NOVOTECH
The Asia Pacific CRO

BioDesk®

CVs

Name	Tracey BROWN
Position	Principal Consultant
Qualifications	Diplomate of the American Board of Toxicology (DABT), 2019 UK Registered Toxicologist, 2016 Eurtotox Registered Toxicologist, 2016 MSc (Biomedical Science), Anglia Polytechnic University, 1996 Postgraduate Training, Principals of Toxicology Pathology, Robens Institute University of Surrey, 1993 Postgraduate Training, Inhalation Toxicology, University of East London, 1993 BSc (Applied Biology), Polytechnic of East London, 1991

Summary

Tracey has over 30 years' experience in the pharmaceutical and drug development industries and has worked directly on international project teams as a Preclinical advisor. Currently, Tracey is a Principal Consultant at Novotech and part of the BioDesk team which is a preclinical programme development and regulatory strategy group with the aim of supporting clients to achieve a successful transition to clinical trials. Tracey has experience of working in large pharmaceutical companies in the United Kingdom for over 20 years holding various positions involving in toxicology study conduct, design and report writing, as well as global toxicology project management and writing of regulatory documents used for clinical trials or regulatory market approval. Since moving to Australia in 2010, Tracey is primarily working as a Regulatory Toxicology Consultant. She is focused on advising on the design and management of toxicology programs, review of client preclinical data packages, writing drug development plans and regulatory documents such as Investigator Brochures, INDs, Briefing packages for pre-IND meetings, and NDAs, and attending regulatory meetings if required.

Key Experience and Skills

- Experienced toxicologist who is focused on giving advice/support in the development of a wide range of small molecules or biological products
- Experienced in the development of respiratory medicines such as medicines for treating influenza, asthma, COPD and rhinitis. Several of these have received marketing approvals.
- Supported clients obtaining regulatory approval for several anti-malarial compounds
- Tracey has a keen eye for detail and can identify key issues and formulate appropriate solutions to the project.
- Tracey has good written and oral communication skills. She communicates honestly, openly and consistently, gaining advice or involving team members when its required to progress a project.

Achievements/Awards

- Diplomate of the American Board of Toxicology (DABT)
- UK Registered Toxicologist
- European Registered Toxicologist (ERT), Eurotox

Memberships

- Member, British Toxicology Society (BTS)
- Member, US Society of Toxicology (SOT)

Publications

- Dow G, **Brown T**, Reid M, Smith B, Toovey S. Tafenoquine is not neurotoxic following supertherapeutic dosing in rats. Travel Medicine and Infectious Disease, 2017, 17:28-34
- Berman J, **Brown T**, Dow G, Toovey S. Tafenoquine and primaquine do not exhibit clinical neurologic signs associated with central nervous system lesions in the same manner as earlier 8-aminoquinolines. Malaria Journal, 2018, 17(1):407

Employment Experience:

Company	Role	Experience
Novotech, Australia	Principal Consultant Jul '20 – Present	
	Principal Consultant (under Clinical Network Services) Jul '19 – Jun '20	
	Senior Consultant (under Clinical Network Services) Aug '15 – Jun '19	
	Consultant (under Clinical Network Services) Jul '13 – Jul '15	
DF Pre-clinical Services Pty Ltd, Australia	Regulatory Toxicology Consultant Sep ' 11 – Dec '12	• Acts as Regulatory Toxicology Consultant Assistant • Review non-clinical toxicology packages to support the conduct of clinical trials and to support marketing applications in Australia • Perform literature reviews related to a development programme or issue • Advise on nonclinical regulatory toxicology requirements
GlaxoSmithKline, United Kingdom	Manager – Non-clinical Safety Projects Sep '01 – Aug '10	• Design and manage toxicology programs that successfully support the conduct of phase I-III clinical trials and market applications in US and Europe. • Represent Safety Assessment Division on international project teams, designing preclinical packages of work as well as executing non-clinical studies to support clinical trials and submissions • Design dose selection of a range of toxicology studies such as dose-range finding/maximum repeat dose studies, acute single dose studies, repeat dose studies, reproductive toxicity studies, carcinogenicity studies, combination toxicology, as well as juvenile toxicity studies • Reviewed study reports; prepared and updated IBs • Prepare US pre-IND (nonclinical) and IND submissions • Literature reviews for regulatory submissions • Preparation of paediatric investigational plans (non-

		clinical focus) • Provide advice and training to less experienced project coordinators on nonclinical regulatory toxicological requirements • Represents the company at regulatory agency meetings including US FDA and European agencies • Prepare scientific advice documentation
Glaxo Welcome, United Kingdom	Toxicologist/Principal Toxicologist Sep '91 – Aug '01	• Acts as Toxicology Study Director and Toxicology Study Monitor for contracted out studies • Liaised with CROs in UK, Europe and Canada for effective study conduct and resolution of study or project issues • Acts as Study Director/Monitor for inhaled toxicology studies using various formulations including powders, nebulisers and metered-dose inhalers • Acts as Study Director for oral, IV and SC studies from acute to chronic studies in rodent and non-rodent species • Performs toxicology study report review • Writes toxicology protocols and study reports, including compilation of data tables • Trains junior staff in various study director-related duties, report writing, inhalation dosing and aerosol generation
Glaxo Group Research, United Kingdom	Laboratory Technician 1986 -1991	

Name	Hiram CHIPPERFIELD
Position	Principal Consultant
Qualifications	Ph.D, University of Queensland, 2003 Research Honours, University of Queensland, 1998 B.Sc, University of Adelaide, 1997

Summary

Hiram is a Principal Consultant with over 10 years of regulatory affairs and product development experience. He has a scientific background with a PhD in Cell Biology followed by academic and commercial post-doctoral research. Prior to joining Novotech, Hiram held roles in a regulatory affairs consulting firm and a global diagnostics company. With experience in products from diagnostics to cell therapies, he has managed projects ranging from preclinical development, first-in-human clinical trials, product registration, through to post-market reimbursement applications. Hiram is based in Brisbane, Australia.

Key Experience and Skills

- Hiram is motivated to develop global strategies to market as quickly as possible
- Phases I – IV; preclinical
- Regions: ANZ (Australia), Europe, North America (USA)
- Secretary of the BioDesk Institutional Biosafety Committee (IBC)
- Adjunct Associate Lecturer in the School of Pharmacy, University of Queensland

Publications

- Teo AK, Ali Y, Wong KY, **Chipperfield H**, Sadasivam A, Poobalan Y, Tan EK, Wang ST, Abraham S, Tsuneyoshi N, Stanton LW, Dunn NR. (2012) Activin and BMP4 synergistically promote formation of definitive endoderm in human embryonic stem cells. Stem Cells. Apr;30(4):631-42
- Hurley P and **Chipperfield H** (2011) Commentary: EMA gives opinion on biomarkers for Alzheimer's disease. MedNous 5(6):9
- **Chipperfield H** and Jackson-Matthews (2010) The impact of recent 'Biologicals' legislation on clinical trials in Australia. Journal for Clinical Studies July: 20-23
- Cai J, Xie D, Fan Z, **Chipperfield H**, Marden J, Wong WH, Zhong S. (2010) Modeling co- expression across species for complex traits: insights to the difference of human and mouse embryonic stem cells. PLoS Comput Biol. Mar 12;6(3)
- Hong F, Fang F, He X, Cao X, **Chipperfield H**, Xie D, Wong WH, Ng HH, Zhong S. (2009) Dissecting early differentially expressed genes in a mixture of differentiating embryonic stem cells. PLoS Comput Biol. Dec;5(12).
- **Chipperfield H** and Dunn NR (2009) Method of differentiating stem cells United States Patent Application number: 12/865, 454
- Phillips BW, Hentze H, Rust WL, Chen QP, **Chipperfield H**, Tan EK, Abraham S, Sadasivam A, Soong PL, Wang ST, Lim R, Sun W, Colman A, Dunn NR. (2007) Directed differentiation of human embryonic stem cells into the pancreatic endocrine lineage. Stem Cells Dev. Aug;16(4):561-78
- Zhou Q, **Chipperfield H**, Melton DA, Wong WH. (2007) A gene regulatory network in mouse embryonic stem cells. Proc Natl Acad Sci USA. 104(42):16438-43
- Wang S. Cowan CA, **Chipperfield H**. Powers RD. (2005) Gene expression in the preimplantation embryo: in-vitro developmental changes. Reprod Biomed Online. May;10(5):607-16
- **Chipperfield H**, Cool SM, Bedi K, Nurcombe V. (2005) Adult CNS explants as a source of neural progenitors. Brain Res Brain Res Protoc. 14(3):146-53

- Hogg RC, **Chipperfield H**, Whyte KA, Stafford MR, Hansen MA, Cool SM, Nurcombe V, Adams DJ. (2004) Functional maturation of isolated neural progenitor cells from the adult rat hippocampus. Eur J Neurosci. May;19(9):2410-20
- **Chipperfield H**, Bedi KS, Cool SM, Nurcombe V. (2002) Heparan sulfates isolated from adult neural progenitor cells can direct phenotypic maturation. Int J Dev Biol. 46(4):661-70
- Nurcombe V, Smart CE, **Chipperfield H**, Cool SM, Boilly B, Hondermarck H. (2000) The proliferative and migratory activities of breast cancer cells can be differentially regulated by heparan sulfates. J Biol Chem. Sep 29;275(39)

Presentations

- Speaker, *Case Studies in Cell Therapy Clinical Development*, BIOplus 2019, Nov 2019, Seoul Korea
- Speaker and panelist, Devices Sponsor Information Day, Oct 2015, Canberra, Australia
- Speaker, Point-of-Care-Testing Scientific Education Seminar, Sep 2015, Sydney Australia
- Speaker and panellist, Sponsor Information and Training Day, Sep 2014, Canberra, Australia

Achivevements

- Managed two successful US INDs for Live Biotherapeutic Products (LB
- Negotiated the registration of the first rapid HIV test for a point of care use in Australia
- Managed more than 50 IVD registrations during the transition to the current Australian regulatory framework

Employment Experience:

Company	Role	Experience
Novotech, Australia	Principal Consultant Aug '20 – Present	• Management and preparation of regulatory documents including Drug Development Plans and Regulatory Strategies • Authoring and management of IND submissions, Regulatory Strategies • Authoring and review of Investigator Brochures (IBs), clinical trial protocols and clinical study reports • Secretary of CNS Institutional Biosafety Committee (IBC) • Management of TGA and US FDA meetingsProject management and consulting. Product development and regulatory projects with a focus on biotech and cell therapy products
	Senior Consultant (under Clinical Network Services) Aug '18 – Aug '20	

Abbott (formerly Alere), Australia	RA and Market Access Manager 2012 – Aug '18	• Chair of IVD Australia regulatory committee and represented industry at TGA Reg-Tech meetings • Managed three (3) MSAC applications for Medicare reimbursement; managed advocacy and stakeholder engagement • Technical management of private labelled products • Internal auditor for ISO 13485 and ISO 9001 certified quality systems • Supported clinical trials of diagnostics • Responsible for pre- and post-marketing compliance of medical devices, compliance distribution, electrical compliance, advertising/marketing review, privacy and import permits • Technical and quality management of third-party manufactured products • Management of ISO 9001 certified quality system
ERA Consulting, Australia	Regulatory Affairs Project Manager and Consultant 2008 – 2012	• Preparation and compilation of Module 3 (CMC/Quality) of a successful European Marketing Authorization Application (MAA) of a complex biological medicinal product • CMC/Quality due diligence, gap analyses and regulatory strategy development activities • Preparation of a range of regulatory documents including IBs, orphan drug applications, CTD modules, clinical trial applications (CTA) and certificates of suitability (CEP) • Preparation of a range of regulatory documents including Investigator's Brochures (IB), orphan durg applications, CTD modules, clinical trial applications (CTA) and certificates of suitability (CEP)
ES Cell International, Singapore	Research Scientist 2006 – 2008	Member of the diabetes team with the goal to differentiate human embryonic stem cells into insulin-secreting beta cells as a therapy for type I diabetes. Managed the development of a simplified, more efficient and defined protocol for the differentiation into pancreatic progenitors. Involved in the culture and qualification of the some of the first human embryonic stem cell lines to be derived under cGMP conditions.
MCB, Harvard University, USA	Post-Doctoral Research Fellow 2003 – 2006	Conducted research into both mouse and human embryonic stem cells, two areas of focus were the directed differentiation of the stem cells and analysis of global transcription using microarray technology.

