Nearly 60% of all protocols require amendments; one-third are avoidable

First-ever study quantifies impact of protocol changes on clinical trials

- Completed protocols across all phases incur an average of 2.3 amendments, with each requiring an average of 6.9 changes to the protocol.

- Incidence of amendments and changes per amendment vary widely by therapeutic area, with GI, cardiovascular, oncology, and respiratory having the highest number of amendments per protocol.

- One-third of all amendments relate to protocol description and patient eligibility criteria.

- Across all phases of clinical trials, 43% of protocol amendments occur before first patients are enrolled, with amendments more likely to occur in Phase I studies.

- The most commonly cited causes of amendments include the availability of new safety information (19.5%), requests from regulatory agencies to amend the study (18.6%), and changes in the study strategy (18.4%).

- Median total cycle time to identify and resolve a protocol problem is 61 days.