



David Tudor, PhD, MBA
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France
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WORK EXPERIENCE:

2003 - Present

Germinal Knowledge, SAS
Owner and Consultant

Partial list of projects/contracts during these 20 years:

Pharmaceutical projects:

Boehringer-Ingelheim (11/23-present): Consultant in biostatistics

Elderbrook (09/22-present): Consultant in biostatistics

Axiom Real-Time Metrics (01/2022-present): Consultant in biostatistics

Vaderis (08/20-present): Consultant in biostatistics for proof of concept study and further clinical development. Statistical development and oversight.

Biontech (09/22-10/23): Consultant in Biostatistics “Centre of Excellence”.

Sanofi (08/2018-06/2019): Consultant and Project Statistician in Biostatistics, Global Medical Affairs, responsible for CHC (Consumer Health Products). Managed 4 statisticians. Work in Oncology, project evaluation and Real World Evidence.

Takeda (06/2017-08/2018): Consultant in Biostatistics. Attached to Global Medical Affairs Gastroenterology. Post hoc exploratory and publications for Vedolizumab. Extensive work in Real World Evidence and simulation.

Philip Morris (9/2016-06/2017): Consultant in Biostatistics. Clinical Studies on the health impact of smoking reduced risk products. Simulation and Bayesian approaches.

Sandoz (Hexal) Pharmaceuticals (05/2015-06/2016): Consultant in Biostatistics FDA and EMEA submissions of Biosimilars 1) to Enbrel (psoriasis) and 2) to Humira (rheumatoid arthritis).

ESI International (2014-2015): Creation of Project Management training for Clinical Trials, including PM, financial analysis and control. This training module looks at a clinical trial from the project management perspective. Starting with the work breakdown structure, we go through resource allocation, baseline budget analysis, risk management, change mgt, stakeholder mgt and finally financial analysis with earned value management.

Novartis (2003-2004; 2008-2011) – several contracts:

These contracts comprise (in order from most recent to last):

1. Creating Statistical Analysis Plans for Clinical Trials; reviewing Figures, Tables and Listings, SDTM and ADAM datasets
2. Building an online platform for execution of Bayesian models of toxicity; the platform was written in PHP, the modeling in R and WinBUGS; the platform was for the whole team -- i.e. one centralized, access controlled, versioned simulation and analysis program, with a training module. It was completed, but not implemented.
3. Clinical trial simulations (writing and running the programs) in R for first-in-man studies; answering questions from the health authorities (primarily concerning cardiovascular side effects)
4. Creating and implementing an online course in CRA training.

Other pharma companies served include:

Gambro (Germany, France and US) – a non-statistical management project. The medical devices company had cross-cultural conflict management issues. I worked with the global management team and subsequently was hired to go to all the sites and train the local management team in conflict management

MSD Netherlands – training course in “critical thinking and problem solving”

Merck (France and US) – training in clinical trial statistics for the non-statistician

Pierre-Fabre – consulting on the study design of an oncology study; CRA training

PSI St. Petersburg, Russia - training course in “critical thinking and problem solving”

For more Pharma experience, see below.

2001 - 2003

Boomerang Pharmaceutical Communications

Director of Business Development

Developed a system of online recruitment of patients into clinical trials



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- 1998 - 2001** **Novartis Pharma, AG**
Senior Biostatistician
Phase I and pre-clinical statistics; developed first SOP in validation of statistical programming, co-wrote SOP on multiple comparisons; served on committee to choose molecules for "first in man"; did Nonmem programming, equivalence studies, general phase I study design, analysis, report writing; interim group leader during medical absence of leader
- 1991-1998** **Synthélabo Recherche**
Group Head, Internal Medicine Biostatistics
Responsible for phases II through IV of all Internal Medicine studies (allergies, respiratory, gastroenterology, dermatology, urology); lead group of 4 statisticians; created and reviewed Clinical Development Plans, developed procedures for outsourcing and CRO management; quality assurance, responsible for all aspects of Japanese studies, responsible for all statistical aspects of Health Economics studies; wrote templates for phase IV observational studies; represented the statistics department at the FDA for the transition of a urology product from phase II to phase III; also worked in the central nervous system and cardiovascular.
- 1983-1991** **Bradley University**
Tenured Associate Professor of Mathematics
Mathematical Modelling in Biology and Epidemiology, teaching applied mathematics (differential equations, numerical analysis, etc.) and statistics