Name	Reshma GANAPATHI
Position	Senior Consultant
Qualifications	MSc (Applied Genetics), Bangalore University, 2008 BSc (Biotechnology), Bangalore University, 2006

Summary

Reshma has over 11 years' experience in Regulatory Affairs as Regulatory Affairs Specialist with Biocon, Regulatory Affairs Officer with DSM Biologics, and Regulatory Affairs & Project Manager with Patheon. Reshma's CMC regulatory expertise spans the entire product lifecycle including developing compliant CMC strategies and pathways for clinical development and commercialization of biopharmaceuticals and medical devices. She is additionally experienced in leading/supporting study teams in preparing for Health Authority (HA) inspections and quality teams in assessing impact of product change, deviations and suitability of proposed CAPAs. Reshma is a highly motivated individual with an open-mind for new ideas and assertive communicator. She leads by mentoring and managing team members through influence. Reshma's proven abilities coupled with her strong work ethics make her a valued addition to the team.

Key Experience and Skills

- Phases I – IV
- Therapeutic areas: oncology (colorectal cancer), ophthalmology (wet AMD), rheumatology (rheumatoid arthritis), respiratory (cystic fibrosis, asthma), dermatology (atopic dermatitis), endocrinology (diabetes), autoimmunology, medical devices
- Regions: ANZ (Australia), Asia (India), Europe, North America
- Strong knowledge and understanding of US and EU regulatory requirements for the development and registration including CE mark and 510(k) approval process for combination products (autoinjector pens and pre-filled syringes)
- Reshma is able to evaluate information quickly, identify key issues and formulate conclusions based on sound, practical judgment, experience, and common sense.
- Reshma is highly motivated and has good interpersonal and communication skills which has allowed her to develop strong working relationships with her project teams and clients.
- Language proficiency: English, Hindi, Kannada, Telgu and Tamil

Achievements

- Developed and implemented less conservative yet lower risk CMC strategies to progress products through to Phase III approval with limited to no CMC concerns raised by Health Authorities
- Implemented a policy to outline key considerations for defining product specification which served as a quick reference guide on one of the aspects of CMC for manufacturing, quality and R&D teams.
- Provided regulatory inteligence and supported project management in a due-diligience resulting in Biocon-Pfizer partnership deal for global registration of biosimilar insulin analogues
- Effectively presented and negotiated with EMA and FDA during scientific advice meetings which resulted to positive outcomes
- Successfully implemented both conservative and relaxed approach of CMC for comparability studies, cell bank characterization, viral clearance studies, and Quality control release tests through developmental and marketing stages of fast-track novel and biosimilar programs

Study Experience:

Company	Role	Experience
Novotech, Australia	Senior Consultant Regulatory Sep '20 – Present	• Draft and review regulatory documents based on the Common Technical Document format and licence applications for GMOs • Communicate directly with Regulatory Authorities • Provide strategic advice verbally and in writing to internal and external stakeholders • Manage projects. This includes negotiating realistic timelines with Clients, planning project timelines according to milestones and deliverables, organizing team members to assist with projects as required, ensuring timelines are met (unless there are extenuating circumstances), providing Client's with regular updates, ensuring deliverables are of high quality before being sent to Clients, reviewing invoices • Review proposals generated by the Business Development team
Patheon (by Thermo Fisher Scientific), Australia	Regulatory Affairs & Program Manager Aug '17 – Sep '20	• Lead a globally dispersed program team with shared resources in a matrix style organization; ensure delegation to appropriate team members based on expertise • Manage multiple early to late phase biopharmaceutical programs that contribute to about 20% of the site's revenue • CMC consultants for a wide range of biologics, produced from mammalian celss for various indications (colorectal cancer, wet AMD, rheumatoid arthritis, cystic fibrosis and anti-inflammatory monoclonal antibodies for asthma and atopic dermatitis • Lead/support site in preparing Health Authoritiy (HA) inspections (including pre-approval inspections), assist site during HA inspections and with any resulting compliance commitments • Support Quality team in assessing impact of product change, deviations and suitability of proposed CAPAs • Serve as primary point of contact between cross-functional areas and clients to facilitate the advancement of programs • Coach highly talented subject matter experts from cross functional teams to develop their client interfacing and team leadership skills thus enabling sustained growth of their aptitude
Patheon, Australia	Associate Program Manager & Regulatory Affairs	• International assisgments to the USA to lead fast-track process validation of biosimilar programs

	Jun ’15 – Dec ‘16	• Demonstrated strong collaboration with cross functional teams situated globally and on site
DSM Biologics, Australia	Regulatory Affairs Officer Oct ’13 – Jun ‘15	• Provide CMC regulatory feedback with respect to cell bank characterization, viral clearance studies and quality control release tests through developmental and marketing stages • Review protocols and reports for analytical methods, pharmaceutical development, viral validation and mammalian cell bank characterization, cell bank stability testing, product stability studies, technical transfer documents, batch manufacturing records, SOPS and process validation • Review technical documents like FMEA protocols and process characterization reports based on QbD approach
Biocon Ltd., India	Senior Regulatory Affairs Specialist Apr ’11 – Jul ‘13	• Regulatory Lead of the due-diligence team that successfully established the strategic collaboration between Biocon-Mylan for the global development and commercialization of biosimilar monoclonal antibodies • Assess competitive landscape for injection devices including all aspects on the commercial, technical and IP front. Formulate the entry strategy and drove board resolution on investments to execute plans • Manage regulatory strategy development and execution for a wide range of recombinant therapeutic proteins for oncology, diabetes, and autoimmune indications • Exhaustive CMC expertise in areas such as but not limited to CHO/human cell line testing, design of stage appropriate viral clearance studies, stability study design, formulation development, process and biosimilar comparability studies, setting specifications and tesing requirements, reference standard development and process validation • Lead a team of expert in successful Regulatory/Health Authority audits for product licensure • Part of the core business team that concluded among the largest out-licensing and in-licensing deals, strategy execution, product development & launch planning and alliance management
	Regulatory Affairs Specialist Aug ’09 – Apr ‘11	• Responsible for managing, creating project plans with respect to regulatiry deliverables such as pre-IND briefing package and materials for pre-IND meeting for a phase I trial of a novel monoclonal antibody

Name	Felicity GRZEMSKI
Position	Consultant
Qualifications	PhD, University of Adelaide, 1998 BSc (Hons), University of Melbourne, 1984 Diploma (Education), University of Melbourne, 1986
Registration	American Board of Toxicology, 2003 - Present

Summary

Felicity is a board certified Regulatory Toxicologist with over 20 years of drug development experience. Prior to joining Novotech, she was with Pfizer Global Research and Development in the United States in positions including the Global Nonclinical Toxicology Licensing Lead, Nonclinical Regulatory Strategist, Research Candidate Management Nonclinical Team Lead in Dermatology, Toxicology Study Director and Early Candidate Team Representative. She has worked as a lecturer in Toxicology at Washington State University in the USA, University of Auckland in New Zealand and at the University of Adelaide, South Australia.

Felicity has comprehensive hands-on understanding of pharmaceutical licensing opportunity evaluations and the scientific and regulatory requirements for nonclinical drug development and registration from early discovery through to generic management. She has breadth of technical knowledge in multiple scientific areas within nonclinical toxicology and has coordinated and directed multiple general toxicology, genetic toxicology, developmental and reproductive toxicology, safety pharmacology and novel exploratory toxicology studies both internally and at Contract Research Organisations. Felicity is a certified with the American Board of Toxicology.

Key Experience and Skills

- Nonclinical evaluation of new and established chemical entities at all phases of drug development
- Preparation of toxicology strategy for drug candidate selection; risk assessment, management and resolution; product development; and registration activities
- Knowledge of global regulatory requirements including preparation and maintenance of the nonclinical dossier required for registration of new chemical entities through to established pharmaceuticals
- Subject matter expert in nonclinical development of pharmaceuticals for topical administration and/or dermatological agents
- Creative thinker known for innovative strategy design and implementation.
- Excellent communicator with background as tertiary educator.

Publications

- Radi ZA, Stewart ZS, **Grzemski FA**, Bobrowski WF (2013). Renal pathophysiologic role of cortical tubular inclusion bodies. *Toxicological Pathology;*41:32-37.
- Mitchell LH, Johnson TR, Lu GW, Du D, Datta K, **Grzemski F**, Shanmugasundaram V, Spence J, Wade K, Wang Z, Sun K, Lin K, Hu LY, Sexton K, Raheja N, Kostlan C, Pocalyko D. (2010) Rational design of a topical androgen receptor antagonist for the suppression of sebum production with properties suitable for follicular delivery. *Journal Medicinal Chemistry;* 53, 4422-4427.
- Tian Q, **Grzemski FA**, Panagiotopoulos S, Ahokas JT. (2006) Peroxisome proliferator-activated receptor alpha agonist, clofibrate, has profound influence on myocardial fatty acid composition. *Chemico Biological Interactions;*160, 241-251.

