CURRICULUM VITAE

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PROFESSIONAL POSITIONS:

Clinical Research Consultant
April, 1993 - present: Biotechnology and pharmaceutical clinical research development

Axion Pharmaceuticals, Inc., South San Francisco, California:
Sept, 1992 - April, 1993: Vice President, Clinical Research

Bayer AG, Miles Inc., Cutter Biological Group, Berkeley, California:
1981 - Sept, 1992: Director of Clinical Research - Biologicals
1980 - 1981: Associate Director, Clinical Research - Biologicals
1979 - 1980: Assistant Director, Clinical Research - Biologicals

EDUCATION:

1964-65: Early admission program (high school), University of California, Los Angeles
1965-69: University of California, Los Angeles, B.S., Chemistry (Honors, Magna Cum Laude)
1969-73: M.D. - Stanford University School of Medicine, Stanford, California
1973-74: Intern, Medicine, University of Michigan Medical Center, Ann Arbor, Michigan
1974-75: Junior Resident, Medicine, University of Michigan Medical Center
1975-76: Senior Resident, Medicine, University of Michigan Medical Center
1976-79: Postdoctoral Fellow, Divisions of Hematology and Oncology, Stanford University School of Medicine
1976 - 1978 National Institutes of Health Fellowship
1978 - 1979 Daland Fellowship, American Philosophical Society

RESEARCH EXPERIENCE:

University of California, Los Angeles:
1966-68: Selected for National Science Foundation Student Research Fellowships in Chemistry, Department of Chemistry, 1966, 1967, and 1968.

Stanford University School of Medicine:
1970: Research Assistant, Department of Medicine, Division of Hematology. Dr. Stanley Schrier, Professor of Medicine. "Hemoglobin Synthesis in Ineffective Erythropoiesis."
1971: Research Assistant, Department of Medical Microbiology. Dr.Sidney Raffel, Professor of Microbiology. Studies in immunology.

RESEARCH EXPERIENCE (continued):

University of Michigan:
1974-76: Clinical research studying epidemiological aspects of Hodgkin's disease. Dr. Joseph Silva, M.D., Jr., Associate Professor of Medicine, faculty sponsor.

Stanford University:
1976-78: National Institute of Health Research Fellow, Division of Hematology, School of Medicine. Peter Greenberg, M.D., Associate Professor, Hematology, faculty advisor.

1978-79: Daland Fellow, American Philosophical Society
Regulation of hematopoiesis: serum inhibitors of granulopoiesis. In vitro studies of microenvironment, aplastic anemia. Leukemia protocol studies: relapsing patterns of leukemia, infectious complications of induction therapy, leukocyte transfusions.

1979: Acting Fellow, Division of Oncology, School of Medicine

HONORS:
Phi Beta Kappa
Phi Lambda Upsilon (Honorary Chemistry Society)
Honors in Chemistry, Magna Cum Laude
Selected for NASA 6 week Space Biology Institute
First National Institutes of Health Pathobiology of Cancer Institute, 1978

SPECIALTY BOARD CERTIFICATIONS AND PROFESSIONAL MEMBERSHIPS:
1976: Board Certification, American Board of Internal Medicine
1978: American Board of Internal Medicine Certification in Hematology
1981: American Board of Internal Medicine Certification in Oncology
1981 - present: Member, American Society of Hematology (ASH)
1993 - present: Member, American Society of Clinical Oncology (ASCO)
California Medical License - Active

AWARDS:
1983 - Cutter Group Corporate Science and Technology Award
6/9/88 - Chairman's Award, American Blood Resources Association (ABRA)

PATENTS:
US Patent No. 4,412,990: J Lundblad, MD Budinger, RS Schwartz. Composition Having Enhanced Opsonic Activity. Granted 11/1/83.

Professional Accomplishments

Cutter Biological, Miles Inc. (1979 - 1992)

1. Product license applications approved by FDA as a result of clinical trials - principal responsibility for inception of study, protocol design and development, and clinical summary report:
   a. Koate®-HT antihemophilic factor
   b. Koate®-HS antihemophilic factor
   c. Konyne®-HT-Factor IX Complex
   d. Konyne®HT-inhibitor treatment indication
   e. Intravenous gammaglobulin
      Gamimune® (pH 5.25) ITP indication
      Gamimune®-N (pH 4.25) ITP indication
      400 mg/kg x 5 and 1000 mg/kg x 2
      Childhood and adult ITP studies
   f. Prolastin® (α_1-antitrypsin) (Orphan Drug)
   g. Thrombate® III (Antithrombin III) - licensed 12/30/91 (Orphan Drug)
   h. Kogenate® (Recombinant Factor VIII) - licensed 2/25/93
   i. Infection prophylaxis of pediatric AIDS patients with intravenous gammaglobulin (Orphan Drug indication) - approved by FDA 12/29/93

2. Clinical brochures prepared
   a. Koate-HT
   b. Koate-HS
   c. Prolastin
   d. Antithrombin III
   e. Recombinant Factor VIII

3. Package inserts approved by the FDA
   a. Konyne®-HT
   b. Konyne®inhibitor indication
   c. Koate®-HT
   d. Koate®-HS
   e. Prolastin®
   f. Hepatitis B immune globulin
   g. Rh immune globulin
   h. Gamimune® (intravenous gammaglobulin) ITP indications for IGIV pH 5.25 and IGIV pH 4.25 for both 400 mg and 1000 mg dose regimens
   i. Thrombate® III (antithrombin III) (orphan drug - licensed 12/30/91)
   j. Kogenate® (recombinant factor VIII - licensed 2/25/93)
   k. Prophylaxis of pediatric AIDS patients with Intravenous Gammaglobulin (Orphan Drug indication)

Professional Accomplishments (continued)

Axion Pharmaceuticals, Inc. (1992 - 1993)

Set up entirely new clinical research program in 6 months, developed three protocols for phase I study of oxaliplatin, a new cancer chemotherapeutic agent (cisplatin analog), developed and submitted clinical IND; IND for all three protocols approved by the FDA on April 5, 1993 as well as IRB approval by four separate institutions.

Clinical Research Consultant (1993 - present)

Prepared complete summary report which was distributed to members of the FDA Antiviral Drug Advisory Committee on behalf of a major pharmaceutical company.

Prepared entire presentation made to the FDA Antiviral Drug Advisory Committee including graphics, tables, charts, and figures (Advisory Panel recommended approval of the new indication based on the presentation).

Created database and conducted extensive data and statistical analysis of clinical trial data to address major questions raised by FDA involving a manufacturer's NDA submission; prepared submission including report, discussion, tables, figures, references, and package insert. Represented manufacturer at the FDA.

Prepared phase I protocol, clinical brochure, informed consent form, and case report forms for IND submission of a new biologic agent.

Conducted analysis of adverse reactions involving investigational oncologic agent resulting in previously undetected pattern of adverse events; made recommendations.

Advised small biotechnology company on clinical study design strategy for investigational oncologic agent.

Prepared analysis of safety and efficacy data involving investigational agent for treatment of infectious diseases on behalf of a small biotechnology company.

Conducted an in-depth analysis of a major clinical study proposal and prepared analysis and recommendations for sponsor.

Through database search and contact with investigators, identified key references previously unbeknownst to manufacturer to permit FDA submittal for new indication of licensed product without need for additional clinical trials.

Prepared analysis on protocol design methodology for phase I and II study of new biologic product and provided extensive revisions to protocol.

Reviewed technical aspects and feasibility analysis of grant requests from external investigators for major pharmaceutical company; prepared written analyses of each research proposal.

Wrote two separate protocols on behalf of young biotechnology company for new IND filing for study of a novel new pharmaceutical compound for treatment of cancer patients - IND clinical plans approved by the FDA with minimal comments, without clinical hold; IRB approval granted.

Prepared background clinical section for IND filing of new drug for cancer treatment, including in-depth analysis of pre-clinical efficacy data for client, including survival analysis, Cox

regression analysis, log-rank analysis, generation of Kaplan-Meier survival curves, and analysis of variables predictive for outcome success.

Gave presentation to client on mathematics of generating Kaplan-Meier curves and determining comparative p values using log-rank analysis.

Conducted an extensive survey of options for setting up the clinical research database for a young biotech company including interviews of data managers, statisticians, programmers (both within the pharmaceutical industry and in consulting groups), regional database representatives, and medical directors of multiple organizations and pharmaceutical companies. Prepared an in-depth report on options available to the client, made specific recommendations for database software, case report form design, and most cost-effective option, provided literature and articles supporting these recommendations, and identified several individuals with the requisite skills and clinical research background to provide the needed programming to set up the clinical research database.

Prepared in-depth analysis and report of clinical trial design options and potential indications for new recombinant DNA-derived protein for an innovative biotechnology company. Identified potential clinical indications, narrowed focus, and made recommendations for priorities for phase I through III clinical investigations to achieve optimal course of study and greatest likelihood of successful outcome. Provided outlines for study designs from phase I through phase III.

Prepared in-depth analysis and report of clinical trial design options and potential indications for new recombinant DNA-derived protein for a young biotechnology company. Identified potential clinical indications, narrowed focus, and made recommendations for phase I through III priorities for clinical study to achieve optimal course of study and greatest likelihood of successful outcome. Provided outlines for study designs from phase I through phase III.

Assisted major pharmaceutical company in preparing FDA presentation; attended FDA pre-IND meeting as consultant.

Reviewed technical aspects and feasibility analysis of grant requests from external investigators for major pharmaceutical company; prepared written analyses of each research proposal.

Prepared in-depth analysis of a clinical investigation being considered for treatment of a serious respiratory disorder. Critically reviewed the literature. Provided recommendations for pre-clinical studies, outlined phase I - III clinical trial including patient entry criteria, recommendation to deal with problem of alternative therapies for same disorder, sample size estimates for clinical study, and time line estimate.

Prepared in-depth analysis of planned clinical trial design for a 20 million dollar clinical investigation involving infectious disease application. Prepared analytical report including analysis of planned study population, made recommendations for alternative study population with higher probability of success while requiring fewer study subjects, provided sample size estimates and supporting documentation for suggested recommendations.

Prepared comprehensive report summarizing results of all phases of a multi-center, international clinical study spanning 6 years for a major international pharmaceutical company.

Conducted an in-depth literature review and prepared a technical report based on this analysis for FDA submission to request an expanded indication and wording in the package insert for a new compound in the final stages of approval.

Prepared technical report analyzing manufacturing and quality assurance issues in support of IND filing for small biotechnology company.

Conducted in-depth analysis utilizing descriptive statistics, univariate and multivariate analysis, and graphical techniques to analyze manufacturing and chemical performance data of a system developed by a small biotechnology company. Prepared technical report summarizing analysis of system performance and made recommendations for optimizing the system. Report to support IND filing. Client decided to continue development of the program based on the data analysis provided in the report.

Prepared report for major pharmaceutical company providing detailed discussion of phase I - III design possibilities for new product currently under development to enable client to determine how to best proceed towards IND.

Prepared entire manuscript on behalf of major pharmaceutical company summarizing phase II and III clinical trial of new product. Accepted for publication, 1997.

Attended symposium at World Health Organization on behalf of major pharmaceutical company; prepared report.

Assisted client in development of final protocol and case report forms for new clinical study.

Prepared phase II protocol for small pharmaceutical company.

Performed medical review of large series of case report forms for biotechnology company.

Prepared analysis of potential new indications including clinical design considerations for licensed preparation for major pharmaceutical company.

Prepared 100 page report summarizing pre-clinical toxicology studies for major biotechnology company.

Advised and assisted small pharmaceutical company in clinical development plans for phase II and phase III pivotal trial studies including rewriting entire phase II/III protocol. Helping to develop Standard Operating Procedures. Acting Medical Monitor.

