
VICE-PRESIDENT, CNS DEVELOPMENT
Michael Gold, M.S., M.D.

EDUCATION

Post-Doctoral Fellowship, 1992-1994
Behavioral Neurology/Neuropsychology
University of Florida College of Medicine
Gainesville, FL

Neurology Residency, 1989-1992
Albert Einstein College of Medicine
Bronx Municipal Hospital/Montefiore Medical Center
Bronx, New York

Internship (Internal Medicine), 1988-1989
Mount Sinai Medical Center, Miami Beach, Florida

Medical Doctor, 1984-1988
University of Miami School of Medicine
Jackson Memorial Medical Center/VAMC
Miami, Florida

M.S. Mathematics/Computer Science
B.S. (cum laude) Chemistry, 1978-1984
University of Miami and University of Miami Graduate School
Coral Gables, Florida

THERAPEUTIC EXPERIENCE

Neurological Disorders: Alzheimer's Disease, Parkinson Disease, Progressive Supranuclear Palsy, Corticobasal Degeneration, Frontotemporal Degeneration, Vascular Cognitive Impairment and Dementia, Lewy-body Dementia, Traumatic Brain Injury, Ischemic Stroke, Spinal Cord Injury Multiple Sclerosis, Restless Leg Syndrome, Epilepsy, Migraine, Neuropathic Pain, Motor Neuron Diseases
Psychiatric Disorders: Anxiety, Depression, Schizophrenia, Cognitive impairment associated with Schizophrenia
Musculoskeletal: Rheumatoid Arthritis, Osteoarthritis
Clinical trial methodology: Phase 1-3 study designs, multi-center, multi-national trials, adaptive designs, translational designs, digital sensors/wearables, Neuropharmacology

PROFESSIONAL EXPERIENCE

AbbVie, North Chicago IL

Vice-president CNS, May 2017-present

- Responsible for the development, maintenance and implementation of the global Neuroscience Therapeutic Area strategy across all stages of drug development including indication selection, clinical development strategies business development activities, staffing and funding
- Accountable for the recruitment, development and retention of physicians, scientists, and support staff for the therapeutic area (now approximately 40 people)
- Responsible for collaboration and joint decision-taking with discovery, commercial and business development partners as part of the design and execution of the CNS Therapeutic Area strategy
- Accountable (as chair of the TA Protocol Review Committee) for the quality of clinical trial designs put forward by this therapeutic area.
- Accountable (as co-chair of the TA Strategy Committee) for the quality of clinical development strategies and plans put forward for funding by asset teams
- Responsible for fomenting innovation in terms of clinical trial methodology, continuous improvement in terms of basic and clinical neuroscience and patient-centric thinking across all stages of development
- Member of the Development Review Committee and responsible for contributing to the review and endorsement of clinical development strategies across various therapeutic areas
- Member of Joint Steering committees for research collaborations with partner companies (e.g. Alector and Calico)
- Accountable for the completion of the integration of legacy Allergan Neuroscience (compounds and people) into AbbVie

PPD, Morrisville NC

Vice-president, Neurosciences July 2015- May 2017

- Responsible for the implementation of portions the CNS TAST Strategy related to clinical expertise and capacity with a primary focus in the area of neurodegeneration
- Responsible for providing clinical expertise, clinical trial methodology expertise to clients and support to project teams during the RFP/RFI process in terms of clinical neurology, clinical trial methodology, clinical development strategy etc.
- Responsible for collaborating with PPD's strategic partners and the internal teams supporting these partners to ensure the delivery of high quality clinical trials
- Responsible for representing PPD in interactions with partners and stakeholders in the CNS space

UCB Biosciences, Raleigh NC

Vice-president & Head, CNS Practice Jan 2013- June 2015

- Accountable for supporting all CNS clinical development programs from Proof-of-Concept forward through the provision of clinical and drug development staff and expertise to project teams across various divisions of UCB
- Accountable for the scientific integrity of all clinical development plans, protocols, and publications
- Accountable for the acquisition, retention and development of key talent including physicians and clinical program directors based in the US and in Germany with a specific focus on clinical neuroscience, drug development and cross-functional team skills.
- Accountable for the deployment of clinical development staff to various project teams and ensuring an appropriate match in terms of skill-sets, strategic value and career development needs