- Zhang J, Tirmenstein MA, **Nicholls-Grzemski FA** and Fariss MW. (2001) Mitochondrial electron transport inhibitors cause lipid peroxidation-dependent and -independent cell death: protective role of antioxidants. *Archives of Biochemistry and Biophysics;*393, 87-96.
- Fariss MW, **Nicholls-Grzemski FA,** Tirmenstein MA and Zhang J (2001) Enhanced antioxidant and cytoprotective abilities of vitamin E succinate is associated with a rapid uptake advantage in rat hepatocytes and mitochondria. *Free Radicals in Biology and Medicine*;31, 530-541.
- **Nicholls-Grzemski FA,** Calder I, Priestly BG and Burcham PC (2000). Peroxisome proliferation and hepatoprotection: glutathione independent mechanisms of resistance to acetaminophen toxicity in hepatocytes from clofibrate-pretreated mice. *Toxicological Sciences;* 56, 220-228.
- Tirmenstein MA, **Nicholls-Grzemski FA,** Schmittgen T, Zakrajek BA and Fariss MW (2000) Characterisation of nitric oxide syntase induction during isolation of rat hepatocytes. *Toxicological Sciences;* 53, 56-62.
- **Nicholls-Grzemski FA,** Belling GB, Burcham PC, Calder IC and Priestly BG. Resistance to oxidative stress associated with exposure of mice to peroxisome proliferators is not due to changes in hepatic fatty acids. *Journal of Biochemical and Molecular Toxicology;* 14, 335-345.
- Tirmenstein MA, **Nicholls-Grzemski FA,** Schmittgen T, Zakrajek BA and Fariss MW (2000) Glutathione-dependent regulation of nitric oxide production in isolated rat hepatocyte suspensions. *Antioxidant and Redox Signalling;*2, 767-777.
- Tirmenstein MA, **Nicholls-Grzemski FA**, Zhang J-G and Fariss MW (2000). Glutathione depletion and the production of reactive oxygen species in isolated hepatocyte suspensions - *Chemico-Biological Interactions;* 127, 201-217.
- Zhang J-G, **Nicholls-Grzemski FA,** Tirmenstein MA and Fariss MW (1999) a-tocopherol succinate (TS) protects hepatocytes against oxidative stress derived from mitochondria. *Free Radicals in Biology and Medicine - in press.*
- Tirmenstein MA, **Nicholls-Grzemski FA,** Okita JR, Fariss MW, and Okita R. Sodium Azide forms nitric oxide in suspensions of rat hepatocytes. *Journal of Biochemical and Molecular Toxicology – Submitted.*
- **Nicholls-Grzemski FA,** Tirmenstein MA and Fariss MW (1999) Time dependent production of nitric oxide by rat hepatocyte suspensions. *Biochemical Pharmacology;* 804, 742-744.
- **Nicholls-Grzemski FA.,** Burcham PC, Calder IC and Priestly BG (1996) Pretreatment with peroxisome proliferators protects mice against some but not all hepatotoxins. *Annals of the New York Academy of Sciences,* 804, 742-744.
- **Nicholls-Grzemski FA,** Calder IC and Priestly BG (1992). Peroxisome proliferators protect against paracetamol toxicity in mice. *Biochemical Pharmacology,* 43, 1395-1396.
- Ahokas JT, **Nicholls FA**, Ravenscroft PJ and Emmerson BT (1985) Inhibition of rat liver glutathione S-transferase by phenoxyacetic acids. *Biochemical Pharmacology,* 33, 2157-2161.
- **Nicholls FA** and Ahokas JT. (1984) Inhibition of glutathione S-transferases by indomethacin. *Biochemical and Biophysical Research Communications,* 119, 1034-1037.

Other Education

- Professional Certification (Regulatory Affairs for Monoclonal Antibodies), Biopharma Institute, 2020
- Certificate of Laboratory Safety, Royal Melbourne Institute of Technology, 1987

Achievements

- *Invited reviewer for* Toxicology Letters, Life Sciences and Chemical-Biological Interactions
- North East Chapter Councilor, Society of Toxicology, 2011 - 2013
- *Judge*- Graduate Student Presentation in Toxicology: ASCEPT, Sydney, 2003
- IUTOX Junior Fellowship award - to attend the ICT-IX meeting in Brisbane, Australia, July 2001

- *Conference Chair*- Oxidative Stress Symposium, International Congress of Toxicology-IX: Brisbane, Australia
- *Publications Committee*- International Congress of Toxicology-IX: Brisbane, Australia
- FASEB Young Scientist award - to attend FASEB meeting in Orlando, Florida, April 2001
- University of Auckland short term research grant. Mechanism of cell death by natural products (1996).
- Toxicology Research Prize - Honourable Mention, ASCEPT (1996)
- Waters Chromatography Scholarship in Toxicology (1983)

Memberships

- Full member, Society of Toxicology, 2002 – Present

Employment Experience:

Company	Role	Experience
Novotech, Australia	Consultant Toxicologist Sep '20 – Present	• Draft and review regulatory documents such as those based on the Common Technical Document format, Investigator Brochures • Provides strategic advice verbally and in writing to internal and external stakeholders as required. • Project manage and coordinate projects to meet program deadlines • Reviews proposals generated by the Business Development team
Pfizer Global Research and Development, USA	Nonclinical Regulatory Strategist in Essential Health Apr '17 – Feb'19	• Strategist utilizing breadth of nonclinical scientific and technical knowledge to author responses to regulatory agency queries of registered drugs in multiple geographies. • Nonclinical representative on short duration teams in post-registration neuroscience area, to investigate and address legal or regulatory matters of concern • Updated drug labels to current regulatory expectations and scientific assessment of nonclinical risk • Nonclinical lead on Antiinfective late stage drug development teams. Provided leadership in promoting understanding of recent regulatory concerns of use of certain anaesthetic and sedative drugs during pregnancy

	Global Nonclinical Licensing Lead Jul '09 – Mar '17	• Coordinated the nonclinical toxicology evaluation of potential in-license assets (new chemical entities, established pharmaceuticals, novel technologies etc). • Prepared external asset due diligence reports including nonclinical risk assessment, impact and ease of risk mitigation; timeline appraisal; regulatory strategy; cost analysis; impact of issues from other lines, and possibility of nonclinical success. • Established nonclinical outlicensing process to support due diligence by external parties. Received company award for individual excellence in support of Out licensing initiatives. • Supported acquisition and integration of licensed assets
	Regulatory Strategy Lead Dec '06 – Jun '09	• Accountable for asset management and regulatory submissions for Dermatology drugs ensuring format and compliance to international standards • Responsible for post-Phase-2/Proof of Concept nonclinical development of dermatology assets • Authored Nonclinical Overview for multiple programs including a critical nonclinical assessment of available pharmacology, pharmacokinetics, and toxicology data • Reviewed correspondence from, and prepared responses to, worldwide regulatory agencies. • Prepared deliverables required for regulatory interactions including Pre-IND meeting packages and carcinogenicity protocol assessment • Planned and implemented strategy (including both internal and external studies) for a change of route of administration from established oral to topical clinical program • Designed critical studies for the successful resolution of a clinical hold which led to an invitation by the FDA to present at the FDA Toxicology Forum. • Devised, prepared business plan and implemented annual meeting/communication forum for Pfizer toxicologists from all international sites.
	Research Candidate Management Team Lead Jun '05 – 'Dec 06	• Responsible for implementing nonclinical safety, risk management strategy regulatory submissions of multiple dermatology programs from identification to clinical proof of concept • Internal subject matter expert in nonclinical dermatology testing including dossier preparation (IND), regulatory filings and interactions • Provided guidance to early discovery stage teams on selecting compounds and early safety evaluation for assets in the dermatology portfolio

	Toxicology Study Director and Early Candidate Team Representative May '01 – Jun'05	• Drug development team lead for nonclinical toxicology and fully trained GLP Study Director • Scientific leader on a number of discovery and/or development teams in dermatology, neurology and inflammation therapeutic areas including transition of several candidates from discovery to full GLP development • Study director on diverse range of nonclinical studies, including rodent and nonrodent general toxicology studies, exploratory, genetic toxicology and safety pharmacology. Independently planned and over saw fit for purpose studies including data analysis, reporting and ensuring quality. • Developed unique studies and strategies to advance topical and oral programs • Monitored outsourced studies at multiple Contract Research Laboratories to ensure quality and adherence to internal Standard Operating Procedures, policies, and safety procedures. • Maintained active relationship with external environment (eg scientific review of research papers submitted to toxicology journals; abstract reviewer for international toxicology meeting; co-supervisor of a PhD candidate at the Royal Melbourne Institute of Technology)
Washington State University, USA	Postdoctoral Research Fellow – Neuropharmacological and neurotoxicological studies of nitrous oxide Natural products as anti-cancer agents Jan '00 – Apr '01	
	Postdoctoral Research. Hepatoprotective effects of tocopherol succinate. Lecturer (Bachelor of Pharmacy program). Jan '00 – Apr '01	
University of Auckland, New Zealand	Course Coordinator – Principles of Toxicology (Bachelor of Science program) May '96 – Mar '97	
University of Adelaide, Australia	Doctoral studies/ Assistant Lecturer – Pharmacology Practical Laboratory Feb '90– Mar '96	
Royal Melbourne Institute of Technology, Australia	Key Centre of Applied and Nutritional Toxicology Technical Officer – Toxicology. Laboratory Practical coordinator Jun '86 – Feb '90	
University of Melbourne, Australia	NH&MRC Research Assistant – Inhibition of Glutathione-S-transferase isoforms by phenoxyacetic acid diuretics and herbicides Dec '83 – Dec '85	

Name	Babasaheb (Babaji) YADAV
Position	Consultant
Qualifications	EU and UK registered toxicologist since September 2019 Ph.D, University of Otago, New Zealand, 2011 M. Pharm, Bharati Vidyapeeth University, Pune, India, 2005 B. Pharm, University of Pune, India, 2003

Summary

Dr. Babaji Yadav is a Consultant with over six years of academic experience in pre-clinical oncology drug development and seven years of industry experience (biotech) in early phase drug development. Babaji has a strong background in pharmaceutical sciences with a PhD in Pharmacology and Toxicology from University of Otago, New Zealand. Previously he has worked as a Research Project Manager to oversee US IND enabling toxicological studies for lead oncology drugs and, prior to joining NOVOTECH, was a Clinical Project Manager at a global CRO. Babaji is a EU and UK Registered Toxicologist and at NOVOTECH he is focussed on providing technical toxicology advice and product development strategies to facilitate entry of client's compounds into clinical trials.

Key Experience and Skills

- Experienced with organising and designing pre-clinical studies to support an IND
- Experienced in early phase clinical drug development and project management of phase I – II clinical trials
- Experienced in writing regulatory documents such as INDs and Investigational Brochures, and evaluating regulatory toxicology packages
- Particular experience in developing oncology (breast, ovarian cancer, gliobastoma), hematology (ALL, AML) compounds
- Language proficiency: English, Hindi and Marathi

Publications

- Abdulmohsen M Alruwetei, Katerina Bendak, **Babasaheb D. Yadav** et al. (2020). Examining treatment responses of diagnostic marrow in murine xenografts to predict relapse in children with acute lymphoblastic leukemia. British Journal of Cancer, 123: 742–751
- **Babasaheb D Yadav** et al. (2016) Heterogeneity in mechanisms of emergent resistance in pediatric T-cell acute lymphoblastic leukemia. Oncotarget, 7 (37):58728-42
- **Babasaheb D Yadav** et al. (2014) A Pre-Clinical Model of Resistance to Induction Therapy in Pediatric Acute Lymphoblastic Leukemia. Blood Cancer J, 4: e232
- **Yadav B D** et al. (2012) RL66, a second-generation curcumin analog has potent *in vivo* and *in vitro* anticancer activity in ER-negative breast cancer models. Int J Oncol. Nov, 41(5):1723-32
- **Yadav B D** et al. (2012) RL71, a second-generation curcumin analog, induces apoptosis and downregulates Akt in ER-negative breast cancer cells. Int J Oncol. 2012 Sep;41(3):1119-27
- **Yadav B D** et al. (2010) Synthesis and cytotoxic potential of heterocyclic cyclohexanone analogues of curcumin. Bioorganic & Medicinal Chemistry 18(18):6701-7
- **Yadav B D**, Khaled Greish (2011) Selective inhibition of HO-1 as a therapeutic target for novel anticancer treatment. Journal of Nanomedicine & Nanotechnology, S4, 1 – 8
- Dzeyk, J, **Yadav B D**, Rosengren RJ, (2011) Experimental therapeutics for the treatment of triple negative breast cancer. In E. Gunduz & M. Gunduz (Eds.), Breastcancer: current and

alternative therapeutic modalities. (pp 371-394). Rijeka, Croatia: InTech

Presentations

- Attended 2015 Lowy Cancer Symposium: Drug discovery and personalised medicine, Sydney
- Attended 2012 Lorne Cancer Conference, Lorne Victoria, Australia
- Taurin S, **Yadav B D**, Nimick M, Rosengren RJ. Poster presented at the American Association of Cancer Research (AACR) 103rd Annual Meeting held at Chicago, USA. 2012
- **Yadav B D**, et al. Poster presented at the 2011 European Multidisciplinary Cancer Congress held at Stockholm, Sweden. September 23 – 27, 2011
- **Yadav B D**, et al. Poster presented at 3rd QMB Cell Signaling meeting held at Queenstown, New Zealand. August 28 – 29, 2011
- **Yadav B D**, et al. Poster presented at QMB Cancer Satellite meeting held at Queenstown, New Zealand. September 2 – 3, 2010
- **Yadav B D**, et al. Poster presented at AACR 101st Annual Meeting held at Washington DC, USA. April 17 – 21, 2010

