

9 BIBLIOGRAFÍA

Abbas I. 2003. Integración de los modelos de simulación en el diseño de los ensayos clínicos. Tesis doctoral presentada en la UPC el 23 de Diciembre de 2003. Directores: Drs. J. Casanovas y J. Rovira.

Abbas I, Cobo E, Casanovas J, Romeu J, Monleón T, Ocaña J. 2003. Optimising Clinical Trials design using simulation. Proceedings of 3th Annual meeting of ENBIS and ISIS3. 21-23 August 2003. Barcelona.

Alfaro V, Prats M, Nadal J, Alami M. 1998. The effect of clinical trials legislation in Spain. Applied clinical trials 3: 52-59.

Amstein R, Steimer J, Holford N, Guentert T, Racine A, y col. 1996. RIDO: Multimedia CD-Rom software for training in drug development via PK/PD principles and simulation of clinical trials. Pharm Res. 13:S452 (Abstr).

Anderson HA, Sargent RG. 1974. An investigation into scheduling for an interactive computer system. IBM Journal of Research and Development, 18: 125-137.

Balci O. 1986. Verification, Validation, and Accreditation. Proceedings of the 1998 Winter Simulation Conference. D.J. Medeiros, E.F. Watson, J.S. Carson and M.S. Manivannan, eds.

Balci O, Sargent RG. 1981. A methodology for cost-risk analysis in the statistical validation of simulation models. Comm of the ACM 24: 190-197.

Balci O, Sargent RG. 1984. Validation of simulation models via simultaneous confidence intervals. American Journal of Mathematical and Management Science 4: 375-406.

Banks J., Carson JS, Nelson BL and Nicol D. 2000. Discrete event system simulation. 3d. Ed. Englewood Cliffs, NJ: Prentice-Hall.

- Barceló J. 1996. Simulación de sistemas discretos. Madrid: Isdefe.
- Boeckmann AJ, Sheiner LB, Beal SL. 1990. NONMEM Users Guides. San Francisco: Univ. Calif. NONMEM Proj. Group. 5th ed.
- Bonillo-Martin, A. Sistematización del proceso de depuración de datos. Tesis doctoral UAB, 2003.
- Cent. Drug. Dev. Sci. 1996. Frontiers in drug development-Computer simulation and modelling. Basel, Switzerland: Eur.Cent.Pharm.Med.
- Cent. Drug. Dev. Sci. 1997. Modeling and simulation of clinical trials in drug development and regulation. Reston VA: Cent. Drug. Dev Sci.
- Cent. Drug. Dev. Sci. 1999. Modeling and simulation best practices Workshop. 1999. Arlington, VA: Cent Drug Dev Sci. <http://www.dml.georgetown.edu/cdsd>.
- Chatterjee S, Hadi AS. 1986. Influential Observations, High Leverage Points, and Outliers in Linear Regression. Statistical Science 1: 379-416.
- Chow SC, Liu JP. 1992. Design and analysis of bioavailability and bioequivalence studies. New York: Marcel Dekker.
- D'Argemio DZ. 1981. Optimal sampling times for pharmacokinetic experiments. J. Pharmacokinetic. Biopharm 9: 739-56.
- Davis JR, Nolan VP, Woodcock J, Estabrook RW (Editors). Roundtable on Research and Development of Drugs, Biologics and Medical Devices, Institute of Medicine, 1999.

De la Llama-Vazquez F, Gutiérrez P. 1996. Auditoría sobre ensayos clínicos. Farmacia Hospitalaria 20: 114-117.

Department of Defense. 1996. Verification, Validation and Accreditation (VV&A) Recommended Practices Guide, Defense Modeling and Simulation Office, Alexandria, VA. (Co-authored by: O. Balci, P. A. Glasow, P. Muessig, E. H. Page, J. Sikora, S. Solick, and S. Youngblood) [www://msiac.dmso.mil/vva](http://msiac.dmso.mil/vva))

Domínguez-Gil A. 2000. La circulación del medicamento en el organismo. Farmacocinética. El ensayo clínico en España. Farmaaindustria. España.

Efron B, Tibshirani RJ. 1993. An Introduction to the bootstrap, New York: Chapman & Hall. USA.

Flexner C, Van der Horst C, Jacobson MA, Powderly W, Duncanson F y col. 1994. Relationship between plasma concentrations of 3'-deoxy-3'-fluorothymidine (alovudine) and antiretroviral activity in two concentration-controlled trial. J. Infect. Dis. 170:1394-1403.

Fonseca P, Casanovas J, Montero J. 2003. LeanSim: Un sistema de simulación para el entrenamiento de personal especializado dentro de sistemas complejos; Proceedings of 2^a Conferencia Iberoamericana en sistemas, cibernética e informática CISCI. Vol I. Orlando FL USA.

Fonseca P, Casanovas J, Montero J. 2004^a. LeanSim® Virtual Reality Distributed Simulation Suite. A: MODELLING, SIMULATION, AND OPTIMIZATION. M.H. Hamza 287-292 (a).

Fonseca P, Casanovas J, Montero J. 2004^b. Adaptación de modelos de simulación estándar a modelos virtuales y/o sistemas de entrenamiento distribuidos, con representación del movimiento continuo de entidades.

Proceedings of 3ra conferencia iberoamericana en Sistemas, Cibernética e informática. Jorge Baralt, Nagib Callaos, Belkis Sánchez 241-246.

Gebski V, McNeil D, Coates A, Forbes J. 1987. Monitoring distributional assumptions and early stopping for a prospective clinical trial using Monte Carlo simulation. Stat Med 6: 667-78.

Girard P, Blaschke T, Kastrissios H, Sheiner L. 1988. A Markov mixed effect regresión model for drug compliance. Stat Med 17: 2313-2333

Golub GH, Van Loan CF. 1986. Matrix computations, 3rd (Baltimore Johns Hopkins University Press). USA.

Guasch A, Piera MA, Casanovas J, Figueres J. Modelado y Simulación. 2002. UPC. Barcelona.

