Democratization of Cancer Clinical Trials through Cybervisits and Crowdsourcing

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What is wrong with this picture?
Why do cancer clinical trials fail?

- Toxicity
- Efficacy
- Trial does not get completed?
Evaluating the cancer clinical trials enterprise
Evolution of ClinicalTrials.Gov

From: The Evolution of Trial Registries and Their Use to Assess the Clinical Trial Enterprise
Why do trials terminate prematurely?

Stensland et al, submitted for publication
Approximately 1 out of every 5 cancer clinical trials terminated prematurely.

These trials enrolled a median of 17 patients.

Stensland et al, submitted for publication
Availability
Awareness
Acceptance
Eligibile
Decision to Enroll
“Sites for clinical trials are frequently selected on the basis of where the investigators are located, as opposed to where the patients are, creating difficulties in patient recruitment.”

Janet Woodcock, Director of the FDA’s Center for Drug Evaluation and Research, Institute of Medicine report, *Transforming Clinical Research in the United States: Challenges and Opportunities*
Are clinical trials accessible?

- ClinicalTrials.gov searched for all clinical trials exploring first-line treatments for metastatic prostate, breast, colorectal, and lung cancers.
- The zip codes for clinical trials sites for each clinical trial were extracted from the registry.
- Objectives
  - Distribution of trial sites in the U.S.
  - Travel distance to trial sites

Galsky et al, Submitted for Publication
Distribution of Prostate Cancer Clinical Trial Sites

Galsky et al, Submitted for Publication
Inequality in Geographic Accessibility to Prostate Cancer Clinical Trials in U.S.

Galsky et al,Submitted for Publication
Minimum driving distance to a prostate cancer clinical trial site in the U.S.

Galsky et al, Submitted for Publication
Can we bring clinical trials to patients rather than bringing patients to clinical trials?
Novel approaches to clinical trial conduct are unlikely to initially offer the performance characteristics of the current paradigm.

Pfizer announces ‘virtual’ clinical trial pilot in US

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PETER MANSELL

Pfizer is taking the randomised clinical trial further than ever into the digital age by announcing the first such study conducted under an US investigational new drug (IND) application in which patients will participate remotely without having to visit trial sites.

The pilot REMOTE (Research on Electronic Monitoring of OAB Treatment Experience) trial will address concerns around the cost-efficiency and accessibility of clinical research by using mobile phone and web-based technology to collect data on the safety and efficacy of Detrol LA (tolterodine tartrate), Pfizer's extended-release treatment for overactive bladder (OAB).

The REMOTE project has been cleared by the US Food and Drug Administration as well as two institutional review boards.
“But this can’t work in cancer clinical trials….”
Pilot Telemedicine Clinical Trial in Oncology

- Relatively indolent clinical disease state
- Motivated and “connected” patient population
- Relatively safe and well tolerated intervention
- Hybrid model
Prostate Cancer Clinical Disease States

Localized Disease → Rising PSA (non-castrate) → Metastatic Disease → Castration Resistant → Death

N=230,000/yr  N=50,000/yr  N=30,000/yr

Survival - 5-10 years  Survival - 24-48 months

Risk of death from prostate cancer
Eligibility: Rising PSA, Post-RP or XRT, No Metastatic disease
Can we crowd-source the design of this trial?

Awareness

Acceptance

Eligible
Crowdsourcing clinical trial design

**Metformin in Prostate Cancer - Researchers Challenges**

**PROTOCOL CHALLENGE 6.1.3 – DOSE**

Subjects will receive metformin 850 mg PO once daily for 4 weeks, followed by 850 mg PO twice daily for the remainder of the study.

- [ ] I agree with this approach and the proposed doses.
- [ ] I disagree.

Please explain your reasoning and/or offer an alternative dose.

![Progress Bar](0% - 100%)
• Currently, funding for pilot study
• Plans
  – Establish feasibility
  – Troubleshoot
  – Partnerships to pilot novel mobile technologies
  – Seek funding for larger randomized trial
  – Explore other interventions (e.g., Pomi-T) and other clinical disease states
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