

## **SDCRN/SDRAN Joint Meeting**

9 May 2016

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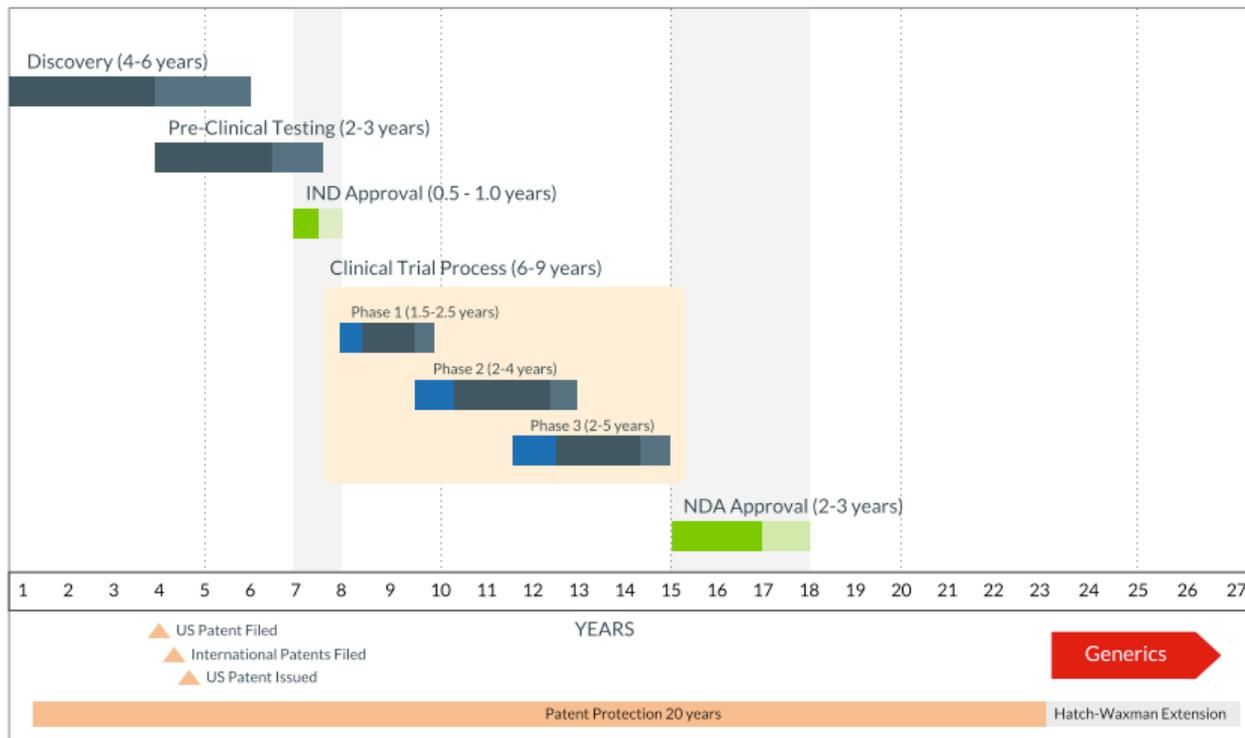
# Science 37

## *A High-Tech, High-Touch Operating Model for Decentralized Clinical Trials*

- Science 37 **transforms the clinical trial model by shifting the center for research** from traditional academic investigative sites to the patient's home and local healthcare system.
- The **S37 metasite™** model offers end-to-end clinical trial services, investigators, and bundled partnerships, which streamlines vendor oversight and eliminates multi-site activations. This approach **results in faster startup, accelerated recruitment, broader geographical access for patients, and reduced total study cost.**
- **NORA®** is our patient-centered **telemedicine/EMR/trial database platform.** **When coupled with S37 recruitment methodologies and screening/consenting tools, NORA®** simplifies the process of participating in trials and connects patients safely and securely to the world's best scientists no matter where they live.

# The Big Problem – 37,000 feet

Clinical trials take too long to plan and execute. This means new drug development is too expensive and prone to risk.

