Michael L. Carniello

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Experience:

2014 - Present — Senior Director, Statistical Programming, Astellas Pharma, Northbrook, Illinois

Serving as the Global Head of Statistical Programming.

Accountable for an employee team of 24 programmers (including people managers), 200+ vendor programmers, and programming expenses of ~10 million USD annually.

Accountable for high-quality, on-time programmed deliverables in all assigned clinical development and Medical Affairs studies and other statistical programming work. Lead the development and implementation of Statistical Programming strategic objectives.

Provide the optimal allocation and management of Statistical Programming resources to Development extended teams and deliverables teams.

Enforce Astellas, industry and regulatory standards in programmed deliverables.

Ensure that all study-level and integrated (cross-study) programmed deliverables are ready to be used in regulatory submissions.

Accountable for the selection and oversight of statistical programming vendors.

Accountable for the company's data sharing platform and operations.

2013 - 2014 — Associate Director, Statistical Programming, Takeda Development Center, Deerfield, Illinois

- People Management
  - 7 direct reports (4 in US/Deerfield, 3 in UK/London)
  - Performance reviews, mentoring, training, and associated HR work
  - Focus on completing assigned projects regarding study-level verification, ad-hoc requests, and submission packages
- Project Management
  - Led sourcing strategy initiative
  - Led statistical programming team on an internal clinical data transparency initiative
  - Led cross-therapeutic area study assignment tracking methods
- Industry Presence

- Program-Chair Elect, ASA Section for Statistical Programmers and Analysts
- Co-Lead, Code Repository Maintenance, PhUSE/CSS Standard Scripts Working Group

2010 - 2013 **Senior Manager**
Statistical Reporting Standards
Takeda Global R&D, Deerfield, Illinois

- Project Management
  - Led cross-functional team to assemble internal guidance on regulatory submissions
  - Led cross-functional team to establish data handling rules for cross-therapeutic areas

- Derived Data Specification Management
  - Developed, maintained, and measured compliance to analysis dataset standards (company format as well as CDISC's ADaM)
  - Designed company "flavor" of CDISC's ADaM standard
  - Responsible for study data submission (SDTM and ADaM) of peginesatide compound with alliance partner

- Template Program Management
  - Worked with direct reports to follow software life-cycle model which produced SAS programs to serve as templates for Phase 1 in-sourced work

- Industry Presence
  - Member Representative to Executive Committee of ASA Section for Statistical Programmers and Analysts
  - Active member of FDA/PhUSE Working Group 5 (Standard Scripts)

- People Management
  - 2 direct reports (senior level)
  - Performance reviews, mentoring, training, and associated HR work
  - Focus on changing role from project work

2007 - 2010 **Senior Manager, Statistical Programming**
Takeda Global R&D, Deerfield, Illinois

- Systems Management
  - Business-side global implementation of TSARS (Takeda Statistical Analysis & Reporting System): hardware, software and processes for statistical data and programming environment targeted for global use (including global SOPs)
  - US implementation of G-MEDAS (Global Medical Analysis System – a data reporting system developed by Takeda/Japan)

- Programming Management
  - Oversight of statistical programmers' efforts in a variety of clinical studies (Phase 1-3, focusing on Ramelteon, peginesatide and the Lundbeck-alliance compounds)
  - Support for implementing industry-wide data structure standards for clinical data (CDISC)
  - Documenting processes for insourced programming work

- Milestone/timeline and resource management of statistical deliverables (datasets, associated Tables/Listings/Graphs)
- Support of Ramelteon registration efforts via supplemental NDA (US) and MAA (EU)

- People Management
  - 6 direct reports (junior and senior levels): five full-time and one contractor
  - Performance reviews, mentoring, training, and associated HR work
  - Recruitment and retention

2003 - 2007 **Senior Manager, Medical Affairs Biostatistics**
Amgen, Thousand Oaks, California

- US Medical Affairs Oncology Therapeutic Area Statistical Programming Lead

- People Management
  - 13 direct reports (junior and senior levels): seven full-time and six contractors
  - Performance reviews, mentoring, training, and associated HR work
  - Recruitment and retention

- Programming Project Management
  - Tracking ongoing clinical trials across four marketed drugs
  - Integration with clinical development studies
  - Participation in developing department standards and procedures
  - Management of year-long "legacy data" integration project
  - Short-term ad-hoc projects (examples: scientific congress abstracts and posters, EMEA response, claims database analysis)
  - Established study start-up, maintenance, and close-out processes for US Medical Affairs Biostatistics oncology trials

- Vendor Management
  - CRO programming oversight (weekly teleconferences, monthly Operational Management Team meetings, quarterly drug-based face-to-face meetings)
  - Led Biostatistics Vendor Selection project (regarding "boutique" statistical vendors for short/medium term projects)
  - Participation in SOP development regarding Preferred Provider selection/management

1994 - 2003 **IT Project Manager**
Searle/Pharmacia/Pfizer, Skokie, Illinois

- IT Project Management
  Experimental Medicine Department

  Genotype data warehouses: project planning and delivery for implementation of vendor products (Oracle server, Java client). Responsible for ensuring technical compatibility in company environment and meeting all regulatory requirements. Consulting with business staff on data models, query-building, and other operational issues.

DNA sample management system: technical support of a laboratory database system located in Montreal, Canada. Audited software and site. Planned and implemented data migration project. Designed DSL/VPN access point.

Statistical analysis applications: project planning and delivery of externally developed web-based applications for specialized data analysis (microarray and haplotype). Assisted business staff in formalizing requirements and specifications.

- Application Development Project Manager
  Oracle Clinical Complementary Systems

  Followed company-standard Software Development Life Cycle. Responsible for developing customer requirements within a defined strategy framework, managing development teams to deliver applications to meet these requirements, and ensuring that the deliverables met user, validation, and regulatory criteria.

