CURRICULUM VITAE: John Kirkpatrick

Personal details

Address:	Tile Barn, High Haden Rd	Title:	Mr
	Glatton	Sex:	Male
	HUNTINGDON PE28 5RU		
Nationality:	British (UK)		
Telephone:	Work: 01487 830838	Date of birth:	20th March 1963
	Fax: 0870 123 1512	Marital status:	Married
	e-mail: john@isc-ltd.co.uk		One child (b 2001)

Employment Details

Mar 1997-	Insight Statistical Consulting Ltd	Director
Sep 1988- Feb 1997	Pfizer Central Research Ramsgate Road SANDWICH CT11 9NJ	Clinical Project Statistician and Global Biometric Team Leader
Sep 1986- Sep 1988	UK Transplant Service Southmead Road BRISTOL BS10 5ND	Senior Scientific Officer
July 1983- July 1984	MoD Stats (E)2 Endsleigh BATH	Placement student

Details of positions and responsibilities are given on pages 2 through 4.

Skills

- Over twenty years experience of all aspects of biometry (including regulatory liaison) in the pharmaceutical industry and National Health Service
- Detailed knowledge of SAS, particularly statistics procedures, the macro language and the Output Delivery System.
- Java
- SQL, MySQL
- PHP
- Visual Basic for Applications
- Extensive use of PC's and Unix boxes
- Conversational French

Professional Memberships

Biometric Society
Royal Statistical Society   CStat
East Kent RSS Local Group: Committee 1991-1992, 1996-1998;
                             Chairman 1992-1995;
                             Secretary 1995-1996
PSI: Main committee (Training) 1994-1997
                             Training subcommittee 1993-2001

Education and Qualifications

1985-1986	University of Reading	MSc Biometry
1981-1985	University of Bath	BSc (Hons) Statistics [II(i)]
1971-1981	St Dunstan's College	2 S-levels
	Catford	3 A-levels
	LONDON	10 O-levels
	(LEA Scholarship 1974-1981)	

Details of positions held and responsibilities

1 Insight Statistical Consulting

Director
Statistical and IT consultancy advice and training for venture capital and blue-chip pharmaceutical companies including Pfizer Global Research & Development, Covance, AstraZeneca, Procter & Gamble, Oxford Biomedica and Amgen. Projects include:
- Membership of the Opinion Leaders Group for a drug development programme in male erectile dysfunction.
- Client representation at various meetings with the MHRA and FDA
- Investigation of the reasons for the failure of a 700 patient Phase III study of a novel biological agent in renal cancer.
- Planning of several novel designs for the assessment of novel biological entities in oncology.
- Membership of various Independent Safety Data Review Boards including studies of new biological entities in rheumatoid arthritis (Phase II), oncology (Phase III), pancreatic cancer (Phase III) and glioma (Phase III).
- Statistical liaison between the client and various Independent Data Monitoring Boards, including a sixteen group, 3000-subject phase II study in acute stroke and a phase III study investigating post-operative ovarian adhesions.
- Author of the SAS Institute training course on *ODS for pharmaceutical users.*
- Statistical input to the design of a series of approximately 120 phase II/III oncology studies.
- Drafting of the *Introduction to Study Reports* document for the Viagra male erectile dysfunction NDA.
- Planning the analysis of, and reporting on, various studies, including major Phase III studies in osteo arthritis (the focus was on disease progression, as

measured by radiographic and arthroscopic variables); a Phase II study in Alzheimer's disease.

- Design, planning and analysis of a number of dose response and methodology studies. Indications ranged from denture cleansers to the use of magnetic resonance imaging as an assessment of nasal patency in influenza.

2 Pfizer Central Research

Global Biometric Team Leader for the Viagra (male erectile dysfunction) development project.

Overall responsibility for the global biometric contribution to the project, including:

- Biometric input to, and attendance at, meetings with the FDA and other regulatory bodies
- Definition of the statistical methods used in the US and European regulatory submissions
- Management and supervisory responsibility for the European biometric project group, including data managers, statisticians and biomteric CROs
- Management responsibility for the US biometric project group.
- Membership of the Advanced Candidate Management Team, the body responsible for the overall design and implementation of the registration programme.

Senior European statistician for a phase III project in osteo and rheumatoid arthritis.

Overall responsibility for the efficacy component of a major IRD dossier, including:

- Management and supervisory responsibility for up to four graduate statisticians.
- Liaison with the Clinical and Regulatory groups in the UK, and the Biometric group in the US.
- Design and statistical input to clinical trials in Phase I/II/III.
- Implementation and maintenance of an IRD rulebook.
- Design and implementation of OCS efficacy summaries.

Other duties included

- Design of, and advisory service for, a comprehensive randomisation and blinding system.
- Training of new recruits.
- Selection interviewing.
- General statistical advice and consultancy.

3 UK Transplant Service

Funded by a grant from Sandoz SA, I was the first statistician employed by UKTS, and my role included research and generally raising awareness of statistical and data management issues.

- Design, implementation and analysis of a multi-centre study investigating

the influence of post operative factors on long-term renal transplant survival.
- Implementation of an automatic data harvesting system for renal transplant centres.
- Production of the UKTS annual report: the yearly summary of all transplant activity in the UK and Eire.
- Responding to ad hoc queries on transplantation, including the provision of data for answers to Parliamentary Questions, and for the media (eg "That's Life").
- General statistical consultancy.

4 MoD Stats (E)2

This placement formed part of my BSc course.
- Development and validation of a model describing the life-cycle of repairable stores items for the Royal Navy.

Details most recent formal courses and training

- Analysis of repeated Categorical Measurement Data Alan Agresti for PSI (2008)
- Adaptive Designs and Interim Analyses: Richard Kay for PSI (2005)

Most recent conferences and general training

- GCP, ICH and Statutory Instrument awareness (2010, 2011)
- PSI Young Statisticians and Programmers meeting (2009) (Speaker)
- PSI Annual conference (1989, 1994 to 1997, 2000, 2003, 2007) Speaker in 2000, 2003 and 2007
- PSI Scientific meeting on New Developments in Software for the Pharmaceutical Industry (2006) (Speaker)
- Introduction to CDISC (2006)
- PhUSE 2005 (Speaker)
- PSI Special Interest Group in Computing: meeting on ODS (2004) (Speaker)

Interests and achievements

- Hockey (Club treasurer; ERHA, Level 2 umpire; Level 1 Umpire Coach)
- Cricket (Club treasurer; indoor captain)
- PADI open water diver
- Photography (ARPS)
- Gliding (Solo pilot)
- Bath University colour (Bridge)
- Duke of Edinburgh's Gold Award
- Duke of Edinburgh's Award Scheme mentor for photography
- GB Youth ten-pin bowling team (1980)