Legal & Ethical Considerations in Clinical Research

Pursuant to National Regulatory approval processes, a drug may not be introduced into market unless a Sponsor has demonstrated, through clinical research, that:

- The drug is safe & effective for intended use;
- Adequate & “well controlled investigations” establish a drug’s safety and effectiveness;
- The intended conditions for use of a drug are listed in the drug’s labeling, which has been reviewed and approved by the Regulator;
- Further, indications for use that are not listed in a drug’s labeling are not deemed to be approved by the Regulator.

In a nutshell, a drug will be approved if the Sponsor can show that data which supports a NDA is derived from a clinical study which has the following criteria:

- Well designed
- Performed by qualified Investigators
- Carefully performed
- Follows Declaration of Helinski ethical principles OR is conducted in accordance with local law.

Industry's Responsibilities

Principles for the Conduct of Clinical Trials are set forth in the ***Declaration of Helsinki*** and the ***Inter Conference on Hamonization GCP Guideline*****,** with the key issues for industry being:

- Protecting research participants
- Conduct of clinical trials (GMP)
- Ensuring objectivity in research
- Providing accurate information about clinical trials
- Expanding access to investigational drugs

Overview: Risks in Clinical Research

Globalization – not all research environments are the same yet the same expectations apply.

Increased regulatory controls & oversight.

Research regulation and rules are complex.

Significant pressure on Regulators to make things "right" where public perception is that something has gone wrong.

Use of multiple Third Parties: CROs, SMOs, Investigators, Hospitals.

Education is non-mandatory and sometimes sparse.

Healthcare resources and qualified personnel are finite and are not necessarily "comparable" in different markets.

There are many Govt Officials to deal with.

Consequences of non-compliance are not well understood.

Patients' safety and rights are paramount, and are "above" other considerations.

Compliance Risks

Patient recruitment and enrolment issues.

Selection of qualified Investigators, Healthcare workers and CROs

Accurate and complete study records

Protocol adherence - Failure to follow or document protocol deviations and reasons why

Billing and / or payment irregularities

Sham research proposals – ghost subjects, false entries

Informed consent issues as well as failure to disclose risks to subjects

Non compliance with IRB protocols – lack of Ethics Review

Failure to review and report adverse events

Institutional conflicts of interest

Drug / device accountability during trial

Onus is on Industry to Maintain High Ethical Standards