OTHER EXPERIENCE:

- Statistical** Full time biostatistician in the pharmaceutical industry for 11 years;
Consultant in biostatistics as described above for the last 15 years
- Clinical Trials - worked in:**
Allergology, Gastroenterology, Respiratory, Urology, Dermatology, Cardiovascular, Central Nervous System, Oncology, Transplantation; Phases I-IV.
- Supervisory** Internal medicine group leader, Chair of Business Department for online MBA,
Interim group leader in clinical pharmacology group
Thesis director for 5 master's theses (1 in Statistics, 4 in Public Health)
- Computing Languages** SAS, R, WinBUGS, JAGS, Python, PHP, others
- Training Certificates in:** Advanced Bayesian Modelling with BUGS, MRC Cambridge Univ.
Project Management (George Washington University Master's Certificate),
Psychotherapy, Health Economics, Quality Assurance, Conflict Mediation

EDUCATION:

- Professor** **Mathematics, Bradley University**
Tenured associate professor of applied mathematics / biomathematics and statistics; lifelong member of the **Fulbright Association**
- PhD** **Mathematics, University of Iowa**
Dissertation "Disease Transmission and Control in an Age-Structured Population" - speciality analysis, differential equations
- Pg Dip** **Cognitive Behavioural Therapy - Derby University**
- MBA** **Leadership in the new economy (Management of dispersed teams)**
- MA** **German**
- MS** **Mathematics**
- Languages** English, French, German (French and American nationalities).



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Selection of Drug Development projects I have worked on

<i>Phase</i>	<i>Molecule</i>	<i>Commercial Name</i>	<i>Indication</i>
1,2,3	Mizolastine	Mizolen®	Allergies
3,3b,4	Zolpidem	Stillnox®, Ambien®	Sleep
1,2	Alfuzosine	Xatral®	Prostate Hypertrophy
1	Oxcarbazepine	Trileptal®	Epilepsy
1	Everolimus/Afinitor	Certican®	Prevention of organ rejection and oncology
1,3	Etanercept	Erelzi®	Psoriasis
1,3	Adalimumab	Biosimilar of Humira®	Rheumatoid Arthritis
4	Vedolizumab	Entyvio®	Ulcerative Colitis, Crohn's Disease
4	Bacillus Clausii	Enterogermina®	Diarrhea, Intestinal Flora
4	Cabazitaxel	Jevtana®	Prostate Cancer
4	Vandetanib	Caprelsa®	Thyroid Cancer
4	Fexofenadine	Allegra®	Allergies
4	Eliglustat	Cerdelga®	Gaucher's Disease
4	Hyoscine butylbromide	Buscopan®	Spasms, Irritable Bowel Syndrome



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Youtube presentations (2020) :

1. Coronavirus : Mathematical Modelling: <https://www.youtube.com/watch?v=vHmhE-bxg6A>
2. Coronavirus : Testing: <https://www.youtube.com/watch?v=xe4ULyww-kE>
3. Coronavirus : Confinement: <https://www.youtube.com/watch?v=gzhthejIonM>
4. Coronavirus : Social distancing: https://www.youtube.com/watch?v=nrrErGz8Y_Q
5. Coronavirus : Asymptomatics: <https://www.youtube.com/watch?v=3KHcJEc8fng>
6. Coronavirus : Light at the end of the tunnel? <https://youtu.be/1TQOcKko9oM>
7. Coronavirus : Lockdown warning: <https://youtu.be/Tb8r0kYwG7k>
8. Coronavirus: Study Design: <https://www.youtube.com/watch?v=Dup3g1iyqPk&t=34s>
9. Coronavirus: New Model for Omicron: https://www.youtube.com/watch?v=of-cINfD_4I&t=7s

Non-youtube video:

Modeling of the use of T-Cells and CAR-T on tumor evolution with comments on immunodepletion
<https://app.screencast.com/JVbSJLrW8TMTA>

Master's Theses Directed

University Liverpool Master's in Public Health

Paul Becker, *The Environmental Impact of Background Fluoride in Drinking Water on Public Health: The Effect on Fluorosis*, University of Liverpool, 2009.

