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The power of one: single-patient trials and the future of research.

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Numbers carry weight. For decades, the gold standard of medical research has relied on quantity. If you want to find out how safe and effective a drug is for the general public, you test it on as many people as you can, average the results, and evaluate the statistics for success.

This one-size-fits-most model of research is the reason we have reliable vaccines, antibiotics, and other regularly distributed medical interventions. For broad-scope medicines that target an "average patient," it remains the most reliable way to protect public health.

In some cases, however, we come to find that the "average patient" doesn't exist. This is when smaller study populations, all the way down to one single patient, become most useful.

What Is an N-of-1 Trial?
In a traditional, randomized controlled trial, researchers compare a group of people receiving an intervention to a group of people receiving a placebo. In an n-of-1 trial, the "group" is one person.

Instead of comparing Patient A and Patient B, n-of-1 trials compare how Patient A responds to different treatments over different periods. The goal is to precisely determine the optimal treatment for that specific individual.

Precision Research
The n-of-1 trial design provides us with a game-changing tool for specific jobs. Large-scale randomized controlled trials are essential for public health and establishing broad safety baselines, but certain cases call for an individualized approach:

- **Rare genetic conditions:** One of the most famous n-of-1 successes involved a girl named Mila Makovec with a unique mutation of Batten disease. Researchers developed a custom drug specifically for her, as she was the only person in the world with that specific mutation. The n-of-1 approach established a tailored, life-extending treatment.
- **Chronic pain:** Individuals who experience chronic pain often cycle through NSAIDs (ibuprofen, naproxen) with a trial-and-error approach and unclear, mixed results. N-of-1 trials like this one have been conducted to help each patient determine their most effective pain control by having them track their symptoms while taking different medications in a blinded fashion.
- **Nutrition:** Diet plays a large role in an individual's general well-being. It can influence many health outcomes, and this n-of-1 trial on personalized nutrition research explored the impact of certain diets on disease prevention at the most precise level.

Technology for Individualized Treatment
On top of what has already been done, n-of-1 trials are becoming more common as certain technologies catch up to the idea.

1. **Wearables:** Smart devices, such as phones and watches, allow people to track their health and habits with ease on a daily basis. In trials, this data allows researchers to see real-time physiological responses from each person.

2. **Genomics:** As seen in the case of Mila Makovec, scientists have developed ways to identify exactly why one person's body might reject a standard treatment, allowing for research on personalized alternatives.
3. **Data analytics:** AI and advanced modeling can now process vast sets of data, analyzing certain information and identifying patterns with great speed to aid in personalized research.

Evolving Clinical Research

Clinical trial designs are always under scrutiny for improvement. There's a balance required to achieve optimal research practices, and that involves analyzing a number of factors, including trial size.

We're likely to find that a hybrid approach, utilizing both large- and small-scale trial designs based on each specific case, will help clinical research grow and evolve in the future.

Praxis is proud to have worked on recruitment for trials of all sizes. Connect with us today to find out how our recruitment strategies could help shape your research.