Decentralized Trial Designs for Clinical Trial Diversity

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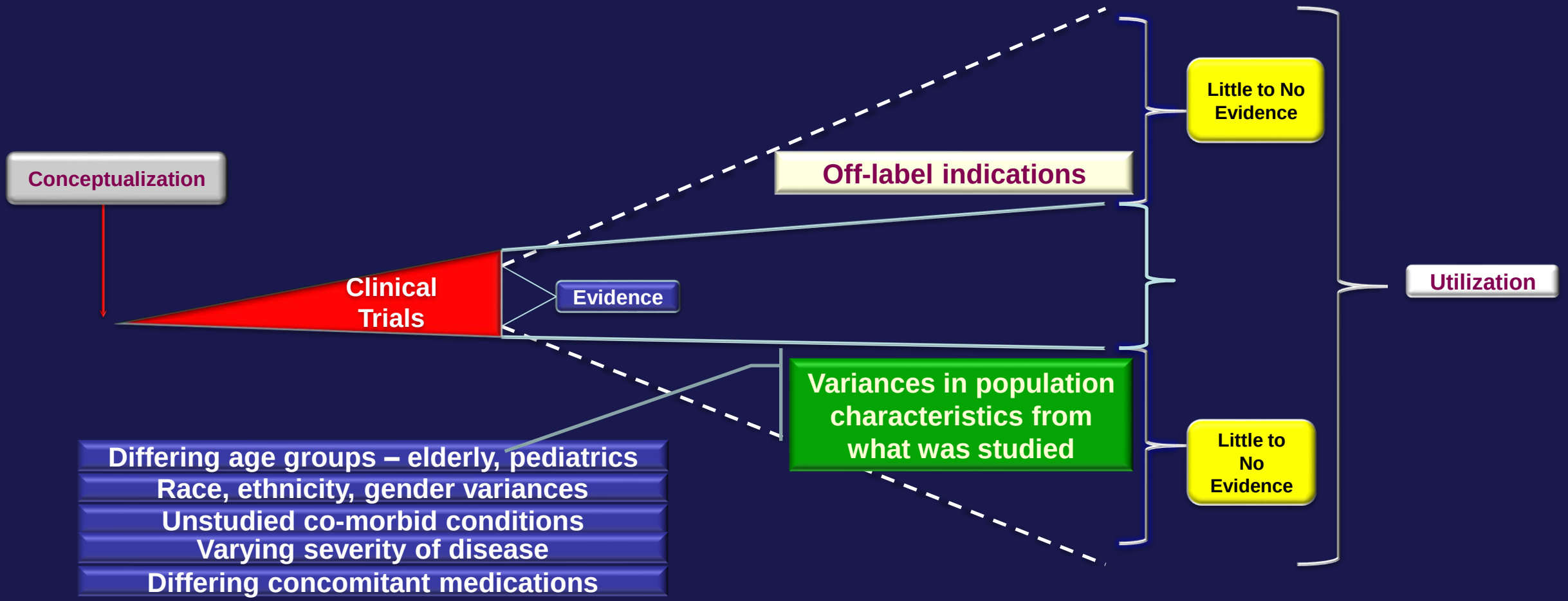
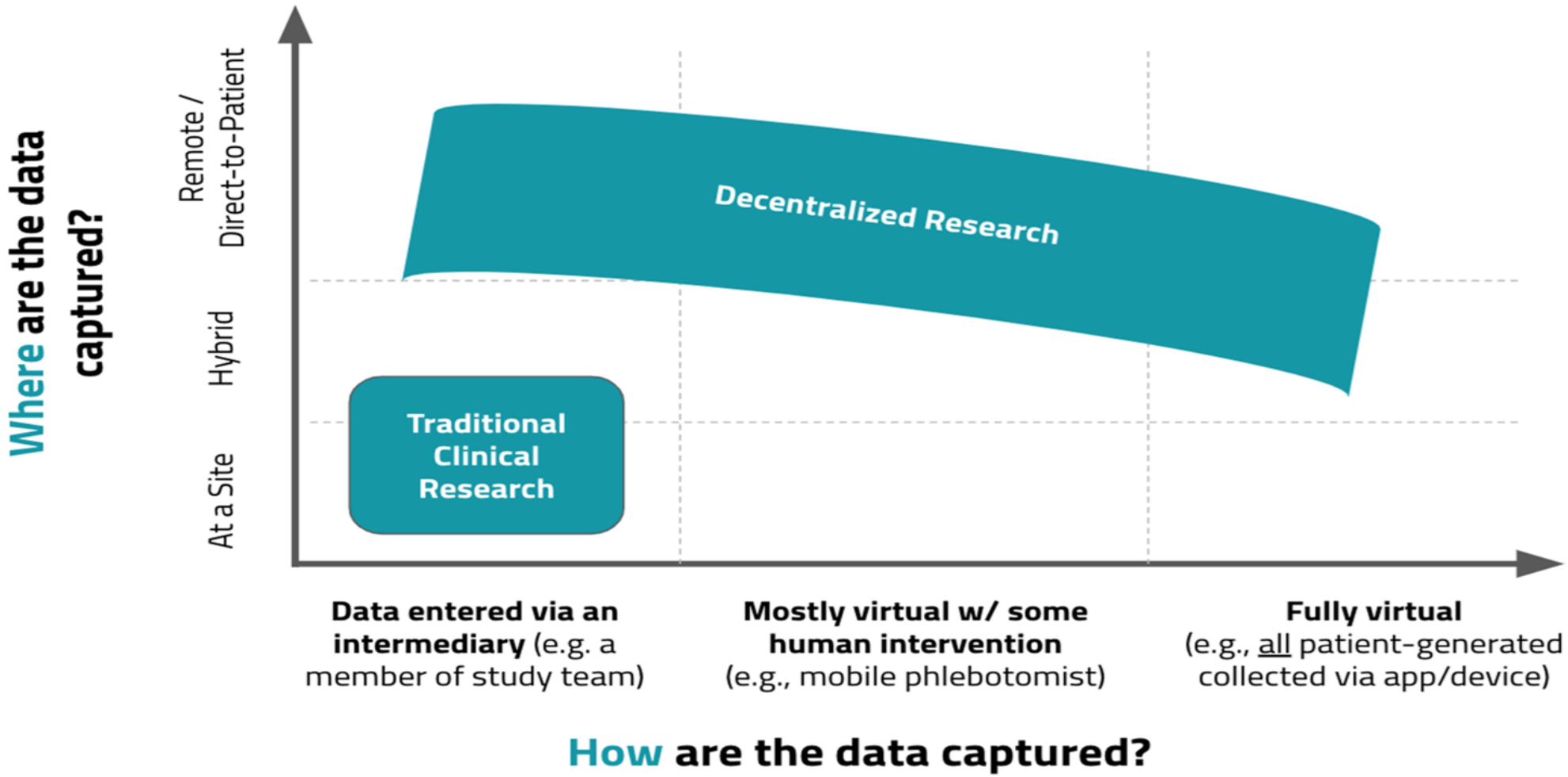
Just 5% of eligible patients participate in clinical research!