- Jointly accountable with the heads of CNS New Medicines for developing, implementing and tracking progress against a UCB-wide Neuroscience strategy
- Jointly accountable with the leadership of CNS New Medicines and Business Development for the evaluation, prioritization and internal championing of in-licensing/acquisition opportunities
- Jointly accountable with the leadership of the Vimpat, Keppra and Brivaracetam teams for the development of innovative patient-centered development strategies in Epilepsy
- Jointly accountable with the leader of the Neupro team with the development of a unique patient-centered strategy in Movement Disorders
- Member of the BioDev Leadership team and responsible for helping craft and implementing UCB corporate objectives and processes in the R&D organization
- Member of the Benefit-Risk Board and responsible for evaluating the benefit risk:profile of all compounds being developed or sold by UCB
- Standing member of the Global Labeling Committee and responsible for ensuring that all UCB product labeling is compliant with applicable regulations in all jurisdictions

Allon Therapeutics, Vancouver BC

*Vice-president and Chief Medical Officer
March 2011- December 2012 [Company liquidated in 2013]*

- Accountable for all clinical studies from a medical, scientific, regulatory and pharmacovigilance perspective with a specific focus on the development of AL-108 for Alzheimer's Disease and Progressive Supranuclear Palsy
- Member of the executive leadership team and responsible for developing and executing plans against corporate objectives
- Responsible for liaising with independent data safety monitoring and study steering committees overseeing clinical trials in AD and PSP
- Accountable for the development and training of staff with regards to drug development
- Accountable for the orderly shut-down of all clinical activities post failure of AL-108, disposition of clinical trial data and samples and completion of the submission of a manuscript reporting the failed trial (see publications)

GlaxoSmithKline RTP, NC

*Vice-President, Neurosciences MDC
January- 2005-March-2011*

Medicines Development Leader, Alzheimer's Disease

March 2008- March 2011

- Accountable for all aspects of the execution of the clinical development plans for several assets in the area of Alzheimer's Disease, including pre-clinical, clinical, operational, regulatory, commercial, manufacturing, and biometric functions on a global basis.
- Accountable for the delivery of Rosiglitazone clinical trial within to agreed-upon budgets (project budget in excess of 60M £) staffing levels (project team encompasses ~ 40 FTEs) and timelines.
- Accountable for the selection, development, mentoring and evaluation of a global core leadership team to manage the development program for each compound

- Accountable to senior management for all decisions regarding the execution of the development plans for these compounds.
- Accountable for all interactions with regulatory authorities related to these compounds.
- Chair of the NS-MDC Protocol Review Forum and charged with ensuring the overall scientific integrity of protocols being developed (through 2009)
- Co-chair of the Neurodegeneration Working group and charged with the development of an R&D-wide strategy for the discovery and development of treatments for neurodegenerative disorders
- Member of the NS-MDC Leadership team and charged with supporting the administrative and managerial aspects of running the organization
- Continued support for drug discovery partners within GSK (i.e. NS-CEDD, Biopharmaceuticals, Vaccines) that have programs of with potential neuroscience applications
- Continued support for business development partners in the identification, evaluation and alliance management of external companies.

Therapeutic Area Head, Neurology and Analgesia

January 2005- March 2008

- Accountable for the quality, scientific integrity and medical governance of all Phase II through IV clinical studies for all neurological indications, including both strategic and tactical approaches in support of global registration and commercialization.
- Accountable for the development and maintenance of clinical development strategies for novel compounds in collaboration with appropriate stakeholders.
- Accountable for the development and provision of clinical perspectives, development strategies and expertise in support of business development opportunities on a global and regional basis
- Accountable for the development and delivery of regional clinical plans and studies in support of marketed compounds
- Accountable for the development, training and recruitment of clinical research staff
- Accountability for Budgets for clinical program(s) within the CNS Therapeutic Area

These accountabilities were accomplished through the following roles and activities:

- Membership on Medicine Development Matrix in role of Medical Leader
- Final arbitrator of issues related to the development of therapeutic strategies and the target product profiles for all stages of development
- Ensure integration of regional clinical strategies into a common global approach
- Manage appropriate representation and allocation of responsibilities between Regional Therapeutic Heads and/or other Regional program heads.
- Serve as clinical MDC point focus of contact for issues relating to labeling committee and Global Safety Board.
- Development and appointment of Clinical Leaders and Global Study Leaders to optimize each project
- Leading and motivating MDC clinical staff and provide supervision of clinical in the planning and coordination for projects.
- Chair MDC protocol review forum and represent MDC on cross-MDC protocol review committees.
- Participation in Centers of Excellence for Drug Discovery (CEDD) matrix or ensure appropriate matrix representation
- Creation of a clinical forum for the application of best clinical practice across the MDC's.

