

## FDA Critical Path

---

In July 2004, the California Healthcare Institute (CHI) assembled academic, government, and industry leaders to discuss ways to address the U.S. Food and Drug Administration (FDA) draft Critical Path Initiative to make medical product development faster, less expensive, and more predictable. In the past few years, the costs of drug development have mushroomed, while the number of new drug approvals has declined. Medical technologies that have been found safe and effective in Europe are sometimes prohibited in the United States, and industry veterans worry that inconsistent standards and outdated guidances prompt expensive and lengthy studies that have limited potential benefit to patients.

Alarmed by these trends, the FDA launched the Critical Path Initiative to foster technologies that will better predict a product's success and thus limit resources squandered on failed products. The initiative relies extensively on feedback from and collaboration with industry and academia to identify the most tractable pain points and to build a set of tools to mitigate them. Over the course of two days in San Diego and Palo Alto, representatives of academia and the biotechnology, pharmaceutical, and medical device industries discussed how the FDA could ease unnecessary burdens and improve efficiency and predictability in medical product development. This submission captures the highlights of these discussions and sets forth a record of key messages for the FDA, as identified by members of CHI:

- Use better science to ease unnecessary regulatory burdens
- Take acceptable risks
- Keep standards and guidances current and consistent
- Improve predictability
- Collaborate with academia, industry, and other agencies

## THE CRITICAL PATH INITIATIVE CAN STIMULATE BETTER REGULATORY SCIENCE

Recent successes in basic biology deserve their optimistic headlines. The first draft of the human genome is complete, as are drafts of the most commonly used model organisms. Knowledge of the extent of human genetic variation and how it might shape susceptibility to disease and response to drugs is leaping forward. Millions of single nucleotide polymorphisms (SNPs) have been deposited in the public domain. Our abilities to sample protein and gene expression levels in human tissue are becoming ever more sophisticated, as are techniques to visualize everything from brain activity, cell growth, and individual molecules. Even more impressive are scientists' attempts to share and integrate these data. Inevitably, innovative ideas to battle cancer and cheat the diseases of aging have sprung from this more sophisticated understanding of human biology.

One example of such success is in blood screening. Gen-Probe, a CHI member firm, has developed amplified nucleic acid tests (NAT) that identify viruses much sooner than have prior generation tests of potential blood donors who do not yet show traditional signs of HIV-1, hepatitis B or C, or West Nile Virus. This will help prevent transfusion of contaminated blood products. The company worked collaboratively with the FDA's Center for Biologics Evaluation and Research (CBER) to protect the blood supply while the test was under investigational status and to achieve a reasonably rapid commercial approval for the initial HIV-1/HCV tests.

Yet this abundance of ideas has not generated an abundance of marketed products, as recent approval rates for new drugs and biologics shows. Spending on basic research has skyrocketed, more than doubling in the last decade. However, during the five-year period 1999–2003, the number of new molecular entities submitted to the FDA fell by one-fifth, and the number of original biologics license applications fell by one-half, compared to the five-year period 1993–1997. Worse, drugs entering trials today are less likely to succeed than drugs were ten years ago. In the Critical Path Report, Lawrence Lesko, the director of the Office of Clinical Pharmacology and Biopharmaceutics at the FDA states, "Currently, a striking feature of this path is the difficulty, at any point, of predicting ultimate success with a novel candidate. For example, a new medicinal compound entering Phase 1 testing, often representing the culmination of upwards of a decade of preclinical screening and evaluation, is estimated to have only an 8 percent chance of reaching the market. This reflects a worsening outlook from the historical success rate of about 14 percent. In other words, a drug entering Phase 1 trials in 2000 was not more likely to reach the market than one entering Phase 1 trials in 1985. Recent biomedical research breakthroughs have not improved the ability to identify successful candidates." Meanwhile, the cost of bringing a new drug to market has shot up 55 percent. Although the FDA has not seen a corresponding downturn in device submissions, there are areas of concern in that field as well.

The problem is that, while the life sciences has vastly improved its capacity to generate

ideas for new product candidates, it has not improved its ability to select successful candidates for development. The science necessary to evaluate and predict safety and efficacy and to enable manufacture of marketable products is not the same as the science that generates new ideas for drugs and devices, but it is no less essential.