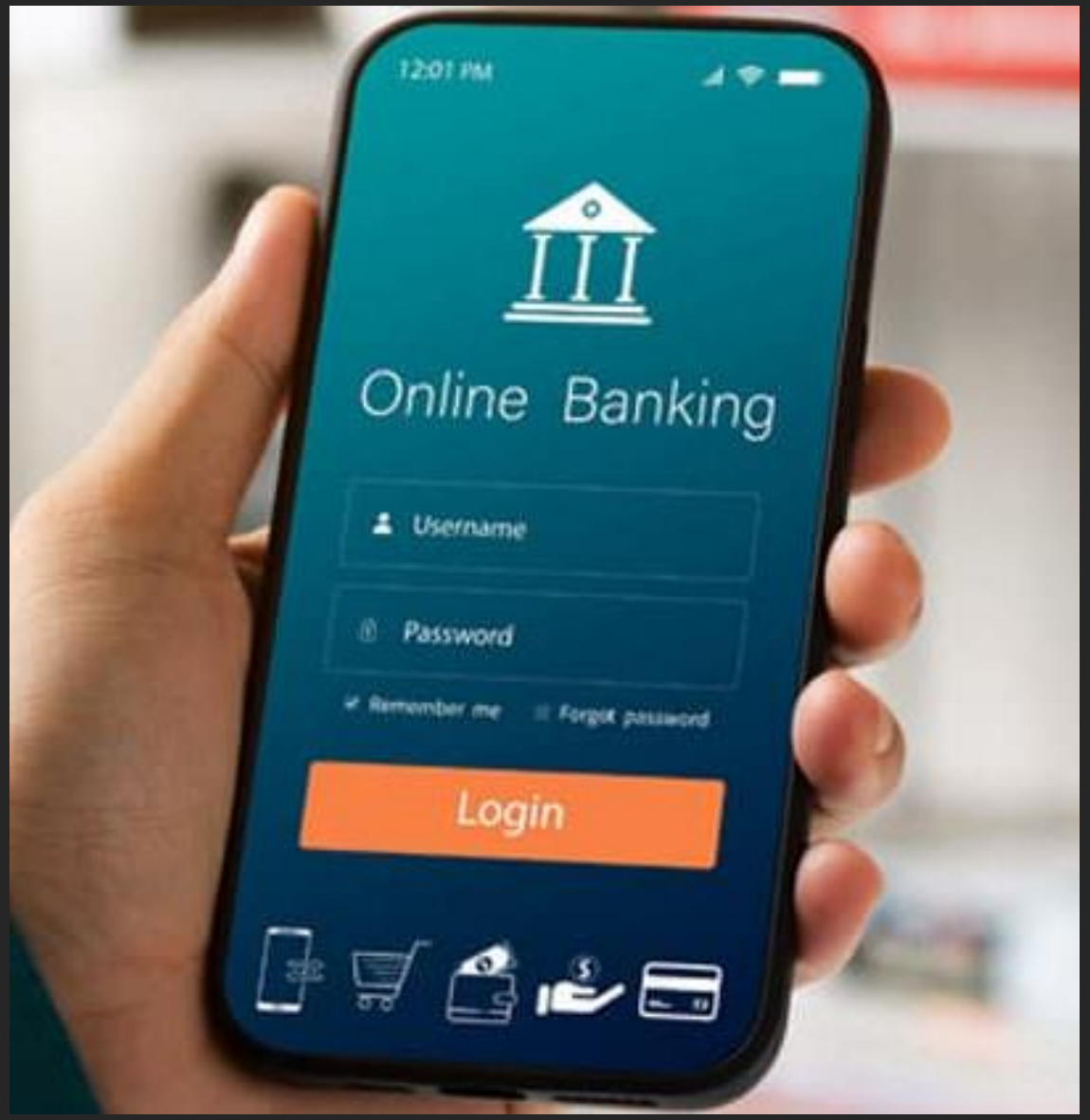


Clinical trial participants travel 67 miles to study sites on average

In 2021, ClinicalTrials.gov had about 350,000 national and international trials registered, which, using the average calculated by the Sustainable Clinical Trials Group, would give a carbon emission of an estimated 27·5 million tonnes of carbon dioxide equivalent (CO2e)