Oluseye B. Babatunde, *Socio-demographics, Clinical Features and Sexual Behaviour of Attendees of a Sexually Transmitted Infection Clinic in Port Harcourt, Nigeria*, University of Liverpool, 2010.

Ute Papkalla, *Patterning chronic diseases from applications for disability classification in two German districts*, University of Liverpool, 2010.

Jamal Yazdi, *A survey of Lebanese high school students' preferences with regards to pursuing studies or a career in a health-related field*, University of Liverpool, 2010.

Université Pierre et Marie Curie Institut de Statistiques

Sandrine Laguerre, *Comparaison de différentes méthodes d'analyse des mesures répétées*, Université Pierre et Marie Curie Institut de Statistiques, 1997.

Publications and Conference Presentations

Publications

2020 "Sustained Corticosteroid-Free Clinical Remission During Vedolizumab Maintenance Therapy in Patients with Ulcerative Colitis on Stable Concomitant Corticosteroids During Induction Therapy: A Post Hoc Analysis of GEMINI 1", E.V. Loftus Jr, B.E. Sands, JF. Colombel, I. Dotan, J.M. Khalid, D.Tudor, P. Geransar, *Clinical and Experimental Gastroenterology*: 13:211—220.

2020 "A mathematical model for weight management with application",
<https://www.researchgate.net/profile/David-Tudor/publications>

2018 "Improvements in Subcomponents of the Inflammatory Bowel Disease Questionnaire in Patients Treated with Vedolizumab: Results from Gemini Trial Data", David Rubin, D. Tudor, Javaria Khalid, Haridarshan Patel. *Journal of Crohn's and Colitis* 12(supplement_1):S394-S395.

2018 "Sustained Corticosteroid-Free Remission with Vedolizumab in Moderate-to-Severe Ulcerative Colitis: A Post HOC Analysis of Gemini 1", Edward Loftus, Bruce Sands, Jean Colombel, Iris Dotan, Javaria Khalid, David Tudor, Parnia Geransar. *Journal of Crohn's and Colitis*, Volume 12, Issue supplement_1, Pages S317–S318.

2018 "Vedolizumab Treatment Persistence Up to 3 Years: Post HOC Analysis in Vedolizumab-Naïve Patients from the Gemini Long-Term Safety Study", Edward Loftus, Severine Vermeire, Javaria Khalid, David Tudor, Mona Akbari, Dirk Demuth, Laurent Peyrin-Biroulet. *Journal of Crohn's and Colitis*, Volume 12, Issue supplement_1, Pages S030–S031.

2018 "Vedolizumab treatment persistence up to 3 years: post hoc analysis in vedolizumab-naïve patients from the GEMINI LTS study" S Vermeire, E V Loftus Jr, J M Khalid, D Tudor, M Akbari, D Demuth, L Peyrin-Biroulet, *Journal of Crohn's and Colitis*: Volume 12, February 2018.

2008 "The Impact of Changes in Socio-Political Attitudes Toward Professional Education: France as a Case Study", D. Tudor, R. Wicks, *Proceedings of the Conference on Professional Education*, Nizhniy-Novgorod, May 2008.

2007 "Meta Nonverbal Communication in Cross-cultural Synchronous Online Teaching", *Usages des Nouvelles Technologies dans l'Enseignement des Langues Etrangères (UNTELE)*, Compiègne, France, 29 - 31 March, 2007.

2006 "Meta non verbal Communication: the missing link?" *Proceedings of ICEL 2006: The International Conference on e-Learning*, Montréal, Canada 22-23 June, 2006.

2003 "Assessment of the Bioequivalence of two oxcarbazepine oral suspensions versus a film-coated tablet in healthy subjects" G. Flesch, D. Tudor, J.Denouel, J.Bonner, R.Camisasca: *International Journal of Clinical Pharmacology and Therapeutics*. 41:7 2003 299-308.