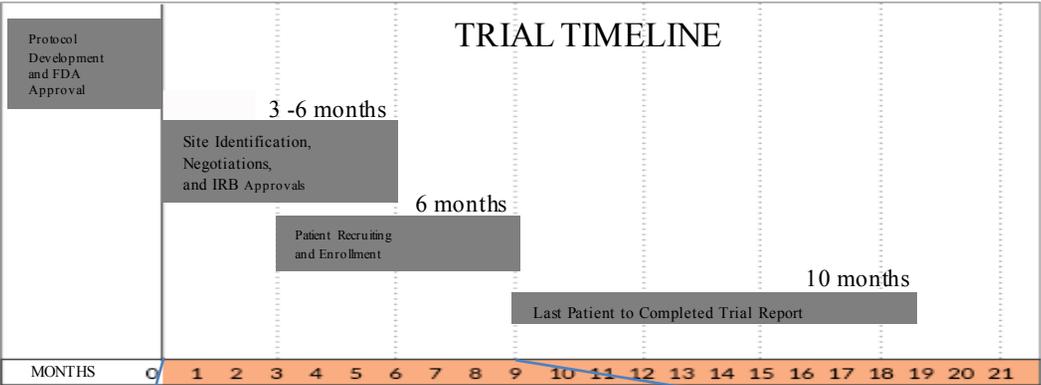


- 15-18 year development cycle.
- Cost often exceeds \$1.0 B.
- Clinical Trials
  - 6-9 years to complete
  - 40% of total cost.
- Leaves sponsors with only 5-8 years to market under patent protection.

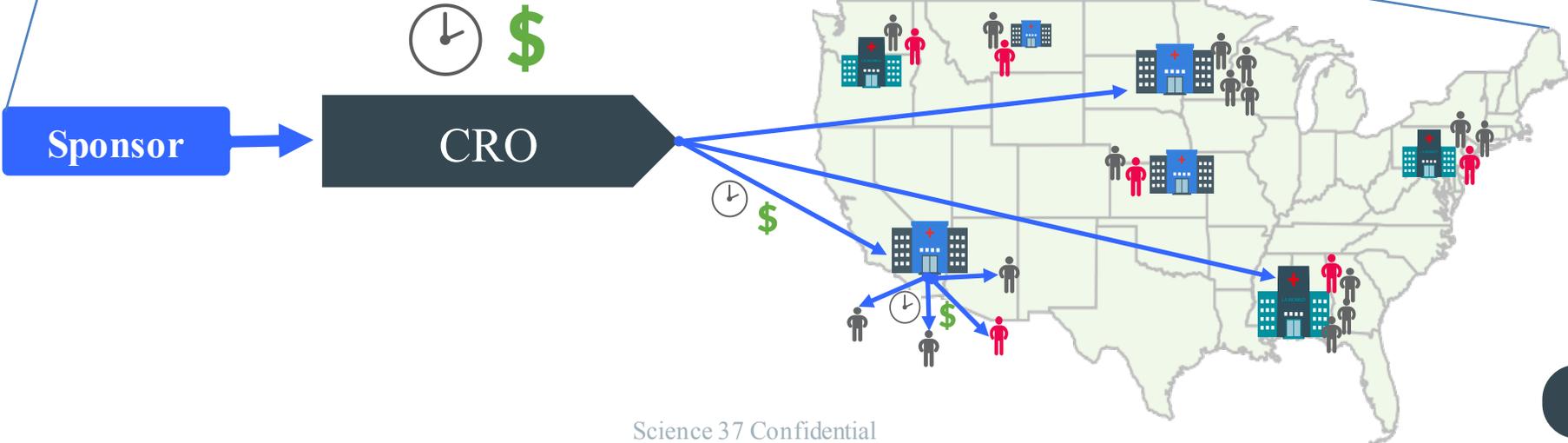
To sponsors, the value of bringing a drug to market one year earlier can exceed \$250M.

# The Problem – The Multi-site Bottleneck

The biggest bottle neck is the trial start-up – CRO engagement, multi-site contracting, and patient recruitment from limited geographic areas.

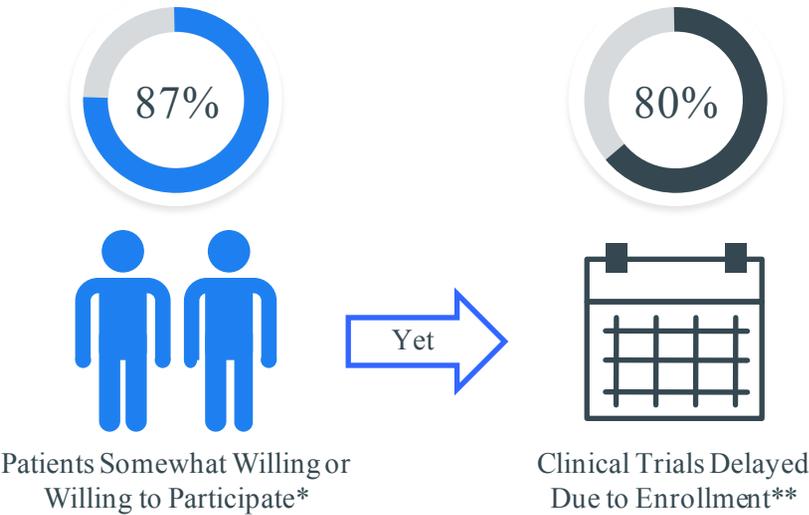


- Complete multi-site ramp up can take up to 12 months
- 48% of sites fail to meet recruitment goals
- Less than 30% of patients live near a site

