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Curriculum vitae

Malcolm Boyce

Managing and Clinical Director

**BSc MB ChB FRCP FFPM FBPharmacolS
FRQA FCMI FCIPD QP**



Certificate no. Q50577

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University and medical school Bristol 1963–69

Qualifications:

BSc Physiology, Upper second class honours	1966
MB ChB	1969
MRCP (UK)	1972
MFPM	1988
FFPM	1990
FRCP (London)	1999
FCMI	2001
FCIPD	2003
FRQA	2003
Plain English Campaign Diploma	2003
QP	2004
FBPharmacolS	2007
Advanced Life Support certified	2007

Student prizes:

Edgeworth prize in physiology, MB ChB	1965
Nuffield Scholarship in Tropical Medicine, Makerere College, Uganda	1968

Laboratory appointments

Laboratory Technician, British Drug Houses, London 1957–60
Development of pilot plant methods to manufacture steroids by fermentation

Medical Laboratory Technician, Courtauld Institute of Biochemistry,
Middlesex Hospital Medical School, London 1960–63
Separation and identification of metabolites of endogenous
and exogenous steroids

Clinical appointments

House Physician to Drs A Tanser (general and respiratory medicine) and Dr A St J Dixon (general medicine and rheumatology), St Martin's Hospital, Bath	1969–70
House Surgeon to Mr T Schofield (general surgery) and Mr S Glaser (general and urological surgery), Royal United Hospital, Bath	1970–70
Senior House Officer (paediatrics) to Professor N Butler, Royal Hospital for Sick Children, Bristol	1970–71
Senior House Officer to Professor D Russell-Davis (psychiatry), Professor A Read (general medicine and gastroenterology) and Dr M Jayson (rheumatology), Bristol Hospitals	1971–71
Registrar Rotation, Bristol Hospitals, Professor A Read (general medicine and gastroenterology), Dr F Page (neurology), Dr J Russell Rees (cardiology) and Dr J Pearson (respiratory medicine)	1971–72
Lecturer in Child Health, The London Hospital and St Bartholomew's Hospital Medical Colleges.	1972–74
Registrar and then Senior Registrar, Queen Elizabeth and Great Ormond Street Hospitals for Sick Children, London	1972–74

Pharmaceutical research appointments

Medical Adviser, International Division, Beecham Pharmaceuticals, Brentford, Middlesex, England	1975–76
Clinical Pharmacologist, Research Division, Beecham Pharmaceuticals, Brockham Park, Surrey, England	1976–77
Senior Clinical Research Physician, Smith Kline and French Research, Welwyn, Hertfordshire, England	1978–79
Area Director of Clinical Research, Smith Kline and French Research, Welwyn, Hertfordshire, England	1980–84

Senior Medical Adviser, Medical Research Department, ICI Pharmaceuticals, Alderley Park, Cheshire, England	1984–85
Cardiovascular Therapeutic Area Team Leader, Medical Research Department, ICI Pharmaceuticals, Alderley Park, Cheshire, England.	1986–87
Associate Medical Director, Merrell Dow Research Institute, Winnersh, Berkshire, England	1987–88
Senior Clinical Project Manager, Marion Merrell Dow Product Development, Strasbourg, France	1989–92
Medical Director, Charterhouse Clinical Research Unit, Royal Masonic Hospital, Ravenscourt Park, London W6 OTN	1992–92
Managing and Clinical Director, Hammersmith Medicines Research, Department of Clinical Pharmacology, St. Bartholomew's Hospital, London EC1A 7BE	1993–93
Managing and Clinical Director, Hammersmith Medicines Research, Cumberland Avenue, London NW10 7EW	1994–
Chief Executive of TRIO Medicines Ltd, a subsidiary of HMR	2006–
Honorary appointments during employment in the pharmaceutical industry	
Senior Registrar, Hospital for Sick Children, Great Ormond Street, London.	1976–77
Research Physician, Cardiology Department, Clinical Research Centre, Northwick Park Hospital, Harrow, Middlesex.	1979–84
Research Fellow, Department of Clinical Pharmacology, St Bartholomew's Hospital Medical College, London.	1993–
Lecturer, MSc course in pharmaceutical medicine , University of Surrey	2000–

Membership of learned societies or professional bodies

British Medical Association	1969–
British Society of Allergy and Clinical Immunology	1975–
Royal Society of Medicine	1975–
British Pharmacological Society	1980–
Association for Human Pharmacology in the Pharmaceutical Industry	1987–
Serotonin Club	1989–
British Association for Psychopharmacology	1990–
British Association for the Study of Headache	1999–
International Headache Society	1999–
American Association of Clinical Pharmacology and Therapeutics	2000–
British Association of Research Quality Assurance	2001–
Chartered Management Institute	2001–
Chartered Institute of Personnel and Development	2001–

