William E. Gannon Jr., MD
Regulatory Experience

- Regulatory Affairs – General:

1. 30+ Pre-IND Mtgs
2. 40 IND Filings
3. 21 ANDA Filings
4. 13 NDA Filings
5. 4 BLA Filings
6. 6 505(b)2 Filings
7. 12 510k Submissions
8. 8 PMA Submissions

- Regulatory Affairs – Vaccines:

1. IND transfer from Academic to Commercial
2. 5 IND filings and pre-Mtgs, etc…
3. Multiple Pre-Submission Mtg & "End of Phase" Mtgs with FDA
4. Successful removal of Client from "Clinical Hold" with Bridge Study design and execution
5. 1 BLA
6. 2 SPA Submissions
7. 3 IND's
8. Annual Reports
9. Safety Reports
10. FDA Liaison for Multiple Clients

- 17+ years of Oncology Clinical Trial Design and Clinical Operations Management Vaccine Development Experience Phases 1 -3:

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

- Additional Clinical Trial Design and Clinical Operations Mgt Experience Phases 1 -4 :
    1. Pediatric
    2. CNS/Psychiatric
    3. GI
    4. OB/GYN
    5. ID
    6. Devices

- Vaccine Safety Monitoring Experience:
    1. Oncology Areas discussed above
    2. Influenza PH III
    3. Monitoring: H1N1 - Commercial Co., NIH, DIMB (Dept of Defense)
    4. DSMB Member: H1N1 - NIH, DIMB (Dept of Defense)