



The Future of Virtual Trials

Outline

- Old models
- New tools
- New approaches

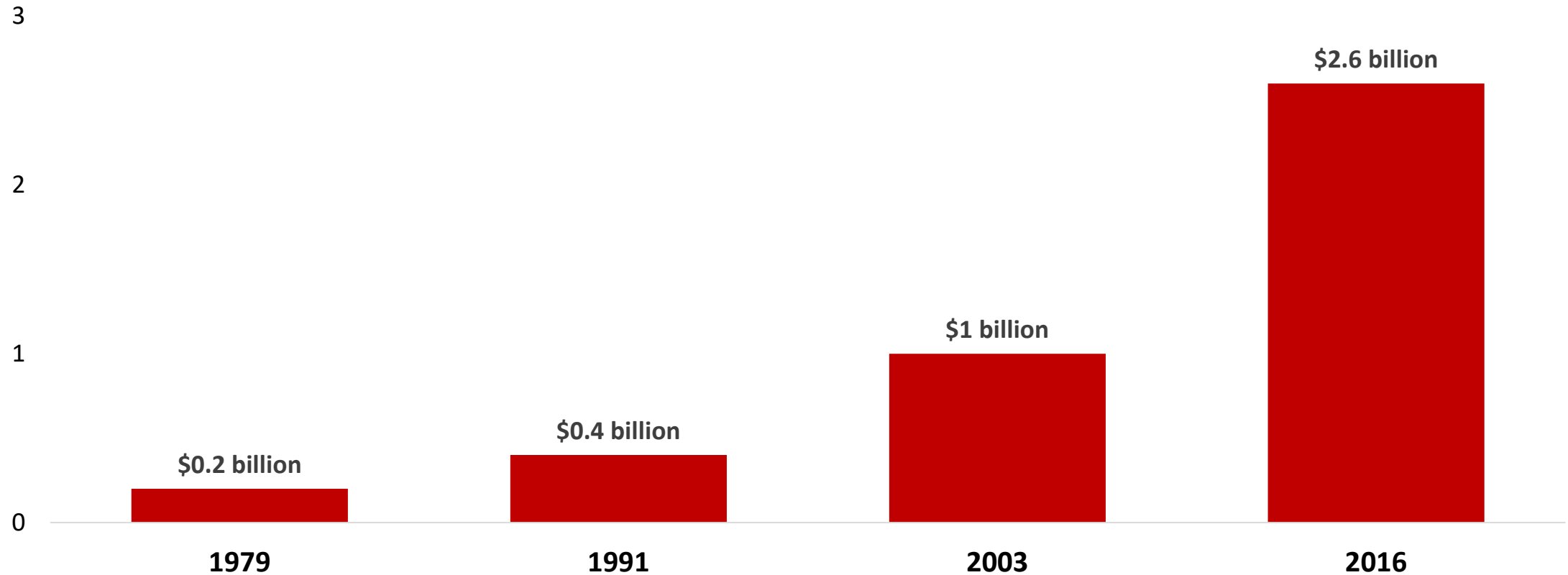
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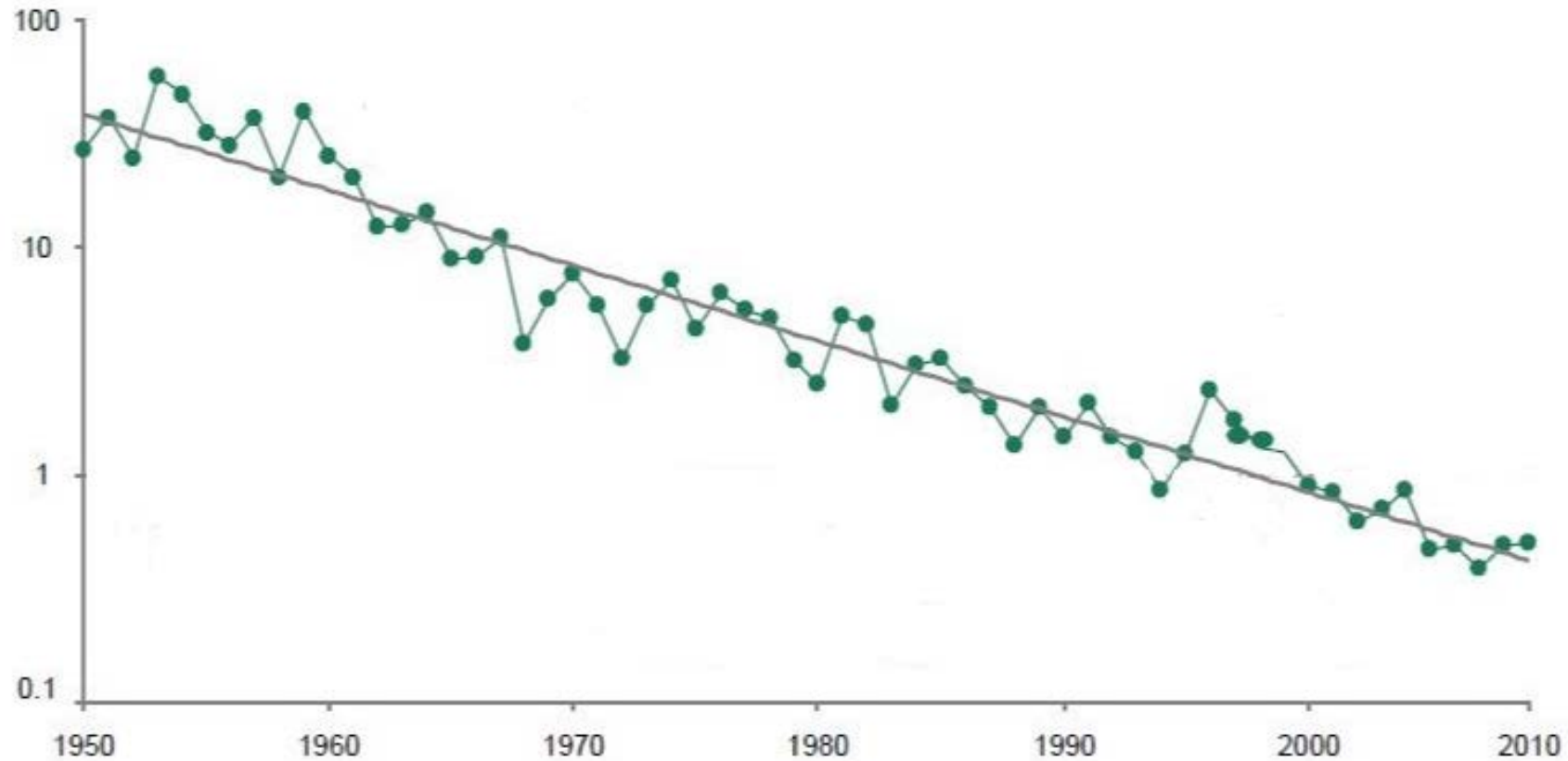
The cost of drug development is rising