Committees

Member and subsequently Alternate Vice Chairman of the London Research Ethics Committee, representing clinical pharmacology	1997–2007
Member of the ABPI Clinical Trials Committee	2002–2003
Member and subsequently Chairman of the Committee of the Association for Human Pharmacology in the Pharmaceutical Industry (AHPPI)	2002–
Member of ABPI Experimental Medicine and Clinical Pharmacology Group	2002–2004
Member of the NRES Working Group on recognition and accreditation of research ethics committees	2002–2005
Member of the NRES Phase I Advisory Group	2004–
Member of the GCP Consultative Committee of the MHRA	2004–
Chairman, Advisory Committee, Diploma and Certificate in Human Pharmacology	2006–

Teaching experience

Teaching general medicine and paediatrics to medical students and postgraduates

MSc course, St Bartholomew's Hospital Medical College: Organiser and teacher of module on early drug development in man, and MSc supervisor

MSc in Pharmaceutical Medicine, University of Surrey: teacher of module on ethics committees, and MSc supervisor

Course organiser for the Thames Valley University Certificate in Practical Clinical Pharmacology. Course is recognised by the Pharmaceutical Industry National Training Organisation (PhINTO)

Numerous postgraduate lectures or teaching sessions on aspects of clinical pharmacology, including good clinical practice, good manufacturing practice, and research ethics

Tutor for BARQA courses on GMP and GCP

Senior Speciality Adviser on Higher Medical Training, Faculty of Pharmaceutical Medicine, Royal College of Physicians

Reviewer of medical and scientific journals

Lancet

British Journal of Clinical Pharmacology

International Journal of Pharmaceutical Medicine

Drugs

Publications

- 1 **Boyce MJ.** Diabetic ketoacidosis and influenza. *Br Med J* 1970; 4: 365–366.
- 2 **Boyce MJ.** Epstein-Barr virus and the Guillain-Barré syndrome. *Lancet* 1972; 2: 1028–1029.
- 3 **Boyce MJ, Lockyer JW, Wood CBS.** Foetus in foetu: serological assessment of monozygotic origin by automated analysis. *J Clin Path* 1972; 25: 793–798.
- 4 **Matthew H, Boyce MJ, Mason P.** Blisters in unconscious patients. *Lancet* 1972; 2: 874.
- 5 **Boyce MJ, Burwood JR, Johnson M, Wood CBS.** Chronic duodenal ulcer in infancy. *J Paed Surg* 1973; 49: 115–118.
- 6 **Pilcher J, Chandrasekhar K, Russell Rees J, Boyce MJ, Pierce TH, Ikram H.** Long term assessment of perhexilene maleate in angina pectoris. *Postgrad Med J* 1973; 49: 115–118.
- 7 **Boyce MJ, France NE, Walker-Smith JA.** Small intestinal damage in a group of infants and young children with delayed recovery after acute diarrhoea and vomiting. *Gut* 1974; 15: 827.
- 8 **Boyce MJ.** Pancreatic exocrine insufficiency. *Proc Roy Med* 1976; 69: 26.
- 9 **Bell A, Boyce MJ, Burland WL, Underwood DD.** Assessment in man of SK&F 92657, a novel compound with vasodilator and beta-adrenoceptor blocking activity. *Br J Clin Pharmacol* 1980; 9: 299–300.
- 10 **Boyce MJ, Wareham K.** Histamine H₁ and H₂ receptors in the cardiovascular system of man. In: Torsoli A, Lucchelli PE, Brimblecombe RW (eds), H₂ antagonists. *Excerpta Medica, Amsterdam* 1980; 280–293.
- 11 **Boyce MJ, Owen DA, Wareham K.** Modification of cardiovascular effects of histamine infusions in man by chlorpheniramine and cimetidine. *Br J Pharmacol* 1980; 70: 110.

