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Building a Global System—Promoting Accountable Research™

Alliance for Clinical Research Excellence and Safety

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Neuroscience Trials of the Future: Ethical Considerations

The Evolving Clinical Research Ecosystem and Its Implications

Greg Koski, PhD, MD

President and Chief Executive Officer

Alliance for Clinical Research Excellence and Safety



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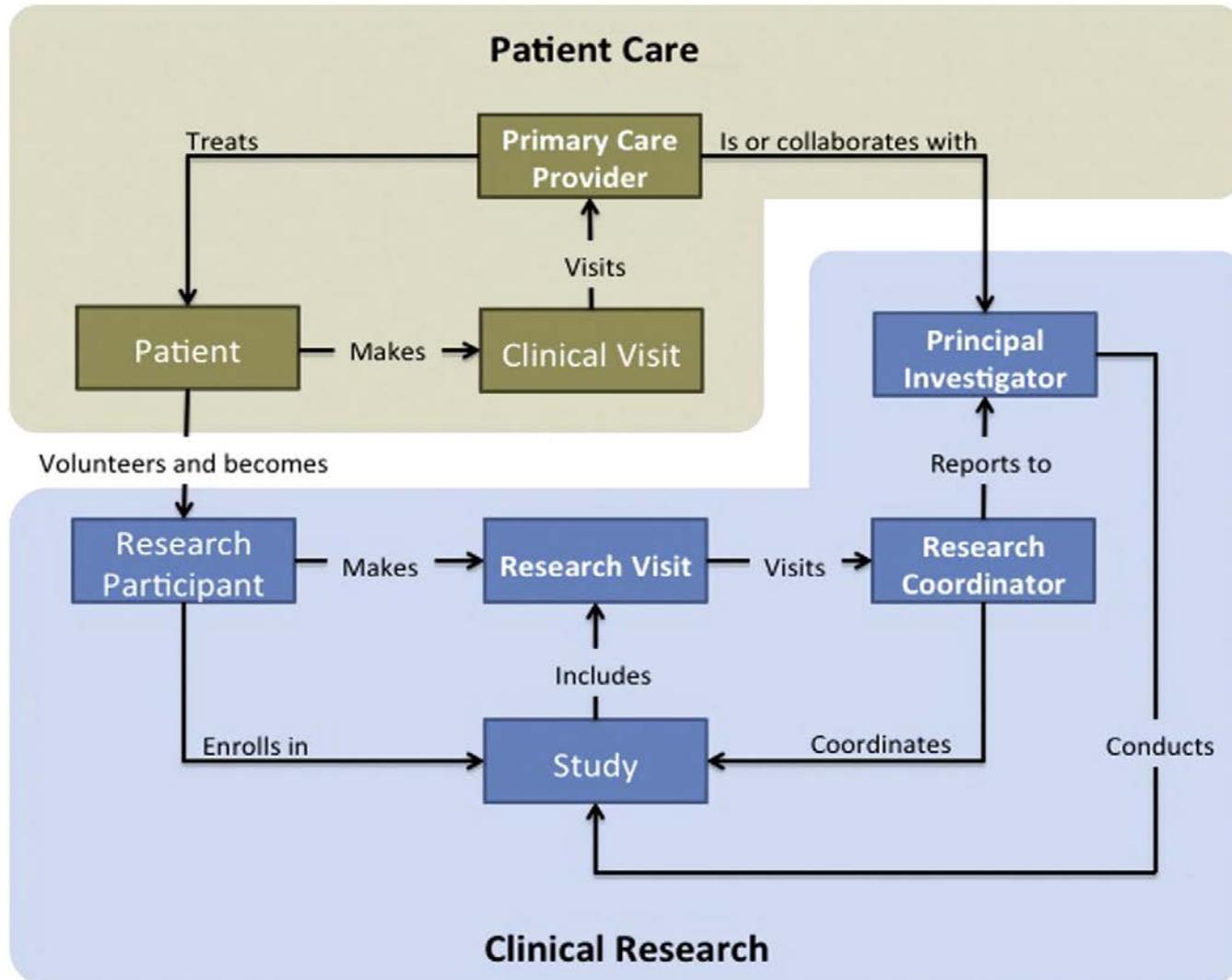