Advised small pharmaceutical company in re-design of phase I IND study. Estimated cost saving from initial recommendations exceeds $900,000 compared to plans developed prior to consultation.

Visited multiple clinical investigators throughout United States on behalf of small pharmaceutical company. Prepared multiple trip reports advising on input learned from investigators regarding redesign of phase II/III clinical trial. Provided new ideas for phase III pivotal study in order to maximize likelihood of successful outcome.

Advising small pharmaceutical company on phase I, II, and III development plans for new product (oncology). Interviewed clinical investigators to develop clinical trial strategy.

Advising small pharmaceutical company on phase II and III development plans for new product (oncology).

Wrote manuscript summarizing phase I and II clinical trial for major pharmaceutical company. Accepted for publication, 1997.

Prepared final medical report for FDA PLA submission on behalf of major pharmaceutical company.

Prepared strategy analysis for phase I and II clinical trials for small pharmaceutical company.

Prepared analysis of potential new product for small pharmaceutical company.

Prepared protocol for small pharmaceutical company.

Prepared three separate clinical summary reports using IHC guidelines for major pharmaceutical company.

Acting medical director for 4 months for a major pharmaceutical company. Reviewed all marketing materials.

Prepared analysis of two new oncology products for small pharmaceutical company.

Critically reviewed phase I safety and efficacy data from oncology clinical study for small pharmaceutical company. Advised on design of phase II study.

Advised small pharmaceutical company on how to develop phase II and III pivotal studies for new oncology therapeutic agent.

Acting medical director for biotechnology company. Critically reviewed major phase II study, developed methods for analysis of data which led to demonstration of efficacy not previously detected, developed new endpoints for demonstration of efficacy, prepared phase III pivotal protocol, presented data on behalf of the company at an FDA end-of-phase II meeting to prepare for implementation of phase III trial.

Prepared protocol for phase II development of oncology product for small pharmaceutical company.

Prepared protocol for phase II development of oncology product for another small pharmaceutical company.

Prepared major medical report based on IHC guidelines summarizing phase IV clinical study for FDA filing on behalf of a major pharmaceutical company.

Prepared brief close-out medical report based on IHC guidelines summarizing phase IV clinical study for FDA filing on behalf of a major pharmaceutical company.

Rewrote investigator's brochure (oncology) for small pharmaceutical company.

Prepared abstract for infectious disease meetings for small biotechnology company; accepted for verbal slide presentation.

Prepared major manuscript for small biotechnology company. Published in Journal of Trauma, 1999.

Identified investigators for phase II oncology study.

Prepared report summarizing prior clinical studies and FDA summary basis of approval of a pharmaceutical for small pharmaceutical company.

Assisted in developing program for an all-day investigator's meeting for a small pharmaceutical company, prepared all of the presentation materials, gave the presentation, and chaired the meeting.

Prepared summary of investigator's meeting.

Prepared report of prior clinical studies.

Presented summary of phase II study to an investigator's meeting for a biotechnology company.

Prepared death summaries for FDA submission for biotechnology company.

Prepared the oral slide presentation for an investigator at an international meeting.

Assisted biotechnology company in defining endpoints for phase III pivotal clinical trial.

Prepared manuscript of phase IV study for major pharmaceutical company. Submitted, 1999.

Identified two key experts for biotechnology company advisory meeting.

Prepared report from chart reviews for biotechnology company.

Prepared and wrote entire major clinical report for PLA submission using ICH guidelines for pharmaceutical company. Guided clinical and statistical departments in analyses, clinical parameters for analysis, and endpoints for analysis.

Prepared poster for presentation at major medical meeting on behalf of a pharmaceutical company. Reanalyzed data for presentation.

Conducted meeting of principal investigators on behalf of pharmaceutical company. Presented new analysis of data.

Prepared and submitted abstract to major medical meeting on behalf of pharmaceutical company.

Conducted extensive independent analysis of biotechnology company clinical study database - identified important new findings not previously recognized. Prepared clinical study report.

Prepared entire clinical study report (ICH format) (>350 pages) of a phase III pivotal study for submission to regulatory agencies on behalf of a biotechnology company. Identified appropriate clinical efficacy endpoints and guided statisticians on appropriate statistical analyses and methods of presentation of data listings.

Assisted biotechnology company in critical analysis of clinical study data to serve as basis for discussion with FDA.

Prepared manuscript on behalf of a biotechnology company summarizing results of a major clinical study (Published in The Lancet, 1999).

Prepared slides for a principal investigator for 30 minute presentation at an international meeting summarizing results of a major phase 3 study.

Prepared entire clinical study report (ICH format) of a pivotal study for submission to regulatory agencies on behalf of a pharmaceutical company. Conducted all of the analyses which served as the basis for the submission.

Prepared package insert for a pharmaceutical company.

Prepared Phase 1 protocol for a biotechnology company (gene therapy).

Prepared clinical Sections 3 and 9 of IND filing (recombinant product).

Prepared manuscript on behalf of a pharmaceutical company summarizing results of a major clinical study (Submitted for publication, 2001).

Reviewed and made extensive revisions in Investigators Brochure for new product IND filing for small biotechnology company (oncology).

Helped design and write protocol for phase II study of new drug for IND filing (oncology).

Helped design case report forms for study of new drug (oncology).

Medical monitor for small biotechnology company (oncology).

Medical monitor for another small biotechnology company (oncology).

Participated in Expert Advisory Meeting for a pharmaceutical company.

Prepared clinical summaries of patients for FDA review (oncology).

Prepared reports for FDA submission (oncology)

Prepared analyses of potential patient populations, study designs, sample size estimates, projected costs for study of drug on behalf of a small company (immunology). Made recommendations to prioritize initial clinical studies and target populations.

Reviewed external protocol for a pharmaceutical company; provided critique, analyzed weakness, problems in study design, advised company on areas needing to be addressed.

Prepared analysis of phase I study design and strategy on behalf of a small biotechnology company (autoimmune disease).

Identified corporate partner for small biotechnology company.

Prepared three protocols for phase I and II study of a new recombinant protein.

Analyzed results of a major phase II study and provided recommendations on behalf of a major biotechnology company (oncology).

Extensively revised and entirely rewrote protocol for phase II protocol for a biotechnology company. Developed new primary and secondary endpoints, totally rewrote statistical section, identified and developed totally new questionnaire based on functional assessments to monitor patient clinical status.

Acting medical monitor, major biotechnology company (ongoing).

Acting medical monitor, small pharmaceutical company (ongoing).

Participated in development of 3 new protocols for small pharmaceutical company (oncology/hematology).

Reviewed data on potential new pharmaceutical product, provided feasibility analysis of conducting clinical studies based on the published data, for small pharmaceutical company (oncology).

Reviewed investigator's brochure for major biotechnology company. Provided extensive list of suggestions for improvement, revision, clarification, updating.

Provided in-depth analyses of a small pharmaceutical company (oncology) and its products under development as part of a due-diligence process for a venture capital company considering investing in the company.

Extensively revised several oncology protocols for small pharmaceutical company to comply with FDA recommendations.

Prepared product monograph for a pharmaceutical company.

Prepared safety report of phase IV study on behalf of a pharmaceutical company for FDA submission.

Conducted extensive literature search on two different products to supply potential clinical endpoints for phase III pivotal studies. Based on these reviews, prepared two reports

summarizing advantages and disadvantages of potential alternative clinical efficacy endpoints that were more realistic and required smaller samples sizes than those previously considered.

Prepared in-depth analyses of two novel products (oncology) being considered for in-licensing by a small, pharmaceutical company.

Identified potential clinical investigators (pulmonary disease) in the US and overseas on behalf of a major biotechnology company.

Identified new clinical investigators (hematology/oncology) who subsequently agreed to participate in the clinical study, on behalf of a small, pharmaceutical company.

Set up meeting with experts in the field to advise a small pharmaceutical company on strategy for development of its clinical program (hematology).

Prepared slides and slide talks for multiple clinical investigators for presentation at an international meeting.

Prepared in-depth analysis of new oncology agent being considered for in-licensing by a major pharmaceutical company.

Developed and prepared clinical development plans for phase I - III clinical trials for a new therapeutic modality (pulmonary medicine) for a biotechnology company.

Developed and prepared clinical development plans for phase I - IV clinical trials for two different indications for a novel biotechnology product for a small biotechnology company. Prepared presentation materials and conducted literature search to support indications.

Revised and rewrote technical documents for biotechnology company (infectious diseases).

Prepared Phase I protocol for small pharmaceutical company (oncology).

Participated in expert advisory meeting for major pharmaceutical company (oncology); prepared summary of meeting and recommendations for study designs.

Prepared complete ICH clinical study report of major phase IV clinical study (immunology) for a major pharmaceutical company.

Developed clinical study design (Phase IV), prepared clinical study protocol synopsis and prepared analysis of alternative study designs for a major pharmaceutical company (oncology).

Analyzed pre-clinical and toxicology data on a novel biotechnology compound (oncology) on behalf of a venture capital company.

Analyzed and critiqued clinical opportunities on a novel biotechnology compound (ophthalmology) on behalf of a venture capital company.

Prepared major document for submission to the FDA (infectious diseases) for a small biotechnology company.

Identified potential clinical investigators for three different indications for a novel biotechnology compound (immunology/hematology) on behalf of a small biotechnology company.

Prepared clinical study designs and cost estimates for phase I - IV for three different indications for a novel biotechnology compound (immunology/hematology) on behalf of a small biotechnology company.

Prepared and gave presentation summarizing clinical study designs, cost estimates, potentials, and risks for a novel biotechnology compound (immunology/hematology) on behalf of a small biotechnology company.

Prepared manuscript for publication on behalf of a small pharmaceutical company summarizing the results of a Phase III (oncology). Published in the Journal of Clinical Oncology, January, 2004.

Advised a biotechnology company on study design and sample size estimates for clinical trial design planning (oncology).

Analyzed and provided a critical analysis assessing the opportunities for a novel biotechnology compound (oncology) on behalf of a venture capital company considering investing in the company developing the chemotherapeutic agent.

Analyzed and provided a critical analysis assessing the opportunities for a new chemotherapeutic agent (oncology) on behalf of a venture capital company considering investing in the company developing the chemotherapeutic agent.

Analyzed and provided a critical analysis assessing the opportunities for new chemotherapeutic agents (oncology) on behalf of a pharmaceutical company considering investing in the company developing the chemotherapeutic agents.

Reviewed corporate documents and prepared extensive due-diligence assessment for a small biotechnology company.

Developed plans for a new indication for a recombinant protein being considered by a small biotechnology company, prepared clinical study design plans for phase I - III, provided cost estimates for clinical studies, identified key clinical investigators, and conducted initial discussions with investigators.

Conducted due-diligence assessments and prepared analyses on multiple biotechnology companies (oncology) on behalf of a venture capital company considering investing in the companies (ongoing project).

Reviewed regulatory filings and prepared extensive due diligence analysis of the clinical trial reports and findings for a major biotechnology company considering in-licensing of the product (oncology).

Helped prepare presentation for company internal advisory committee.

Prepared clinical trial strategies (phase I -III) for 3 potential indications for a new novel recombinant biotechnology protein on behalf of a small biotechnology company (transplantation, hematology).

Analyzed and provided a critical analysis assessing the opportunities for a new chemotherapeutic agent (oncology) on behalf of a venture capital company considering investing in the company developing the chemotherapeutic agent.

Analyzed and provided a critical analysis assessing the opportunities for a new chemotherapeutic agent (oncology) on behalf of a venture capital company considering investing in the company developing the chemotherapeutic agent.