Achievements/Awards

- Received nominations for NovoStar Award designed to recognise and appreciate Novotech employees for outstanding behaviour and contribution in May and August 2020, Novotech Sydney
- Shout Out Award for delivering on an important milestone for IB data cleaning, 2017, IQVIA Ltd, Sydney
- Best poster presentation at 3rd QMB Cell Signaling meeting held at Queenstown, New Zealand, 28 – 29th August 2011
- Best poster presentation at PhD colloquium session organized by Otago School of Medical Sciences at Otago, New Zealand, 2011
- Travel grant from Maurice and Phyllis Payket Trust, New Zealand to attend The 2001 European Mulitidisciplanry Cancer Congress held at Stockholm, Sweden in September 2011
- Received Professional Development Award from Genesis Oncology Trust, New Zealand to attend the 2011 European Multidisciplinary Cancer Congress held at Stockholm, Sweden in September 2011
- Received scholarship from University of Otago, New Zealand, for PhD studies in Pharmacology and Toxicology, November 2008.

Memberships

- UK Registered Toxicologist (By Review) – Royal Society of Biology and British Toxicology Society
- Eurotox Registered Toxicologist – Eurotox
- Member of British Toxicology Society since July 2020

Employment Experience:

Company	Role	Experience
Novotech, Australia	Consultant Jun '20 – Present Consultant (under Clinical Network Services) Jul '18 – May '20	• Review of nonclinical toxicology packages and conducting gap analyses for various therapeutic indications for submission in Australia, US and/or EU countries. • Preparation of drug development plans to support the conduct of clinical trials and to support marketing applications for various therapeutic indications in Australia, USA and EU • Provide strategic advice and technical expertise to clients and guide project and program activities. • Review literature related to pharmacology and nonclinical toxicology of a drug and/or excipient(s) under development in order to support their use in the clinical studies • Writing regulatory documents for submission to various regulatory bodies across the globe and writing of nonclinical modules of IND applications for submission to the US FDA • Assist in preparing written responses to queries raised by regulatory agencies across the globe. • Review and/ or design new drug toxicology programs that include a range of toxicology studies such as does-range/MTD finding studies, pivotal toxicology studies, genotoxicity studies and combination toxicology • Perform project management activities to enable meeting project deadlines and budget targets
IQVIA, Australia	Associate Clinical Project Manager Jul '17 – Jul '18	• Managed phase I and II clinical development of immuno-oncology drugs for biotech companies across the globe • Negotiated budget and contract with the sponsor • Review or develop as needed, all key documents/deliverables in the trial such as regulatory and ethics submissions, eCRF, data management plan, clinical operational plan, integrated project management plan, safety plan, pharmacy manual, randomisation plan, statistical analysis plan and clinical study report • Ensuring frequent and effective communication with all study sites, consultants and other vendors in Australia and overseas if necessary • Manage investigational product distribution • Proactively manage the timely resolution of any identified problems with study sites, CRAs, consultants, other vendors and internal team • Support sponsors in set-up, implementation and execution of the assigned clinical study • Prepare and present project information at internal and external meetings

		• Support feasibility and site identification activities • Support medical writing activities (PK/PD and biomarker section of the clinical protocol • Produce and distribute status, tracking and financial reports for internal and external team members and senior management • Coordinate with other support staff within and across the global project management unit to identify and consolidate support processes • Serve as the primary contact for internal project team and for external stakeholders • Responsible for financial reporting on project including tracking, revenue recognition and invoicing • Trained and mentored Junior Project Support Staff
Kazia Therapeutics, Australia	Project Manager Sep '15 – May '17	• Successfully planned and completed IND enabling non-clinical pharmacology and toxicological studies for a lead oncology lead molecule (orphan drug) with CROs. These studies included acute/repeat dose toxicity studies in rodent and non-rodent species, toxicokinetic studies, safety pharmacology studies, genotoxicity studies, and immunotoxicity studies. Moreover, *in vitro/in vivo* pharmacology and pharmacokinetic studies were also conducted using various models • Assisted in reviewing and quality controlling IND application for Cantrixil, another lead molecule for ovarian cancer. Cantrixil IND application was successful in June 2016 • Assisted clinical/regulatory director in reviewing phase I clinical trial protocol for Cantrixil. The phase I clinical trial of Cantrixil commenced in December 2016 • Assisted in managing and quality controlling HREC application for phase I study of Cantrixil • Prepared and presented toxicological/drug safety data to internal (scientific advisory board) and external stakeholders • Assisted clinical research director in setting up a phase II glioblastoma study • Liaised with internal and external cross functional teams (chemists, biologists, clinicians, chief medical officer, chief business development officer and CROs) to remain abreast of the project development and ensure project success. Worked with contract research and manufacturing organisations (CROs and CMOs) across the globe (USA, China, India & UK) • Demonstrated critical thinking and creative problem-solving skills to ensure timely and successful implementation of projects • Participated in writing the pharmacology and toxicology section of the Investigator's brochure (IB) and IND application for regulatory submissions • Participated in writing FDA annual reports for orphan

		drugs under development • Managed and collected all pre-clinical research data from contract research organisations and prepared ICH compliant reports for IND application • Set-up and maintained budgets in liaison with the Project Director
Children's Cancer Institute, Australia	Post-Doctoral Research Fellow Apr '12 – Aug '15	
Alard College of Pharmacy, India	Lecturer Feb '07 – Sep '08	
Vishal Institute of Pharmaceutical Education and Research, India	Lecturer Aug '06 – Feb '07	
Sanofi – Aventis Ltd, Goa, India	Research Trainee Aug '05 – Aug '06	

Name	Daniel MOBASSERI
Position	Associate Consultant
Qualifications	MPhil, The University of Queensland, 2018 PharmD., Tabriz University of Medical Sciences, 2009

Summary

Daniel has 2 years' experience in Regulatory Affairs as Regulatory Affairs Associate with Commercial Eyes. He graduated from Tabriz University of Medical Sciences with a degree in Doctor of Pharmacy and later pursued his Masters in Pharmaceutical Sciences at The University of Queensland. He started his career as Pharmacy in Charge for a hospital pharmacy and a community pharmacy. He later held the position of Head of Production with Sobhan Oncology Pharmaceutical where he managed the production of pharmaceutical products such as liposomal doxorubicin, a nanotechnology-based anticancer agent. Daniel in depth experience coupled with his enthusiasm and good work ethics make him a valued addition to the team.

Key Experience and Skills

- Experienced in major variations such as Category 1 type J submission and CMC change such as Category 3 variations
- Experienced in labelling reviews (TGO91 and TGO92), safety related requests (SRR) and PI reformat and CMI updates
- Regions: ANZ (Australia), Asia (Iran)
- Experienced in publishing electorinc dossiers (eCTD): Extedo
- Daniel is hardworking and reliable and works in an efficient manner.
- Daniel thrives on expanding his knowledge and is always keen to take on opportunities to share his expertise with teams which he is a part of.
- Language proficiency: Farsi (Persian), English

Other Education

- Design and Interpretation of Clinical Trials, Johns Hopkins University, July 2020 (https://www.coursera.org/account/accomplishments/certificate/CN8DCL22EG3R)
- Research Commercialism Workshop, UNIQUEST Australia, July 2016
- Making Biologic Medicines for Patients: The Principles of Biopharmaceutical Manufacturing, Massachusetts Institute of Technology (MIT), December 2015 (https://courses.edx.org/certificates/0ecd1fffebf84638b55c651b93c5563c)
- TetraQ Preclinical Drug Development Workshop, Translational Research Institute (TRI) Australia, July 2015

Achievements

- Poster Presentation, "Formulation and evaluation of ultrasound responsive topical formulations for the management of chronic infected wounds," Translation Research Institute Symposium, Australia, August 2017
- Research Training Program (RTP) scholarship, the University of Queensland, Brisbane, Australia, 2016
- Poster Presentation, 12th Pharmacy students seminar, Sari, Iran, 2006

Employment Experience:

Company	Role	Experience
Novotech, Australia	Associate Consultant Regulatory Sep '20 – Present	• Draft and review regulatory documents based on the Common Technical Document format and licence applications for GMOs • Communicate directly with Regulatory Authorities • Provide strategic advice verbally and in writing to internal and external stakeholders • Manage projects. This includes negotiating realistic timelines with Clients, planning project timelines according to milestones and deliverables, organizing team members to assist with projects as required, ensuring timelines are met (unless there are extenuating circumstances), providing Client's with regular updates, ensuring deliverables are of high quality before being sent to Clients, reviewing invoices • Review proposals generated by the Business Development team
Commercial Eyes Pty. Ltd., Australia	Regulatory Affairs Associate May '18 – Aug '20	• Regulatory maintenance activities • Assistance in the preparation of regulatory documentation for submission to the TGA and other regulatory agencies • Control and update of internal regulatory templates • Assist with development of proposals • Administrative support to the regulatory service team
Sobhan Oncology, Iran	Head of Production Jan '12 – Mar '13	• Manage the manufacturing of pharmaceutical products such as nanotechnology-based anticancer (i.e. liposomal doxorubicin) • Identify production issues and liasing with other departments (i.e. R&D, Engineering and QA) to troubleshoot • Collaborating with R&D department with regards to development of new formulations and transfer of biopharmaceutical product manufacturer
Dr. Mobasseri Pharmacy, Iran	Pharmacist in Charge Oct '10 – Jan '12	
Besat Hospital Pharmacy, Iran	Pharmacist in Charge Jun '09 – Oct '10	

Name	Narelle BRAMICH
Position	Medical Writing Manager
Qualifications	Graduate Diploma (Internet & Web Computing), RMIT University, 2002 PhD (Neurophysiology), University of Melbourne, 1991 BSc (Hons) (First class), University of Melbourne, 1988 BSc (Zoology & Genetics), University of Melbourne, 1987

Summary

Narelle has over 20 years of experience in the scientific and biopharmaceutical sectors. She has an impressive track record of creating high-performing teams, fostering a culture of excellence through mutual trust and respect. Narelle's proven ability to critically analyse and synthesise complex scientific information, and write strategically to different audiences in a clear and informative manner make her a valuable addition to Novotech.

