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THERAPEUTIC and MANAGEMENT EXPERIENCE

Project & Program Management (since 2006) experience in Phases I-IV [4 Health Authority Approvals]:

- Clinical Develop Ops consultant for start-up providing strategy for trials and Quality at the program level. ClinOps: data review, monitoring activities, generating documents, data-driven decisions. Locked clinical database with vendor for the Ph2b in 2Q24. Both BIOS & DM facilitation for TLFs and subsequent required CSR. Guiding staff in Ph3 orphan drug (O.D.D.) complex trial.
- Contract (2021-24) as Clinical Program Director in Early Clinical Development (ECD). Collaborated in the development of TPPs and CDPs by generating scenario plans, high-level forecasting of timelines, assessing program-level feasibility, estimation and allocation of resource & budget, and development of strategies. Served as a primary consultant to senior-level colleagues. Accountable for meeting operational deliverables. Mentored primary leads of studies. Supported BD deals across portfolio for due diligence. Indications of AD and MS; CS-AKI; DKD; CD; PG. aGVHD (acute Graft vs Host Disease) for Ph 2 with direct communication and collaboration w/Mt. Sinai Consortium ("MAGIC") as part of immunoinflammatory portfolio.
- (2020) Phase 1b in Australia & New Zealand as sponsor ClinOps consultant lead on Rosacea trial, as well as develop internal quality program and SOPs to strategically position asset for future commercialization. Small US pharma-direct contract client
- (2020) eCOA Associate Director consultant ffor global IBS program (UC & CD studies) to improve data integrity & services from vendors for primary endpoints and to execute clinical tasks within Global Development Operations (GDO) department.
- (2017-2019) Global *rescue study* for SHIRE: enrolled, DBL & sNDA Submission: ***FDA approved Lialda expanded indication for Pediatrics 26Jul2020***. N=11 countries over 2 continents (~40 sites), as Sr. CPM managing ~20 external vendors (CRO, ePRO, IRT, DSMB, BIOS, DM, suppliers, etc.) and internal study team. Worked w/QA on *backlog of CAPAs to ensure appropriate documentation and follow-up for the sNDA and overall quality*. Managed Post-Trial Access (PTA), 2018 GDPR initiative, MHRA dossier, vendor & site audits; beta-tested over-monitoring program; CSR & Regulatory submissions.
- (2016) Ran Phase 1b for US emerging company in Alzheimer's Disease-2016- (8 clinical sites across Australia, with Australian vendors) and assisting in DDI study and the Phase 2 enabling program. Helped develop & maintain overall quality for start-up
- (2015) Assisting CEO and managing vendors for emerging CF biotech from CRO ID, selection, budgeting, protocol, monitoring & regulatory assistance for CTA to running FIH (HNV: SAD/MAD) at Phase 1 clinic in Canada (N=64 Healthy Volunteers)
- Global (US, UK & Canada) Cystic Fibrosis study for 0-24 month olds & 2-5 yr old study (w/LCI). Both recruiting subjects with specific genotyping/mutations. Managing 10 vendors total per study, as well as internal staff and needed PM tasks-VERTEX
- Primary responsibility for Clinical Operations with VP of ClinOps for a global Phase II Sickle Cell Disease trial: 50 SCD centers in US, Brazil, Argentina and Jamaica. Responsibilities were not limited to RegOps, Financials, site relationships. International CRO Group Heads: DM, Central Lab, Biostats, PVG, DMC, Crisis Review Committee (CRC)-adjudication for SCD pain crisis event. SSU such as legal collaboration for required documents. Non-CRO vendor management (3). Tools for IRT, PROs, etc. to simplify procs for site systems. Sponsor site staff representative at on-site qualifying visits and subsequent training at SIVs (e.g., Unblinded pharmacists trained in administration and pharmacy set-up (at times negotiating infusion time with Onc. Team) for infusion dosing. *Selexys Pharma's* Phase II results acquired by *Novartis* 4Q16 and ***FDA approved ADAKVEO 16Nov19: First-in-class targeted monoclonal antibody that binds to P-Selectin; reduces vaso-occlusive crises (VOCs)-16+ age***
- Primary responsibility of cardiovascular and cerebrovascular events preventative long-term study, at 50 US sites. Oversight of twin efficacy studies (~80 US sites/study; 1300 pts) for Gastric Ulcer prevention for those taking aspirin as part of prophylactic use for re-occurring event. All Phase III studies for an NDA submission for 2 different doses on the CV indication. Absorbed 2 other Sr. PM roles and worked directly with the COO, after CEO decisions. ***FDA finally approved YOSPRALA in Sept 2016***.
- Pivotal Osteoarthritis (~170 US sites for ~1140 pts) for NDA Submission partnered with *AstraZeneca* for both funding and commericialization ,***received and approved upon initial submission by FDA: VIMOVO approval 30 April***
- Twin Global Respiratory studies (IV-VENTOLIN HFA) ~60 US sites and 3 other regions for Rest of World (RoW), and management of International Study Managers and all vendors associated with a Phase IV trial for GSK from 18 month contract
- Prostate Cancer (IV-Avodart) (~30 US sites; for 1200 patients to randomize); majority of focus/time while at GSK-6 months
- OverActive Bladder (III) (~50 US & Canadian sites) contractually at GSK locking database shortly upon arrival-3 months
- Post-Operative Ileus (POI) in colon cancer and polypectomies (III)-US study *placed on clinical hold (CMC)* after start

