

CURRICULUM VITAE

Dr Philip Nichols

BMedSci MBBS FRCP DPhil (PhD. Oxford)

GMC Registration: 3555637

Personal Profile	I am a UK Board Certified Neurologist with extensive Clinical Development experience within Brain Health and Neurology.
Qualifications	<p>B.Med.Sci. (Medical Sciences): First Class</p> <p>1987-1988 Project: "Studies on the effectiveness of parathyroidectomy in the control of hyperparathyroidism secondary to chronic renal failure".</p> <p>MBBS (Medicine): First Class</p> <p>1986 Stage I Part I MBBS Distinction 1987 Stage I Part II MBBS Distinction 1990 Part I Finals Distinction 1991 Part II Finals First Class Honours</p> <p>Scholarships and Awards 1990 - 1991:</p> <p>Goyder Memorial Scholarship (Medicine and Surgery) Charlton Scholarship (Medicine) Dickinson Scholarship (Surgery) John T. Ingram Prize (Dermatology) Philipson Scholarship (Clinical Ability)</p> <p>POSTGRADUATE QUALIFICATIONS:</p> <p>FRCP (UK) Fellow of the Royal College of Physicians D.Phil. (PhD Medicine), St. John's College, University of Oxford</p> <p>POSTGRADUATE PRIZES:</p> <p>1994 18th Edinburgh Neurology Course: Advanced Clinical Neurology Prize.</p>

Medico Legal Experience

Joint clinics with Dr Steven Alder, Consultant Neurologist focusing on traumatic brain injury.

Employment History

2014 – '16

Global Head Medical Affairs & Clinical Development in Brain Health at Nestlé Health Science, (US based, Boston Office)

This was a Global Lead Executive position defining strategy and co-ordinating Medical Affairs and Clinical Development operations for the "Brain Health" product pipeline of Nestlé Health Science. I was recruited for this role to Switzerland but the

team was relocated to Boston to establish the Nestlé Health Science “Boston Office”. This role was approximately 40% Medical Affairs and 60% strategic Clinical Development and involved:

Medical Affairs

- Establishment of clinical networks, medical advisory boards and high level key opinion leader management around our key target areas of Dementia (*CerefolinNAC*), Depression (*Deplin*), Peripheral Neuropathy (*Metanx*) & Epilepsy (*Betaquick*) to support products marketed by our wholly owned subsidiaries (*Pamlab* and *Vitaflor*)
- Review and approval for all Investigator Sponsored Studies
- Direct support for the Commercial team in the development and implementation of the medical marketing strategy to engage customers and key stakeholders including co-ordinating product and therapeutic area education and training for the sales force and the development of focused conference, advocacy and publication strategies
- Member of the Business Development Committee defining in-licencing and product acquisition strategies and opportunities
- Due diligence operations for new product opportunities

Clinical Development

- Defining the Clinical Development programmes for new and lifecycle product developments
- Chair of cross functional Clinical Development committee coordinating R&D, Regulatory Affairs, Clinical Development, Market Access and Medical Affairs
- Co-ordinating in-house and outsourced Clinical Development Programmes for Phase I-IV programs
- Liaison with FDA and EMA Regulatory bodies in co-ordination with Regulatory Affairs

COMMERCIAL/PHARMACEUTICAL INDUSTRY EXPERIENCE:

2010 -'13

Director of Health Innovation & Education Cluster (HIEC) for the North East of England. This was the lead executive role in a Health Innovation body created to stimulate the uptake of Innovative healthcare technologies and service delivery models into the wider UK National Health System and involved innovation collaborations with academic, hospital and the private Biotech sector.

2005 -'10

Chief Medical Officer & Head of Clinical Development, Cambridge Laboratories (Ireland) Ltd. A UK & Ireland based entrepreneurial speciality pharmaceuticals company focussed on highly specialised CNS and oncology markets.

Roles and responsibilities included:

Medical Affairs

- Establishment of clinical networks and medical advisory boards.
- High level key opinion leader management.
- Direct support for the Commercial team in development & implementation of medical marketing strategy.
- Development of focused conference, advocacy and publication strategies
- Medical product and therapeutic area education and training for the sales team.
- Responsibility for ABPI (Association of British Pharmaceutical Industry) compliance and Final Signatory sign off for promotional materials.
- Support for International Business Development (Europe, USA and Japan).

Clinical Development programme(s) Phases I to IV

The US NDA for Tetrabenazine (*Xenazine*) was based on a Phase III study in Huntington's Disease (Orphan indication) which recruited in the US. I assisted our US partner with the NDA process which included drafting the *Complete Response* to an *Approvable Letter* from the FDA, followed by a further response to additional questions and support for an Advisory Committee before achieving final US Marketing Authorisation in August 2008.

