

VITA
Robert P. Thiel, Ph.D.

SUMMARY

I am a recognized expert in the design and statistical analysis of clinical trials in the area of *in vitro* diagnostics, medical devices and phase I, II and III pharmaceutical trials. In the past fourteen years I have been involved with or directly responsible for the clinical and/or the statistical portions of over 70 510(k) and PMA submissions to the FDA. All have been approved.

PROFESSIONAL EXPERIENCE

Present	CEO, THIEL Statistical Consultants 45 Tram Drive Oxford, CT 06478 <ul style="list-style-type: none"> • Develop and implement SAP for Major Medical Device and Pharmaceutical Companies • Supervise other Statisticians on a per project basis
	Professor Emeritus Southern Connecticut State University Adjunct Professor, Southern Connecticut State University <ul style="list-style-type: none"> • Plan and Teach Introductory and Advanced Statistic Courses
	Adjunct Research Professor, New York University, Department of Urology <ul style="list-style-type: none"> • Develop and carry out statistical plans for research projects in the area of <ul style="list-style-type: none"> ○ Prostate Cancer ○ Infertility ○ General Urological Diseases or Conditions
10/96 –02/01	Vice President, Biostatistics and Clinical Services, (Cofounder) DIAGNOSTIC ONCOLOGY CRO, Inc. 73 Cogwheel Lane Seymour, CT 06483 <ul style="list-style-type: none"> • 2 direct Reports: Director of Data Services, Director of Clinical Trial • Total personnel supervised varied with project size • Responsible for <ul style="list-style-type: none"> ○ the design and analysis of SAP for Medical Device Trials ○ preparation of budgets for clinical trials ○ preparation of contracts for clinical investigators ○ obtaining contracts with regional or institutional IRB committees ○ coordination with laboratory services to acquire relevant clinical chemistry results
11/94 – 01/97	Director, Biostatistics and Clinical Services (10/96-01/97) Director of Clinical and Biostatistical Services DIANON Systems, Inc. Stratford, Connecticut 06497 <ul style="list-style-type: none"> • Supervised staff of 12 employees in the areas of data collection and analysis • Planned clinical trial programs using external investigators

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1972-1994	<p>Professor, Epidemiology and Public Health (1988-94) Associate Professor, Epidemiology and Public Health (1980-88)</p> <ul style="list-style-type: none"> • Responsible for the management of over 200 students per academic year • Responsible for the development and teaching of <ul style="list-style-type: none"> ○ Undergraduate and Graduate Epidemiology ○ Undergraduate and Graduate Research Methods ○ Graduate Biostatistics • Supervision of Masters Thesis Projects <p>Assistant/Associate Professor. Science Education (1972-80) Southern Connecticut State University 501 Crescent Street New Haven, CT 06515</p>
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EDUCATION

Ph.D.	University of Pennsylvania	Psychometrics	1973
M.S.	Southern Connecticut State University	Counseling	1983
M.S.	Drexel University	Physics	1969
B.S.	Drexel University	Physics	1967

AREAS OF EXPERTISE

Cancer assays	Design and analysis of clinical trials for FDA approval of <i>in vitro</i> markers as aids in monitoring and/or diagnosis of cervical cancer, breast cancer, colon cancer, ovarian cancer, pancreatic cancer and prostate cancer.
Infectious Disease assays	Design and analysis of clinical trials for hepatitis C assays, <i>h. pylori</i> assays and HIV sequencing for drug-resistant mutations
Medical Devices	Analysis of clinical trial data for bone growth enhancers and prosthetic devices
Pharmaceutical	Design and Analysis Phase I and Phase II Clinical Trials in the area of breast, gastric, pancreatic and colon cancer and in diabetes, COPD and geriatric dementia disorders

CLIENTS

ARQULE PHARMACEUTICALS ACCUMETRIX BAYER HEALTHCARE PHARMACEUTICALS BIOMERIEUX CHROMOVISION DPC INC EGENIX PHARMACEUTICALS DIADEXIS INC FUJIREBIO DIAGNOSTICS INC. MTM LABORATORIES NOVACARDIA PHARMACEUTICALS	ONCOGENE SCIENCE DIAGNOSTICS INC (SEIMANS) PERKINS ELMER PERSONADX, INC ROCHE DIAGNOSTICS TOSOH MEDICS INC (USA) TRIPATH INC VENTANA MEDICAL SYSTEMS INC
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PUBLICATIONS AND PATENTS

RECENT PUBLICATIONS

Sultan R, et al: 2006 *Time to return to work and physical activity following open radical retropubic prostatectomy*. Journal of Urology: 176, p1420

Patel R, et al 2005 *Prostate-specific antigen velocity accurately predicts response to salvage radiotherapy in men with biochemical relapse after radical prostatectomy*. Urology, 66, p561

Rosenberg W et al 2004 *A cohort study of a panel of serum markers as predictors of hepatic fibrosis as assessed with liver histology and image analysis*. Gastroenterology

Partin AW et al 2003 *Complexed PSA improves specificity for prostate cancer detection: The results of a prospective multicenter clinical trial*. Journal of Urology, Vol. 170:1787-1791

Schwartz, PE et. al. 1999 *Neoadjuvant chemotherapy for advanced ovarian cancer: long-term survival*. Gynecol. Oncol. 72 (1):93-99.

Thiel RP et al. 1996. *A multi center comparison of the diagnostic performance of free PSA*. Urology 48 #6a, 45-50.

Soloway MS et al. 1996. *Use of a new tumor marker, Urinary NMP22, in the detection of occult or rapidly recurring transitional cell carcinoma of the urinary tract following surgical treatment*. J. Urology 156, 363-367.

Chen YT et al. 1996. *Using proportions of free to total prostate-specific antigen, age, and total prostate-specific antigen to predict the probability of prostate cancer*. Urology 47, 518-524.

Luderer AA et al. 1995. *Measurement of the proportion of free to total prostate-specific antigen improves diagnostic performance of prostate-specific antigen in the diagnostic gray zone of total prostate-specific antigen*. Urology 46, 187-194.

Rossmann M et al. 1994. *Prognostic indicators for poor risk epithelial ovarian cancer*. Cancer 74, 1322-1328.

PATENTS

Luderer AA, Carlson G, Thiel RP, Soriano TF, Kramp W. Issue Date: 16 December 1997. United States Patent Number 5,698,402. Novel Methods for Diagnosing Benign Prostatic Hyperplasia.

Luderer AA, Carlson G, Chen YT, Soriano TF, Thiel RP. Issue Date: 20 January 1998. United States Patent Number 5,710,007. Novel Methods for Diagnosing Prostatic Adenocarcinoma.

Luderer AA, Carlson G, Thiel, RP, Soriano TF, Kramp, WJ. Issue Date: 15 June 1999. United States Patent Number 5,912,135. Methods for Diagnosing Benign Prostatic Diseases.

Luderer AA, Carlson G, Thiel, RP, Soriano TF, Kramp, WJ. Issue Date: 08 August 2000. United States Patent Number 6,100,049. Methods for Diagnosing Benign Prostatic Diseases.