Prepared clinical presentations for small biotechnology company and have given multiple presentations on behalf of the company.

Conducted due diligence analysis of the clinical trial reports and findings for a major biotechnology company considering in-licensing of the product (oncology).

Conducted due diligence analysis of the clinical trial reports and findings for a major biotechnology company considering in-licensing of the product (oncology).

Prepared manuscript summarizing two phase I clinical trials (oncology) on behalf of a major biotechnology company - accepted for publication in a major oncology journal, 2004.

Conducted in-depth interviews with clinical experts and potential clinical investigators on behalf of a small biotechnology company (hematology).

Analyzed data, updated results, and prepared presentation for investigator meeting (oncology) for a major biotechnology company.

Analyzed toxicology reports of a new chemotherapeutic agent (oncology) and prepared written analysis of the findings and implications for human clinical trials for a small biotechnology company considering in-licensing the product.

Analyzed pre-clinical results and investigator brochure of a new chemotherapeutic agent (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a small biotechnology company developing the product.

Analyzed pre-clinical and clinical results and investigator brochure for two new chemotherapeutic agents (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a venture capital company considering investing in the company.

Identified key expert investigators for three separate indications (hematology, transplantation, trauma) for a biotechnology company.

Conducted extensive due diligence interviews and analyses and prepared written summaries and analyses, involving three separate indications (hematology, transplantation, trauma) for a biotechnology company.

Developed development strategies, protocol designs, and protocol synopses for three separate indications for a novel biotechnology product for a biotechnology company.

Developed presentation materials and chaired meetings for two separate expert advisory meetings on behalf of a biotechnology company. Prepared written minutes and recommendations for both meetings.

Numerous technical presentations for a small biotechnology company, ongoing.

Analyzed pre-clinical and clinical results for several new chemotherapeutic agents (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a small pharmaceutical company considering investing in the company.

Developed Data Safety Monitoring Board Charter for a pharmaceutical company.

Acting Chief Medical Officer, small biotechnology/pharmaceutical company (ongoing).

Analyzed pre-clinical and clinical results for three new chemotherapeutic agents (oncology) and provided objective, independent critical analysis of the findings and implications for

human clinical trials for a small pharmaceutical company considering investing in the company.

Analyzed pre-clinical and clinical results for a new chemotherapeutic agents (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a venture capital company considering investing in the company.

Prepared synopses for three phase II clinical trials (oncology) for a small pharmaceutical company. Identified a target population not previously considered for study.

Represented small pharmaceutical company at the FDA pre-IND meeting (oncology).

Prepared clinical programs for three phase II/III clinical studies, on behalf of a small biotechnology company, for its lead compound (transplantation, thrombosis, hematology).

Identified numerous clinical investigators for three phase II/III clinical studies, on behalf of a small biotechnology company, for its lead compound (transplantation, thrombosis, hematology).

Analyzed pre-clinical and clinical results for a new chemotherapeutic agents (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a small pharmaceutical company considering investing in the biotechnology company.

Analyzed pre-clinical and clinical results for a new chemotherapeutic agents (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a small pharmaceutical company considering investing in the biotechnology company.

Analyzed pre-clinical and clinical results for a new chemotherapeutic agent (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a small pharmaceutical company considering in-licensing the compound.

Analyzed pre-clinical and clinical results for a new chemotherapeutic agent (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a small pharmaceutical company considering in-licensing the compound.

Prepared a complete phase II/III protocol, on behalf of a small pharmaceutical company, for study of an oncology compound, to serve as the basis of an IND filing. IND filing accepted by the FDA after minimal questions.

Identified more than 30 potential clinical sites and principal investigators for phase II/III study of a new oncology compound, on behalf of a small pharmaceutical company.

Prepared a complete phase I protocol, on behalf of a small pharmaceutical company, for study of a new oncology compound in a combination chemotherapy regimen (oncology).

Analyzed pre-clinical data, on behalf of a small biotechnology company, of its lead compound, in order to identify potential clinical indications. Identified multiple potential indications and developed clinical development plans for phase I - III clinical studies of each target indication. Ranked the potential indications by the potential for success and the time and costs of the required clinical programs.

Prepared a phase III clinical protocol, on behalf of a small pharmaceutical company, for study of a new oncology compound (hematology).

Prepared web page for small pharmaceutical company to help recruit potential clinical investigators and patients to the study.

Prepared data safety monitoring board (DSMB) charter for a phase II clinical study (oncology), on behalf of a small pharmaceutical company.

Prepared two phase II/III protocols for a small pharmaceutical company for development of a new oncology compound (hematologic malignancy).

Analyzed pre-clinical and clinical results for a new chemotherapeutic agent (oncology) and provided objective, independent critical analysis of the findings and implications for human clinical trials for a small pharmaceutical company.

Prepared in-depth analyses of an oncology product being considered for in-licensing by a small, pharmaceutical company.

Prepared a complete phase II protocol on behalf of a small biotechnology company (oncology).

Updated Investigators' Brochure for small oncology company

Participated in multiple investigator meetings and summarized the minutes for a small oncology company.

Identified multiple potential indications for a new class of drugs, prepared an extensive analysis of each one, including advantages and disadvantages of each clinical trial target population, and made recommendations for prioritization, based upon clinical trial design and likelihood of success criteria. Small pharmaceutical company.

Identified two key investigators, one with unique, one-of-a-kind laboratory facility, for phase I dose escalation, proof-of-principle clinical study of a new pharmaceutical, with a novel mechanism of action. Small pharmaceutical company.

Prepared in-depth analyses of an oncology product being considered for in-licensing by a small, pharmaceutical company.

Reviewed and extensively revised phase I/II oncology protocol, including preparation of the rationale and background sections, for a small pharmaceutical company (oncology).

Identified multiple clinical investigators for a phase II oncology program (hematologic malignancy), for a small pharmaceutical company (oncology).

Prepared in-depth analysis of study design options and sample size estimates for phase II oncology program (hematologic malignancy), for a small pharmaceutical company (oncology).

Prepared and presented two major training presentations on treatment of leukemia, on behalf of a small pharmaceutical company.

Prepared in-depth analysis of need assessment and clinical opportunities for a novel, recombinant protein (coagulation), on behalf of a small, biotechnology company.

Prepared clinical development program, phase I – III, for a novel, recombinant protein (coagulation), on behalf of a small, biotechnology company.

Prepared in-depth analysis of need assessment and clinical opportunities for a novel, recombinant protein (coagulation), on behalf of a small, biotechnology company.

Prepared an extensive literature review and analysis of treatment options for a specific tumor type (oncology) on behalf of a small, pharmaceutical company.

Assisted with preparation of NDA preparation (oncology), on behalf of a small, pharmaceutical company.

Prepared two protocols for phase II/III trial of novel therapeutic (hematologic malignancy).

Reviewed phase I/II data and proposed phase III clinical development plan for an oncology product (CNS oncology). Prepared an objective evaluation of the development plan, risks, recommendations.

Prepared promotional materials for clinical trial mailing announcement (oncology).

Prepared slide presentation for Investigator Meeting (oncology).

Prepared slide presentation for use booth at major international conference (oncology).

Prepared extensive revision of Investigator Brochure for small pharmaceutical company (brain diseases)

Acting medical monitor for two clinical studies being conducted by a biotechnology company (immunology).

Prepared corporate presentation (PowerPoint) for small pharmaceutical company (oncology).

Prepared presentation for Clinical Advisory Board meeting and participated as an advisor, on behalf of a small biotechnology company (hematology/coagulation).

Prepared manuscript summarizing phase I data for a small biotechnology company (pulmonary disease).

Prepared extensive revision of Investigator Brochure (Hematology/Oncology)

Prepared analysis of clinical trial considerations for prostate cancer for small pharmaceutical company (oncology)

Participated in analysis of the data and Powerpoint presentation for ASCO presentation (oncology).

Reviewed in-licensing opportunities for several new oncology agents and prepared an in-depth analyses of the opportunities, on behalf of a small oncology company.

Developed clinical design, development phase I development plan, and prepared protocol synopsis for FDA submission for development of a novel therapeutic coagulant agent on behalf of a small biotechnology company.

Acting medical monitor for large, multicenter clinical trial (rheumatology) on behalf of a major biotechnology company.

Prepared in-depth analysis of clinical opportunities for a novel, therapeutic agent, on behalf of a contract research organization (oncology). Made recommendations for target populations. Prepared synopses for multiple phase II studies involving multiple target populations.

Provided in-depth analyses of a small pharmaceutical company novel product (oncology) and its products under development, as part of a due-diligence process for a venture capital company considering investing in the company. Prepared in-depth report of the therapeutic options, alternative treatments currently under development for the same target populations, and recommended alternative target populations for phase II/III study. Prepared in-depth report, including clinical study design options for the phase II/III development program for multiple tumor types, potential risks, status of competing clinical trials, and sample size estimates.

Provided in-depth analyses of a small pharmaceutical company novel product (oncology) and its products under development, as part of a due-diligence process for a venture capital company considering investing in the company. Prepared in-depth report of the therapeutic options, alternative treatments currently under development for the same target populations, and recommended alternative target populations for phase II/III study. Prepared in-depth report, including clinical study design options for the phase II/III development program for multiple tumor types, potential risks, status of competing clinical trials, and sample size estimates.

Prepared Phase I protocol, on behalf of a small pharmaceutical company (oncology/hematology), for a novel, therapeutic agent.

Prepared in depth Powerpoint presentation of key abstracts involving a specific hematologic malignancy, presented at recent American Society of Hematology Annual meeting, on behalf of a small biotechnology company.

Prepared Amendment of protocol, on behalf of a small pharmaceutical company (oncology/hematology), for a novel, therapeutic agent.

Prepared guidelines for patient management, on behalf of a small pharmaceutical company (oncology/hematology), for a novel, therapeutic agent.

Prepared Phase II protocol, on behalf of a small pharmaceutical company (oncology), for a novel, therapeutic agent.

Edited and enhanced pharmacology summary for FDA filing, on behalf of a small pharmaceutical company (oncology).

Prepared multiple Powerpoint presentations for training and investigator meetings, on behalf of a small pharmaceutical company (oncology).

Prepared analysis of adverse events, on behalf of a small pharmaceutical company (oncology).

Prepared Phase 1 – 3 study synopses, analysis of study designs, projected clinical study costs and timelines of Phase 1 – 3 studies, on behalf of a small pharmaceutical company (hematology).

Medical monitor for two large, multicenter phase 2 clinical trials – reviewed all enrollment requests, waivers, adverse event reports, made numerous investigator contacts, for 12 months, on behalf of a small pharmaceutical company (hematological malignancies)

Prepared extensive analysis of safety data and prepared presentations for Safety Oversight Group, as well as being member of the group, on behalf of a small pharmaceutical company (hematological malignancies).

Prepared abstracts (2) for submission to major medical meeting (hematology-oncology) – both accepted for oral presentation at American Society of Hematology Annual Meeting, December, 2008.

Prepared Powerpoint presentations (2) for major medical meeting (hematology-oncology) – both accepted for oral presentation at American Society of Hematology Annual Meeting, December, 2008.

Prepared in-depth analysis of novel treatment modality for colorectal cancer, on behalf of a small pharmaceutical company (oncology).

Developed study design and synopsis of phase 1 study of novel treatment for colorectal cancer, on behalf of a small pharmaceutical company (oncology).

Prepared comprehensive, 1.5 hour-long Powerpoint presentation of the most important abstracts from the recent American Society of Hematology meeting, on behalf of a small pharmaceutical company (hematologic malignancies).

Analyzed oncology literature on treatment results (oncology), on behalf of major biotechnology company.

Prepared Powerpoint presentation for protocol kick-off meeting (oncology), on behalf of major biotechnology company.