Hale MD. 1997. Using population pharmacokinetics for planning a randomised concentration controlled trial with a binary response. In European Cooperation in the field of Scientific and Technical Research, ed. L Aarons, L.B. Balant, M. Danhof, pp. 227-235. Geneva Swithzerland: Eur. Comm.

Hale MD, Gillespie WR, Gupta SK, Tuk B, Holford NH. 1996. Clinical trial simulation: streamlining your drug development process. Applied Clinical Trials 5: 35-40.

Hale MD, Nicholls AJ, Bullingham RES, Hene RH, Hoitsman A, Squifflet JP y col. 1998. The pharmacokinetic-pharmacodynamic relationship for mycophenolate mofetil in renal transplantation. Clin. Pharmacol. Ther. 64: 672-83.

Hartley HO, Rao JNK. 1967. Maximum likelihood estimation for the mixed analysis of variance model. Biometrika 54: 93-108.

Holford NHG. 1997. Modelling therapeutic effects and disease progress. In modelling and simulation of clinical trials in drug development and regulation. Pp 61-62. Washington DC: Cent. Drug. Dev. Sci. Georgetown Univ. Med. Cent. USA.

Holford NHG, Hale M, Ko HC, Steimer J-L, Sheiner LB, Peck CC. 1999. Simulation in drug development: good practices. Center for Drug Development Science (CDDS), Georgetown University, USA.
<http://cdds.georgetown.edu/research/sddgp723.html>

Holford NHG, Kimko HC, Monteleone JPR, Peck CC. 2000. Simulation of clinical trials Annual review of pharmacology and toxicology 40: 209-234.

Hollis S, Campbell F. What is meant by intention to treat analysis?. 1999. Survey of published randomised controlled trials. BMJ 319: 670 – 674.

Jackson R. 1996. Computer Techniques in Preclinical and Clinical Drug Developement. CRC press.

Johnson RA. 1994. Miller and Freund´s Probability and Statistics for engineers, 5th edition. Englewood Cliffs, NJ: Prentice-Hall.

Jørgensen B. 2004. Mixed model theory II: Tests and confidence intervals. Master in Applied Statistics. Danish institute of Agriculture Sciences.
<http://www.dina.dk/~per/Netmaster/courses/st113/Module10/index.html>.

Kleijnen JPC. 1999. Validation of models: statistical techniques and data availability. Proceedings of the 1999 Winter Simulation Conference, P. A. Farrington, H. B. Nembhard, D. T. Sturrock, and G. W. Evans, eds.

Kleijnen JPC. 2003. Course on simulation: Validation & Verification. Tiburg University.

Kleijnen JPC, Sánchez SM, Lucas TW, Cioppa TM. 2004. A user's guide to the brave new world of designing simulation experiments. INFORMS Journal on Computing (aceptado para publicación).

Kleijnen JPC, Deflandre D. 2005. Validation of regression metamodels in simulation: Bootstrap approach. European Journal of Operational Research (en prensa).

Laporte JR. 1993. Principios básicos de investigación clínica. Ediciones Ergón.

Law MA, Kelton WD. 1999. Simulaton modelling & analysis. New York: McGraw-Hill.

LCFIB. 2005. Documentación LEANSIM.

Lesaffre E, Scheys I, Frohlich J, Bluhmki E. 1993. Calculations of power and sample size with bounded outcome. Stat Med 12: 1063-1078

Lewis JA. Modelling and Simulation of Clinical trials. 1998. International Society for Clinical Biostatistics Meeting. Ag 24-28. (Dundee UK).

Liang KY, Zeger SL. 1986. Longitudinal data analysis using general linear models. Biometrika 73: 13-22.

Mallet A, Mentré F, Steimer JL, Lokiec F. 1988. Nonparametric maximum likelihood estimation for population pharmacokinetics, with application to cyclosporine. J. Pharmacokinetic Biopharm 16:311-327.

Maloney A. 2004. Non-linear mixed effects modelling using the SAS system - An overview. 17 June. Proceedings of PAGE2004 meeting. Uppsala (Sweeden).

Mateu S. Farmacología. 2004. Master de Medicina en la Industria Farmacéutica. Hospital de Sant Pau. UAB.

Mitchell EEL. 1978. Advanced continuous language (ACSL) In numerical methods for differential equations and simulation, ed. AW Bennet, R. Vichnevetsky. Amsterdam: North Holland Publ.

Monleón T. 2000. La farmacoeconomía, una ciencia esencial que se ocupa de los recursos y evalúa el control del gasto sanitario. La Vanguardia-Especial sanidad privada. 27 Marzo 2000.

Monleón T, Ocaña J, Abbas I, Casanovas J, Cobo E., Arnaiz JA, Carner X. 2003^a. Simulación de ensayos clínicos de medicamentos. Ajuste del modelo. 27 Proceedings of Congreso Nacional de Estadística e Investigación Operativa. Lleida, 8-11 de Abril de 2003.

Monleón T, Ocaña J, Vegas E, Fonseca P, Abbas I, Casanovas J, Cobo E, Arnaiz JA, Carner X, Gatell. 2003^b. Optimization of AIDS pilot clinical trial using LeanSim. Value in Health 6: 794.

Monleón T, Ocaña J, Vegas E. 2003^c. Simulación realista de un ensayo clínico sobre SIDA. Proceedings of IX Conferencia Española de Biometría. La Coruña, 28-30 de mayo de 2003.

Monleón T, Hernández JC, Carreño A. 2003^d. Planificación de un estudio clínico. Metodología de investigación y estadística en oncología y hematología. Novartis Oncology. Ed. Editec. Barcelona.

Monleón T, Pérez P, Moral I. 2003^e. Métodos estadísticos. Metodología de investigación y estadística en oncología y hematología. Novartis Oncology. Ed. Editec. Barcelona.

Monleón T, Ocaña J, Vegas E, Fonseca P, Riera A, Montero J, Abbas I, Casanovas J, Cobo E, Arnaiz JA, Carne X, Gatell JM. 2004. Flexible discrete events simulation of clinical trial using LeanSim. Proceedings of COMSTAT. Abril 2004.