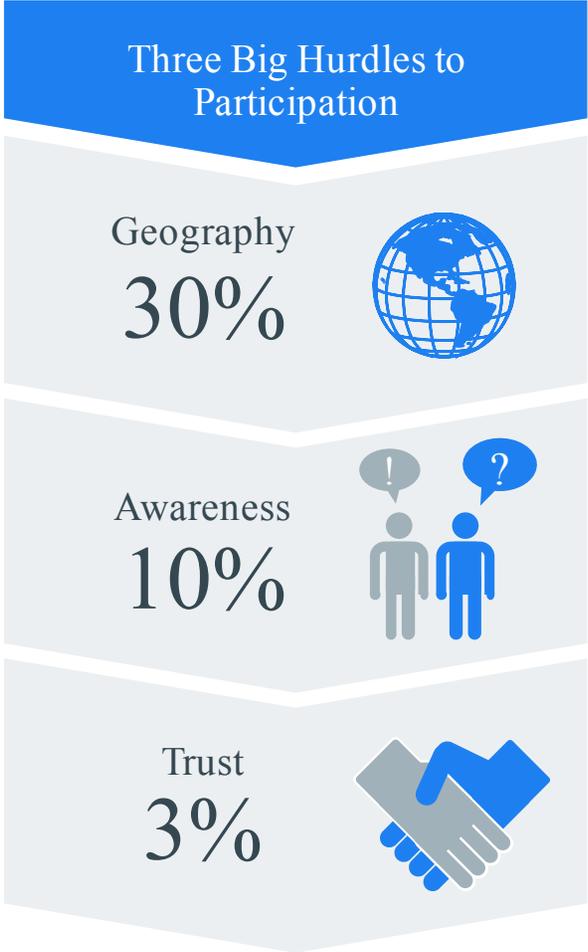


# The Problem – Patient Access & Burden

Recruiting patients to sites is a major challenge and is the lengthiest step in the process. Travel time and repeated study visits severely inhibit the ability to enroll AND retain patients.



Data Indicate that the real problem revolves around patient access to trials, not a lack of patient interest.



\* Tufts CISCRP 2013 International Survey on Public and Patient Attitudes About, and Experiences with, Clinical Research Studies \*\* Lamberti "State of Clinical Trials Industry", 292

Science 37 has created and launched a new approach to conducting clinical trials that disrupts the site-based model into a faster moving, patient-centric solution. We've created the metasite™.



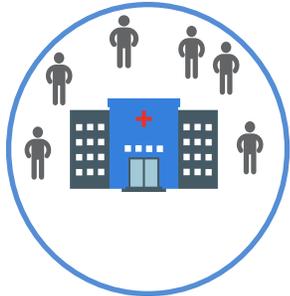
# Metasites™

# Our Solution – Bringing the Trial to the Patient

Science 37 has created and launched a new approach to conducting clinical trials that disrupts the site-based model into a faster moving, patient-centric solution. We bring the trials to the patients.

## Science 37 Patient-Centric Metasite™ Model

Traditional Site Based Approach



Virtual e-Consent



Local care network



Home health devices



Mobile nurse



Rx and IMP



Telemedicine

Technology



Clinical  
Research

Digital  
Strategy



- **Trial-Oriented EMR**
- **Telemedicine Platform**
- **Mobile Data Collection Tool**
- **Virtual E-Consent**
- **Patient Engagement**
- **Structured Database**
- **IxRS and Trial Logistics**
- **Recruitment Platform**
- **Sponsor and Site Real-Time Dashboards**

# How We Do It – NORA can transform trial logistics

Science 37 built NORA (Network Oriented Research Assistant), a first-in-class technology to connect the patient with the Physician-Investigator and S37 study team and collect all trial data from home.