Cost per approved drug in billions of 2013 dollars

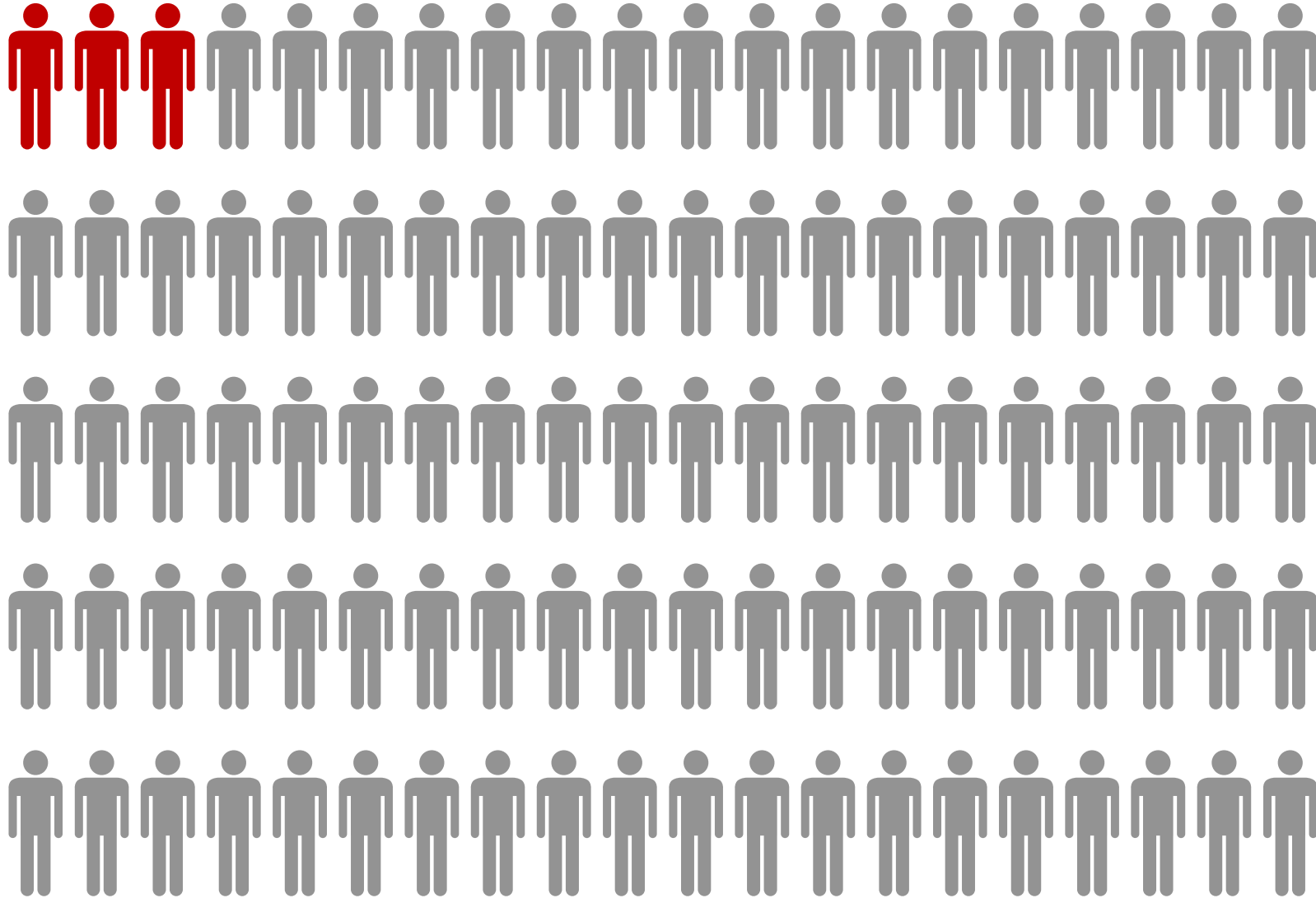


Productivity within the pharmaceutical industry is declining

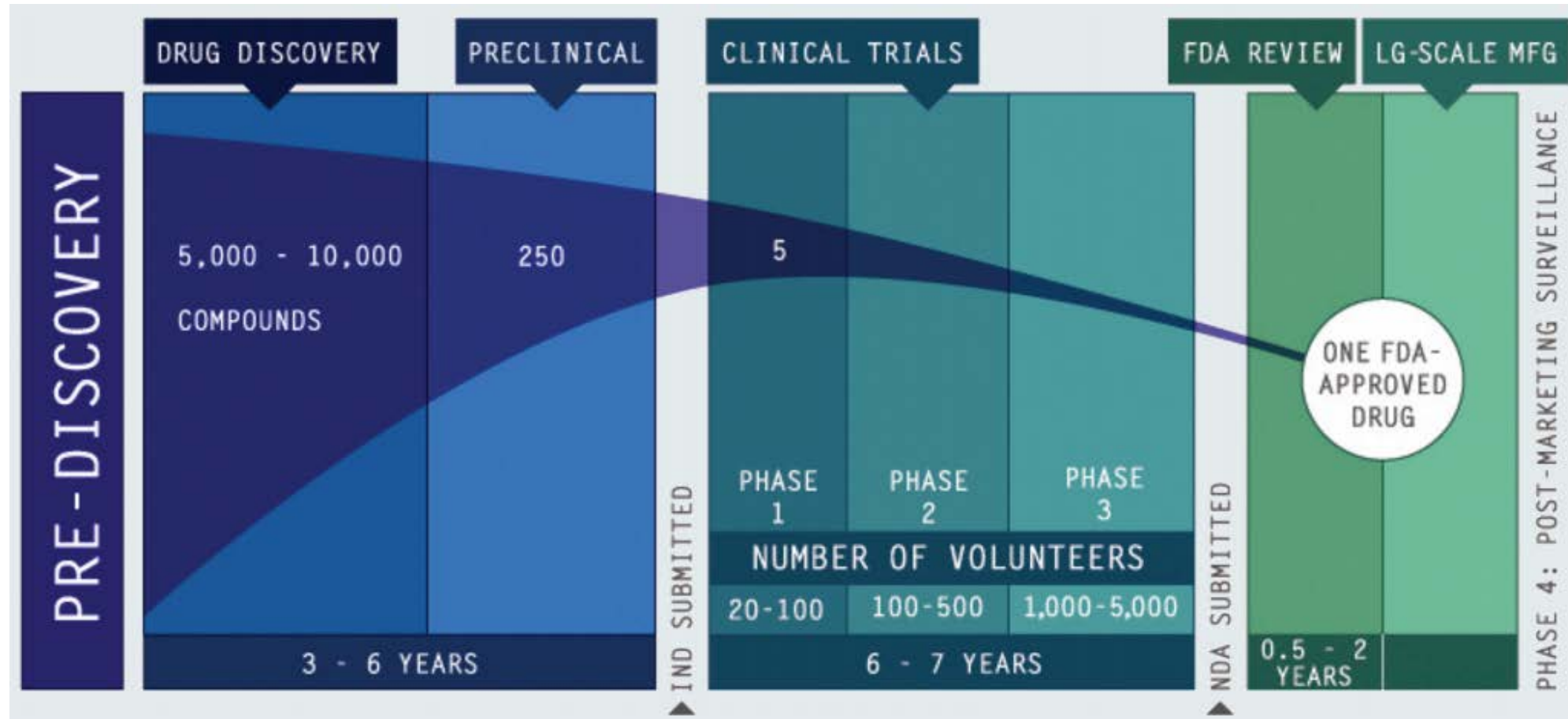
New molecular entities per \$1 billion in R&D (inflation adjusted), 1950-2010