Monleón T, Ocaña J, Arnaiz JA, Carner X, Riba N, Soy D. 2005. Modelización, simulación y validación de un ensayo clínico de Fase I. Proceedings of IX Conferencia Española de Biometría. Oviedo Mayo 2005.

Nance RE, Sargent RG. 2002. Perspectives on the evolution of simulation. Operations Research 50: 161-172.

National Center for Health Statistics. 1994. The tirad National Health and Nutrition Examination Survey, 1988-94 (NHANES III). <http://www.cehn.org/cehn/resource guide/nhanes.html>.

Neter J, Kutner MH, Nachtsheim, CJ, Wasserman W. 1996. Applied Linear Statistical Models, 4th Edition, Richard D. Irwin, Inc., Burr Ridge, Illinois.

Oracle Corporation. 1996. Oracle Clinical Version 3.0: User's Guide. Redwood Shores, CA.

Peck C. 1997. Drug development: improvement the process. Food Drug. Law J 52: 162-167.

Peck C. Modeling and Simulation (M&S) of clinical trials. 1998. International Society for Clinical Biostatistics Meeting. Ag 24-28 1998. (Dundee UK).

Pharsight Corp. 1997. Pharsight Trial designer User´s Guide. Mountain View, CA: Pharsight Corp.

Pita-Fernández S. 1996. Elementos básicos de diseño de los estudios. Cad. Atención primaria 3: 83-95.

Pinheiro JC, Bates DM. 1995. Approximations to the log-likelihood function in the nonlinear mixed-effect model. Journal of Computational and Graphical Statistics 4: 12-35.

Nadkarni PM, Brandt C, Frawley S, Sayward FG, Einbinder R, Zelterman D, Schacter L, Miller PL. 1998. Managing Attribute—Value Clinical Trials Data Using the ACT/DB Client—Server Database System. J Am Med Inform Assoc 5: 139–151.

Press WH, Teukolsky SA, Vetterling WT and Flannery BP. 2002. Numerical Recipes in C++. The Art of Scientific Computing. Second Edition. Cambridge University Press.

Regalado A. 1998. Re-engineering drug development. I: Simulating clinical trials. Star Up, Jan. 13-18.

Reynolds MR, Deaton HL. 1982. Comparison of some test for validation of stochastic simulation models . Commun Statistics simula. Computa.

Richardson DJ, Chen S. 2001. Data quality assurance and quality control measures in large multicenter stroke trials: the African-American Antiplatelet Stroke Prevention Study experience. Current Controlled Trials in Cardiovascular Medicine 2: 115-117.

Robinson S. 1997. Simulation model verification and validation: increasing the user´s confidence. Proceedings of the Winter Simulation Conference. USA.

Roset M, Bonfill X, Monleón T. 2003. Introducción a la metodología de investigación. Metodología de investigación y estadística en oncología y hematología. Novartis Oncology. Ed. Editec. Barcelona.

Samara E, Granneman R. 1997. Role of population pharmacokinetics in drug development. A pharmaceutical industry perspective. Clin Pharmacokinet 32: 294-312.

Sánchez JA, Ocaña J. 2002. Computer intensive methods for mixed models. Proceedings of the COMSTAT Congress. Heidelberg. Germany.

Sargent RG. 2003. Verification and validation of simulation models. Proceedings of the 2003 Winter Simulation Conference. USA.

SAS Institute Inc. 1992. SAS Technical Report P-229,SAS/STAT Software: Changes and Enhancements, Release 6.07, Cary, NC: SAS Institute Inc.

SAS Institute Inc. 1994. SAS/STAT Software: Changes and Enhancements, Release 6.10, Cary, NC: SAS Institute Inc.

Schuirmann D. 1987. A comparison of the two one-sided procedure and power approach for assessing the bioequivalence of average bioavailability. J Pharmacokin Biopharm 15: 657-680.

Shao J, Tu D. 1995. The Jackknife and Bootstrap, New York: Springer-Verlag.

Sheiner LB, Beal SL. 1980. Evaluation of methods for estimating population pharmacokinetics parameters. I. Michaelis-Menten model: routine clinical pharmacokinetic data. J. Pharmacokinetic. Biopharm 8: 553-71.

Sheiner LB, Grasela TH. 1984. Experience with NONMEM: análisis of routine phenytoin clinical pharmacokinetic data. Drug Metab. Rev. 15: 293-303.

Sheiner LB, Hashimoto Y, Beal SL. 1991. A simulation study comparing designs for dosi ranging. Stad Med. 10: 302-21.

Sheiner LB, Ludden TM. 1992. Population pharmacokinetics/dynamics. Annu Rev Pharmacol Toxicol 32: 185-209.

Sim I, Rennels G. 1996. Standardized Reporting of Clinical Trials into Electronic Trial Banks: InSupport of Computer-assisted Evidence-based Medicine. Stanford Medical Informatics technical reports SMI-96-0630. (smi-web.stanford.edu/pubs/SMI_Reports/SMI-96-0630.pdf).

Schlesinger y col. 1979. Terminology for model credibility. Simulation 32: 103-104.

Smith MK. 2004. Software for non-linear mixed effects modeling. RSS meeting, London. 12 May 2004. <http://www.rss.org.uk/PDF/mikesmith.pdf>.

Stanski DR, Jenkins JK. 2004. Model based drug development: a critical path opportunity. www.fda.gov/oc/initiatives/criticalpath/stanski/stanski.html .

Sun A. 1997. Generación de una distribución normal multivariante mediante el método de Jacobi. (<http://www.geocities.com/WallStreet/9245/vba.htm>)

Tiefenbrunn AJ, Graor RA, Robison AK, Lucas FV, Hotchkiss A y col. 1986. Pharmacodynamics of tissue-type plasminogen activator characterized by computerassisted simulation. Circulation 73: 1291–99.

Vallvé C. 1990. Buena práctica clínica. Recomendaciones internacionales en investigación terapéutica. Madrid: Ed. Farmaindustria: 36.

Verbeke G, Molenberghs G. 2001. Mixed Models for longitudinal data with SAS. Curso del SEA (Servei d'Estadística Universitat Autònoma de Barcelona). UAB.

