

WHY N-OF-1 & SMALL DATA?

THE CHALLENGE OF RECONCILING BIG DATA AND PERSONALIZED MEDICINE

STEVEN SCHWARTZ, PHD

Evidence-based medical research and medical services are undergoing dramatic change. In the twentieth century, clinical evidence rested upon 2 fundamental principles and 3 supporting corollaries. Promising treatments were compared to a standard (placebo or standard of care) under controlled conditions and evaluated using statistical inference to reduce the potential for interpretive error in evaluating results. Supporting the strength of any causal conclusions are the corollary features of a meaningful control (comparison) condition, randomization to treatment conditions and blinding.

Group statistics and deductive inference provide a **forest view** of clinical outcomes relative to determining the greatest overall good. Their reign as the gold standard is well deserved given the associated advances in the clinical outcomes that have yielded a strong evidence base of treatments that *help the most people the most* (i.e. deductive reasoning). However, the need to still treat individuals uniquely is never fully addressed using group statistics no matter how rigorously derived.



It is becoming clear that group methods alone, while still quite valuable, are increasingly inadequate as treatment development and testing moves towards measuring **individual differences** inherent in every person and every treatment response (or non-response) even though this information is latent within most outcomes and data (if collected properly). That is the **tree view**. **IndividuALLYtics® integrates forest and tree view.**

Wearable technologies, like FitBit and Apple Watch, now commercially available and widely distributed, collect nearly continuous time series data on a variety of behavior health risk/protective factors (steps, heart rate, GPS location, sleep/wake cycle and more) that adds to the data integrity while simultaneously relieving the data collection burden for patient and clinician.

Unfortunately, group data and more recently big data approaches for generating new knowledge have ignored a quieter and complimentary measurement and evaluation technology that makes greater use of inductive reasoning, namely N-of-1 treatment “Small Data” designs and analysis. The rigor and logic of these designs have been well articulated and expanded upon for over a half century. [1] Yet they have never achieved widespread adoption by practitioners or patients because the self-monitoring labor and time required for collect data in N-of-1 analyses prohibitive. With the growing ubiquity of digital mobile and wearable technology this barrier is no

longer at issue where momentary ecological assessment and intervention are now commercially feasible.

By using more refined time-ordered data to optimize individual level understanding you can immediately provide feedback to the consumer/user that tells them exactly what in their specific lives is influencing their behavior and outcomes. The architecture and metric strategy of any digital program that structures and optimizes time-ordered data with this technology can arrive at a customer/user value level that is, by definition personalized and without the classic paradox of needing large initial data sets for meaningful insights.

IndividuALLYtics® patent-pending N-of-1 evaluation technology uses repeated measures (i.e. time series data) to assess treatment efficacy with accuracy up to 5x better than standard of care for each patient.



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N-of-1 evaluation creates the opportunity to evaluate each individual uniquely (IAQplus™). Small Data use of N-of-1 approaches are truer to life, than current clinical practice, by providing individualized feedback to each user (or clinician) about the quality and strength of their unique treatment response. Further, like more traditional approaches, N-of-1 can incorporate biological (genomic), behavioral, psychological and digital health data such that users themselves can begin to evaluate the relationships of their own treatment response patterns and the contingencies that impact them. For the clinician, this revitalized form of scientific and behavioral interaction evaluation can help them validate or reject the impact a given treatment has for a given patient with increase efficiency and accuracy. For single chronic conditions provides up to 5 times and for 2 to 4 chronic conditions provides over 20 times improved multi-therapy population effectiveness.



This framework does not challenge group science but complements with strategies around time-ordered data within a single individual and then aggregates across multiple individuals. Further, by using N-of-1 methodology, time-ordered data gets optimized by providing a new metric, IndividuALLYtics Quotient™ (IAQplus™), from the growing deluge of time-ordered data now coming from the advances in new measurement technologies (wearable devices, nano-technology, quantified-self movement, pervasive wireless connectivity, Internet of

Things, ecological momentary assessment and intervention, etc.).

Dr. Eric Topol points out: *“A combined series of N-of-1 trials can be particularly informative, but that has not yet led to the routine use of such a study design.”* Dr. Topol further explains that the shift to using a large number of investigational variables, for a smaller number of individuals: *“...has extraordinary promise for the future of research and discovery. Whether it is in the form of a series of N-of-1 trials that are combined or just much smaller clinical trials to test innovative treatments for a chronic disease, there is a new large P, small N path of research going forward.”*

By advancing a proven Small Data perspective on data analytics and design, IndividuALLYtics employs a proprietary patent pending approach to individual level evaluation developed by PhDs and seasoned clinical and business professionals in the fields of applied statistics, behavioral science, medicine as well as marketing, customer service, and product development.

IndividuALLYtics' products and services combine the best of group average statistics with N-of-1 methodology, along with specialized supervised learning models to allow for evaluation of need and value for each patient at scale affordably. Let us help you accelerate improved outcomes and value for your digital health application to your targeted communities. Further, IndividuALLYtics can also incorporate pharmaceutical, genetic, and systems biology disciplines and access to experts aligned with your target user's digital health community journey that better bridges improved treatment insights into the broader social milieu.

IndividuALLYtics® digital connected-care solution enables a new more precise way to establish a personalized, yet evidence-based health approach that advances efficiency and effectiveness without the dependence on Big Data. Small Data spots individual's signals and significance.

Learn More: Web – www.individuALLYtics.com

Email – hello@individuALLYtics.com

[1] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3118090/> The n-of-1 clinical trial: the ultimate strategy for individualizing medicine?