J&J Pharmaceutical R&D, Titusville NJ

Senior Director July 2001- December 2004

Compound Development Team Leader (Galantamine) January 2003 - December 2004

- Led a cross-functional team responsible for all aspects of drug development and compound support including clinical, medical affairs, operational, regulatory, commercial, manufacturing and clinical pharmacology for Reminyl.
- Responsible for the mentoring and the professional development of physicians and scientists.

Clinical Leader

- Responsible for the medical oversight of multiple clinical trials, including review of safety data and adherence to GCP principles, global regulatory guidelines and safety reporting.
- Responsible for the medical input, review, and approval of Investigator's Brochures, clinical study reports, integrated summaries, and other clinical documents for regulatory submission including analysis plans and report shells in accordance with established processes and timelines.
- Responsible for the development of clinical plans and other materials and communicating key clinical assumptions, risks and mitigation strategies to senior management. Provision of high quality, timely medical input into sections of key planning documents relevant to area of responsibility including clinical functional plan, operational planning documents etc. from both internal and external functional groups.
- Accountable for ensuring projects met timelines and milestones, agreed-upon deliverables and were of superlative quality.
- Participated in a strategic development team in the area of neurodegenerative disorders that evaluated external opportunities for potential licensing and collaborating with internal partners/sister companies in the evaluation of novel compounds or technologies.
- Responsible for maintaining scientific expertise in therapeutic area concordant with current knowledge and practice

Director July 2001- January 2003

- Leadership of a cross-functional team of drug discovery, clinical, commercial and regulatory experts charged with identifying new opportunities in the area of neurodegenerative disorders from pre-clinical targets, candidate molecules to drugs at various stages of development.
- Strategic, scientific and clinical guidance to drug discovery groups at multiple sites in order to align them with the goals and priorities of the CNS franchise.
- Streamlining and expediting of pre-clinical development and facilitation of entry of novel compounds into man through the implementation of original paradigms, use of innovative biomarkers or novel outcome instruments to provide proof-of-concept as well as to validate new instruments for use in full clinical development.
- Leadership of the early clinical (drug evaluation) development operation in order to align them with the franchise's requirements and priorities. Liaised with business development organizations in identifying new opportunities
- Collaborated with clinical experts within the CNS franchise to establish priorities and develop plans for the future development of the franchise. Responsible for the scientific integrity, conduct, and medical/safety supervision of two global phase III trials with an enrollment of over 2000 subjects.

BMS Lawrenceville, NJ
2001

Director, Clinical Pharm/Experimental Medicine July 1998 – June

- Accountable for the development and execution of clinical development plans as well as supervision of the team responsible for implementation of clinical trials ranging from first-in-man through pharmacological proof-of-concept.
- Accountable for the medical governance and the safety of subjects in multiple clinical trials within the clinical pharmacology/experimental medicine group.

- Responsible for the design, execution and medical supervision of supportive clinical pharmacology studies required for the successful registration of novel compounds including ADME, drug-drug interactions and formulation studies.
- Provision of neurological and clinical pharmacology expertise to licensing teams and participation in any due diligence processes related to licensing candidates in the neurosciences

PROFESSIONAL AFFILIATIONS

Member of the American Academy of Neurology

Member of the Scientific Advisory Boards for: CurePSP, Alzheimer's Disease Drug Discovery Foundation

Former member of Scientific Advisory Boards for: Treventis Inc. and Anavex Inc

Associate editor: Alzheimer's Disease.

