

MICHAEL D. THORN, Dr.P.H.

EDUCATION:

- 1992 Dr.P.H., Biostatistics, University of North Carolina, Chapel Hill, NC
- 1982 M.S., Biostatistics, University of North Carolina, Chapel Hill, NC
- 1980 Pharmacy Practice Residency, University of North Carolina, Chapel Hill, NC
- 1982 M.S., Pharmacy Practice, University of North Carolina, Chapel Hill, NC
- 1978 B.S., Pharmacy, Rutgers University, New Brunswick, NJ

PROFESSIONAL (Pharmacy) CERTIFICATION:

North Carolina State Board of Pharmacy License # 7284

North Carolina Office of Emergency Medical Services – Medical Responder

WORK EXPERIENCE:

- 1996-Present *President*
Statistical Resources, Inc.
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I have been involved in all aspects of development of pharmaceutical, biologic, and medical devices, from the founding of new companies, the strategic design of clinical developmental plans, the design of clinical trials, meetings with regulatory agencies (US and Canada), including Pre-IND and IDE, end of phase II, Pre-NDA, Pre-PMA, and presentations for FDA Advisory Panel meetings (at least three). I have been completely involved in the programming, review, and statistical write-ups of statistical analysis plans, clinical trial reports, ISSs, ISEs, SSEs, and other regulatory documents. I have also been involved in many analyses for publication in the biomedical literature. I have also done the statistical analyses for over 15 thorough QTc studies and a variety of other ECG trials.

Additionally, I have been involved in the planning and/or administration of at least 25 Data and Safety Monitoring Boards (DSMBs) which are ongoing or have been completed,

including the areas of Cardiology, Rheumatology, Psychiatry, Endocrinology, and Hepatology. Roughly half of these were safety only DSMBs, while the other half reviewed safety and efficacy. Most of those reviewing safety and efficacy (or effectiveness – devices) used death as the primary endpoint. I have served as the Co-Chair for one of these DSMBs and as a US statistical representative on an International DSMBs for 7 of these committees. As of January 2001, 3 of these DSMBs are ongoing, and an additional 3 DSMBs are in planning stages.

1994-1996 *BRI International, Inc., Chapel Hill, NC*
Director of Biometrics and Director of Chapel Hill Operations

Responsible for the entire Chapel Hill North Carolina operations. Directs the office, and is responsible for all the day to day and long term planning of this office and of the entire Biometrics staff across all the North American operations office. This includes budgeting, resource planning and allocation, facilities management, computer and network support (Novell Network).

Assists Senior Director, Project Operations Division, in oversight of administrative functions associated with the scientific and technical staff. Supervises the staff of biostatisticians, scientists, research programmers, and medical writers. Provides technical expertise and administrative direction to specific projects involving clinical research. Supervises and delegates tasks for biostatisticians, scientists, programmers, and medical writers in POD. Maintains client communications.

Develops study design with other project team members. Develops literature review strategy with Medical Writer. Designs database with System Analyst and provides database management advice to CRAs. Oversees technical quality assurance of data, analyses, and documents. Develops analysis plans, oversees analyses, provides interpretation of results, and oversees generation of reports. Oversees tables generation and preparation and submission of major FDA regulatory documents.

1988 - 1994 *Burroughs Wellcome Co., Research Triangle Park, NC*
Senior Statistician I and II

Was responsible for protocol design, protocol writing (statistical section), and review; analysis plans; data monitoring (statistical); statistical computing (data listings and analyses); statistical report writing; final study report writing and review; management of statisticians assigned to project; cross-study summaries of safety and efficacy (NDA); manuscript preparation; Data and Safety Monitoring Board analyses (when required); and investigator's meeting preparation.

Responsible for statistical manuscripts and presentation; continuous improvement process team; and statistical designs for optimal drug development. Six years of experience as project statistician plus 1 year of experience in administrative management.

- 1986 - 1988 *UNC School of Pharmacy, Chapel Hill, NC*
Visiting Assistant Professor
- 1983 - 1986 *UNC Department of Biostatistics, Lipids Research Clinics Program, Chapel Hill, NC*
Research Assistant (Statistician)
- 1981 - 1982 *UNC Department of Biostatistics, Lipids Research Clinics Program, Chapel Hill, NC*
Graduate Assistant
- 1980 - 1981 *North Carolina Memorial Hospital, Chapel Hill, NC*
Staff Pharmacist
- 1978 - 1980 *UNC School of Pharmacy, Chapel Hill, NC*
Pharmacy Practice Resident
- 1977 - 1978 *Middlesex General Hospital, New Brunswick, NJ*
Pharmacy Technician
- 1972 - 1974 *Hunt's Pharmacy, Paterson, NJ*
Clerk

PROFESSIONAL AFFILIATIONS:

The Biometrics Society

American Statistical Association

PUBLICATIONS:

Tennison M.D., Greenwood R., Lewis D., and Thorn M.D. Discontinuing Antiepileptic Drugs in Children with Epilepsy: Comparison of a Six-Week and Nine-Month Taper Period. *New England Journal of Medicine*. 1994; x():

Thorn M.D. Automated Classification of Fatal Cardiovascular End Points in Large Scale Multi-Center Clinical Trials. Dr.P.H. dissertation, Department of Biostatistics, UNC School of Public Health.