Key Experience and Skills

- Phases I – IV
- Therapeutic areas: haematology (haemophilia A and B, acute myeloid leukaemia), cardiovascular, immunology and neurology (primary immunodeficiency disease, chronic inflammatory demyelinating polyneuropathy, hereditary angioedema), respiratory (emphysema), oncology, respiratory
- Regions: ANZ (Australia), Asia (Japan), Europe (United Kingdom, Germany, Switzerland), United States
- Narelle provides leadership and oversight of the Medical Writing function to ensure the on-time delivery of high-quality documents in alignment with client expectations.
- Narelle thrives on expanding her knowledge and is always keen to take on opportunities to share her expertise with teams which she is a part of.

Publications*

- Stretton S, **Bramich NJ**, Keys JR, Monk JA, Ely JA, Haley C, Woolley MJ, Woolley KL. Publication misconduct and plagiarism retractions: a systematic, retrospective study. Curr Med Res Opin 2012 Oct;28(10):1575-1583
- Woolley KL, Lew RA, Stretton S, Ely JA, **Bramich NJ**, Keys JR, Monk JA, & Woolley MJ. Lack of involvement of medical writers and the pharmaceutical industry in publications retracted for misconduct: a systematic, controlled, retrospective study. Curr Med Res Opin 2011;27(6):1175-1182
- Furness JB, Pontell L, Ferens D, **Bramich N**, McKeon B, & O'Connell HE. Re-innervation of smooth muscle that is transplanted to provide urethral sphincter augmentation. Autonom Neurosci 2011;159:71-76
- Sandow SL, **Bramich NJ**, Bandi HP, Rummery NM, & Hill CE. Structure, function and endothelium-derived hyperpolarizing factor in the caudal artery of the SHR and WKY rat. Arterioscler Thromb Vasc Biol 2003;23:822-828

- Sandow SL, **Bramich NJ**, Bandi HP, Rummery N, & Hill C. Structural changes maintain endothelium-derived hyperpolarizing factor activity in hypertensive caudal artery. In: EDHF 2002. Ed. PM Vanhoutte, Taylor and Francis. UK

Achievements

- Expanded and restructured the Medical Writing department of CSL, ensuring that the function was able to meet the needs of a growing Research and Development portfolio
- Led CSL's cross-functional, process improvement initiatives to improve both the quality and development efficiency of key clinical documents
- Integrated the CSL Japan Medical Writing group into the global function, substantially improving the development of clinical content for marketing authorisation applications to Japan

*Further Publications are available upon request

Employment Experience:

Company	Role	Experience
Novotech, Australia	Medical Writing Manager Jun '20 – Present	• Oversee of preparation and delivery of high-quality clinical and regulatory documentation • Manage the performance, motivation and development of the medical writing team • Maintain a high level of technical knowledge in the area of product development and international regulatory affairs • Ensure documents are developed in alignment with client goals, local regulations and Good Clinical Practice (GCP) • Maintain a high level of technical knowledge in the area of product development and international regulatory affairs • Develop and maintain medical writing Standard Operating Procedures (SOPs), processes and templates and training materials to Novotech's standards
CSL Ltd, Australia	Director, Medical Writing 2016 – Apr '20	• Provided strategic leadership and managerial oversight of the global Medical Writing department (20+ fulltime employees and contractors) • Ensured the provision of strategically aligned medical writing deliverables to support the clinical development and regulatory requirements of the company's clinical programs • Coached, trained, and mentored staff • Responsible for budgeting, resource planning, and forecasting for medical writing activities
	Senior Medical Writer 2012 – 2016	• Led the messaging strategy and the efficient development of high-quality clinical documents at all stages of clinical development. Included regulatory submissions (clinical overview and clinical summary modules), clinical study

		protocols, clinical study reports, investigator's brochures, regulatory briefing packages, clinical development plans • Proactively developed effective global working relationships with key stakeholders across multiple functions including Clinical Development, Global Clinical Safety and Pharmacovigilance, and Regulatory Affairs • Clinical representative for critical infrastructure processes both within medical writing and across the broader organisation.Mentored senior medical writers and onboarded new staff • Contributed to budgeting, planning, and forecasting for medical writing activities across multiple clinical programs • Liaised with the Disclosure team to ensure compliance with clinical trial disclosure requirements
ProScribe Medical Communications, Australia	Senior Medical Writer 2011 - 2012	• Medical communication company providing writing services to pharmaceutical, biotechnology, academic, and allied health organizations. • Regulatory and clinical documentation: authored clinical study protocols, clinical study reports, investigator brochures, literature-based submissions, manuscripts, slide presentations, literature reviews, standard operating procedures • Advisory Board management: assisted with development of Advisory Board charters and meeting agendas, acted as liaison between client and Advisory Board members, and prepared meeting reports • Conference and medical education events: worked with subject matter experts and pharmaceutical sponsors to develop agendas, presentations, and summary reports
	Medical Writer 2008 - 2011	
Continence Control Systems International Pty., Ltd., Australia	Clinical Research Manager 2004 - 2008	
University of Melbourne, Australia	Senior Research Fellow – Department of Zoology (with M7 Pty Ltd) 2001 – 2004	
Australian National University	Research Fellow – John Curtin School of Medical Research 2001	
University of Melbourne, Australia	Senior Research Officer – Department of Zoology 2000 - 2001	
	RD Wright Fellow – Australian National Health and Medical Research Council 1996 - 1999	
	CJ Martin Fellow – Australian National Health and Medical Research Council	

	1994 - 1995
University Department of Pharmacology, Oxford, United Kingdom	CJ Martin Fellow – Australian National Health and Medical Research Council 1992 - 1993
Glaxo Australia Ltd	Regulatory Affairs Assistant 1992

Name	Kelly BURNS
Position	Senior Medical Writer
Qualifications	B.Sc (Physiological Science), University of Newcastle, 2012 Certificate IV Finance, Melbourne institute of Technology

Summary

Kelly has been with Novotech since 2013 when she joined as Office Administrator under Clinical Network Services (CNS). She has progressed to Project Administrator in 2016, Associate Consultant in 2017 and Biodesk Consultant in 2019 having proven to be highly motivated and efficient individual. Kelly has a Bachelor of Science in Physiological Science from University of Newcastle and she has also a Certificate IV Finance from Melbourne Institute of Technology. Kelly, as a Consultant is currently focused on handling various roles that include, preparation and reviewing of clinical and regulatory documents, interpreting data for clinical study reports and drug safety update reports. She has worked across a range of therapeutic areas including cardiovascular, immunology, inflammatory diseases, endocrinology, respiratory, oncology, musculoskeletal to name but a few. Kelly's enthusiasm, hardwork and willingness to help where needed make her a valued addition to her teams.

Key Experience and Skills

- Phases I – II
- Therapeutic areas: cardiovascular, immunology, inflammatory diseases, endocrine, respiratory, oncology, musculoskeletal, neurology, gastrointestinal, ophthalmology, dermatology, autoimmune, urology, haematology
- Regions: ANZ (Australia), Europe (United Kingdom)
- Kelly is a process driven individual who focuses on innovation and finding efficiencies.
- Kelly enjoys collaborating with multiple stakeholders to produce high quality documents.

Publication

- Chen A, Karolczak-Bayatti M, **Morrissey K**, et al. Lysine deacetylase inhibition promotes relaxation of arterial tone and C-terminal acetylation of HSPB6 (Hsp20) in vascular smooth muscle cells. Physiol Rep. 2013;1(6):e00127. doi:10.1002/phy2.127

Employment Experience:

Company	Role	Experience
Novotech, Australia	Senior Consultant – Medical Writer Aug '20 – Present	
	Consultant – Medical Writer Jun '20 – Jul '20	
	Consultant (under Clinical Network Services) Aug '19 – May '20	• Preparation of clinical and regulatory documents including clinical study reports, Investigator Brochures, regulatory submissions and other documents as required • Reviewing clinical and regulatory documents including protocols and clinical study reports

		• Reviewing and interpreting data for clinical study reports and drug safety update reports • Liaison with clients, colleagues and literature to develop GCP compliant documents • Working across multiple therapeutic areas to develop documents that are aligned with client goals, local regulations and GCP requirements • Training and mentoring less experienced medical writers
	Associate Consultant (under Clinical Network Services) Aug '17 – Jul '19	• Preparation of clinical and regulatory documents including clinical study reports, Investigator Brochures, regulatory submissions and other documents as required • Liaison with clients, colleagues and literature to develop GCP compliant document • Working across multiple therapetuc areas to develop documents that are aligned with client goals, local regulations and GCP requirement
	Project Administrator (under Clinical Network Services) Apr '16 – Aug '17	• Draft ethics and regulatory applications • Submission of CTN applications • Collection, tracking and filing of all documents generated throughout a clinical study • Reconciliation of Investigator Site Files and Trial Master Files • Assist in producing clinical and regulatory documents including reports, project plans, manuscript and patient information documentation
	Office Administrator (under Clinical Network Services) Sep '13 – Feb '14	• Draft work instructions and company policies • Database management/maintenance • Scheduling and travel arrangements
Sullivan Nicolaides Pathology, Australia	Histology Scientist Feb '13 – Sep '13	
PPC Worldwide, Australia	Critical Incident Coordinator Jul '12 – Feb '13	
Newcastle University Institute of Cellular Medicine, UK	Research Scientist Mar '11 – Jul '12	

Name	Catherine TABRETT
Position	Senior Medical Writer
Qualifications	PhD (Agricultural Chemistry), University of Sydney, 1999 BScAgr (Hons1), University of Sydney, 1995

Summary

Catherine completed her PhD in Agricultural Chemistry at the University of Sydney and then worked in academic medical research in Australia and the United Kingdom for over a decade. After which she worked in Clinical Research Associate and Medical Writing roles for national and international companies across a large range of therapeutic areas, including neurodegenerative disease, oncology, inflammatory diseases, dermatology, infectious diseases, respiratory diseases, immunology, rheumatology, ophthalmology, and gastrointestinal disease. Catherine has also previously worked as a Chemistry Teacher and Laboratory Demonstrator at tertiary institutions, and as a freelance Scientific/Medical Editor.

Catherine has been with Novotech Australia since 2019 when she joined as a Consultant Medical Writer under Clinical Network Services (CNS). She has progressed to Senior Consultant Medical Writer in November 2020 having proven to be highly motivated and focused individual who is very keen attention to detail. She works on core documents, such as protocols, investigator brochures and clinical study reports for drugs, vaccines and devices. Her medical writing experience, coupled with enthusiasm and strong work ethic make her a valued member of her team.

Key Experience and Skills

- Phases I – IV
- Therapeutic areas: neurodegenerative disease (Alzheimer's disease), oncology (HPV-associated cancers, solid tumor cancers), inflammatory diseases, dermatology (atopic dermatitis), infectious diseases (seasonal flu, sepsis, malaria, COVID-19), fibrosis, respiratory diseases (lung fibrosis, COPD), gastrointestinal disease (liver fibrosis, ulcerative colitis), rheumatology (rheumatoid arthritis), immunology (GVHD), opthalmology
- Regions: ANZ (Australia, New Zealand), Asia and Africa
- Catherine is a well-organized and cooperative individual who works in an efficient manner
- Catherine thrives on expanding her knowledge and is always keen to take on opportunities to share her expertise with other members of the team

Publications*

1. Matthias, L.J., Azimi, I., **Tabrett, C.A**., Hogg, P.J. (2010) 'Reduced Monomeric CD4 is the Preferred Receptor for HIV' Journal of Biological Chemistry 285:40493-40499
2. **Tabrett, C.A**., Harrison, C.F., Schmidt, B., Bellingham, S.A., Hardy, T., Sanejouands, Y., Hill, A.F., and Hogg, P.J. (2010) 'Changing the Solvent Accessibility of the Prion Protein Disulfide Bond Markedly Influences its Trafficking and Effect on Cell Function', Biochemical Journal, 428:169 – 182.
3. **Tabrett, C.A**., and Coughtrie, M.W.H., (2003) 'Phenol Sulfotransferase 1A1 Activity in Human Liver: Kinetic properties, Interindividual Variation and Re-evaluation of the Suitability of 4-Nitrophenol as a Probe Substrate' Biochemical Pharmacology, 66:2089-97.
4. **Tabrett, C.A**., and Copeland, L., (2002) 'Enzymes of malate metabolism in *Mesorhizobium ciceri* CC 1192' Canadian Journal of Microbiology, 48:279-284.