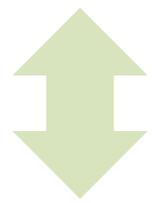
## Physician-Investigator



Telemedicine-based trial visits at home



Coordination & Support



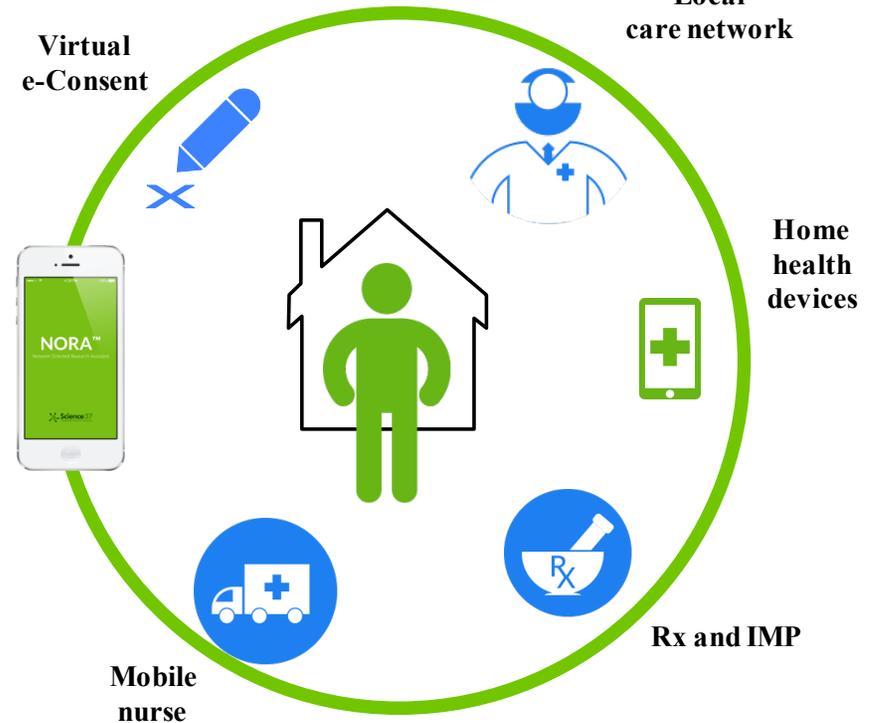
## Science 37 Study Team



- Patient recruiting
- Electronic consent
- Patient set-up and training
- Local medical ecosystem
- Patient calendar & coordination
- Home Infusions and IMP Delivery
- Mobile Nursing and trial logistics
- Patient and local provider data collection

## Virtual e-Consent

## Local care network

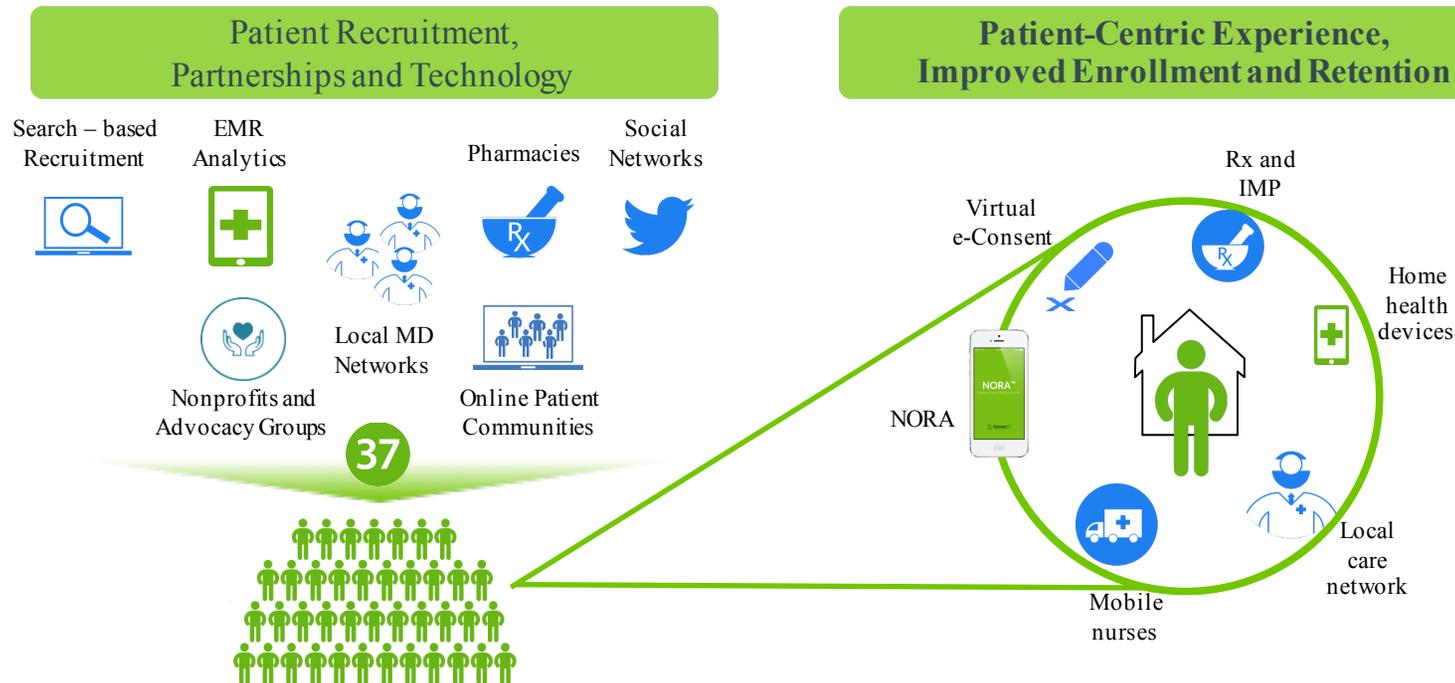


Home health devices

Mobile nurse

Rx and IMP

Recruiting and engaging patients at home and then building a clinical trial around a patient has only recently become possible through new technologies and emerging market capabilities.



