The Future of Clinical Trials

Implications For Data-Sharing

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Why things are changing

• Costs and timeline... $100 billion/year, 15 years... unaffordable, unacceptable

• Patients’ involvement
  ➢ As pharma’s focus narrows, patients are organizing... controlling own data
  ➢ Renewed sense of urgency

• New technologies... the digitization of medicine
  ➢ Biosensors, devices and real-time data capture... high quality, inexpensive
  ➢ Genotyping, tissue banking, imaging, phenotypic, behavioral, real life data... rich, regulator-friendly
  ➢ New ways to share and aggregate data... powerful
  ➢ Access to ~3000 approved drugs that can help lots of diseases... fast

• New attitudes towards privacy and IP... no sacred cow

• New tools and methods... creative, powerful
What can we expect?

• If new data exists, it will be used

• RCTs will remain the gold standard for clinical research
  ➢ Rigorous way to test hypotheses

• RCTs will be supplemented, enriched and improved by novel data flows

• Lots of resistance... current costs are someone’s income
Implication for data-sharing

• There are issues:
  ➢ **Infrastructure**... who hosts the data?
  ➢ **Ownership**... who owns it?
  ➢ **Access**... who can use it?
  ➢ **Privacy**... How to protect patients’ privacy
  ➢ **IP**... who owns the IP created from the data?

• There are solutions... **patient-driven solutions**
  ➢ Quite a few initiatives have already been piloted, and more are being implemented
  ➢ FasterCures’ key role as clearinghouse for data-sharing initiatives

• Patients must speak out
  ➢ There are still people interested in not solving the problem
When will it happen?

• The technologies needed have already been invented
  ➢ Smart phones, biosensors and devices, wireless transmission, the cloud, Watson

• Integration more than innovation challenge
  ➢ Apple, Samsung, Google, Qualcomm, Microsoft are helping

• A solution will be available yet in this decade
Thank you!

Questions?
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