Beza J.B., Stritter F.T., Caiola S.M., McDermott J.H., and Thorn M.D. The effects of a preceptor development program. *American Journal of Pharmaceutical Education*. 1992; 56(1): 44-47.

Miles M.V., Snead O.C., and Thorn M.D. Predictability of Unbound Antiepileptic Drug Concentrations in Children Treated with Valproic Acid and Phenytoin. *Clinical Pharmacy*. 1988; 7:688-693.

Abernathy J.R., Thorn M.D., Ekelund L.G, Holme I., Stinnett S.S., Shestov D.B., and Deev A.D. Correlates of Systolic and Diastolic Blood Pressure in Men Aged 40-59 Years Sampled From the United States of America and Union of Soviet Socialist Republics Lipid Research Clinics Populations. *American Journal of Cardiology*. 1988; 61:1071-1075.

Abernathy J.R., Thorn M.D., Trobaugh G., Ekelund L., Maciolowski M., Loupovetsky B., Shelnova S., Zhukovsky G.S., Shestov D.B., and Deev A.D. Prevalence of Ischemic Resting and Stress ECG Abnormalities and Rose Questionnaire Angina in Men Aged 40-59 in the US and USSR Lipid Research Clinics Program Populations. *Circulation*. 1988; 77:270-278.

Thorn M.D., Ingram D.D., Abernathy J.R., and Maciolowski M. The Lipid Research Clinics Population Studies Data Book. Volume III The USSR First Prevalence Study. U.S. Department of Health and Human Services, NIH Publication, November 1986; No. 87-2727.

Ingram D.D., Thorn M.D., Stinnett S.S., and Deev A.D. US and USSR Nutrient Intake, Plasma Lipids and Lipoproteins in Men Ages 40-59 Sampled From Lipid Research Clinics (LRC) Populations. *Prevention Medicine*. 1985; 14:264-271.

Thorn M.D., Pulliam C.C., Symons M.J., and Eckel F.M. Statistical and Research Quality of the Medical and Pharmacy Literatures. *American Journal of Hospital Pharmacy*. 1985; 42:1077-1082.

Thorn M.D. A Method of Computerization of Individually Prescribed Non-Trial Medication. M.S. paper, Department of Biostatistics, UNC School of Public Health.

Thorn M.D. A Comparative Review of the Research and Statistical Methods of the Medical and Pharmacy Literatures. M.S. paper, Division of Pharmacy Practice, UNC School of Pharmacy.

Bernstein C., Thorn M.D, Monees K., Spell R., and O'Connor J.B. A Prospective Study of Factors that Determine Cecal Intubation Time at Colonoscopy. *Gastrointestinal Endoscopy* 2005; 61:72-75.

SYMPOSIA PUBLICATIONS:

Abernathy J.R., Furberg B., Thorn M.D., Ekelund L.G., Deev A.D., Shestov D.B., Zhukovsky G.S., and Tyroler H.A. Correlates of Systolic and Diastolic Blood Pressure in Men Aged 20-39 Years From US and USSR Lipid Research Clinic Populations. *Atherosclerosis Reviews*. 1988; 17:111-124.

Furberg B., Abernathy J.R., Thomas R.P., Ekelund L.G., Thorn M.D., Shestov D.B., Deev A.D., Levy R.I., and Perova N.V. Correlates of Lipids and Lipoproteins in Men Aged 20-39 Years From US and USSR Lipid Research Clinic Populations. *Atherosclerosis Reviews*. 1988; 17:125-138.

Thorn M.D., Furberg B., Abernathy J.R., Ekelund L.G., Deev A.D., Shestov D.B., Rifkind B.M., and Oganov R.G. Correlates of Systolic and Diastolic Blood Pressure in Women-Aged 20-69 Years From US and USSR Lipid Research Clinics Populations. *Atherosclerosis Reviews*. 1988; 17:157-186.

Furberg B., Abernathy J.R., Thorn M.D., Ekelund L.G., Irving S.H., Deev A.D., Shestov D.B., Williams O.D., and Oganov R.G. Correlates of Systolic and diastolic Blood Pressure in Women-Aged 20-69 Years From US and USSR Lipid Research Clinics Populations. *Atherosclerosis Reviews*. 1988; 17:185-200.