Achievements/Awards

- Australian Postgraduate Award
- Dean's List of Excellence in Academic Performance, University of Sydney
- Joyce Winfred Rouse Prize in Agricultural Chemistry, University of Sydney
- Simon Leake Sydney Environmental and Soils Laboratory Prize, University of Sydney
- Pig Research and Development Corporation Undergraduate Summer Scholarship
- Recipient, Parexel Reward and Recognition Program – Outstanding Customer Service and Teamwork

Memberships

- Member, Australasian Medical Writiers Association

*Additional publications are available upon request.

Study Experience:

Company	Role	Study
Novotech, Australia	Senior Consultant (Medical Writer) - Biodesk Nov '20 – Present	
	Consultant (Medical Writer) - Biodesk Jan '19 – Oct '20	Regional, pre-market Alzheimer's disease Regional, phase I atopic dermatitis, HPV associated cancers, lung and liver fibrosis, GVHD, immunoproteasome inhibitor, seasonal flu, sepsis, COVID-19, increased dosing of approved drug, glaucoma, emmetrope Regional, phase Ia/Ib lung and liver fibrosis, GVHD, immunoproteasome inhibitor, oncology Regional, phase Ib atopic dermatitis, HPV associated cancers, malaria Regional, phase II malaria Regional, phase IIb lung and liver fibrosis, GVHD, immunoproteasome inhibitor, seasonal flu Regional, phases II/III COVID-19 Regional, phases IIIb/IV malaria
The Expert Editor, Australia	Freelance Editor and Scientific/Medical Editor for The Expert Editor Apr '16 – Jan '19	
UNSW Global Pty. Ltd., Australia	Chemistry Teacher and Demonstrator May '16 – Dec '18	
PAREXEL International, Australia	Clinical Monitoring Associate II Dec '11 – Oct '15	Global, phase III Alzheimer's disease
Datapharm Australia Pty. Ltd., Australia	Medical Writer/Clinical Research Associate Oct '10 – Nov '11	Global, phases I, II and III solid tumor cancers, rheumatoid arthritis, cosmetics, COPD, ulcerative colitis Regional, phases I, II and III solid tumor cancers, rheumatoid arthritis, cosmetics, COPD, ulcerative colitis

The University of New South Wales, Australia	Senior Research Officer and Conjoint Lecturer – Lowly Cancer Research Center Jan ‘05 – Oct ‘10
	Research Officer and Conjoint Lecturer - Centre for Vascular Research Jan ‘04 – Dec ‘04
Prince of Wales Hospital, Australia	Research Officer and Conjoint Lecturer UNSW– Diabetes Transplant Unit Jul ‘02 – Jan ‘04
University of Dundee, Ninewells Hospital and Medical School, United Kingdom	Postdoctoral Research Assistant – Department of Mellecular and Cellular Pathology Jan ‘00 – Dec ‘01
University of Sydney, Australia	Laboratory Demonstrator – Agricultural Chemistry Jan ‘95 – Dec ‘99

Name	Rosemarie PEREIRA
Position	Medical Writer
Qualifications	Graduate Diploma (Education), University of Adelaide, 2002 Ph.D. (Immunology), Australian National University, 1986 B.Sc. (First Class Hons) (Medical Microbiology), University of Malaya, 1981

Summary

Rosemarie has 15 years' experience in Clinical Research as Senior Clinical Research Associate from CNS, ICON Clinical Research, University of South Australia, Numico Research Australia Pty. Ltd. and as a free-lance clinical service (CRA and project manager) provider from her own company Synapse Research Connexions. She completed her Ph.D. in Immunology at the Australian National University and thereafter, she authored numerous scientific publications. She is experienced across a range of therapeutic areas including autoimmune, dermatology, ENT, genetic disorders, immunology, infectious diseases, neurology, oncology, ophthalmology, paediatrics, reproductive, nutrition, respiratory and hepatology. She is additionally experienced as Project Manager for a paediatric allergy study. Rosemarie's rich clinical research experience coupled with her excellent scientific writing skills make her a valuable addition to the wider Novotech group.

Key Experience and Skills

- Phases I – III
- Therapeutic areas: autoimmune (rheumatoid arthritis, psoriatic arthritis, ulcerative colitis); dermatology (atopic dermatitis, psoriatic arthritis); ENT (chronic sinusitis); genetic disorders (mucopolysaccharidosis IIIa); immunology (paediatric allergy); infectious diseases (meningitis B, RSV, rotavirus, human immunodeficiency virus, antibiotic resistant *Staphylococcus aureus* in chronic sinusitis); musculoskeletal (tourniquet-induced sarcopenia in total knee arthroplasty); neurology (epilepsy, MPS IIIa, autism); oncology (metastatic non-small cell lung cancer, human papilloma virus-associated cancers); ophthalmology (geographic atrophy, primary open angle glaucoma, macular atrophy, vision loss associated with Stargardt's disease); reproductive (contraception); respiratory (bronchiectasis, idiopathic pulmonary fibrosis/interstitial lung disease); transplant (renal); vaccine (meningitis B, respiratory syncytial virus); nutrition (addressing malnutrition with colostrum); pediatric (meningitis B, RSV, rotavirus, pediatric allergy, MPS IIIa), hepatology (non-alcoholic steatohepatitis)
- Regions: ANZ (Australia), Asia (Indonesia, Sri Lanka)
- eDC systems: Medidata RAVE, ClinCapture, Merge (eCos), Oracle Clinical, Datalabs
- Rosemarie is a highly motivated individual who excels in her research work and at the same time, enjoys new challenges to improve her skills.
- Rosemarie has strong interpersonal and communication skills which allow her to interact well with her colleagues and maintain professional relationships.
- Language proficiency: English, French, Bahasa Malaysia/Bahasa Indonesia

Publications

- **Pereira R** and Simmons A (2001) Cutting Edge: A natural killer complex linked locus governs acute versus latent herpes simplex virus infection of neurons. **J Immunol** 166:5869-73
- **Pereira, R.**, Simon, M., Simmons, A. (2000): *Granzyme A, a non-cytolytic component of CD8+ T cell granules, restricts the spread of herpes simplex virus in the peripheral nervous systems of*

experimentally infected mice. **J Virol.** 74: 1029-1032.

- **Pereira, R.** and Simmons, A. (1999): *Cell surface expression of H-2 antigens on primary sensory neurons in response to acute but not latent herpes simplex virus infection in vivo.* **J Virol.** 73: 6484-6489.
- **Pereira, R.**, Tscharke, DC., Simmons, A. (1994): *Up-regulation of class I MHC gene expression in primary sensory neurons, satellite cells and Schwann cells of mice in response to acute but not latent HSV infection in vivo*. **J Exp Med.** 180: 841-850.

Presentations

- 25th International Herpesvirus Workshop, Portland, Oregon, USA (July 2000): **Oral presentation** and poster entitled "Induction of neuronal Class I MHC expression by replication impaired strains of HSV-1"; **Oral presentation** and poster entitled "Rhs-1: A novel genetic locus proximal to Ly55 and CMV-1, influences the magnitude of acute and latent herpes simplex virus infection of the nervous system"; Poster entitled "Granzyme A is an essential downstream effector molecule for perforin dependent clearance of herpes simplex virus from sensory nerve ganglia"
- 23rd International Herpesvirus Workshop, York, U.K (July 1998): **Oral presentation** and poster entitled "Granzyme A, a non-cytolytic component of CD8+ -cell granules, influences the severity of herpes simplex in the nervous system"; **Oral presentation** and poster entitled "Mice in which the delta T-cell receptor chain is disrupted fail to clear herpes simplex virus from the nervous system"; Poster entitled "Cultured satellite cells are non-permissive for HSV replication"
- 22nd International Herpesvirus Workshop, University of San Diego, La Jolla, California, USA (July 1997): **Oral** presentation and poster entitled "Cell-surface expression of H-2 antigens on primary sensory neurons in response to acute but not latent Herpes Simplex Virus infection in vivo"
- V International Conference on AIDS, Montreal, Canada (1989): **Oral presentation** entitled "Susceptibility of immature CD3-4-8- thymocytes to HIV infection"
  Valentin H, Nugeyre M-T, Vuillier F, Boumsell L, Schmid M, Barre-Sinoussi F, **Pereira RA**. (1994). Two subpopulations of human triple-negative thymic cells are susceptible to infection by human immunodeficiency virus type 1 in vitro. **J Virol.** 68: 3041-50.

Achievements/Awards

- Recipient, start-up grant (USD 250,000) from Sealy Foundation, University of Texas Medical Branch
- Recipient, NHMRC grant (AUD 225,000) for study: *Molecular Anatomy of the Host Response to a Neurotropic Viral Infection: Herpes simplex*
- Recipient, French Government Fellowship
- Recipient, ANU Ph.D. scholarship

Study Experience:

Company	Role	Study
CNS-Novotech, Australia	Medical Writer Nov '19 – Present	• Support in creation and delivery of high-quality study documents for clients including development of study protocols and clinical study reports (Phase I/1b, II and III) • Current - create Clinical Study Report for studies on atopic dermatitis, macular atrophy and vision loss associated with Stargardt's disease type I, post-surgery recovery from total knee arthroplasty, non-alcoholic steatohepatitis and autism spectrum disorder • Current - create protocol for study on idiopathic pulmonary fibrosis/interstitial lung disease
CNS, Australia	Senior Clinical Research Associate Sep '15 – Nov '19	Global, phase III rheumatoid arthritis Global, phase III psoriatic arthritis Global, phase IIb ulcerative colitis Local, phase I (FIH) chronic sinusitis Global, phase I/II MPS IIIa Global, phase III paediatric allergy Global, phase II and III meningitis B Global, phase II and III RSV Local sponsor, Indonesian sites (10), phase III rotavirus G/R/L, phase I (FIH) antibiotic resistant S. aureus in chronic sinusitis ANZ, phase II total knee arthroplasty Global, phase Ib epilepsy Global, phase IIb metastatic NSCLC Global, phase I/Ib HPV-associated cancers G/R/L, phase II geographic atrophy Local, phase I (FIH) primary open angle glaucoma Local, phase I contraception Global, phase III bronchiectasis Global, phase III renal transplant Local sponsor, Sri Lankan site, phase III malnutrition
ICON Clinical Research, Australia	Senior Clinical Research Associate Apr '13 – May '14	
Synapse Research Connexions, Australia	Private Clinical Research Consultant/Director Jul '07 – Oct '12 Regional, phase III infant formula for allergy prevention (PM and SCRA, 6 sites)	
Centre for Pharmaceutical Research, University of South Australia, Australia	Senior Clinical Research Associate Jan '07 – Jun '07	Local, phase I contraceptive study Numico liaison for Australia for Global, phase III trial of a clinical nutritional supplement for HIV patients