Prepared full protocol for mechanism of action study (oncology), on behalf of major biotechnology company.

Prepared full QTc assessment protocol (oncology), on behalf of major biotechnology company.

Prepared Clinical Overview section for major FDA submission (oncology), on behalf of major biotechnology company.

Prepared phase III protocol for oncology indication, on behalf of major biotechnology company. Provided major input on statistical design and target population, as well.

Prepared Powerpoint presentation for internal management review (oncology), on behalf of major biotechnology company.

Reviewed individual responses for oncology patients (RECIST), on behalf of major biotechnology company.

Review promotional materials (oncology), on behalf of major biotechnology company.

Provided guidance to small pharmaceutical company (oncology) on formatting summary tables for regulatory submission.

Prepared analysis of safety data and prepared Powerpoint presentation for regulatory presentation (oncology), on behalf of major biotechnology company.

Conducted extensive review of safety data from Phase 1 trial, prepared in depth analysis of the data, including recommendations for dose for Phase II trial (oncology), on behalf of a small pharmaceutical company.

Review Promotional Review Committee materials (oncology), on behalf of a major biotechnology company.

Assisted with preparation of clinical study report (oncology), multiple sections, on behalf of a major biotechnology company.

Prepared complete Phase 1 protocol, on behalf of a small pharmaceutical company (hematology-oncology).

Identified potential major clinical investigators and clinical sites for Phase I protocol (hematology-oncology, transplantation), on behalf of a small pharmaceutical company.

Reviewed, modified, and answered queries, for a large number of safety narratives for major biotechnology company (oncology).

Prepared Clinical Overview section for major regulatory filing (oncology), on behalf of a major biotechnology company.

Prepared major sections of a clinical study report (oncology), including efficacy and safety conclusions and the entire discussion section, on behalf of a major biotechnology company.

Prepared complete Phase II protocol (oncology), on behalf of a major biotechnology company.

Prepared phase I clinical protocol for a small pharmaceutical company (transplantation).

Identified key investigator, to advise small pharmaceutical company (hematology-oncology).

Prepared Phase II protocol (oncology), on behalf of a major biotechnology company.

Extensive review of laboratory and safety data, issue queries, data resolution, pivotal clinical trial, on behalf of a major biotechnology company (oncology).

Prepared safety narratives, pivotal clinical trial, on behalf of a major biotechnology company (oncology)

Assisted in data analysis and preparation of report for Post-Marketing Commitment (PMC) filing, on behalf of a major biotechnology company (oncology).

Prepared phase I clinical protocol for a small pharmaceutical company (oncology).

Reviewed and updated safety databases for a phase II and a pivotal, phase III study, on behalf of a major biotechnology company (oncology).

Reviewed and critiqued CRF's for phase I clinical trial, on behalf of a small pharmaceutical company (hematology).

Reviewed and critiqued CRF's for phase 1 clinical trial, on behalf of a small pharmaceutical company (oncology).

Provided major input into the design of a phase 2/3 clinical trial, including sample size, on behalf of a major biotechnology company (oncology).

Provided major input into the design of phase III pivotal clinical trial, on behalf of a major biotechnology company (oncology).

Reviewed CSR and re-analyzed the safety data, identifying significant new findings; rewrote sections and extensiverevisions of safety tables, on behalf of a small biotechnology company (cardiology).

Wrote entire CSR for Phase 1 study, on behalf of a small biotechology company (oncology).

Prepared and wrote entire, full protocol, phase II, on behalf of a major biotechnology company (oncology).

Reviewed and modified protocol for phase 1, on behalf of a small biotechnology company (oncology).

Acting medical monitor for phase 2 oncology protocol (hematologic malignancy, completed).

Prepared entire full protocol, for PMC, on behalf of a major biotechnology company (oncology).

Prepared full protocol for CYP3A4 inhibition study, on behalf of a major biotechnology company (oncology)

Prepared full protocol for CYP3A4 induction study, on behalf of a major biotechnology company (oncology)

Prepared two full drug-drug interaction (DDI) protocols, on behalf of a major biotechnology company (oncology)

Prepared full rollover (extension) protocol, on behalf of a major biotechnology company (oncology)

Reviewed all CT scan and RECIST data and issued all queries to sites for entire phase 3 study (oncology).

Prepared and gave two major traning presentations to contract research organization on clinical trial design and review of 3 protocols (oncology).

Prepared clinical response for inquiries from European regulatory agency, including draft study proposal (oncology).

Assisted with preparation of clinical study report (CSR). Reviewed all data listings, extensive editing and writing of the report (oncology).

Technical advisor to company on competitive market analysis (coagulation). Provide technical analyses, interpret data, participate in market research meetings.

Preparation of Investigator Brochure annual update, including preparation of launch materials, review of data, extensive editing of the IB.

Prepared amendment of phase I protocol (oncology).

Led cross-functional team, involving numerous departments (pre-clinical, clinical, medical affairs, safety, regulatory affairs) in major update of investigator brochure (oncology).

Conducted major technical analysis and authored extensive document for regulatory filing (oncology).

Reviewed study proposal and provided extensive input into study design for phase 1 study of a new, recombinant protcin (hematology).

Provided extensive input into preparation of Investigator Brochure, adverse event grading systems, phase 1 protocol design – prepared protocol synopsis (immunology).

Conducted major analysis of phase 1 safety data, which served as the basis for a major regulatory filing (oncology).

Analyzed phase I data and demonstrated to the sponsor that study drug had anti-tumor activity. Provided extensive statistical analysis of the phase 1 data, provided extensive statistical tables for phase 2 study designs, assessment of study sites, prepared extensive Powerpoint presentations for external presentations, regarding potential study designs, sample sizes, power analyses, 95% confidence intervals, stopping rules, interim analyses, and overall development pathway through phase III (oncology).

Devised study design and full protocol synopsis for phase II clinical study (oncology).

Identified key investigators for phase II clinical study (oncology).

Devised study design and full protocol synopsis for first-in-man clinical study (oncology).

Wrote entire phase I protocol, first-in-man clinical study (12 different hematologic malignancies), small pharmaceutical company (oncology).

Identified clinical investigators for phase I protocol, first-in-man clinical study (12 different hematologic malignancies), small pharmaceutical company (oncology).

Prepared clinical section regulatory filings for for first-in-man clinical study (oncology).

Prepared sample size estimates and power analyses for phase II clinical trial design (oncology).

Wrote review article summarizing the history, rationale, multiple agents, clinical trials, targeting novel cancer pathway, biotechnology company (oncology).

Conducted extensive review of database for major biotech company (oncology).

Reviewed and critiqued phase 3 protocol for major biotech company (oncology).

Prepared analysis and summary of all biologicals with approved oncology indications, for small biotechnology company (oncology).

Developed study design and prepared protocol synopsis for first-in-man novel therapeutic (coagulation).

Prepared major white paper on clinical trial endpoints for phase 3 protocol, to support NDA submission and accelerated approval (transplantation). Reviewed listings and tables, as well, for accuracy, formats, comments.

Reviewed and analyzed two separate databases, patient profiles, patient listings, tables (hematologic malignancy).

Prepared major white paper on clinical trial target populations, study design considerations, for phase III clinical trial (hematologic malignancy).

Prepared major white paper on phase III clinical trial endpoints (transplantation).

Conducted extensive literature review on transplantation complications

Reviewed and critiqued 3 separate clinical study reports (hematologic malignancy) for small biotech company.

Reviewed patient profiles for two clinical trials (hematologic malignancy).

Developed major strategy for phase III clinical trial design.

Recommended key experts for clinical advisory board (hematologic malignancy).

Prepared complete, extensive Powerpoint presentation for clinical advisory board, including statistical analysis, sample size estimates, flow charts, study design, questions, discussion points (malignant hematology).

Led clinical advisory board meeting (malignant hematology).

Prepared synopsis and study design for phase 3 protocol (malignant hematology)

Prepared in –depth due diligence evaluation and report on in-licensing opportunity for biotech company (malignant hematology).

Conducted survival analysis and prepared Kaplan-Meier survival curve analysis for small pharmaceutical company (oncology).

Reviewed patient profiles, prepared spreadsheets of queries, for two phase 3 studies (malignant hematology).

Reviewed concomitant medications, adverse events, past medical history listings for two phase 3 studies, prepared spreadsheets of queries (malignant hematology).

Reviewer for multiple clinical study reports (CSR's) for small biotechnology company (malignant hematology).

Prepared exhaustive clinical overview module 2.5 for IND submission for small biotechnology company (malignant hematology).

Prepared Powerpoint in-depth presentation reviewing education company staff about a specific hematologic condition/disease, reviewing prior clinical trials, with analysis of strengths, weaknesses, clinical trial designs, opportunities, risks, challenges, on behalf of a medium-sized pharmaceutical company (hematology).

Prepared due-diligence analyses on eight different company clinical research programs and clinical trial results, with critical analyses of the results, clinical trials designs, potential for regulatory approvals, risks, challenges, strengths, weaknesses, on behalf of a medium-sized pharmaceutical company (hematology).

Analyzed phase 1 clinical trial data, prepared Kaplan-Meier survival analyses, sample size estimates for phase 3 clinical trial, for small pharmaceutical company (oncology).

Prepared multiple in-depth analyses and recommendations on phase 1 – 3 clinical trial designs for a novel targeted agent, including analysis of prior clinical trials, published studies, articles, strengths, weaknesses, challenges, detailed analyses and recommendations on multiple disease targets, sample size estimates, clinical trial feasibility analyses, for infectious disease indication (small biotech company).

Prepared in-depth due diligence analysis of novel agent for in-licensing (biotech company) (hematology).

Prepared in-depth due diligence analysis of novel agent for in-licensing (transplantation) (biotech company) (transplantation).

Prepared in-depth due diligence analysis of novel agent for in-licensing (transplantation) (biotech company) (transplantation).

Prepared in-depth due diligence analysis of novel agent for in-licensing (biotech company) (hematology).

Prepared in-depth due diligence analysis of novel agent for in-licensing (biotech company) (hematology).

Prepared in-depth due diligence analysis of novel agent for in-licensing (biotech company) (hematology).

Prepared in-depth due diligence analysis of novel agent for in-licensing (biotech company) (hematology).

Prepared in-depth due diligence analysis of novel agent for in-licensing (biotech company) (hematology).

Prepared majority of clinical study report (phase 3), hematologic malignancy (biotech company)

Reviewed safety listings (oncology), issue queries (major biotech company).

Prepared major sections and reviewer of phase 3 study clinical study report (CSR) (hematology) (pharmaceutical company).

Prepared major sections and reviewer of 2nd phase 3 study clinical study report (CSR) (hematology) (pharmaceutical company).

Prepared in-depth analysis and recommendations for possible target indications and study designs for novel oncology agent (small pharmaceutical company).

Extensive review of patient profiles, issue queries, review query responses, for phase 3 pivotal clinical trial (oncology) (biotech company).

Extensive review of patient profiles, issue queries, review query responses, for second phase 3 pivotal clinical trial (oncology) (biotech company).

Reviewed safety listings (oncology), phase 1 study, issue queries (small biotech company).

Reviewed safety listings (oncology), 2nd phase 1 study, issue queries (small biotech company).

Reviewed safety and efficacy electronic databases (oncology) for accuracy, compliance with protocol, discrepancies, issue queries, review responses, clean database, for large, international pivotal phase 3 clinical trial (biotech company).

Extensive, mutl-level review or major laboratory value database (oncology) for accuracy, units, ranges, values, issue queries, provide instruction to multinational personnel, for large, international pivotal phase 3 clinical trial (biotech company).

Participated in selection of contract research organization for phase 3 clinical trial (oncology) for small, pharmaceutical company.

