

DORIS J. ROUSE

Summary of Professional Experience

Doris Rouse is the Vice President of RTI International's Center for Global Health. She manages the coordination of diverse disciplines to address major global health needs with a focus on maternal and child health as well as infectious diseases. Dr. Rouse has been the Project Director for three Bill & Melinda Gates Foundation grants, including the development of the MANDATE model to inform decision making on maternal and neonatal technology investments. She has extensive experience in forming public and private consortia. For example, she has contributed to the formation and activities of the Global Alliance for TB Drug Development (TB Alliance), an international public/private consortium to develop new drugs for tuberculosis. In her tenure as Director of the Center for Technology Applications at RTI, she managed technology assessment, outlicensing, and technology sourcing projects for numerous government and corporate clients. Product areas addressed in these projects included medical diagnostics and therapeutics, assistive devices, sensors, communication technologies, and materials. Dr. Rouse served on the national bioengineering advisory board for the Association for Retarded Citizens (now ARC) and chaired an American National Standards Institute committee for development of wheelchair safety and effectiveness standards.

Education

Program for Technology Managers, Kenan-Flagler Business School, University of North Carolina, Chapel Hill, NC, 1990.

PhD, Physiology and Pharmacology, Duke University, Durham, NC, 1980.

BA, Chemistry, Duke University, Durham, NC, 1970.

Selected Project Experience

GSK Models Preterm Birth and Maternal Health (2014 to 2016)—*Project Director*. Funded by GlaxoSmithKline, RTI is supporting GSK's international maternal and child health initiatives by conducting literature reviews and surveys and modeling potential benefits for specific interventions in low- and middle-income countries.

Model for Assessment of Pediatric Interventions for Tuberculosis (MAP-IT) (2015-date). Co-PI. Funded by the Global Alliance for TB Drug Development and UNITAID, RTI is adapting the MANDATE model to assess impact of prevention, diagnostic and treatment interventions on the reduction of pediatric tuberculosis.

Understanding the Role of Partnerships in Medical Product Development (2012 to date)—*Project Director*. Funded by the Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, this project is examining various types of partnerships among and between entities within the public and private sectors and their outcomes with respect to supporting drug development. It is important to understand various partnership models and their relative success as a means to determine how they can be used to spur medical product development.

Maternal and Neonatal Directed Assessment of Technology (MANDATE) (2009 to 2014)—*Project Director*. This project, funded by the Bill & Melinda Gates Foundation, is assessing major causes of maternal and neonatal morbidity and mortality in low-resource settings and evaluating the feasibility and impact of technologies for prevention or treatment. Model (<http://mnhitech.org>) has been accessed by more than 60,000 users in 185 countries. RTI has adapted MANDATE to model averted pregnancies in Zimbabwe (the ZAP model).

Global Alliance for TB Drug Development (2002 to date)—*Project Director*. Supporting the TB Alliance, Dr. Rouse served as the initial project manager for the development of a drug candidate, PA-824, in a new series of compounds with promising potential for improved treatment of tuberculosis. In this role, Dr. Rouse prepared a development plan, managed the preclinical studies, and managed the Investigational New Drug application preparation. Currently, Dr. Rouse leads an RTI team supporting the TB Alliance in preclinical, clinical, and regulatory activities to advance a portfolio of new drugs for treatment of tuberculosis.

Medication Initiative for Tobacco Dependence: A New Product Development Partnership (2011 to 2012)—*Principal Investigator*. The National Institute on Drug Abuse planned to establish an innovative Product Development Partnership, entitled “Medication Initiative for Tobacco Dependence (MITD),” to accelerate the development of more effective antismoking medications by leveraging the strengths and resources of public, non-profit, and private-sector organizations. In this initial phase, RTI established a business plan and partners for the formation and operation of MITD.

European and Developing Country Clinical Trial Partnership: TB Consortium Support (2008)—*Project Director*. With support from the Bill & Melinda Gates Foundation, Dr. Rouse served as a coordinator to bring together three groups planning clinical trials for tuberculosis therapies with 12 sub-Saharan Africa sites to conduct clinical trials. The outcome was a consortium entitled PanACEA: Pan African Consortium for Evaluation of Antimicrobial Antibiotics. Dr. Rouse led the preparation of a proposal for this European–African consortium to conduct clinical trials on new drugs to shorten and simplify the treatment of tuberculosis. The proposal was submitted to the European and Developing Countries Clinical Trials Program and funding for this consortium was approved in August 2008.

