

PERSONAL INFORMATION

Deborah Ashby

WORK EXPERIENCE

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- January 2018–Present **Director of the School of Public Health**
Imperial College London (United Kingdom)
- October 2008–December 2017 **Co-Director of Imperial Clinical Trials Unit and Professor of Medical Statistics**
Imperial College London (United Kingdom)
- September 1997–October 2008 **Professor of Medical Statistics**
Barts and the London School of Medicine and Dentistry, Queen Mary, University of London (United Kingdom)
- September 1987–September 1997 **Lecturer (1987-1992) / Senior Lecturer (1992 -1995) / Reader in Medical Statistics (1995-1997)**
University of Liverpool (United Kingdom)
- September 1983–September 1986 **Research Fellow / Honorary Lecturer in Medical Statistics**
Royal Free Hospital School of Medicine, University of London (United Kingdom)

EDUCATION AND TRAINING

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- September 1981–June 1983 **PhD in Medical Statistics**
Royal Free Hospital School of Medicine, University of London (United Kingdom)
Completed thesis on 'A statistical investigation of the relationship of serum biochemistry and haematology to alcohol consumption' (supervisor Prof SJ Pocock).
- September 1980–June 1981 **MSc in Medical Statistics**
London School of Hygiene and Tropical Medicine, University of London (United Kingdom)
- September 1977–June 1980 **BSc (Hons) in Mathematics (First Class)**
University of Exeter (United Kingdom)

ADDITIONAL INFORMATION

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- Expertise** Professor Deborah Ashby holds the Chair in Medical Statistics and Clinical Trials at Imperial College London, where she is also Co-Director of Imperial Clinical Trials Unit and Deputy Head of Imperial School of Public Health. Her research interests are in clinical trials, risk-benefit decision making for medicines, and the utility of Bayesian approaches in these areas.
- Professor Ashby has recently chaired the HTA Commissioning Board, and was Deputy Chair of the HTA Programme for the National Institute for Health Research. She is Chair of the Population Research Committee for Cancer Research UK. She is President of the Royal Statistical Society for 2019 and 2020.
- Publications** Selection of Peer Reviewed Articles
- Modi N, Santhakumaran S, Gray D, Statnikov Y, Battersby C, Ashby D, Survival of very preterm infants admitted to neonatal care in England 2008-2014: time trends and regional variation, *ADC Fetal*

and Neonatal (in press)

Winston A, Weber J, Ashby D, Quinn K, Doyle N, Bouliotis G, Libri V, A first-in-human study of the novel HIV-fusion inhibitor C34-PEG4-Chol., *Scientific Reports* (in press)

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Gordon AC, Perkins GD, Singer M, McAuley DF, Orme RML, Santhakumaran S, Mason AJ, Cross M, Al-Beidh F, Best-Lane J, Brealey D, Nutt CL, McNamee JJ, Reschreiter H, Breen A, Liu KD, Ashby D, (2016), Levosimendan for the Prevention of Acute Organ Dysfunction in Sepsis, *N Engl J Med*, 375: 1638-1648, ISSN: 0028-4793

Hallgreen C, Mt-Isa S., Liefucht A, Phillips LD, Hughes D, Talbot S, Asimwe A, Downey G, Genov G, Hermann R, Noel R, Peters R, Micallef A, Tzoulaki I, Ashby D, and On behalf of PROTECT Benefit–Risk group (2016) Literature review of visual representation of the results of benefit–risk assessments of medicinal products. *Pharmacoepidemiol Drug Saf*, 25: 238–250.

Hughes D, Waddingham E, Mt-Isa S, Goginsky A, Chan E, Downey GF, Hallgreen CE, Hockley KS, Juhaeri, J, Liefucht A, Metcalf MA, Noel RA, Phillips LD, Ashby D, Micallef A, and PROTECT Benefit–Risk Group (2016) Recommendations for benefit–risk assessment methodologies and visual representations. *Pharmacoepidemiol Drug Saf*, 25: 251–262.