- 12 **Boyce MJ**, Bala Subramanian V, Wareham K. Cardiovascular effects in man of impromidine, a novel and specific histamine H₂-receptor agonist. *Br J Pharmacol* 1980; 70: 157–158.
- 13 **Boyce MJ**. Cardiovascular effects of intravenous cimetidine. *Br J Clin Pharmacol* 1981; 12: 268.
- 14 **Boyce MJ**, Wareham K, Bala Subramanian V. Oral cimetidine antagonises cardiovascular histamine H₂-receptors but does not affect normal cardiovascular function. *Clin Sci* 1981; 60: 28.
- 15 **Boyce MJ**. Cimetidine and the Cardiovascular System. In: Baron JH (ed), *Cimetidine in the 80's*. Churchill Livingstone, Edinburgh 1981; 227–237.
- 16 Smith R, Grossman A, **Boyce MJ**, Besser GM, Rees LH. Effect of histamine infusion on circulating methionine-enkephalin and catecholamine concentrations. *Neurosci Lett* 1985; 55: 289–292.
- 17 Dalton N, **Boyce MJ**, Clancy A, Toseland P. Plasma catecholamine responses to exogenous histamine in normal man. *Clin Sci* 1981; 61: 46.
- 18 Owen DAA, Harvey CA, **Boyce MJ**. Effects of histamine on the circulatory system. *Klinische Wochenschrift* 1982; 60: 972–977.
- 19 **Boyce MJ**. Pharmacological characterisation of cardiovascular histamine receptors in man in vivo. *Klinische Wochenschrift* 1982; 60: 978–982.
- 20 **Boyce MJ**. Effect of SK&F 93944, a new H₁-antagonist, on the cardiovascular responses to betahistine in healthy subjects. *Br J Clin Pharmacol* 1984; 18: 277–278.
- 21 **Boyce MJ**, Dalton N, Goodwin B, Walker P, Weg M, Sandler M. Disposition of equimolar oral doses of epinine and ibopamine, the di-isobutyl ester of epinine, in healthy subjects. *Br J Clin Pharmacol* 1985; 19: 143–144.
- 22 Bastain W, **Boyce MJ**, Stafford LE, Morton PC, Clarke DA, Marlow HF. Pharmacokinetics of xamoterol (ICI 118,587) after intravenous and oral administration to volunteers. *Eur J Clin Pharmacol* 1988; 34: 469–473.

- 23 The German and Austrian Xamoterol Study Group. Double-blind placebo-controlled comparison of digoxin and xamoterol in chronic heart failure. *Lancet* 1988; i: 489–93. (Coordinator: **MJ Boyce**)
- 24 **Boyce MJ**, Green D, Hinze C, O'Grady P. Characterisation of MDL 73,005EF, a novel 5-HT_{1A} ligand, in man. *J Psychopharmacol* 1990; 4: 261.
- 25 **Boyce MJ**, Orwin JM. MDL 72,222, a 5-HT₃ antagonist: a review of clinical studies. Abstract presented at the Perugia International Cancer Conference: supportive therapy: June 14–16, 1990.
- 26 Smith R, **Boyce MJ**, Lewis P. Clinical pharmacology of terfenadine in asthma: a review. *Eur J Clin Res* 1991; 2: 115–133.
- 27 Smith R, **Boyce MJ**, Lewis P. Efficacy and safety of terfenadine in asthma: a review. *Eur J Clin Res* 1991; 2: 135–151.
- 28 **Boyce MJ**, Hinze C, Haegele KD, Green D, Cowen PJ. Initial studies in man to characterise MDL 73,005EF, a novel 5-HT_{1A}-receptor ligand and putative anxiolytic. In: Fozard JR, Saxena PR (eds), *Serotonin: Molecular biology, receptors and functional effects*. Birkhauser, Verlag. Basel 1991; 471–482.
- 29 Hinze C, **Boyce MJ**, Cowen PJ. Effect of MDL 73,005EF on temperature and basal or buspirone-stimulated neuroendocrine function in man. *Fund Clin Pharmacol*. 1991; 5: 389.
- 30 **Boyce MJ** for the European MDL 73,147EF Study Group. Multicentre study of the safety and anti-emetic activity of MDL 73,147EF, a new 5-HT₃ antagonist, in patients requiring cisplatin ≥ 50 mg/m². Proceedings of the Fourth International ARTAC workshop on Therapeutic Trials in Cancer. Sept 25–27, 1991; Paris, France.
- 31 Kirchner V, Aapro M, Alberto P, O'Grady P, Busch B, **Boyce M**. Early clinical trial of MDL 73,147EF, a new HT₃ antagonist, for the prevention of chemotherapy-induced nausea and vomiting. *Annals Oncol* 1993; 4: 481–484.
- 32 European Dolasetron Study Group. Acute anti-emetic effect and safety of dolasetron mesylate, a new 5HT₃ antagonist, in cancer patients treated with cisplatin-containing chemotherapy. *Am J Clin Oncol* 1994; 17(2): 97–102. (Coordinator: **MJ Boyce**)