Venture Investment Technical Assistance (VITA) (2007 to 2011)—*Project Director*. With support from the Bill & Melinda Gates Foundation, this 3-year grant provided technical and business assistance for a venture capital firm’s portfolio companies to encourage them to develop devices, diagnostics, and information technology solutions appropriately tailored for underserved markets in developing countries.

Tuberculosis Technology Transfer Support, contract with the National Institute of Allergy and Infectious Diseases (NIAID) (2000 to 2011)—*Principal Investigator*. The goal of this multidisciplinary project was to facilitate the development and commercialization of new tuberculosis treatments. In the initial year of the contract, Dr. Rouse assisted in the formation and ongoing operation of the TB Alliance. Ongoing activities under this contract included the identification of candidate anti-TB compounds, preparation of dossiers, and discussions with industry and academic labs to establish collaborations for compound development. With NIAID support, RTI supported the TB drug development program of the Lilly Initiative for TB Drug Discovery, a collaboration between Lilly and NIAID through a subcontract with SRI International.

Working Group on Economics of TB Drug Development (2000 to 2001)—*Secretariat*. Dr. Rouse served as secretariat for an international working group to prepare a report entitled “Economics of TB Drug Development.” Responsibilities included developing the content strategy and process for the study,

selecting and managing consultants, developing working group consensus, identifying and developing collaborations with key data sources, reviewing content, and presenting a final report.

American National Standards Institute Committee on Wheelchair Standards (1983 to 1986)—*Chair*. Dr. Rouse organized and developed funding support for the development of international safety and efficacy standards for wheelchairs. She developed support and participation by the U.S. Food and Drug Administration, wheelchair manufacturers, the Veterans Administration, International Standards Organization (ISO), and consumer groups. The committee produced ISO standards for wheelchair safety and efficacy.

National Aeronautics and Space Administration (NASA) Technology Applications Team (1980 to 2000)—*Director*. Under Dr. Rouse's management, project staff worked with industry, associations, user groups, federal agencies, and NASA engineers to adapt aerospace technology to meet priority national technology needs. In 2000, NASA awarded the RTI Applications Team the NASA Public Service Group Achievement Award.

Professional Experience

1976 to date	RTI International, Research Triangle Park, NC. <u>Vice President</u> , Global Health (2007 to date). <u>Director</u> , Global Health Technologies (2001 to 2007). <u>Director</u> , Center for Technology Applications (1983 to 2000). <u>Research Physiologist</u> (1976 to 1983).
2013 to date	University of North Carolina, Chapel Hill, NC. Gillings School of Public Health <u>Adjunct Professor</u>
1971 to 1976	Burroughs Wellcome Company, Durham, NC. <u>Research Scientist</u>
1970 to 1971	U.S. Peace Corps, Liberia. <u>Volunteer</u> (science teacher).

Honors and Awards

RTI Knox Award for Excellence. 2014
Triangle Business Journal, Women in Business Award for Innovation. 2014.
RTI President's Award, 2003, 2004, and 2005
NASA Public Service Group Achievement Award, 2000
NASA Marshall Space Flight Center Technology Transfer Award, 2000
Distinguished Service Award, Rehabilitation Engineering Society of North America, 1984
NASA Public Service Group Achievement Award, 1979
Who's Who in America
Who's Who in Medicine and Healthcare
Who's Who in the World

Professional Associations

Member, United Nations Every Woman, Every Child Innovation Working Group, 2012 to date
Member, Global Health Advisory Committee, University of North Carolina, 2006 to 2013
Co-Chair, Symposium on Technology for Maternal, Newborn and Child Health, New York, October 22, 2012
Member, STOP-TB Working Group on New Drugs, 2004 to date.
Member, Advisory Board, Academy Venture Fund, 2000 to 2002
Member, Board of Directors, North Carolina Technology Development Initiative, 2001 to 2004
Member, Advisory Panel, Consumer Assistive Technology Network, 1997 to 2000
Member, RTI Scientific Integrity Committee, 1996 to 2004
Member, Advisory Committee on the Development and Transfer of Biotechnology, North Carolina Biotechnology Center, 1992 to 1996
Board Member, Simon Foundation, 1985 to 1995
Member, Tenneco Innovation Award Review Panel, 1997 to 1998
Member, Advisory Panel, Assistive Technology Research Center, National Rehabilitation Hospital, 1994 to 1996
Chair, RTI Institutional Review Board, 1990 to 1995
Associate Editor, International Journal of Technology and Aging, 1989 to 1995
Member, National Forum on Technology and Aging, 1986 to 1988
Chair, Wheelchair Standards Technical Advisory Group, American National Standards Institute, 1983 to 1986
Member, Advisory Design Committee, Association for Retarded Citizens (now ARC), 1982 to 1986
Member, Technology and Aging Information Advisory Panel, Western Gerontology Society, 1982 to 1984
Chair, Wheelchair Committee, Rehabilitation Engineering Society of North America, 1981 to 1986