- Drug retailer patient databases
- EMR and analytics partners
- Pathology and Lab networks
- Institutional Partnerships and KOLs
- Foundations & Patient Support Groups
- e-Enrollment, virtual consent from home
- Mobile Nursing and lab draws from home
- Local ecosystem of medical providers and care circles
- Family and support group involvement



**Metasite Operating Model** – Supported by our proprietary Network Oriented Research Assistant (NORA) technology platform, the metasite model overcomes the normal restrictions of geography and awareness.



**Design thinking** – A core methodology that we leverage to develop our platform, services, and trial designs resulting in User-Centered Solutions

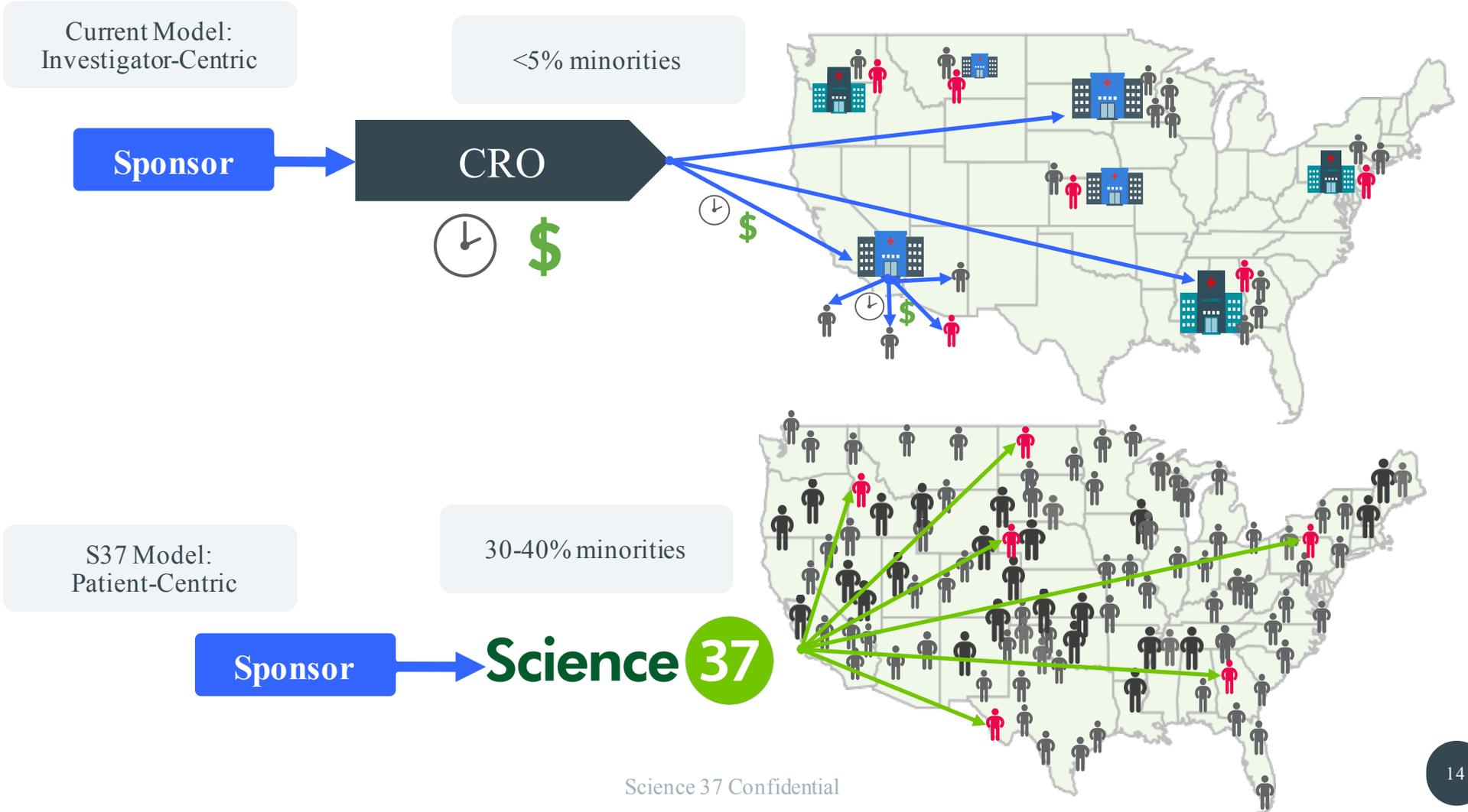


**Adaptive recruitment** – Built into our fabric to facilitate continuous learning and rapid iteration within trials. Our process is agile and collaborative with the IRB and study teams.