- 33 Sardina M, Warrington SJ, **Boyce MJ**, Johnston A, Bianchini C. Hemodynamic and humoral effects at rest and after head-up tilt tests during 24 hour infusion of a new nitrate ester, ITF-296, compared with ISDN and placebo in healthy volunteers: A double-blind, randomised, within subject study. *J Cardio Pharmacol*, 1995, 26 (supp 4) S80–S90
- 34 **Boyce MJ**, Warrington SJ. A comparison of the discomfort from subcutaneous injection of two citrate-buffered formulations of epoetin alfa. *Br J Clin Res* 1995; 6: 209–212.
- 35 **Boyce MJ**, Warrington SJ. A comparison of the discomfort from subcutaneous injection of epoetin beta and phosphate-buffered epoetin alfa from a pre-filled syringe. *Br J Clin Res* 1995; 6: 213–217.
- 36 Bench CJ, Lammertsma AA, Grasby PM, Dolan RJ, Warrington SJ, **Boyce M**, Gunn KP, Brannick LY, Frackowiak RSJ. The time course of occupancy of striatal dopamine D₂ receptors by the neuroleptic Ziprasidone (CP-88,059-01) determined by positron emission tomography. *Psychopharmacology* 1996; 124: 141–147.
- 37 Watts MJ, Addison I, Long S, Hartley S, Warrington S, **Boyce M**, Linch D. Crossover study of the haematological effects and the pharmacokinetics of glycosylated and non-glycosylated G-CSF in healthy volunteers. *Br J Haematology* 1997; 98: 474–479.
- 38 Watts MJ, Addison I, Long S, Hartley S, Warrington S, **Boyce M**, Linch D. Optimal timing for collection of peripheral-blood progenitor cells after glycosylated G-CSF administration. *Bone Marrow Transplantation* 1998; 21: 365–368.
- 39 Khattar RS, Senior R, Sardina M, **Boyce M**, Lahiri A. Safety, tolerability and anti-ischaemic efficacy of ITF-296, a nitric oxide donor, in patients with chronic stable angina. *J Cardio Pharmacol* 1998; 32: 295–299.
- 40 Warrington S, **Boyce M**, Rolfe L, Clarke A, Mallard N, Johnson E. Higher bioavailability of selegiline from Zydys than Deprenyl formulations does not lead to increased potentiation of the pressor response to oral tyramine. *Br J Clin Pharmacol* 1998; 46: 284P.
- 41 Warrington S, **Boyce M**, Rolfe L, Clarke A, Mallard N, Rowkins S, Johnson E. Are the metabolites of selegiline, rather than the parent compound, responsible for the potentiation of the pressor response to oral tyramine? *Br J Clin Pharmacol* 1998; 46: 297P.

- 42 Marshall E, Howell AH, Powles R, Hunter MG, Edwards M, Wood LM, Czaplewski L, Puttick R, Warrington S, **Boyce M**, Testa N, Dexter TM, Lord BI, Millar A. Clinical effects of human macrophage inflammatory protein alpha MIP-1 alpha (LD78) administration to humans: a phase I study in cancer patients and healthy volunteers with the genetically engineered variant, BB100010. *Eur J Cancer* 1998; 34: 1023–1029.
- 43 Webster A, **Boyce M**, Edmundson S, Miller I. Co-administration of orally inhaled zanamivir with inactivated trivalent influenza vaccine does not adversely affect the production of anti-hemagglutinin antibodies in the serum of healthy volunteers. *Clinical Pharmacokinetics*, 1999; 36 (suppl 1): 51–58.
- 44 Gémesi LI, Kapás M, Farkas S, Warrington S, **Boyce M**. Pharmacokinetics of silperisone in healthy volunteers. Poster presented at the 7th European ISSX meeting (Budapest 22–26 August 1999).
- 45 Warrington S, **Boyce M**. Testing genetically modified micro-organisms in man. *European Pharmaceutical Contractor*. November 1999.
- 46 Cabaroccas X, Warrington S, Jansat J, Zayas JM, **Boyce M**, Ferrer P. Pharmacokinetics and tolerability of oral almotriptan in the elderly. *Headache* 1999; 39: 346.
- 47 Warrington S, Johnson N, Cattoni M, **Boyce M**. Tolerability and pharmacodynamic effects of single doses of ganstigmine, a new cholinesterase inhibitor, in healthy men. *Br J Clin Pharmacol* 2000; 49 :503–504.
- 48 Johnson N, Cattoni M, Warrington S, **Boyce M**. Tolerability and pharmacodynamic effects of repeated doses of ganstigmine, a new cholinesterase inhibitor, in healthy men. *Br J Clin Pharmacol* 2000; 49: 492–493.
- 49 Boyce M, Mertens A, Mannaert E, de Smedt H, Willenbacher R. Cardiac safety and tolerability of prucalopride in healthy volunteers. Presentation to the American College of Gastroenterology, 65th Annual Scientific Meeting, 2000.
- 50 Grattan TJ, Hickman RA, Darby-Dowman A, Hayward MA, **Boyce M**, Warrington S. A five way crossover human volunteer study to compare the pharmacokinetics of paracetamol following oral administration of two commercially available paracetamol

