Curriculum Vitae

Geoffrey Martin Nichol

Latest position SVP, Global Clinical Research and Chief Medical Officer, BioMarin Pharmaceutical, San Rafael CA

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Educated Christchurch Boys' High School, Christchurch, New Zealand, 1968-72
Otago University Medical School, New Zealand, 1972-9
Graduated BMedSc, MB, ChB (MD equivalent)

Postgraduate Fellowship of Royal Australasian College of Physicians, Thoracic/Internal Medicine, December 1987 (equivalent of Medical/Pulmonology Boards in US)
MBA, Warwick University (UK), 1996 (with distinction)

Summary of experience

- A pulmonologist MD/MBA with extensive pharmaceutical industry experience spanning early development to Phase IV and compound commercialization in a range of therapeutic areas, with special reference to anti-infectives, pulmonary, cardiovascular, arthritis/bone metabolism, inflammatory diseases and oncology with small molecules, monoclonal antibodies and cell/gene therapies.
- Personal leadership of successful development programs resulting in approval of *Augmentin BID* for children and adults, *Foradil*, *Xolair* and *Yervoy*
- Foundational clinical leader in the development of current breakthrough immune-oncology antibodies (αCTLA4, αPD-1)
- Management experience, to senior executive level, spanning multiple therapeutic areas, in both product development and product medical affairs-commercialization as a member of the senior management team of a major pharmaceutical company (Novartis), both in support of global and US-focused business. Led major process improvement initiatives in diverse areas of product development and commercialization.
- Proven success in managing Product Development strategy (clinical development, regulatory affairs, pre-clinical safety, project management) in the biotechnology industry, building a portfolio of over 10 clinical development projects, in oncology, inflammatory diseases and infectious

disease over seven years, with positive proof-of-concept for 3 novel candidates.

- Extensive experience interacting internally with finance, research and business development functions, and externally with scientific leaders, large and small pharma collaborators including a long-term large pharma collaboration with a major Phase III stage asset, and with the investment community as a member of the senior executive team.
- Successful exit management with completed acquisition of Medarex by a major pharmaceutical company (BMS).
- 5 years leading an R&D team in the fields of in vivo and ex vivo genome editing and gene therapy; 3 successful INDs
- SVP of Clinical Development and CMO, BioMarin, leading clinical development for treatments of multiple rare diseases, including gene therapies for hemophilia

Positions held

Nov 2016 – present	Sr VP, Global Clinical Development, CMO, BioMarin
July 2011 – October 2016	Executive VP, R&D, Sangamo BioSciences
June 2010 – July 2011	Chief Medical Officer, Ikaria
Sep 2002 – Jan 2010	Senior VP, Product Development, Medarex Inc until its acquisition by BMS
May 2002 – Sep 2002	VP and Head, Global Medical-Marketing Excellence, Novartis Pharmaceuticals
May 1999 – May 2002	Vice President and Global Head, Project Management, Novartis Pharmaceuticals, reporting to Head of Global Development
October 1997 - May 1999	Vice President and Head, US Medical Affairs, Novartis Pharmaceutical Corporation, East Hanover, NJ
February 1996-Oct 97	VP and Global Head, Respiratory, Bone and HRT Clinical Research, and chair, Respiratory Therapeutic Area Strategy Team, Novartis Pharmaceuticals
1992-96	Group Director, Antibiotic Products, Clinical Research and Medical Affairs, North America, SmithKline Beecham Pharmaceuticals

1989-92	Clinical Research Physician, Cardiopulmonary and Anti-Infective Therapeutic Areas, SmithKline Beecham Pharmaceuticals, Reigate, Surrey, UK
1987-89	Senior Medical and Research Registrar, Brompton Hospital and National Heart and Lung Institute, London, UK
1985-87	Senior Registrar, Thoracic Medicine, Repatriation General Hospital and Flinders Medical Center, South Australia
1982-85	Medical Registrar, Canterbury Hospital Board, Christchurch, New Zealand. Rotations in General Medicine, Thoracic Medicine, Critical Care, Cardiology, Gastro-enterology, Endocrinology

Pharmaceutical Industry Experience Summary

SmithKline Beecham

- Global and US Phase II and III Clinical Research experience in pulmonary, arthritis, HRT, cardiovascular,oncology and anti-infective therapeutic areas

- Four personally-supervised NDA submissions since 1994 (*Augmentin* BID adult NDA, *Augmentin* BID Pediatric sNDA, *Bactroban* MRSA NDA). Multiple NDA submissions and approvals in all therapeutic areas since then.