Languages

French

Country Experience

Liberia, Brunei

Peer-Reviewed Journal Articles

Kamath-Rayne, B. D., Griffin, J. B., Moran, K. H., Jones, B. M., Downs, A., McClure, E. M., Goldenberg, R., Rouse, D. J., & Jobe, A. H. (in press). Resuscitation and obstetrical care to reduce intrapartum-related neonatal deaths: A MANDATE study. *Maternal and Child Health Journal*. Advance online publication. doi:10.1007/s10995-015-1699-9

Goldenberg, R. L., Jones, B. M., Griffin, J. B., Rouse, D. J., Kamath-Rayne, B. D., Trivedi, N. M., & McClure, E. M. (in press). Reducing maternal mortality from preeclampsia and eclampsia in low-resource countries—what should work? *Acta Obstetrica et Gynecologica Scandinavica*.

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- McClure, E. M., Jones, B. M., Rouse, D. J., Griffin, J. B., Kamath-Rayne, B. D., Downs, A., & Goldenberg, R. L. (in press). Tranexamic acid to reduce postpartum hemorrhage: A MANDATE systematic review and analyses of impact on maternal mortality. *American Journal of Perinatology*.
- Winter, H., Egizi, E., Murray, S., Erondy, N., Ginsberg, A., Rouse, D. J., et al. (2015). Evaluation of the pharmacokinetic interaction between repeated doses of rifapentine or rifapicin and a single dose of bedaquiline in healthy adult subjects. *Antimicrobial Agents and Chemotherapy*, *59*(2), 1219–1224. doi:10.1128/AAC.04171-14
- McClure, E. M., Rouse, D. J., MacGuire, E. R., Jones, B. M., Griffin, J. B., Jobe, A. H., Kamath-Rayne, B., Shaffer, C., & Goldenberg, R. (2013). The MANDATE model for evaluating interventions to reduce postpartum hemorrhage. *International Journal of Gynecology and Obstetrics*, *2*, 10–30.
- Winter, H., Egizi, E., Erondy, N., Ginsberg, A., Rouse, D. J., Severynse-Stevens, D., et al. (2013). Evaluation of pharmacokinetic interaction between PA-824 and midazolam in healthy adult subjects. *Antimicrobial Agents and Chemotherapy*, *57*(8), 3699.
- Diacon, A. H., Dawson, R., Hanekon, M., Narunsky, K., Maritz, S., Venter, A., Donald, P. R., van Niekerk, C., Whitney, K. D., Rouse, D. J., Laurenzi, M. W., Ginsberg, A. M., & Spigelman, M. K. (2010). Early bactericidal activity and pharmacokinetics of PA-824 in smear-positive tuberculosis patients. *Antimicrobial Agents and Chemotherapy*, *54*, 3402–3407.
- Ginsberg, A. M., Laurenzi, M. W., Rouse, D. J., Whitney, K. D., & Spigelman, M. K. (2009). Assessment of the effects of the nitroimidazo-oxazine PA-824 on renal function in healthy subjects. *Antimicrobial Agents and Chemotherapy*, *53*, 3726–3733.
- Ginsberg, A. M., Laurenzi, M. W., Rouse, D. J., Whitney, K. D., & Spigelman, M. K. (2009). Safety, tolerability, and pharmacokinetics of PA-824 in healthy subjects. *Antimicrobial Agents and Chemotherapy*, *53*, 3720–3725.
- Rouse, D. J. (1991). Technology twice used: NASA spinoffs for health & medicine. In E. Bernstein (Ed.), *Encyclopedia Britannica medical and health annual*. Chicago, IL: Encyclopedia Britannica.
- Rouse, D. J.; Winfield, D. L.; Canada, S. C. (1991). NASA Spinoffs to Bioengineering and Medicine. *Acta astronautica*, *25*(2), 103–110.
- Rouse, D. J. (1990). Futurist technology improves care of the elderly. *Geriatrics*, *45*, 68–72.
- Rouse, D. J. (1988). Critical factors in technology transfer. In G. R. Bopp (Ed.), *Federal lab technology transfer: Issues and policies*. New York, NY: Praeger.
- Rouse, D. J. (1988). Translations of technologies to meet needs of the elderly. In *Aging in a technological society*. New York, NY: Human Science Press.
- Winfield, D. L., Trachtman, L. H., & Rouse, D. J. (1988). Space solutions for earthbound medical problems. *Soma*, *2*, 42–48.
- Rouse, D. J. (1986). Technology transfer. *Generations*, *11*, 15–17.
- Rouse, D. J., Brown, N., Jr., & Whitten, R.P. (1981). Methodology for NASA technology transfer in medicine. *Medical Instrumentation*, *15*, 234–236.
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- Rouse, D. J., & Lack, L. (1980). Short-term studies of taurocholate uptake by ileal brush border membrane vesicles. *Biochimica et Biophysica Acta*, 599, 324–329.
- Rouse, D. J., & Lack, L. (1979). Ionic requirements for taurocholate transport by ileal brush border membrane vesicles. *Life Science*, 25, 45–52.
- Rouse, D. J., & Brent, D. A. (1974). Field desorption mass spectrometry of ten medicinal carbamates. *Biomedical Mass Spectrometry*, 1, 256–262.
- Brent, D. A., Rouse, D. J., Sammons, M. C., & Bursey, M. M. (1973). Field desorption mass spectrometry: Quaternary ammonium salts. *Tetrahedron Letters*, 42, 4120–4130.