Screened all patients to be enrolled in phase 3, international clinical trial (oncology) for mid-sized pharmaceutical company.

Medical monitor for phase 3 pivotal clinical trial (oncology), interact with international team, answer all medical and enrollment questions, for mid-sized pharmaceutical company.

Participated in the data base structure and design of electronic case report forms for phase 3 clinical trial (oncology), for small pharmaceutical company.

Participated in the design and writing of protocol for phase 3 clinical trial (oncology), for small pharmaceutical company.

Participated in the design and writing of protocol for phase 2 clinical trial (oncology), for small pharmaceutical company.

Analyzed survival data, using Cox proportional hazards model, exploratory analyses, prepare presentation (oncology), for small pharmaceutical company (oncology).

Analyzed toxicity data, using logistic regression, to identified factors predictive for toxicity, for small pharmaceutical company (oncology).

Analyzed survival data, using Cox proportional hazards model, to identify factors predictive of survival duration, for small pharmaceutical company (oncology).

Prepared tables of critical lab values to trigger data flags and automatic queries in RAVE, for large biotechnology company (oncology).

Extensive analysis of laboratory value database for out-of-range lab values, lab value unit mismatches, incorrect units, incorrect ranges, to query, for large biotechnolocy company (oncology).

Analyzed toxicity data, using logistic regression, to identified factors predictive for toxicity, for small pharmaceutical company (oncology).

Analyzed survival data, using Cox proportional hazards model, to identify factors predictive of survival duration, for small pharmaceutical company (oncology).

Analyzed efficacy data listings, to verify correct response assessments, provide listing of queries identified based on review, biotechnology company (oncology).

Extensive analysis of laboratory data, correlating toxicity with baseline lab data and prior treatment history, using univariate and multivariate logistic regression analysis and univariate and multivariate linear regression analysis, identified baseline factors and pre-study treatments that were predictive of increased risk for toxicity, and prepared large number of graphics, demonstrating the results, with p-values, small pharmaceutical company (oncology).

Extensive analysis of treatment cycles completed, correlating treatment cycles with baseline lab data and prior treatment history, using univariate and multivariate logistic regression analysis and univariate and multivariate linear regression analysis, identified baseline factors and pre-study treatments that were predictive of the number of treatment cycles, and prepared large number of graphics, demonstrating the results, with p-values small pharmaceutical company (oncology).

Analyzed prior treatment data listings, review treatments for accuracy, sensibility, regimens make sense, start, stop dates, appropriate treatments received, errors, tabulate extensive list of queries, biotechnology company (oncology)

Acting medical monitor (oncology)

Review efficacy listings and database; prepared extensive list of queries for resolution (oncology).

Extensive analysis of safety database, using logistic regression analysis and multivariate regression analysis. Identified safety target signals and analyzed predictive factors. Prepared extensive graphs of the analysis, then 1 hr Powerpoint presentation summarizing the analyses and results (oncology).

Interim Chief Medical Officer, Global Head of Translational Medicine (malignant hematology).

Analyzed single ascending dose phase 1 data using univariate and multivariate regression analysis, prepared extensive analyses (pulmonary medicine).

Analyzed multiple ascending dose phase 1 data using univariate and multivariate regression analysis, prepared extensive analyses (pulmonary medicine).

Prepared phase 2 synopsis and revised full protocol (pulmonary medicine)

Prepared investigator brochure update of safey and efficacy sections – extensive revision, principal author of the efficacy and safety sections (oncology).

Extensive efficacy database review of large, internation, multi-center phase 3 clinical trial; issued large number of queries, database reconciliation (oncology).

Extensive safety database review of large, internation, multi-center phase 3 clinical trial; issued large number of queries, database reconciliation (oncology).

Prepared and presented to company international medical monitors Powerpoint presentation (Part 1) on the virtual ASCO 2020 Scientific Meeting and virtual European Hematology Association 2020 Abstracts involving a specific hematologic malignancy (oncology).

Prepared and presented to company international medical monitors Powerpoint presentation (Part 2) on the virtual ASCO 2020 Scientific Meeting and virtual European Hematology Association 2020 Abstracts involving a specific hematologic malignancy (oncology).

Prepared clinical sections summarizing multiple clinical trials for Asian Health Authority Queries for drug approval (oncology).

Extensive efficacy database and numerous listings review of large, international, multi-center phase 3 clinical trial; issued large number of queries, database reconciliation (oncology).

Extensive safety database and numerous listings review of large, international, multi-center phase 3 clinical trial; issued large number of queries, database reconciliation (oncology).

Reviewed codings for AEs, concomitant medications, medical history for phase 3 clinical trial; provided recommendations (oncology).

Prepared regulatory filing summarizing results of phase 3 clinical trial (oncology).

Prepared extensive amendment of protocol (oncology)

Prepared extensive amendment of Investigator brochure (oncology).

Prepared clinical summary and training slides for site initiation visit (oncology).

Prepared response for health authorities regarding clinical question (hematology).

Prepared response for clinical site regarding protocol (hematology).

Demonstrated and taught colleague how to review adverse event listings for MedDRA coding review.

Demonstrated and taught colleague how to review concomitant medication listings for indications review.

Editorial review of orphan drug applications x 2, comments, revisions (oncology).

Extensive review of clinical and safety databases, identified queries, recommendations (oncology).

Extensive review of adverse event and concomitant medication databases, identified queries (oncology).

Extensive, complex univariate, multivariate, regression analysis, one-way and two-way analysis-of-variance (ANOVA) statistical analysis of safety database, identified biological responses, safety analyses, trend and multiple statistically significant findings and correlations (oncology).

Prepared extensive series of figures and graphs, based on complex statistical analysis of safety databases, identified biological effects, trends, signals, dose-responses, safety analyses results (oncology).

Prepared protocol synopsis, including developed the study design and inclusion/exclusion criteria, for a Japanse-Caucasian pharmacokinetic bridging study (hematology).

Extensive review of potential indications for a novel compound, first-in-human study. Prepared extensive analysis and presentation identifying multiple porential target indications, the rationale for each (literature, scientific), potential study designs (phase 1 and 2), sample size estimates, literature review, strengths and weaknesses, recommendations for potential indications with the highest likelihood of positive outomes to demonstrate proof of concent

biologic activity (autoimmune diseases). Presented powerpoint presentation to company with recommendations for target populations.

Extensive literature review and analysis of minally important difference (MID) and minimally clinically important difference (MCID) for two patient reported outcomes (PRO) for regulatory consideration; determined the required MCID for each and provided the scientific basis and FDA guidance for the MCID's (hematology).

Extensive statistical analysis of raw data for two patient reported outcomes (PRO's), including breakpoint, benchmark, and serial measurement analysis, response analysis, identified new efficacy results, recommended modified statistical endpoints for efficacy analysis for registration pathway (hematology).

Reviewed draft phase 2 protocol design and strategy, including target populations. Provided in-depth critical review, recommended modified design and statistical analysis considerations (oncology).

Reviewed protocol synopsis for basket clinical trial. Provided critical review of the study design, worked with the lead statistician, modified clinical trial design and statistical analysis of efficacy endpoints (hematology).

Analyzed safety and laboratory data for dose cohort, prepared Power Point Presentation and gave presentation for the safety review committee (phase 1 study).

Reviewed an unexpected adverse event. Identified the underlying cause and based on the findings, provided recommendations for revising the inclusion/exclusion criteria (phase 1 study).

Analysis of multiple approaches (clinical and statistical) to define "minimally clinically important difference (MCID)" for a pivotal patient report outcome (PRO) for regulatory registration of a phase 3 registration study. Provided supporting documentation and recommendation for the MCID definition to utilize for the study (hematology).

Analyzed efficacy data for ongoing phase 2 clinical trial. Prepared in-depth analysis and report and prepared Power Point Presentation of the analysis and recommendations for executive management (hematology).

Reviewed phase 2 protocol design, inclusion criteria, and statistical analysis plan (oncology), provided recommendations for future amendment.

Prepared an in-depth analysis of potential target populations for an agent with a novel mechanism of action, provided recommendations as to which target populations might have the highest likelihood of success and which the least, for proof-of-concept (POC) study.

Prepared an in-depth analysis of RECIST versus modified RECIST (mRECIST) and recommendations as to which criteria to utilize for a phased protocol (oncology).

Provided guidance on the which content to include/not include in the design of summary tables for an FDA integrated summary of efficacy (ISE) and an FDA integrated summary of safety (ISS), along with supporting references and guidance documents (hematology).

Extensive revision of a journal manuscript, analysis of data, creating of new tables, answered all of the journal reviewer's comments and requests, which required extensive analysis, revised and wrote major new sections to the text (oncology).

Extensive analysis and narrative of a SUSAR for a regulatory filing. Resulted in change in diagnosis and grade (oncology).

Prepared abstract for submission to ASCO (oncology).

Prepared abstract for submission to ESMO (oncology).

Prepared efficacy analysis and graphics, determined a minimally clinically important difference (MCID) for the efficacy parameter (hematology).

Reviewed safety data as part of Safety Review Team external advisory board, phase 1 cohort dose-escalation study, for small biotech company (autoimmune disease). Provided post-meeting recommendations.

Prepared an in depth "Concept Sheet" for a proposed indication for novel drug, including proposed target population (solid tumor), background, rationale, 1st-line vs. 2nd-line treatment populations, monotherapy vs. combination therapy, study design, sample size estimates, executive summary, and references (oncology).

Prepared an in depth "Concept Sheet" for a proposed indication for novel drug, including proposed target population (solid tumor), background, rationale, 1st-line vs. 2nd-line treatment populations, monotherapy vs. combination therapy, study design, sample size estimates, executive summary, and references (oncology).

Prepared an in depth "Concept Sheet" for a proposed indication for novel drug, including proposed target population (malignant hematology), background, rationale, 1st-line vs. 2nd-line treatment populations, monotherapy vs. combination therapy, study design, sample size estimates, executive summary, and references (malignant hematology).

Extensive review of response data and numerous listings from phase ½ clinical stud. Involved complex, custom strategies to merge data from multiple sources to assess response and improvement (malignant hematology). Created custom analyses to determine clinical improvement. Issued queries.

Reviewed entire safety database and numerous listings from phase ½ clinical study. Involved complex strategies to enable review of data from multiple sources to analyze safety and quality control of the database; issued queries (malignant hematology).

Reviewed entire efficacy and safety databases from phase ½ clinical study. Involved complex strategies to enable review of data from multiple sources to conduct through quality control of the database and numerous listings; issued queries (malignant hematology).

Independent member of safety review committee for phase 1 study (hematology)

Member of dose-escalation committee (DEC) review of phase 1 safety data (oncology).

In depth, exhaustive review of laboratory and safety data to assess if an investigational agent was associated with a specific hematologic laboratory abnormality; extensive review of the literature, as well. Prepared extensive report, with statistical analyses, and a large number of supporting figures. (neurology).

Prepared abstract for submission to a major medical meeting in 2024 (oncology)

Member of dose-escalation committee (DEC) review of phase 1 safety data (study 2) (oncology)

Prepared an analysis of blinded efficacy data. Collaborated with an eminent statistician to provide critical guidance to the sponsor (malignant hematology).