Major Therapeutic Areas Managed and exposed to for exploration (i.e., Business Development & Target Product Profile efforts)**:**

Cardiology:CAD, CABG	Dermatology: Rosacea	GI: Chron's, UC, etc.	Hematology: Sickle Cell	Immunology: aGVHD
Endocrinology: AKI, etc	Neurology: AD, MS, etc	Oncology: Prostate, etc	Orthopedics: knee (OA)	Psychiatry: GAD, etc.
Rare:PyroGangrenosum	Respiratory: CF,non-CF	Rheumatology: RA	Transplants: BLT, etc.	Urology: OAB

Countries conducted Clinical trials within:

Argentina	Canada*	Ireland	New Zealand	Russia	South Africa
Australia*	Chile	Italy	Philippines	Serbia	Taiwan
Belgium	Denmark	Israel	Poland	Singapore	Ukraine
Brazil	France	Jamaica	Portugal	Slovakia	United Kingdom
Bulgaria	Germany	Netherlands	Romania	South Korea	United States

Clinical Trial Monitoring Indications and visit types (2002-2006**) Phases II-IV** (* for Oncology limitations)**:**

Adolescent Migraine	Irritable Bowel (IBS)	Oncology-Breast	SQV
Alzheimer's Disease	Osteoarthritis (OA)	Oncology-Esophagogastric	SIV
Chronic Kidney (CKD)	*Oncology-HNSCC	Parkinson's Disease	IMV
Depression	Oncology-NSCLC	Rheumatoid Arthritis	COV
Gastric Ulcer	Oncology-Urothelial	Sickle Cell Disease	Booster
Generalized Anxiety	Oncology- Lung Adenocarcinoma	Sleep Apnea	On-site Training

Other Professional Experience:

- Advisory Board member on a consultative basis for life science groups. Consultative services for CRO & site selection, etc.
- Assisted in generating Market Research Reports for medical devices & pharmaceuticals (approved and pre-market)-consultant
- Please also note experiences as a Clinical Psychologist: Familiar with all DSM-5 disorders and have presented workshops within academic, medical, and community settings. Worked in both private and public settings conducting psychotherapy.
- *See "Other Relevant Details"* ***at end of CV*** for variety of assessments administered & interpreted prior to writing reports for a variety of referrals sources (court evaluations, public schools, parents, etc.).