Vonesh EF, Chinchilli VM. 1997. Linear and nonlinear models for the analysis of repeated measurements. Marcel Dekker, Inc.

Walker G. 2002. Common Statistical Methods for Clinical Research with SAS Examples. SAS Institute, Cary, NC, USA.

Wang CM. 1988. One-sided confidence intervals for the positive linear combination of two variances. Communications in Statistics - Simulation and Computation, B17: 283-292.

Wang CM. 1988. Beta-expectation tolerance limits for balanced one-way random-effects model. Probability and Statistics: Essays in Honour of Franklin A. Graybill, J.N. Srivastava Ed., p.285, Amsterdam: North Holland.

Wang CM. 1990. On ranges of confidence coefficients for confidence intervals on variance components. Communications in Statistics - Simulation and Computation, B19: 1165-1178.

Wang CM. 1990. On the lower bound of confidence coefficients for a confidence interval on variance components Biometrics 46: 187-192.

Wang CM. 1991. Approximate confidence intervals on positive linear combinations of expected mean squares. Communications in Statistics - Simulation and Computation B20: 81-96.

Wang CM. 1992^a. Approximate confidence intervals on positive linear combinations of expected mean squares Communications in Statistics - Simulation and Computation B20: 81-96.

Wang, C.M. 1992^b. Prediction intervals for a balanced one-way random-effects model. *Communications in Statistics - Simulation and Computation* B21: 671-687.

Wang CM. 1994. On estimating approximate degrees of freedom of chi-squared approximations. *Communications in Statistics - Simulation and Computation*, B23: 769-788.

Wang CM, Graybill FA. 1981. Confidence intervals on ratio of variance in the two-factor nested components of variance models. *Communications in Statistics - Theory and Methods*, A10: 1357.

Wang CM, Iyer HK. 1994. Tolerance intervals for the distribution of true values in the presence of measurement error. *Technometrics* 36: 162-170.

Whitner RG, Balci O. 1989. Guideline for selecting and using simulation model verification techniques. *Proceedings of 1989 Winter Simulation Conference*. 559-568.

9.1 OTRA BIBLIOGRAFÍA DESTACABLE

Esta bibliografía aunque no ha sido revisada, se ha creido interesante citarla en este trabajo de doctorado por el interés que presenta.

9.1.1 BIBLIOGRAFÍA SOBRE ENSAYO CLÍNICO Y FARMACOLOGÍA

Beal SL, Sheiner LB. 1982. Estimating Population Kinetics. CRC Crit. Rev. Biomed. Eng. 8: 195 -222.

Cobo E, Calle ML, Videla S, Corchero C, Clotet B, Gómez G, De Gruttola V, Langohr K. 2003. Investigación clínica y estadística. Una visión multidisciplinar con aplicaciones en estudios de VIH/Sida. Fundació de Lluita contra la Sida. Badalona.

European Comission. Detailed guidance on the European clinical trials database (EUDRACT Database). April 2003. Brussels, ENTR/F2/BL D.

Dupond Pharma. 1995. Tipos de Estudios clínicos epidemiológicos. Tratado de epidemiología clínica. Dupond Pharma. Madrid.

FDA. Guidance for Industry: Computerized systems used in clinical trials. FDA, USA. April 1997.

FDA Guidance for Industry: Population Pharmacokinetics. V- Simulation. Sept. 1997.

Friedman L. 2001. Guidelines for data quality assurance in clinical trials and observations studies. National Heart, Lung, and Blood Institute, National Institutes of Health (<http://www.nhlbi.nih.gov/funding/policies/dataqual.htm>).

ICH (International Conference on Harmonization): Guidance for Good Clinical Practice (<http://ctep.info.nih.gov/ctc3/ctc.htm>)

Sankok AJ, Huque MF, Dubey SD. Some comments on frequently used multiple endpoint adjustment methods in clinical trials. Stat Med 1997. Nov 30;16(22) p.2529-42

Verny A. A 6-Month Process for Planning Multinational Clinical Trials. 2003. Applied Clinical Trials (February). Electronic versión.

9.1.2 BIBLIOGRAFÍA SOBRE SIMULACIÓN DE ENSAYOS CLÍNICOS

Armijo RR. Epidemiología básica en Atención primaria de salud. Madrid: Díaz de Santos; 1993.

Eason G, Colles CW. 1977. *Mathematics and Statistics for the Bio-Sciences*. Ellis Horwood, Masson, Paris. Pp 47-56.

Edler L. Computational Statistics for Pharmacokinetic Data Analysis 1998.

Ellison NE, Loprinzi CL, Kugler J y col. 1997. Phase III Placebo controlled trial of capsaicin cream in the management of surgical neurophatic pain in cancer patients. Journal of Clinical Oncology 15: 2974-2980.

Fletcher RH, Fletcher SW, Wagner EH. 1998. Epidemiología clínica. 2^a ed. Barcelona: Masson-Williams & Wilkins.

Hennekens CH, Buring JE. 1987. Epidemiology in Medicine Boston: Litte, Brown and Company.

Hoover SV, Perri RF. 1989. Simulation: a problem solving approach. New York: Addison-Wesley

Jaquez JA. 1983. Compartmental Analysis in Biology and Medicine. The University of Michigan Press. 3-9: 277-285.

Jenicek M, Cleroux R. 1996. Epidemiología: la lógica de la medicina moderna. Barcelona: Masson.

Jones DS, Sleeman BD, Diferential Equations and Mathematical Biology. George Allen & Unwin, London, 1-7, 70-93, 159-169.

Kazemier BH, Vuysje D editor. 1960. The Concept of the Model in Mathematics and Natural and Social Sciences. D.Reidel Publishing Company, Dordrecht 99-103.

Kelsey JL, Thompson WD, Evans AS. 1986. Methods in Observational Epidemiology. New York: Oxford University Press.

Kleinbaum DG, Kupper LL, Morggenstern H. 1982. Epidemiologic Research. Principles and Quantitative Methods. Belmont, California: John Wiley & Sons.