Clinical trials are inaccessible



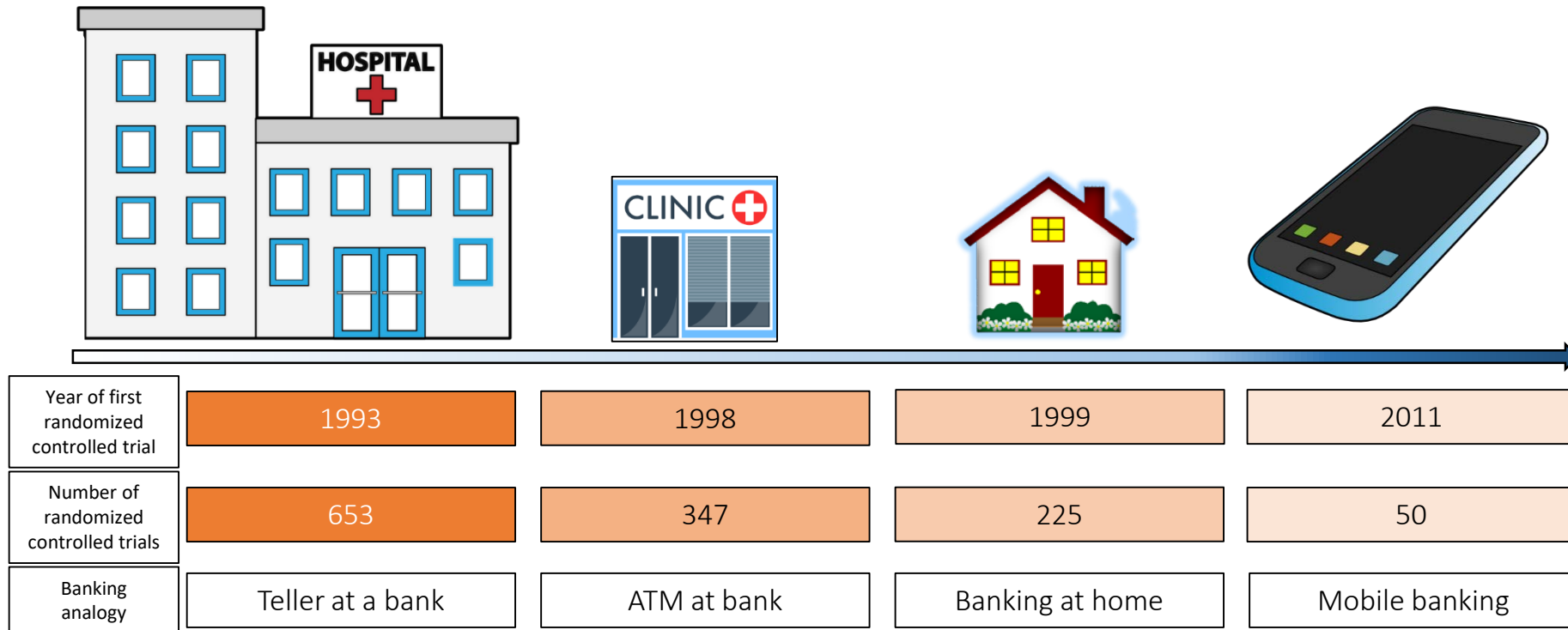
Drug development is long, inefficient, and likely to fail



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New tools can bring care and research to individuals



Seven years ago, Craig Lipset and Pfizer conducted the first completely virtual trial

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 visiting a clinic.

