

A drug revolution in the making

The National Institute of Biomedical Innovation (NIBIO) is extending bridges to new areas of drug discovery.

Despite pioneering research by many Japanese biologists, the application of this expertise has proceeded slowly. But change is coming quickly.

NIBIO was established in April 2005 by the Japanese government to fill crucial gaps in the path from discovery to drug development. A unique institute, NIBIO carries out basic science aimed at developing shared technologies at its laboratories in the Saito Life Science Park, standardizes and shares biological resources throughout Japan, and funds external research in a similar fashion to the National Institutes of Health in the US. "It's the only place like it in Japan," says Koichi Yamanishi, director general of NIBIO.

The Japanese government has recognized NIBIO's special mission in several ways. In 2008, NIBIO was awarded two coveted 'Super Special Consortium' designations for the development of cutting-edge medical care — two of only 24 that were approved nationwide. NIBIO has also taken a leadership position in the Japanese government's Knowledge Cluster Initiative — a five-year project to stimulate cooperation between research

institutes, universities and industry in biomedical sciences. NIBIO maintains a host of joint research projects with pharmaceutical manufacturers in fields ranging from toxicogenomics and biomarker exploration to animal models and vaccine development. "We meet regularly with companies to ask what they need from us," says Yamanishi.

Next-generation infectious disease vaccine innovation project

"When I started at NIBIO, few people were interested in vaccine development. Immunology progressed, but manufacturers are too small to do much R&D," says Yamanishi, a virologist with decades of experience studying herpes and other viruses.

Following panics caused by the SARS coronavirus, the H5N1 avian flu and most recently the H1N1 pandemic flu, governments and industry have started paying attention.

Yamanishi leads a Super Special Consortium in which universities, national research centres, pharmaceutical companies and hospitals aim to create next-generation vaccines for HIV, malaria, influenza and other infectious diseases.

The consortium's goal is to improve vaccines by studying new vectors that will enable single

vaccines to convey immunity to multiple infectious diseases. NIBIO has significant capabilities in the genetic recombination technology needed to create these vectors, which will make vaccination programs easier and cheaper.

The consortium is also developing nasally, dermally and orally administered vaccines as safer and more convenient alternatives to injections. "This type of immunization is closer to our natural immunity," says Yamanishi.

The consortium will develop new adjuvants to enhance the effect of vaccines and allow the use of smaller doses. Uncertainty about how adjuvants work has been an obstacle to their implementation, but Japanese scientists have led the analysis of toll-like receptors and other related components of the immune system. "A new generation of effective adjuvants will come from Japan," says Yamanishi with confidence.

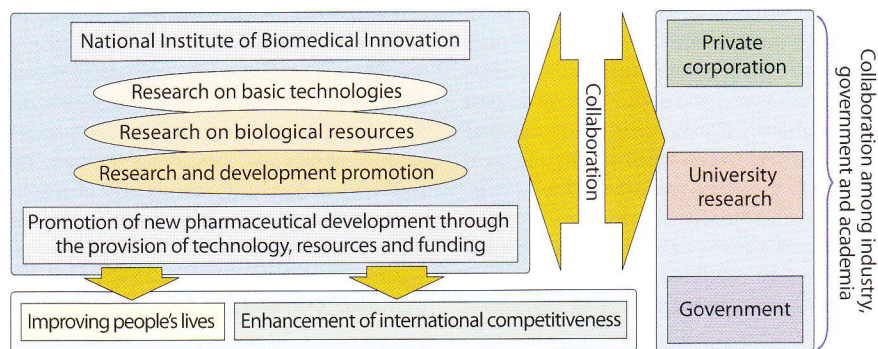
Development of a novel drug toxicity testing system using induced pluripotent stem cells

Pharmaceutical companies are increasingly using embryonic stem (ES) cell-derived cell lineages for *in vitro* testing of drugs. But ES cells are in short supply.

Induced pluripotent stem (iPS) cells, first created in Japan in 2006, offer an alternative. iPS cells are made by reprogramming somatic cells to an embryo-like state. Scientists can do this with anyone's cells, offering an infinite source of fresh cells with defined genetic backgrounds.

Research groups by the dozens have embraced iPS cell technology. Before they can be used in drug development, however, they need to be standardized and quality controlled in a manner that facilitates clinical studies by pharmaceutical companies. "Japan is leading the examination of iPS cells," says NIBIO's Hiroyuki Mizuguchi, "but most university groups stop at the research level."

Mizuguchi leads a Super Special Consortium to establish a drug toxicity testing system based on iPS cells. Such a system will limit controversial



The unique role of NIBIO in Japan. NIBIO combines extensive collaboration with basic research, valuable biological resources and project funding to support the pharmaceutical industry.

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