

Curriculum Vitae



Julia Barrett, M.D., M.P.H.

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Senior Clinical Consultant

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EXPERIENCE

Biologics Consulting Group, Inc. *Senior Clinical Consultant*
Evergreen, CO (Dec. 2004 - present)

Biologics Consulting Group, Inc. *Affiliate*
Evergreen, CO (1998 - Dec. 2004)

Clinical and Regulatory Consultant
Evergreen, CO (1998 - Dec. 2004)

CONSULTING EXPERTISE

- Dr. Julia Barrett provides clinical and regulatory consulting services to the biotechnology industry, pharmaceutical industry and academia.

- Dr. Barrett's five years of experience as a clinical reviewer at the FDA, in addition to her training in Internal Medicine and Public Health, enhances her ability to consult in a number of clinical and regulatory areas. These areas include:
 - Consultation regarding clinical and public health issues as they pertain to the development of new products and clinical trials
 - Clinical development plans for biologics, drugs and combination products
 - Comprehensive FDA style review of pre-IND, IND, BLA, and NDA submissions
 - Design, preparation and implementation of Phase 1, 2, 3 and 4 clinical trials
 - Clinical protocol development
 - Assistance with GCP compliance
 - Comprehensive review of safety and efficacy data
 - Medical monitoring
 - Assistance with the conduct of clinical trials, including consent forms, case report forms, IRBs, DSMBs, selection of investigators, safety monitoring and reporting
 - Preparation for FDA meetings and advisory committees
 - CRO oversight of ongoing studies



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SouthPark Internal Medicine

Littleton, CO (1999-2004)

- Practice of Internal Medicine

Women's Health Specialists

Denver, CO (1998)

- Practice of Internal Medicine

National Naval Medical Center, Department of Medicine

Bethesda, MD (1997)

- Part-time staff physician at the NNMC
- Preceptor of first year medical students for a physical diagnosis course.

Food and Drug Administration, Center for Biologics Evaluation and Research (CBER),

Office of Vaccines Research and Review, Division of Vaccines and Related Products

Applications, Clinical Trials Branch, *Senior Clinical Reviewer*

Bethesda, MD (1992-1997)

- **IND Review:**
 - Responsible for the comprehensive review of protocols for Phase 1, 2 and 3 clinical studies.
 - Assessed the rationale, safety and design of clinical studies submitted to over 80 INDs (Investigational New Drug Applications) for bacterial, viral (including HIV) and DNA vaccines, as well as several biological therapeutic products.
 - Recommended whether a study was allowed to proceed or placed on clinical hold.
 - Responsible for training new physicians who joined the Division.
- **PLA/BLA Review:**
 - Responsible for the review of clinical data submitted in BLAs to support the licensure of new vaccines and other biological products.
 - Performed a complete review of all clinical data submitted and then formally presented conclusions and recommendations at FDA Advisory Committees.
- **Guidance to Industry:**
 - Provided guidance regarding the overall clinical development of investigational products, including the type and quantity of preclinical data necessary to initiate Phase 1 studies, the need for dose-ranging studies, the choice of efficacy endpoints for pivotal Phase 3 trials, and the size of the safety database required for licensure.
- **Policy and Regulatory Document Development:**
 - Participated in a variety of FDA projects and committees ranging from combination pediatric vaccines to HIV vaccines to the inclusion of women in clinical trials.
 - Served on FDA policy committees and participated in the writing and review of regulatory documents.



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National Cancer Institute, Division of Cancer Treatment, Medicine Branch, Retroviral Diseases Section, HIV Clinic (Dr. Robert Yarchoan, Director)
Bethesda, MD (1993-1995)

- Part-time staff physician at the NIH
- Assisted in conducting Phase 1 and 2 studies of HIV therapeutics.

George Washington University, Department of Health Care Sciences
Fellowship in General Internal Medicine
Washington, DC (1990-1992)

University of Minnesota
Internship and Residency in Internal Medicine
Minneapolis, MN (1987-1990)

EDUCATION

B.A. in Biology *cum laude*, Smith College, Northampton, MA (1982)

Trinity College of Music, London, England, Non-Degree Program in Violin Performance
(1982-1983)

M.D., Northwestern University School of Medicine, Chicago, IL, (1987)

M.P.H. (Masters in Public Health) George Washington University, Washington, DC (1992)

HONORS AND AWARDS

1997 FDA Commendable Service Award for superior performance in the clinical review of vaccine and therapeutic products.

CERTIFICATIONS

2000 American Board of Internal Medicine Recertification

1990 American Board of Internal Medicine Certification

1988 National Board of Medical Examiners

MEDICAL LICENSURES

1997-Present Colorado (inactive status since 2005)

