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The digital twin: in silico clinical trials

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For a long time, there was no way to accurately simulate clinical research trials. We went from cells in a lab to animals, and then directly to human volunteers. More recently, advancing technologies have allowed us to develop a new kind of trial: in silico.

You may have heard the terms *in vivo* (testing in a living organism) and *in vitro* (testing in a test tube). *In silico*, in turn, [literally means “in silicon,”](#) referring to the silicon chips in a computer. In silico trials involve the use of advanced computer modeling and virtual patients to test medical interventions. These trials are beginning to complement, and in some cases may even replace, traditional clinical research steps.

How do in silico trials work?

An in silico trial uses algorithms and biological datasets on a computer to create what we call [digital twins](#). These are virtual representations of human organs, body systems, or even entire disease pathways. Researchers can “give” a virtual drug to thousands of virtual patients in a matter of hours and then [observe how those digital bodies react](#).

How does simulation complement traditional trials?

We are certainly not at a point where we can press a button on a computer and skip human testing altogether. However, in silico models are becoming an essential partner to traditional trials in several key ways:

- **Refining trial design:** Before recruiting a single person, researchers may use simulations to [predict the most effective dosage](#) of a drug. This could potentially make the dose-finding phase much more efficient.
- **Bridging the gap in rare diseases:** Finding participants for rare disease research is incredibly difficult. In silico models can act as augmented control groups, providing data to start with where human volunteers may not exist.
- **Predicting long-term side effects:** Some complications may not show up in a standard-length trial. [Computer models can simulate years of drug interaction](#) in a short amount of time, flagging potential safety issues early.

Can simulation replace traditional trials?

The short answer is: possibly, sometimes. Regulatory authorities such as [the FDA](#) have already begun advancing health through modeling and simulation. For example, [this study](#) at the University of Leeds showed that virtual trials for certain heart valve devices could produce results that accurately mirrored human trials. In these cases, simulation can reduce the number of people exposed to experimental risks and significantly lower the cost of bringing a device to market.

However, for complex systemic drugs like immunotherapies, the human body is still far more complex than even the best code. We still need large-scale human trials to confirm that what happens on a screen actually happens in a living, breathing person.

Is recruitment evolving too?

To build accurate digital twins, researchers need diverse, real-world data from actual patients. In this way, recruitment could become more about the long-term relationship. By participating in a trial today, a patient's data might help create the virtual model that contributes to even more research tomorrow.

With that being said, in silico trials aren't about replacing humanity with machines. They are about using math and data to make human trials safer, faster, and more likely to succeed. By integrating simulation with traditional research, we could be moving toward a hybrid future where in silico simulations ensure that, by the time a drug reaches a human volunteer, the path to success is already well-charted.

At Praxis, we understand that the future of clinical research is a blend of the traditional and the digital. If you're looking for support with trial recruitment, [connect with us](#) today!