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in Neonates (NEON) trial of amino acid regimen and intravenous lipid composition in preterm parenteral nutrition: a randomised double-blind controlled trial. *Efficacy Mech Eval* 2016;3(2).

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Tsilidis KK, Capothanassi D, Allen NE, Rizos EC, Lopez DS, van Veldhoven K, Sacerdote C, Ashby D, Vineis P, Tzoulaki I, Ioannidis JP. Metformin Does Not Affect Cancer Risk: A Cohort Study in the U.K. *Clinical Practice Research Datalink Analyzed like an Intention-to-treat Trial*. *Diabetes Care*

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preparation and administration of intravenous medicines: a systematic review and Bayesian analysis. *Postgraduate Medical Journal* 2010;86(1022):734-8.

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Griffiths P., Baboonian C. and Ashby D. (1985) The demographic characteristics of pregnant women infected with cytomegalovirus. *International Journal of Epidemiology*, 14, 447-452.

Pocock S.J. and Ashby D. (1985) Environmental lead and children's intelligence: a review of recent epidemiological studies. *The Statistician*, 34, 31-44.

Shaper A.G., Pocock S.J., Ashby D., Walker M. and Whitehead T.P. (1985) Biochemical and haematological response to alcohol intake. *Annals of Clinical Biochemistry*, 22, 50-61.

Mann A.H., Graham N. and Ashby D. (1984) Psychiatric illness in residential homes for the elderly: a survey in one London borough. *Age and Ageing*, 13, 257-265.

Pocock S.J., Shaper A.G., Ashby D. and Whitehead T.P. (1984) Blood lead concentration, blood pressure and renal function. *British Medical Journal*, 289, 872-874.

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Thelle D.S., Shaper A.G., Whitehead T.P., Bullock D.G., Ashby D. and Patel I. (1983) Blood lipids in middle-aged British men. *British Heart Journal*, 49, 205-213.

Projects

Selection of Grants Awarded

Grants Awarded

£101,137 D Ashby, V Cornelius NIHR Research Methods Fellowship 2017-19

£134,582 CRUK Clinical Research Committee 2017-2020

Rapid Evaporative Ionisation Mass Spectrometry for Examination of Circumferential Surgical Excision Margins [REI-EXCISE Trial]

Z Takats D Leff, E St John, M Rossi, J McKenzie, J Balog, R Ramakrishnan, X Liu, J Nicholson, RC Coombes, A Darzi, D Ashby

£ 2,007,448 NIHR EME 2016 – 2022

M Thursz, D Ashby, G Foster, W Rosenberg, S Ryder, E Nastouli, K Agarwal, M Maini
Nucleos(t)ide withdrawal in HBeAg negative hepatitis B virus infection to promote HBsAg clearance. (NUC-B)

£88,380 D Ashby, C Wilhelm-Benartzi, NIHR Research Methods Fellowship 2015-17

£3,953,796 MRC 2014 – 2016

S Bloom, TM Tan, D Ashby

Next Generation of Y Analogue for Treatment of Obesity

£812,477 NIHR EME 2013 – 2018

T Maher, D Ashby, C Denton, S Wort, A Mawdsley, H Parfrey, J Pepper, A Wells, M Flather

A randomized, double blind controlled trial comparing rituximab against intravenous cyclophosphamide in connective tissue disease associated interstitial lung disease

£181,587 MRC ECF 2013 – 2017

S Bloom, D Ashby

Do gut hormones mediate the beneficial effects of Roux-en-Y bypass surgery?