Lectures

April 5, 1999: Guest lecturer, "Clinical Studies of Pharmaceutical and Biotechnology Drugs", graduate course "Pharmaceutical and Biotechnology Drug Development", Department of Chemical Engineering, University of California, Berkeley.
March 14, 2000: Guest lecturer, "Clinical Studies of Pharmaceutical and Biotechnology Drugs", graduate course "Pharmaceutical and Biotechnology Drug Development", Department of Chemical Engineering, University of California, Berkeley.
November 8, 2005: Invited speaker, Pharmaceutical Education and Research Institute, Inc. (PERI) training course for Genentech personnel, Introduction to Oncologic Product Development. *New Perspectives in Colorectal Cancer*
November 8, 2005: Invited speaker, Pharmaceutical Education and Research Institute, Inc. (PERI) training course for Genentech personnel, Introduction to Oncologic Product Development. *Lymphomas*
March 16, 2006: Invited speaker, Pharmaceutical Education and Research Institute, Inc. (PERI) training course for Genentech personnel, Introduction to Oncologic Product Development. *New Perspectives in Colorectal Cancer*
March 16, 2006: Invited speaker, Pharmaceutical Education and Research Institute, Inc. (PERI) training course for Genentech personnel, Introduction to Oncologic Product Development. *Lymphomas*

Miscellaneous

Webmaster for the following web sites, all of which Richard Schwartz designed and created:

www.pahomes.com
www.mainlinehomes.com (oversaw design by professional web design company)
www.mainlinepahomes.com (oversaw design by professional web design company)
www.philadelphia-realtors.com
www.philadelphia-real-estate-agent.com
www.mainlinerealestate.info
www.main-line-real-estate.net
www.brynmawrchiropractic.com
www.dontoverreact.com

Created Facebook pages for www.mainlinehomes.com and www.brynmawrchiropractic.com, www.themainlinetutor.com.

Created Google Adwords campaign and active monitoring for website (active).
Created Yelp ads campaign and active monitoring for website (active)
Created Facebook ads campaign and active monitoring for three different websites (active).

Web designer courses taken:

Dreamweaver (1 course)
Adobe Photoshop (2 courses)
Web site search engine optimization (SEO) – 12 sessions x 1.5 hr = 18 hrs

Webmaster for two web sites for a pharmaceutical company to recruit patients for its clinical studies.

Semi-professional pianist - classical and popular music styles. Know hundreds of songs by memory.

Downhill skier.

Publications

Abstracts:

l. Eastman PM, Schwartz R, Schrier SL: Differences in hemoglobin synthesis in idiopathic ineffective erythropoiesis and diGuglielmo's disease. Clin Res l9:4l7, l97l.

2. Callen J, Schwartz R, Silva J: Epidemiology of Hodgkin's disease: A report of a cluster. Presented at the American Federation of Clinical Research, New Orleans, Louisiana, January l976. Clin Res 24:7A, l976.

3. Plouffe J, Callen J, Schwartz R, et al: Lymphocyte hyperreactivity in a town with a cluster of Hodgkin's disease. Presented at national meeting, American Federation of Clinical Research, Atlantic City, New Jersey, l976. Clin Res 24:249A, l976.

4. Schwartz R, Greenberg P, Chen S: Regulation of granulopoiesis by serum lipoprotein inhibitors. Blood 50 (Suppl l): l59, l977.

5. Schwartz R, Richardson S, Greenberg P: Human endosteal bone production of colony stimulating activity (CSA). Blood 52 (Suppl l): 23l, l978.

6. Schwartz RS, Greenberg PL: Infectious complications occurring during AML induction therapy. Blood 54:Suppl l:l60a, l979. Presented at 22nd Annual Meeting, American Society of Hematology, Phoenix, Arizona. December l-4, l979.

7. Schwartz R, Halpern J, Greenberg P: Multivariate analysis of factors predicting outcome of treatment for adults with acute myelogenous leukemia (AML). Presented at the l6th Annual Meeting, American Society of Clinical Oncology, San Diego, California, May 26-27, l980. ASCO Proc 2l:C460, l980.

8. Hill HR, Boline JA, Hogan N, Rote NS, Schwartz RS: Fibronectin deficiency: A correctable defect in the neonate's host defense mechanism. Presented at the Western Meeting, American Federation for Clinical Research, Carmel, California, l983. Clin Res 3l:ll8A, l983.

9. Schwartz R, Ewing N, Boylen AL, Kasper C, Gorenc T. Spero J, Lewis J: Comparative efficacy of treatment with non-heated (NHT) and heat-treated (HT) Konyne in hemophiliacs with inhibitors. Presented at the American Society of Hematology, San Francisco, California, December 6-9, 1986. Blood 68 (Suppl 1): 302a, 1986.

10. Kurtzberg J, Friedman HS, Falletta JM, Kinney TR, Chaffee S, Schwartz, RS, Kurlander R: The efficacy of IGIV in autoimmune mediated pediatric blood dyscrasias. Blood 68 (Suppl 1): 112a, 1986.

11. Schwartz R, Kavanagh E, Bauer K, Rosenberg R, et al: Antithrombin III concentrate (AT-III) for prophylaxis and treatment of congenital and acquired AT-III deficiency. Presented at the XIth International Congress on Thrombosis and Haemostasis, Brussels, Belgium, July 1987. Thrombosis Haemostasis 58: 238, 1987.

12. Schwartz RS: Status of Clinical Trials of Human FVIII derived from recombinant DNA. Presented at the NIH-NHLBI Workshop FVIII concentrates: Current Issues and Future Prospects, March 9-10, 1989, Bethesda, MD.

13. Schwartz RS, Abildgaard C. Aledort L, Bloom A, Brackmann H, Brettler D, Dietrich S, Egli J, Fujimaki M, Fukui H, Hilgartner M, Inwood M, Kasper C, Kernoff P, Levine P, Lusher J, Mannucci P, Scharrer I. Status of Clinical Investigation of Human FVIII derived from Recombinant DNA (rFVIII). Presented at National Hemophilia Foundation Annual Meeting, Oakbrook, Il. Oct 12, 1989 (Poster Session).

14. Schwartz RS, Abildgaard C. Aledort L, Bloom A, Brackmann H, Brettler D, Dietrich S, Egli J, Fujimaki M, Fukui H, Hilgartner M, Inwood M, Kasper C, Kernoff P, Levine P, Lusher J, Mannucci P, Scharrer I, Allred R, Cox C, Fallise J, Kuo H, MacKenzie S, Maruhn D, Neumann R, Pancham R, Pennington J. Preliminary report of phase I and II clinical investigation of human FVIII derived from recombinant DNA. Presented at the XIIth International Congress on Thrombosis and Haemostasis, Tokyo, Japan, August, 1989. Thrombosis Haemostasis 62: p 181 (#548), 1989.

15. Schwartz RS, Abildgaard C, Aledort L, Arkin S, Bloom A, Brackmann H, Brettler D, Dietrich S, Egli J, Hilgartner M, Inwood M, Kasper C, Kernoff P, Levine P, Lusher J, Mannucci P, Rose E, Scharrer I. Safety and efficacy of recombinant DNA derived FVIII. Presented at the 31st Annual meeting of the American Society of Hematology, Mini-Plenary session, Atlanta, Georgia, December 2, 1989. Blood 74 (Suppl 1): 49a (#175), 1989.

16. Schwartz RS: Recombinant derived blood clotting factors, inclding factor VIII and their potential. Presented at Symposium "Applications of biotechnology in therapeutics and preventive medicine" Royal Society of Medicine, London, United Kingdom, December 6, 1989.

17. Schwartz RS: Clinical trials of factor VIII produced by recombinant technology. Presented at the 21st Annual Scientific Symposium, American Red Cross, May 16, 1990, Washington, DC.

18. Kasper CK, Inwood M, Scharrer I, Bloom A, Schwartz RS: Safety of recombinant factor VIII in home infusion. Presented at the 33rd Annual meeting of the American Society of Hematology, Denver, Colorado, December, 7, 1991. Blood 78 (Suppl 1): 56a (#213), 1991.

19. Schwartz RS, Gabriel DA, Aledort LM, Green D, Kessler CM: Clinical experience with high dose intravenous gammaglobulin (IGIV) (Gamimune®-N) in treatment of acquired FVIII inhibitors. Presented at the World Federation of Hemophilia, Athens, Greece, October, 1992.

20. Lusher JM, Arkin S, Abildgaard CF, Mannucci PM, Schwarts RS, and the Kogenate Study Group: rFVIII (Kogenate) in previously untreated subjects with hemophilia A - a three year study. Presented at the International Congress of the World Federation of Hemophilia, Athens, Greece, October, 1992.

21. Abildgaard CF, Inwood MJ, Zimmermann R, Lusher JM, Rousell RH, Schwartz RS: Immune tolerance induction with Kogenate recombinant Factor VIIII in previously untreated patients with high titer inhibitors. Presented at the International Congress of the World Federation of Hemophilia, Athens, Greece, October, 1992.

22. Schwartz RS, Gabriel DA, Aledort LM, Green D, Kessler CM: Clinical experience and treatment of acquired factor VIII inhibitors with high dose intravenous gammaglobulin (IGIV) (Gamimune N). Presented at the International Congress of the World Federation of Hemophilia, Athens, Greece, October, 1992.

23. Schwartz RS, Gabriel DA, Aledort LM, Green D, Kessler CM: A prospective study of treatment of acquired Factor VIII inhibitors with high dose intravenous gammaglobulin. Presented at the 34th Annual meeting of the American Society of Hematology, Anaheim, CA, December, 1992. Blood 80 (Suppl 1): 230a (# 912), 1992.

24. Mannucci PM, Abildgaard CF, Aledort LM, Lusher JM, Brettler DB, Bogdanoff DA, Schwartz RS and the Kogenate Study Group. Immunologic studies in HIV positive and HIV negative hemophiliacs receiving recombinant factor VIII (Kogenate®) - a 3 year update. Presented at the 34th Annual meeting of the American Society of Hematology, Anaheim, CA, December, 1992. Blood 80 (Suppl 1): 230a (# 909), 1992.

25. Lusher JM, Schwartz RS: Incidence of inhibitor development in infants and children with hemophilia A. Presented at the 34th Annual meeting of the American Society of Hematology, Anaheim, CA, December, 1992. Blood 80 (Suppl 1): 231a (# 914), 1992.

26. Mannucci PM, Abildgaard CF, Aledort LM, Lusher JM, Brettler DB, Bogdanoff DA, Schwartz RS, Hurst D and the Kogenate Study Group: Immune Function over 3.5 years in HIV Positive and HIV Negative Hemophilia Patients receiving Recombinant FVIII

(Kogenate®). Presented at 13th Congress of the International Society on Thrombosis and Haemostasis, July, 1993.

27. Mannucci PM, Chediak J, Hanna W, Byrnes JJ, Kessler CM, Ledford M, Retzios AD, Kapelan BA, Gallagher P, Schwartz RS. Treatment of von Willebrand's Disease (vWD) with a high purity factor VIII concentrate: Dissociation between correction of the bleeding time (BT), vWF multimer pattern, and treatment efficacy. Blood 94 (Suppl 1, Part 2): 98b (#3601). 1999.

28. John M. Bennett, Andrew D. Zelenetz, Oliver W. Press, Julie M. Vose, John A. Radford, Susan J. Knox, Mary Wilkinson, Richard S. Schwartz, Mark S. Kaminski, Robert Capizzi.. Incidence of Myelodysplastic Syndromes (tMDS) and Acute Myeloid Leukemia (tAML) in Patients with Low-Grade Non-Hodgkin's Lymphoma (LG-NHL) Treated with Bexxar™. John M. Bennett, Andrew D. Zelenetz, Oliver W. Press, Julie M. Vose, John A. Radford, Susan J. Knox, Mary Wilkinson, Richard S. Schwartz, Mark S. Kaminski, Robert Capizzi. Blood (Suppl 1, Part 2): 335a (#1416), 2001. Presented at the American Society of Hematology Annual Meeting, Orlando, FL, December, 2001.