2002 "Oxcarbazepine final market image tablet formulation bioequivalence study after single administration and at steady state in healthy volunteers" G. Flesch, D .Tudor, C. Souppart, J. D'Souza, M. Hossain. *International Journal of Clinical Pharmacology and Therapeutics*: 40:524-532.

- 2002 "Comparison of the bioavailability of two Oxcarbazepine oral suspensions and the Final Market Image tablet formulations after single administration and at steady state in healthy subjects" G. Flesch, D. Tudor, J. Denouel, J. Bonner, R. Camisasca, *International Journal of Clinical Pharmacology and Therapeutics*.
- 2001 "RAD in stable lung and heart/lung transplant recipients: safety, tolerability, pharmacokinetics, and impact of cystic fibrosis" R L Doyle 1, M I Hertz, J M Dunitz, J E Loyd, A A Stecenko, R L Wong, K A Chappell, T Brazelton, J M Kovarik, S Appeldingemanse, L Dou, H T Smith, D Tudor, R E Morris, *J Heart Lung Transplant*. Mar;20(3):330-9.
- 1997 "Is an antihistamine able to delay appearance of hayfever symptoms when given prior to the pollen season?" A. Stern, C. Dunmore, D. Tudor. *Allergy: European Journal of Allergy and Clinical Immunology*, April:410-414.
- 1996 "The effect of behavioural change on the prediction of R_0 in the transmission of AIDS", D. Tudor, K. Dietz, H. Heesterbeek, in *Models for Infectious Human Diseases*, V. Isham and G. Medley, editors, Cambridge University Press.
- 1994 "Local treatment of pressure sores in the elderly: amino acid copolymer membrane versus a hydrocolloid dressing", C. Hondé, C. Derks, D. Tudor, *Journal of the American Geriatrics Society*, 42: 1180-1183.
- 1994 "Association of helicobacter pylori and reflux esophagitis in symptomatic children", G. Cargill, P. Atlan, D. Tudor, C. Regnault, *Gastroenterology*, 106:4A59, April.
- 1993 "The basic reproduction ratio for sexually transmitted diseases: part 2: Effects of variable HIV-infectivity", K. Dietz, H. Heesterbeek, D. Tudor, *Mathematical Biosciences* 117:1-2:35-48.
- 1992 "Triangles in heterosexual AIDS transmission", K. Dietz, D. Tudor, in *AIDS Epidemiology: Methodological Issues*, N. P. Jewell, K. Dietz, V. T. Farewell, editors, Birkhäuser, Boston, 143-155.
- 1992 "Modeling the effect of public health campaigns on the spread of AIDS", D. Tudor, *SIAM Review*, June.
- 1991 "The hermeneutics of mathematical modeling", D. Tudor, *Humanistic Mathematics Network Newsletter*, 6:78-85.
- 1990 "A deterministic model for herpes infections in human and animal populations", D. Tudor, *SIAM Review*, 32:1:136-1140.
- 1989 "Miller's Tale", D. Tudor, *Illinois Writer's Review*, 8:1:9-12 (literature).
- 1987 "Preselecting test score means", M. McAsey, D. Tudor, *Mathematics and Computer Education*, 21:3:187-194.
- 1985 "An age-dependent epidemic model with applications to measles", D. Tudor, *Mathematical Biosciences*, 73:131-147.
- 1980 "Integral equation models of infectious diseases", H. Hethcote, D. Tudor, *Journal of Mathematical Biology*, 9:37-48.

1976 A Solutions Manual for Methods of Real Analysis, D.Tudor, John Wiley and Sons.

Conference Presentations

2014 "How to Choose a Soft Skills Consultant", Global Leadership Competence: Personal Qualities, Culture, Language, Konstanz, 13-14 June.

2014 "Compétences Relationnelles pour un Management de Projet Efficace", PMI Chapter Alsace, 2 July.

2011 "Der Projekt-Manager als Mediator", PMI Chapter München, November 7.

2010 "Managing Workplace Conflict", 3ème Conférence Européenne de la Médiation, Bourg-la-Reine, May 27-28, co-presenter Ruud van Herpen.

2008 "The Impact of Changes in Socio-Political Attitudes Toward Professional Education: France as a Case Study", D. Tudor, R. Wicks, Proceedings of the Conference on Professional Education, Nizhniy-Novgorod, May 2008.