**Radical Collaboration** – A mindset and platform approach that simplifies collaboration between many vendors across the ecosystem and creates a single contract/partner to provide an end-to-end solution for clinical trials.

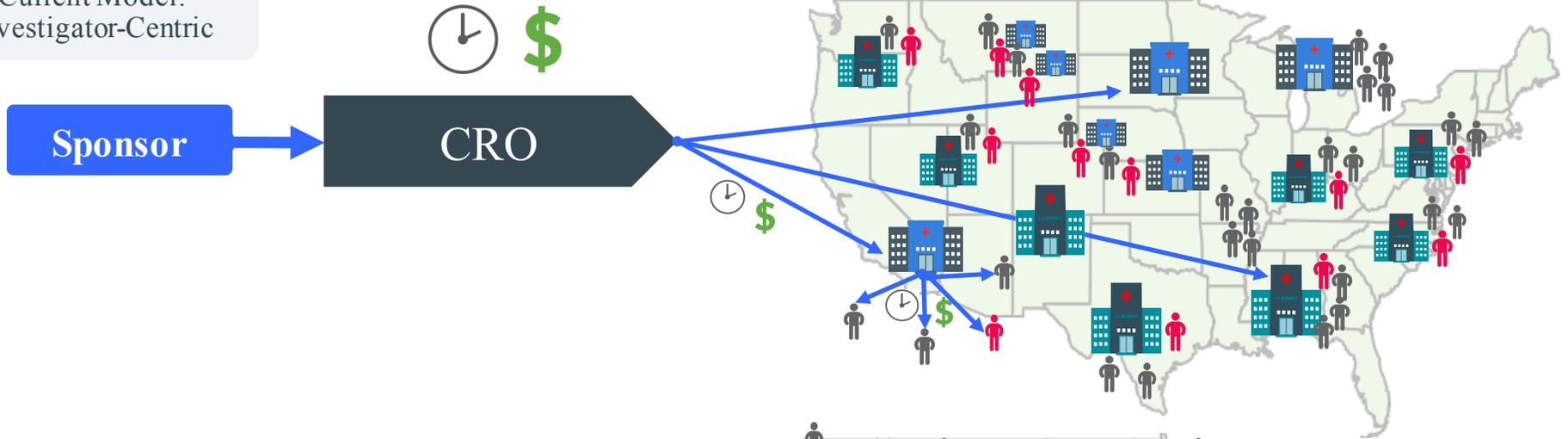
The Science 37 highly-networked approach allows engagement, recruitment, screening, and enrollment of large numbers of patients.



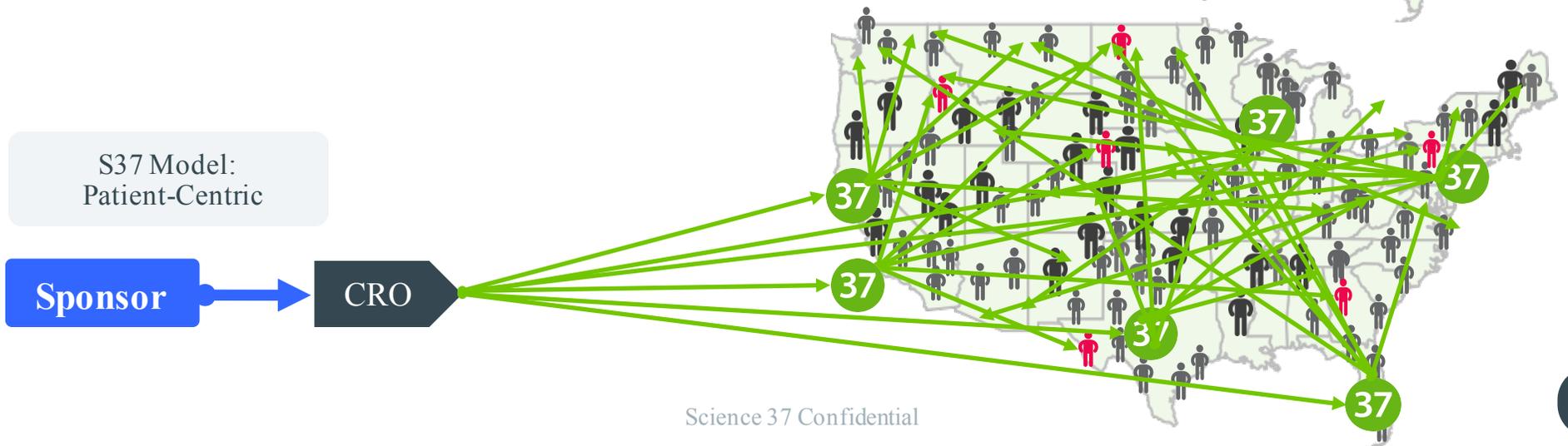
# Impact of the S37 Approach

The Science 37 highly-networked approach can be partnered with existing CROs to enable multiple metasites to function for global trials.