Selected Technical Reports and Publications

- Rouse, D. J., & Curran, C. (2003). *Factors in the success of health franchises*. WHO Working Group on Select Diseases. Committee on Health Franchising.
- Rouse, D. J. (Working Group secretariat). (2001). *Economics of tuberculosis drug development*. Global Alliance for TB Drug Development. New York, NY.
- Rouse, D. J. (1996). New competitive realities demand new ways of doing business. *Technology Transfer Business Magazine*, September.
- Rouse, D. J., & Dix, M. O. (1994). Industry association/government partnerships: A model for meeting industry-wide technology needs. In *Proceedings of the Technology Transfer Society annual meeting*. Indianapolis, IN: Technology Transfer Society.
- Brent, D. A., & Rouse, D. J. (1973). Analysis of a mixture via mass spectrometry: Varian application notes: Varian CHGDF/MAT311. Application Note 12.

Presentations

- Rouse, D. J. (2013 November). MANDATE workshop. *WHO Second Global Forum on Medical Devices*, Geneva, Switzerland.
- Rouse, D. J. (2013 January). *Global health product development*. Carolina Innovations Seminar, University of North Carolina, Chapel Hill, NC.
- Rouse, D. J. (2012 December). *Global health: Trends and relevance to N.C.* NC Joint Legislative Oversight Committee on Health and Human Services, Raleigh, NC.
- Rouse, D. J. (2011 April). *MANDATE: Defining maternal and neonatal product needs and profiles*. Unite for Site Conference, New Haven, CT.
- Rouse, D. J. (2011 November). *MANDATE: Informing maternal and neonatal technology investment priorities*. In *Grand Challenges in Global Health (Bill & Melinda Gates Foundation)*. New Delhi, India.
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- Rouse, D. J. (2011 September). *MANDATE: Defining maternal and neonatal product needs and profiles*. Poster Session. In *WHO First Global Forum on Medical Devices*, Bangkok, Thailand.
- Rouse, D. J., (2010, June). *MANDATE: Defining clinical opportunities and product profiles*. In *Pacific Health Summit, Post-Summit workshop: MNCH technologies: Moving innovation toward product development*. London, UK.
- Holden, E. W., Hoerger, T. J., Trisolini, M., Rouse, D. J., & Wetterhall, S. F. (2010 February). *Influencing the economics of health care*. Background paper and presentation at the Jeddah Economic Forum, Dubai, United Arab Emirates.
- Rouse, D. J. (2008, November 7). *Strategies for sustainable global health product development*. Duke University Conference on Bioengineering Applications to Address Global Health, Durham, NC.
- Rouse, D. J. (2004, October 31). *PA-824 and analogs*. International Union Against Tuberculosis and Lung Disease (IUATLD). World Conference on Lung Health, Paris.
- Rouse, D. J. (2003, June 23). *Tuberculosis drug development: PA-824, in session*. Adding value through partnering: BioPharma companies contributing to global health. Biotechnology Industry Organization Conference, Washington, DC.
- Rouse, D. J. (2002, May 20). *Who should develop new drugs for tuberculosis and malaria?* International Society for Pharmacoeconomics and Outcomes Research. Issues Panel Chair, Crystal City, VA.
- Rouse, D. J. (2002, March 26). *Public-private partnerships for tuberculosis drug development*. WHO Conference on Biotechnology and Genomics for Improvement of Health in Developing Countries, Havana, Cuba.
- Rouse, D. J. (2001, November 4). *Economics of tuberculosis drug development*. 32nd IUATLD World Conference on Lung Health, Paris, France.
- Rouse, D. J. (2001, May 1). *Technology marketing*. Federal Laboratory Consortium National Meeting. Session Chair, Burlington, VT.