Overall Responsibility for:

- Orphan Drug Applications to EMA and FDA
- Clinical Trial Protocol design
- Liaison with Regulatory Authorities: One of the main aims in Europe was to extend the use of Tetrabenazine (*Xenazine/Nitoman*) which already had a historical license in the UK. My role involved supporting the regulatory team in submissions for marketing authorisations around the major European markets, Germany, Italy, Spain & France. This required interaction with the Regulatory Authorities of each country.
- Management of Clinical Trial Programs via CROs: including a successful Phase II study in Russia/Ukraine and a number of UK based Phase I studies.
- Management of investigator meetings.
- Presentation of clinical data to key opinion leaders and Regulatory Authorities.

Member of Value Realisation Team

Member of Value Realisation Team negotiating the sale of the major pharmaceutical asset (Tetrabenazine, *Xenazine/Nitoman*) to BIOVAIL in 2009.

MEDICAL CAREER EXPERIENCE:

2002 -'13 **UK “Board Certified” Neurologist and Senior Lecturer in Neurology** Department of Neurology, Royal Victoria Infirmary, Newcastle Upon Tyne, UK & Institute of Cellular Medicine, The Medical School, Newcastle University.

Sub-speciality: Multiple Sclerosis

Lead clinician for the MS Disease Modifying Drug clinic. Extensive clinical and trial experience with MS DMDs including *B-Inteferon (Axonex, Rebif, Betaferon), Copaxone, Tysabri & Gilenya*.

LEMTRADA (Alemtuzumab) trial experience when under development as CAMPATH by Cambridge University UK (Addenbrooks Hospital, with Prof Alastair Compton, Prof Alasdair Coles).

2002-'07 **Department of Health Clinician Scientist.** A five year post associated with research funding of ~£665,000 to study multiple sclerosis. Post ran concurrently with the Neurologist & Senior Lecturer post (see above).

1999 -'02 **Neurology Specialist Registrar**, Northern Deanery, Neurology Rotation, UK 1995 -'99

Honorary Clinical Registrar and Neurology Specialist Registrar,

Department of Clinical Neurology, The Radcliffe Infirmary, Oxford, UK.

1994 **Neurology Senior House Officer**, National Hospital for Neurology and Neurosurgery, Queen Square, London, UK

RESEARCH EXPERIENCE:

UNIVERSITY of OXFORD D.Phil (PhD) – St John’s College

Medical Research Council MRC CLINICAL RESEARCH FELLOW 1995-1998: Neurosciences Group, Institute of Molecular Medicine, John Radcliffe Hospital.

“Transcriptional regulation of the human muscle nicotinic acetylcholine receptor genes and their role in congenital myasthenia.” (Supervisors: Prof. J. Newsom-Davis & Prof. D. Beeson). This project involved the molecular characterisation of acetylcholine receptor subunit gene promoter regions and the identification of promoter region mutations which result in a congenital myasthenic syndrome phenotype.

Department of Health Clinician Scientist (2002-'07). After receiving the Clinician Scientist Award (£665,000) I formed the Multiple Sclerosis Research Group within the Medical School, University of Newcastle upon Tyne, UK. The Group employed PhD students and post doctoral research assistants over a five year period researching axonal loss in multiple sclerosis and the role of mitochondria and ion channels in the accumulation of neurological disability in secondary progressive multiple sclerosis.

UNIVERSITY OF NEWCASTLE UPON TYNE 1985 - 1991:

B.Med.Sci. (Medical Sciences): **First Class**

1987-1988 Project: "Studies on the effectiveness of parathyroidectomy in the control of hyperparathyroidism secondary to chronic renal failure".

MBBS (Medicine): **First Class**

1986 Stage I Part I MBBS	Distinction
1987 Stage I Part II MBBS	Distinction
1990 Part I Finals	Distinction
1991 Part II Finals	First Class Honours Scholarships

and Awards 1990 - 1991:

Goyder Memorial Scholarship (Medicine and Surgery) Charlton
Scholarship (Medicine)
Dickinson Scholarship (Surgery) John T. Ingram
Prize (Dermatology)
Philipson Scholarship (Clinical Ability)

POSTGRADUATE QUALIFICATIONS:

FRCP (UK) Fellow of the Royal College of Physicians
D.Phil. (PhD Medicine), St. John's College, University of Oxford

POSTGRADUATE PRIZES:

1994 **18th Edinburgh Neurology Course:** Advanced Clinical Neurology Prize.

GRANTS:

2002-'07 **UK Department of Health Clinician Scientist Award.** "Axonal loss in Multiple Sclerosis: Role of mitochondria and ion channels". Five year award ~£665,000.

NON-MEDICAL CAREER EXPERIENCE:

1995 **European Commission**, Directorate General XII (Science, Research and Development), BIOMED 2 programme, Neurology Co-ordinator. This six month post between finishing my general professional training and starting my D.Phil (PhD) at the University of Oxford was a unique opportunity to examine the workings of the medical division of the European Commission.

SOCIETY MEMBERSHIPS:

Association of British Neurologists.
Fellow Royal College of Physicians (FRCP London).

PUBLICATIONS:

Nichols P., J. Owen, H. Ellis, J. Farndon, P. Kelly, M. Ward. Parathyroidectomy in Chronic Renal Failure. A nine year follow up study. *Quart. J. Med.* 1990;**283**:1175-1193.

