Science 37®

Decentralization: An Ethical Obligation.

We can make *every* clinical trial more accessible and it's our obligation to do so.

David Coman
Chief Executive Officer, Science 37

Nearly every clinical trial, regardless of indication or phase, should be agile—incorporating technology and decentralized approaches—to make drug and therapy development faster, easier and more representative.

60 Years of Excluding Patients

For more than 60 years, the traditional clinical trial model has relied on a disparate network of independent investigator sites to find, enroll and matriculate patients through a study to determine drug efficacy and safety. To participate, each of these sites must establish their own processes, people, and technology to accommodate clinical trials, which creates a significant barrier to entry. As a result, less than three percent[1] of all healthcare providers participate as clinical trial investigators.

Once up and running, this exclusive number of investigators has the ability to recruit patients into clinical trials, however, as you'd expect, these recruitment efforts tend to be limited to patients from their practice or those who live in the vicinity. So, what happens if you're not lucky enough to live near a research site?

Unfortunately, for more than 90% of patients[2], it means you would be excluded from participating, and this exclusion comes at a cost. And enormous consequences.

The Consequences of Exclusion

Economic and social consequences

It's well documented now that more than 80% of trials fail to complete on time[3] and the number-one cause for these delays is the speed of patient enrollment. Every day a drug is delayed from commercialization represents $600k to $8M of lost commercial revenue for drug sponsors.

Not only do these delays represent an opportunity cost, but they also delay the time it takes to bring viable products and potentially life-saving therapies to the patients who need them most.

Exclusion also means that certain populations do not get access. Today, the percentage of people of color who participate in trials is only about one third representative of the U.S. populations. Which means the population on whom the drug was tested is not necessarily representative of the population of patients taking the drug. This is a significant problem given that 20% of approved drugs perform differently by race[4].

Personal consequences

Beyond the macro economic and social consequences, exclusion as a result of the traditional site-based approach leads to consequences that hit closer to home for many of us.

Think about it: do you have a loved one with a medical condition, but has never been invited to join a clinical trial? How many of those whom you care deeply about have a condition that make them eligible for one of the more than 100,000 active studies that are listed on ClinicalTrials.gov today? And how many of those trials have they been approached to participate in?

The ethics of exclusion hit home for me and my family. Not too long ago, a family member was diagnosed with Amyotrophic lateral sclerosis (ALS). Knowing I was in the clinical research industry, he and his wife came to me in desperation to help find a clinical trial that might help turn the course of this terrible disease. While I poured through the more than 200 ALS trials listed on ClinicalTrials.gov that were actively enrolling, none were available anywhere close to him, and he didn't feel confident that he could make the long journey to participate given his condition. Sadly, this family member went through the full, agonizing disease progression, and is not with us today.

I know this experience is not unique to my family, and this issue doesn't necessarily have to be about life and death. There are too many examples to count about the ways access to clinical trials could have helped people — across all conditions — while enabling faster, safer, and more efficient research. I am sure you can cite an example or two in your own life where access would have or could make an enormous difference today.

Our Ethical Obligation: Enable Universal Access

As a board member of the Association of Clinical Research Organization (ACRO), I was honored to participate in the organization's 20th anniversary celebration a couple weeks ago where I was touched by a profound statement by Dr. Janet Woodcock, former Food and Drug Administration (FDA) Commissioner, who declared, "Access to clinical research is a right for any patient."

Of course access should be a right for any patient; however, if we continue to myopically focus on a traditional site-based approach to patient recruitment we will never get there.

Today, we live in a world where we have the capability to reach anyone, anywhere utilizing decentralized clinical trial techniques and more agile clinical trial designs, and we have an ethical obligation to implement them. There are no excuses. We all must embrace and leverage decentralization to enable universal access for anyone.

A Multitude of Options: Agile Approaches

Fortunately, you don't necessarily have to let go of your traditional sites completely. Instead, as a pioneer in decentralized approaches, Science 37 has developed an operating system (OS) to provide a multitude of options and will help to assess your protocols to identify ways to enable decentralization.

That can manifest by adding the Science 37 OS as a virtual site or Metasite™ to supplement a traditional brick-and-mortar site network. In this case, you just eliminate the bottom 10% of your sites, and replace it with a single, virtual site targeting the more than 90% of the population who don't live near your other brick and mortar site locations. When Science 37 acts as a virtual site among a traditional brick and mortar network, it is — at minimum — the highest enrolling site and we often represent 50%-85% of the entire participant volume.

The Science 37 OS can be deployed to find and enroll patients from anywhere, with study-specific procedures conducted via telemedicine, in-home nurses, or even local community providers. When study-specific procedures require specialized training, traditional clinical trial sites may be used to perform these procedures, but patient burden can be dramatically reduced to enable follow up via telemedicine, in-home nurses, or local providers.

There are countless agile designs incorporating decentralized clinical trial techniques to make clinical research significantly faster, easier, and more representative. To date, Science 37 has achieved up to 15x faster enrollment, saving crucial time in bringing drugs to market. It has also yielded up to 28% greater patient retention, which has extraordinary benefit for long during and long-term follow up studies. And our OS has been proven to improve diversity by up to 3x relative to traditional studies.

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A Call-to-Action

It's incumbent on all of us to unequivocally advocate for more equitable access to clinical research and clinical trials participation. We can do it now with more agile approaches and we must do it now. It's our ethical obligation to patients, providers and to each other.

David Coman
Chief Executive Officer

David Coman is the chief executive officer of Science 37, which makes it easier for people to participate in clinical research by connecting patients with doctors and nurses through telemedicine visits and home health screenings, then managing trial logistics from an integrated, comprehensive platform.

David came to Science 37 from ERT, where he led its data and analytics business after serving as the company's chief strategy officer. As the leader of ERT's data and analytics business, David reimagined the way the pharmaceutical industry looks at performance and risk management for clinical trials while more than doubling the company's bookings from analytics over a two-year period. In his strategy role, David spearheaded the acquisition of four companies in a 12-month period, generating more than $1 billion in enterprise value, while repositioning ERT as the market leader in clinical trial data generation.

David joined ERT from Quintiles (now IQVIA), where as chief marketing officer and founder of its Digital Patient business, he helped lead the company's growth from $2.7 billion in 2007 to $4.3 billion in 2015. It was here that David pioneered some of the industry's first decentralized clinical trials while also driving significant growth and enterprise value.

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[1] https://academic.oup.com/jnci/article/111/3/245/5307078?login=false
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7342339/
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