

Critical Path Question 1: FDA's Roles in Modernizing the Critical Path: principles to guide FDA decision-making on how to spend limited resources on Critical Path activities.

*Background:* The first National Critical Path Opportunities List will identify priority hurdles to medical product development, and point to some initial steps for overcoming those hurdles. Based on the List, FDA will identify steps it can take within current resource constraints toward overcoming some of those hurdles. FDA hopes that the List will serve as a catalyst to industry, patient groups, the academic community and others to address Critical Path hurdles.

*Question:* Are the following appropriate principles for FDA to use to guide its decision-making on how to spend its limited resources on Critical Path projects?

1. FDA is uniquely situated to bring stakeholders together: FDA should choose activities that promote collaboration, both with external stake holders, other federal agencies, and among the FDA Centers.
2. FDA is a public health agency: FDA decisions should give weight to urgent public health needs and at-risk populations.
3. FDA is responsible for promoting innovation in all industry sectors and along the full span of the product development pipeline, from discovery to use of the product in health care: FDA decisions should give weight to those activities that can provide benefits across product types, diseases, and industry sectors, and should look for a balance among activities with short term benefits and more complex efforts with longer-term payoffs.
4. FDA is uniquely situated to identify hurdles that are causing product development bottle necks industry-wide: FDA should devote some resources to continue problem identification activities.
5. FDA is responsible for setting science-based standards for product development: FDA decisions should give weight to those activities from which science-based standards and guidances can be developed.

Critical Path Question 2: Stakeholders' Roles in Modernizing the Critical Path.

*Background:* The FDA is uniquely situated to undertake some Critical Path activities -- such as identification of priority product development hurdles that are causing bottleneck industry wide, and setting scientific standards for product development. However, modernizing the Critical Path must be a joint effort among all stakeholders; FDA cannot and should not do this alone. FDA hopes that the National Critical Path Opportunities List will serve as a catalyst to industry, patient groups, the academic community and others to address Critical Path hurdles. In the docket and through our outreach efforts we have heard a variety of good ideas that are beyond our capacity or that do not necessarily need government involvement. (For example, several dockets comments point to the need for stronger academic programs in key Critical Path disciplines.)

*Question:* What roles should industry, patient groups, and other stakeholders play in modernizing the Critical Path? What should FDA do to encourage others to undertake these key Critical Path activities?