William E. Gannon Jr., MD
Vaccine Clinical/Regulatory Experience

- 15+ years of Oncology Clinical Trial Design and Clinical Operations Management Vaccine Development Experience:

  Phase I – III:

  1. Breast - HER2Nu
  2. Colon - Autologous & Traditional
  3. Bladder
  4. Rectal - Autologous & Traditional
  5. Prostate
  6. Ovarian

- Vaccine Safety Monitoring Experience:

  1. Oncology Areas discussed above
  2. Influenza - Ph 3
  3. Anthrax - Ph 1
  4. TB – Multiple Phases
  5. Monitoring: H1N1 - Commercial Co., NIH, DIMB (Dept of Defense)
  6. DSMB Member: H1N1 - NIH, DIMB (DoD - Fed)

- Regulatory Affairs – Vaccines:

  - IND transfer from Academic to Commercial
  - 5 IND filings and pre-meetings
  - Multiple Pre-Submission Mtg & “End of Phase” Meetings with FDA
  - Successful removal of Client from “Clinical Hold” with Bridge Study design and execution
  - 1 BLA
  - 2 SPA Submissions
  - 3 IND’s
  - Annual Reports
  - Safety Reports
  - FDA Liaison for Multiple Clients
  - Multiple DSMB’s

- DHHS/NIH/NAID/DEA – CTU **Grant Reviewer Vaccine Program** – (Current)

- Company X– Medical Monitor - Recombinant Protective Antigen (**rPA) Anthrax Vaccine (Ph2)** – (2012-Present)

- Company X – (Acting) VP Reg Affairs & Med. Director - Vaccine **(Ph1)** (Current) – **Ovarian**

- NIH/DIMB (2010) – DSMB Board Member – 3 Vaccines **(H1N1 (2) & Seasonal Flu (1)** - US Military Use

- NIH/DIMB (2008-09) – Safety Monitor – **H1N1 (Ph2)** - (potential) US Domestic Use

- Med Immune (2009) – Safety Reviewer **- H1N1 -** Clinical Trial Program – Commercial Use

- Galena Pharma (formerly Apthera, Inc.) (2005-09) - CMO - **HER2Nu (Ph 2 & 3) – Breast**

- Vaccinogen, Inc. (formerly INTRACEL, Inc.) (1999- 2000) - VP Medical Affairs - Autologous Vaccine **(Ph 2& 3) – Colon & Rectal**