MacMahon B, Trichopoulos D. 1996. Epidemiology: Principles and Methods. 2nd ed. Boston: Lippincott Williams & Wilkins.

Miettinen OS. Theoretical Epidemiology. 1985. New York: Jhon Wiley & Sons.

Mazumdar J. 1989. *An Introduction to Mathematical Physiology and Biology*, Cambridge University Press, Cambridge 87-106.

Peck CC, Beal SL, Sheiner LB, Nichols AI. 1984. Extended least square nonlinear regression: a possible solution to the choice of weights problem in analysis of individuals pharmacokinetic parameters. *J. Pharmacokinetic Biopharm.* 12(5): 545-57

Pennacchi R. 1984. I modelli matematici e l'ambiente naturale. *Le scienze, quaderni* 81: 63-70.

Rothman KJ. 1987. *Epidemiología Moderna*. Madrid: Ediciones Días de Santos.

Rouvray DH. 1984. Topologia e previsione delle proprietà chimiche. *Le scienze, quaderni* 81: 71-75.

Rothman KJ. (ed). 1988. *Causal Inference*. Chesnut Hill: Epidemiology Resources Inc;.

Sargent D. 1987. A general Gibbs sampling algorithm for analyzing linear models using the SAS system. Paper 266

<http://www2.sas.com/proceedings/sugi24/Stats/p266-24.pdf>

Sackett DL, Haynes RB, Guyatt GH, Tugwell P. 1994. *Epidemiología clínica. Ciencia básica para la medicina clínica*. 2^a ed. Madrid: Editorial Médica Panamericana.

Susser M. 1991. *Conceptos y estrategias en epidemiología. El pensamiento causal en ciencias de la salud*. México: Biblioteca de la Salud.

Vinci P, Vies R. 2000. Improving clinical trials via simulation and estimation methods. IIR Pre-conference symposium 2001. Washington 6 August, 2000

9.1.3 BIBLIOGRAFÍA SOBRE OPTIMIZACIÓN DE ENSAYOS CLÍNICOS

Albert JM, Demets DL. 1994. On a model-based approach to estimating efficacy in clinical trials. Stat Med Nov 13(22):2323-2335

Ebling WF, Levy G. 1996. Population pharmacodynamics: strategies for concentration-and effect-controlled clinical trials. Ann Pharmacother Jan 30(1):12-19

Egan TD. 1995. Remifentanil pharmacokinetics and pharmacodynamics. A preliminary appraisal. Clin Pharmacokinet Aug;29(2):80-94

Elashoff JD, Koch GG, Chi GY. 1988. Designing a clinical trial to demonstrate prevention of ulcer recurrence: modelling simulation approaches. Stat Med Aug;7(8):877-888

Endrenyi L, Zha J. 1994. Comparative efficiencies of randomized concentration-and dose-controlled clinical trials. Clin Pharmacol Ther Sep;56(3):331-338

Gebski V, McNeil D, Coates A, Forbes J. 1987. Monitoring distributional assumptions and early stopping for a prospective clinical trial using Monte Carlo simulation. Stat Med Sep;6(6):667-678

Girard P, Laporte-Simitsidis S, Mismetti P, Decousus H, Biossel JP. 1995. Influence of confounding factors on designs for dose-effect relationship estimates. Stat Med May;14(9-10):987-1005.

Gooley TA, Martin PJ, Fisher LD, Pettinger M. 1994. Simulation as a design tool for phase I/II clinical trials: an example from bone marrow transplantation. Control Clin Trials Dec 15(6):450-462

Hughes MA, Glass PS, Jacobs JR. 1992. Context-sensitive half-time in multicompartment pharmacokinetic models for intravenous anesthetic drugs. *Anesthesiology* Mar 76(3):334-341

Kodlin D, Cohn I. 1978. Simulation experiments of tumor measurement in clinical trials. *Cancer Treat Rep* Dec 62(12):2077-2083

Lemmens HJ, Dyck JB, Shafer SL, Stanski DR. 1994. Pharmacokinetic-pharmacodynamic modeling in drug development: application to the investigational opioid trefentanil. *Clin Pharmacol Ther* Sep;56(3):261-271

Levy G, Ebling WF, Forrest A. Concentration- or effect-controlled clinical trials with sparse data. 1994. *Clin Pharmacol Ther* Jul;56(1):1-8

Machado SG, Gail MH, Ellenberg SS. 1990. On the use of laboratory markers as surrogates for clinical endpoints in the evaluation of treatment for HIV infection. *J Acquir Immune Defic Syndr*;3(11):1065-1073

Mandema JW, Stanski DR. 1996. Population pharmacodynamic model for ketorolac analgesia. *Clin Pharmacol Ther* Dec;60(6):619-635

Mark SD, Gail MH. 1994. A comparison of likelihood-based and marginal estimating equation methods for analyzing repeated ordered categorical responses with missing data: application to an intervention trial of vitamin prophylaxis for oesophageal dysplasia. *Stat Med* Mar;13(5-7):479-493

Minto CF, Schnider TW, Shafer SL. 1997. Pharmacokinetics and pharmacodynamics of remifentanil. II. Model application. *Anesthesiology* Jan;86(1):24-33

Nani FK, Oguztoreli MN. 1994. Modelling and simulation of Rosenberg-type adoptive cellular immunotherapy. *IMA J Math Appl Med Biol* 11(2): 107-147

O'Quigley J, Pepe M, Fisher L. 1990. Continual reassessment method: a practical design for phase I clinical trials in cancer. *Biometrics* Mar 46(1):33-48

Piantadosi S, Liu G. 1996. Improved designs for dose escalation studies using pharmacokinetic measurements. *Stat Med* Aug 15(15):1605-1618

Rouse DJ, Owen J, Goldenberg RL, Vermund SH. 1995. Zidovudine for the prevention of vertical HIV transmission: a decision analytic approach. *J Acquir Immune Defic Syndr Hum Retrivirol* Aug;9(4):401-407

Sanathanan LP, Peck CC. 1991. The randomized concentration-controlled trial: an evaluation of its sample size efficiency. *Control Clin Trials* Dec;12(6):780-794

Schentag JJ, Nix DE, Adelman MH. 1991. Mathematical examination of dual individualization principles (I):Relationships between AUC above MIC and area under the inhibitory curve for cefmenoxime, ciprofloxacin, and tobramycin. *DICP* Oct;25(10):1050-1057

Sheiner LB, Hashimoto Y, Beal SL. 1991. A simulation study comparing designs for dose ranging. *Stat Med* Mar;10(3):303-321.