Predictive, translational research can establish both the principles and methods to speed product development and to make it more efficient. Products' safety and efficacy are currently probed with tests developed decades ago. New ways to assess these qualities could be more accurate and less expensive. However, more practical algorithms have not materialized; traditional funding agencies, such as the National Institutes of Health (NIH), do not support this kind of research. Meanwhile, as costs increase and the number of successful development programs for drugs and biologics decreases, the industry shies away from risky projects, even in areas of important unmet medical needs. Indeed, whole fields of promising medical research may stagnate if the results from early commercialized products and those still undergoing testing are discouraging.

Thus, the need for new tools is clear. Patients could be treated with a greater array of more-effective and less-expensive products if the path to drug development were more efficient. New ways to identify which patients are most likely to respond to a drug, biologic, or preventive treatment, or which have a predisposition to a disease, could make clinical trials smaller, faster and cheaper. Computer modeling techniques might be able to yield the same information

that's currently gathered from *in vivo* studies. Better biomarkers, assays, and more meaningful clinical endpoints could show, with more certainty and in less time, whether or not a treatment is benefiting patients. Better ways to insure consistent manufacturing could reduce costs, keep regulatory inspections more focused, and let industry know that certain projects are technically and commercially feasible.

Nonetheless, new predictive tools, no matter how powerful, will be largely useless unless the FDA recognizes them as predictive. The agency has taken a brave and necessary step in launching its Critical Path Initiative, and in so doing, has demonstrated to industry that it will go beyond accepting new tools and techniques; it will actively seek and promote them, and will welcome input on its regulatory system. The FDA's openness to work with industry to establish specific objectives and measures of success has been met with resounding enthusiasm and support.

In response to the FDA's request for suggestions as to which efforts will be the most effective, CHI recommends that it focus on easing unnecessary burdens, maintaining current and consistent guidelines, and encouraging development of analytical tools and methodologies to increase predictability.

Most important, CHI believes the Critical Path Initiative could usher in a more productive mindset in which the agency identifies opportunities for success and continually works with industry and academia to establish research and regulatory priorities that will best serve patients.

## USE BETTER SCIENCE TO EASE UNNECESSARY REGULATORY BURDENS

### Focus on Essential Information

Industry and the FDA share the same ultimate goal: making sure tests, devices, and treatments that are likely to help patients are made available to them as soon as possible. If barriers to proving safety and efficacy are too high, life-sustaining products will be delayed in getting to patients who need them. In one case, the agency required trials with more than three-quarters of a million patients to demonstrate safety for an embolic protection device; the project was postponed indefinitely. The industry is replete with similar scenarios.

Judging whether treatments will be safe and effective is better achieved by relying on rigorous science than on a rigid process that requires an accretion of tests developed before astronauts landed on the moon.

The FDA recognizes that many of its currently required tests consume time, exhaust resources, and are minimally informative. There is no need to spend time and money measuring and re-measuring variables that are not going to help a single patient. For example, legitimate concerns that led to testing requirements for genetic stability two decades ago now seem to have been overly cautious. Even though this issue has yet to result in real problems, regulatory policy has not been updated to completely reflect 25 years' worth of data. Indeed, specific tests required for genetic stability have not been replaced with less-expensive tests that are widely believed to be more predictive.

In addition, cell-based assays can be just as predictive for determining certain safety risks as *in vivo* testing. Various toxicology tests date from the 1950s and were developed using sets of compounds and data that were different from what's available today. Perhaps suites of surrogate computer models, cell model, and *in vitro/in vivo* models could be used in addition to animal studies to minimize the number, size, and duration of studies.

The key to developing the most informative tests is determining what information is most essential. More resources should be allocated to studying the most likely risks.

There is an overwhelming notion among industry executives that too many preclinical and early clinical tests—perhaps more than half—have no useful predictive value. The resources devoted to these tests should be redirected toward searching for effects that truly matter. For example, a drug that affects angiogenesis may be required to go through an extensive battery of tests that assess potential impact on pancreatic function. Instead, some of those resources should be directed to developing more tests for assessing risks in embolism, blood clotting, and kidney function.

Obtaining essential information need not require exhaustive resources. The FDA has already demonstrated ways to evaluate efficacy without collecting excessive data and, more importantly, without sacrificing certainty. Recently the FDA used a clever clinical trial design to demonstrate that digital mammography was more accurate than conventional screens at detecting breast cancer. To

demonstrate that the digital mammograms actually increased patient survival via traditional methods, a 40,000-patient study was required. Though no company was prepared to run such a trial, the FDA was able to collect the necessary data to demonstrate efficacy by arranging for four companies each to study 10,000 patients. The companies used a common protocol and pooled results to obtain the necessary numbers for the study. In this way, no company was faced with an overwhelmingly expensive trial, nor was improved efficacy accepted with insufficient data.