tablets and three development tablets containing paracetamol in combination with sodium bicarbonate or calcium carbonate. *Eur J Pharm Biopharm* 2000; 49: 225–229.

- 51 **Boyce M**, Warrington S, Johnston A, Harris A. Effect on gastric pH of single doses of YF476, a new gastrin antagonist, compared with ranitidine and placebo. *Br J Clin Pharmacol* 2000; 49: 493–494.
- 52 Curtis SP, Eardley I, **Boyce M**, Larson P, Haesen K, Gottesdiener K, Gertz BJ. Single dose methodology to assess the influence of alpha-1 adrenoceptor antagonist on uroflowmetric parameters in patients with benign prostatic hyperplasia. *Br J Clin Pharmacol* 2000; 49: 269–273.
- 53 **Boyce M**, Warrington S, Johnston A, Harris A. Effect on gastric pH of repeated doses of YF476, a new gastrin antagonist, compared with omeprazole and placebo. *Br J Clin Pharmacol* 2000; 50: 383–384.
- 54 Bryan S, O'Connor BJ, Matti S, Leckie MJ, Kananbar V, Khan J, Warrington SJ, Renzetti L, Rames A, Bock JA, **Boyce MJ**, Hansel T, Holgate ST, Barnes PJ. Effects of recombinant human interleukin-12 on eosinophils, airway hyper-responsiveness, and the late asthmatic response. *Lancet* 2000; 356: 2149–2153.
- 55 Ravic M, Warrington S, **Boyce M**. The safety and pharmacokinetics of thioridazine during co-administration with donepezil. Submitted to the Meeting of the American Society for Clinical Pharmacology and Therapeutics. Lake Buena Vista, Florida. 3–6 March, 2001.
- 56 **Boyce M**, Dunn K, Warrington S. Hemodynamic and electrocardiographic effects of almotriptan in healthy volunteers. *J Cardiovasc Pharmacol* 2001; 37: 280–289.
- 57 Moore KHP, Cass LM, Dallow N, Hardman TC, Jones A, **Boyce M**, Prince WT. Pharmacokinetics and tolerability of GW420867X, a new non-nucleoside reverse transcriptase inhibitor, following escalating doses in healthy male volunteers. *J Clin Pharmacol* 2001; 41: 1098–1105.
- 58 Moore KHP, Cass LM, Dallow N, Hardman TC, Jones A, **Boyce M**, Prince WT. Pharmacokinetics and safety of escalating single and repeat oral doses of GW420867X, a novel non-nucleoside reverse transcriptase inhibitor. *Eur J Clin Pharmacol* 2001; 56: 805–811.

