

Professional Experience



President

(2005 - Present)

Biostudy Solutions, LLC, Wilmington, NC.

- Design/analyze pilot and pivotal Bioavailability/Bioequivalence studies.
- Assist in design and analyses of studies with Clinical and/or Pharmacodynamic endpoints.
- Interpret results of in-vivo studies to guide formulation development.
- General PK, Statistical and Clinical consultation for ANDA and NDA 505(b)(2) projects.
- Audits of BE studies with regard to Bioanalytics, Pharmacokinetics and Biostatistics.

Biostatistician (Head of Statistics Department)

(1996 - 2004)

AAI Development Services/AAI Pharma, Wilmington, NC.

- Provide experimental designs for Bioavailability/Bioequivalence studies.
- Perform pharmacokinetic and statistical analyses for Bioavailability/Bioequivalence studies.
- Interpret results for the final reports of Bioavailability/Bioequivalence studies.
- Provide statistical support for drug development and drug manufacturing at Wilmington facilities.
- Provide Statistical consulting to outside clients.

Director of Scientific Information

(1984 - 1996)

Novum Inc. (formerly Biodecision Laboratories, Inc) Pittsburgh, PA.

- Manage bioequivalence protocol development and statistical services.
- Manage the production of final reports.
- Manage computer and programming services.
- Provide pharmacokinetic services to Novum's clients.
- Involved in providing regulatory services to clients.
- Perform final review of Bioavailability/Bioequivalence final reports.

Director of Analytical Services

(1982 - 1984)

Biodecision Laboratories, Inc. Pittsburgh, PA.

- Manage the analyses of samples from Bioavailability/Bioequivalence studies.
- Provide statistical and pharmacokinetic analyses and interpretation of data from studies.
- Provide scientific computer programming.

Supervisor of Laboratories

(1978 - 1982)

Biodecision Laboratories, Inc. Pittsburgh, PA.

- Manage the analyses of samples from Bioavailability/Bioequivalence studies.
- Provide pharmacokinetic/statistical analyses and interpretation of data from studies.
- Provide support to scientific computer programming.

Charles Bon

Supervisor of Microbiology

(1973 - 1978)

Biodecision Laboratories, Inc. Pittsburgh, PA.

- Manage and perform analyses of samples from Bioavailability/Bioequivalence studies of antibiotics.
- Provide pharmacokinetic/statistical analyses and interpretation of Bioavailability/Bioequivalence study results.
- Provide scientific computer programming.

Education

(Biometry), Department of Biostatistics,
GRADUATE SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF PITTSBURGH
(**Ph. D candidate**) 54 credit hours. 1984-1993

INDIANA UNIVERSITY OF PENNSYLVANIA
M.S. Graduated magna cum laude. 1976

INDIANA UNIVERSITY OF PENNSYLVANIA
B.S. 1971

Publications

Josefsson K, Levitt MJ, Kann J, Bon C. "Erythromycin Absorption from Enteric-Coated Pellets Given in Multiple Doses to Volunteers, in Comparison With Enteric-Coated Tablets and Film-Coated Stearate Tablets." *Current Therapeutic Research* 39 (1986): 131-142.

Kann J, Lyon J, Bon C. "Availability of Iron From Four Prenatal Multivitamin/Multimineral Products." *Clinical Therapeutics* 10 (1988): 287-293.

Krol G, Lettieri JT, Mazzu AL, Burkholder DE, Birkett JP, Taylor RJ, Bon C. "Bioequivalence of Different Nitrendipine Tablet Dosage Formulations." *Journal of Cardiovascular Pharmacology* 9 Supplement 4 (1987): s129-s135.

Brennan J, Foley J, Bon C, Ivashkiv E, Tu J. "The Effect of Cimetidine and Ranitidine on the Pharmacokinetics of SQ 26,333 Given as Zofenopril to Healthy Volunteers." Presented at the 9th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, March 1989.

Rosenbaum, SE, Rhodes CT, Bon C. "Area Under the Curve Estimation in Bioequivalence Studies". *Drug Development and Industrial Pharmacy*, 16(1), 157-163 (1990).

Romero AJ, Bon C, Johnson E, Rosenbaum, SE, Rhodes CT. "Use and Limitations of the Truncated Area Under the Curve in Bioequivalence Testing". *Clinical Research Practice and Drug Regulatory Affairs*, 8(2), 123-151 (1990).

Gibbs L, Alonzo G, Bon C, Brennan B, Calvarese B, Chaudhuri B, Chavdarian C, Wagner G. "Systemic exposure to butenafine is low after topical administration of Mentax[®]". *Journal of Dermatological Treatment*, 8, 237-241 (1997).

Charles Bon

Bon C. "Statistical Methods" published in Encyclopedia of Pharmaceutical Technology, 2nd edition. Marcel Dekker, Inc. New York. 2002.

Bolton S and Bon C. "Statistical Considerations: Alternate Designs and Approaches for Bioequivalence Assessments". Chapter 7. 123-141. in Kanfer I and Shargel L. Generic Drug Product Development Bioequivalence Issues. Informa Health Care USA, Inc. New York. 2008.

Bolton S and Bon C. Pharmaceutical Statistics, 5th edition. Informa Healthcare, New York. 2009.

Affiliations

American Association of Pharmaceutical Scientists, member.

American Statistical Association, member.

FDA Blue Ribbon Panel for Individual Bioequivalence, member (2000 - 2002)

FDA Expert Panel for Bioequivalence of Topical Corticosteroids, member (1995)