In addition, the FDA developed statistics that can shrink by more than half the number of samples required for imaging device trials. In this case, a new mathematic methodology allowed trials to proceed with much smaller sample sizes. This innovation changed the regulatory algorithm, allowing beneficial products to be marketed years earlier than classic market trials have allowed. The methodology also allowed hypertension trials with automated blood pressure monitoring to be conducted without a placebo group. And Bayesian statistics are now used routinely to show efficacy for medical devices, though their use was controversial in the 1990s. Some experts think the use of Bayesian statistics could mean that the results of a single clinical trial, plus supporting natural history, would be sufficient to demonstrate a product's safety and efficacy. Although along with the Public Health Service Act, the FDA Modernization Act of 1997 allows the approval of a drug or biologic on the basis of one well-controlled clinical trial (plus substantial evidence supporting safety and efficacy), the FDA has traditionally required at least two independent trials.

These examples demonstrate that focusing on collecting the essential information, rather than relying on a particular process, can make product development more efficient without sacrificing the quality of the information. By collaborating with industry, additional routes for collecting evidence could be identified. *In vivo* tests and computer modeling could supply solid evidence for predicting safety and efficacy. Significant efforts should be directed toward developing and rigorously evaluating such tests. For instance, the uniform acquisition of tumor material in the pivotal Herceptin<sup>®</sup> trial permitted Genentech to quickly re-evaluate a new diagnostic technology Fluorescence in Situ Hybridization (FISH), which enabled the FDA to approve the technology without additional large clinical trials.

More informative and more  
efficient tests and studies must replace,  
not supplement,  
less-informed methods.

If new requirements increase the regulatory burden, rather than decreasing it, companies will have a strong disincentive to collaborate, or even develop, new tests or analytical methods. Industry already feels that it's required to collect useless data; it will strongly resist policies that pile on additional tests, instead of just requiring essential ones.

An example of larger-than-necessary sample sizes can be seen in CBER's new "equipment migration" algorithm. While attempting to reduce burden by eliminating the need for a new clinical trail when new test equipment is proposed, the data requirements for such

migration studies are even larger than some clinical trials. When asked for the basis of the study sizes, CBER relies on “policy” rather than science. CHI recommends that sample sizes for all types of testing be justified by FDA centers and then reviewed by independent (i.e., nongovernmental) biostatisticians. CHI offers, as one critical path suggestion, the development of new guidelines for determining what sample sizes are necessary to achieve FDA approvals.

Similarly, the Center for Devices and Radiological Health (CDRH) often requires multiple predicates to establish substantial equivalence. In evolving fields where new products can be slightly better than existing products, multiple comparisons cause regulatory restrictions and confusions that are not safety based. Another critical path item should direct CDRH to allow a sponsor to limit clinical evaluations to a single marketed predicate device. The resulting labeling will show the comparison, and it should be enough for marketing clearance. Not only will this speed reviews and clearances, it also will greatly reduce the cost and time of clinical trials.

For example, the need for animal reproductive studies should be dependent upon the product, the clinical indication, and the intended patient population. If the product is known to have an effect on reproduction based on its mechanism of action—say, angiogenesis—there is little value in performing an animal reproductive toxicity study.

The FDA’s primary aim should not be to expand the number and kinds of tests and studies it requires, but to improve the quality of information available about each product.

By focusing on the FDA’s primary goal, industry, academia, and the agency can work together to develop analytical methods, studies, biomarkers, and endpoints that are more accurate and less costly than existing ones. They can also collaborate to determine what kinds of evidence can be used to demonstrate that dropping an old requirement in lieu of a newer one does not sacrifice any information about safety or efficacy. Indeed, the FDA is in an ideal position to shepherd the process of ensuring that all requirements produce the most reliable information most efficiently.

Finally, FDA policy yields redundant work and wasted effort in its poor use of data collected by cooperative groups. There are currently thousands of people-hours devoted simply to repeating things that have already been done by other, cooperative groups. Vast resources could be freed up to study biomarkers or other science if data collected by such groups could be used by the agency without being reprocessed or redone. A patient should not have to wait a year or two for a much-needed therapy while federally funded data is scrubbed for submission to the FDA. Organizations like the Eastern Cooperative Oncology Group and the Cancer and Leukemia Group B have much more potential to help patients receive effective, inexpensive drugs than is currently being realized.

## TAKE ACCEPTABLE RISKS

Risks are an inherent part of both product development and medical treatment.

