

**Nicola Little (Schmitt)**  
[Nicolalittle@alphamedicalstatistics.co.uk](mailto:Nicolalittle@alphamedicalstatistics.co.uk)  
mobile +44 (0) 7599406653

Accomplished **Statistician** with expertise in study design, strategic development plans and representing statistical views to worldwide regulatory agencies. Developed the Tagrisso<sup>R</sup> (Oncology) study designs and represented AstraZeneca at FDA and EMA meetings. Analytically minded with a breadth of experience across phases I to IV and statistical lead for in-licensing and due diligence.

## KEY SKILLS

**Technical Experience** – utilises SPLUS, SAS, R, NQuery, EAST to develop study design and analyse data to improve precision

**Collaborative Approach** – operates cross-functionally to design studies and interpret information, providing support and guidance to colleagues

**Communication Excellence** – translates complex concepts into information that can be readily understood by non-statisticians

**Organisation Capabilities** – applies time-management to ensure successful outcomes when managing multiple projects, statisticians, programmers, and information scientists

**Regulatory Knowledge** – receives acknowledgement from colleagues through attending regulatory meetings and providing input to submissions

## PROFESSIONAL EXPERIENCE

### **Statistical Science Director and Biometrics Team Lead for AstraZeneca (2004 to 22<sup>nd</sup> Dec 2016).**

Design and analysis of clinical trials (phases I to IV) and strategic development plans.

- Therapy areas include Oncology (immuno-oncology, lung, breast [advanced and neo-adjuvant], melanoma, uveal melanoma, pancreatic, colorectal, gastric cancers and leukemia) and Infection
- Regulatory experience with FDA (Type B, C meetings; 3 submissions), EMA (scientific advice and submissions) and worldwide regulatory authorities
- Developed the study designs and programme for Tagrisso<sup>R</sup> (FSI to US approval in 2yrs, 8mo) and statistical lead for regulatory interactions with FDA and EMA
- Statistics lead for in-licensing and due diligence in the Haems area

### **Biostatistician for Adis Evidence, Adis International Cheshire (2003-2004), UK.**

Provided health economic and competitor analyses to the Pharma Industry.

- Therapeutic areas included oncology, cardiovascular, and respiratory medicine

### **Biostatistician. Medical Data Research Centre, Providence Health System, St Vincent Hospital, Portland OR, USA (2001-2003).**

- Analysed large cardiothoracic datasets
- Led design and analysis of state-wide cluster randomised trial, and primary care studies

### **Biostatistician. Department of Cardiology, University of Wales College of Medicine, UK (1998 – 2001)**

- Research Statistician and UK co-ordinator for a multi-centre study
- Design and analysis of research projects within cardiology, pharmacology, and respiratory medicine

## **CV- Nicola Little (formerly Schmitt)**

### **EDUCATION**

**Master of Philosophy (MPhil)**, Departments of Medical Statistics and Cardiology, University of Wales College of Medicine, UK. Thesis entitled “A multi-centre study of dobutamine stress echocardiography with 'off-line' Doppler myocardial imaging - a new modality for the diagnosis of coronary artery disease.” **(1999-2001)**

**BSc Mathematics** with Honours (2.1), University of Wales College of Cardiff. Content: statistics 50%, pure mathematics 40%, and mechanics 10% **(1995-1998)**

**A levels** in Mathematics, Further Mathematics, German, and English Literature. Brockenhurst College, Brockenhurst, England Awarded ‘A’ Levels **(1993-1995)**

**GCSEs.** The Arnewood School, Hampshire. Awarded 13 GCSEs (12 Grade ‘A’) and an AS level in Mathematics **(1988-1993)**

### **EXTERNAL PRESENTATIONS:**

- DIA (Oct 2016) - plenary presentation on risk based monitoring
- PSI (May 2016) – presentation on Tagrisso
- EFSPI, Brussels (2013) – “Missing data in survival analysis”
- RSS webinar (2013) – “Attenuation of treatment effect due to measurement variability in assessment of progression-free survival”
- PSI conference (2012) – “Variability by Stealth”
- PSI One day Oncology (2012)– presentation on predicting PIII success
- PSI One day Oncology meeting (2010) – presentation of recommendations from the global PhRMA PFS expert team
- PSI poster (winner) and oral presentation on measurement error and impact on PFS (2010). [I also presented this work to the PhRMA PFS expert team and responded to challenge from the different organisations. Paper published in Pharmaceutical statistics]
- PSI conference plenary Data Analysis session (2009) –involved analysing a safety dataset and presenting recommendations in a plenary session

### **OTHER SKILLS**

**Teaching:** Line management and coaching at AstraZeneca; delivered mock stats vivas for Members of the Royal College of Physicians (MRCP) 2002-2004

**Other:** German; Certified Scuba Diver; climbing, running, swimming

### **REFEREE**

Mr Andrew Stone, Parklands, Alderley Park, Macclesfield. Cheshire SK10 4TF

## SELECTED PUBLICATIONS

(publications.co.uk)

