Virtual Clinical Trials
Session 1:
Opportunities to Improve Clinical Trials

Craig Lipset
@craiglipset
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Centralization Followed by Decentralization…

Centralization followed by decentralization: Computing

The decentralization that follows centralization is only beginning in healthcare
Centralization Followed by Decentralization…

Centralize:
• Investigator
• Coordinator
• Labs
• Diagnostic Reads
• IRBs

Decentralize Participation:
• Improve Access
• Reduce Burden
• Improve Representation
Industry Evolution Since the Pfizer REMOTE Trial

Pfizer’s ‘virtual’ clinical trial could have far-reaching implications for future research productivity

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As Pfizer begins enrolling the first-ever FDA-approved “virtual” clinical trial, which allows patients to participate from home using smartphones and computers instead of visiting a clinic, industry executives believe the study has far-reaching implications for improving the productivity of clinical trials in the future.
Destination for Virtual Trials

- Brick-and-Mortar Sites
- Select Visits From Home
- Fully Remote
- Location Flexible
Virtual Trials: Primary Obstacles

- Legal/Regulatory variability (by state, by country)
- Ensure healthcare providers are engaged (rather than marginalized)
- Robust efficacy & safety endpoints that may be captured with confidence agnostic to location
Roadmap to Improving Trial Efficiency

Near-Term

• Anticipate cost-neutral for direct costs
• Location is shifted, but procedures and staff-time may be minimally changed
• Increased cost where study team capabilities are added but none replaced
• Potential indirect cost savings associated with reduced speed (without compromising quality)

Long-Term

• Potential for savings over long-term
  – Use existing consumer technologies
  – Replace (rather than add) study team capabilities
  – Better embed research participation within healthcare settings