

# HUMPHREY TEBIT

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## PROFILE

**Senior Research & Development Professional** with extensive experience in clinical study design, statistical analysis and building strong relationships within and between teams. Outgoing and articulate with excellent communications skills. In-depth understanding of clinical research is complimented by a proven ability to develop business through R&D activities. Fully bilingual in French and English.

## PROFESSIONAL EXPERIENCE

### HT PHARMACEUTICALS

*A Clinical Research Consultancy*

#### Principal

**2008-Present**

- Engaged by a pharmaceutical company to design pharmacokinetic pilot and pivotal studies for an ANDS submission due by year end. Successfully completed the pilot study and used the results to design the pivotal study.
- Selected the CRO to carry out study and managed the study activities from protocol writing through to final report.
- Analyzed concentration-time data for a pharmacokinetic study and wrote a Statistical Analysis Plan (SAP) for a CRO.
- SAS programming and data analysis using the FDA population bioequivalence approach.
- Presented at the Canadian Society of Pharmaceutical Scientists (CSPS) 2009 symposium on the topic *Clinical Endpoint Studies - An Overview and Sponsor's Perspective*.

### BIOVAIL CONTRACT RESEARCH

**2008**

*A Contract Research Organization (CRO) focused on early clinical trials and bioanalysis.*

#### Associate Director, Pharmacokinetics and Statistics

- Managed a team of 8 and recruited 3 new staff members for the team within 4 months of joining the company, which helped stabilize the group.
- Created a cohesive team by providing strong leadership and expert knowledge on how to carry out their work effectively, increasing the number of projects completed.
- Provided strategic future directions for the group by introducing new techniques such as in-vitro in-vivo correlation and data modelling that could generate \$500K in new business for the company.
- Reviewed at least 4 study designs a week for developing protocols and quotations, facilitating contracted studies from pharmaceutical companies and clearing a back-log of study designs from the past, enabling additional quotations to be made and developed more protocols for contracted studies.
- Provided expert advice to clients on their clinical program and submission strategy, saving time and money for the duration of the programs and improving on the success rate of their submission.
- Made presentations to develop the clinic and laboratory groups within the company, making changes to existing procedures which led to better efficiency on how clinic data is collected for PK analysis.
- Managed the validation process (IQ/PQ/OQ) of a newer version of the SAS software.
- Actively participated in the consultation meeting in Ottawa with TPD on the development of guidelines for Secondary Entry Biologics (SEBs). Presented results of the meeting to Senior Management and the Marketing/Sales and made recommendations on utilizing this new area to grow the business.
- Supported business development via discussing Biovail's services with clients during conferences. Brought in 3 new clients within one conference, generating a projected \$1M in new billings.

### CANTEST BIOPHARMA SERVICES

**2006-2008**

*A bioanalytical laboratory focused on developing methods to analyze pre-clinical and clinical samples.*

#### Director, Pharmaceuticals

- Designed bioequivalence studies and wrote protocol synopsis for pharmaceutical companies.

- Analyzed pre-clinical data and wrote reports for pharmaceutical companies used for pre-IND submission to the FDA.
- Provided in-house training to the laboratory Research and Development group on pharmaceutical requirements for studies, pharmacokinetics and study designs. This facilitated their understanding of the area of pharmacokinetics in working closely with the biopharmaceutics team.
- Liaised with the FDA and TPD on study design requirements on behalf of pharmaceutical companies to ensure the correct studies were performed.
- Wrote controlled correspondence for different companies on non-standard studies to obtain information from the FDA that will be required for designing specialized difficult studies.
- Managed technical report writers and assisted in their training and development which improved on their working knowledge and understanding of the biopharmaceutics area.
- Contributed strategic insights and recommendations to Senior Management identifying ways for five different departments to function more efficiently in current and future development programs.
- Provided significant support to the bioanalytical laboratory on method development for pharmacokinetic studies, improving on the success rate of the bioanalytical methods that needed to be developed.
- Developed a process flow of activities on how the pharmaceuticals group relates to the clinic, bioanalytical, QA/QC and project management groups. This fostered understanding of how the different groups related to each other and enhanced functionality between the groups.
- Actively participated in business development client meetings which increased the number of requests for quotation and potential studies to be contracted to the company by approximately 20%.