Decentralized studies have two components: decreased reliance (1) on an intermediary and (2) on a physical location

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Online Banking
Username
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Remember me
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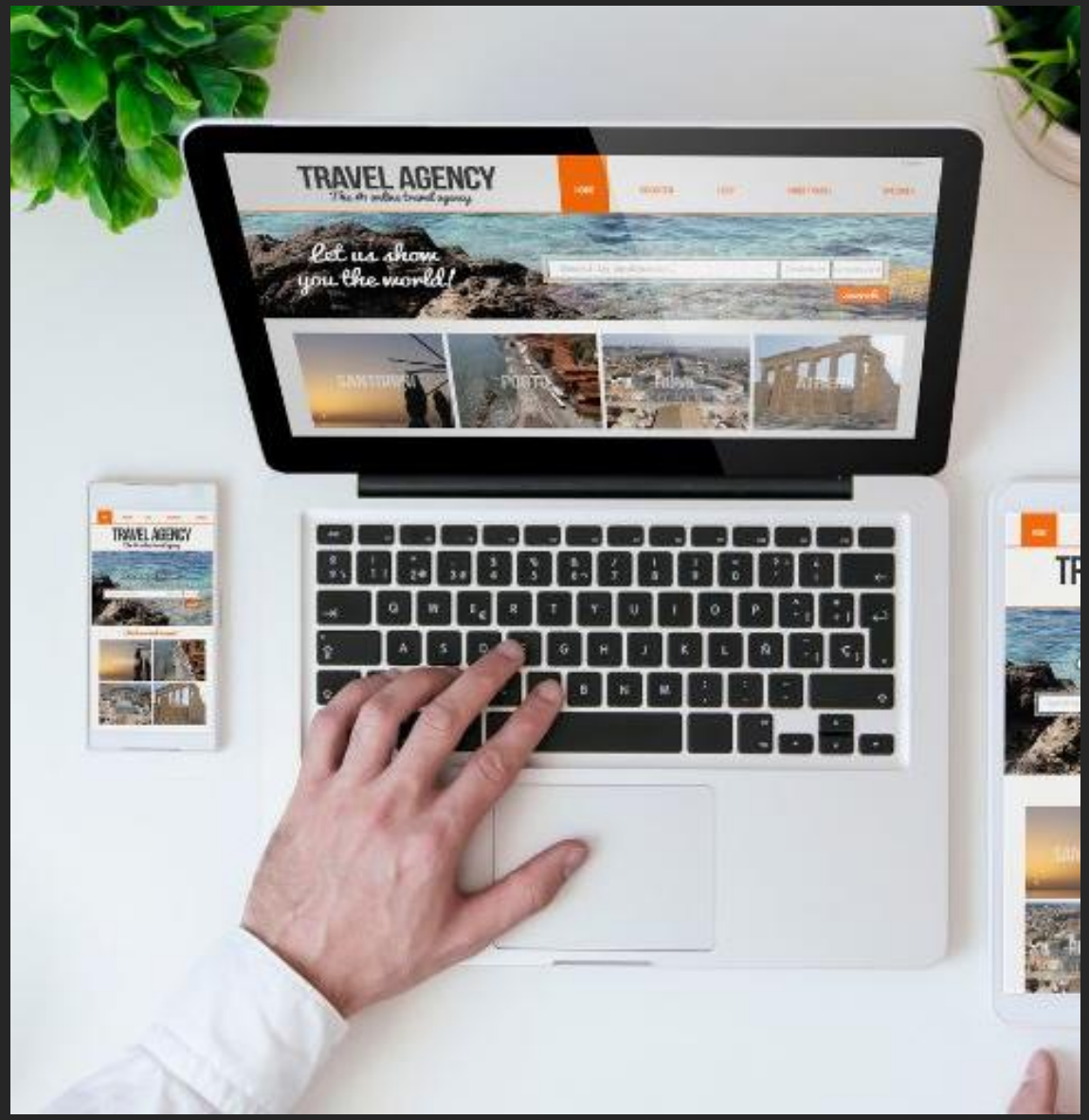

