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## Mary F. Johnson, PhD

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### Professional Experience

**MJBiostat, Spring Lake, NJ** *10/2011 - Present*

***Independent Statistical Consultant***

- Provide statistical and regulatory advice in the design, analysis, and reporting of clinical trials; prepare and review protocols, statistical analysis plans, and product development plans; review regulatory submissions and correspondence; participate in FDA meetings; serve on Data Safety Monitoring Boards (DSMBs) and scientific advisory panels

**PharmaNet, Princeton, NJ** *05/1996 – 10/2011*

***Executive Vice President, Biostatistics*** *(01/2007 – 10/2011)*

***Senior Vice President, Biostatistics*** *(01/2003 – 12/2006)*

***Vice President, Biostatistics*** *(05/1996 – 12/2002)*

- Member of executive team and global head of department (50+ staff) responsible for statistical analysis and programming functions of a full-service contract research organization
- Participated in the development and review of research protocols, data collection tools, statistical analysis plans, programmed table output, clinical trial reports, and regulatory submissions
- Served as consultant to pharmaceutical and device companies in clinical development planning, pre-review of regulatory documents, FDA interactions, DSMBs, and scientific advisory panels

**Covance, Princeton, NJ** *04/1986 – 04/1996*

***Vice President, Biostatistics*** *(05/1990 – 04/1996)*

*Therapeutic areas – oncology, hypertension, diabetes, allergic rhinitis, asthma, cystic fibrosis, headache, dysmenorrhea, post-surgical pain, fibrin glue, stroke, gastrointestinal disease, osteoporosis, Alzheimer’s disease, amyotrophic lateral sclerosis, dental caries, organ transplant, antibiotics, anti-virals, hormone replacement therapy, Parkinson’s disease, panic disorder*

- Managed and coordinated statistical department
- Directed statistical aspects of national and international drug development projects
- Served as company spokesperson in business development efforts

***Executive Director, Biostatistics*** *(09/1988 – 04/1990)*

*Therapeutic areas – cardiovascular, oncology, depression, anxiety, organ transplant, anesthetics, analgesics, rheumatoid arthritis, osteoarthritis, analgesia*

- Coordinated projects and supervised statisticians involved in the design, analysis and interpretation of clinical trials

***Principal Statistician*** *(04/1986 – 08/1988)*

*Therapeutic areas – hypertension, depression, anxiety, panic disorder, rheumatoid arthritis, osteoarthritis, analgesia*

- Reviewed protocols and statistical reports
- Assisted clients in formulating integrated reports for NDA submissions

**Center for Drug Evaluation and Review,** 05/1978 – 03/1986  
**Food and Drug Administration (FDA/CDER),** Rockville, MD

*Group Leader, Division of Biometrics* (05/1982 – 03/1986)

*Mathematical Statistician, Division of Biometrics* (05/1978 – 04/1982)

*Therapeutic areas – cardio-renal drugs, endocrine/metabolic drugs, oncologic drugs, anti-inflammatory drugs, analgesics, neuropharmacologic drugs, anti-virals, drugs for pulmonary, gastrointestinal/dental diseases*

- Supervised statisticians and computer programmers involved in the review of NDAs
- Reviewed statistical aspects of NDAs and provided consultation to physicians and other scientists at FDA

**Yale University,** New Haven, CT 09/1973 – 04/1978

*Teaching Assistant, Department of Biostatistics* (09/1976 – 04/1978)

*Research Assistant* (06/1975 – 08/1976)

*Connecticut Cancer Epidemiology Unit*

*Data Analyst* (09/1973 – 05/1974)

*Department of Epidemiology and Public Health*

## **Education**

**Yale University,** New Haven, CT *PhD – Biostatistics*

*MPH – Epidemiology*

**Tufts University,** Medford, MA *BS – Mathematics*

*BA – Philosophy*

## **Professional Memberships / Certifications**

Award of Merit, FDA Honor Award for work in Statistical Evaluation Branch

U.S. Public Health Traineeship, Yale University

Graduated Magna Cum Laude, Tufts University