Numico Research Australia Pty. Ltd., Australia	Research and Vaccine Manager Mar '04 – Dec '06	Global, phase II nutritional supplement for HIV patients – worked as part of the Numico Netherlands team in concept development, Product Information Brochure and Protocol development Global, phase III clinical nutritional supplement for HIV patients study – worked as part of the Numico Netherlands team in preparation of Product Information Brochure and protocol development; recruited participating sites in Australia, assist with start-up activities including IP import license, source and set up links with local contract researchers Phase III Infant formula with bovine antibodies to rotavirus study: Local (supervise product development, manufacture and testing; study set up - protocol writing, paper CRF generation; write CSR); Indonesia – set up (including staff training, supervision of translation of study documents) and manage (project management and monitoring)
Department of Paediatrics and Sealy Centre for Vaccine Development, University of Texas Medical Branch, USA	Assistant Professor and Scientist Jan '01 – Dec '01	
Division of Infectious Diseases, Children's Hospital Medical Centre, USA	Visiting Fellow Aug '00 – Jan '01	
Institute of Medical and Veterinary Science, Australia	Senior Research Officer Jan '90 – Jul '00	
Pasteur Institute, France	Post-Doctoral Fellow Aug '88 – Nov '89	
Institute of Medical and Veterinary Science, Australia	Research Officer May '86 – Aug '88	

Name	Padmakala MUNJAMPALLY
Position	Medical Writer
Qualifications	MSc. (Medical Microbiology), Middlesex University, 2010 BTech. (Biotechnology), Jawaharlal Nehru Technological University, 2009

Summary

Padma has over 9 years' experience in Clinical Research as Medical Writer. Padma graduated with a degree of Bachelor of Technology in Biotechnology from Jawaharlal Nehru Technological University in 2009 and obtained her Master of Science in Medical Microbiology from Middlesex University in United Kingdom in 2010. She started her career as a Laboratory Assistant at Middlesex University where she developed further her scientific writing. Before joining Novotech, she held the positions of Medical Writer and Senior Medical Writer with MaKroCare Clinical Research Organization and Medical Writer II with Novartis Healthcare. Padma has worked across a range of therapeutic areas including infectious disease, ophthalmology, neurology, psychiatry, respiratory, immunology, oncology, endocrinology, dermatology, rheumatology, gastroenterology, cardiology and women's healthcare. She is additionally experienced in regulatory writing. Padma's competencies in literature review, scientific data analysis, summarization of complex data and excellent verbal and written communication skills make her a valued addition to the team.

Key Experience and Skills

- Phases I – IV
- Therapeutic areas: infectious disease, ophthalmology, neurology (acute ischemic stroke), allergology, respiratory, cardiovascular (coronary artery disease), psychiatry (treatment-resistant depression), endocrinology, oncology (advanced solid tumors, brain metastases, non-small cell lung cancer, cervical high grade squamous intraepithelial lesions, triple negative breast cancer, relapsed or refractory lymphoma, primary HCC), dermatology (mild to moderate atopic dermatitis, hidradenitis suppurativa), women's healthcare, gastroenterology (non-alcoholic fatty liver disease and non-alcoholic steatohepatitis), rheumatology (relapsing-remitting multiple sclerosis)
- Regions: ANZ (Australia), Asia (India, China, Japan, Indonesia, Taiwan, South Korea, Thailand, Singapore), Africa (South Africa,), Europe (United Kingdom, Germany, UAE, Switzerland), North America (United States, Canada,), South America (Brazil)
- Padma is highly motivated and has good interpersonal and communication skills which has allowed her to develop strong working relationships with her project teams and clients '
- Padma thrives on expanding her knowledge and is always keen to take on opportunities to share her expertise with teams which she is a part of

Publications

- Published white paper as newsletter in MakroCare NL and MakroCare portal on "Radio Frequency Identification (RFID) in Pharmaceuticals"

Other Education

- Certification on Basic Program in Pharmaceutical Program (PPM) – Novartis Healthcare Pvt. Ltd.
- Certification on GCP Accreditation Test based on E6 Guidelines – I5 Clinical Research Pvt. Ltd.

Achievements/Awards

- Recipient, Novartis "Applause" Award in 2016 in recognition of delivering document with good quality, effective collaboration and great teamwork
- Recipient, "You Extra Miller" and "You Rookie" in 2014 and 2013, respectively, for delivering good work more than that was expected and timely delivery.
- 2009 Merit Scholarship Award from Middlesex University
- Winner-Paper Presentation 2nd, Bachelor of Technology at NIT Warangal.
- Winner-Paper Presentation 1st, Bachelor of Technology at Vaagdevi College of Engineering.

Study Experience:

Company	Role	Study
Novotech, India	Medical Writer Aug '19 – Present	Authoring and review of Protocols: Local, phase I healthy volunteers Regional, phase I advanced solid tumors Local, phase I mild to moderate atopic dermatitis Regional, phase II brain metastases secondary to non-small cell lung cancer Authoring and reviewing of CSRs: Local, phase I healthy volunteers Local, phase I triple negative breast cancer Regional, phase I cervical high grade squamous intraepithelial lesions Authoring Clinical Summaries for CTD (2.5 and 2.7): Local, phase I healthy volunteers Authoring and reviewing of DSURs: Global, phase I advanced solid tumors Local, phase I relapsed or refractory lymphoma Local, phase I refractory patients with primary HCC or tumors to the liver Local, phase II acute ischemic stroke
Novartis Healthcare Pvt. Ltd., India	Medical Writer II Sep '15 – Jul '19	Authoring and review of Protocols: Global, phase I healthy volunteers Global, phase I non-alcoholic fatty liver disease and non-alcoholic steatohepatitis Local, phase I atopic dermatitis Global, phase I hidradenitis suppurative Local, phase I advanced solid tumors Local, phase II atopic dermatitis Global, phase II hidradenitis suppurativa

		Local, phase II relapsing-remitting multiple sclerosis Local, phase II non-small cell lung cancer Authoring and reviewing of CSRs: Global, phase I healthy volunteers Local, phase I breast cancer Local, phase I advanced solid tumors Local, phase I atopic dermatitis Global, phase II hidradenitis suppurativa Local, phase II relapsing-remitting multiple sclerosis Local, phase II coronary artery disease Local, phase II non-small cell lung cancer Local, phase II atopic dermatitis Global, phase III treatment-resistant depression Authoring and reviewing Clinical Summaries for CTD (2.5 and 2.7); DSURs and RMPs of the investigational products for global, regional and local phase I – II studies
MakroCare Clinical Research Organisation, India	Senior Medical Writer May '14 – Aug '15	Authoring and review of Protocols, CSRs and IBs for regional and local phase I – III studies in healthy volunteers and across various therapeutic areas including local chronic obstructive pulmonary disease (COPD) study; global lung cancer study; local breast cancer and depression studies. Authoring and reviewing DSURs of the investigational products for global, regional and local phase I – II studies Development and review of PSURs and PBRERs, Addendum to clinical Overview (ACO) (United States and EMEA)
	Medical Writer May '11 – Apr '14	Authoring and review of Protocols, CSRs and IBs for regional and local phase III – IV studies across various therapeutic areas including ophthalmology, neurology, endocrinology, oncology, allergy, respiratory, and women health care Development and review of PSURs and PBRERs, Addendum to clinical Overview (ACO) (United States and EMEA) Preparation of core data sheet updates (CDS), patient information leaflets (PIL), responses to HA queries and different regulatory requests as per EMEA requirements
Middlesex University, United Kingdom	Laboratory Assistant Sep '09 – Dec '10	

Name	David SYLVESTER
Position	Medical Writer
Qualifications	MA. Medical Science (Drug Development), University of New South Wales Australia 2011 B.Arts. (English, Text and Writing), University of Western Sydney, 2006

Summary

David is an experienced clinical research professional who has acquired 12 years working with both CRO and Sponsor organisations across Australia, New Zealand and Europe.
In his previous roles working for a US Biotech, David researched and presented his recommendations for study design and feasibility and, following input from the wider study team, was responsible for taking the study outline forward to complete all protocol development activities. He also prepared protocol amendments, master informed consent forms, and clinical study reports.
David has comprehensive experience in drafting of protocols for early phase studies as well as a contributor to phase III protocols, coordinating the input of medical, regulatory, legal, clinical, statisticians, and overseeing the review and approval process. Moreover, he is experienced in production of protocol amendments, master informed consent forms, and clinical study reports and he has broad experience in the drafting and writing of other clinical documents. David has gained exposure to a multitude of therapeutic areas including oncology, infectious diseases, respiratory, haematology, inflammatory diseases, and endocrinology. He is additionally experienced on First In Human studies, patient studies, and vaccines.
David's indepth medical writing experience coupled with his versatility and passion in clinical research make him a valuable asset to the wider Novotech group.

Key Experience and Skills

- Phases I - III
- Therapeutic areas: oncology (lung cancer, breast cancer, NSCLC, solid tumours, RCC, HCC), haematology (cutaneous T cell lymphoma, chronic lymphocytic leukemia), immunology (flu vaccine), endocrinology (diabetes – type II, obesity), infectious diseases (candidemia, acinetobacter, ABSSSI, complicated UTI, carbapenem-resistant Enterobacteriaceae), rheumatology (rheumatoid arthritis), respiratory & allergy (COPD)
- Regions: ANZ (Australia, New Zealand), Europe (Germany)
- Clinical Project Manager for studies in the therapy area of infectious diseases.
- Sole country representative and Lead CRA for phase I studies conducted in Australia and New Zealand.
- David is a good problem solver and a results-oriented person with good communication skills allowing him to interact well with team members coming from different backgrounds.
- David is an enthusiastic individual who is passionate about his craft and enjoys a good challenge at work to improve his skills.

Achievements

- Completed startup, initiation, recruitment, and monitoring for a phase I study within six months, ahead of the other trials in the program reaching initiation.
- Authored and oversaw review and approval of a protocol amendment and identified additional sites for a study that was falling behind on recruitment.