Nichols P., R. Rutter, D. Beeson, A. Vincent, J. Newsom-Davis. Transcriptional Control of the human muscle nicotinic acetylcholine receptor genes. *J. Neurol. Neurosurg. Psychiatry* 1997;**63**:269-270.

Nichols P. and D. Beeson. Gene regulation of the human muscle acetylcholine receptor. *J. Neurol.* 1997;**244** (3):S115 .

Nichols P., R. Croxen, A. Vincent, J. Newsom-Davis, D. Beeson. Congenital Myasthenia associated with muscle AChR subunit gene promoter mutations. *J. Neurol.* 1998;**245**(6/7):381.

Nichols P., R. Croxen, A. Vincent, J. Newsom-Davis, D. Beeson. Congenital Myasthenia associated with a homozygous acetylcholine receptor gene promoter mutation. *J. Neurol. Neurosurg. Psychiatry* 1998; **65**(3):419.
Croxen R., C. Newland, **P. Nichols**, A. Vincent, J. Newsom-Davis, D. Beeson. Recent Molecular Genetic Studies in Congenital Myasthenia. *Muscle & Nerve* 1998;**S7**:S39.

Nichols P. and D. Beeson. Control of gene expression of human muscle acetylcholine receptor. *Ann. N. Y. Acad. Sci.* 1998;**841**:111-114.

Nichols P., R. Croxen, A. Vincent, R. Rutter, M. Hutchinson, J. Newsom-Davis, D. Beeson. Mutation of the acetylcholine receptor ϵ -subunit promoter in congenital myasthenic syndrome. *Ann. Neurol.* 1999;**45**:439-443.

Trivedi R.A., **P. Nichols**, S. Coley, T. Cadoux-Hudson, M. Donaghy. Leptomeningeal glioblastoma presenting with multiple cranial neuropathies and confusion. *Clin. Neurol. Neurosurg.* 2000;**102**:223-226.

Beeson D., S. Brownlow, R. Croxen, **P. Nichols**, M. Weih, A. Vincent. Mutation in the human muscle AChR ϵ -subunit promoter in congenital myasthenic syndrome. *J. Neurol. Neurosurg. Psychiatry* 2000;**69**:410-425.

Nichols P., D. Scoones, P. Newman. Progressive Multifocal Leucoencephalopathy (PML) complicating occult pulmonary sarcoidosis. *J. Neurol. Sci.* 2001;**187**:S92.

Mulleague L., S.M. Bonner, A. Samuel, **P. Nichols**, M. Khan, S. Shaw, T. Gruning. Wound botulism in drug addicts in the United Kingdom. *Anaesthesia* 2001;**56**:120-123.

Barron M., P. Griffiths, D.M. Turnbull, D. Bates, **P. Nichols**. The distributions of mitochondria and sodium channels reflect the specific energy requirements and conduction properties of the human optic nerve head. *Br. J. Ophthalmol.* 2004;**88**(2):286-290.

Andrews H.E., **P. Nichols**, D. Bates, D.M. Turnbull. Mitochondrial dysfunction plays a key role in progressive axonal loss in Multiple Sclerosis. *Med Hypotheses* 2005;**64**:669-677.

Andrews H.E., K. White, C. Thomson, J. Edgar, D. Bates, I.R. Griffiths, D.M. Turnbull, **P. Nichols**. Increased mitochondrial activity as an adaptation to myelin deficiency in the *Shiverer* mouse. *J Neurosci Res* 2006;**83**:1533-1539.

Samarasekera S.R., A. Vincent, J.L. Welch, M. Jackson **P. Nichols**, TD Griffiths. The course and outcome of limbic encephalitis with negative voltage-gated potassium channel antibodies. *J. Neurol. Neurosurg. Psychiatry* 2007;**78**(4):391-394.

Davies V.J., A.J. Hollins, M.J. Piechota, W. Yip, J.R. Davies, K.E. White, **P. Nichols**, M.E. Boulton, M. Votruba. Opa1 deficiency in a mouse model of autosomal dominant optic atrophy impairs mitochondrial morphology, optic nerve structure and visual function. *Human Molecular Genetics* 2007;**16**(11):1307-1318.

Davies V.J., K.A. Powell, K.E. White, W. Yip, V. Hogan, A.J. Hollins, J.R. Davies, M. Piechota, D.G. Brownstein, S.J. Moat, **P. Nichols**, M.A. Wride, M.E. Boulton, M. Votruba. A missense mutation in the murine Opa3 gene models human Costeff syndrome. *Brain* 2008;**131**:368-380.

Hogan V, White K, Edgar J, McGill A, Karim S, McLaughlin M, Griffiths I, Turnbull D, **Nichols P**. An increase in mitochondrial density within axons and supporting cells in response to demyelination in the Plp1 mouse model. *J Neurosci Res* 2009; **87**:452-459.

White KE, Davies V, Hogan V, Piechota M, **Nichols P**, Turnbull DM, Votruba M. OPA1 deficiency is associated with increased autophagy in retinal ganglion cells in a murine model of dominant optic atrophy. *Invest Ophthalmol Vis Sci.* 2009; **50**:2567-2571