1. Bettiol,E, Wetherington J, **Schmitt N**. Challenges and Solutions for Clinical Development of New Antibacterial Agents: Results of a Survey among Pharmaceutical Industry Professionals. *Antimicrobial agents and chemotherapy* 2015; 59: 3695-3699
2. Stone A, **Schmitt N**. Can a treatment be licenced on the basis of post-treatment predictive biomarkers? *Pharmaceutical Statistics* 2014; 13, 214-221
3. Bernard G, Francois B, Mira J-P, **Schmitt N**. Evaluating the efficacy and safety of two doses of the polyclonal anti-tumor necrosis factor- $\alpha$  fragment antibody AZD9773 in adult patients with severe sepsis and/or septic shock: randomized, double-blind, placebo-controlled phase IIb study\*. *Crit Care Med* 2014 42(3):504-11
4. Hagop M. K, Giovanni M,.., **Schmitt N** et al. Stage I of a Phase 2 Study Assessing the Efficacy, Safety, and Tolerability of Barasertib (AZD1152) Versus Low-Dose Cytosine Arabinoside in Elderly Patients With Acute Myeloid Leukemia. *Cancer* 2013;119(14):2611-9
5. Johnston S, Chia S, Kilburn L. Fulvestrant vs exemestane for treatment of metastatic breast cancer in patients with acquired resistance to non-steroidal aromatase inhibitors – a meta-analysis of EFACT and SoFEA (CRUKE/03/021 & CRUK/09/007). *San Antonia Breast Cancer Symposium* 2012
6. Hong S, **Schmitt N**, Stone S, Denne J. Attenuation of treatment Effect Due to Measurement Error in Assessment of Progression-Free Survival. *Pharmaceutical Statistics* 2012; 11: 394-402

(maiden name : Payne)

7. Hunt JS, Siemenczuk J, Touchette D, **Payne N**. Impact of educational mailing on the blood pressure of primary care patients with mild hypertension. *J Gen Intern Med.* 2004;19(9):925.
8. Schmitt M, Qasem A, McEnery C et al. Role of natriuretic peptides in regulation of conduit artery distensibility. *Am J Physiol Heart Circ Physiol.* 2004;287(3):H1167-71.
9. Fuke D, Hunt J, Siemenczuk J, Estoup M, Carroll M, **Payne N**, Touchette D. Cholesterol management of patients with diabetes in a primary care practice based research network. *Am J Manag Care* 2004;10: 130-6.
10. Schmitt M, Gunaruwan P, **Payne N** et al. Effects of exogenous and endogenous natriuretic peptides on forearm vascular function in chronic heart failure. *Arterioscler Thromb Vasc Biol.* 2004;24(5):911-7.
11. Doshi SN, Kini A, Kim MC, **Payne N**, Kamran M, Sherman W, Marmur JD, Sharma SK. A Comparative Study of Rotational Atherectomy in Acute and Stable Coronary Syndromes in the Modern Era. *Am J Cardiol* 2003; 92: 1404-08
12. Schmitt M, Broadley AJ, Nightingale AK, **Payne N** et al. Atrial Natriuretic Peptide regulates regional vascular volume and venous tone in humans. *Arterioscler Thromb Vasc Biol* 2003; 23: 1833-8
13. Fraser AG, **Payne N**, Mädler CF for the MYDISE Investigators. Feasibility and reproducibility of off-line tissue Doppler measurement of regional myocardial function during dobutamine stress echocardiography. *Eur J Echocardiogr* 2003; 4: 43-53.
14. Grunkemeier GL, **Payne N**, Jin R, Handy JR Jr. Propensity score analysis of stroke after off-pump coronary artery bypass grafting. *Ann Thorac Surg* 2002; 74: 301-5.
15. Zamvar V, Williams D, Hall J, **Payne N**, Cann C, Young K, Karthikeyan S, Dunne J. Assessment of Neurocognitive Impairment after Off-Pump and On-Pump Techniques for Coronary Artery Bypass Graft Surgery: Prospective Randomized Study. *BMJ* 2002; 325: 1268.

2002;105: 22-6.

17. Butchart EG, **Payne N**, Li HH, Buchan K, Mandana K, Grunkemeier GL. Better Anticoagulation Control Improves Survival After Valve Replacement. *J Thorac Cardiovasc Surg* 2002; 123: 715-23.
18. Ashfield-Watt PAL, Knowles RM, Cole SB, **Payne N**, Ian FW McDowell: A folate enriched diet lowers plasma homocysteine in patients with hyperlipidaemia: a randomised controlled trial. *The British Journal of Cardiology* 2001; 8: 28-35
19. Ionescu AA, Ionescu AA, **Payne N**, Obieta-Fresnedo I, Fraser AG, Shale DJ. Subclinical right ventricular dysfunction in cystic fibrosis. A study using tissue Doppler echocardiography. *Am J Respir Crit Care Med* 2001; 163: 1212-8.
20. Griffiths TL, Burr ML, Campbell IA, Lewis-Jenkins V, Mullins J, Shiels K, Turner-Lawlor PJ, **Payne N**, Newcombe RG, Ionescu AA, Thomas J, Tunbridge J. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. *Lancet* 2000; 355: 362-368.