Current Model:  
Investigator-Centric

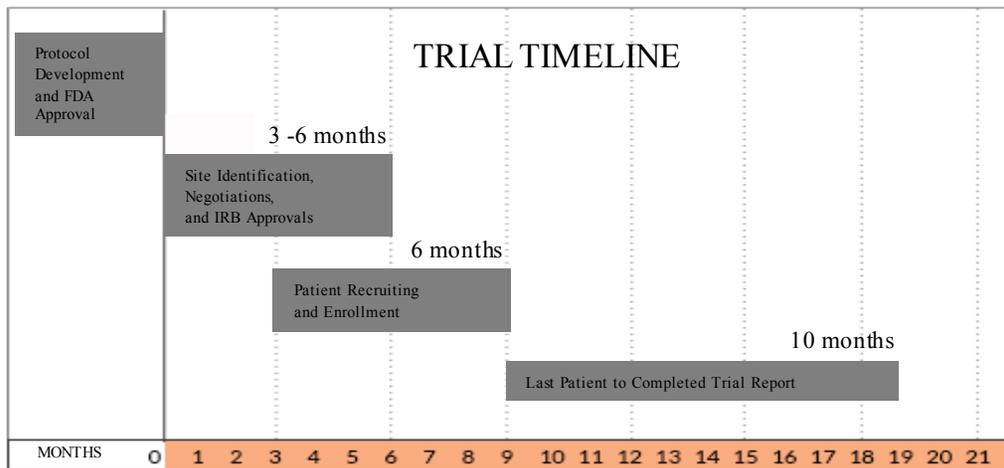


S37 Model:  
Patient-Centric



# Our Value Proposition

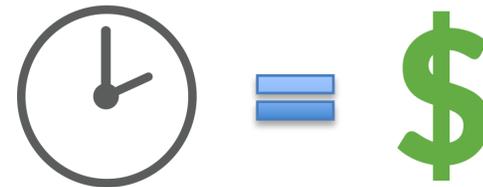
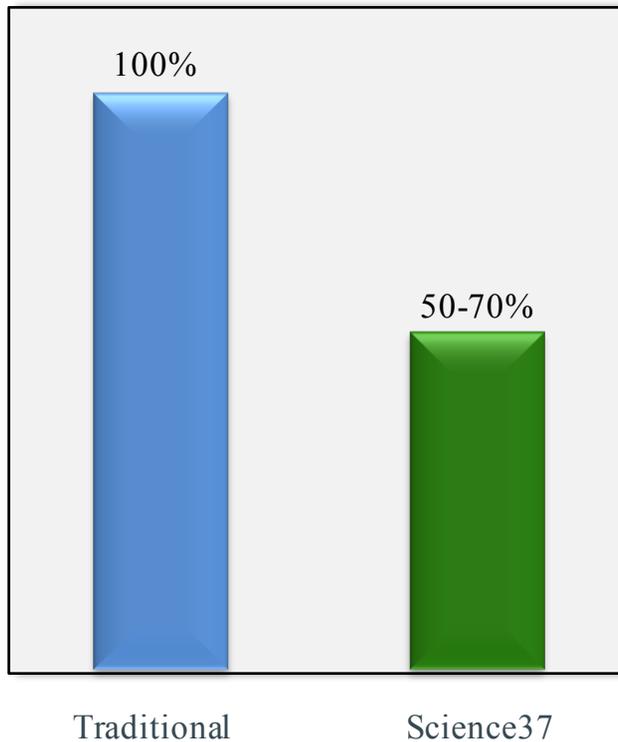
The Science 37 patient-centric trial eliminates the time to set-up multiple sites, engages a faster patient enrollment process and can reduce the time required for a typical trial by at least 30%.



- Phase II Studies: 25-30% faster
- Phase III Studies: 40-50% faster
- Overall time saved in drug life-cycle: 1-2 years
- Value of 1 year in the market can exceed \$250M

Science 37 contracts faster, recruits patients no matter where they live, retains patients, reduces set-up time, and leverages network efficiencies to conduct faster, cheaper, and higher quality clinical trials.