Publications

- **Sylvester, D.** (2016) "Interference of Oritavancin on Coagulation Tests as Assessed In Vitro and in a Phase 1 Study of Normal Healthy Volunteers." Open Forum Infectious Diseases, Volume 3, Issue suppl_1, 1 December 2016, 1807, https://doi.org/10.1093/ofid/ofw172.1355

Study Experience:

Company	Role	Study
Novotech, Australia	Medical Writer Dec '19 – Present	• Drafting protocols for phase I studies • Providing input and review of phase III protocols • Drafting protocol synopses based on a high-level study outlines, and drafting the body of protocols by coordinating the input of medical, regulatory, legal, clinical, statisticians, and overseeing the review and approvals processes • Drafting other study documents including monitoring plans, quality plans, pharmacy manuals, PK and laboratory manuals, master patient information sheets and informed consent forms. Maintaining version control and coordinating the review process through to final version • Drafting interim and final CSRs and coordinating the review process through to final version, including collation of appendices, tables and listings
	Senior Clinical Research Associate Oct '18 – Nov '19	Regional, phase III candidemia Local, phase I/IIa solid tumors (Lead CRA, 1 site) Regional, phase I RCC & HCC (Lead CRA) Regional, phase I solid tumours
The Medicines Company,	Clinical Project Manager/CRA Sep '13 – Apr '18	Regional, phase I nosocomial infection (PM, 2 sites) Regional, phase I Acinetobacter (Lead CRA, 1 site) Regional, phase I ABSSSI (Lead CRA, 1 site) Global, phase III serious infections Global, phase III complicated UTI Local, phase I carbapenem-resistant Enterobacteriaceae
Novartis Vaccines and Diagnostics Pty Ltd	Clinical Research Associate Feb '13 – Aug '13	Global, phase III flu vaccine (paediatric)
Novo Nordisk Pty Ltd,	Clinical Research Associate May '12 – Feb '13	Global, phase III obesity Global, phase III diabetes type 2
Quintiles Pty Ltd,	Clinical Research Associate	Global, phase III lung cancer GLOBAL, PHASE III CHRONIC OBSTRUCTIVE PULMONARY DISEASE

	Apr ’11 – Apr ‘12	Global, phase III rheumatoid arthritis
Clinical Research Consultants (Biocryst Pharmaceuticals)	Clinical Research Associate May ’08 – Apr’11	Global, phase III cutaneous T cell lymphoma Global, phase III chronic lymphocytic leukemia
Clinical Research Consultants (Pierre Fabre Medicament Australasia)	Clinical Research Associate May ’07 – May’08	Global, phase III breast cancer Global, phase III NSCLC

Name	Gayatri PANSE
Position	Medical Writer
Qualifications	MSc (First Class with Distinction) (Bioinformatics), Sikkim Manipal University of Health, Medical Technological Sciences, 2008 BSc (First Class) (Microbiology), University of Pune, 2006

Summary

Gayatri has over 7 years' experience in Clinical Research as Clinical Research Associate with Evolvus Research and Medical Writer with Sciformix Technologies. Gayatri has worked across a range of therapeutic areas including infectious diseases, metabolic disorders, ophthalmology, cardiology, obstetrics and gynecology, and oncology, and is additionally experienced in identifying appropriate journals for manuscript submission as well as giving support to manuscript submission. She has authored common technical modules including clinical/nonclinical overviews and summaries and major global responses to queries of healthcare providers. Gayatri's time-conscious coupled with her result-oriented attitude and good analytical abilities make her a valued addition to the team.

Key Experience and Skills

- Phases I – III, preclinical
- Therapeutic areas: infectious diseases (influenza), metabolic disorders (type 1 and 2 diabetes mellitus), oncology (prostate cancer), ophthalmology (glaucoma), cardiovascular disorders (hypertension), obstetrics and gynecology (miscarriages), neurology (vertigo)
- Regions: ANZ (Australia), Asia (India), Europe, North America (USA, Canada),
- Gayatri is time conscious and result-oriented.
- Gayatri is able to evaluate information quickly, identify key issues and formulate conclusions based on sound, practical judgment, experience, and common sense.
- Language proficiency: English, Hindi, Marathi

Study Experience:

Company	Role	Study
Novotech, Australia	Medical Writer Jul '20 – Present	
Toll/Probe, Australia	Escalation and Support Customer Service Representative (Logistics) May '17 – Jun '20	
Sciformix Technologies Pvt Ltd, India	Medical Writier May '12 – Jan '17	Global, phase III prostate cancer Regional, observational vertigo, recurrent miscarriages, hypertension Local, phase II type 2 diabetes mellitus Local, phase II type 2 influenza

Evolvus Research, India	Clinical Research Associate Aug '08 – Nov '11	• Analyzed and updated information related to regulatory authority's (US FDA, EMA, MHRA, TGA etc) decisions before and after approval of the drugs • Worked on a prescription pharmaceutical intelligence tool to track development of prescription drugs from preclinical to post marketing studies • Extensive search for tracking abstracts, posters presented in various conferences by pharmaceutical companies • Worked as a Team Leader on a project on classification of pharmaceuticals as per their licensing history; train new team members

Name	Sandra KENT
Position	Medical Writer
Qualifications	MSc (Biopharmaceuticals), King's College London, 2011 Graduate Certificate (Drug Development), University of New South Wales, 2004 BSc (Biology), University of Sydney, 2000

Summary

Sandra has over 10 years' experience in Clinical Research as Research Assistant – Writer with University of Technology Sydney, Clinical Research Scientist with GSK, Clinical Research Associate with Eli Lily, Clinical Study Coordinator with GSK, and Clinical Administrative Assistant with Johnson & Johnson. Sandra has worked across a range of therapeutic areas including oncology, respiratory, endocrinology, nephrology, psychiatry, urology and infectious disease. She is additionally experienced in early phase including first-in-human (FIH) clinical studies. Sandra's broad experience paired with her commitment to quality patient care make her a valued addition to the team.

Key Experience and Skills

- Phases I – IV, IIT
- Therapeutic areas: respiratory (asthma, allergic rhinitis, breathlessness, chronic obstructive pulmonary disease, cystic fibrosis, interstitial lung disease), oncology (malignant inoperable bowel obstruction, breast cancer), endocrinology (diabetes, dyslipidaemia), infectious disease (HIV), nephrology (uremic pruritus), psychiatry (anxiety), urology (erectile dysfunction)
- Regions: ANZ (Australia, New Zealand), Europe (Austria, France, Germany, The Netherlands, United Kingdom), Africa (South Africa), North America (USA), Middle East (Israel).
- Sandra demonstrates a positive cheerful attitude. She is always keen to take on opportunities to share her expertise with teams which she is a part of.
- Sandra can evaluate information quickly, identify key issues and formulate conclusions based on sound, practical judgment, experience, and common sense.
- Language proficiency: English, Maltese

Achievements

- Clinical Matrix Team contributor. Generated evidence to commit lead candidates to full protocol development. First Time in Human to Proof-of-concept clinical trials.
- Medical writer generating clinical trial documents including protocols and clinical study reports.
- Authored and published three manuscripts with 10 key opinion leaders (KOLs).
- Extensive clinical trials' lifecycle experience gained from world leading pharmaceutical companies.

Study Experience:

Company	Role	Study
Novotech, Australia	Medical Writer Jan '21 – Present	Global, phase I – IIb lymphoma
University of Technology Australia	Research Assistant – Writer 2019 – 2020	Global, phase III breathlessness/chronic obstructive pulmonary disease/interstitial lung disease Local, IIT uremic pruritus Local, IIT anxiety Local, IIT malignant inoperable bowel obstruction
Kent House	Head of House 2012 - 2018	
GlaxoSmithKline Plc, United Kingdom	Clinical Research Scientist 2007 – 2011	Global, phase I asthma Global, phase I allergic rhinitis Global, phase IIa asthma Global, phase IIa allergic rhinitis Global, phase IIa chronic obstructive pulmonary disease Global, phase IIb cystic fibrosis
Eli Lily & Co., United Kingdom	Clinical Research Associate 2005 – 2006	Regional, phase III diabetes Regional, phase III breast cancer
GlaxoSmithKline Pty., Ltd., Australia	Clinical Study Coordinator 2003 – 2005	Local, phase I asthma Local, phase IIa asthma Local, phase I dyslipidaemia Local, phase IIa dyslipidaemia Local, phase IV erectile dysfunction
Johnson & Johnson Research Pty., Ltd., Australia	Clinical Administrative Assistant 2001 – 2003	Global, phase IIb HIV

Name	Austin BARRON
Position	Quality Control Specialist
Qualifications	Grad. Cert. (Health Services Management), Monash University, 2020 BSc (Medical Laboratory Science), Royal Melbourne Institute of Technology (RMIT), 2003

Summary

Austin is a highly skilled professional with over 16 years' experience working as a Scientist in a diagnostic pathology setting, including three years' experience in quality liaison for external clinical trials. He has extensive quality control documentation experience, coupled with excellent time management, planning, and organisational skills which ensures his work is delivered on time and of consistent high quality. Austin works both collaboratively and autonomously to achieve organisational objectives and continuously participates in improvement of the current systems and processes in order to deliver better results for patients, clients, and his colleagues. Austin is a valued team member and has earned great respect from the team on his detailed review and feedback in improving the quality of their documentation.

Key Experience and Skills

- Phases I – III
- Therapeutic areas: oncology/haematology (FLT3 mutated acute myeloid leukaemia, multiple myeloma, breast cancer, lung cancer), immunology
- Regions: ANZ (Australia, New Zealand), Asia (China, Japan, Malaysia, Singapore, Taiwan, Thailand)
- eDC systems: Abbott Study Portal
- Austin has excellent communication and interpersonal skills. He has proven ability to build rapport with people of diverse cultures and strong relationships with internal and external stakeholders.
- Austin has strong analytical and problem-solving skills utilised in incident investigations, data analysis, risk assessments, and identifying process improvements.

Clinical Trial Task Exposure

- Monitoring Visits: SSV (7), SIV (4), IMV (9), COV (4)
- In-house Systems: Excel databases; Q-Pulse quality management system.
- Tasks involved with to date: Assisted with the management of Essential Documents (hardcopies), archiving of printed trial documentation, assist with preparation for SSV/SIV, audit preparation, pre-visit preparation, followed up on outstanding issues from previous visit report, post visit follow-up, review of Protocol deviations, reviewed training records, communication with EC for study start-up and close-out acknowledgments

Achievements/Awards

- Acted as the main Quality contact for sponsor pre-qualification visit for a phase III study in FLT3 mutated AML, resulting in successful qualification with no major findings
- Acted as the main Quality contact for sponsor led FDA-preparedness audit for several phase II and III studies in breast cancer

Study Experience:

Company	Role	Study
Novotech, Australia	QC Specialist Aug '20 – Present	• Responsible for independent, quality control review of core regulatory/clinical documents prepared by Medical Services & BioDesk teams • Ensuring compliance with all relevant applicable guidelines of regulatory authorities, and accuracy and consistency of documentation
Peter MacCallum Cancer Centre, Australia	Quality Manager Nov '17 – Feb '20	• Worked in a NATA ISO15189 and ISO/IEC 17025 compliant diagnostic pathology laboratory, overseeing, developing, and implementing the delivery of the Quality Management System • Contributed to the successful passing of NATA accreditation as well as a number of external audits of the quality system by clinical trial sponsors
Peter MacCallum Cancer Centre, Australia	Clinical Trial Quality Officer May '16 – Nov '17	Regional, phase III non-small-cell lung cancer Regional, phase III FLT3-mutated AML Regional, phase II Multiple Myeloma Regional, phase II/III breast cancer • Worked to develop, implement, and oversee the Quality Management System for the laboratory testing component of clinical trials in oncology patients, ensuring compliance with Good Laboratory Practice, GCP, and relevant legislation and regulations • Acted as the main contact for clinical trials quality matters, including external audits, reporting of non-conformances, and liaising with regulatory bodies
Peter MacCallum Cancer Centre, Australia	Grade 1 Medical Scientist Jan '04 – May '16	Worked in a NATA ISO15189 accredited diagnostic haematology laboratory providing a service to oncology patients. Excellent communication and interpersonal skills developed working as part of a multi-disciplinary team, building rapport and strong relationships with internal and external stakeholders from a variety of backgrounds.
Peter MacCallum Cancer Centre, Australia	Acting Grade 2 Cryopreservation Scientist Dec '14 – Sep '15	Worked in a Therapeutic Goods Administration (TGA) licensed Good Manufacturing Practices facility processing autologous HPC, products for oncology patients using aseptic techniques