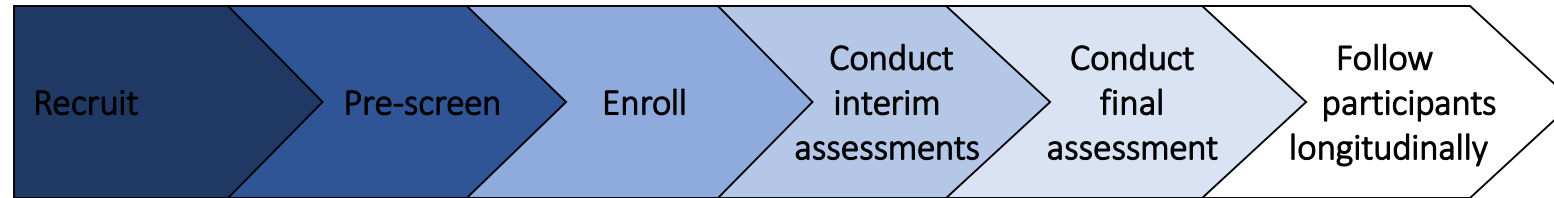
The company plans to compare the results to those obtained from a previous, traditional trial of the same drug. The study involves the company's overactive-bladder drug Detrol.

If successful, the methods used in the study might eventually be used to help drive down the high cost of bringing new medicines to market.

The Food and Drug Administration recently signed off on Pfizer's study, which is believed to be the first all-electronic, home-based study of a drug to receive agency approval.

