William E. Gannon Jr., MD
Oncology/CNS/ Neuro Experience

Clinical – Trial & Operations, Safety and Reg. Affairs with regard to my experience in the areas of Oncology:

Clinical Operations Management:

Medical/Safety Monitor on over 20 pharma-related products in the oncology arena and (Executive) Clinical Operations responsibility on over a dozen trials. These trials included: prostate, breast, lung, GI, vaccine compounds (not discussed below), oncology related imaging agents and oncology related pain management products. Involvement has ranged from: strict medical monitoring; protocol design (Phase I – IV); IRB approval through CRA/MD training; project management; DSMB creation or participation - including Charter development and oversight and NDA filing.

Other experience includes; development, implementation and management of clinical trials for neurological tumors (skull-based surgery), oncological endoscopic sinus surgery procedures and CT & MRI imaging procedures and trials for these areas.

Capital City Technical Consulting:
www.capcitytek.com

- Retrospective compilation of PH I & II vaccine clinical trials in HER2-Neu trial for Breast Cancer
- Designed and implemented PH III multi-site, international clinical trial in HER2-Neu Vaccine for Breast Cancer
- Designed, implemented & completed an NCI PH I (all comers) oncology trial with a "nanotechnology" compound
- Designed (implementation is anticipated) 3 PH II trials for a Nanotechnology compound" in small cell lung cancer, liver and colon cancer
- CLIA test validations for Breast and Pancreatic Cancer compounds
- Medical Monitoring Services: All of the Above; Melanoma, GI, Hepatoma

Industry Experience:

- Two Phase II studies in Breast Cancer (small & large tumor)
- Phase I study in post mastectomy Chest Wall tumors (Chemo agent + Thermal ablation)*
- Phase I trial in Prostate Cancer (Chemo agent + Thermo ablation)*
- Phase I trial in Liver Cancer (Chemo agent + RF Ablation)*

- Phase III study for Bladder Cancer In-Situ utilizing the agent KLH. It is a 15 site 150 patient study, based on a Phase I/II that was conducted and then retrospectively compiled (this year) and submitted to the FDA.
- Phase I/II (50 subjects) trail for an Autologous Tumor Vaccine Prep for Colon Cancer utilizing sterile prepped vaccines to serve as a "bridging study" to the 4 retrospective studies discussed below.*
- Retrospective Compilation of 3 Phase III studies (2 US & 1 European) (total of 850 subjects) with the use of autologous (non-sterile) tumor vaccine preps in the treatment of colon cancer – Dukes Stage II & III.
- Retrospective Compilation of 2 Phase I/II studies (60 subjects) conducted prior to the Phase III studies in relation to the bullet above.
- Design & (future) execution of a prospective Phase III (US & European - 700 subjects) & Phase IV (European – 550 subjects) in sterile prep colon cancer vaccines.
- Design & execution of an initial 510k, leading to a PMA, for a Urological stent device in the treatment of urethral cancer.

* Filed IND

Regulatory:

- **ANDA** submissions (3) for oncology related pain products
- **IND s**ubmissions (15+)
- **NDA** submissions (5)
- **Final Study Reports** (25+) in PH, I, II, III & IV (post market)
- **DSMB** reports
- **IRB** reports
- **SAE & AE** submissions
- **Pre-IND, pre-NDA, end of PH II and pre-PH III FDA meetings** on various oncology products
- **FDA** roundtable and panel discussions and meetings
- **SPA Submission** for a PH III Breast Cancer Trial, leading to a BLA submission
- **IND Transfers**: Commercial entity to entity; Investigator IND to commercial entity; Military IND to commercial entity