Tufts Center for the
Study of Drug Development

“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*

Integration of Healthcare and Health Research



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



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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

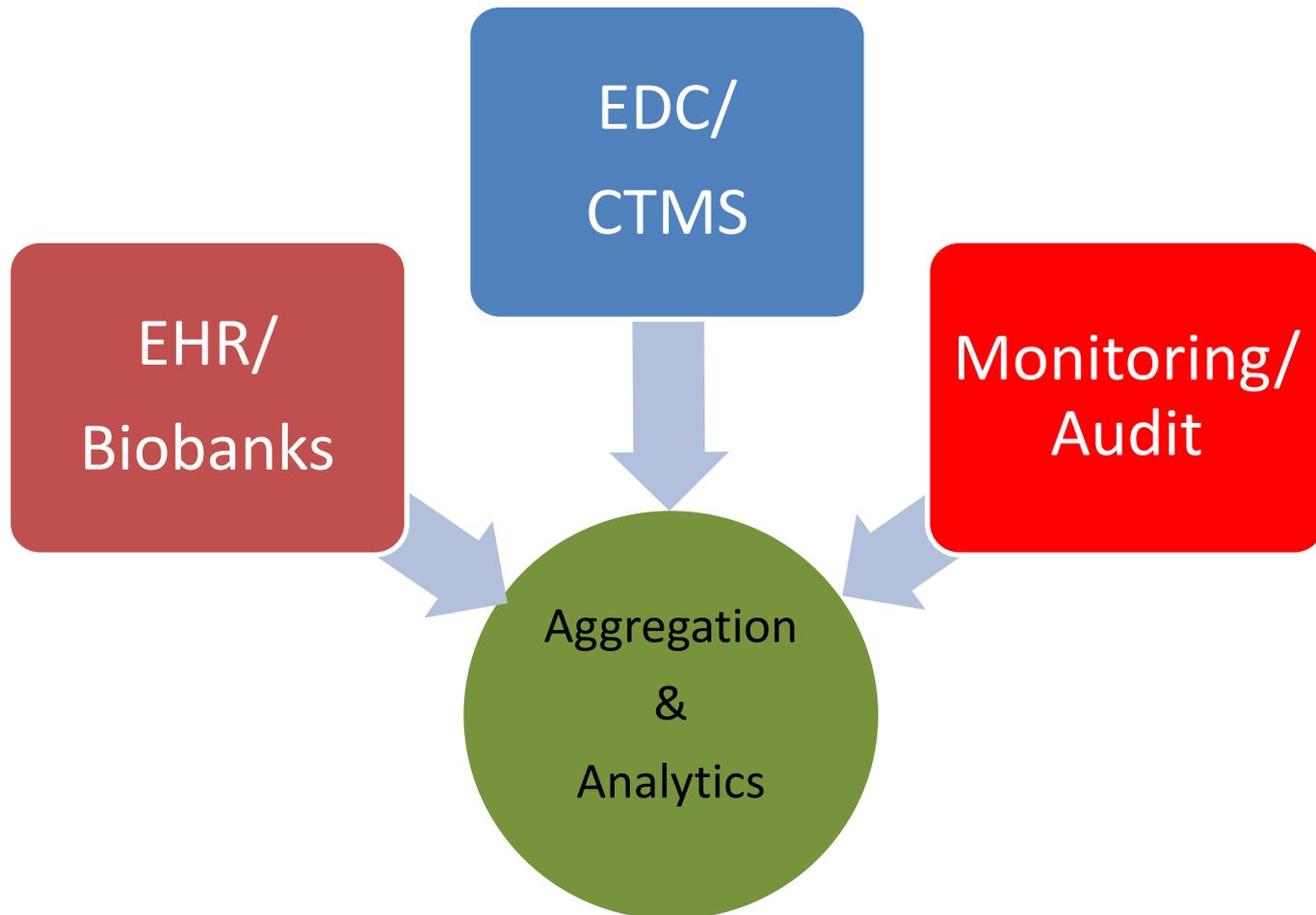


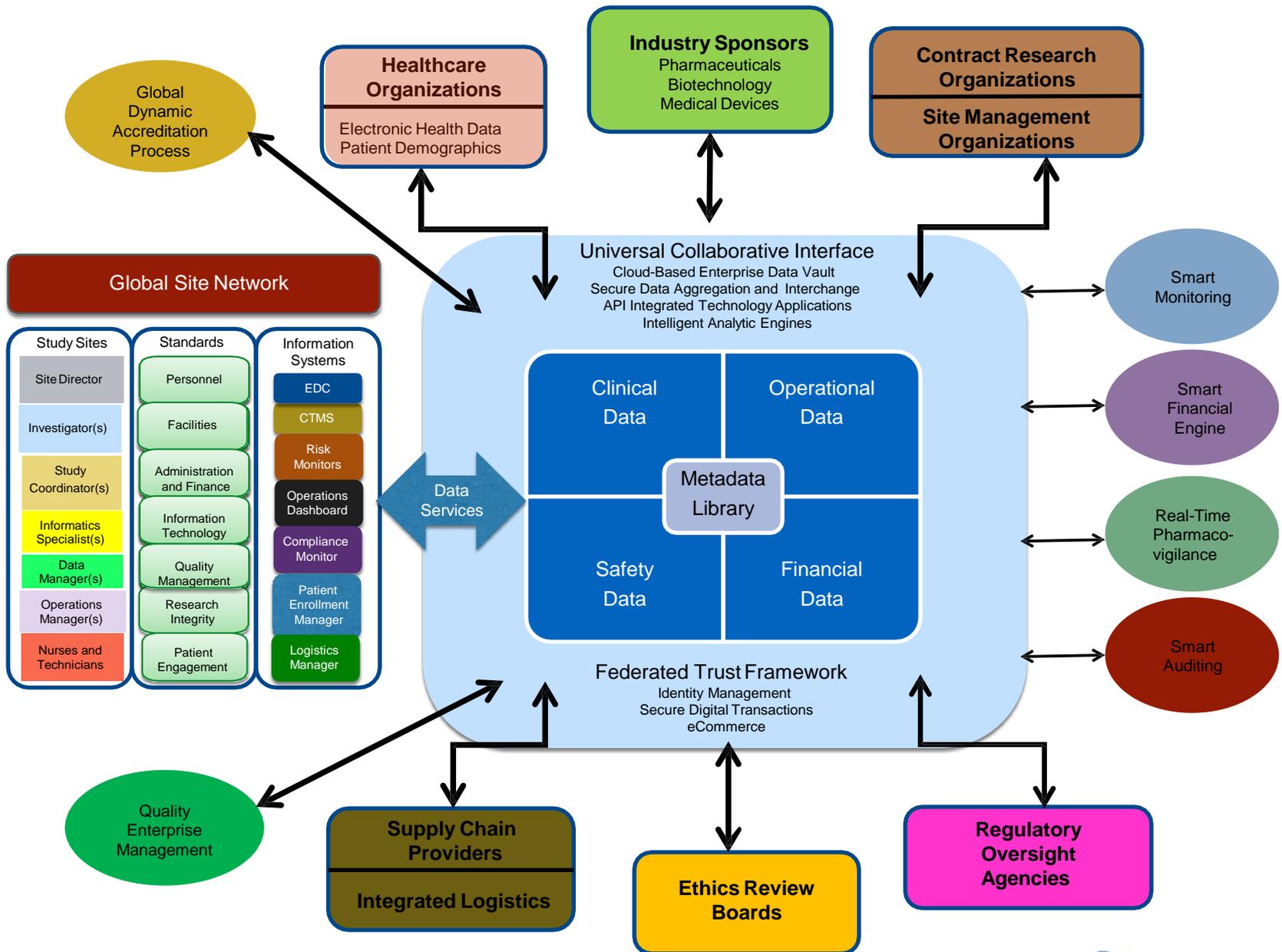
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The Use of Data Standards, Sharing, Aggregation and Analytics Will Grow







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Implications for Ethics, Ethical Review and Protection of Human Subjects

**Committed to Systems Solutions
for Accountable Research™**



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