



21st Century Cures - Digital Health Care

Leveraging Technology to Advance the Discovery, Development, and Delivery of Better Treatments and Cures

Biomedical research and therapeutic innovation are happening at lightning speed alongside of, and supported by, advancements in digital and personalized medicine. Genomics, data analytics, health information, and other constantly evolving data sources, technologies, and platforms have already fundamentally transformed many aspects of our health care delivery system. However, in some areas, the committee understands that significant gaps remain between practice and potential. What can Congress do to improve the entire digital health care landscape? The 21st Century Cures initiative aims to accelerate the discovery, development, and delivery cycle to get promising new treatments and cures to patients more quickly. To achieve this, we must close these gaps and embrace new technologies in every phase of the cycle.

Data sources and innovative products that harness their power have emerged since the mapping of the human genome, enabling researchers to discover new ways to proactively diagnose and target conditions and diseases at the molecular level. Large scale analysis and predictive modeling of big data can play a critical role in providing patients with more personalized prevention or treatment options based on their unique set of circumstances.

Mobile medical applications and consumer-focused products can empower a new generation of patients by supporting engagement, both individually and with a medical provider, in health and wellness activities. Further, advances in communications technologies have enabled patients to communicate in real-time with researchers, providers, and other patients about their experiences with certain therapies or treatment regimens. The potential of such technologies to transform clinical trials and real-world evidence development is large and relatively uncharted. How can the increased utilization of these technologies improve patient care? How can Congress ensure such innovation continues while mitigating risks? What needs to be done to create a sufficiently tailored legal and regulatory framework that accounts for the unique nature of these technologies in order to foster continued innovation, reduce uncertainty, and minimize risk?

Increased data sharing through electronic health records (EHRs), clouds, and other platforms can better inform health care delivery but can also lead to new research and discovery. To fully realize the potential of big data and the benefits of innovative new technologies, such

tools and the information they contain must be able to communicate and work together. What legal or commercial barriers prevent these technologies from being used on a larger scale at both the point of care and for additional research and development activities? What role can Congress play in addressing them?

New technology and data can shift our health care system from a reactive one defined largely by its silos into a predictive and integrated care continuum. To fully and responsibly achieve this goal, Congress must carefully consider how patient privacy may be affected by broader aggregation and more detailed data analysis. In the health care setting, are the existing systems to address privacy and informed consent sufficient to protect individual patient interests while facilitating the type of information exchange necessary to ensure the right treatments are prescribed and the best care is provided?

Through the 21st Century Cures initiative, we are committed to making sure our legal and regulatory framework fosters the development of such a digital health care ecosystem and allows it to serve as a catalyst for the discovery, development, and delivery of new treatments and cures for patients. We are not there yet. The committee seeks guidance about how this vision can become a reality and what role Congress can play in the process. The committee welcomes the public's input and feedback to cures@mail.house.gov by July 22, 2014. 21st Century Cures is a truly collaborative effort. Please be advised that submissions sent to cures@mail.house.gov will be made publicly available on energycommerce.house.gov/cures as part of the effort to encourage continued discussion about opportunities and ideas to accelerate the pace of cures. We thank you for participating.