

SCIENCE IS...

cooperative

Betsy Hospodar is participating in a Phase III clinical trial of pimagedine for the potential prevention of advancement of the kidney disease that is a complication of her Type 1 diabetes.



NOTHING IS DONE AS WELL WITHOUT COOPERATION. WHETHER EXPRESSED AS THE TEAMWORK BETWEEN A PATIENT AND PHYSICIAN, OR AS A BUSINESS ALLIANCE BETWEEN GENENTECH AND OUTSIDE PARTNERS, TEAMWORK CREATES BETTER RESULTS AND GREATER POSSIBILITIES. GENENTECH WORKS DILIGENTLY TO CREATE PARTNERSHIPS WHEREVER SUCH COLLABORATIONS AND ALLIANCES WOULD INCREASE THE LIKELIHOOD OF SUCCESS. GENENTECH'S TEAMWORK EXTENDS FROM WITHIN THE RANKS OF THE COMPANY'S EMPLOYEES TO UNIVERSITIES, GOVERNMENT RESEARCH AND INDUSTRY.

Scientific progress typically relies on a cooperative effort. Nobel Prize winners James Watson and Francis Crick were the first to elucidate the structure of DNA in part because they collaborated together effectively. Cooperative efforts are likewise essential to success at Genentech. Whether internal multidisciplinary project teams; global, multicompany collaborations; or cooperative efforts toward a shared goal with regulatory agencies or government health organizations, the ability of Genentech employees to cooperate effectively with a wide range of people inside and outside the company is essential to Genentech meeting its goals.

One key 1997 Genentech success stems from such an effective group effort. In developing Rituxan (Rituximab), employees of Genentech, IDEC Pharmaceuticals Corporation, Roche (who will market Rituximab as MabThera outside the United States, excluding Japan) and Zenyaku Kogyo Co., Ltd. of Japan worked together to develop Rituximab in an international development project that has led to regulatory approvals in the United States and Switzerland. Teamwork among representatives from regulatory, manufacturing, clinical and marketing, to name only a few functions, ensured that all project concerns were appropriately considered at each step. Close cooperation with the Food and Drug Administration ensured a smooth U.S. regulatory process. Genentech is now applying lessons learned from this alliance to other collaborative development projects. Examples include the joint development of the anti-IgE antibody for allergic rhinitis and allergic asthma with Novartis AG and Tanox Biosystems, Inc., and, with Alteon, Inc., the development of pimagedine for kidney complications associated with diabetes.

Genentech's majority stockholder, Roche, is also a frequent Genentech collaborator. In line with the governance agreement between Roche and Genentech, both companies collaborate as true partners. One current collaborative global development effort by Genentech and Roche is on Genentech's nerve growth factor in diabetic patients with peripheral neuropathy.

Cooperation with the FDA is fundamental to all of Genentech's product development efforts. Genentech also works with the FDA on a broader level whenever appropriate. For example, as part of a cooperative legislative process, Genentech provided input and feedback on recent FDA reform legislation. The resulting changes in the way in

which pharmaceutical products are regulated and approved enable Genentech to design and execute clinical trials more effectively and efficiently.

Genentech also works with the government to advise on legislation affecting the biotechnology and pharmaceutical industries. In January 1998, Vice President Al Gore chose Genentech as a forum for discussion on the day of an important announcement that would benefit these industries. The White House announced that its proposed budget, submitted to Congress in February 1998, included an increase in the level of research funding to the National Institutes of Health (NIH) and a one-year extension to the industry tax credit for research and experimentation expenditures. The Genentech forum, which included Genentech employees and guests from government, industry and academia, and was moderated by the Vice President, explored how investment in research and development leads to both the creation of jobs and to innovation that can positively affect people's lives.

On many levels, Genentech partners with the medical community. The company works with medical organizations to support needed public education campaigns. For example, Genentech is currently supporting the National Stroke Association in its efforts to help hospitals educate their communities about the signs and symptoms of stroke and the urgent need to seek medical treatment. It is also continuing to help medical centers establish stroke treatment protocols as recommended by the National Institute of Neurological Disorders and Stroke (NINDS), one of the National Institutes of Health.

Working with another NIH arm, Genentech partners with the National Cancer Institute (NCI) in various ways. In one effort, Genentech and the NCI seek to increase the geographic availability of the Herceptin expanded access program for eligible breast cancer patients through its Treatment Referral Center program, which works with cancer centers across the United States. Genentech and the NCI also collaborate in other areas of medical need in breast cancer and other cancers. Genentech is part of a consortium supporting the NCI's Cancer Genome Anatomy Project.

Genentech works closely with investigators at hundreds of medical centers in the United States and Europe on more than a dozen clinical trials in progress. Through a collaborative approach with managed care organizations, Genentech provides important information on the medical value of its product offerings. Aiming to help all of its customers, as it has since its first product was launched, Genentech works with medical providers to gather postmarketing clinical data on the safety and efficacy of its marketed products (see table on the next page).

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In line with this effort, Genentech is currently planning a new postmarketing registry in growth hormone-deficient adults. To be called the National Cooperative Somatropin Surveillance (NCSS), this registry addresses the latest indication of certain of Genentech's growth hormone products.

GENENTECH OBSERVATIONAL CLINICAL STUDIES

Physicians, hospitals and managed care organizations work closely with Genentech's Medical Affairs group to gather valuable information that Genentech in turn makes available to these medical providers. Such data help physicians to optimize patient care. The table below indicates the variety of observational clinical studies Genentech conducts in cooperation with clinical investigators or sponsors.

STUDY NAME	PARTICIPATING GROUPS	PATIENTS INCLUDED IN STUDY
National Cooperative Growth Study (NCGS)	>650 pediatric endocrinologists	>29,000 patients treated with growth hormone
CRI Arm of North American Pediatric Renal Transplant Cooperative Study (NAPRTCS)*	Pediatric nephrologists at >120 medical centers	>3,300 children treated with growth hormone for growth failure related to chronic renal insufficiency
National Registry of Myocardial Infarction (NRFMI)	>1,500 medical centers	>1 million heart attack patients
Epidemiological Study of Cystic Fibrosis (ESCF)	>200 medical centers	>20,000 cystic fibrosis patients

*Genentech sponsors the CRI arm of NAPRTCS, but, unlike the other studies listed here, NAPRTCS is not a Genentech study.

Genentech cooperates daily with the global scientific community. One mutually beneficial way it does so is through its Research Contracts and Reagents Program. Through this program, based on scientific merit and availability, the company makes available free of charge to researchers worldwide many of its scientific reagents for medical research projects. Genentech, which retains product rights, also benefits by gaining new leads and scientific information on potential development opportunities.

Almost every business interaction of each Genentech employee involves cooperation and collaboration on some level. For example, Genentech views its vendors as partners and teams with them to seek innovative ways to solve problems and reduce costs. Because in today's scientific, business and medical environments, the organizations that succeed best will be those that can best cooperate.