£1,280,619 Wellcome Trust TA 2013 – 2015

S Bloom, TM Tan, D Ashby

Treatment of obesity with the pancreatic polypeptide analogue PP1420

£1,139,470, NIHR EME 2013 - 2016

A Gordon, R Orme, D McAuley, M Singer, G Perkins, D Ashby, A Morelli, K Liu, A Mason

LeoPARDS - Levosimendan for the Prevention of Acute oRgan Dysfunction in Sepsis

Memberships

Honours and Awards

President, Royal Statistical Society 2019 and 2020

Fellowship of the Academy of Medical Sciences; FMedSci – 2012

NIHR Senior Investigator 2010 – 2015, renewed 2015-18

OBE for services to medicine - New Year's Honours List 2009

Professional Societies

Honorary Member of the Royal College of Radiologists 1998 - present

Royal Statistical Society, Fellow 1980, Chartered Statistician 1994 - present

Honorary Member of the Faculty of Public Health Medicine 1992 - present

Editorial work

Statistics in Medicine Editorial Board 1991-2005, Associate Editor 2007 - 2013

Bayesian Analysis Associate Editor 2004 - 2012

British Medical Journal Hanging Committee 2003-2006, Statistical Editor 2006 - 2009

Biometrics Editorial Panel 1997 - 2000

Statistics in Society Editorial Panel 1997 - 1999

Statistical Methods in Medical Research Editorial Board 1995 - 2009

Applied Statistics Editorial Panel 1991 - 1994

Cochrane Collaboration

Adverse Effects Methods Group member of Specialist Advisory Group 2007 - 2010

Cochrane Cystic Fibrosis and Genetic Disorders Group Editor Emeritus 2010 – date, Editor 1997 – 2009

Other Relevant Information

Evidence of Esteem, External Visibility and Professional Activities

Royal Statistical Society

President-Elect, 2017- 2018

Member of Academic Affairs Advisory Group, 2011 – 2016

Member of Honours Committee, 2011 - 2014

Chair of Long-Term Strategy group 2008 - 2009

Co-ordinator of 175th Anniversary Celebrations in 2009, 2008 - 2009

Vice-President, 1993-1995; Honorary Secretary, 1998 - 2004

Member of Council, 1992-1997, Member of Executive, 1993 - 1996

Mersey Local Group Committee, 1994 - 1997, Deputy Chair 1995 - 1997

Medical Section Committee, member 1987 - 1989, Honorary Secretary 1989 – 1992

National Institute of Health Research

NIHR HTA Programme, Deputy Chair, 2016 - 2018

NIHR HTA Commissioning Board, Chair, 2016-2018, member 2005-11

NIHR Strategic Review of Training Advisory Group 2017

NIHR Clinical Trial Unit Fellowship Panel, 2012-2015

NIHR Senior Investigators Appointment Panel 2011-2014

NIHR Fellowship Advisory Board 2011 – 2016

NIHR Post-doctoral Fellowship Panel 2011

External Chair of the NIHR Trial Managers Network Oversight Group, 2011 – 2014

NIHR Research Methods Panel, chair 2011 - 2016

NIHR Carbon Guidelines Working Group 2009 - 2010

NIHR HTA Commissioning Strategy Group 2008 - 2011

Advisor NIHR Capacity Building, Statistics, Clinical Trials and Economics 2008 - 2011 (20% secondment)

NIHR Programme Grants for Applied Research Programme, Core Methodological Expert 2010 - 2012, College of Panellists 2008 - 2010