Grant Proposal Reviewer: Alzheimer's Association, CurePSP, Association for Frontotemporal Degeneration, ADDF

Co-chair of the Cure PSP Research Roundtable

Industry representative for CPAD (Critical Path Initiative/Alzheimer's Disease): Term completed 2020

Industry representative (non-voting) to the FDA's CNS/PNS Advisory Committee

PUBLICATIONS AND PRESENTATIONS

Publications:

Book Chapters:

Gold M, Felsenstein KM, Molinoff PB. Treatment Approaches to Alzheimer's Disease. In: Molecular Mechanisms of Neurodegenerative Diseases. MF Chesselet ed. Humana Press NJ, 2001

Journal Articles:

Gold M, Amatniek J, Carrillo MC, Cedarbaum JM, Hendrix JA, Miller BB, Robillard JM, Rice JJ, Soares H, Tome MB, Tarnanas I, Vargas G, Bain LJ and Czaja SJ. Digital technologies as biomarkers, clinical outcomes assessment, and recruitment tools in Alzheimer's disease clinical trials. *Alzheimer's & Dementia: Translational Research & Clinical Interventions*. 2018;4 :234–242

Gold M. Phase II clinical trials of anti-amyloid β antibodies: When is enough, enough? *Alzheimer's Dement*. 2017; 3(3):402-409

Gold M, Gauthier-Campbell C, Morimoto BH (2016) Concomitant Medication Use in Progressive Supranuclear Palsy Clinical Trial Participants. *Ann Neurodegener Dis*. 2016; 1(4): 1017.

Gold M, Lorenzi S, Stewart AJ, Morimoto BH, Williams DR and Gozes I. Critical appraisal of the role of davunetide in the treatment of progressive supranuclear palsy. *Neuropsychiatric Disease and Treatment*. 2012;8:85-93.

Gold M, Alderton C, Zvartau-Hind M, Egginton S, Saunders AM, Irizarry M, Craft S, Landreth G, Linnamägi U and Sawchak S. Rosiglitazone Monotherapy in Mild-to-Moderate Alzheimer's Disease: Results from a Randomized, Double-Blind, Placebo-Controlled Phase III Study. *Dement Geriatr Cogn Disord*. 2010;30:131-146

Gold M. Study Design Factors and Patient Demographics and Their Effect on the Decline of Placebo-Treated Subjects in Randomized Clinical Trials in Alzheimer's Disease. *J Clin. Psychiatry* 2007;68:430-438

Gold M. Tau Therapeutics: The Promise and the Challenges. *Journal of Molecular Neuroscience*. 2002; 19: 331-334.

Gold M. The effects of naftidrofuryl in patients with vascular or mixed dementia. *Clinical Therapeutics*. 2000; 22(10):1251-2.

Gold M, VanDam D, Silliman S. An open-label trial of bromocriptine in non-fluent aphasics: Differential effects on word storage and retrieval. *Brain and Language*. 2000;74(2):141-156.

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Gold M, Rojiani A, Murtaugh FR. A 66-year old woman with rapidly progressive dementia and basal ganglia abnormalities. *Journal of Neuroimaging* 1997;7:171-175.

Gold M, Cimino C, Crawford F, Mullan M. Clinical and Neuropsychological Features of a patient with Chromosome 14-mediated Alzheimer's Disease JINS (abstract) 1997;3:46.

Gold M, Lightfoot LA, Hanth-Chisolm T. Hearing loss in a Memory Disorder Clinic population: A specially vulnerable population. *Archives of Neurology* 1996;53:922-928.

Gold M, Welker R. A relational database system for Memory Disorder Clinics. [abstract] CAMH, May 20, 1995, Miami, FL.

Gold M, Chen MC, Johnson K. Plasma and erythrocyte thiamine deficiency in patients with Alzheimer's Disease. *Archives of Neurology* 1995;52:1081-1086.

Gold M, Nadeau SE, Jacobs DH, Adair JC, Rothi LJG and Heilman KM. Adynamic Aphasia: A transcortical motor aphasia with defective semantic strategy formation. *Brain and Language* 1997;57:374-393.

Gold M, Adair JC, Jacobs DH and Heilman KM. Gerstmann's Syndrome: A model for body-centered spatial orientation. *Cortex* 1995;31: 267-283.

