Neuroscience Trials of the Future: Ethical Considerations

The Evolving Clinical Research Ecosystem and Its Implications

Greg Koski, PhD, MD
President and Chief Executive Officer
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“The drug development model has not fundamentally changed in more than 50 years, when the Kefauver-Harris Amendments of 1962 established the current standard for the clinical testing of investigational drugs”....

--Kenneth I. Kaitin, PhD
Tufts CSDD Director
An Integrated Model for Patient Care and Clinical Trials (IMPACT) to support clinical research visit scheduling workflow for future learning health systems. *Journal of Biomedical Informatics*, Volume 46, Issue 4, Pages 642-652

Chunhua Weng, Yu Li, Solomon Berhe, Mary Regina Boland, Junfeng Gao, Gregory W. Hruby, Richard C. Steinman, Carlos Lopez-Jimenez, Linda Busacca, George Hripcsak
Big Data Will Get Even Bigger, But Its Use Will Remain Challenging

- Personal Health and Biological Information (including Genomics)
- Clinical Trials and Trial-Generated Adverse Reaction Data
- Monitoring and Oversight Data
The Ecosystem is Evolving from Silos to Networked Systems

The Application and Impact of Technology Will Grow and Accelerate Across the Endeavor
The Use of Data Standards, Sharing, Aggregation and Analytics Will Grow
Implications for Ethics, Ethical Review and Protection of Human Subjects