  Systems:

  Randomization - loading data into Oracle instance prior to study close so that upon study close, analysts can quickly access unblinded data (speeds up reporting time)

  Laboratory data - matching lab assay data with normal ranges, converting units, flagging out-of-range values, handling Common Toxicity Criteria grading.

  Laboratory data pre-cleaning - move incoming lab data into temporary storage so that veracity can be assessed prior to loading into official instance.

  Global networking - formalized requirements and specifications for global network link from US to Bangalore, India for new Clinical Data Management data entry site. Worked with network engineers from global sites and used open-source Linux tools to demonstrate to internal CDM staff the viability of such a project.

- Support of clinical data management applications [DLB/Recorder, Oracle, in-house produced add-ons]

- 24x7 on-call support for Celebrex submission work

- Supervision of one systems analyst and one Oracle DBA

  Responsible for assistance in career planning, technical growth and training, and week-to-week activities

- Implementation and upgrades of vendor applications, Oracle, Unix, and all associated hardware [SAS, Splus, Mathematica, StatXact]

- Maintenance of network connectivity with 3rd party organizations [CROs, global data entry centers]

- Implementation of the NONMEM (non-linear mixed effect modeling) software as a complete application on HP/Unix

- R&D-wide SAS liaison [software licensing and tracking, programming, networking, graphics]

    - SAS user since 1983 (mainframe, OpenVMS, Unix, Windows; expertise in standard SAS modules + client/server connections)

    - In-house SAS expert [support to SAS programmers and clinical statisticians]

    - SAS application development: bioassay analysis, systems analysis

- Statistical computing support (SAS, NONMEM, Splus, Mathematica, StatXact, Minitab)

1998 - 2000 **Instructor**
DePaul University, Chicago, Illinois

- Taught sections of CSC 323 (Data Analysis and Statistical Software)

- Responsible for course syllabus, homework, exams and grading for 40 students each quarter

- Subject material included normal distribution, regression, correlation, and the use of SAS software for data analysis

1990-1994 **Technical Consultant**
BBN Software Products, Northbrook, Illinois

- Sales support for RS/1 (statistical package) and BBN/Clintrial (clinical trial data management) in Midwest and West Coast

- Responsible for software demonstrations, and technical (statistical and computing) support of trial users and current customers

- Assisted clients with integration of databases, terminal emulation, networks, printers

Awards: President's Club 1993, Top Technical Performer
(Q4 FY91; Q3 FY93; Q2, Q3, Q4 FY94).

1990-1993 **Instructor**
Chicago Actuarial Assoc., Chicago, Illinois

- Taught applied statistics (regression, analysis of variance, time series) review class for students taking Actuarial Exam 120.

1985 - 1990 **Senior Statistician**
G.D. Searle and Company, Skokie, Illinois

- Responsible for statistical support of research biologists and chemists (gastrointestinal, cardiovascular disease, toxicology/pathology groups)
- Developed systems for user-based data analysis
- Statistical methods concentrated in analysis of variance, regression analysis and survival analysis

1983-1985 **Statistical Engineer**
Pratt & Whitney, West Palm Beach, Florida

- Worked with engineers in assessing reliability, maintainability, and safety of engines
- Statistical methods included regression analysis, statistical quality control and experimental design.

1982-1983 **Graduate Assistant**
Purdue University, West Lafayette, Indiana

- Taught class on introductory statistics for technology undergraduates
- Consulted with graduate students in other departments on thesis work
- Taught section of beginning calculus recitation

1979-1981 **Reporter/Editor**
Purdue Exponent, West Lafayette, Indiana

- Served independent student newspaper in various roles, including reporter, assistant sports editor, layout editor
- Duties included weekly column and copy editing.

Publications: "Drives Results" (A 2021 PhUSE video)
https://phuse.global/Communications/PHUSE_Blog/drives-results

"Pharmaceutical Users Software Exchange (PhUSE) - a quick overview"
Presentation – 2013 Joint Statistical Meetings

"Transitioning to Big Data: What Every Statistical Programmer/Analyst Should Know"
Invited Session Chair – 2013 Joint Statistical Meetings

"SAS Template Programs for Standardized Statistical Output"
Poster - 2012 FDA/PhUSE CSS Annual Meeting
with Yu Xie and Faye Yeh

"Using SAS® for Modeling and Simulation in Drug Development – A Review and Assessment of Some Available Tools"
Paper - 2011 PharmSUG Annual Meeting
with Melvin Munsaka

"Building a Legacy Data Warehouse"
Poster - 2005 DIA Annual Meeting

"Filgrastim for the Neutropenia Associated With Combination Therapy in Chronic Hepatitis C"
D. Farmer, R. Collantes, S. Makay, J.P. Ong, H. Gujral, L. Farquhar, M.L. Carniello, R. Sjogren, Z. Younossi
Poster – 2005 Digestive Diseases Week Conference

"The Design of an Experiment Using Statistical Power with a Startle Chamber Study as an Example" (With R.M. Bittman), Journal of Applied Toxicology, Vol. 10 (2), pp. 125-128 (1990).

Education:

1983, M.S. Applied Statistics
Purdue University, West Lafayette, Indiana
GPA: 5.9/6.0

1981, B.S. Statistics
Purdue University, West Lafayette, Indiana
GPA: 5.6/6.0

Technical/ Computer Skills

Clinical Data Packages: Oracle Clinical, Recorder, Clintrial
Databases: Oracle
Statistical Packages: SAS, R
Operating Systems: Unix, Windows, MacOS X, OpenVMS
Networks: TCP/IP
Languages: Perl, SQL*Plus, Unix shell, Java
General: Software validation/verification