- Managed Phase IV and Medical Affairs anti-infectives area in US (SB, *Augmentin, Timentin, Bactroban* and related antibiotics)(15 reports)

Novartis

- Managed Phase II/III Global Clinical Research therapeutic area, Novartis, Respiratory/Bone/Arthritis/HRT (30 reports), US and global development responsibilities. Developed long-acting inhaled beta-agonist (*Foradil*) in asthma and COPD, several phase II compounds in respiratory indications (oral LTD4 inhibitor, *Xolair* anti-IgE Mab, neurokinin antagonist)

- Direction of respiratory therapeutic area strategy proposals (chair of multi-functional Therapeutic Area Strategy Team) for a major global pharmaceutical company (Novartis Pharmaceuticals), including major partnership search, licensing strategy and execution, and determination of R&D strategy

- Managed US Phase IV/Medical Affairs department with global links to Central Medical Affairs, covering all therapeutic areas, Novartis (100 reports). Led

team of MD's, clinical scientists and supporting staff to design and implement Phase IV programs in US, support commercial function with medical and scientific product strategy, supported medical input into promotional activities including promotional policy management, maintained adverse event reporting and medical information support for all US marketed products. Close liaison with newly-established field medical liaison group, pharmaco-economics.

- Led global Project Management (PJM) organization at Novartis (100 reports). Reported to Head, Global Development. Sat on Innovation Management Board managing all Development assets (chair, CEO Pharma). Led staff of 80 professional project managers in US, EU and Japan (organized into 7 VP-led therapeutic areas - Oncology, Transplantation/Immunology, Cardiovascular/Metabolic/Anti-infective, Respiratory, Ophthalmology, Arthritis/Bone/Dermatology, Nervous System), a ten-person portfolio management group, and a ten-person resource management group managing budgets for entire Development portfolio at Novartis. Project Leaders in Novartis led multi-functional teams in drug development, planned and proposed project strategy and budgets to Novartis global development program review board, and managed day-to-day project implementation. Portfolio management included assessment of asset value, and analysis/optimization of Development portfolio. TA Heads in PJM (my direct reports) led strategy process for respective therapeutic area in Novartis drug development.

- Sponsored Novartis PRIDE (early development) group in cardiovascular, metabolic, endocrine, arthritis, bone, anti-infective and gastrointestinal disease areas. PRIDEs were special project teams dedicated to early development (from early lead selection to proof-of-concept) comprising commercial, pre-clinical, early clinical, and research representatives. PRIDE sponsors were senior management figures who guided the PRIDE and advocated for PRIDE proposals at senior management boards.

- Established Global Medical Marketing Excellence group (12 reports) at Novartis, responsible for process improvement initiatives covering full range of US and global medical commercialization processes including Phase IV design and budgeting, scientific input into commercial aspects of development, key opinion leader development, field liaison skills transfer, pharmacoeconomics.

Medarex Inc

- Led entire Product Development organization, comprising 160 personnel in clinical development [4 MDs with clinical scientists, clinical operations, data management, biostatistics, pharmaco-vigilance and medical writing], pre-clinical safety, regulatory affairs, regulatory compliance/quality assurance

(including GMP QA) and project management functions in a leading fully-human monoclonal antibody biotechnology company, reporting to the CEO, integral part of the C-level management team developing and implementing corporate strategy in concert with the Board of Directors.

- Overseeing monocolonal antibody candidate development from hybridoma/transfectoma development point onwards, including portfolio analysis input (with Research), development and regulatory strategy, IND submission, proof-of-principle testing and subsequent Phase II/III development. Designed the entire development program leading to the approval of *Yervoy*; foundational in establishing the Phase I proof-of-principle for anti-PD1/PD-L1 blockade (designed the current nivolumab dosage regimen).

