

## Curriculum Vitae for Philip McCloud

### Principal Statistician

#### Tertiary Education/Qualifications

- B.A. (Hons) in Mathematical Statistics with 1st Class Honours, Flinders University, 1972 – 1975
- Diploma of Computer Science, The University of Adelaide, 1976 – 77
- Ph.D. Flinders University, Title: “Some Log-Linear Models For The Analysis Of Categorical Repeated Measurements”, 1983-1987

#### Employment History

##### Director and Principal Statistician

Oct 2010 –Current

McCloud Consulting Group

- August 2015: MCG employed 12 people
- Over 50 clients in Australia, US, Asia and Europe across several therapeutic areas including oncology.

##### Site Head of Pharma Development, Roche Products Pty Ltd

1997 – 2010

##### Asia-Pacific Head of Biometrics/Biostatistics

1997 – 2010

Roche Products Pty Ltd

- Commence and build the Biometrics Department in Sydney.
- Reported to the Global Head of Biometrics.
- Influential in growth of Biometrics from 1 individual in 1997 to 70 in 2006.
- Management of approximately 20 clinical trials at any one time.
- Development of Pegasys in hepatitis B, Xeloda in metastatic gastric cancer, and Herceptin in metastatic gastric cancer.

#### Responsibilities

- To manage the department to provide a quality and timely biometrics service.
- To liaise with Global Biometrics to secure the necessary project work and resources.
- To liaise with Global Biometrics to ensure the consistency of processes and systems across the Global Development Sites.
- To manage the budget of the department.
- To ensure that all members are trained in GCP, and are qualified and trained to do their jobs.
- To provide statistical expertise in the design, conduct, and analysis of data, in particular clinical trial data.
- To provide opportunities for staff to develop their expertise.
- To hire staff as needed.

#### Major Achievements at Roche

- The establishment and management of the Biometrics department in Sydney from one in 1997 to 70 people in 2006.
- Proven ability to lead a team to produce excellent results.
- Member of the Medicines Australia (then APMA) Weighted Average Monthly Treatment Cost (WAMTC) working group.
- Proven ability to successfully collaborate with people of different cultural backgrounds.
- Project Statistician for the Regional Study Program.
- Skilful ability to argue in a cogent and credible manner at the industry level. (I.e. Medicines Australia, FDA.)
- Demonstrated ability to work with industry providers in an innovative and creative way.
- Develop use of IVRS in Australia.
- Created an Asia-Pacific Regional Clinical Trial program.

- Initiated the registration for Xeloda in Metastatic gastric cancer in Switzerland.
- Demonstrated ability to communicate with upper management.
- Close liaison with Regulatory colleagues in preparation of new drug applications and addressing health authority questions.
- Represented Medicines Australia at PBPA and PBB MEETINGS.
- Assist Sales and Marketing Teams in the interpretation of data.
- Excellent rapport with investigators.

**Lecturer / Senior Lecturer**

**1989 – 1997**

**Director of the Monash University Statistical Consulting Service  
Monash University**

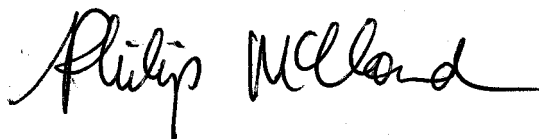
- Lecturer Department of Mathematics at Monash University.
- Supervisor of Honours, Masters and PhD Students.
- Director of the Monash University Statistical Consulting Service (MUSCS)
- Trainer of new graduates in the MUSCS.
- Grew the MUSCS from 1989 to 1997 from \$5000 to \$400,000 pa.

**Senior Biometrician**

**1975 – 1989**

**South Australian Department of Agriculture**

- Worked across many fields of application
  - Agronomy
  - Fisheries
  - Livestock
  - Plant Pathology
  - Poultry
  - Veterinary
  - Viticulture
  - Zoology
- Applied many statistical methods
  - Generalised Linear Models
  - Categorical data analysis
  - Analysis of repeated measurements
  - Analysis of (Co) Variance



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Philip McCloud  
Director