

Pragmatic trials embedded in health care: We've done 20, how about 2000?

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Our tradition: Every trial must be special!

- Driven by individual investigator “passions”
- Study-specific “rigorous” evaluation
- Artisanal informatics
- Bespoke consent processes
- “Innovative” methods, whether they’re needed or not

A national embedded research infrastructure would:

- Systematically highlight defined points of consequential clinical decision
- Assess and document important prognostic and tailoring characteristics
- Identify areas of uncertainty or clinical equipoise
- Document choices and the logic behind them
- Standardize timing and content of outcome assessments

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That's not just a health system where I'd like to do research. It's where I'd want to get my health care!

Important strategic questions

- Right scale – big enough, but not necessarily everywhere
- Right clinical scope – versatile enough, but not too heavy to fly
- Right research “phase” – from first-in-humans to implementation is probably too bit a stretch

Challenging political questions

- Who pays?
- Who governs?
- Who says No to unnecessary things?

Our traditional research business model

Community Engagement				
Trial Design				
Clinical Informatics				
Eligibility Assessment				
Intervention Delivery				
Fidelity Monitoring				
Outcome Ascertainment				
Data Analysis				
Academic Reporting				
Dissemination				

Should it be flipped to look like this?

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Random assignment is the tough nut to crack

- Admitting and acknowledging uncertainty is always hard
- Many people are averse to participating in experiments