- Representing development function to several corporate partners, external investors, regulatory authorities. Analyst contacts/presentations several times per month, R&D Days, etc. Leading major corporate partnership (Novartis/Genentech *Xolair*; Bristol-Myers Squibb, ipilimumab Phase III, approved as *Yervoy*). Successful partnering of innovative new immunotherapy for cancer (ipilimumab, after generation of Phase II proof-of-principle data, Phase III under SPA, and completion of successful international Phase III in advanced melanoma[28] which formed basis for approval of *Yervoy*; BMS), and innovative therapy for prevention of *C difficile* relapse (Mabs to toxins A and B, after generation of proof-of-principle Phase II data[27]; Merck)

- Leading medical and scientific analysis of licensing candidates

- Leading organizational development of all Product Development functions, maturing an organization responsible, in 2002, for a single Phase I program, to one that was progressing multiple projects ranging from Phase I to Phase III. Creating Product Development strategies, standards and procedures, including GXP and compliance/risk management aspects of relevant functions.

- Responsible for full range of investor relations activities, including extensive analyst interactions and presentations to analyst meetings to present pipeline and explain development progress. Spearheaded Medarex efforts to engage clinical and scientific opinion leaders and advisers, built strong industry/academia/regulator relationships in developing immunotherapy area, co-authored guidelines for clinical testing of immunotherapy candidates[24].

Ikaria

- Reported to EVP, R&D

- Led clinical development organization – MDs (who also acted as Project Leads for all clinical-stage programs); Clinical Operations; Biometrics (Biostatistics and Data Management)

- Member of R&D Management Team; responsible for overall development activities of teams covering nitric oxide life-cycle management (Phase I-III); novel device for preventing remodeling following STEMI (Phase II-III); terlipressin in Type I hepato-renal syndrome (Phase III)

- Lead medical leadership of business development activities

Sangamo

- Report to CEO

- Lead R&D organization – VP Research, CMO, VPs of Clinical Development, Regulatory Affairs, Technical Operations and Project Management are direct reports. The R&D organization comprises approximately 80 staff covering basic research, lead generation and optimization, pre-clinical development/manufacturing and clinical development for cell and gene therapy programs using the company's zinc-finger-based gene editing technology; successful partnerships forged with Shire (Huntington, hemophilia) and Biogen Idec (hemoglobinopathies). 3 successful INDs (genome edited AAV-based vectors for MPS I and II; FVIII cDNA AAV for hemophilia A).

- Member of senior management team; responsible for all R&D-related input to company strategy; operational oversight of all R&D activities; investor relations presentations and meetings

BioMarin

- Report to President R&D

- Lead Global Clinical Development organization (Clinical Sciences, Biometrics, Pharmacovigilance and Clinical Operations/Patient Advocacy groups (200 staff)

- Multiple Phase II and III programs for rare diseases – Brineura for CLN2 CNS disease, pegvaliase for PKU, vosoritide for achondroplasia, BMN 250 for MPS Type III disease, BMN 270 gene therapy for hemophilia A

Publications

1. Phase 5 of the single-breath washout test. **GM Nichol**, DB Michels and HJB Guy, J Appl Physiol 1982; 52(1):34-43

2. A case of severe *Strongyloides stercoralis* infection with jejunal perforation in an Australian ex-POW. S Kennedy, RM Campbell, JE Lawrence, **GM Nichol**, DM Rao, Med J Aust 1989; 150(2):92-3

3. Effect of inhaled furosemide on metabisulfite- and methacholine-induced bronchoconstriction and nasal potential difference in asthmatic subjects. **GM Nichol**, A Nix, KF Chung and PJ Barnes, Thorax 1990; 45(9):694-698

4. Effects of prostacyclin on bronchoconstriction and neutropenia induced by inhaled platelelt activating factor in man. J-W Lammers, I Kioumis, M McCusker, **GM Nichol**, PJ Barnes, KF Chung, J Allergy Clin Immunol 1990; 85:763-9