- 59 **Boyce M**, Clark E. Single doses of YF476 suppress gastric acid secretion, but tachyphylaxis occurs with repeated dosing. 2001 Annual meeting of the American Society for Clinical Pharmacology and Therapeutics, Orlando, Florida.
- 60 **Boyce M**, Mertens A, Mannaert E, Smedt H, Willenbacher R. Tolerability and cardiac safety of prucalopride in healthy volunteers. *Amer J Gastroenteology* 2000; 95(9): 2529.
- 61 Shangold G, Fisher AC, Rubin A, on behalf of the multicentre EVRA 002 study group. Pharmacodynamics of the contraceptive patch. *Obstet Gynecol* 2000; 95 (4 suppl 1): S36.
- 62 Creasy G, Hall N, Shangold G, on behalf of the multicentre EVRA 004 study group. Patient adherence with the contraceptive patch dosing schedule versus oral contraceptives. *Obstet Gynecol* 2000; 95 (4 suppl 1): S60.
- 63 Warrington S, Tejura B, **Boyce M**, Morocutti A, Miller N. Rabeprazole is more potent than esomeprazole in control of gastric pH in healthy volunteers. Poster presentation. European Union Gastroenterology Week, Amsterdam, Autumn 2001 & American College of Gastroenterology, Las Vegas, Autumn 2001.
- 64 Baisley K, **Boyce M**, Warrington S, Bukofzer S, Compaire F. Pharmacokinetics, safety and tolerability of three dosage regimens of buccal adhesive testosterone (BATT) in men suppressed with leuprorelin. *J Endocrinology* 2002; 175: 813–819.
- 65 Warrington S, Baisley K, **Boyce M**, Tejura B, Morocutti A, Miller N. Effects of rabeprazole, 20 mg, and esomeprazole, 20 mg, on 24-h intragastric pH and serum gastrin in healthy subjects. *Aliment Pharmacol Ther* 2002; 16: 1301–1307.
- 66 **Boyce M**, Warrington S, Lewis Y, Nentwich H, Harris A. Adaptation to the antisecretory effect of YF476, a new gastrin antagonist, in healthy men. *Br J Clin Pharmacol* 2002; 53: 437P.
- 67 **Boyce M**, Dunn K, Lewis Y, Wicks J, Warrington S. Potential impact of the European Clinical Trials Directive on UK phase I studies. *Br J Clin Pharmacol* 2002; 53: 417P.
- 68 **Boyce M**, Bowell A, Clark E, Dunn K, Evans A, Johnson R, Norris V, Warrington S. Assessment by questionnaire of the process of informing study subjects. *Br J Clin Pharmacol* 2002; 53: 436P.

- 69 Suzuki N, Cho N, Furuya S, Harada M, Urishibara T, Takekawa S, Horinouchi A, Onda H, Clark E, **Boyce M**. TAK-013: A novel, potent, and orally active nonpeptide antagonist for the human gonadotropin-releasing hormone receptor. The Endocrine Society's 84th Annual Meeting, San Francisco, 19 June 2002.
- 70 Clark E, **Boyce M**, Johnston A, George M, Davies J, Hibberd M. Effects of repeated oral doses of TAK-013, a new non-peptide gonadotropin-releasing hormone antagonist, in healthy pre-menopausal women. *Fertility and Sterility* 2002; 78: S280–S281.
- 71 **Boyce M**, Clark E, Johnston A, George M, Davies J, Hibberd M. Effects of repeated oral doses of TAK-013, a new non-peptide gonadotropin-releasing hormone antagonist, in healthy post-menopausal women. *Fertility and Sterility* 2002; 78: S281–S282.
- 72 **Boyce M**. Observational study of 353 applications to London Multicentre Research Ethics Committee 1997–2000. *Br Med J* 2002; 325: 1081.
- 73 **Boyce M**, Lillieborg S, Englund G. The minimum clinically significant difference in visual analog pain score in migraine. 10th World Congress on Pain. San Diego, USA, August 2002.
- 74 **Malcolm Boyce**. *Lancet* peer reviewer, 8 March 2002.
On line: <http://image.the.lancet.com/extras/rev02web.pdf>
- 75 Harada M, Susuki N, Cho Nobuo, Urushibara T, Takekawa S, Horinouchi A, Clark E, Furuya S, Onda H, **Boyce M**, Fujino M. TAK-013: a novel, potent, and orally active, nonpeptide antagonist for the human gonadotropin-releasing hormone receptor. *Endocrinology* 2002.
- 76 **Boyce M**, Warrington S. Analysis of 312 studies of investigational medicinal products in healthy subjects to assess the impact of the European Union Clinical Trials Directive. *Int J Pharmaceut Med* 2002; 16: 179–183.
- 77 **Boyce M**. Observational study of 353 applications to the London Multicentre Research Ethics Committee, 1997–2000. *Int J Pharmaceut Med* 2002; 16: 209–213.
- 78 Baisley KJ, **Boyce MJ**, Pradhan R, Warrington, SJ. Pharmacokinetics, safety and tolerability of three dose regimens of buccal adhesive testosterone tablets in healthy men suppressed with leuprorelin. *Journal of Endocrinology* 2002; 175, 813–819.