NIHR Clinical Trials Unit Advisory and Steering Group 2007 - 2013

Department of Health/ Medicines and Healthcare Products Regulatory Agency

Commission on Human Medicine (CHM), commissioner 2005 - 2014
Committee on Safety of Medicine, (CSM) member 1999 - 2005
External Expert Panel 1995 - 1999
CSM Safety and Efficacy Sub-Committee (SESC), 1993 – 1995
Working Groups of these:
CHM Alteplase Working Group 2014 - 2015
CHM Nicotine Containing Products Working Group 2013 - 2014
CHM Pharmacy Supply Usage modelling & Antibiotic Resistance Working Group 2008 - 2009
CHM Specialist Working Group: ORACLE Children Study – Antibiotic use in premature labour Ad-Hoc Group 2008
CHM Bioequivalence Ad Hoc Group 2007- 2010
CHM Patient Information Expert Advisory Group (CHM observer) 2006 - 2007
CSM Selective Serotonin Re-uptake Inhibitor Working Group 2003 - 2005
CSM Safety of Vaccines Working Group 2000 – 2005
CSM Hormone Replacement Therapy Working Group 2002
CSM Safety of Meningitis C Vaccines Working Group 2000 – 2001
Panel of Expert Assessors for Artificial Implants and Medical Devices, 1992 - 2006
European Medicines Evaluation Agency
CHMP representative on Highly Active Anti-Retroviral Therapy Oversight Committee 2010 - 2017
Cardiovascular Issues Scientific Advisory Group 2010 – 2015
European Network of Centres of Pharmacovigilance and Pharmacoepidemiology Implementation Advisory Group 2008 - 2010
European Expert 2004 - 2010
Department of Innovation, Universities and Skills (Government Office for Science)
Steering Group for Science Review of the Department of Health 2007- 2008
Medical Research Council
International Advisory Group of the MRC Network of Hubs for Trials Methodology Research 2015-present
MRC Doctoral Training Partnerships Panel 2015
Review of the EME programme, member 2014
PhD Studentship Skills Portfolio Advisory Group 2011
Biostatistics/ Methodology/ Population Health Scientist Fellowships panel 2009 – 2011; Chair Biostatistics sub-panel 2010 - 2011
Biostatistics Fellowships Panel 2007 and 2008
Hubs in Trials Methodology Research Panel 2008
Patient Research Cohort Initiative Oversight Group 2008 - 2010
Patient Research Cohorts Initiative Panel 2008
College of Experts 2004 - 2008
Cancer Research UK
Population Research Committee, Chair 2016- present, Vice-Chair 2014-2016, member 2013-2014
Cystic Fibrosis Trust
Statistical Advisor to Gene Therapy Consortium 2006 - 2009
Clinical Trials Advisory Group 1998 - 2005
Academy of Medical Sciences
Advisory Board for the Academy of Medical Sciences' Starter Grants for Non-Clinical Lecturers Scheme, 2015
Steering Group for Wellcome Trust/AMS project on treating epidemic influenza 2014 - 2015
Academic Careers Committee, 2013- 2016

Sectional Committee 6 2013 – 2016

Working group to review the regulation and governance of medical research. 2010

International Society for Bayesian Analysis

Constitution and Byelaws Committee 2013-2018

Mitchell Prize Committee (for best applied Bayesian paper) chair 2009; member 2008

Executive Secretary 2004 - 2006

Board of Directors 2000 - 2002

International Society for Clinical Biostatistics

ISCB/Society for Clinical Trials joint meeting Programme Co-Chair, London 2003

International Clinical Trials Methodology Conference

3rd International Clinical Trials Methodology Conference (ICTMC2015) co-Chairs for the Scientific Committee, Glasgow 2015

Committee of Professors of Statistics

Executive 2005 – 2007

Marie Curie Innovative Training Network (ITN)

IDEAS (Improving Drug Development) External Advisory Panel, 2015-date

Canada Foundation for Innovation (CFI),

Expert review committee for the Major Science Initiatives, 2014

Health Research Board, Dublin

Expert review committee for Trials Methodology Research in Ireland, Chair 2017, member 2014

University of Queensland

Review of the School of Population Health, member of review committee, 2014

German Federal Ministry of Education and Research (BMBF)

"Health Care Research and Public Health" Funding initiative board on Interventional trials in health care research, 2013

Health Research Board Clinical Research Facility, Galway

Member of Scientific Advisory Board 2010

National Perinatal Epidemiology Unit, University of Oxford

Advisory Group 1997 - 2001

North West Regional Health Authority

Liverpool Adult Ethics Committee, 1996 - 1997

Small Grants and Research Training Committee, 1993 - 1995

Merseyside and Cheshire Cancer Registry Deputy Director and Statistician (Honorary Contract), 1990-1994, Statistician (Honorary Contract) 1994 - 1996

