

Table 7. Implications for biopharma and medical device companies

Goal of Cures	Implications for biopharma	Implications for medtech
Faster drug approvals		
<p>Enable faster drug approvals by modernizing the approach to clinical trials—incorporating new sources of evidence and new tools to shorten the drug development process</p>	<p>Engage in proactive conversations with the FDA early on in development to understand which innovative tools or sources of evidence might apply to their program and expedite development</p> <p>Expand capabilities required to access, collect, and analyze RWD</p> <p>Leverage incentives to develop drugs for specific populations, including pediatric rare disease and antimicrobials</p> <p>Continuing to work with the FDA, patient advocacy groups, and provider groups to delineate pathways for patient and caregiver involvement</p>	<p>No direct impacts from Cures. Medtech companies should however continue to work with the FDA to understand how to incorporate patient-centered approaches and RWE into product development plans</p>
Health care economic information communications		
<p>Provide clarity on certain HCEI communications between biopharma and health care stakeholders</p>	<p>Expand the dialogue on economic evidence with health care stakeholders and explore value-based contracting</p>	<p>No direct impacts from Cures. Medtech companies should, however, continue to work with stakeholders to determine how to best structure value-based contracts within current regulatory constraints</p>
Regenerative medicine		
<p>Establish approval pathway for regenerative medicine</p>	<p>Engage in a dialogue with the FDA on how to advance regenerative medicine products while guidance on approval pathways are being developed</p>	

Table 7. cont.

Goal of Cures	Implications for biopharma	Implications for medtech
Medical device innovation		
<p>Clarify and improve existing approval process, create regulatory flexibility for devices that treat life-threatening conditions or impact small populations</p>	<p>No direct impacts from Cures</p>	<p>Encourage greater investment in medical technology innovation and consider partnerships with companies that are developing life-changing innovations</p> <p>Generate data to support regulatory approval but also market access—consider investing early in evidence that supports coverage and reimbursement as well as regulatory approval</p> <p>Invest in RWE capabilities to incorporate new sources of data into the device development and approval process</p>
<p>Improve access to POC diagnostics</p>	<p>Biopharma companies should consider how POC diagnostics could be used to increase patient engagement and drive utilization of products, especially for chronic disease</p>	<p>Take advantage of opportunities to advance POC diagnostics that can expedite diagnosis in lower cost care-delivery settings and get treatments to patients faster</p>
Combination products		
<p>Improve regulation of combination products and increase opportunity for sponsor engagement in dispute resolution</p>	<p>Take advantage of the opportunity to advance combination products through increased dialogue with FDA, leveraging evidence that supports a product’s primary mode of action</p>	
Regulation of medical software		
<p>Clarify regulation of medical software</p>	<p>Engage in ongoing dialogue with the FDA to develop the framework for the regulation of software that will be regulated as a medical device, particularly devices that might be used to drive greater patient engagement</p>	
<p>Advance interoperability initiatives</p>	<p>Deepen partnerships and collaborations with health systems to access RWE</p>	