

Victoria A. Reder

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PROFESSIONAL ACHIEVEMENTS WRITING EXPERIENCE

Prepared numerous clinical reports and other materials for inclusion in briefing documents, INDs, and CTDs.

Types of Documents

- Prepared protocols for drug trials (Phases 1 through 3) and device trials.
- Produced investigator's brochures.
- Worked with interdisciplinary teams to produce Pre-IND Briefing Documents.
- Wrote previous human experience section and collaborated with project manager to coordinate submission of an IND.
- Worked closely with the regulatory department to write a Pre-NDA Briefing document in preparation for a client's meeting with FDA.
- Completed numerous integrated clinical/statistical reports (Phases 1 through 3) for submission to FDA and other regulatory authorities.
- Collaborated with physicians from PAREXEL, an academic medical center, and/or the client's regulatory department to write clinical expert reports for EC Dossiers.
- Collaborated with project manager to coordinate submission of an IND
- Prepared summary documents for CTDs.
- Developed manuscripts for publication.

Types of Agents

- Agents to treat
 - active rheumatoid arthritis
 - asthma
 - basal cell carcinoma
 - chronic hepatitis C
 - C. difficile*-associated diarrhea
 - lysosomal storage disorders
 - psoriasis
- Analgesics
- Antidepressants
- Antifungal agents
- Antihypertensives
- Antimicrobial agents to treat opportunistic infections in HIV/AIDS patients
- Antiretrovirals to treat AIDS
- Contrast agents for cardiovascular diagnostics
- Hormone therapy for prostate cancer
- Monoclonal antibodies to combat rejection of organ transplants
- Monoclonal antibodies to treat cancer
- Opioids
- Thrombolytics
- Vaccines

Types of Devices

- Implantable prosthesis
- Cardiac bypass device
- Stents
- Cytology laboratory device

PUBLICATIONS

Bolognini, V.¹: The Swan Ganz pulmonary artery catheter: implications for nursing. Heart and Lung 3: 967-981, 1974.

Greenblatt, D.J., Gross, P.L., Bolognini, V.¹: Pharmacotherapy of cardiopulmonary arrest. American Journal of Hospital Pharmacology 33: 579-583, 1976.

Thibault, G.E., Mulley, A.G., Barnett, G.O., Goldstein, R.L., Reder, V.A., Sherman, E.L., Skinner, E.R.: Medical intensive care: indications and outcomes. New England Journal of Medicine 302: 938-942, 1980.

Mulley, A.G., Thibault, G.E., Hughes, R.A., Barnett, G.O., Reder, V.A., Sherman, E.L.: The course of patients with suspected myocardial infarction: the identification of low risk patients for early transfer from intensive care. New England Journal of Medicine 302: 943-948, 1980.

Reder, V.A., Fineberg, H.V., Rosoff, C.B., White, L.S.: Shorter length of stay for simple cholecystectomy: cost-effectiveness of alternative strategies. Medical Care 21, 7: 745-754, 1983.

Campion, E.W., Reder, V.A., Mulley, A.G., Thibault, G.E.: Age and the declining rate of autopsy. Journal of the American Geriatric Society 34: 865-868, 1986.

Campion, E.W., Avorn, J., Reder, V.A., Olins, N.J.: Overmedication in the low weight elderly. Archives of Internal Medicine 147: 945-947, 1987.

Eagle, K.A., Quertermous, T., Singer, D.E., Mulley, A.G., Reder, V.A., Boucher, C.A., Strauss, H.W., Thibault, G.E.: Left ventricular ejection fraction: Physician estimates compared with gated blood pool scan measurements. Archives of Internal Medicine 148: 882-885, 1988.

Mahoney, J.D., Gross, P.L., Stern, T.A., Brown, B.J., Pollack, M.H., Reder, V.A., Mulley, A.G.: Quantitative serum toxic screening in the management of suspected overdose. American Journal of Emergency Medicine 8, 1: 16-22, 1990.

Eagle, K.A., Mulley, A.G., Skates, S.J., Reder, V.A., Nicholson, B.W., Sexton, J.O., Barnett, G.O.: Length-of-stay in the intensive care unit: effects of practice guidelines and feedback. Journal of the American Medical Association 264, 8: 992-997, 1990.

¹ maiden name