2007 "Meta Nonverbal Communication in Cross-cultural Synchronous Online Teaching", Usages des Nouvelles Technologies dans l'Enseignement des Langues Etrangères (UNTELE), Compiègne, France, 29 - 31 March, 2007.

2006 "Meta non verbal Communication: the missing link?" ICEL 2006: The International Conference on e-Learning, Montréal, Canada 22-23 June, 2006.

2000 Session chair and Organizing Committee member PAGE 2000 (population pharmacokinetics), Salamanca, Spain, June 15-16.

1999 Session organizer at the DIA national conference, Baltimore, MD. Session title "Recent Trends in PK/PD Modeling".

1998 "Validation of statistical programming: deficiencies of ICH-E9", BBS Conference on ICH-E9, 9 May, Lugano, Switzerland.

1997 "Une application d'un processus de Markov aux essais cliniques long terme", ASU: 29ième Journées de Statistiques, 26-28 May, Carcassonne, France.

1997 "Transitional models: an application of continuous Markov processes to longitudinal categorical data", DIA Conference, 7-9 April, Nice, France.

1994 "Mathematical models for the activity of antihistamines", PSI Annual Conference, September, Coventry, England.

1994 "Opportunities for multicenter clinical trials in joint US-European drug development", co-author A. Zipfel, ASA annual conference, August, Toronto, Canada.

1994 "Statistics in medicine: choosing a statistical model to test drug effectiveness", colloquium, Bradley University, 5 April, Peoria, Illinois, USA.

1994 "Incorporation of configurations of concurrent partnerships into models of sexually transmitted diseases", Joint Mathematics Meetings, 12-15 January, Cincinnati, Ohio.

1993 "Modelle für die Ausbreitung von HIV unter Homosexuellen mit Berücksichtigung möglicher Dreiecksverhältnisse", Institut für Medizinische Biometrie, June, Tübingen, Germany.

1993 "Verzweigungsprozesse in der Modellierung von Epidemien", Workshop: Mathematische Modellierung stochastischer und deterministischer Probleme in den Biowissenschaften, Pfalzakademie, 11-14 May, Lambrecht, Germany.

1993 "The behavioral differences between susceptibles and infectives with respect to HIV transmission and their influence on R_0 ", co-authors K.Dietz, H.Heesterbeek, Human Diseases Workshop, Isaac Newton Institute for the Mathematical Sciences, 28 March to 2 April, Cambridge, England.

1993 "Analyse der räumlichen Verteilung von Habichtbrutplätzen", presented by co-author G.Dobler, second co-author K.Dietz, Biometrisches Kolloquium, Annual conference of the International Biometric Society, 16-19 March, Berlin, Germany.

1992 "Verzweigungsprozesse in der Epidemiologie mit Anwendung auf die Ausbreitungsdynamik von HIV/AIDS", Abteilung für Mathematik in den Naturwissenschaften und Mathematische Biologie; Technische Universität Wien, Vienna, Austria.

1992 "Comment compter des événements dans la transmission du SIDA: une application du processus de Markov", ASU: 24^{ième} Journées de Statistiques, 18-22 May, Brussels, Belgique.

1991 "Problematik der Schätzung von Kontaktraten", Institut für Medizinische Biometrie, Tübingen, Germany.

1986 "Differential equations models for the spread of disease", Colloquium, University of Alabama in Huntsville, USA.

1986 "Age dependent disease models", Colloquium, Biomathematics Group, University of Iowa, Iowa City, Iowa, USA.

1984 "Data structures for sparse matrices", Colloquium, Computer Science Department, College of Charleston, Charleston, SC, USA.

1981 "Numerical analysis as a focal point in the first two years of college", MAA Regional Meeting, Birmingham, AL, USA.

1980 "Sensitivity analysis in disease modeling", Colloquium, Biostatistics Department, Medical University of South Carolina, Charleston, SC, USA.

1979 "Disease transmission in an age-structured population", Joint Mathematics Meetings, January, Biloxi, MS, USA.

1979 "Mathematical modeling of childhood diseases", Ninety-first meeting of the Iowa Academy of Sciences, Mt. Vernon, IA, USA.