- Rouse, D. J. (2000, February 6). *Pharmacoeconomics of tuberculosis drug development*. R&D Meeting on Tuberculosis Drugs, Cape Town, South Africa.
- Rouse, D. J. (2000, January 12). *Creating new value from technology assets*. Transportation Research Board Annual Meeting, Washington, DC.
- Rouse, D. J. (1998, June 19). NASA Langley Research Center's Annual Inventors' Luncheon. Keynote speaker, Hampton, VA.
- Rouse, D. J. (1998, February 26). *Technology marketing*. Association of Federal Technology Transfer Excellence Conference, San Antonio, TX.
- Rouse, D. J. (1997, February 20). *Technology assessment*. Association of Federal Technology Transfer Executives Conference, San Francisco, CA.
- Rouse, D. J. (1994, November 11). *Medical benefits from NASA technology*. Media and Medicine Conference, Orlando, FL.
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- Rouse, D. J. (1994, June 22–24). *Industry association/government partnerships: A model for meeting industry-wide technology needs*. Technology Transfer Society Annual Meeting, Huntsville, AL.
- Rouse, D. J. (1994, February 1–3). *Industry association/government partnerships: A model for meeting industry-wide technology needs*. First Annual Dual-Use Space Technology Transfer Conference, Houston, TX.
- Rouse, D. J. (1993, April 29). *Dividends from space: How NASA technology has provided a competitive advantage for U.S. industry*. Thirtieth Space Congress, Cocoa Beach, FL.
- Rouse, D. J. (1992, November 4). *Technology commercialization: How to make products the result of your process*. Federal Laboratory Consortium National Conference, Scottsdale, AZ.
- Rouse, D. J. (1991, June 10). *NASA technology application program*. Technology Transfer Society Conference, Denver, CO.
- Rouse, D. J. (1990, November 28). *NASA's application engineering program*. Technology 2000 Conference, Washington, DC.
- Rouse, D. J. (1988, September 21). *How business can benefit from space*. Space Business Roundtable, Houston, TX.
- Rouse, D. J. (1986, November 21). *Systems for management of wandering in older persons*. Gerontological Society of America National Meeting, Chicago, IL.
- Rouse, D. J. (1986, September 29–30). *Translation of technologies to meet needs of elderly*. National Conference on Technology and Aging, Worcester, MA.
- Rouse, D. J. (1986, May 5–6). *Federal agency and industry initiatives in new product development for elders*. Aging in a Technological Society, sponsored by the American Society on Aging, Minneapolis, MN.
- Rouse, D. J. (1985, September 18). *Criteria for CAD/CAM fabrication of orthopedic shoes*. Veterans Administration Insensate Foot Workshop, La Jolla, CA.
- Rouse, D. J. (1985, August 19). *Programmable hydrocephalus shunt system*. Health Care Expo, Washington, DC.
- Rouse, D. J. (1981, July 30–August 1). *The NASA technology transfer process*. National Research Conference on Technology and Aging, Racine, WI.
- Rouse, D. J. (1981, May 10–13). *Methodology for NASA technology transfer in medicine*. Sixteenth Annual Meeting of the Association for the Advancement of Medical Instrumentation, Washington, DC.
- Rouse, D. J. (1981, March 22). *Target group and human factor considerations in product design*. Symposium on Product Design in the '80s, sponsored by the National Endowment for the Humanities, Wilmington, DE.
- Rouse, D. J. (1980, November 3–4). *External collection devices*. National Institute on Aging Workshop on Urinary Incontinence in the Elderly, Bethesda, MD.
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