William E. Gannon Jr., MD
Summary of Safety/Medical Monitoring Experience

All positions held during my career have involved safety monitoring and reporting, trend analysis, pharmacovigalence database management:

- **Medical Monitoring** responsibilities for **over 60 trials** during career **to date**

- Experience and responsibility in all facets of safety reporting:

    - Medical reporting of SAE' & AE's (where appropriate to regulatory agencies
    - study/case review, report writing and submission (where appropriate) to regulatory agencies: FDA – CDER, CBER, CDRH; EU Regulatory Agencies; IRB's, DSMB's and Ethics Committees
    - DSMB & IBC Committee member(s)
    - IRB committee member

- Establishment of DSMB's (Data Safety Monitoring Boards) for multiple clinical trial programs

- Development and implementation of SOP's for Safety Reporting, Report Templates and tracking processes (data analysis)

- Development and implementation of IBC & DSMB charters, guidelines and procedures

- SOP development and implementation or evaluation/assessment(s) of external (commercial/national) IBC's, DSMB's and IRB's

- American Academy of Pharmaceutical Physicians and The PERI Institute in Safety Monitoring & Reporting certified