Many parts of a clinical trial can be virtual

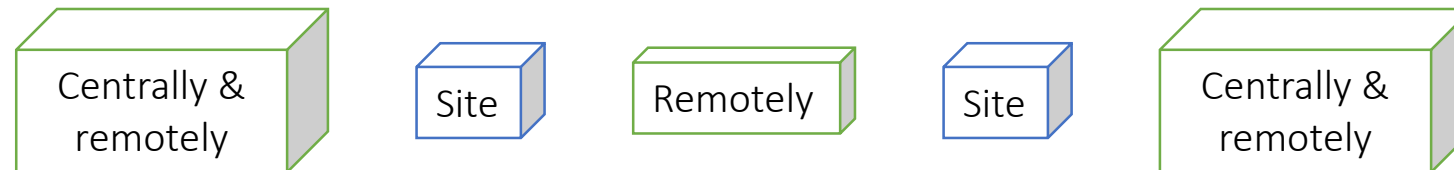
Short-term, hybrid model



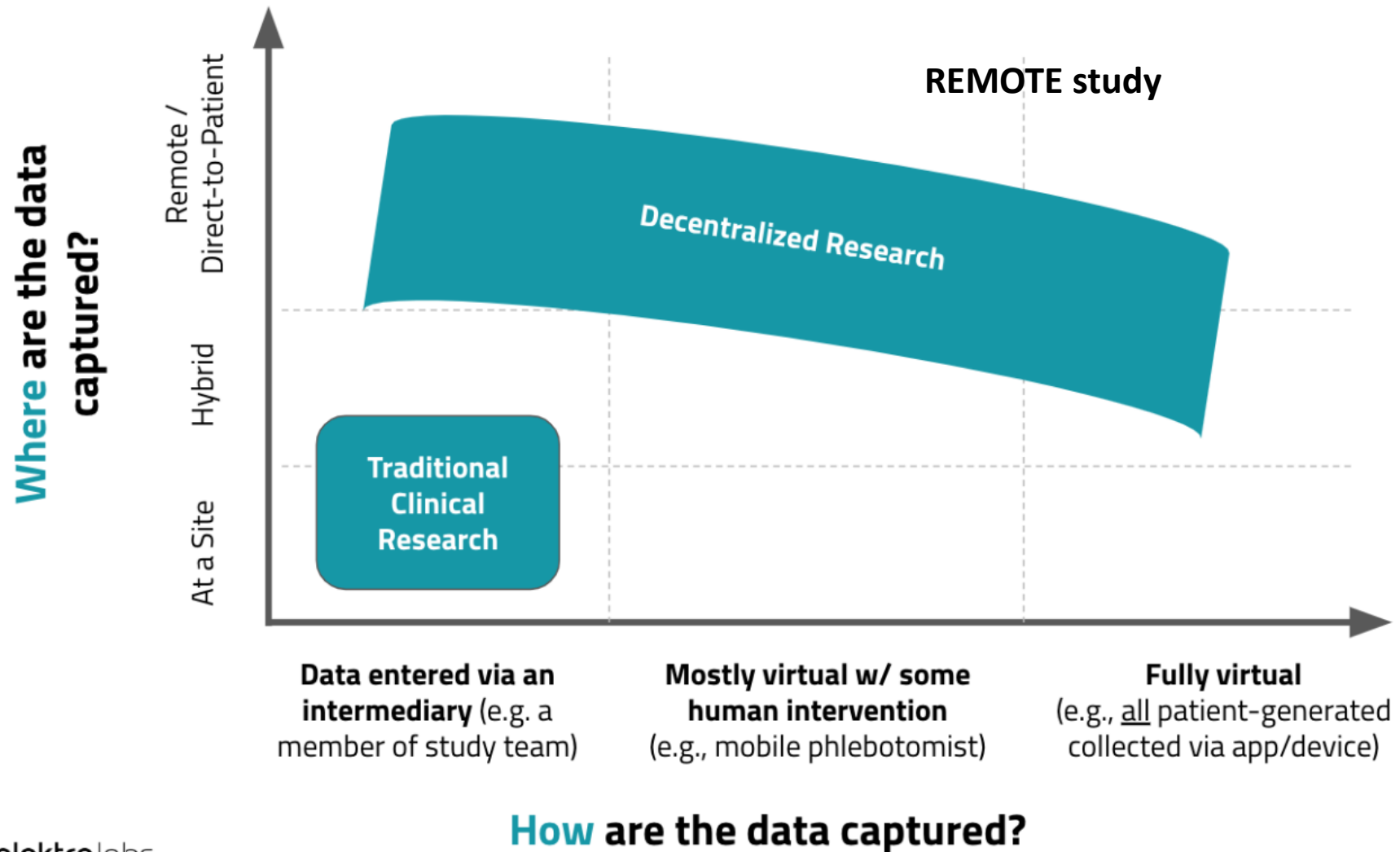