University of Lancaster

Adjunct Senior Lecturer in Statistics 1995 – 1998; Senior Visiting Research Fellow 1994 - 1995

External Interview panels

External member of interview panels for chairs and other appointments in UK universities and Eire, and for appointments at the Medicines and Healthcare Regulatory Products Agency

BMA Book of the Year competition 2000

Highly commended in Primary Care category for Eldridge S. and Ashby D. (2000) Statistical Concepts. Eds: Carter Y., Shaw S. and Thomas C. Royal College of General Practitioners. London. Master Classes in Primary Care Research No 3

Clinical Trials Unit Advisory Boards

Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) Clinical Advisory Committee 2016 - present

York Clinical Trials Unit 2015-present

Sheffield Clinical Trials Unit (chair) 2014-present

Queen Mary Pragmatic Trials Unit (chair) 2010-present

Current and Previous External Membership of Trial Steering Groups

PROteKT Aminoglycoside-Induced Kidney Toxicity in Children with Cystic Fibrosis (Moulton Charitable Foundation) (Chair) 2014-2017

Phase IIa, Randomised, Controlled, Open-Label Trial of Rosuvastatin for the Prevention of N-Alive Prison-based Naloxone-on-release pilot randomized controlled prevention trial (MRC) (Chair) 2012-2014

UK Lung Cancer Screening Trial (NIHR HTA, University of Liverpool) 2008-2016

OSCAR High frequency oscillatory ventilation in patients with acute respiratory distress syndrome (NIHR HTA, University of Oxford) (Chair) 2008-2012

CF-WISE inhaled steroid withdrawal in cystic fibrosis (CF Trust, Imperial College) 2001-2005

Current and Previous External Membership of Data Monitoring Committees

ALIC4E: Antivirals for influenza-Like Illness? an rCt of Clinical and Cost effectiveness in primary Care, (EU FP7, University of Oxford) (Chair), 2015- present

MYPAN Trial: An Open Label Randomised Controlled Trial of Mycophenolate Mofetil Versus Cyclophosphamide for the Induction of Remission of Childhood Polyarteritis Nodosa (Arthritis Research UK, University College London) 2014-present

Protect Prostate Testing for Cancer and Treatment (NIHR HTA, University of Bristol) 2011-2015

INFANT trial of decision-making in management of labour (NIHR HTA, University of Oxford) (Chair) 2008- 2016

CEQUEL trial of of QUETiapine-Lamotrigine combination versus quetiapine monotherapy, and folic acid versus placebo, in people with bipolar depression (MRC, University of Oxford) 2008-2011

DOMINO-AD donepezil and memantine in moderate to severe Alzheimer's disease (MRC, Institute of Psychiatry) 2006-2011

CALM-AD donepezil and risperidone in agitation in Alzheimer's disease (MRC, Institute of Psychiatry) 2003-2006

INIS neonatal immunotherapy (MRC, National Perinatal Epidemiology Unit) 2001-2011

TOPIC once versus thrice daily tobramycin in cystic fibrosis (CF Trust, University of Nottingham) (Chair) 1999-2004

SIOP chemotherapy regimes in childhood liver cancers (CRUK) 1998-present

Botulinum toxin for leg spasticity in cerebral palsy (Action for Medical Research, University of Liverpool) (Chair) 1997-1999

OE02 pre-operative chemotherapy in oesophageal cancer (MRC Clinical Trials Unit) 1992-1999

Other External Research Involvement

Current and Previous Steering Groups Memberships:

BISECT Development of a fully Bayesian framework for the identification and estimation of subgroup effects in Randomised Controlled Trials (BISECT) - Advisory Group (MRC Methodology Research Panel Grant University of Glasgow, London School of Hygiene and Tropical Medicine and the University of Sheffield.) 2017-2020

ADRIC Adverse Drug Reaction in Children Research Programme (NIHR Programme grant, Prof RL Smyth, University of Liverpool) 2008 - 2013

Drug Intervention Programme Children and Young People (Matrix Research and Consultancy Ltd) 2006-2007