WORK EXPERIENCE

Scott Kelly Consulting, Inc. – *Principal Consultant*
Durham, North Carolina Jan
2013 – Current

- Program & Project Management, as well clinical research tasks requested for life science companies in clinical development and operations to prepare, conduct & complete clinical trials. Clients have included: Genentech (gRED), Esanex (Lilly Venture), Selexys Pharma (Novartis partnership), VERTEX, Cognition Therapeutics, Renovion, Botanix, SHIRE (now Takeda), Theravance Biopharma, Spyryx Biosciences and CSS (lone CRO). Advisory Board for industry providers, on as needed basis.
- Vendor Management; budget & timeline development and management; strategic engagement and execution; data review and analysis; trip & audit report reviews and any required follow-up documentation; clinical site identification, support and operationalization for study conduct/publication; QC & QA completions as needed; and oversight & input towards clients' goals
- Relationship development & management amongst project partners: internal and external stakeholders to achieve objectives
- Clients have included start-ups (e.g., Selexys & Renovion), as well as more established companies such as Vertex. I've been a consultant for sponsors who needed tasks as assets matured in their pipeline. *To date*, I have participated in 4 NDA approvals
- Monitoring experience prior to entering into Project Management in 2006 to have the site experience in both large, global Pharma (GSK, Roche/Genentech) and CRO (IQVIA) experiences as well as smaller, nimble pharmas (Selexys) and CROs (HDI) and their partners-so I have a breadth of exposure in different environments and at different places within the life cycle

Selexys Pharmaceuticals Corporation - *Clinical Trial Manager-functioned as A.D. (***N=7** *total staff)*
RTP, North Carolina branch for Clinical Operations (Headquartered in Oklahoma City, OK)
April 2013 – March 2015 [Note during this time period did not take on a client for SKC after established]

- Responsible for all clinical operational budget and flow for program projections & site needs for a file-ready Phase II Sickle Cell Disease (SCD) study for a monoclonal antibody (mAb) infusion study medication.
- *Work directly with the Sr. VP of Clinical Development daily, as well as function in back-up role as needed*; contributed and strategized with Sr. VP and COO in meeting company goals (Recruitment, Retention, Regulations, program milestones, etc.)
- Management of CRO/vendors in the US & Rest of World (ROW)
- Initial point of contact for CRO monitoring, budgetary items, site evaluations (both US and ROW), operationalization of program systems (eDC, IXRS, safety databases, study website, CRO shared area, etc.) and process and data reviews
- Sponsor representative at on-site qualification (assisting PI & study staff on study set-up, site logistics, needs, etc.) for participation and initiation visits (SIV) w/CRA (US & ROW). Provided training to the unblinded pharmacists on-site in hospital (academic and non-academic) settings and via teleconference, as well as management of Almac access for both blinded and unblinded users (N=500+). Management of IXRS for subject & study activities for accurate reflection of study & site progress.
- Site relations as a sponsor representative and assist site staff in recruitment and strategies thereof
- Study start-up, initiations, recruitment, program maintenance throughout, towards database lock
- Assist in IP strategies and implementations for clinical sites and inventory management; periodic Data Monitoring Committees (DMC); and Crisis Review Committee (CRC) in their adjudication of Sickle Cell Pain Crisis events (SCPCs)
- Co-development of all clinical external (i.e., CRO) and internal (sponsor) and documents for program. US sites ~61 & ROW ~9
- Management of short & long-term timelines to achieve company milestones for the SCD program prior to Novartis transfer.

POZEN, Inc. - Sr. Project Manager (Contract to Permanent Employee- *PA Program (***N=27** *total staff)*
Chapel Hill, North Carolina April 2008 – Dec 2012

- Sr. Project Manager for 50 US sites in Phase III safety study aspirin-associated ulcer prevention in subjects with previous cerebrovascular and cardiovascular (CV) events over a 12 month time span (300 evaluable subjects) in addition to twin efficacy studies ~160 US sites (500 evaluable per study) for a 6 month gastric ulcer prevention within the CV population.

Individually selected each of the 50 sites within 2 months for the safety study (feasibility, target pts., etc.). Recruitment & evaluation discussions about the efficacy studies to strategize & execute amendment within the Study Protocol Agreement (SPA) and meeting company goals. Site visits to evaluate and discuss individual site recruitment efforts and pt. population on site with site staff. Performed **Completing all 3 studies' database locks in time for NDA preparation for successful submission**. Limited interaction with Commercial for product in strategizing company vision and product launch.

- CRO selection process and developed flow of work & infrastructure for operationalization of program (e.g., selection of LCRAs that were internalized into POZEN as an extension of the company). Streamlined and delegated tasks in the field and internally for optimal collaboration and transparency of communication.
- Internal study team coordination (i.e., Biostats, DM, Regulatory, Compliance, Records Management, QA, CMC, Finance, Legal, Safety, Marketing, & ClinOps management), as well as personnel management and responsible for all site financials, data listings reviews, all vendor budgets, & central labs and IRB interaction. Performed COVs, as needed.
- Streamlined the internal financial process between A/R and sites, vendors, and contractors. Developed accountability and standards for internal entities (CMC, ClinOps, etc.) to document specific, for Finance to track and keep consistent for clarity.
- Data Management components that are reviewed and provide feedback in development: eDC edit checks, e-CRF & IWR (Interactive Web-Response) guidelines, Data Management Plan (DMP), e-CRF design, and UAT of databases.
- Coordination of vendor kick-offs, and virtual Investigator Meeting & ongoing trainings for program.
- Management of suppliers: central IRB & lab, central ad campaign vendors for subject recruitment, study start-up (regulatory and contract negotiations) & monitoring group, study staff training, and eDC vendor.
- Updated protocols for safety study. Assisted in generating guidelines and processes for internal safety tasks.
- ISS & ISE reviews; reviewed Narratives in ISS for logic flow and consistency; performed data searches via databases throughout for in-stream cleaning, monitoring and real-time data review; obtained MACE & MAGIE that were adjudicated; etc.

PN Studies

- Sr. Project Manager of 80 US sites in Phase III OA-flare study over 12-week time span, with secondary responsibility for a twin sister study 90 US sites (~570 randomized per study; N=1100 total)
- Management of CRO (site management, etc.). Electronic Data Capture (e-DC), e-diary Palm (Patient Report Outcome- PRO), patient recruitment, central laboratory, study drug & comparator supplies, central IRB, and patient accessories.
- Maintain study documents and monitoring quality of twin studies in collaboration with QA in-house team and outside contract vendor in managing the CRO. Maintain study and NDA timelines for the twin studies.
- Provided feedback to partnering external investors (A/Z who will manufacture and market) and for internal investment updates
- Data listings review for formatting and consistencies; writing of AE narratives; Individual Patient Profile (IPP) e-CRF review; Table summaries review. Appendices, Integrated Summary of Safety (ISS), & Integrated Summary of Efficacy (ISE), review within CSRs for NDA submission; reviews of parts of CSR for **505(b)(2)** NDA submission.
- Conduction of different types of monitoring visits with CRO to ensure adherence to CRO & Sponsor SOPs and ensure quality.
- Daily interaction with senior management concerning NDA submission details of two twin Phase III studies (N = 170 sites total)

GlaxoSmithKline - *Co-Global Study Manager (GSM)/Clinical Regional Study Manager (SM)* (18 month Contract via Smith Hanley**)**
Research Triangle Park, North Carolina
October 2006 – April 2008

- Co-Global Study Manager (GSM) and primary Regional SM for ~60 US sites in Phase IV.
- Provide support/guidance to International (3 countries) and Canadian SMs.
- Contingency planning for global recruitment (1200 randomized & 2000 screened patients)
- Spearheaded US efforts for Enthusiasm site TCs for re-absorption of subjects from other countries • GSM is primary budgetary holder/resolver and accountable for these multi-country global budgets • Autonomous SM for a 4 year study (prostrate cancer Phase IV) 32 US sites for ~ 8 months.
- DBR of a urology trial prior to timelines of approximately 50 sites US and Canada for ~ 3 months.
- Accountable to ensure all relevant studies follow GSK SOPs and GCP.
- Managed the operational implementation of clinical development programs, including but not limited to the following clinical trial tasks: site budgets, CRF design, investigator meeting (IM) content and presentations, protocol review, input into generating informed consent templates, site recruitment, and patient recruitment strategies.
- Provided input into development of e-CRF, site selection with coordinated input, and input into content and execution of IMs.
- Presented selected topics at IMs, as well as facilitated IM.
- Managed start-up, conduct, and closeout of a trial.
- Management of CROs or other outsourcing partners as appropriate.
- Key clinical operations contact on cross-functional study conduct teams and matrix team partners.
- Assist with maintaining relationships and monitored performance of CROs and other vendors.
- Collaborated with GSK Clinical Operations functional groups (i.e., US monitoring, Data Management, Operations Management, etc.) to ensure on time delivery of studies.

Health Decisions, Inc. - Independent Contract CRA
Chapel Hill, North Carolina June
2006 – Sept 2006

- Contract CRA for Chronic Kidney Disease (CKD) trial taking on mentoring role with other monitors.
- Responsible for high enrolling sites and/or sites that required a more seasoned CRA for management.

RTI – Health Solutions - *Associate Project Manager* (3 months – SRG Woolf Group Contract)
Research Triangle Park, North Carolina March 2006 – June 2006

- Managed all areas of a Post-Operative Ileus study for subjects undergoing a laparoscopic resection due to colon issues.
- Areas included, but were not limited to, implementation and negotiation of sub-contracts with data management, clinical study supplies, key opinion leaders (KOLs), and regulatory; site and vendor payments; timeline and budgetary management; etc.
- Created/assisted in creating clinical documents for study with Clinical Director: protocol, IB, specs for study drug labeling, ICD, contract & study budget, Site Interest & Feasibility, CRFs and Case Record Form (CRF) Completion Guidelines, site and tracking tools, source docs, vendor processes and guidance documents
- Regulatory submissions and site regulatory oversight
- Management of all sites: initial site contact with the PI, to all site staff for trial (e.g., SC, Finance, etc.), selection of sites, etc

Peripheral training of in-house staff on processes as needed; established central clinical files and maintained levels of QA.

- Client/sponsor interaction throughout the study with the Clinical Director; safety surveillance via vendor; interaction with all internal entities for the clinical trial: legal, regulatory in the form of a central company IRB, biostatistics, quality assurance, etc.
- Assistance in facilitating the IMP brokering from outside the US, stability testing of drug, and facilitation of generation and implementation of randomization blocks between the supply vendor and biostatistics.
- Development of SOPs and/or work project documents for different study specific and general RTI-Health Solutions processes.

Health Decisions, Inc. - Associate Project Manager/Lead Clinical Research Associate - Sr. Clinical Research Associate Chapel Hill, North Carolina
December 2004 – February 2006

- Direct contact with sponsor Project Manager and study vendors, as well as sponsor Pharmacovigilance team for study flow.
- Primary contact when PM was unavailable for CKD study.
- Reviewed & approved final monitoring reports to the sponsor.
- Supervision of Inv. Meeting planner assistant, Clinical Trial Assistant, and monitors for CKD study.
- Designed Case Report Forms, source, and site worksheets for CKD study. Author of Study Manual and Monitoring Guidelines.
- Assisted with clinical database framing & consultation with department heads (e.g., IT, QM, DM, etc.) in start up.
- Assisted with study specific web-based products, via clinical input, for randomization, screening logs, and query resolution. Collaborated in study budget negotiations and assisting in timeline construction and maintenance throughout study.
- Managed site selection process in conducting visits and training monitors on Pre-Study Site visits (PSSVs) and SOPs.
- Negotiated with Site Management Organizations (SMOs) in pre-study site selection phase in conjunction with the sponsor to complete PSSVs. Trained staff and assisted the PM in regulatory review and tracking databases.
- Responsible for such deliverables as monitoring reports as well as various study documents for study start up.
- Presentations targeted to an audience with various skill sets and educational backgrounds, from PI to administrative staff. Mentored CRA trainees during the time period as a Sr. CRA, mostly on Alzheimer's Dementia (A.D.) trial.

Quintiles, Inc. - *Clinical Research Associate II, Clinical Research Associate I, Sr. Clinical Trials Associate* Morrisville, North Carolina
February 2002 – November 2004

- Ongoing monitoring of clinical research protocols, site management including: on site monitoring of clinical data and essential documents, assessing incoming data (including specialized testing and Laboratory results of the Central Reference Laboratories), provided data clarifications (via PhaseForward platform) and assisting in database closure procedures.
- Maintained adherence of quality assurance (QA) in all operations through continuous data verification and procedural review.
- Conducted all types of visits: Pre-Study, Initiation, Monitoring, Closeout, and Booster Visits.
- Multidisciplinary project management by interacting in a team environment with Project Physicians/Medical Monitors, Project Leaders and assistants, Clinical Research Associates, Data Managers, and Regulatory Affairs.
- Trained and mentored newly hired Clinical Research Associates on Pre-Study Visits and Monitoring Visits. Experience working with multiple vendors, Electronic-data capture (sponsor-specific and web-based only), and IVRS.
- Primary sponsor POC for HIPPA updates working with sponsor liaison and ongoing sites to adhere to these Federal regulations without delay in Diabetic Neuropathy study.
- Primary contacts for site regulatory items as a Sr. CTA for start-up and support through out study.