**APOTEX INC**

2004-2005

*The number one generic pharmaceutical company in Canada***Consultant, Clinical Development**

- Developed strategies, protocol synopsis and clinical development plans for clinical studies in various therapeutic areas, including allergic rhinitis and respiratory for FDA, TPD and EU submissions.
- Actively involved in feasibility assessments, requests for proposal, vendor selection recommendations for the most suitable study specific CRO that can carry out the study. Conducted contract negotiations and directed the execution of complex, multi-centre trials with time frames of 12 to 24 months.
- Developed strategies for meetings with TPD, FDA and MHRA to ensure successful discussions.
- Provided advice and support on design aspects for pharmacokinetic and clinical studies to enhance the success rate of clinical development programs.
- As designated technical resource to project teams, liaised with peers and Senior Management across the organization in providing in-depth expertise that facilitated a deeper understanding of customer needs and satisfaction.
- Received an award for exceptional team performance for significant contributions in a project team working in the first clinical study in the allergic rhinitis therapeutic area for the company.

**MERCK GENERICS**

1994-2004

*A global generic pharmaceutical company with offices in Europe, Australia and North America***Principal Biometrics Officer/Team leader, Clinical Consultant**

- Developed a suite of SAS programs used worldwide within the Merck Generics Group to calculate pharmacokinetic parameters and perform statistical analysis for the data obtained; trained staff on use.
- Designed and implemented 100+ bioequivalence studies at a cost of about \$2 M/year. Studies were used for successful submissions to obtain marketing license of the pharmaceutical products in Europe.
- Designed and managed the project activities for a \$5M pre-clinical and clinical studies for inhaled corticosteroids, short and long acting  $\beta_2$ -agonists products. Studies were submitted and accepted by the UK health authorities used to support drug approval in Canada and Australia.
- Presented to Health Canada the pre-clinical and clinical plans of a suite of respiratory clinical studies for use in Europe, Canada and US markets, resulting in identifying study design requirements.
- Used marketing and *in vitro* information to make decisions on the global strategy to draw up clinical development plans, identifying which drug candidates are suitable for which market in a priority order.
- Managed the development of a Lotus Notes database used world-wide within the Merck Generics Group to manage bioequivalence and clinical study activities. It was also used as an archive database.

- Seconded to Genpharm to assist the development of the newly recruited Biopharmaceutics manager and the group enhancing working relationships with all other Merck Generics groups globally.
- Provided significant input into the training and development of the Genpharm Biopharmaceutics group with the group benefiting in achieving their goals and objectives from my expertise and experience.
- Wrote technical SOPs that facilitated the understanding, implementation and interpretation of applicable statistical techniques required to carry out the biometrics activities.
- Provided statistical support on techniques needed for analyzing study data within the Merck Generics group, ensuring data is analyzed according to the regulation and correct interpretation of the results.
- Organized the first joint meeting between the European and Canadian biometric groups identifying activities to enhanced collaboration resulting in efficient sharing of results for designing new studies.
- Saved the company thousands of dollars by negotiating discount agreements with CROs and identifying territories worldwide that would perform good quality studies at a less expensive cost.

**INSTITUTE OF ANIMAL RESEARCH**  
**Research Assistant**

**1987-1991**

- Performed and supervised biochemical diagnostic tests of animal diseases. Used statistical techniques in research on drug activities in laboratory animals.

**EDUCATION**

M.Sc. in Biometry (Applied Statistics), University of Reading, UK, 1992-1994  
Preliminary Postgraduate Program in Statistics, University of Reading, UK, 1991-1992  
B.Sc. (Hons) in Biochemistry, University of Ilorin, Nigeria, 1984-1987

**PROFESSIONAL DEVELOPMENT**

**Management Training Courses**

Interpersonal Skills Development  
Management Development Program

**Technical and Scientific Training Courses**

Pharmacokinetic, Bioavailability and Bioequivalence  
Asthma Clinical Trials  
GCP for Clinical Trials  
The Fundamental Principles of Toxicology  
Sample Size and Power Calculations, Equivalence, Non-Inferiority and Superiority Trials

**SAS Courses**

Advanced Programming and Efficiency Techniques  
SAS Macro Language  
Customized Application Development using the SAS System

**WinNonlin Courses**

WinNonlin Hands-On Version 5.0.1  
Intermediate PK/PD Modeling Methodology using WinNonlin

**AFFILIATIONS**

Canadian Society of Pharmaceutical Scientist (CSPS)  
American Association of Pharmaceutical Scientist (AAPS)