

MICHELE C. DADDIO, BSc, RN

mdaddio@comcast.net

120 Myrtle St
Waltham, Ma 02453
978-855-6794

PROFILE: Articulate and creative professional and problem solver, motivated in technology driven environments.

OBJECTIVE: Progressive position in clinical research that requires medical and trial knowledge as well as computer and programming skills.

COMPUTER SKILLS

- Read/write C++, JAVA, MS query, SQL and HTML
- EDC trial development with InForm Architect and Designer
- MS Office: Access, Word, Excel, PowerPoint, MS Project
- MEDITECH, Nursing Documentation Build
- MEDITECH NPR writing, Class I & II
- Adobe Photoshop
- FLASH and various CGI modeling software

EDUCATION

MassBioEd, Boston, Ma – Certificate; Introduction to Clinical Trials Boston University, Boston, Ma – Graduate Certificate; Software Development (C++ Track)
Quinnipiac University, Hamden, Ct – BS Health Sciences
Quinnipiac College, Hamden, Ct – AS Nursing

PROFESSIONAL EXPERIENCE

SENIOR IRT DESIGN CONSULTANT 2010

PHASE FORWARD, Waltham, Ma

Provide review and design of IRT systems for pharmaceutical, biotechnology, medical device, CRO, and academic/public health clients.

SENIOR CLINICAL DESIGN CONSULTANT 2008-2010

CLINICAL DESIGN CONSULTANT 2007-2008

PHASE FORWARD, Waltham, Ma

Provide quality eClinical trial design, development, project management and consulting to pharmaceutical, biotechnology, medical device, CRO, and academic/public health clients. Responsible for management for a variety of clinical trial functions including eCRF design and development, preparation of edit checks and validation plan, development of trial extract specifications, reports, laboratory uploads, and Clintrial design and development. Trial Responsibilities include but are not limited to:

- Advise customers to ensure that the trial design is configured in such a way that it meets the customer's goals and offers the full benefits of EDC (Electronic Data Capture).
- Work as a high profile member of the project team to ensure excellent customer relationships

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are established throughout the development/implementation of the trial.

- Gather and interpret customer requirements and using Phase Forward's trial design software, translate these into design specifications.
- Generate data export specifications to map data to customer requirements.
- Function as the design expert to advise internal and external customers regarding best practice for trial design
- Work with the study team and sales to scope required effort and define timelines.
- Provide advice and implement study design related changes throughout the trial life-cycle.
- Actively contributes to the continuing development of the product function and improvement of the clinical design working practices.
- Provide mentoring to junior staff and client users.

CLINICAL EVENTS COMMITTEE COORDINATOR I -II 2005-2007

HARVARD CLINICAL RESEARCH INSTITUTE, Boston, Ma

The Clinical Events Committee is a physician panel that reviews data from clinical trials and provides adjudication of adverse events. The CEC Coordinator II organizes The Committee and is involved with all clinical trials requiring adjudication of events. Trial involvement includes but is not limited to:

- Start-up collaboration Project Managers, Clinical Reviewers and sponsors regarding protocol review, identification of endpoints and interpretation of definitions relative to CEC adjudications.
- Creation of the CEC Manual of Operations / DSMB Charter.
- Review of clinical event codes and narratives, reconciling data with CRFs (Medical writing as necessary).
- Chair of the Clinical Events Committee meeting, provide physicians with protocol design and specific SAE/AE definition information.
- Utilize and create SQL scripts to review triggers and database event trends.
- Provide review and supervises assigned tasks of the CEC support staff.

DIRECTOR OF SURGICAL SERVICES 2003-2005

MERRIMACK VALLEY HOSPITAL, Haverhill, Ma

Responsible for the clinical and financial management of all surgical services including the Operating Room, Post Anesthesia Care Unit, Same Day Surgery Unit, Pain Clinic and the Central Sterile Supply Department, with 40 FTE's covering 2 Endoscopy and 4 Surgical Suites. Monitor compliance and initiate QC programs. Compile capital budget requests and annual budget. Work closely with the Chief Hospital Officers and leadership team. Develop and Implement MEDITECH nursing documentation module.

MATERNAL SERUM SCREENING PROGRAM COORDINATOR 2002-2003

CENTER FOR HUMAN GENETICS, BOSTON MEDICAL CENTER, Boston, Ma

Manage and supervise laboratory personnel and testing protocols. Maintain CAP laboratory accreditation by assuring GLP and implementing necessary changes to existing standards. Compile and calculate serum results and made recommendations to physicians and their staff

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based upon findings. Generate monthly and annual departmental reports. Develop and implement a computer-organized database for data collection and reporting.

REGISTERED NURSE 1997-2002

DIVISION OF CARDIOLOGY, New England MEDICAL CENTER, Boston, Ma
Member of the interventional cardiac catheterization team. Extensive experience in coronary artery stent placement techniques and technologies. Assist with myocardial biopsy as well as treatment /evaluation of heart transplant patients. Involvement in clinical trials on efficacy of cardiac pharmacological, device and biologic treatments. Performed manual femoral sheath removal, with use of hemostatic adjuncts. Charge and call RN on a rotating basis.

REGISTERED NURSE 1996-1997

TOBY HOSPITAL, Wareham, Ma
Operating Room, Endoscopy, Post Anesthesia Care Unit, Intensive Care Unit, Bronchoscopy and Laser Nurse.

REGISTERED NURSE 1994-1996

COMMUNITY HOME HEALTH, Sunrise, Fl
Responsible for primary home-based care of patients, administration of PO and IV medication, phlebotomy and skilled wound care. Patient and family education regarding pathophysiology of disease, actions and administration of medication, exercise and diet Instruct and evaluate Home Health Aide provision of care. Designed and implemented a diabetic teaching program.

REGISTERED NURSE 1992-1994

HOLLYWOOD MEMORIAL MEDICAL CENTER, Hollywood, Fl
Operating Room, Circulating, Scrub, and First Assistant in a 23 bed level Trauma II Institution. ECMO, Laser, Cryosurgery, CUSA, Cell Saver and laparoscopic experience. Organ procurement and preservation with The University of Miami Surgical team. Preceptor, monitor and resource person for Surgical Technician students.

REGISTERED NURSE 1990-1992

FLORIDA KEYS MEMORIAL HOSPITAL, Key West, Fl Operating Room, Endoscopy and Post Anesthesia Care Unit. Scrub Nurse Certification.

REGISTERED NURSE. 1988-1990

HOSPITAL OF ST RAPHAEL, New Haven, Ct
Surgical Intensive Care Unit.

REGISTERED NURSE 1986-1988

YALE-NEW HAVEN HOSPITAL, New Haven, Ct
Medical Intensive Care Unit. Chemotherapy Certification.

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REGISTERED NURSE 1984-1986

VETERAN'S MEMORIAL MEDICAL CENTER, West Haven, Ct
Stroke /Neuro Intensive Care Unit, Surgical Intensive Care Unit and Post Anesthesia Care Unit. Critical Care Certification.

ACCREDITATIONS

- Registered Professional Nurse with licensure in Connecticut, Florida and Massachusetts.
- ACLS/BLS Certified.
- 12 Lead EKG Certified.

***REFERENCES FURNISHED UPON REQUEST**