Gold M, Shuren J, Heilman KM. Proximal intentional neglect: A case study. *Journal of Neurology, Neurosurgery and Psychiatry* 1994;57:1395-1400.

Gold M, Adair JC, Jacobs DH, Heilman KM. Anosognosia for hemiplegia: An electrophysiological investigation of the feed-forward hypothesis. *Neurology*. 1994;44:1804-1808

Gold M, Rapin I. Non-Mendelian mitochondrial inheritance as a cause of progressive genetic hearing loss. *Int. J. of Pediatric Otolaryngology*. 1994;30:91-104

Gold M, Rapin I, Shanske S. Mitochondrial Genetics of Deafness. *Annals NY Acad Science*. 1991;630:301-302

Höglinger GU, Litvan I, Mendonca N, Wang D, Zheng H, Rendenbach-Mueller B, Lon HK, Jin Z, Fisseha N, Budur K, Gold M, Ryman D, Florian H and Arise Investigators. Safety and efficacy of tilavonemab in progressive supranuclear palsy: a phase 2, randomised, placebo-controlled trial. *Lancet Neurology*. 2021;20(3):182-192. doi: 10.1016/S1474-4422(20)30489-0

Conrado DJ, Burton J, Hill D, Willis B, Sinha V, Stone J, Coello N, Wang W, Chen D, Nicholas T, **Gold M**, Hartley E, Kern VD, Romero K; Alzheimer's Disease Neuroimaging Initiative; Critical Path for Alzheimer's Disease (CPAD). Hippocampal neuroimaging-informed clinical trial enrichment tool for amnesic mild cognitive impairment using open data. *Clin Pharmacol Ther*. 2020 Jan 3

Boxer AL, **Gold M**, Feldman H, Boeve BF, Dickinson SL, Fillit H, Ho C, Paul R, Pearlman R, Sutherland M, Verma A, Arneric SP, Alexander BM, Dickerson BC, Dorsey ER, Grossman M, Huey ED, Irizarry MC, Marks WJ, Masellis M, McFarland F, Niehoff D, Onyike CU, Paganoni S, Panzara MA, Rockwood K, Rohrer JD, Rosen H, Schuck RN, Soares HD, Tatton N. New directions in clinical trials for frontotemporal lobar degeneration: Methods and outcome measures. *Alzheimers Dement*. 2020 Jan;16(1):131-143. doi: 10.1016/j.jalz.2019.06.4956

Khachaturian AS, Hayden KM, Mielke MM, Tang Y, Lutz MW, Gold M, Kukull WA, Mohs R, Gauthier S, Molinuevo JL, Zetterberg H, Khachaturian ZS. New thinking about thinking, part two. Theoretical articles for Alzheimer's & Dementia. *Alzheimers Dement*. 2018 ;14(6):703-706

Bang J, Lobach IV, Lang AE, Grossman M, Knopman DS, Miller BL, Schneider LS, Doody RS, Lees A, Gold M, Morimoto BH, Boxer AL; AL-108-231 Investigators. Predicting disease progression in progressive supranuclear palsy in multicenter clinical trials. *Parkinsonism Relat Disord*. 2016;28;41-8

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Morimoto BH, Fox AW, Stewart AJ, Gold M. Davunetide: a review of safety and efficacy data with a focus on neurodegenerative diseases. *Expert Rev Clin Pharmacol*. 2013;6(5):483-502

Karantzoulis S, Novitski J, Gold M, Randolph C. The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS): Utility in Detection and Characterization of Mild Cognitive Impairment due to Alzheimer's Disease. *Arch Clin Neuropsychol*. 2013 PMID: 23867976

Morimoto BH, Schmechel D, Hirman J, Blackwell A, Keith J, Gold M. A double-blind, placebo-controlled, ascending-dose, randomized study to evaluate the safety, tolerability and effects on cognition of AL-108 after 12 weeks of intranasal administration in subjects with mild cognitive impairment. *Dement Geriatr Cogn Disord*. 2013;35(5-6):325-36.