Wientjes MG, Badalament RA, Au JL. 1993. Use of pharmacologic data and computer simulations to design an efficacy trial of intravesical mitomycin C therapy for superficial bladder cancer. *Cancer Chemother Pharmacol*;32(4):255-262

9.1.4 BIBLIOGRAFÍA SOBRE MODELOS LINEARES MIXTOS Y MEDIDAS REPETIDAS

Anders K. 2002. Command reference to the Rienemann library (<http://w1.463.telia.com/~u46304521/riemann/rmnref.pdf>).

Lindsey JK. 1999. Models for repeated measurements. Oxford University press. USA: New York.

Littel RC, Milliken GA, Stroup WW and Wolfinger RD. 1996. SAS System for Mixed Models, Cary, NC: SAS Institute, Inc.

SAS Institute Inc. 1989. SAS/STAT User's Guide: Version 6, Fourth Edition, Volume 2, Cary, NC: SAS Institute Inc.

Singer D. 1998. Using SAS PROC MIXED to Fit Multilevel Models, Hierarchical Models, and Individual Growth Models, J Educational and Behavioral Statistics, 24(4): 323-355. (<http://gseweb.harvard.edu/~faculty/singer/>)

Wolfinger RD. 1992. A tutorial on mixed models, Cary, NC:SAS Institute, Inc.

9.1.5 BIBLIOGRAFÍA SOBRE MÉTODOS DE SIMULACIÓN Y ESTADÍSTICA

Averill M, Law, Kelton WD. 1991. Simulation Modeling & Analysis. Second Edition. McGraw-Hill International Editions. Industrial Engineering Series.

Coakley KJ. 1991. Bootstrap Analysis of Asymmetry Statistics for Polarized Beam Studies. Proceedings of the 23rd Symposium on the Interface between

Computer Science and Statistics. Interface Foundation of North America, pp. 301-304, April 1991.

Coakley KJ, McClelland JJ, Kelley MH, Celotta RJ. 1993. Uncertainty intervals for polarized beam scattering asymmetry statistics. Rev. Sci. Instrum., 64(7), pp. 1888-1894, July, 1993.

Coakley KJ. 1993. Analysis of scattering asymmetry statistics when background corrected counts are negative. Rev. Sci. Instrum., 64(7), pp. 1895-1898, July, 1993.

Eberhardt KR, Mee RW. 1994. Constant-Width Calibration Intervals for Linear Regression. Journal of Quality Technology, Vol 26, No. 1, pp. 21-29.

Eberhardt, KR, Mee RW, Reeve CP. 1991. Calibration and Simultaneous Tolerance Intervals for Regression. Technometrics, Vol. 33, No. 2, pp. 211-220.

Eberhardt, KR, Mee RW, Reeve, CP. 1989. Computing Factors for Exact Two-Sided Tolerance Limits for a Normal Distribution. Communications in Statistics, Simulation and Computation, Issue 18, No.1.

Eberhardt KR, Reeve CP, Spiegelman CH. 1989. A Minimax Approach to Combining Means, With Practical Examples. Chemometrics and Intelligent Laboratory Systems, Vol 5, pp. 129-148.

Graybill FA, Wang CM. 1980. Confidence intervals on nonnegative linear combinations of variances. Journal of the American Statistical Association, 75, 869.

Graybill FA, Wang CM. 1979. Confidence intervals for proportions of variability in the two-factor nested variance component models. Journal of the American Statistical Association, 74, 368.

Hsu JC, Hwang JT, Liu HK, Rugreg ST. 1994. Confidence intervals associated with tests for bioequivalence. *Biometrika*, 81 103-114.

Hwang JT, Liu HK. 1990. Sequential confidence regions in inverse regression problems. *Annals of Statist.* 18: 1389-1399.

Hwang JT, Liu HK. 1992. Existence and nonexistence theorems of finite diameter sequential confidence regions for errors-in-variables models. *Statistics and Probability Letters* 13: 45-55.

Kleijnen JPC, Feelders AJ, Cheng RCH. 1998. Bootstrapping and validation of metamodels in simulations. *Proceedings of the Winter Simulation Conference*. USA.

Lam CT, Wang CM. 1995. Confidence limits for proportion of conformance In revision for *Journal of Quality Technology*.

Liu HK. 1990. Confidence intervals in bioequivalence assessment. *Proceedings of the Biopharmaceutical Sections, American Statist. Assoc.*, 51-54.

Manly B. 1997. *Randomization, Bootstrap and Montecarlo methods in Biology*, Chapman & Hall.

Sargent RG. 1984. Simulation model validation. Chapter 19 in *Simulation and model-based methodologies: An integrative view*, ed T.I.Oren, B.P.Ziegler, and M.S. Elzas, 537-555. Heidelberg, Germany: Springer-Verlag.

Vangel, MG. 1995. Confidence Intervals for a Normal Coefficient of Variation. Resubmitted, *The American Statistician*.

Vangel MG. 1995. One-Sided -Content Tolerance Intervals for Mixed Models. Proceedings of the Physical and Engineering Sciences Section of the American Statistical Association, to appear.

Vangel MG. 1995. Design Allowables form Regression Models Using Data From Several Batches. Proceedings of the 12th ASTM Symposium on Composite Materials: Testing and Design, to appear.

Vangel MG. 1994. One-Sided Nonparametric Tolerance Limits. Communications in Statistics: Simulation and Computation, 23, 1137.

9.1.6 BIBLIOGRAFÍA SOBRE METODOLOGÍA DE PROGRAMACIÓN ORIENTADA A OBJETOS, ALGORITMOS Y OTRAS TÉCNICAS INFORMÁTICAS

Ames AL, Napeau DR, Moreland JL. 1997. VRML 2.0 Sourcebook. Editorial Wiley, New York.

Appleman D. 1998. Dan Appleman's Developing Active X Components with Visual Basic 5.0. Sams.

Box D. 1998. Essential COM: (The Addison-Wesley Object Technology Series). Addison-Wesley Pub. Co.

Chappell D. 1996. Understanding ActiveX and OLE. Microsoft Press.

Gray J, Reuter A. 1992. Transaction Processing: Concepts and Techniques (Morgan Kaufmann Series in Data Management Systems). Morgan Kaufmann Publishers,.

Goralski, Walter, Poli, Matthew, Vogel, Meter. 1997 .VRML Mundos virtuales en Internet. Prentice Hall, Madrid.

Guerrero J. 1998. VRML 2.0. Editorial ABETO. Madrid.

Isaacs S. 1997. Inside Dynamic HTML. Microsoft Press.

Kirtland M. 1998. Designing Component-Based Applications, Microsoft Press.

Lafore R. 1990. Programación en Microsoft C para IBM y compatibles. Anaya Multimedia. Madrid.

Maguire S. 1993. Writing Solid Code. Microsoft Press.

McCarthy J. 1995. Denis G. Dynamics of Software Development. Microsoft Press.

McConnell S. 1996. Rapid Development. Microsoft Press.

Mitchell M. 1997. Developing Enterprise Apps with Microsoft Visual J++. Sams Publishing. Indianapolis.

Pattison T. 1998. Programming Distributed Applications with COM and Microsoft Visual Basic 6.0. Microsoft Pres.

Redmond F E. 1997. DCOM: Microsoft Distributed Component Object Model. IDG Books Worldwide.

Rogerson D. 1997. Inside COM (Programming Series). Microsoft Press.

Schwarze D. 1997. El gran libro de Visual C++. Marcombo. Barcelona.

Sessions R. 1997. COM and DCOM: Microsoft's Vision for Distributed Objects. John Wiley and Sons.

Viktor Toth 1997. Visual C++ 4. Unleashed. SAMS Publishing.

9.1.7 BIBLIOGRAFÍA SOBRE GENERACIÓN DE NÚMEROS ALEATORIOS

Abramovitz M, Stegun IA. 1965. Handbook of Mathematical Functions with Formulas, Graphs and Mathematical Tables. Dover, N.Y.

Beckers M, Haegemans A. 1992. Comparison of Numerical Integration Techniques for Multivariate Normal Integrals. Computer Science Department preprint, Catholic University of Leuven, Belgium.

Berntsen J, Espelid T O, Genz A. 1991. Algorithm 698: DCUHRE-An Adaptive Multidimensional Integration Routine for a Vector of Integrals. ACM Transactions on Mathematical Software 17, pp. 452-456.

Black SC, Kennedy AD. 1989. Gaussian random number generators on a CYBER-205, V. 3 No. 3, pp. 59 - 67.

Box GEP, Muller ME. 1958. A note on the generation of random normal deviates, Annals Math. Stat, V. 29, pp. 610-611.

Carter EF. 1994. The Generation and Application of Random Numbers , Forth Dimensions Vol XVI Nos 1 & 2, Forth Interest Group, Carmel California.

Collins JJ, Fanciulli M, Hohlfeld RG, Finch DC, Sandri GVH, Shtatland ES. 1992. A random number generator based on the logit transform of the logistic variable, *Computers in Physics*, V. 6 No. 6, pp. 630 - 632.

Cooper NG. ed. 1989. *From Cardinals to Chaos, Reflections on the Life and Legacy of Stanislaw Ulam*, Cambridge Univ. Press, New York, 316 pages

Cornish E A. 1954. The Multivariate t-Distribution Associated with a Set of Normal Sample Deviates. *Australian Journal of Physics* 7, pp. 531-542.

Cranley R, Patterson TNL. 1976. Randomization of Number Theoretic Methods for Multiple Integration. *SIAM J. Numer. Anal.* 13, pp. 904-914.

Davis PJ, Rabinowitz P. 1984, *Methods of Numerical Integration*, Academic Press, New York.

Deák I. 1980. Three Digit Accurate Multiple Normal Probabilities. *Numer. Math.* 35, pp. 369-380.

Deák I. 1986. Computing Probabilities of Rectangles in Case of Multinormal Distribution. *J. Statist. Comput. Simul.* 26, pp. 101-114.

Deák I. 1990. Random Number Generation and Simulation, Akadémiai Kiadó, Budapest, Chapter 7.

Devroye L. 1986. *Non-Uniform Random Variate Generation*. Springer Verlag, N.Y.

Fang KT, Wang Y. 1994. *Number-Theoretic Methods in Statistics*, Chapman and Hall, London, pp. 167-170.

Genz A. 1992. Numerical Computation of the Multivariate Normal Probabilities. *J. Comput. Graph. Stat.* 1, pp. 141-150.

Genz A. 1993. A Comparison of Methods for Numerical Computation of Multivariate Normal Probabilities. *Computing Science and Statistics* 25, pp. 400-405.

Genz A, Kwong KS. 1999. Numerical Evaluation of Singular Multivariate Normal Distributions. Submitted.

Genz A, Bretz F. 1999. Numerical Computation of the Multivariate t Probabilities with Application to Power Calculation of Multiple Contrasts', *Journal of Statistical Computation and Simulation* 63, pp. 361-378.

Gibson G J, Glasbey CA, Elston D A. 1992. Monte-Carlo Evaluation of Multivariate Normal Integrals. Scottish Agricultural Statistics Service preprint, University of Edinburgh, Scotland.

Hammersley JM, Handscomb DC. 1964. *Monte Carlo Methods*. Methuen, London

Hajivassiliou V, McFadden D, Rudd O. 1996. Simulation of Multivariate Normal Rectangle Probabilities and Their Derivatives: Theoretical and Computational Results. *Journal of Econometrics*, 72, pp. 85-134.

Hickernell FJ. 1998. A Generalized Discrepancy and Quadrature Error Bound. *Mathematics of Computation*, 67, pp. 299-322.