Center for Psychological and Family Services - *Clinical Psychologist, M.A*
(Private Practice & individual contracts)
Chapel Hill, North Carolina
October 1999 – June 2002 • Served as consulting psychologist for a Raleigh neuropsychologists' practice conducting assessments in the area disability services: clients had numerous medical complaints including, but not limited to attention deficit difficulties, neurological damage of various etiologies, severe and migraine headaches, and affective disorders (e.g., Bi-Polar Disorders I & II, seasonal affective disorder, cyclothymia, generalized anxiety disorder, social phobia, and specific phobias).

- CPT coding, medical writing, risk management, timeline management, within a less clinical role.
- Created, developed, and managed data for clinicians within the practice to recruit patients & manage patient data.
- Conducted analytical, insight-oriented individual psychotherapy with adults and couples.
- Formed database for communal resources and referrals for specific psychiatric needs for practice. Held private contracts with Durham & Wake County school systems in conducting L.D., E.M.H., and B.E.H. evaluations.
- Created and maintained Policy and Procedure Manual for Fellow clinicians for billing, insurance reimbursement, and accounting & clinician purposes, within the practice that shared resources.

Johnston County Mental Health Center (JCMHC)- Staff Psychologist II
Smithfield, North Carolina April
1998 – April 2000

- Program Founder and Coordinator for the Turn Around Program (T.A.P.) a countywide program initiative between the

Johnston County Public School System (JCPSS) and JCMHC for youth apprehended with drug paraphernalia on their possession. The program was a 6-week psychoeducational intervention for the youth and their families/legal guardians to inoculate the participants with skills to deter them from any future use of mind-altering substances & delinquent behavior.

- Performed psychological evaluations including intellectual, projective, personality, and adaptive assessments for residential program referrals, court cases, and other community referral questions within Child Services, as well as Adult Services.
- Designed various questionnaires and patient diary-type forms to capture data for individual modification plans for children.
- Completed COA (Council on Accreditation), Medicaid, and State (N.C.) forms for audits from the source documentation.
- Completed Consumer Outcome Inventory (COI) for randomized patients, in a state outcome study, for the state DHHS.
- Proficient coding of state level of eligibility (L.O.E.), global assessment functioning (G.A.F.), DSM-IV and DHHS forms.
- Completed source documentation of in-patient forms/charts from Johnston County Memorial Hospital for in-patient commitments and patients that need crisis stabilization.
- Liaison and consultant with various state hospital staff in providing re-entry resources for adolescents. Generated and enriched various psychiatrists' relationships through these communicative processes.

Learning Services Corporation - *Psychological Associate on Multidisciplinary Team*
Durham, North Carolina
September 1997 – October 1997 (1 month after hiring, *new HMO deleted the acute portion of services hired for*)

- Psychological Associate in a neurorehabilitation residential center within the acute unit for Traumatic Brain Injuries (TBI).
- Assessed neurological and adaptive functioning as a result of TBI in conjunction with other professionals (e.g., speech, physical, & vocational therapists; registered nurses, physiatrists, etc.).
- Collected & quantified data for problematic behaviors to construct a personalized behavior modification plan for residents.
- Performed medical writing within medical charts & reports, coding, and summary submissions for third party reimbursements.
- Assessed differential functioning and individual abilities as the mental health component on a multi-disciplinarian team.
- Researched materials and programming for TBI patients and their families. Program focused on differential functioning of the patient in the areas of cognitive functioning: memory, sequential processing, and decision making; and emotional functioning.
- Analysis of G.A.F. as it related to occupational, social, interpersonal, and other pertinent areas of functioning and subsequent recommendations to the team, physiatrist, family, and insurance company(ies) for future patient placement and capabilities.