TRAVEL AGENCY
Let us show you the world!

Decentralized clinical trials meet patients where they are.

Clinical-trial designs

Fully decentralized ← → **Hybrid** ← → **Fully centralized**

All trial procedures are conducted virtually, enabled by digital technologies and supply delivery

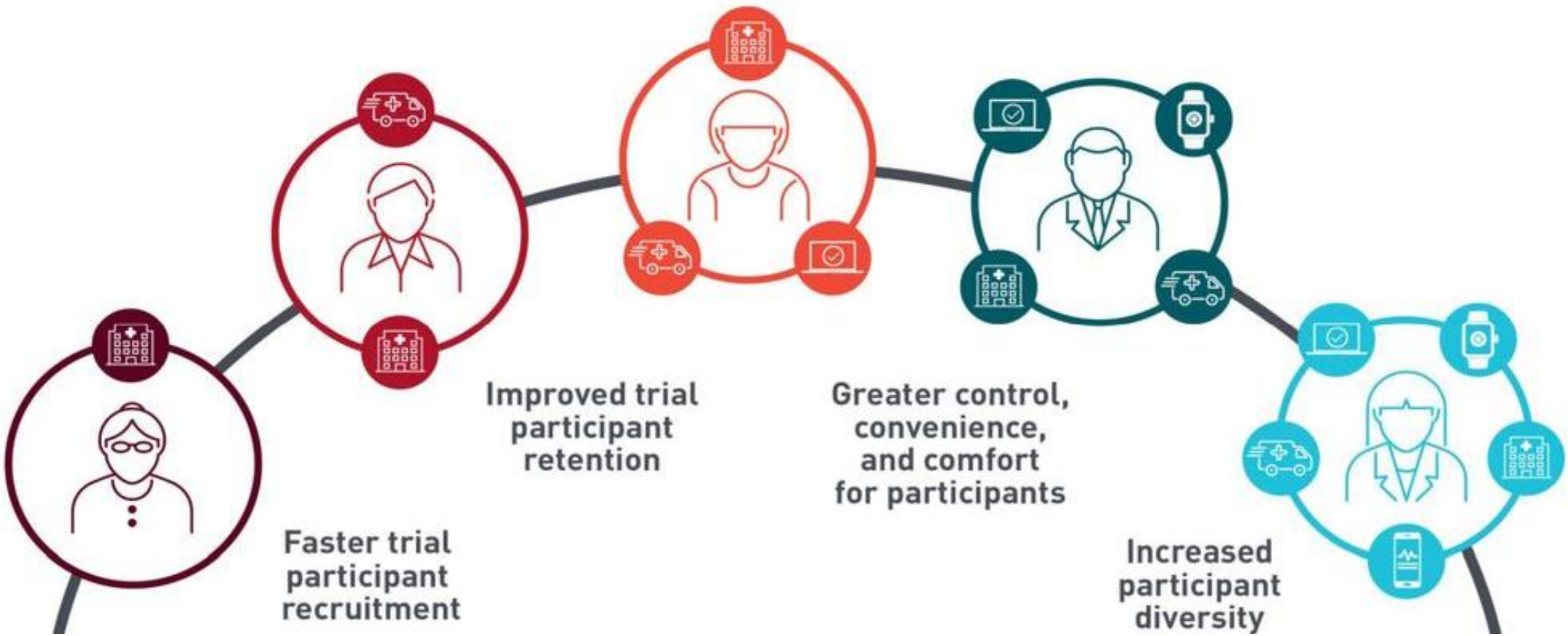
Less complex trial procedures that don't require in-person visits (eg, vital signs, electrocardiograms) are conducted via telehealthcare, remote data collection, or direct-to-patient supply