Just as a patient contemplating surgery to ease back pain or excise a malignant growth must weigh the safety risks against the expected advantages, so too should the FDA balance safety data requirements with the magnitude of likely benefit.

Such considerations are already routine for enrollment in some clinical trials for cancer and other fatal diseases. *In vivo* tests and computer models, as well as assays for protein and gene expression, could provide solid evidence for safety and efficacy even with limited human testing. In these cases, patients should be able to receive a product with less human safety data than would normally be required for less-serious diseases or slow, chronic, progressive conditions. Though policy would play the largest role in such decisions, predictive technologies could be developed to gauge the level of risk in various kinds of patients and indications and to pinpoint products that most merit such a process.

In contrast, if a product is likely to pose very low safety risks, postmarketing studies could be used to confirm efficacy. While the commercial and ethical problems with postmarketing studies are indeed difficult, they are not intractable. Further, if a treatment is more likely to help than to harm a patient, keeping such a product from market also poses commercial and ethical problems. Developing effective postmarketing study techniques hews to the goals of the Critical Path Initiative.

## KEEP STANDARDS AND GUIDANCES CURRENT AND CONSISTENT

As graduate students attest, optimizing experimental and analytical techniques often takes far more time than does collecting the data. As scientific fields mature, standard conditions for running experiments emerge. These conditions often represent an ideal balance in terms of accuracy, convenience, cost, safety, and reliability. Such conditions make experiments easier to design and interpret and can be as important as a common language. In product development, guidances and standards from regulatory bodies serve a similar but more comprehensive purpose.

Perhaps the most straightforward way to improve product development will come from more and more consistent use of guidances and standards, especially where in-house analytical data can replace some or most clinical trials. This could be especially useful in diagnostics by testing samples in the manufacturers' laboratories. These sets of guidelines are invaluable in product development because they set forth the kinds of data that will be routinely accepted by the agency. This information allows companies to forecast product development costs and timelines more accurately and to evaluate whether a project is worth pursuing. Without the ability to make such projections, risks cannot be gauged, and therefore companies are less likely to undertake new projects. Companies that do take the plunge are likely to regret it: when guidances are not in place, the risk that a product will fail is much higher. According to the FDA, new medical products are twice as likely to be approved for premarket approvals (PMAs)

submitted in areas where comprehensive guidances exist. However, several of the guidances in place are very old, still in draft form, or both. For example, ten-year-old draft guidance currently covers decisions on class-III medical devices and leaves several issues unaddressed.

When guidances change without sufficient advance notice, companies are forced to switch development activities midstream. Such changes generally do not make results more accurate or informative, but they do interfere with patients, physicians, and company plans. Sometimes they can delay enrollment in clinical trials by years. Unless patients' health is at risk, midstream changes should be required only for clinical trials approved after the relevant guidance or standard has been issued. Otherwise, sponsors are forced essentially to redo research, a process that rarely supplies useful data and severely increases the time and cost of new medical products.

While the FDA has contributed greatly to developing standards, it often does not recognize international consensus standards, forcing companies to comply with two possibly inconsistent sets of standards despite an increasingly harmonized and global marketplace. As science progresses, standards are updated by international agencies. Often major revisions to standards occur as frequently as every five years. Revisions to standards encourage corresponding updates to products and product testing, and improve the treatments that are offered to patients. However, since the FDA does not automatically recognize updates, the agency's version of a standard is often an old version, not the one currently recognized by the International

Standards Organization (ISO). In other cases, the FDA will partially accept the standards, but will rarely explain why parts are excluded. Differences between international and national standards cause setbacks and redundant activities in product development, with the attendant expenditure of resources, time, and precision funding. Sometimes inconsistent standards can mean that new technologies are adopted first outside the United States, denying Americans valuable treatment.

Also problematic is the agency's tendency to pick and choose among recognized standards. Among the standards for heart valves, for example, the FDA recognizes obsolete versions of two, does not recognize the amendment to a third, and fails to recognize a fourth standard altogether. This inconsistency causes confusion and inefficiency in product development and distracts from efforts that could otherwise be spent improving products.

In the case of FDA standards for sleep apnea breathing-therapy devices and accessories, ISO17510-1 and -2 are recognized internationally, but not by the FDA. The agency is working with industry on revising these standards, with harmonization as the goal. However, there is concern that if harmonization cannot be achieved between industry and the FDA, the FDA will adopt some of the standard and create its own deviations. This will not help industry, as it will lead to additional requirements (possibly contradictory) and cost.