Johansson S., Thorn M.D., Furberg B., Chang I.Y., Ekelund L.G., Oganov R.G., and Sheffield L.T. Electrocardiographic Abnormalities and Rose Questionnaire Angina in Women Aged 30-69 Years. A Cross-Sectional Study of Selected US and USSR Populations. *Atherosclerosis Reviews*. 1988; 17:243-256.

Shestov D.B., Deev A.D, Zhukovsky G.S., Thorn M.D., Davis C.E., and Klimov A.N. Coronary Heart Disease Risk Factors and Mortality in the USSR Lipid Research Clinics Follow-up Study. *Atherosclerosis Reviews*. 1988; 17:261-276.

Tyroler H.A., Levy R.I., Thorn M.D., Davis C.E., Deev A.D., and Shestov D.B. High Density Lipoprotein Cholesterol and coronary Heart Disease Mortality: Experience of White Men Aged 40-59 Years From the US Lipid Research Clinics Mortality Follow-up Study. *Atherosclerosis Reviews*. 1988; 17:277-286.

PRESENTATIONS:

Thorn M.D., and Hurley F.L. Statistical Issues in Medical Devices: An Industry Perspective. American Statistical Association 1996 Statistical Meetings (Special Contributed Session. August 7, 1996. (INVITED)

Thorn M.D. Using Sequential Trial Methodology for Interim Analyses - Practical Applications and Issues. Joint Annual Meeting Statistical Society of Canada and Institute of Mathematical Statistics. Montreal Canada July 10-13, 1995. (INVITED)

Thorn M.D., Small R., Huffman C., McSorley P., and Souza K. Applications of Total Quality Management in Clinical Research in the Pharmaceutical Industry. American Statistical Association 1994 Winter Conference. Atlanta GA January 6-9, 1994. (INVITED)

Hinderliter A.L., Willis P.W., Thorn M.D., Long W., and the North American Primary Pulmonary Hypertension Study Group. Echocardiographic Effects of Prostacyclin in Primary Pulmonary Hypertension. 66th Scientific Session American Heart Association Meeting. Atlanta, GA. November 8-11, 1993.

Thorn M.D. Using Sequential Trial Methodology for Interim Analyses - A Congestive Heart Failure Survival Study Experience. 15th Annual Midwest Biopharmaceutical Statistics Workshop. Muncie, IN May, 1992.

Miles M.V., Bass J., Tennison M.B., Holcomb B.J., and Thorn M.D. Effects of Liquid Enteral Feeding on Carbamazepine (CBZ) Suspension Absorption. American Society for Clinical Pharmacology and Therapeutics, 1989 meeting.

SYMPOSIA PRESENTATIONS:

Sznajd J., Pajak A., Misiowiec P., Magdon M., Rywik S., Przystalska-Malkin H., Kupsc W., Williams O.D., Thomas R.T., Irving S.H., Abernathy J.R., and Thorn M.D. Poland and US Collaborative Study on Cardiovascular Epidemiology: Introductory Baseline. Presented at the 3rd US-Poland Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Pajak A., Celinski A., Morawski R., Furberg B., Abernathy J.R., Thomas R.P., Irving S.H., Williams O.D., and Thorn M.D. Poland and US Collaborative Study on Cardiovascular Epidemiology: Correlates of Systolic and Diastolic Blood Pressure in Men Aged 35-64 Years From Selected Poland and US Samples. Presented at the 3rd US-Poland Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Czarnecka H., Pajak A., Konopka M., Furberg B., Irving S.H., Thomas R.P., Abernathy J.R., Williams O.D., and Thorn M.D. Poland and US Collaborative Study on Cardiovascular Epidemiology: Correlates of Systolic and Diastolic Blood Pressure in Men Aged 35-64 Years From Selected Poland and US Samples. Presented at the 3rd US-Poland Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Czarnecka H., Pajak A., Konopka M., Furberg B., Irving S.H., Thomas R.P., Abernathy J.R., Williams O.D., and Thorn M.D. Poland and US Collaborative Study on Cardiovascular Epidemiology: Correlates of Lipids and Lipoproteins in Men Aged 35-64 Years From Selected Polish and US Samples. Presented at the 3rd US-Poland Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Misiowiec P., Pajak A., Mizera R., Furberg B., Abernathy J.R., Thomas R.P., Irving S.H., Thorn M.D., and Williams O.D. Poland and US Collaborative Study on Cardiovascular Epidemiology: Correlates of Systolic and Diastolic Blood Pressure in Women Age 35-64 From Selected Polish and US Samples. Presented at the 3rd US-Poland Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Baczynaska E., Pajak A., Morawska I., Sznajd J., Furberg B., Thomas R.P., Irving S.H., Abernathy J.R., Williams O.D., and Thorn M.D. Poland and US Collaborative Study on Cardiovascular Epidemiology: Correlates of Lipids and Lipoproteins in Women Aged 35-64 Years From Selected Polish and US Samples. Presented at the 3rd US-Poland Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Furberg B., Abernathy J.R., Thorn M.D., Ekelund L.G., Irving S.H., Deev A.D., and Shestov D.B. Correlates of Systolic and Diastolic Blood Pressure in Men Aged 20-39 Years From US and USSR Lipid Research Clinic Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Furberg B., Abernathy J.R., Thorn M.D., Ekelund L.G., Irving S.H., Shestov D.B., and Deev A.D. Correlates of Lipids and Lipoproteins in Men Aged 20-39 Years From US and USSR Lipid Research Clinic Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Dennis B., Thomas R.P., Irving S.H., Thorn M.D., Abernathy J.R., and Furberg B. Nutrient Intake in Men Aged 20-39 From US and USSR Lipid Research Clinic Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Thorn M.D., Furberg B., Abernathy J.R., Ekelund L.G., Irving S.H., Deev A.D., and Shestov D.B. Correlates of Systolic and Diastolic Blood Pressures and Lipids and Lipoproteins in Men Aged 20-69 From US and USSR Lipid Research Clinics Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Furberg B., Abernathy J.R., Thorn M.D., Ekelund L.G., Irving S.H., Deev A.D., and Shestov D.B. Correlates of Systolic and Diastolic Blood Pressure in Women Aged 20-69 Years From US and USSR Lipid Research Clinics Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Furberg B., Abernathy J.R., Thorn M.D., Ekelund L.G., Irving S.H., Shestov D.B., and Deev A.D. Correlates of Lipids and Lipoproteins in Women Aged 20-39 Years From US and USSR Lipid Research Clinics Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Dennis B., Thomas R.P., Irving S.H., Thorn M.D., Abernathy J.R., and Furberg B. Nutrient Intake in Women Aged 20-69 Years From US and USSR Lipid Research Clinics Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Johansson S., Thorn M.D., Furberg B., Chang I.Y., Irving S.H., Ekelund L.G., and Abernathy J.R. Electrocardiographic Abnormalities and Rose Questionnaire Angina in Women Aged 30-69 Years. A Cross-Sectional Study of Selected US and USSR Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Shestov D.B., Thorn M.D., Deev A.D., and Davis C.E. Correlates of Mortality in Men Aged 40-59 Years From USSR Lipid Research Clinics Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

Tyroler H.A., Thorn M.D., Bangdiwala S.I., Deev A.D., and Shestov D.B. Correlates of Mortality in Men Aged 40-59 Years From the US Lipid Research Clinics Populations. Presented at the 3rd US-USSR Symposium, NHLBI, NIH, Bethesda, MD, September 22-23, 1986.

POSTER PRESENTATIONS:

Long W., Rubin L., Barst R., Rich S., Badesch D., Groves B., Tapson V., Bourge R., Brundage B., Keller C., Koerner S., Langleben D., Murali S., Uretsky B., Clayton L., Jobsis M., Thorn M.D., and McGoon M. Randomized Trial of Conventional Therapy Alone Vs. Conventional Therapy + Continuous Infusion of Prostacyclin in Primary Pulmonary Hypertension: A 12 Week Study. San Francisco, CA American Thoracic Society/American Lung Association International Conference. May 18, 1993.

Rubin L.J., Thorn M.D., Mendoza J., Hood M., Barst R., McGoon M., Crow J., and Long W. The influence of continuous therapy with intravenous prostacyclin on survival in primary pulmonary hypertension. 7th International Conference on Prostaglandins and Related Compounds, 323, May 28 - June 1, 1990.

Thorn M.D., Caiola S.M., and Smith R.L. A Computerized Experiential Site Selection Program: Administrative Uses. AACP meeting, Charleston, SC July 1987.

Thorn M.D., Caiola S.M., Smith R.L., and Sawyer W.T. Student Use of a Computerized, Experiential Site Selection Program. AACP Meeting, Charleston, SC July 1987.

AWARDS AND HONORS:

Rho Chi Pharmacy Honor Society

Rho Chi Certificate of Achievement

INTERNATIONAL CONSULTANT ACTIVITIES:

Visiting Scientist, US Component of Joint US-Peoples Republic of China Cooperation on Cardiovascular Disease (National Heart, Lung, and Blood Institute). Visit of Beijing and Guangzhou, PRC April 7 through June 1, 1985 to set up Data Entry System for data collection on an IBM PC/XT and statistical analysis.