Less complex trial procedures that require in-person visits (eg, injections) are conducted via mobile clinicians or alternative sites (eg, mobile clinics, retail sites)

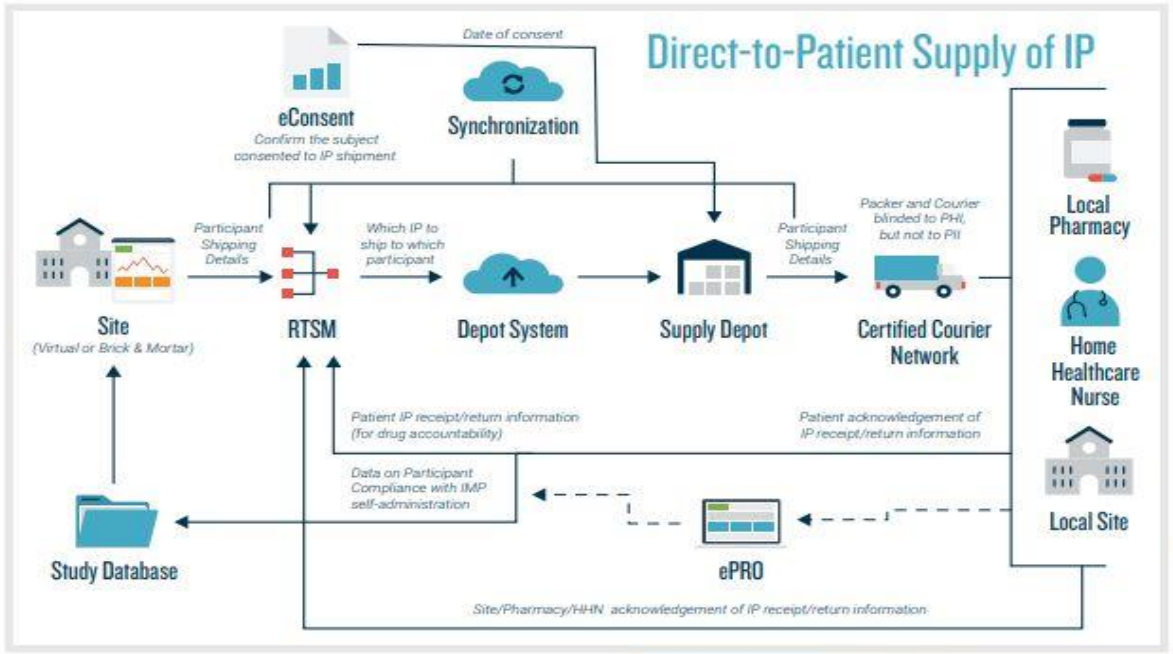
Complex trial procedures (eg, complex screening protocols, cell therapy, magnetic resonance imaging) are conducted via research sites (eg, academic medical centers) or local hospitals