Sometimes the FDA has valid reasons for diverging from an ISO standard. After all, the United States dominates the world market in drugs, biologics, and devices. Yet the United

States holds only one vote in the ISO, which includes 25 European countries, Japan, and Canada. Still, the FDA standards process could automatically recognize updates to international standards and take exception only when an update is unacceptable in terms of patient protection. Such a policy would not restrict the FDA in carrying out its mission, but would minimize overlapping, inconsistent standards in the global environment.

Industry and academia might also be able to take a more active role in setting and reviewing standards and, thus, ease problems caused by conflicting sets of standards. Perhaps standards could be assigned to FDA reviewers who work with experts in industry and academia in a model similar to that of a dissertation committee. With these experts doing much of the legwork, one FDA reviewer would be able to supervise and coordinate several standards groups, so that the standards in place reflect the current state of science.

Such a system could also allow for the timely creation of new and desperately needed guidances. Guidance documents for emerging technologies will encourage research and innovation in these fields. New standards are also needed to demonstrate how evidence from computer modeling can be used, to specify clinical trial requirements for new products, and to allow for better use of postmarketing and natural-history data.

Effective Critical Path projects would put experts together to work out new guidances in significant areas of research. In particular, guidances and standards should be drafted

for the processes outlined above. Clear procedures will benefit the entire industry's product development process; it will also help FDA officials respond quickly and consistently to individual sponsors' requests that data be accepted as evidence of safety and efficacy.

Ultimately, industry experts, academics, and the FDA must collaborate on guidance documents. However, the FDA's "Good Guidance Policy" development requirements preclude industry from coordinating with the FDA on the development of new guidelines. This policy must be changed to encourage directly-collaborative work and to institute project timelines that the FDA management respects." Legitimate legal barriers must be respected, but these do not exclude collaboration. An open guidance-writing process that involves all interested parties and consults the relevant experts is highly preferable to processes that exclude those with the knowledge most applicable to each technical and therapeutic area. Perhaps industry experts could be invited onto steering committees or into standards-writing workshops.

Whatever process is ultimately adopted for updating and writing guidances, CHI strongly urges the FDA to publish and maintain a regularly scheduled, updated list of pending guidance documents along with targeted dates of completion and identifying the official responsible for meeting the publication objective. Ultimately, the standards process can be linked to the guidance process, and all of that can enhance the rate we increase scientific knowledge. This will help push products into market and assess methods for doing so.

## IMPROVE PREDICTABILITY

Potentially lifesaving products are stalled in development because companies are unsure of the risks posed in developing them.

Predictability weighs heavily when companies decide whether to pursue or abandon projects.

More predictive technologies, and more reliable ones, will encourage innovation in unmet medical needs.

However, applying these technologies consistently in the development process will be just as important as developing them, if not more so. Thus, FDA centers and divisions should consult with one another about how new predictive technologies will be considered during the regulatory process and communicate this information to product sponsors.

Simply establishing a framework for these kinds of discussions will be useful. Particularly for early, innovative ideas, companies need feedback from the FDA to decide how best to proceed with development. More accessible FDA officials and more opportunities to receive feedback from the agency would encourage companies to take risks. This recognizes that the FDA will be taking risks also, because they will be asked for decisions in advance of data. Decisions on policy, and the data needed to make such decisions, must be provided and held firmly, especially with IND protocols. Often a new reviewer will cause a sponsor to modify data requirements late in a trial. This practice of changing FDA reviewers needs to stop.

When new project ideas do not fall neatly under the purview of standing committees or when they fall under the purview of more than one review group or even one center, companies may not be able to identify the best people to contact. Currently, discussions about early products are initiated haphazardly, often through personal connections. While resulting conversations are invaluable, they may not always occur with the most appropriate people or in the most constructive format.

Perhaps cross-disciplinary teams at the FDA could be formed to vet combination and innovative products. The Office of Combination Products has been established to provide a uniform consultative approach to sponsors regarding the centers and contacts who will deal with primary and secondary reviews of combination products across centers. Examples of highly useful teams include pharmacokinetic experts from CDER working with engineers from CDRH, with the latter providing feedback on new kinds of pumps. Staff from CBER and CDRH could advise companies with early products that use human tissues. If a standing review group within the agency does not exist, sponsors should be able to request access to the expertise they need, and companies should be made aware of the opportunities available to them. Perhaps this can be a published role of the Ombudspeople throughout the FDA.

As products advance through development they often come under review by different reviewing divisions within the FDA. Mixed messages from the agency are a large source of uncertainty and anxiety in product development. Frequently, proposed trial designs that were enthusiastically approved by one center

or integrated review group must be drastically revised after a product falls under another group's jurisdiction. Sometimes switching groups can require so much backtracking that further development is not commercially feasible. Specifically, new reviewers often cause a sponsor to modify data due to new requirements late in a trial.

Another goal of the Critical Path Initiative should be to encourage rigorous study of approved medicines for new uses. Off-label prescribing is common and full of guesswork, but drug, biologics, and device firms often cannot justify the costs of launching new clinical trials to demonstrate safety and efficacy in a new indication. The long, drawn-out clinical trial for the Prostate Specific Antigen test for screening was required long after the existing test was well-known to be useful for this indication. The approval should have been based purely on literature, but instead, a new clinical trial was required, at great cost. Better ways to use existing evidence, as well as innovations in study design, could lower these barriers. In the ideal case, more-efficient development would provide two medicines for the cost of developing one, and drug companies could provide treatment in both indications, at half price.

### **COLLABORATE WITH ACADEMIA, INDUSTRY, AND OTHER AGENCIES**

Collaboration with agencies like the NIH could assure that the critical path science keeps pace with discovery science. Worthwhile projects are currently not eligible for funding because they do not fall into predefined

categories. For example, a tiny device that could store drugs without refrigeration and be administered by nonphysicians would relieve suffering in the undeveloped world. Wearable biosensors could monitor patients continuously without requiring frequent hospital visits and blood draws; such technology could improve compliance, validate biomarkers, and improve patients' lives. Unfortunately, neither of these projects fits neatly into an NIH study section, and companies cannot justify pursuing them because of commercial risks. Perhaps the FDA could work with the NIH or other appropriate agencies to set up study sections to handle proof of safety, efficacy, and industrial feasibility.

The NIH's Center for Scientific Review (CSR) organizes the peer review groups that evaluate most of the research grant applications sent to the NIH. CHI recommends that the FDA evaluate CSR processes for organizing study sections that include broad participation from government and non-government scientists to develop FDA study sections for peer-review of proposed clinical trials for drugs, biologics, and devices.

Collaboration should go far beyond sources of funding. Industry and the FDA should develop open methods to collaborate on writing guidances and to determine what guidances are most needed. The agency could establish standing, integrated review groups and workshops for regulatory science, involving industry and academia as appropriate. These groups could explore "proof of concept" clinical trials, better clinical endpoints, and manufacturing scale-up. University co-op programs that bring in graduate students and postdocs could establish cross communications

and help the FDA to recruit and retain the brightest scientists. Exchange programs with academia and industry could infuse new knowledge, bridge communication gaps, and help everyone in the development community approach issues from diverse perspectives.

### STAY ON THE PATH

Critical path science should result in more than a series of workshops. Fostering better medical product development should be built into the FDA's mandate and pursued on a continuous basis. To insure that it is, the agency could organize a steering committee that includes industry and academia partners. The committee could help structure how the initiative is run and evaluated, and also help in developing, publishing, and prioritizing clear project deliverables.

The FDA, industry, and academia all want development processes that can produce more effective and better understood medical products as quickly and efficiently as possible. The FDA has correctly pointed out that

achieving this goal relies on regulatory science, not rigid regulatory processes. Like all science, successful regulatory science relies on supportive infrastructure, specific objectives, and clear measures of achievement.

Ongoing collaboration between the industry and the FDA is crucial to establishing the science necessary to make medical product development most efficient—and to make sure that the science to move products from bench to bedside not only catches up to basic science but continues to keep pace with it. CHI welcomes the opportunity to collaborate with the agency to help design these structures.

White Paper Sponsored by



Pillsbury  
Winthrop  
Shaw  
Pittman<sup>LLP</sup>

**C · H · I**

CALIFORNIA  
HEALTHCARE  
INSTITUTE

[WWW.CHI.ORG](http://WWW.CHI.ORG)

CHI represents more than 250 leading academic research, biotechnology, medical device, diagnostics, and pharmaceutical organizations in California. CHI's mission is to advance responsible public policies that foster medical innovation and promote scientific discovery.

#### Headquarters

1020 Prospect Street, Suite 310  
La Jolla, California 92037  
858-551-6677 or 858-551-6688 fax

#### Sacramento

980 Ninth Street, Suite 2200  
Sacramento, California 95814  
916-498-3307 or 916-498-3372 fax