PHARMA DATA ASSOCIATES LLC

A Contract Research Organization Specialized in Providing Biostatistics and Programming Services for the Clinical Development, Regulatory Submission, and Medical Affairs

www.PharmaDataAssociates.com

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N/Power
Endpoints
Protocol/CRF
EDC/IWRS
Randomization
SAP/Table Shells
TLFs
CSR
ISS/ISE
DSMB
SDTM/ADaM
aCRF
Define.xml
Hyperlinks
FDA eSubmission

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Table of Contents

Who We Are

We are a team of experienced statisticians, SAS programmers, and clinical data manager who worked together under the leadership of Chao Wang, PhD, president of Pharma Data Associates (PDA).

Individually or as a team, we provided a full range support to the clinical development. We supported protocol development, designed Case Report Forms (CRFs), wrote Statistical Analysis Plans (SAPs) and Data Management Plans (DMPs), cleaned and locked clinical databases, programmed in SAS for Tables/Listings/Figures (TLFs), conducted ad hoc analyses, reviewed or coauthored Clinical Study Reports (CSRs). We successfully prepared the statistics data packages in the FDA eSubmission-compliant format for New Drug Applications (NDAs), supported the preparation of the FDA briefing books, and prepared Q/As for the FDA Advisory Committee meetings.

Prior to forming Pharma Data Associates (aka PDA), we worked in the biopharmaceutical companies and the government agencies (FDA and NIH) with growing responsibilities. We struggled with insufficient headcount and poor data quality from outside contractors. As a result of our experiences, we grew to appreciate the value of having an extension of ourselves that (1) would complement or supplement our internal resources, (2) would not have to be justified as a permanent full-time headcount, and (3) would work with us as a contributing member of our team. PDA's goal is to turn our perceived value of having "extended biometrics staff" into real value for our clients. This leads to our Vision statement.

Vision Statement

To serve as an extension of the client's Biometrics (Statistics, Programming, and Clinical Data Management) team providing support equal to or better than what the client would have expected from their own Biometrics staff.

Mission Statement

To integrate with the client's in-house staff as the supported team members providing the best Biometrics support measured by

- Quality - sustainable for the regulatory submission
- Speed - fitting the client’s timeline
- Flexibility – like the in-house staff
- Results - meeting the client's objective

What We Do

Biostatistics Support for Clinical Studies

- Provide input on the power/sample size for various study designs
- Generate randomization schedule
- Review CRF design to ensure data collection meets the protocol objective and consistent with CDISC standards
- Assist protocol design and write the statistical section
- Support interim analysis and data safety monitoring board
- Develop SAP including mock tables for individual studies or ISS/ISE (Integrated Summary of Safety/Integrated Summary of Efficacy)
- Assist data review, and protocol deviation/violation and per protocol eligibility determination
- Create patient profile listings or plots for data review and case presentation
- Program in SAS for TLFs
- Review CSR to ensure data analysis/presentation meets the study objective and the relevant FDA guidance
- Review ISS/ISE and NDA Sections 2.7.3, and 2.7.4 (Summary of Clinical Efficacy/Summary of Clinical Safety) to ensure data analysis/ presentation matches with the intended drug label and the regulatory requirements
- Represent the client in the FDA meeting
- Ad hoc analysis or data mining

Standardization and Compliance to the FDA eSubmission Requirement

- Annotate the CRF for SDTM datasets
- Create CDISC SDTM (Clinical Data Interchange Standards Consortium Study Data Tabulation Model) datasets from raw datasets
- Create Define.xml for SDTM datasets
- Create analysis datasets or CDISC ADaM datasets (Analysis Data Model) and the associated Define.xml
- Program in SAS for TLGs using the FDA recommended linear process (from raw data to SDTM to analysis data (or ADaM) to TLGs)

Preparation of the Statistics Package in the FDA eSubmission-ready format

- Check datasets for compliance to the FDA eSubmission requirements
- Create datasets in SAS v5 Xport format for all studies
- Create the folder structure per eSubmission requirement

- Copy SAS datasets, aCRFs, Define.xml, and programs into the respective folders
- Create hyperlinks in the Define.xml for SAS datasets, aCRFs, and programs
- Create data sets and listings per the FDA BIMO requirement

Data Management Support

- Provide data management oversight
- Review or develop DMP, eCRF, data entry guidance, and edit checks
- Participate or manage third party data management activities (data cleaning, query resolution, data review and lock)
- Act as liaison between client, PDA biostatistics, and the third party data management

What Makes Us Different From Others

- Former FDA statistical reviewer and current CDISC SDS committee member
- Advised by the former FDA medical team leader and biostatistical division director
- Supported by consultant physicians who held CMO positions and worked with us closely in the past
- Partnering with a reputable EDC/Data Management vendor to jointly provide low cost, full Biometrics services
- Strong Desire to work with you as your extension, providing quality, speed, and flexible support

PDA's Recent Accomplishments (2012-2014)

- 1 NDA successfully filed
  - SAPs for ISS/ISE covering 3 Phase 3 and over 9 Phase 2 and 1 studies
  - SDTM and ADaM compliant
  - All ISS/ISE TLFs, plus FDA's BIMO data set and listings
  - Section 2.7.3 and 2.7.4 review
- 3 Phase 3 studies and 3 Phase 2 studies
  - SAP/TLF shells, statistical analysis and TLFs generation
  - SDTM and ADaM compliant (phase 3)
  - CSR review
- Protocol development
  - 1 Phase 3 study and 8 Phase 2 studies
- Passed the client's pre-Phase 3 and Post NDA biostatistics audits

Our Experience

System	Disease	Drug/Biologic	P1	P2	P3	NDA	P4
Infection/ Inflammation	Psoriasis	Tezorac®			X	X	
		Amevive®				X	
	Allergic Asthma	Xolair®				X	
	Ankylosing Spondylitis	Enbrel®				X	
	Rheumatoid Arthritis	Confidential		X	X		
	HPV	Confidential			X		
Oncology	Breast cancer	Herceptin®				X	
	Lung/Ovarian/ Pancreatic/Prostate/ Colon/Glioblastoma	Confidential	X	X	X		
	NHL/MDS	Confidential	X	X	X		
	Mucositis, Anemia	Confidential		X	X		
CVS	PCI/ACS	ReoPro®				X	
	MI/IS	Confidential			X		
Gastroenterology	Celiac disease	Confidential		X			
	OINV/OIC	Confidential	X	X	X		
	CINV	Confidential			X	X	
Endocrinology	Anemia	EPOGEN®			X	X	X
		ARANESP®	X	X	X	X	
		Confidential			X		
	Obesity/T2DM/Diabetic Neuropathy/Renal Vasculitis	Confidential	X	X			
Hematology	ITP	Confidential	X	X	X		
CNS	ADHD	Kapvay®				X	X
	Sedation	Lusedra®		X	X	X	
	Pain	EMBEDA®			X	X	
		Confidential		X			
	Major Depressive Disorder	Confidential		X			X
	Parkinson Disease/Cerebral Palsy/Drooling	Confidential		X	X		X

Curriculum Vitae of the President

Chao Wang, PhD, President and Principal Statistician

SKILLS

- Write, submit and defend relevant sections of BLAs/NDAs and protocols of all development phases
- Prepared or reviewed 11 NDAs/BLAs as the primary company statistician or the FDA statistician
- Build and manage Biometrics (Statistics, Programming, and Data Management) departments
- Provide sample size calculations, study design and endpoints selection, EDC vendor selection, eCRF and CDSIC database design, SAP/DMP development, SAS programming for TLFs, and CSR review
- Provide group sequential trial design, futility analysis, non-inferiority design, survival analysis, mixed effects models, and missing data imputation
- Conversant in oncology, analgesic/sedation, dermatology, immunology, nephrology, cardiac, and CNS disease areas and current study design

PROFESSIONAL EXPERIENCE

President and Principal Statistician - Pharma Data Associates, June 2011 – Present

- Manage PDA to provide full biostatistics support for the clients' phase 3 development program, including CRF design, SAPs for studies and SAPs for ISS/ISE development, data review, statistical programming for tables/listings/figures, and report review
- Consult to the biopharmaceutical companies for phase 3 designs and the overall development program
- Act as the client's internal statistician, assisting in the trial design, protocol development, CRF, SAP, database review, and CSR review for phase 1 and 2 studies, conduct exploratory analysis to address ad hoc questions
- Generate subject and kit randomization schedules
- Sit in the data monitoring committees (DMC) for multiple phase 1 and 2 trials

Senior Director, Biometrics – Shionogi, 2010 – June 2011

- Built and managed the US Biometrics department for the clinical development
- Saved 50% cost by terminating a phase 2b trial and its extension trial with a statistical futility analysis
- Supported the negotiation with the FDA for a package insert and provided critical input for the ISS/ISE of an NDA

Executive Director, Biometrics - Abraxis BioScience, 2009 – 2010

Senior Director, Biometrics – Pfizer/King/Alpharma, 2008 –2009

- Rescued an incomplete NDA submission with a new ISS, new statistics data package compliant to the FDA requirement, and revised CTD Sections 2.5, 2.7.2, 2.7.3 and 2.7.4
- Reduced re-submission time line for the NDA by 4 months and obtained FDA approval

Senior Director, Biometrics - Eisai/MGI/Guilford, 2003 – 2008

- Built and managed the Biometrics department for the clinical development
- Prepared the ISS/ISE, CTD, and the statistics data package in CDISC format for an NDA submission
- Conducted multiple discussions with the FDA on non-inferiority study designs

Mathematical Statistician - FDA CBER, 2001 – 2003

- Reviewed 70 BLAs, INDs, and IDEs
- Represented the FDA at the advisory committee meetings
- Designed a graphical data review tool for the medical officers

Project Statistician - Amgen, 1995 – 2001

- Prepared 2 BLAs and negotiated with the FDA for the package insert

Biostatistician - Allergan, 1992 – 1995

- Assisted the phase 3 study designs and ISS/ISE for 2 NDAs

EDUCATION

- Ph.D. in Biostatistics, 1992, School of Public Health, UCLA

AWARDS

- Four FDA Outstanding Service Awards

Select List of SOPs and WIs PDA Developed and Follow

Name	Type	Title
AD-01	SOP	Creation, Approval, Distribution, and Training of Standard Operating Procedures
AD-02	SOP	Confidential Agreement and Employment
IT-01	SOP	Computer System Configuration and Testing
IT-02	SOP	Back Up, Restore, and Archive Network Files
IT-03	SOP	PC and Network Folder Structure
IT-04	SOP	SAS System Installation and Operational Qualification
IT-05	SOP	File Transfer To/From Pharma Data Associates
PG-01	SOP	Statistical Deliverable Life Cycle Management
PG-01a	WI	Requirements, specifications, development, QC/Validation, and change control of CDISC SDTM Datasets
PG-01b	WI	Guidelines for Annotating and Bookmarking submission ready CRFs for SDTM
PG-01c	WI	Requirements, specifications, development, QC/Validation, and change control of CDISC ADaM or Analysis Datasets
PM-01	SOP	Project Master File
ST-01	SOP	Biostatistics Protocol Development and Review
ST-02	SOP	Generation and Distribution of Randomization Information for Clinical Trials
ST-03	SOP	Development of the Statistical Analysis Plan
ST-04	SOP	Writing Statistical Methods and Results for Clinical Trials
ST-05	SOP	Locking/Unlocking Clinical Trial Database
ST-06	SOP	Unblinding of Study Treatment

How to Contact Us

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