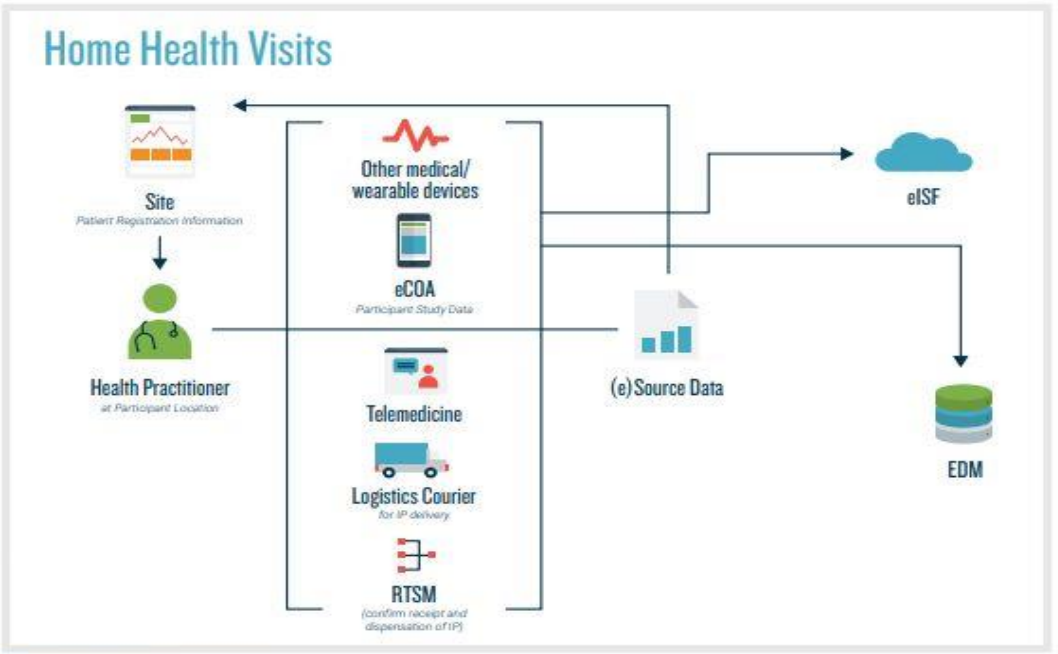
All trial procedures are conducted at a research site (eg, academic medical center)

Benefits of Using Decentralized Trials

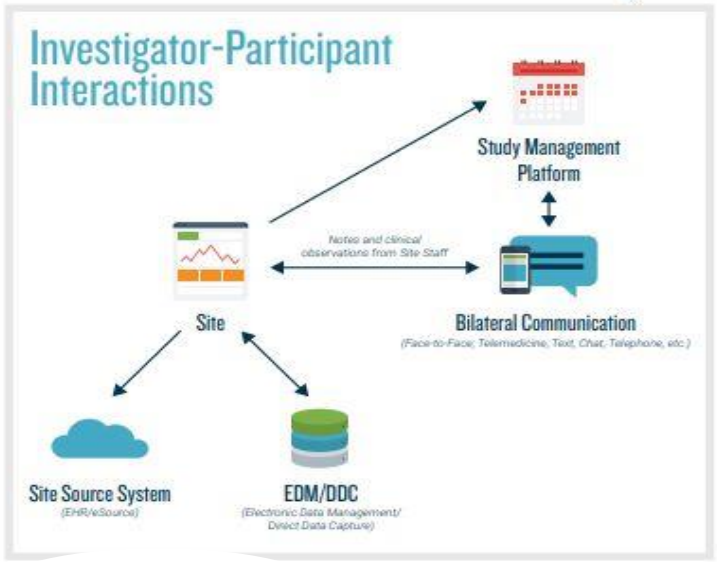


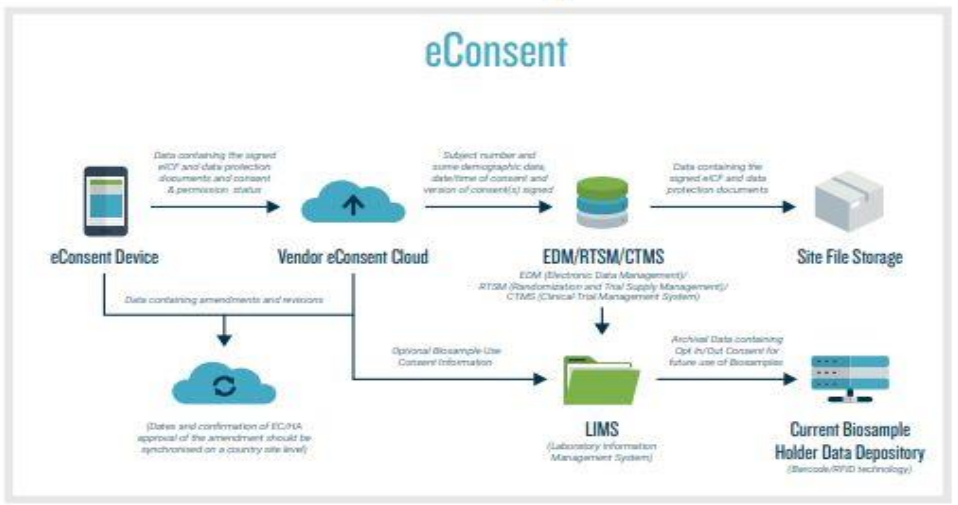
Overview of a Decentralized Clinical Trial

