

## Personalize medicine: A research miracle or ethical nightmare

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Personalized medicine is the ability to determine an individual's unique molecular characteristics and to use those genetic distinctions to diagnose more finely an individual's disease, select treatments that increase the chances of a successful outcome and reduce possible adverse reactions. It involves identifying genetic, genomic, and clinical information including biomarkers and metabolic pathway inhibitors that allows accurate predictions to be made about a person's susceptibility of developing disease, the course of disease, and its response to treatment. However, one must ask whether our industry is ready for more and more 'rare diseases'? As clinical research advances, by identifying sub-populations through biomarkers and surrogate endpoint, it will necessitate conducting clinical trials through the use of stratified medicine or personalized medicine. Patients will be profiled to identify metabolic pathway mutations that may be targeted if and when a disease presents itself. These advances create new ethical challenges such as what entity should control access to new pharmacogenetic and pharmacogenomic tests and companion diagnostics and why. Patients have a right to information that can affect their care yet shouldn't this right be balanced with evidenced-based research? This demand may be mitigated by ability to pay and balanced by institutions and insurance company's reluctance to pay for tests unless or until the cost-benefit and cost-effectiveness ratio is solidly proven. Then there is the individual patients 'hope'; life can change in an instant, but the one thing that always abides is hope- the unfailing feeling and expectation that tomorrow will be better. Is personalized medicine the answer to everyone's hopes?

### Biography

Linda Strause with over 25 years experience she has held senior management positions within the biotechnology, site management and CRO industries. She brings her personal and professional experience together in the field of ethics and end-of-life care. She is Senior Research Scholar and Founding Chair of the San Diego Hospice & Palliative Care IRB, where she served as chair of the IRB for over 15 years. She sits on numerous boards and committees to promote excellence in clinical research and protection of human research subjects. She is an invited speaker and has published numerous articles within the clinical research enterprise.

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