Current



Future



New models bring research to participants

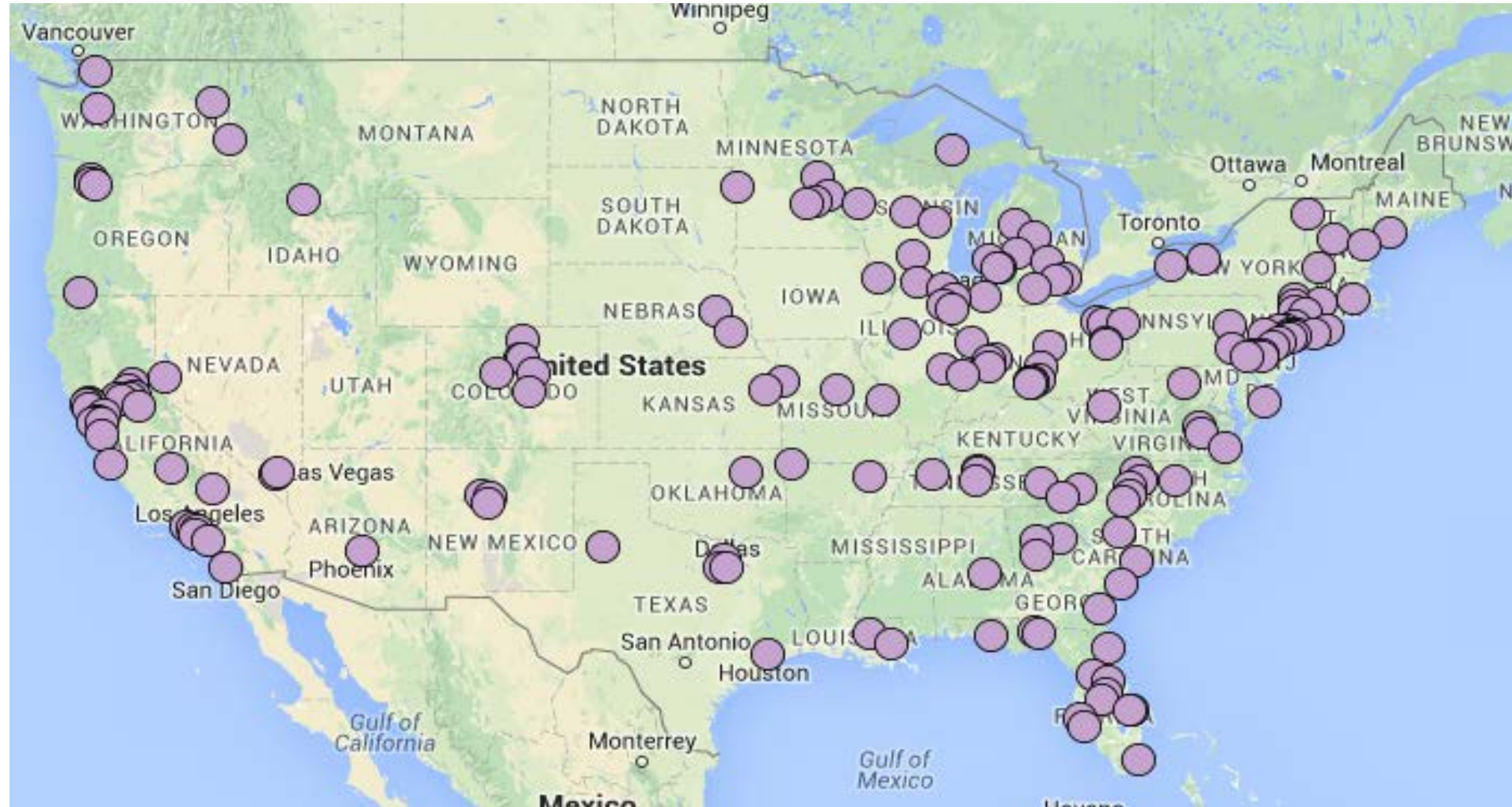


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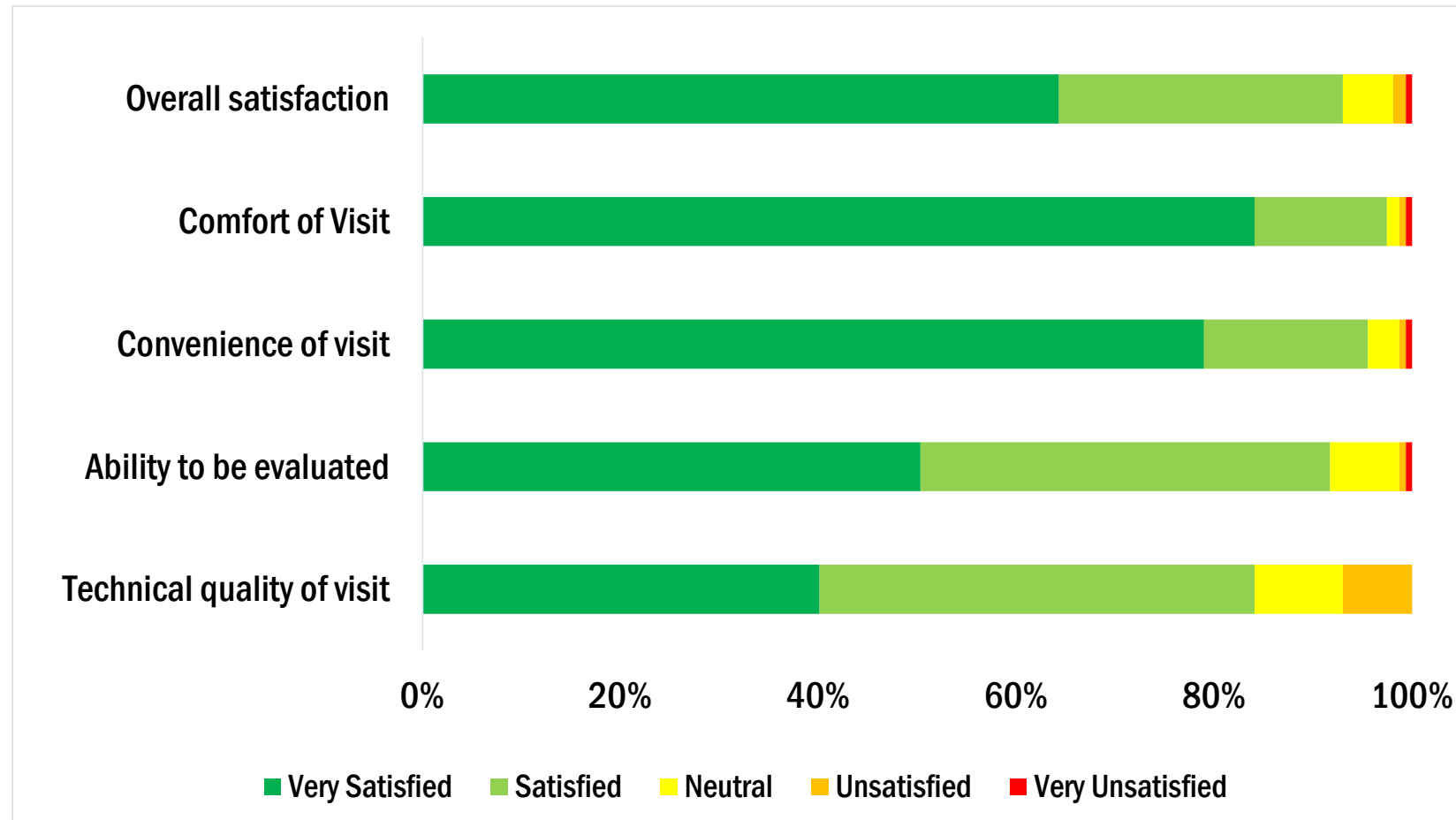
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National studies can be conducted from single sites