- 79 Carey W, Warrington S, **Boyce M**, Luria X. Inhibition of the histamine wheal by ebastine compared with cetirizine, fexofenadine and loratadine at steady state. *Drugs Exp Clin. Res* 2002; 28: 243-247.
- 80 Warrington S, Cole T, Baisley K, **Boyce M**. Effects of the selective COX-2 inhibitor, flosulide on renal homeostasis in salt-loaded men. *Br J Clin Pharmacol* 2003; 55: 430.
- 81 Sciberras D, Calder N, **Boyce M**, Posner J. AHPPI survey of UK phase I units, 1999–2000. *Br J Clin Pharmacol* 2003; 55: 433.
- 82 Johnston A, Holt D, Lee T, Clark E, Dunn K, **Boyce M**. Urinary 6 β -hydroxycortisol / cortisol ratio as an in vivo marker of CYP3A4 activity: spot versus 24-hour collections. *Br J Clin Pharmacol* 2003; 55: 440.
- 83 Kaeser B, Akintola D-J., Saifulanwar A, **Boyce M**, Smith P. Improved gastrointestinal tolerability of Roche nelfinavir 625 mg film-coated tablets in comparison with nelfinavir 250 mg film-coated tablets (Viracept[®]). 4th International Workshop on Clinical Pharmacology of HIV therapy. 27–29 March 2003, Cannes, France.
- 84 Andrews JM, Honeybourne D, Jevons G, **Boyce M**, Wise R, Bello A, Gajjar D. Concentrations of garenoxacin in plasma, bronchial mucosa, alveolar macrophages and epithelial lining fluid following a single oral 600 mg dose in healthy adult subjects. *J Antimicrobial Chemotherapy* 2003; 51: 727–730.
- 85 **Malcolm Boyce**. Lancet peer reviewer, 29 March 2003.
On line: <http://image.the.lancet.com/extras/03webcmt72webreviewers.pdf>
- 86 Carey W, Clark E, Warrington S, **Boyce M**, Kerns W, Fishman P, Cohn I, Silverman M. Single oral doses of CF101, a new adenosine A₃ receptor agonist, in healthy men. *Br J Pharmacol* 2003; 140 (Suppl): 25P.
- 87 Troostenberg A, Clark E, Warrington S, **Boyce M**, Kerns W, Fishman P, Cohn I, Silverman M. Repeated oral doses of CF101, a new adenosine A₃ receptor agonist, in healthy men. *Br J Pharmacol* 2003; 140 (Suppl): 26P.
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- preference and selectivity for MAO-B inhibition. *J Neural Transmission*; 2003; 110: 1257–1271.
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- 90 **Boyce M**, Nentwich H, Melbourne W, Warrington S. TOPS: the overvolunteering prevention system. *Br J Clin Pharmacol* 2003; 55: 418P–419P.
- 91 Calder N, **Boyce M**, Posner J, Sciberras D. Clinical pharmacology studies in UK phase I units: an AHPPI survey 1999–2000. *Br J Clin Pharmacol* 2004; 57: 76–79.
- 92 Norris V, Choong L, Tran D, Corden Z, **Boyce M**, Holgate S, O'Connor B, Kirkesseli S. A placebo-controlled, double-blind, crossover study of 8 days' treatment with IVI745, a VLA-4 antagonist, in mild atopic asthma. *Br J Clin Pharmacol* 2004; 57: 676.
- 93 **Boyce M**, Warrington S, Nentwich H, Norris V, Hull R, Black J. Effect of repeated doses of YF476, a gastrin antagonist, on pentagastrin-induced changes in volume, H⁺ content and pH of gastric aspirate in healthy subjects. *Br J Clin Pharmacol* 2004; 57: 684.
- 94 **Boyce M**, Baisley K, Clark E, Warrington S. Are published normal ranges of serum testosterone too high? Results of a cross-sectional survey of serum testosterone and LH in healthy men. *Br J Urology Int* 2004; 94: 881–885.
- 95 Ravic M, Warrington S, **Boyce M**, Dunn K, Johnston A. Repeated dosing with donepezil does not affect the safety, tolerability, or pharmacokinetics of single-dose thioridazine. *Brit J Clin Pharmacol* 2004; 58:S1: 34–40.
- 96 Erin EM, Leaker BR, Zacharasiewicz AS, Higgins LA, Jose PJ, Williams TJ, **Boyce MJ**, de Boer P, Durham SR, Barnes PJ, Hansel TT. Single dose topical corticosteroid inhibits IL-5 and IL-13 levels in nasal lavage following grass pollen challenge. *Allergy* 2005; 60: 1524–1529.

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Summary of experience in the pharmaceutical industry

I worked in the pharmaceutical industry from 1975 to 1992. I spent the first year in the International Division, Beecham. My main role was to provide a phase IV service (clinical trials with marketed drugs, training, advertising copy etc) for designated territories – Europe, Africa and the Middle East. The products were mainly semi-synthetic penicillins. There was some phase III work with novel antibiotics and a NSAID. I transferred to the Research Division of Beecham for the second year. My primary role was to establish a programme of work with modified allergens in phase I in the UK, and in phase II (rhinitis and asthma) in the USA, Canada and the UK. Also, I did some phase I and II studies with other novel compounds, including an oral cromoglycate compound (BRL 10833), in the U.K.

