holston A, Creamer K. Pediatrics in the Military. Presentation to American Academy of Pediatrics, District 1 and 10 Annual Meeting. August 2007.

INVITED LECTURES

Pediatric Clinical Trials Review and Patient Forum. PhRMA Research in Your Backyard. East Carolina University. Greenville, NC. Oct 2017.

A novel clinical trials unit model. University of North Carolina. Chapel Hill, NC. Oct 2017.

Etiologies of birth defects. University of Virginia. Charlottesville, VA. Sept 2011.

CLINICAL RESEARCH EXPERIENCE

Children's Miracle Network. Vidant Foundation. Neonatal Brain Structure and Function following In Utero Opioid or Marijuana Exposures.

East Carolina University RCAA Grant. Assessment of associations between folate, vitamin B12 and omega-3 fatty acid status and postpartum depression.

East Carolina University IRA Grant. Detection of Drugs in Neonatal Umbilical Cords using Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) to Quantify Exposure During Pregnancy, Determine Risk of Neonatal Abstinence Syndrome (NAS) and Association with Neonatal Outcomes.

Nutrinia. Study to Assess the Efficacy and Safety of NTRA-2112 on Intestinal Malabsorption in Preterm Infants.

SunTech Medical. Clinical Validation of SunTech Advantage 2 with Neonate Cuff Line against Invasive Intra-Arterial Reference.

ONY Inc. Comparison of Aerosol Delivery of Infracurf to Usual Care in Spontaneously Breathing RDS Patients.

Lyric Pharmaceuticals. Determination of Alpha-1 Acid Glycoprotein Levels in Neonatal and Pediatric Intensive Care Unit Patients.

Discovery Labs, Inc. A Multinational, Multicenter, Masked, Randomized, Controlled Study to Assess the Safety and Efficacy of Lucinactant for Inhalation in Preterm Neonates 26 to 32 Weeks Gestational Age with Respiratory Distress Syndrome.

Chiesi. A Multicenter, Double Blind, Randomized, Single Dose, Active-Controlled Study to Investigate the Efficacy and Safety of Synthetic Surfactant (CHF 5633) in Comparison to Porcine Surfactant (Curosurf®) in the Treatment of Preterm Neonates with Respiratory Distress Syndrome.

East Carolina University. Metabolic acidosis study in preterm neonates on acidified liquid human milk fortifier.

Shire. Determination of the rhIGF-1/rhIGFBP-3 Dose, Administered as a Continuous Infusion, Required to Establish and Maintain Longitudinal Serum IGF-1 Levels Within Physiological Levels in Premature Infants, to Prevent Retinopathy of Prematurity.

NICHHD, PTN Trials Network. Antibiotic Safety in Infants with Complicated Intra-Abdominal Infections (SCAMP Trial).

Mead Johnson. Method of fortification and impact on length of stay. An analysis nested within a randomized trial.

Department of Defense Congressionally Directed Medical Research Programs. Autism Research Program. Risk Factors, Co-morbid Conditions, and Epidemiology of Autism in Children.

Eunice Kennedy Shriver National Institute of Child Health and Human Development. University of Chile/NICHHD Alcohol in Pregnancy Study.

Eunice Kennedy Shriver National Institute of Child Health and Human Development. New York State Birth Defects Study.

Walter Reed National Military Medical Center Department of Research Programs. Does the increased ponderal index persist after the NICU?

Walter Reed National Military Medical Center Department of Research Programs. Anthropometric and nutritional correlations with neonatal fat distribution and quantification by MRI/MRS.

Walter Reed National Military Medical Center Department of Research Programs. Timing and cause of death of infants born on the edge of viability.

Uniformed Services University. Caffeine Use in the NICU: A Retrospective Chart Review.

Walter Reed Army Medical Center Department of Clinical Investigation and National Naval Medical Center. Prevalence of Iron Deficiency via Reticulocyte Hemoglobin Content in Toddlers.