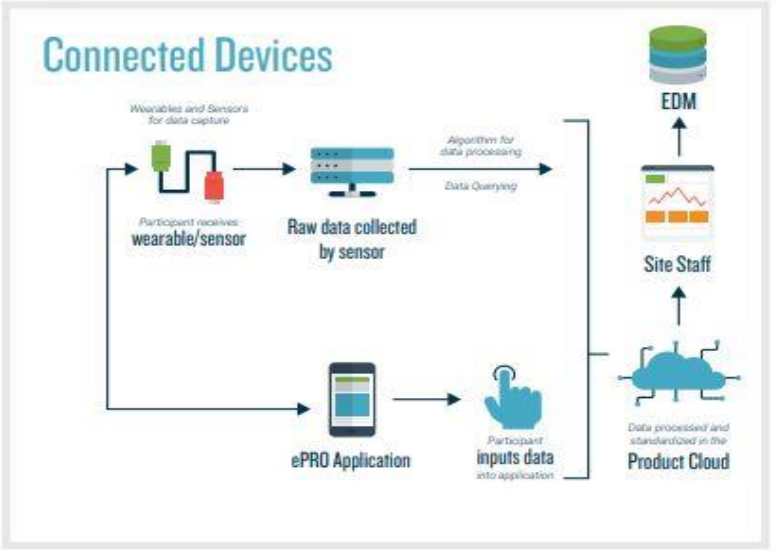




Participant







Augment delivery with DCT medication adherence solutions, e.g., reminders, photos, videos, smart packaging

At-home self-collection kits increasingly familiar due to COVID-19, home healthcare visits, collect samples through local labs or pharmacies

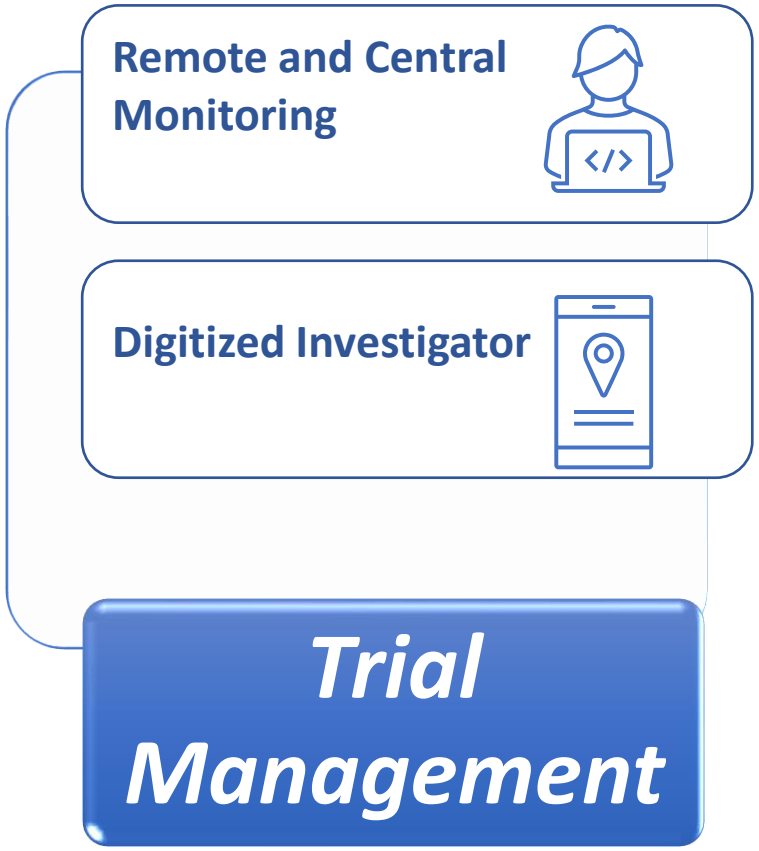
Trial Procedures Decentralized Directly to Participants´ Homes