5. Effect of theophylline on airway responses to inhaled platelet activating factor in man. KF Chung, J-W Lammers, M McCusker, NM Roberts, **GM Nichol**, PJ Barnes, Eur Respir J 1989; 2(8):763-8

6. Effect of exercise on atrial natriuretic peptide (ANP) levels in patients with COPD (Letter). **GM Nichol**, PA Frith, KM Latimer, PJ McCarthy, JR Oliver, Am Rev Respir Dis 1988; 138(2):488

7. Furosemide inhibits the indirect bronchoconstriction of adenosine 5'-monophosphate but not the direct bronchoconstriction of histamine (Abstract). BJ O'Connor, **GM Nichol**, YM Chen-Worsdell, RW Fuller, KF Chung, PJ Barnes, Am Rev Respir Dis 1990; 141(4):A175

8. Prolonged attenuation of bronchial hyper-reactivity by methacholine by the long-acting beta-agonist formoterol (Abstract). **GM Nichol**, A Nix, PJ Barnes, KF Chung, Am Rev Respir Dis 1990; 141(4):A210

9. Metabisulphite aerosol increases bronchial blood flow despite anticholinergic, furosemide, nedocromil or antihistamine pretreatment (Abstract). **GM Nichol**, GH Parsons, PJ Barnes, KF Chung, Am Rev Respir Dis 1990; 141(4):A360

10. Inhibitory effects of inhaled furosemide against the induction and potentiation of cough responses in normal subjects (Abstract). P Ventresca, **GM Nichol**, PJ Barnes, KF Chung, Am Rev Respir Dis 1990; 1412(4):A361

11. Effect of a neutral endopeptidase inhibitor on airway function in asthmatic subjects (Abstract). **GM Nichol**, BJ O'Connor, KF Chung, PJ Barnes, Am Rev Respir Dis 1990; 141(4):A663

12. Effect of inhaled furosemide on metabisulfite- and methacholine-induced bronchoconstriction and nasal potential difference in asthmatic subjects. **Nichol GM**, Alton EW, Nix A, Geddes DM, Chung KF, Barnes PJ. Am Rev Respir Dis. 1990 Sep;142(3):576-80

13. Prostaglandin F2 alpha enhancement of capsaicin induced cough in man: modulation by beta 2 adrenergic and anticholinergic drugs. **Nichol G**, Nix A, Barnes PJ, Chung KF. Thorax. 1990 Sep;45(9):694-8

14. Inhaled furosemide inhibits cough induced by low chloride content solutions but not by capsaicin. Ventresca PG, **Nichol GM**, Barnes PJ, Chung KF. Am Rev Respir Dis. 1990 Jul;142(1):143-6

15. Effects of prostacyclin on bronchoconstriction and neutropenia induced by inhaled platelet-activating factor in man. Lammers JW, Kioumis I, McCusker M, **Nichol GM**, Barnes PJ, Chung KF. J Allergy Clin Immunol. 1990 Apr;85(4):763-9

16. Effect of formoterol, a long-lasting beta 2-adrenoceptor agonist, against methacholine-induced bronchoconstriction. Nix A, **Nichol GM**, Robson A, Barnes PJ, Chung KF. Br J Clin Pharmacol. 1990 Mar;29(3):321-4

17. Effect of frusemide on the induction and potentiation of cough induced by prostaglandin F2 alpha. Ventresca PG, **Nichol GM**, Barnes PJ, Chung KF. Br J Clin Pharmacol. 1992 May;33(5):514-6.