Greenberg BD, Carrillo MC, Ryan JM, Gold M, Gallagher K, Grundman M, Berman RM, Ashwood T, Siemers ER. Improving Alzheimer's disease phase II clinical trials. *Alzheimer's & Dementia* - (2012) 1–11. doi:10.1016/j.jalz.2012.02.002

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Maher-Edwards G, Zvartau-Hind M, Hunter AJ, Gold M, Hopton G, Jacobs G, Davy M, Williams P. Double-Blind, Controlled Phase II Study of a 5-HT₆ Receptor Antagonist, SB-742457, in Alzheimer's Disease. *Curr Alzheimer Res*. 2010 ;7(5):374-85.

Irizarry MC, Webb DJ, Ali Z, Chizh,BA, Gold M, Kinrade FJ, Meisner PD, Blum D, Silver MT, Weil JG. Predictors of Placebo Response in Pooled Lamotrigine Neuropathic Pain Clinical Trials. *Clinical Journal of Pain*. 2009;25 (6):469-476.

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Crawford F, Abdullah L, Schinka J, Suo Z, Gold M, Duara R, Mullan M. Gender-specific association of the angiotensin converting enzyme with Alzheimer's Disease. *Neuroscience Letters* 2000;280(3); 215-219.

Crawford F, Freeman M, Abdullah L, Schinka J, Gold M, Duara R, Mullan M. No association between the NOS3 codon 298 polymorphism and Alzheimer's disease in a sample from the United States *Ann Neurology*. 2000;47(5):687

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Town T, Paris D, Fallin D, Duara R, Barker W, Gold M, Crawford F, Mullan M. The -491A/T apolipoprotein E promoter polymorphism association with Alzheimer's disease: independent risk and linkage disequilibrium with the known APOE polymorphism. *Neurosci Lett* 1998 14;252(2):95-8

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Triggs W, Gold M, Adair JC and Heilman KM. Intentional neglect following a parietal lobe lesion. *Neurology*. 1994;44:1164-1166.

Breier JJ, Adair JC, Gold M, Fennell EB, Gilmore RL and Heilman KM. Dissociation of anosognosia for hemiplegia and aphasia during left hemisphere anesthesia. *Neurology* 1994;45:65-67.

Adair JC, Gold M. Neurotoxicity of Acyclovir. *Southern Medical Journal* 1994;87:1227-1231.

Lightfoot LA, Hanth-Chisolm T, Gold M. Incidence of hearing loss in Patients Diagnosed with Alzheimer's Disease [abstract] ASHA, 1995.

Presentations:

(USF Department of Neurology unless otherwise noted)

February 1994	USF Department of Psychiatry "Neglect Syndromes"
April 1994	"Evaluation of Dementia"
October 1994	"Prion Dementias"
November 1994	USF Department of Psychiatry "Sub-Cortical Dementias: The role of frontal-striatal circuits"
April 1995	USF Department of Internal Medicine "Memory Lost and Found"
September 1995	"Neuronal Networks: Reverse Engineering of the Brain"
November 1995	"Agnosias: When what you see is not what you get"
April 1996	"Traumatic Brain Injury in the Elderly"
December 1996	"Research Update: Stochastic Models in Anomia"
April 1997	Family Practice Grand Rounds "Advances in the diagnosis of Alzheimer's Disease"
April 1997	Neurosurgery Grand Rounds "Cognitive Evaluation"
June 1997	VA Bay Pines Psychiatry Grand Rounds Update on Dementia and Diagnosis
September 1997	Aphasia: Development of current models
September 1997	Psychiatric Manifestations in Cognitive Disorders RCS 6408 Psychopathology Course (Graduate School)
November 1997	Apraxias: Current models and definitions
March 1998	Suncoast Hospital Grand Rounds

Dementia: The Basics

October 2011 University of North Carolina, Department of Neurology
Development of CNS Drugs, Why is it so tough?

November 2012 University of South Florida Department of Neurology
Davuntide: The Evolution of a New Therapy University of California, San Diego,

COMPUTER EXPERIENCE

Operating systems: Microsoft Windows, UNIX, Linux
Applications: MS Office Applications, R, SQL, Python

LANGUAGES

Native Tongue is English; Fluent in Spanish and proficient in German

CLINICAL TRIAL EXPERIENCE

Please see publication list for clinical trial experience

AUDIT EXPERIENCE

N/A

I have authored this document and confirm that the information is accurate and complete.

Signed:

Date: