Project Zero Delay accelerates drug's path to clinical trial

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A phase I clinical trial enrolled its first patient only two days after U.S. Food and Drug Administration clearance of the experimental drug for a first-in-human cancer trial, a milestone that normally takes three to six months. Investigators from The University of Texas M. D. Anderson Cancer Center and pharmaceutical company AstraZeneca have reported their work in the *Journal of Clinical Oncology* published online on August 3rd.

The joint effort, dubbed Project Zero Delay, is part of a strategic collaboration between the two organizations designed to safely accelerate development of new cancer drugs. In many cases that process takes about 12 years and the cost of bringing a new drug to patients has been estimated at around $1.3 billion. [Ref: J. A. DiMasi and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics 28 (2007): 469-479.]

"Project Zero Delay demonstrates how we can shrink the time it takes to bring new drugs to cancer patients," said Robert C. Bast Jr., M.D., vice president for translational research at M. D. Anderson and the paper's senior author. "We need to find out as promptly as possible whether new therapies will help. Zero Delay is a significant step in that direction. Close cooperation allowed us to eliminate unnecessary delays while fully meeting regulatory requirements for scientific and human safety review."

The key to Zero Delay was performing most tasks in parallel instead of

sequentially, said lead author Razelle Kurzrock, M.D., professor and chair of M. D. Anderson's Department of Investigational Therapeutics. In addition, tasks usually done after FDA clearance of an Investigational New Drug (IND) application were instead done in advance. No administrative steps were skipped.

This approach can be applied in other areas of drug development and by other institutions willing to cooperate closely, the authors note. "Zero Delay addressed one aspect of drug development - clinical trial start-up time," Kurzrock said. "Substantial time could be cut from other steps by applying the same principles."

The time between having a complete written protocol and enrollment of the first patient is typically 135 days in M. D. Anderson's Phase I Clinical Trial Program when processing of the protocol starts after IND approval. Zero Delay went from having a complete written protocol to first patient in 46 days, with FDA clearance of the IND on day 44. Research elsewhere cited in the Zero Delay paper indicates enrollment of the first patient after having a final protocol typically takes 3-6 months.

Administrative tasks accomplished before the FDA's ruling included budget and contract negotiations, site visits and preparation, training and a series of mandatory institutional reviews at M. D. Anderson.

"M.D. Anderson and AstraZeneca share a common goal of using leading edge science to deliver medicines that will benefit patients now and in the future, while speeding up the process and making it more cost efficient," said Alan Barge, vice president and Head of Oncology at AstraZeneca. "AZ is always looking to improve our processes and to optimize value along our pipeline. This achievement is a great example of what can be accomplished when we pair our first class internal capabilities with the strengths of one of our key alliance partners in the

U.S."

In 2005, M. D. Anderson and AstraZeneca established a strategic alliance that includes a master agreement for clinical and translational/preclinical research specifying terms for standard items that can cause lengthy negotiations. The master agreement ensures that new research projects and clinical trials are initiated without delays caused by contracting issues. New clinical trials can simply be appended to an existing master agreement, often as quickly as in a day.

"Zero Delay demonstrates what can be accomplished in an atmosphere of trust and collaboration that we've cultivated through our strategic alliance," Bast said. The alliance agreement also includes a commitment to regular meetings, a point of contact to remove obstacles, support of collaborative projects and a commitment to accelerate drug development.

"The next challenge, said Barge, will be to do this consistently in order to develop truly innovative therapies that will someday offer new benefits to cancer patients."

Source: University of Texas M. D. Anderson Cancer Center (news : web)