Map of participants in virtual research study

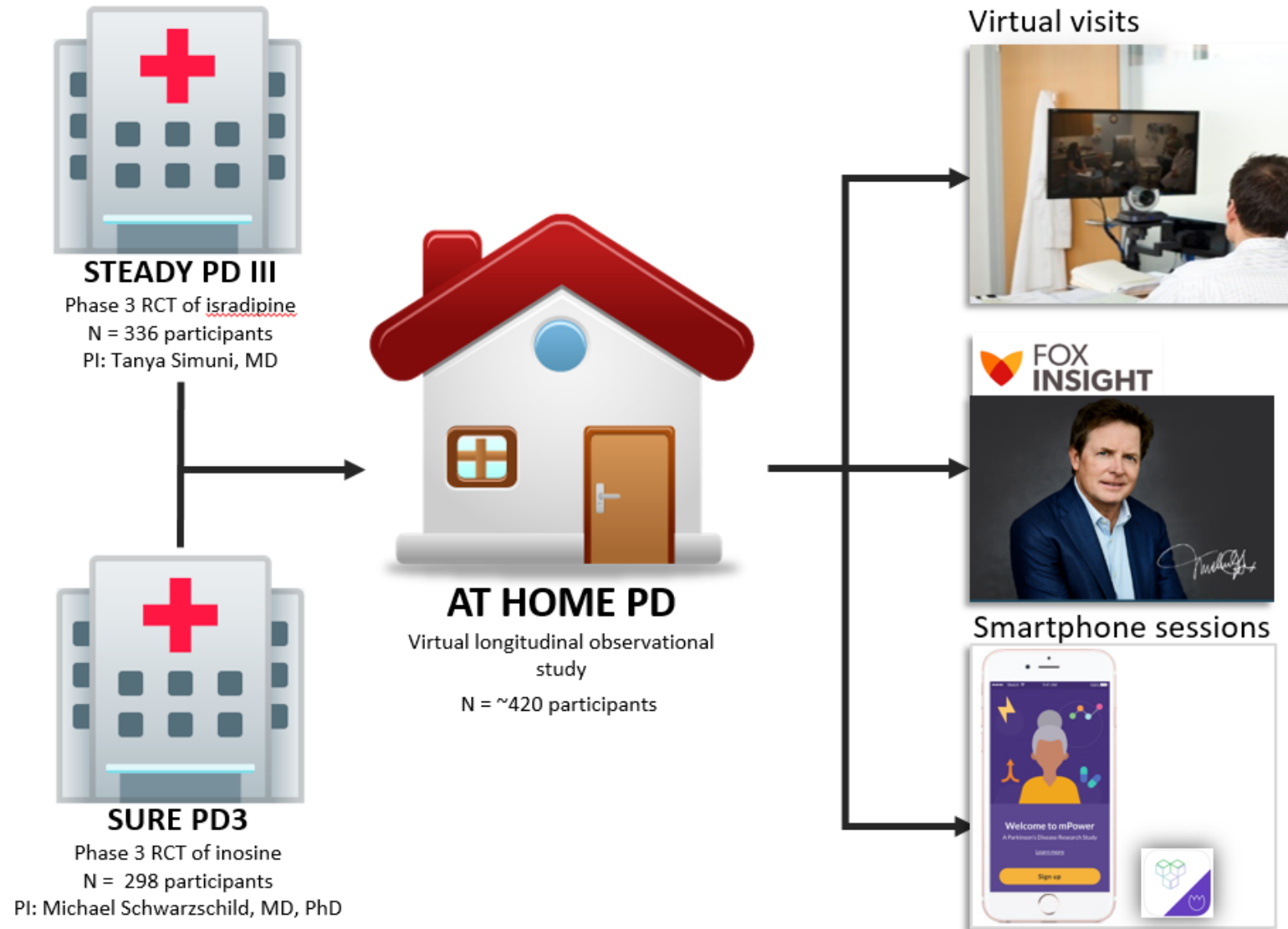


Participants like virtual visits



Over 80% of participants said they would be more willing and able to participate in future research studies if they could do so remotely

AT-HOME PD is a virtual longitudinal observational study with three components



23andMe aims to recruit, characterize, and retain a virtual national cohort of LRRK2 carriers



300 LRRK2 Carriers

- 250 without Parkinson disease
- 50 with Parkinson disease

Annual virtual visits



- Questionnaires
- Cognitive testing
- Remote examination

Virtual studies offer numerous advantages

Characteristic	Traditional study	Virtual study
Focus	Participants, investigators, and sites	Participants
Geographic reach	Sites	Internet access
Sites	Many	One
Institutional review boards	Many	One
Time to initiate study	Long	Medium
Investigators	Many	Handful
Assessments	Episodic	Frequent
Variance	High	Low
Comfort	Low	High
Convenience	Low	High
Confidentiality	Low	High
Cost	High	Moderate