Johnston County Mental Health Center - *Staff Psychologist II*
Smithfield, North Carolina
January 1997 – August 1997

- Six-month federal (F.E.M.A.) grant to conduct various presentations county-wide with the medical & local community.
- Conducted local radio interviews and presentations for mental health issues post-Hurricance Fran.
- Presented research and data to medical staff concerning PTSD; followed up with specific pediatricians.
- Also, presented in school systems with posters, pamphlets, etc. in communicating about time-limited resources available through the grant to address Hurricane Fran-related psychological difficulties.
- Performed individual, conjoint, and group psychotherapy.

Completed psychological assessments for a variety of referral questions such as intellectual functioning/capacity, potential for violence, psychotic thinking, adaptive functioning, etc. Most referral questions were generated by the court system and Adult Service therapists whose patient population may have had delusional, paranoid, or psychotic thinking and an assessment was needed to perform a risk management scenario for patient placement, and subsequent judicial and social communal standing.

East Carolina University - *Research Assistant*
Greenville, North Carolina
August 1994 – December 1996

- Assisted Associate Professor in abstract reviews and construction of presentations at conferences and others.
- Responsible for data collection, transference, coding, and initial data entry. Performed statistical analyses consisting of, but not limited to, analysis of variance (ANOVA), chi-square, t-test, etc.
- Used various statistical programs such as SPSS, SAS, and Minitab to analyze survey data from scales & questionnaires.
- Researched memory and learning publications (i.e., literature reviews).

EDUCATION

1996 East Carolina University M.A. Clinical Psychology
Greenville, NC

1994 Clemson University (entered as Engineer) B.A. Psychology (Psi Chi)
Clemson, SC

LICENSURE BY THE NORTH CAROLINA PSYCHOLOGY BOARD

LPA #2111 issued 30 July 1997. Currently maintained via biannual update in completing required CEUs in various courses

OTHER RELEVANT DETAILS and Certifications

Administration and interpretation of the following psychological assessments as a Clinical Psychologist:

Bayley Scales of Development	Children's Memory Scales	Millon Clinical Multiaxial Inv.	Rorschach inkblot projective
Beck Inventories (BDI & BAI)	Conner's Scales	Mini-Mental Status Exam	Thematic Apperception Test
Bender Gestalt-Neuro Screen	Global Assessment Functioning	Minnesota Multiphasic: MMPI	Woodcock Johnson Achieve
Child Behavior Checklist:CBCL	House Tree Person projectives	Personality Assessment Inv.	Vineland

Wechsler family of intellectual and achievement tests-WISC-III; WAIS-II; WIAS-III; WPPSI-R; WIAT; WIAT-2; WMS-R; etc.

WISC-V training (Spring 2015)

Diploma in Dementia Certification by MENAA (Middle East & North Africa Association on Aging & Alzheimer's) (Fall 2022)

Roundtable Discussion leader at the North Carolina Regulatory Affairs Forum (NCRAF) on Consulting in Biopharma (Nov 2022)

Familiarity with Patient Report Outcome (PRO) outcomes such as VAS, WOMAC, etc. as a Sr. PM over twin Phase III trials

Monitored the following cognitive scales for CRO/pharma for Alzheimer's Disease: ADAS-Cog, CIBIC-Plus, CDR, DADs, NPI, MMSE

ADDITIONAL ASSESSMENTS for AD trial (2016): C-SSRS, GDS, ADAS-COG-14, COWAT, AND CFT

Note: CITI (Collaborative Institutional Training Initiative) GCP Training at University of Miami 2017; CITI most up to date re-cert: **2025**

VOLUNTEER EXPERIENCE AND INTERESTS

Summit Church Service team: 2024 to Present
High School Youth Group discussion leader/Volunteer at local church: 2020-2021
Compassion International volunteer, seasonal: 2015-2018
Duke Hospital's Pediatric Bone Marrow Transplant (PBMT) Best Buddy Program: 2010-2016
Sunday School Teacher, Church of the Good Shepherd (tracked with same cohort): 2001-2016
DurhamCares Volunteer (Storyboards, research, etc.): Winter 2013
Durham Rescue Mission supporter and seasonal volunteer: 2010-2012