29. Kuhn JG, Burris HA 3rd, Jones SF, Hein DW, Willcutt NT, Greco FA, Thompson DS, Meluch AA, Schwartz RS, Brown DM.. Phase I/II dose-escalation trial of amonafide for treatment of advanced solid tumors: genotyping to optimize dose based on polymorphic metabolism. J Clin Oncol 25 [18S]: 2503, 2007. Oral presentation at the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June, 2007.

30. H. Jean Khoury, Mauricette Michallet, Selim Corm, Lydia Roy, Dan Jones, Andreas Hochhaus, Hagop Kantarjian, Annie-Claude Benichou, Richard Schwartz, and Jorge Cortes. Safety and Efficacy Study of Subcutaneous Homoharringtonine (SC HHT) in Imatinib (IM)-Resistant Chronic Myeloid Leukemia (CML) with the T315I Mutation – Initial Report of a Phase II Trial. Presented at The American Society of Hematology Annual Meeting, Atlanta, Georgia, December 8, 2007. Blood 110, issue 11, November 16, 2007 Abstract #1050.

31. Le M., Schwartz R, Alsina M, Trudel S, Goy A, Kunkel L Incidence and severity of peripheral neuropathy in heavily pre-treated patients with hematologic malignancies receiving the selective proteasome inhibitor, carfilzomib (PR-171), in a Phase I study. Presented at the Chemotherapy Foundation Symposium XXVI, November 4 – 8, 2008, New York, NY.

32. Sundar Jagannath, Ravi Vij, A. Keith Stewart, George Somlo, Andrzej Jakubowiak, Tony Reiman, Suzanne Trudel, Jessica Taylor, Diana Fuhrman, Scott Cruickshank, Richard Schwartz, Lori Kunkel, David Siegel, and The Multiple Myeloma Research Consortium (MMRC). Initial Results of PX-171-003, An Open-Label, Single-Arm, Phase II Study of Carfilzomib (CFZ) in Patients with Relapsed and Refractory Multiple Myeloma (MM). Presented at the American Society of Hematology Annual Meeting, San Francisco, CA, December 9, 2008 Abstract #5718 (oral presentation).

33. Ravi Vij, Michael Wang, Robert Orlowski, A. Keith Stewart, Sundar Jagannath, Vishal Kukreti, Jessica Taylor, Diana Fuhrman, Scott Cruickshank, Richard Schwartz, Lori Kunkel, David Siegel, and The Multiple Myeloma Research Consortium (MMRC). Initial Results of PX-171-004, An Open-Label, Single-Arm, Phase II Study of Carfilzomib (CFZ) in Patients with Relapsed Myeloma (MM). Presented at the American Society of Hematology Annual Meeting, San Francisco, CA, December 9, 2008 Abstract #6116 (oral presentation).

34. Sundar Jagannath, Ravi Vij, A. Keith Stewart, George Somlo, Andrzej Jakubowiak, Tony Reiman, Suzanne Trudel, Jessica Taylor, Diana Fuhrman, Scott Cruickshank, Richard Schwartz, Lori Kunkel, David Siegel, and The Multiple Myeloma Research Consortium (MMRC). Carfilzomib in Relapsed and Refracdtory Myeloma. Presented at the 12th International Myeloma Workshop (IMW), Washington, DC, February 27, 2009 (oral presentation).

35. Ravi Vij, Michael Wang, Robert Orlowski, A. Keith Stewart, Sundar Jagannath, Vishal Kukreti, Jessica Taylor, Diana Fuhrman, Scott Cruickshank, Richard Schwartz, Lori Kunkel, David Siegel, and The Multiple Myeloma Research Consortium (MMRC). Phase II Study of Carfilzomib in Relapsed Myeloma. Presented at the 12th International Myeloma Workshop (IMW), Washington, DC, February 27, 2009 (oral presentation).

36. S. Jagannath, R. Vij, K. Stewart, G. Somlo, A. Jakubowiak, S. Trudel, R. Schwartz, D. Siegel, L. Kunkel, The Multiple Myeloma Research Consortium (MMRC). Final results of PX-171-003-A0, part 1 of an open-label, single-arm, phase II study of carfilzomib (CFZ) in patients (pts) with relapsed and refractory multiple myeloma (MM). J Clin Oncol 27:15s, 2009 (suppl; abstr 8504). Presented at the American Society of Clinical Oncology Annual Meeting, Orlando, FL, June 1, 2009 (oral presentation).

37. KC Shih, JA. Bacha, D Brown, W Garner, A Steino, R Schwartz, HA. Burris III. Phase I/II Study of VAL-083 in Patients with Malignant Glioma. Presented at Society of Neurooncology, November, 2012, Washington, DC (poster).

38. KC Shih, JA Bacha, D Brown, WJ Garner, R Schwartz, HA. Burris, III. Phase I/II study of VAL-083 in patients with recurrent malignant glioma or secondary brain tumor. Presented at the American Association for Cancer Research annual meeting, April 10, 2013, Washington, DC (poster).

39. KC Shih, JA Bacha, D Brown, WJ Garner, A Steino, R Schwartz, S Kanekal, M Li, L Lopez, HA Burris III. hase I/II Study of VAL-083 in Patients with Recurrent Malignant Glioma or Progressive-Secondary Brain Tumor. Presented at Society of Neuro-oncology, November 22, 2013, San Francisco, CA (poster).

40. KC Shih, MR Patel, J Bacha, DM Brown, WJ Garner, A Steino, RS Schwartz, S Kanekal, M Li, LM Lopez, HA Burris, III. Phase I/II study of VAL-083 in patients with recurrent glioblastoma multiforme. Presented at the American Association for Cancer Research annual meeting, April 9, 2014, San Diego, CA (poster).

41. Shih KC, Patel MR, Butowski NA, Bacha JA, Brown D, Garner WJ, Steino A, Schwartz RS, Kanekal S, Lopez L, Burris HA. Phase I/II study of dianhydrogalactitol in patients with recurrent malignant glioblastoma multiforme (GBM). Presented at the American Society of Clinical Oncology annual meeting, May 30, 2014, Chicago, IL. J Clin Oncol 32:5s, 2014 (suppl; abstr TPS2109) (poster).

42. Shih KC, Patel MR, Butowski NA, Bacha JA, Brown D, Steino A, Schwartz R, Kanekal S, Lopez LM, Burris HA. Phase I/II Study of Dianhydrogalactitol in Patients with Recurrent Malignant Glioma. Presented at Society of Neuro-oncology, November 14, 2014, Miami Beach, FL (poster).

43. Shih KC, Patel MR, Butowski NA, Bacha JA, Brown D, Steino A, Schwartz RSS, Kanekal S, Lopez L, Jones SF, Burris HA. Phase I/II study of dianhydrogalactitol in patients with recurrent malignant glioma. Presented at the American Association of Cancer Research, April 20, 2015, Philadelphia, PA. (abstract CT217) (poster).

44. Shih KC, Patel MR, Butowski NA, Bacha JA, Brown D, Steino A, Schwartz RSS, Kanekal S, Lopez L, Jones SF, Burris HA. Phase I/II study of dianhydrogalactitol in patients with recurrent malignant glioma. Presented at the American Society of Clinical Oncology annual meeting, May 29, 2015, Chicago, IL. J Clin Oncol 33, 2015 (suppl; abstr 2023) (poster).

45. Shih KC, Patel M, Butowski N, et al. Update on Phase 1/2 study of VAL-083 (dianhydrogalactitol) in patients with recurrent malignant glioma. II International Symposium on Clinical and Basic Investigation in Glioblastoma (GBM) 2015, Toledo, Spain, Sep 9-12, 2015 (poster).

46. Shih KC, Patel MR, Butowski N, Bacha JA, Brown DM, Steino A, Schwartz R, Kanekal S, Lopez LM, Burris HA, III. Phase I/II Study of Dianhydrogalactitol in Patients with Recurrent Malignant Glioma. Presented at Society of Neuro-oncology, November 20, 2015, San Antonio, TX (poster).

47. Shih KC, Patel MR, Butowski N, Falchook G, Kizilbash SH, Bacha JA, Brown DM, Steino A, Schwartz R, Kanekal S, Lopez LM, Burris HA III. Phase I/II study of Dianhydrogalactitol (VAL-083) in patients with recurrent glioblastoma. Presented at the American Association of Cancer Research, April 19, 2016, New Orleans, LO. (abstract CT074) (poster).

48. Shih KC, Patel MR, Butowski N, Falchook G, Kizilbash SH, Bacha JA, Brown DM, Steino A, Schwartz R, Kanekal S, Lopez LM, Burris HA III. Phase I/II study of Dianhydrogalactitol (VAL-083) in patients with recurrent glioblastoma. Presented at the American Society of Clinical Oncology annual meeting, June 5, 2016, Chicago, IL. J Clin Oncol 34, 2016 (suppl; abstr 2063) (poster).

49. O'Brien BJ et al. Phase II study of dianhydrogalactitol in patients with MGMT-unmethylated bevacizumab-naïve recurrent glioblastoma. Canadian Neuro-Oncology (CNO) Biennial Meeting 2016, abstract 155 (poster).

50. Bacha JA, et al. Clinical trials of VAL-083 in patients with chemoresistant glioblastoma. Society for Neuro-Oncology (SNO) Annual Meeting Nov, 2016, abstract ACTR-42 (poster).

51. O'Brien BJ, et al. Phase II study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve recurrent glioblastoma. AACR Annual Meeting 2017, abstract CT054 (poster).

52. Bacha JA, et al. Clinical trials of VAL-083 in patients with chemo-resistant glioblastoma. ASCO Annual Meeting June, 2017, abstract TPS2082 (poster).

53. Bacha JA, et al. Clinical Trials of VAL-083 in Patients with Chemo-Resistant Glioblastoma. WFNOS Annual Meeting 2017, abstract 09.57 (poster).

54. Bacha JA, et al. Clinical trials with Dianhydrogalactitol (VAL-083) in MGMT-unmethylated glioblastoma. Society for Neuro-Oncology (SNO) Annual Meeting, Nov, 2017, Abstract #5235 (poster).

55. O'Brien B, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with bevacizumab-naïve recurrent glioblastoma, MGMT-unmethylated. AACR Annual Meeting 2018, abstract CT167 (poster).

56. Chen Z, et al. Phase 1/2 study of dianhydrogalactitol (VAL-083) with radiation therapy in patients with newly diagnosed glioblastoma, MGMT-unmethylated. AACR Annual Meeting 2018, abstract CT168 (poster).

57. Bacha JA, et al. Phase 2 studies of dianhydrogalactitol (VAL-083) in patients with glioblastoma, MGMT-unmethylated. Canadian Neuro-Oncology meeting, May, 2018 (poster).

58. Shih K, et al. Dianhydrogalactitol in Bevacizumab-refractory GBM: Further Analysis of a Phase 1-2 Trial. ASCO Annual Meeting, Chicago, IL, June 2, 2018, Abstract 2061 (poster).

59. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with bevacizumab-naïve recurrent glioblastoma, MGMT-unmethylated. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with bevacizumab-naïve recurrent glioblastoma, MGMT-unmethylated. AACR Annual Meeting, April 18, 2018, Chicago, IL, Abstract CT167 (poster).

60. Chen ZP, et al. An open-label, biomarker driven, Phase 1/2 study of dianhydrogalactitol (VAL-083) with radiation therapy in patients with newly diagnosed MGMT-unmethylated GBM. AACR Annual Meeting, April 18, 2018, Chicago, IL, Abstract # CT168 (poster).

61. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve recurrent glioblastoma. Society of NeuroOncology (SNO) Annual Meeting, Nov 20, 2018, Phoenix, AZ, Abstract #ACTR-27 (poster).

62. Chen ZP, et al. Phase 1/2 study of dianhydrogalactitol (VAL-083) with radiation therapy in patients with newly diagnosed, MGMT-unmethylated glioblastoma. Society of NeuroOncology (SNO) Annual Meeting, Nov 20, 2018, Phoenix, AZ, Abstract ACTR-71 (poster).

63. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the adjuvant or recurrent setting. AACR Annual Meeting, April 1, 2019, Atlanta, GA, Abstract #CT115 (poster).

64. Chen ZP, et al. Phase 2 study of dianhydrogalactitol (VAL-083) with radiation therapy in patients with newly diagnosed, MGMT-unmethylated glioblastoma. AACR Annual Meeting, April 1, 2019, Atlanta, GA, Abstract CT116 (poster).

65. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the recurrent and adjuvant setting. Society of NeuroOncology (SNO) Annual Meeting Nov 22, 2019, Phoenix, AZ, Abstract ACTR-12 (poster).

66. Chen ZP, et al. Clinical Trial of VAL-083 in Newly Diagnosed MGMT-unmethylated GBM: Half-Way Report. Society of NeuroOncology (SNO) Annual Meeting Nov 22, 2019, Phoenix, AZ, Abstract ACTR-06 (poster).

67. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the adjuvant or recurrent setting. AACR Virtual Annual Meeting II, July 22, 2020, Abstract CT272 (poster).

68. Chen ZP, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with newly diagnosed, MGMT-unmethylated glioblastoma. AACR Virtual Annual Meeting II, July 22, 2020, Abstract 10227 (poster).

69. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the recurrent and adjuvant setting. Society of NeuroOncology (SNO) Virtual Annual Meeting, Nov 19, 2020, Abstract CTNI-72 (poster).

70. Chen ZP, et al. Phase 2 Clinical Trial of VAL-083 in Newly Diagnosed MGMT-unmethylated GBM. Society of NeuroOncology (SNO) Virtual Annual Meeting, Nov 19, 2020, Abstract CTNI-76 (poster).

71. Chen ZP, et al. Phase 2 clinical trial of dianhydrogalactitol (VAL-083) in patients with newly diagnosed MGMT-unmethylated GBM. AACR Virtual Annual Meeting, April 10, 2021. Abstract CT172 (poster).

72. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the adjuvant or recurrent setting. AACR Virtual Annual Meeting, April 10, 2021. Abstract CT238 (poster).

73. Chen ZP, et al. Phase 2 clinical trial of dianhydrogalactitol (VAL-083) in patients with newly diagnosed MGMT-unmethylated GBM. Society for Neuro-Oncology Annual Meeting, Nov 18, 2021. Abstract CTNI-21.

74. O'Brien BJ, et al. Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT unmethylated, bevacizumab naïve glioblastoma in the adjuvant or recurrent setting. Society for Neuro-Oncology Annual Meeting, Nov 18, 2021. Abstract CTNI-26.

75. Guo C, et al. Phase 2 Study of VAL-083 and Radiotherapy in Newly Diagnosed MGMT-unmethylated GBM. Society for Neuro-Oncology Annual Meeting, Nov 18, 2022. Abstract 32.

Articles:

l. Eastman PM, Schwartz R, Schrier SL: Distinctions between idiopathic ineffective erythropoiesis and diGuglielmo's disease: clinical and biochemical differences. Blood 40:487-99, l972.

2. Schwartz RS, Callen J, Silva J: Epidemiology of a Hodgkin's disease cluster in a small Michigan community: evidence for environmental factors. American Journal of Epidemiology l08:l9-26, l978.

3. Plouffe J, Silva J, Schwartz R, et al: Abnormal lymphocyte responses in residents of a town with a cluster of Hodgkin's disease. Clinical and Experimental Immunology 35:l63-70, l979.

4. Schwartz RS, Cohen J, Schrier S: Therapy of primary amyloidosis with Melphalan and Prednisone. Archives Internal Medicine l39:ll44-47, l979.

5. Schwartz RS, Greenberg P: The stromal microenvironment of hemopoietic and non-hemopoietic bone in man. Blood 57:77l-80, l98l.

6. Schwartz RS, MacKintosh FR, Schrier SL, Greenberg PL: Multivariate analysis of factors associated with invasive fungal disease during remission induction therapy for acute myelogenous leukemia. Cancer 53:411-19, 1984.

7. Schwartz RS, MacKintosh FR, Halpern J, Schrier SL, Greenberg PL: Multivariate analysis of factors associated with outcome of treatment for adults with acute myelogenous leukemia. Cancer 54:1672-81, 1984.

8. Hill RH, Shigeoka AO, Augustine NH, Pritchard D. Lundblad JL, Schwartz RS: Fibronectin enhances the opsonic and protective activity of monoclonal and polyclonal antibody against Group B streptococci. J Exp Med 159:1618-28, 1984.

9. Schwartz RS, MacKintosh FR, Greenberg PL: Correlative patterns of leukocyte counts at presentation and relapse in acute myelogenous leukemia. Acta Haematologica 75:79-82, 1986.

10. Kurtzberg J, Friedman HS, Chaffee S, Falletta JM, Kinney TR, Schwartz RS, Matthews TJ, Kurlander R: The efficacy of intravenous gammaglobulin in autoimmune mediated pediatric blood dyscrasias. Am J Med 83 (4A): 4-9, 1987.

11. Schwartz RS: Overview of the biochemistry and safety of a new native intravenous gamma globulin, IGIV, pH 4.25. Am J Med 83 (4A): 46-51, 1987.

12. Schwartz RS: Intravenous gammaglobulin in clinical use. The Bulletin of burn Injuries 4: 20-24, 1987.

13. Schwartz RS: The biochemistry and safety of native intravenous gamma globulin (IGIV, pH 4.25). J Clinical Apheresis 4: 89-92, 1988.

14. Schwartz RS, Ewing NP, Gorenc TJ, Spero JA: Comparative efficacy of nonheated and heat-treated factor IX complex concentrate in treatment of hemophiliacs with inhibitors. Am J Hematology 30: 22-26, 1989.

15. Rousell RH, Kasper CK, Schwartz RS: The pharmacology of a new pasteurized antihemophilic factor concentrate derived from human blood plasma. Transfusion 29: 208-212, 1989.

16. Schwartz RS, Bauer KA, Rosenberg RD, Kavanagh EJ, Davies DC, Bogdanoff DA, and the Antithrombin III study group. Clinical experience with antithrombin III concentrate in treatment of congenital and acquired deficiency of antithrombin. Am J Med 87(3B): 53S-60S, 1989.

17. Schwartz R: Appropriate Uses of Intravenous IgG. Proceedings of the 13th Annual Cancer Symposium, Scripps Memorial Hospitals. pp 259-275, Nov, 1989.

18. Sullivan KM, Kopecky KJ, Jocom J, Fisher L, Buckner D, Meyers JD, Counts GW, Bowden RA, Petersen FB, Witherspoon RP, Budinger MD, Schwartz RS, Appelbaum FR, Hansen JA, Sanders JE, Thomas ED, Storb R: Immunomodulatory and antimicrobial efficacy of intravenous immunoglobulin in bone marrow transplantation. N Engl J Med 323: 705-12, 1990.

19. Schwartz RS, Abildgaard CF, Aledort LM, Arkin S, Bloom AL, Brackmann HH, Brettler DB, Fukui H, Hilgartner MW, Inwood MJ, Kasper CK, Kernoff PBA, Levine PH, Lusher JM, Mannucci PM, Scharrer I, MacKenzie MA, Pancham N, Kuo HS, Allred RU, and the Recombinant Factor VIII Study Group: Human recombinant DNA-derived antihemophilic factor (Factor VIII) in the treatment of hemophilia A. New England J Med 323: 1800-5, 1990.

20. Schwartz RS: Clinical trials of factor VIII produced by recombinant technology. In: Hoyer LW, Drohan WN, eds. Recombinant Technology in Hemostasis and Thrombosis. New York, Plenum Press, 1991, 229-233.

21. Pennington JE, Schwartz RS: Design of clinical studies with recombinant factor VIII. Seminars in Hematology 28 (Suppl 1): 27-28, 1991.

22. Schwartz RS, Rousell RH: A summary of the world-wide clinical investigations of recombinant factor VIII. Seminars in Hematology 28 (Suppl 1): 53-54, 1991.

23. Schwartz RS: Recombinant FVIII in hemophilia. New Engl J Med (Letter) 324: 1516, 1991.

24. Intravenous immune globulin for the prevention of bacterial infections in children with symptomatic human immunodeficiency virus infection. The NICHD Intravenous Immunoglobulin Study Group. New Engl J Med 325: 73-80, 1991.

25. Hoffman DL, Quart KA, Schwartz RS: Purification and large scale preparation of antithrombin III and clinical experience in treatment of congenital and acquired deficiency of antithrombin. Miles Science Journal 13: 33-39, 1991.

26. Schwartz RS: Recombinant derived blood clotting factors including factor VIII and their potential. Sangre 36 (Suppl 3): 55-56, 1991.

27. Schwartz R, Boedeker B, Schroeder D, Horlein D: Recombinant derived blood clotting Factor VIII (Kogenate®). Miles Science Journal 14: 19-26, 1992.

28. Lusher JM, Arkin S, Abildgaard C, Schwartz RS and the Kogenant previously untreated patient study group: Recombinant FVIII for the treatment of previously untreated patients with hemophilia A - safety, efficacy, and development of inhibitors. New England Journal of Medicine 328: 453-459, 1993.

29. Mannucci PM, Brettler DB, Aledort LM, Lusher JM, Abildgaard CF, Schwartz RS, Hurst D and the Kogenate Study Group: Immune status of human immunodeficiency virus seropositive and seronegative hemophiliacs infused for 3.5 years with recombinant factor VIII. Blood 83: 1958-1962, 1994.

30. Schwartz RS: Clinical studies utilizing antithrombin III in patients with congenital antithrombin III deficiency. Seminars in Hematology 31 (Suppl 1): 42-51, 1994.

31. Schwartz RS: Clinical studies utilizing antithrombin III in patients with acquired antithrombin III deficiency. Seminars in Hematology 31 (Suppl 1): 52-59, 1994.

32. Mannucci PM, Brettler DB, Aledort LM, Lusher JM, Abildgaard CF, Schwartz RS, Hurst D. Immune status of human immunodeficiency virus seropositive and seronegative hemophiliacs infused for 3.5 years with recombinant factor VIII. The Kogenate Study Group. Blood. 1994 Apr 1;83(7):1958-62.

33. Schwartz RS, Gabriel DA, Aledort LM, Green D, Kessler CM: A prospective study of treatment of acquired (autoimmune) factor VIII inhibitors with high dose intravenous gammaglobulin. Blood 86: 797-804, 1995.

34. Mannucci, PM, Chediak J, Hanna W, Byrnes J, Ledford M, Kapelan BA, Schwartz RS, Kessler C, and the Alphanate® Study Group. Treatment of von Willebrand Disease with a High Purity Factor VIII/von Willebrand Concentrate. Blood 99: 450-456, Jan 15, 2002.

35. Lusher J, Abildgaard C, Arkin S, Mannucci PM, Zimmermann R, Schwartz L, Hurst D. Human recombinant DNA-derived antihemophilic factor in the treatment of previously untreated patients with hemophilia A: final report on a hallmark clinical investigation. J Thromb Haemost. 2004 Apr;2(4):574-83.

36. Guo C, Yang Q, Li J, Wu S, Deng M, Du X, et al. Phase 2 clinical trial of VAL-083 as first-line treatment in newly-diagnosed MGMT-unmethylated glioblastoma multiforme (GBM): Halfway report. Glioma 2019;2:167-73.