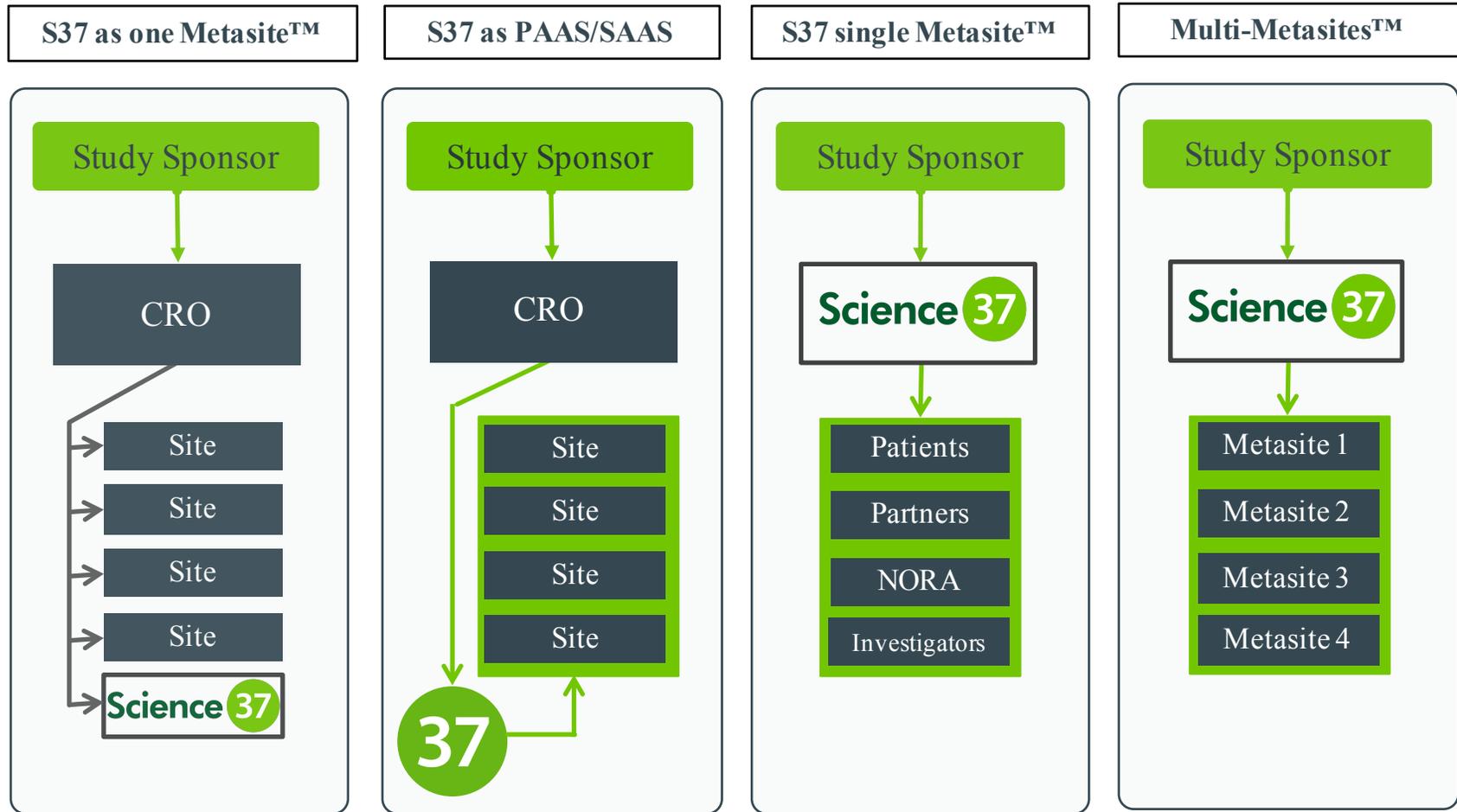
Time to Perform a Trial



- Single site set-up, contracting, and IRB process
- Faster patient recruitment and screening
- Faster time to execute eliminates study overhead
- Single site to monitor eliminates inconsistency in study procedures and improves data
- Ability to remotely engage best talent (PIs and KOLs) to conduct study
- Availability of more frequent and consistent patient-centric outcomes technology
- Enables risk-based and remote monitoring

# Sponsor/Partner Engagement Options

Science 37 has a flexible engagement model and can easily fit into current and new studies. Science 37 can operationalize the DCT model under four general schemes: 1) as one metasite™ in a larger multi-site trial; 2) as a PaaS/SaaS offering to sponsors, institutions, or CROs to create multiple metasites™ for larger trials; 3) as a single metasite™ contract for the entire trial; or 4) supporting multiple metasites™ directly in large trials.



The mission of Science 37 is to transform the clinical research process – to accelerate biomedical discovery and reduce clinical trial costs by shifting the center for research from traditional academic investigative sites to the patient’s home and local healthcare system.

We use patient-centered technology to simplify the process of participating in trials and connect patients safely and securely to the world’s best scientists no matter where they live.

Empowered patients lead to better, faster, less expensive people-powered science.





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