Hsu JC. 1996. *Multiple Comparisons*. Chapman and Hall, London.

Joe S. 1995. Approximations to Multivariate Normal Rectangle Probabilities Based on Conditional Expectations. *Journal of the American Statistical Association*, 90, pp. 957-964.

James F. 1990. A Review of Pseudorandom number Generators. Computer Physics Communications, 60:329-344, North-Holland

James F. 1994. RANLUX: A FORTRAN implementation of the high-quality pseudorandom number generator of Luscher. Computer Physics Communications, V. 79, pp. 111-114

Johnson ME. 1987. Multivariate Statistical Simulation, Wiley, New York.

Keast P. 1973. Optimal Parameters for Multidimensional Integration. SIAM J. Numer. Anal. 10, pp. 831-838.

Kalos MH, Whitlock PA. 1986. Monte Carlo Methods, Volume I: Basics. Wiley, N.Y.

Keppler K. 1993. Random Variables made Simply, Computer Language, June, pp. 67 - 79

Kirkpatrick S, Stoll E. 1981. A Very Fast Shift-Register Sequence Random Number Generator, Journal of Computational Physics, V. 40. pp. 517-526

Knuth DE. 1981. The Art of Computer Programming. Addison-Wesley, Reading, M.A.

Knuth DE. 1981. The Art of Computer Programming, Volume 2 Seminumerical Algorithms, Addison-Wesley, Reading Mass., 688 pages, ISBN 0-201-03822-6

Kocis L, Whiten WJ. 1997. Computational investigations of low-discrepancy sequences, ACM Trans. Math. Software 23:2 (June 1997), 266-294.

Lepage GP. 1978. A New Algorithm for Adaptive Multidimensional Integration. J. Computational Physics 27, pp. 192-203.

Lohr S. 1990. Accurate Multivariate Estimation using Triple Sampling. Ann. Statist. 18, pp. 1615-1633.

Luban M, Stauton LP. 1988. An efficient method for generating a uniform distribution of points within a hypersphere, Computers in Physics, V. 2 No. 6, pp. 55 - 60

Luscher M. 1994. A portable high-quality random number generator for lattice field theory simulations, Computer Physics Communications, V. 79, pp. 100-110

MacDougall MH. 1987. Simulating Computer Systems, M.I.T. Press, Cambridge, Ma., 292 pages, ISBN 0-262-13229-X

Maier WL. 1991. A Fast Pseudo Random Number Generator, Dr. Dobb's Journal, May, pp. 152 - 157

Marsaglia G, Olkin I. 1984. Generating Correlation Matrices. SIAM Journal of Scientific and Statistical Computing 5, pp. 470-475.

Marsaglia G, Zaman A. 1994. Some portable very-long-period random number generators Computers in Physics, V. 8, No. 1, pp. 117-121

Niederreiter H. 1992. Random Number Generation and Quasi-Monte Carlo Methods SIAM

Ochs T. 1991. Deterministic random numbers ?, Computer Language, Jan. pp. 104 - 107

Park SK, Miller KW. 1988. Random Number Generators: Good Ones are Hard to Find, Comm. of the ACM, V. 31. No. 10, pp 1192-1201

Press WH, Flannery BP, Teukolsky SA, Vetterling WT. 1986. Numerical Recipes, The Art of Scientific Computing, Cambridge University Press, Cambridge, 818 pages, ISBN 0-512-30811-9

Press WH, Teukolsky SA. 1989. Quasi- (that is, Sub-) Random Numbers, Computers in Physics, V. 3 No. 6, pp. 76 - 79

Press WH, Teukolsky SA. 1992. Portable Random Number Generators, Computers in Physics, V. 6, No. 5, pp. 522-524

Ripley BD. 1987. Stochastic Simulation. Wiley, N.Y.

Rose C, Smith MD. 1996. The Multivariate Normal Distribution. Mathematica J. 6, 32-37.

Rose C, Smith MD. 1996. Manipulating Probability Density Functions. Ch. 16 in Computational Economics and Finance (Ed. H. Varian). New York: Springer-Verlag, 1996.

Rose C, Smith MD. 2002. The Multivariate Normal Distribution. 6.4 in Mathematical Statistics with Mathematica. New York: Springer-Verlag, pp. 216-235, 2002.

Rubinstein RY. 1981. Simulation and the Monte Carlo method. John Wiley & Sons, ISBN 0-471-08917-6

Schervish MJ. 1984. Multivariate Normal Probabilities with Error Bounds." Appl. Stat.: J. Roy. Stat. Soc., Ser. C 33, 81-94.

Schervish MJ. 1984. Corrections to Multivariate Normal Probabilities with Error Bounds. Appl. Stat.: J. Roy. Stat. Soc., Ser. C 34, 103-104.

Schervish M. 1984. Multivariate Normal Probabilities with Error Bound. *Applied Statistics* 33, pp. 81-87.

Sloan IH, Joe S. 1994. *Lattice Methods for Multiple Integration*, Oxford University Press, Oxford.

Somerville PN. 1997. Multiple Testing and Simultaneous Confidence Intervals: Calculation of Constants. *Comp. Stat. & Data Analysis* 25, pp. 217-223.

Somerville PN. 1998. Numerical Computation of Multivariate Normal and Multivariate-t Probabilities Over Convex Regions. *J. Comput. Graph. Stat.* 7, pp. 529-545.

Somerville PN. 1999. Critical Values for Multiple Testing and Comparisons: One Step and Step Down Procedures. *J. Stat. Plan. & Inf.* 82, pp. 129-138.

Stewart GW 1980. The Efficient Generation of Random Orthogonal Matrices with An Application to Condition Estimation', *SIAM J. Numer. Anal.* 17, 403-409.

Tezuka S, L'Ecuyer P. 1991. Efficient and Portable Combined Tausworthe Random Number Generators, *ACM TOMACS*, April 1991, Volume 1, Number 2, pp. 99--112

Tong YL. 1990. *The Multivariate Normal Distribution*, Springer-Verlag, New York.

Tong L 1990. *The Multivariate Normal Distribution*. New York: Springer-Verlag.