

Overview of US Strategic Roadmap and Goal: Connect End-users with the Developers of New Approach Methodologies

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The successful implementation of new approach methodologies (NAMs) will depend on research and development efforts developed cooperatively by industry partners and federal agencies. Currently, technologies too often emerge in search of a problem to solve. To increase the likelihood of NAMs being successfully developed and implemented, regulatory agencies and the regulated industries who will ultimately be using new technologies should engage early with test-method developers and stay engaged throughout the development of the technologies.

There are three specific aims under this goal:

1. **Identify anticipated testing requirements.** Agencies and industry stakeholders need to work together to identify and communicate their anticipated science and technology needs for safe product development and registration.
2. **Encourage the establishment of grant review criteria tailored to the development of alternative methods.** Funding development of NAMs should begin as early in the research and development process as possible. However, most current grant review processes are tailored to reward research involving animal models. To better support NAM development, processes for influencing the distribution of funding to NAMs by the federal government should be explored.
3. **Develop mechanisms to improve communication between end-users and researchers.** One of the most cost-effective and impactful actions that can be taken immediately is to foster efforts that improve the dialog between end-users and test-method developers. Federal agencies and industry stakeholders should collaborate to develop programs and processes that encourage an open dialog between test-method developers and end-users. For example, end-users could host workshops or webinar series aimed at identifying agency and industry priorities with accompanying examples of use-cases within or outside of regulated testing space.