SUSAN M. JERIAN, MD
CURRICULUM VITAE

Personal details

Name:
Susan M. Jerian, MD

Education:
Fellowship Medical Oncology - National Cancer Institute (1991-1994)
Residency Internal Medicine - U. of Arizona (1988-1991)
Medical School - George Washington U. (1984-1988)
Undergraduate - Occidental College (1980-1984)

Professional experience

Current positions:

- Member, NDA Advisory Board (2017 – present)
- President and Founder, ONCORD, Inc. (2006 – present) Providing regulatory and clinical development technical expertise to pharmaceutical and biotechnology companies worldwide. ONCORD has worked with over 200 pharmaceutical and biotechnology companies in the US, EU, Australia and Asia.

Previous positions:

- Visiting Faculty, Keck Graduate Institute of Applied Life Sciences (2006 – 2008) Teaching a graduate level course on Clinical Trials Design, Conduct and Strategy as part of a 2 year masters program preparing students for careers in the pharmaceutical and biotechnology industries.
- Director Clinical Research, Amgen, Inc. (2003 – 2005) Global Development Leader for two programs: Panitumumab (Vectibix) and Panitumumab combined with AMG 706 Directed all aspects of clinical program development (~15 clinical studies) and led multifunctional team encompassing clinical operations (clinical trial management, clinical data management, clinical site management), safety, biostatistics, programming, preclinical, toxicology, pharmacology, pharmacokinetics, regulatory, quality assurance and quality control, labeling, medical writing, basic science, diagnostic testing, immunology, pathology, and finance. Scope included US, EU and Japan. Achieved enrollment of pivotal Phase 3 study ahead of schedule and final data analysis demonstrated successful outcome. Panitumumab was approved by FDA September 2006.

- Medical Officer, Team Leader; FDA (2001 – 2003) Center for Biologics Evaluation and Research, Division of Clinical Trials Design and Analysis, Oncology Branch. Led a team of 5 oncologists conducting clinical regulatory reviews and oversight for a portfolio of hundreds of INDs as well as multiple license applications and supplements. Product classes included antibodies, therapeutic proteins, tumor vaccines, cell and gene therapies, and devices. Clinical indications included adult and pediatric solid tumors, lymphoma, leukemia, supportive care, and graft-vs.-host disease.
- Medical Officer, FDA (1995 – 2001) Center for Biologics Evaluation and Research, Division of Clinical Trials Design and Analysis, Oncology Branch Primary clinical reviewer for over a hundred INDs and multiple license applications and supplements.

Clinical appointments

- National Naval Medical Center (1996 to 2000)
- Community Oncology (part time) (1995 - 1996)

Area of Expertise

- National Cancer Institute (NCI) trained oncologist, with over two decades of leadership and experience in the Pharmaceutical/Biotechnology Industry and the Food and Drug Administration (FDA); a track record of product approvals (over 20) and successful clinical programs. Areas of particular strength:
- Strategic oncology product development including drugs, biologics (antibodies, therapeutic proteins, tumor vaccines, cellular and gene therapies), and therapeutic aspects of devices (stem cell selection devices and in vitro diagnostics).
- Design and analysis of Phase 1, 2 and 3 human clinical studies.
- Regulatory expertise for all phases of development: pre-IND, IND, NDA, BLA, post-marketing commitments, safety, product labeling, and FDA advisory committee meetings
- Expertise coordinating global initiatives for U.S. based teams, multinational teams and corporate partnership scenarios.
- Critical program analysis and solution implementation: Identification of program strengths and rate limiting weaknesses with assistance in development and implementation of solutions.

Major projects

- Provided expertise for preparation for FDA meetings including briefing document preparation, coaching sponsor teams regarding FDA interactions and participation in FDA meetings. Typical meetings include pre-IND, Type A, B, and C, end of phase 1,

end of phase 2, pre NDA/BLA, clinical hold, Breakthrough Designation request, Fast Track request, and public advisory meetings.

- Provided expertise to assist with design and drafting of clinical protocols, informed consent documents, charters and other protocol related documents, regulatory briefing documents, clinical study reports, and marketing authorization applications.
- Designed and authored clinical development and regulatory strategic plans
- Designed and analyzed complex or novel regulatory strategies.
- Served on clinical trial oversight committees (e.g. safety oversight)
- Worked with academic institutions to establish novel product development programs including spinoff start-up companies.
- Reviewed or assisted with the filing of hundreds of INDs and dozens of NDAs/BLAs
- Conducted due diligence assessment of therapeutic products

Associations

- American Society of Clinical Oncology
- American Association of Cancer Research
- American College of Physicians

Full list of publications available on request.