1991-1997 Maryland

1990-1992 District of Columbia

1989-1990 Minnesota



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COMMITTEE MEMBERSHIPS

- 2004-present Member of several NIH grant review committees
- 1997 Member of the FDA Pregnancy Registry Working Group that evaluated product labeling pertaining to the use of drugs and biologics during pregnancy
- 1994-1997 Reviewer of documents from the Second International Conference on Harmonization (ICH)
- 1994-1997 FDA representative on the AIDS Clinical Trials Group (ACTG) HIV Specific Immunity Subcommittee of the Pediatric Vaccine Committee
- 1994-1995 Member of the FDA Information Standards Steering Committee' Clinical Laboratory Data Working Group
- 1994 Member of an FDA committee that discussed issues and policy regarding the inclusion of women in clinical trials
- 1993-1994 Member of an FDA committee that produced a document entitled "Evaluation of Combination Vaccines: Production, Testing and Clinical Study"

RESEARCH AND PUBLICATIONS

- 2008 AA McCormick, S Reddy, SF Reinl, TI Cameron, DK Czerwinski, F Voljdani, KM Hanley, SJ Garger, EL White, J Novak, J Barrett, RB Holtz, D Tuse, R Levy (2008). Plant-produced idiotype vaccines for the treatment of non-Hodgkin's lymphoma: Safety and immunogenicity in a phase I clinical study. *PNAS*: 105 (29): 10131-10136.
- 1997 Book chapter entitled "The Biological IND" Biologics Development: A Regulatory Overview, Authors: Jeanne Novak, Julia Barrett, Loris McVittie and Donna Chandler, Editor: Mark Mathieu, Published by Parexel International Corporation
- 1997 Book chapter entitled "The IND for Biological Products" Global Biotechnology Product Registration: E.U., U.S. and Japan, Authors: Jeanne Novak, Julia Barrett, Loris McVittie, Donna Chandler and Mark Mathieu, Editor: Mark Mathieu, Published by Parexel International Corporation
- 1991-1992 National Cancer Institute, Bethesda, MD, Division of Cancer Prevention and Control, Early Detection and Community Oncology Program, Epidemiological study examining rural-urban differences in the stage at diagnosis of breast and cervical carcinoma

PRESENTATIONS AND CONFERENCES

- Aug 2008 Presentation at CHI's conference "Clinical Risk Management and Safety for Vaccines" entitled "Clinical and Regulatory Considerations for the Development of Vaccines." Boston, MA.
- Mar 2007 Presentation at the World Vaccine Congress 2007 entitled "Clinical Development Considerations for Vaccines." Washington, DC.
- Oct 2005 Presentation at bioLOGIC 2005 entitled "Clinical Development of Biodefense Vaccines." Boston, MA.
- July 2001 Presentation at DIA 2001 entitled "Making the Most of FDA Clinical Expertise to Support a Successful Clinical Development Program." Denver, CO.
- July 1999 Presentation entitled "Establishing and Using Serological Correlates of Protection" and "Preparation and Use of Documents to Support Clinical Trials." Pentagon City, VA.
- 1999-present Multiple presentations regarding Good Clinical Practices (GCP)
- May 1997 Presentation entitled "Adverse Event Reporting: What, When and How? A Vaccine Perspective." Walter Reed Army Medical Center. Silver Spring, MD.
- July 1996 Presentation before the FDA's Vaccines and Related Biological Products Advisory Committee (CBER) regarding clinical data submitted to support an acellular DTP vaccine. This new pediatric vaccine was approved by FDA. Rockville, MD.
- Apr. 1996 Presentation on the topic of IND Clinical Review at a conference entitled "Regulatory Issues Related to Novel Product and Process Technologies." This conference was sponsored by the Pacific Region biotechnology industry in conjunction with the Food and Drug Administration. Irvine, CA.
- Nov. 1995 Co-chair at a conference entitled "Improving the Performance of Influenza and Pneumococcal Vaccines in Adults." This session addressed immunogenicity and safety issues in influenza and pneumococcal vaccine development. Washington, DC.
- May 1993 Presentation before the FDA's Antiviral Drugs Advisory Committee (CDER) regarding clinical data submitted to support the use of intravenous Immune Globulin (IVIG) to prevent bacterial infections in HIV-infected children. This new indication for IVIG was approved by the FDA. Rockville, MD.