18. Peptide mediator effects on bronchial blood velocity and lung resistance in conscious sheep. Parsons GH, **Nichol GM**, Barnes PJ, Chung KF. J Appl Physiol. 1992 Mar;72(3):1118-22

19. Effect of neutral endopeptidase inhibitor on airway function and bronchial responsiveness in asthmatic subjects. **Nichol GM**, O'Connor BJ, Lecomte JM, Chung KF, Barnes PJ. Eur J Clin Pharmacol. 1992;42(5):491-4

20. Effect of sodium metabisulphite on bronchial blood flow in conscious sheep: pharmacological modulation. **Nichol GM**, Parsons GH, Chung KF. Br J Pharmacol. 1994 Mar;111(3):918-22

21. Effect of sodium metabisulfite on bronchial blood flow in conscious sheep: pharmacological modulation. **GM Nichol**, GH Parsons and KF Chung, Br J Pharmacol 1994; 111:918-922

22. Autoimmunity in a phase I trial of a fully human anti-cytotoxic T-lymphocyte antigen-4 monoclonal antibody with multiple melanoma peptides and Montanide ISA 51 for patients with resected stages III and IV melanoma. Sanderson K, Scotland R, Lee P, Liu D, Groshen S, Snively J, Sian S, **Nichol G**, Davis T, Keler T, Yellin M, Weber J. J Clin Oncol. 2005 Feb 1;23(4):741-50. Epub 2004 Dec 21

23. Autoimmunity correlates with tumor regression in patients with metastatic melanoma treated with anti-cytotoxic T-lymphocyte antigen-4. Attia P, Phan GQ, Maker AV, Robinson MR, Quezado MM, Yang JC, Sherry RM, Topalian SL, Kammula US, Royal RE, Restifo NP, Haworth LR, Levy C, Mavroukakis SA, **Nichol G**, Yellin MJ, Rosenberg SA. J Clin Oncol. 2005 Sep 1;23(25):6043-53. Epub 2005 Aug 8

24. A clinical development paradigm for cancer vaccines and related biologics. Hoos A, Parmiani G, Hege K, Sznol M, Loibner H, Eggermont A, Urba W, Blumenstein B, Sacks N, Keilholz U, **Nichol G**; Cancer Vaccine Clinical Trial Working Group. J Immunother. 2007 Jan;30(1):1-15. Review

25. Prognostic factors related to clinical response in patients with metastatic melanoma treated by CTL-associated antigen-4 blockade. Downey SG, Klapper JA, Smith FO, Yang JC, Sherry RM, Royal RE, Kammula US, Hughes MS, Allen TE, Levy CL, Yellin M, **Nichol G**, White DE, Steinberg SM, Rosenberg SA. Clin Cancer Res. 2007 Nov 15;13(22 Pt 1):6681-8. Epub 2007 Nov 2.

26. Phase I/II study of ipilimumab for patients with metastatic melanoma. Weber JS, O'Day S, Urba W, Powderly J, **Nichol G**, Yellin M, Snively J, Hersh E.J Clin Oncol. 2008 Dec 20;26(36):5950-6. Epub 2008 Nov 17

27. Guidelines for the Evaluation of Immune Therapy Activity in Solid Tumors: Immune-Related Response Criteria. Jedd D. Wolchok, Axel Hoos, Steven O'Day, Jeffrey S. Weber, Omid Hamid, Celeste Lebbé, Michele Maio, Michael Binder, Oliver Bohnsack, **Geoffrey Nichol**, Rachel Humphrey and F. Stephen Hodi. Clin Cancer Res 2009 15(23):7412-20

28. Treatment with monoclonals against Clostridium difficile toxins. I Lowy, DC Molrine, BA Leav, BM Blair, R Baxter, DN Gerding, **G Nichol**, WD Thomas, M Leney, S Sloan, CA Hay, DM Ambrosino N Engl J Med 2010 362(3):197-205

29. Improved survival with ipilimumab in patients with metastatic melanoma. Hodi FS, O'Day SJ, McDermott DF, Weber RW, Sosman JA, Haanen JB, Gonzalez R, Robert C, Schadendorf D, Hassel JC, Akerley W, van den Eertwegh AJ, Lutzky J, Vaubel JM, Linette GP, Hogg D, Ottensmeier CH,

Lebbe C, Peschel C, Quirt I, Clark JI, Wolchok JD, Weber JS, Tian J, Yellin MJ, **Nichol GM**, Hoos A, Urba WJ. N Engl J Med 2010 Aug 19;363(8):711-23