



Virtual Clinical Trials

Session 1:

Opportunities to Improve Clinical Trials



Craig Lipset

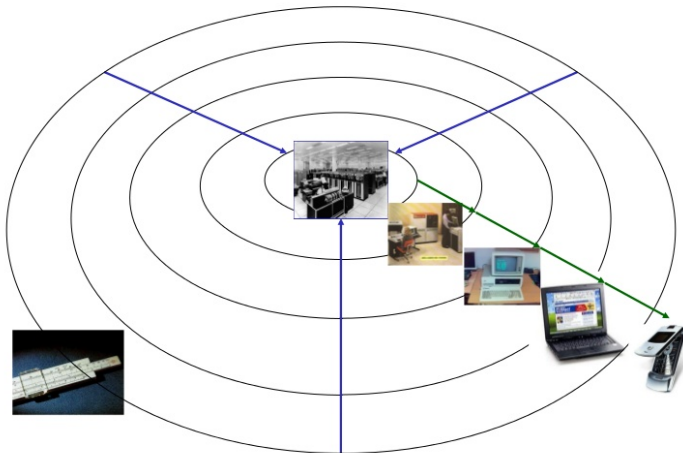
@craiglipset

November 28 2018

National Academies

Centralization Followed by Decentralization...

Centralization followed by decentralization: Computing

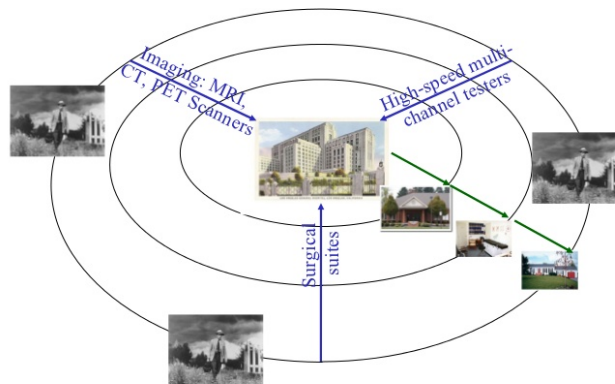


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The decentralization that follows centralization is only beginning in healthcare



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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

MONDAY, JUNE 20, 2011

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.

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HEALTH

A Clinical Drug Trial Via Phone, Computer

By JENNIFER CORBETT DOOREN
June 7, 2011

Pfizer Inc. is conducting a drug trial in which patients participate from their homes using computers and smartphones rather than

Contemporary Clinical Trials 38 (2014) 190–197

Contents lists available at ScienceDirect

Contemporary Clinical Trials

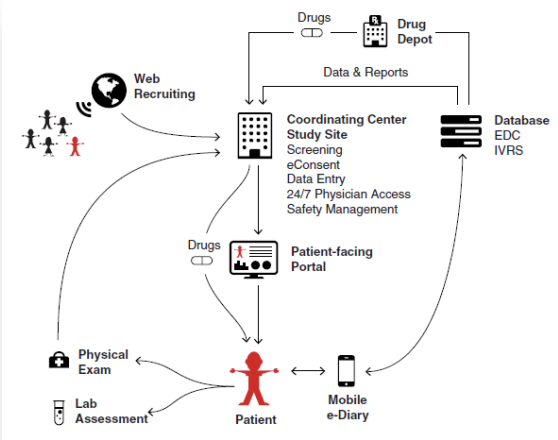
journal homepage: www.elsevier.com/locate/conclintrial

ELSEVIER

Web-based trial to evaluate the efficacy and safety of tolterodine ER 4 mg in participants with overactive bladder: REMOTE trial

Miguel Orri^{a,*}, Craig H. Lipset^b, Bradley P. Jacobs^{c,d}, Anthony J. Costello^e, Steven R. Cummings^{c,d,e}

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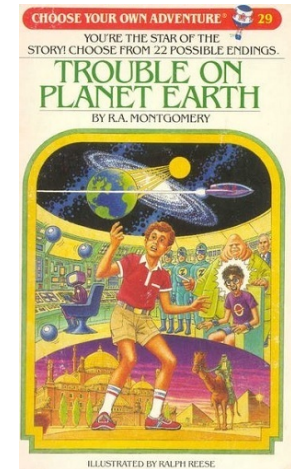
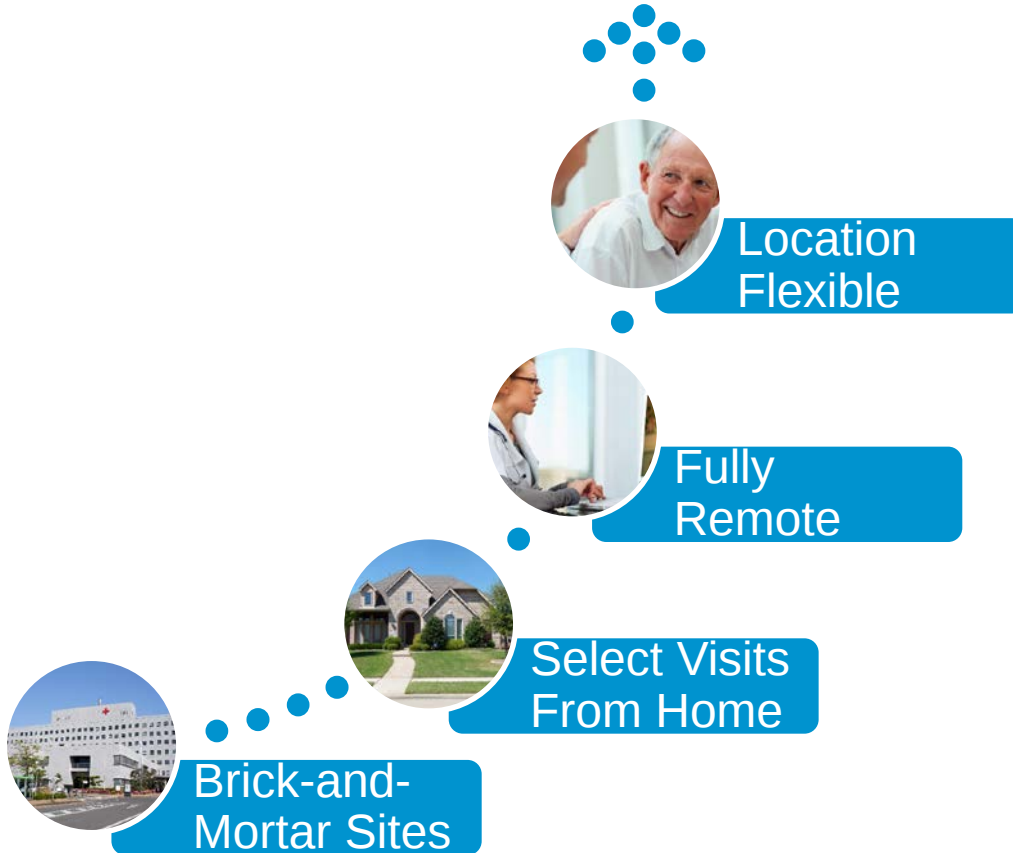
Novartis becomes deeper Science 37 partner, as pair aim for 10-trial launch

Centre of excellence – remote decentralised clinical trials

Wednesday 28 March, 15:00 CET
Register: bit.ly/IMI2Call14webinars
Read the topic text: bit.ly/IMI2Call14



Destination for Virtual Trials



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