eCOA

ePRO

Trial Conduct

Berwanger O, Machline-Carrion MJ. Stroke. 2022;53:2967–2975



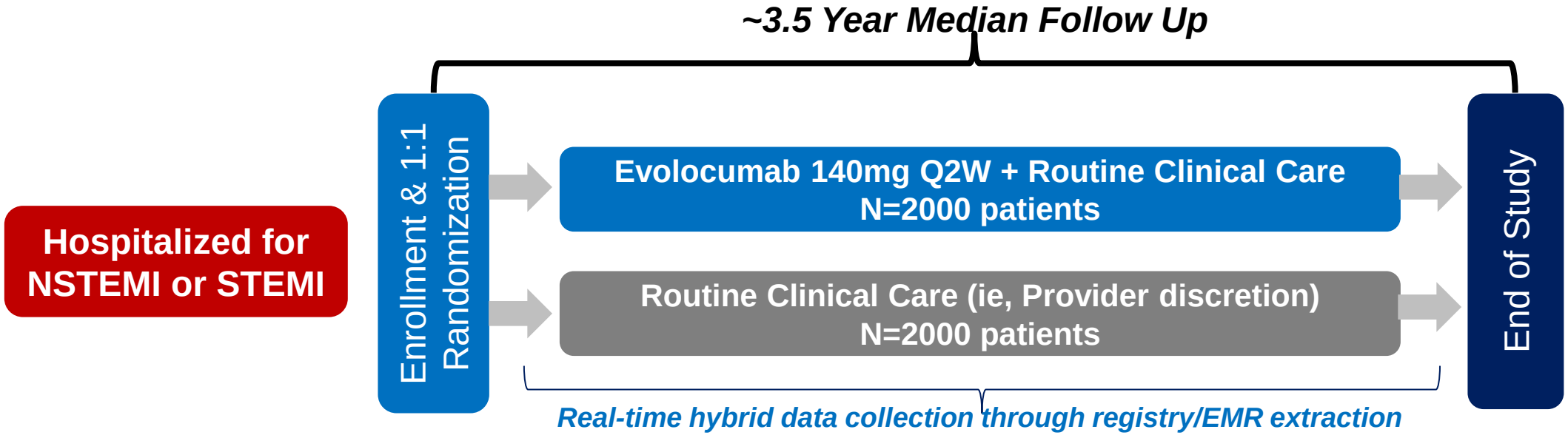
Involve diverse groups in participants in the trial design, conduct and interpretation

Share results with study participants in a language and format that is easy to read

Berwanger O, Machline-Carrion MJ. Stroke. 2022;53:2967–2975

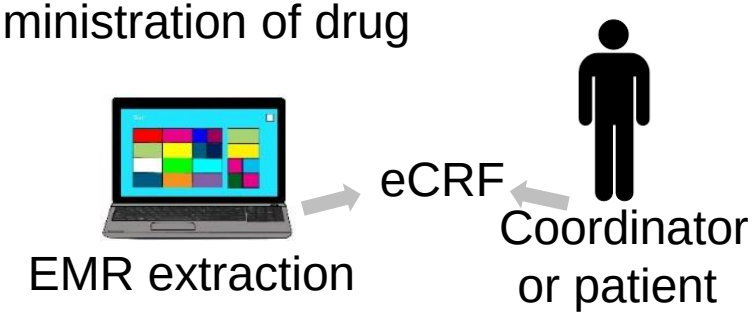
Mobile Clinical Trials Unit

EVOLVE-MI: EVOLOCUMAB VERY EARLY AFTER MI – STUDY DESIGN



1° endpoint: total (first and subsequent) MI, ischemic stroke, any arterial revascularization, all-cause death

- Evolocumab dosed within 10 days of index MI. Home delivery and self-administration of drug
- ***Pragmatic data collection through EMR, patient- or coordinator-completed eCRF and national registries (in Sweden)***



eCRF electronic case report form, EMR electronic medical record, NSTEMI non-ST elevation myocardial infarction, STEMI ST elevation myocardial infarction

ALBERT EINSTEIN
SOCIEDADE BENEFICENTE ISRAELITA BRASILEIRA

CPC Clinical Research

UCR

Potential Networks for Large-Scale Pragmatic Decentralized Trials

- HF Trial (N=18,000 patients)
- Type 2 Diabetes and Atherosclerotic Cardiovascular Disease (N=9,000 patients)

MESSAGE
Medical Science Sex and Gender Equity

wellcome

The Future (or The Present?)

- " Giant Simple Trial" (1MM, 5MM, 10MM…)
- Global
- Very Few (if any) Inclusion and Exclusion Criteria
- 99% CIs
- No Sample Size Calculation