

**Julia Barrett, MD, MPH**  
Senior Clinical Consultant



Julia Barrett, MD, MPH, joined Biologics Consulting Group, LLC, as a Senior Clinical Consultant in December 2004 and served as an affiliate to our group for several years prior to joining.

Dr. Barrett received a BA in Biology from Smith College in 1982; an MD from Northwestern University School of Medicine in 1987; completed an internship and residency in Internal Medicine at the University of Minnesota in 1990; and completed a Fellowship in General Internal Medicine and received a Masters Degree in Public Health from George Washington University in 1992. From 1992-1997 she was a Senior Clinical Reviewer in the Clinical Trials Branch, Division of Vaccines and Related Products Applications, Center for Biologics Evaluation and Research, FDA.

As a Senior Clinical Reviewer at CBER, Dr. Barrett was responsible for the comprehensive review of clinical protocols for Phase 1, 2, and 3 clinical studies, including assessment of the rationale, safety, and design of proposed trials for bacterial, viral (including HIV), and DNA vaccines as well as several biologic therapeutic products. While at CBER, Dr. Barrett reviewed clinical data submitted to over 80 INDs and BLAs, contributed to decisions regarding the licensure of several vaccines, made presentations before FDA advisory committees, and participated in a variety of special FDA projects and committees. Since 1998, Dr. Barrett has divided her time between the practice of Internal Medicine and her own consulting business which has focused on assisting clients with the clinical development of new biological products, both vaccines and therapeutics.

At the Biologics Consulting Group, Dr. Barrett will utilize her clinical, regulatory, and public health expertise to assist clients in the following areas of clinical drug development:

- Global clinical development planning for drugs and biologics
- Design of clinical protocols and other study documents which are compliant with FDA regulations and expectations
- Leads a clinical team to assist clients with the planning and conduct of clinical trials

- Provides an experienced physician as liaison between clients and CROs to insure well-conducted studies
- Represents clients in interactions with FDA
- Assists clients in writing clinical sections of pre-IND, IND and BLA/NDA submissions
- Provide clients with a comprehensive “FDA style” review of IND, BLA and NDA clinical submissions
- Serves as a medical monitor
- Assists clients in preparing for FDA meetings and advisory committees
- Provides GCP compliance training
- Conducting site selection and site initiation visits
- Oversees BCG staff in writing clinical protocols, study reports and other study documents
- Oversees BCG staff in setting up safety databases for the monitoring of adverse events pre- and post-licensure