For the next seven years, I worked in the Clinical Research Department, SK&F. At first I did phase I studies and phase II studies (hypertension) with a beta-adrenoceptor antagonist and vasodilator (SK&F 92676, prizidilol), and I assessed the potential use of cimetidine for indications (cardiovascular, immunological) other than peptic ulcer disease. Then I did the clinical pharmacology of various novel histamine agonists and antagonists: oxmetidine (H₂-antagonist); SK&F 93479 (long-acting H₂-antagonist); SK&F 93319 (combined H₁- and H₂-antagonist); and SK&F 93944 (non-sedative H₁-antagonist). All but SK&F 93319 progressed to phases II or III. I did some of the work in the Cardiology Department, Clinical Research Centre, Northwick Park Hospital, where I held an honorary appointment. In the last years of my period with SK&F, my role expanded both on a project and a territorial basis. I managed a portfolio of compounds including ibopamine, an oral dopamine agonist, in phase I and phase II (heart failure) and two inhibitors of adrenaline synthesis, SK&F 64139 and 29661 in phases I and II (hypertension). My territories were UK, Scandinavia, Benelux countries and Eire.

Next, I spent nearly three years in the Medical Research Department, ICI. Initially, I worked as a Senior Medical Adviser with territorial responsibilities (UK, Germany and Holland) within a drug team. Subsequently, I was made leader of that team and then a larger team (Cardiovascular II), the largest of the ICI drug teams at that time. I worked solely on ICI 118,587 (xamoterol, "Corwin"), a selective β_1 partial agonist, which at the time was in late phase III development for heart failure. The compound was subsequently given a product licence in several countries.

For the next five years or thereabouts, I worked in the Clinical Research Departments of Marion Merrell Dow. During the first year, I was based in the UK and I prepared an application for extension of the product licence for terfenadine. After that, I relocated to

Strasbourg, France, where I was responsible for the clinical development throughout Europe of two 5-HT₃ receptor antagonists (MDL 72,222 and MDL 73,147EF), for several indications, and a 5HT_{1A} receptor partial agonist (MDL 73,005EF), for CNS indications.

Thus, I have wide experience of all phases of drug development in the pharmaceutical industry, including preparation of applications for clinical trial certificates or exemptions and product licences, and with a variety of new and established drugs. I have been the principal investigator for many phase I studies in healthy subjects, and set up, monitored and brought to fruition many studies in patients, ranging from small, early phase II studies to large, multicentre, multinational phase III studies, in various clinical areas. Also, I have some experience of phase IV studies.

Since 1993, I have been Managing and Clinical Director for Hammersmith Medicines Research (HMR), a Contract Research Organisation, close to an NHS hospital. Also, I am the Quality System Manager for ISO 9001, a quality system based on Good Clinical Practice and Good Manufacturing Practice. HMR has 100 beds and about 150 permanent staff, including 7 physicians, 35 nurses, and 75 graduates or PhD. To date, I have been the principal investigator or co-investigator for over 500 studies done by HMR, mainly phase I (about 95 % of studies) but also early phase 2 (about 5 % of studies). Almost all those studies have involved investigational medicinal products – mostly ‘small molecules’ but also ‘biological’ products, such as inhibitors of individual components of the immune system, recombinant peptides or proteins, antibodies, cytokines, and vaccines made from genetically modified micro-organisms. Many of the studies were first-administration-to-man trials.

The achievements of HMR include:

1995: Rubicon Award for New Business of the Year;

1998: The Queen’s Award for Export Achievement;

1998: R & D Affiliate of the Association of the British Pharmaceutical Industry (ABPI);

1999: Rubicon Award for Growing Business of the Year;

1999: ISO 9001 accreditation;

1999: Fast Track 100 company;

2002: The Queen’s Awards for Enterprise: International Trade;

2002: Laboratory accreditation by the College of American Pathologists;

2002: Setting up TOPS (The Over-volunteering Prevention System), a registered charity;

2002: Establishing the Certificate in Professional and Personal Development (CPPD) for Good Clinical Practice (GCP), Thames Valley University;

2002: Establishing Module 4 of an MSc course in early drug development, Barts and the London Hospitals Medical College;

2003: Pharmacy registration by the Royal Pharmaceutical Society;
2004: Manufacturer's Authorisation for Investigational Medicinal Products;
2004: National Training Award for the CPPD course in GCP; and
2008: MHRA Phase 1 Supplementary Accreditation.