Summary of proceedings

Jacques Demotes-Mainard

We now come to the last part of our session this afternoon which is the summary of today's proceeding. We learned today about the two hospitals as well as translational research organizations both in Japan and in France for clinical trials. We also have learned the rule of the triangle, that is, industry, university and hospital cooperation to promote these clinical trials. What I understood from Dr. Fukushima is that if we have industry-university relation, if we have hospital-industry relation and if we have university-hospital relation, the triangle is very difficult to gather together. We also heard about the description of initiatives about the trials conducted for the university, the institute on government-labelled or government-approved of translational research. Finally, we had some presentation from biostatisticians on translational research informatics as well as cell processing center which are very important tools to ease this translational research protocols. What I understood is that there overall progress in Japan and France in terms of promoting translational research in clinical trials. There is definitely a necessity to improve the administrative and international aspect of investigator-initiated clinical trial both on the side of harmonization as well as quality control. And in Japan there is a need for a law to protect human subjects for clinical trials. So we need to lobby for the creation of such law and its implementation in clinical trials. Both countries have recognized the need to reinforce the complex university-industry relationship.

Masanori Fukushima

From this symposium, we recognized the similarities of our countries in the scientific situation and translational research systems, and our differences in terms of law, regulation, facilities and equipment. From the Japanese side, we also recognized that we are behind EU and US in terms of law and regulation, funding and systematic and strategic approaches in conducting clinical trials. But recent results and outcomes of our initiatives are very similar, so I think we can catch up quickly with the US and EU. For example, our islet transplantation program is a success, and we have other success stories aside from this. In such cases, we cannot expand the product worldwide as an established medicine or therapeutics because the development of the drug by University-academy was done under non-GMP system. That is the problem we have now. So I propose law for human rights protection.

We need to encourage investigator-sponsored registered trial in Japan. In terms of GMP, GLP and GCP. I think there is no question about it. We also need to encourage academia-industry relationship as a new business scheme. We have different business culture from US and EU, and so we need Japanese own systems. I think this is must if we are to succeed in raising fund for clinical trials. And again I have to say we need a law for protection of human subjects, as well as assurance on medical practice quality. Without such law, without such quality control, we cannot succeed. We have to take strategic approach so we can push

our government to make appropriate strategies to promote translational research. Now government is moving to accelerate translational research and clinical trials. Hopefully, next year our government will allocate new budget to such enterprise so we can develop GMP-grade cell processing center in major university hospitals that is very similar to the Clinical Investigation Center (CIC) system. At present we have at least 10 translational or innovative research centers very similar to the CIC in France. Our first task is to improve that system to reach the level of the CIC system, in terms of IND-registered trial facilities.

Fabien Calvo

In summary, I would like to focus on 3 unsolved problems. Obviously, there is need for regulation and protection of patient-volunteers in clinical trials. But you have to be aware that the 3 ICH regions, including Japan and France (as member of EU) gathered in 1988 for development of specific regulation for this. It was very important for the patients, but at the same time implementation of the rules made the clinical research very bureaucratic. And so it remains a problem to perform clinical research. It ŝ long and painful. And although it is basically safe for the patients, sometimes it is very difficult to set up clinical research. So that ŝ the first unsolved problem.

Another problem is the sharing of intellectual property with the industry. This is really an unsolved problem. I guess even in the US it is not solved. When a drug company comes to the hospital, the academic people work for the development of the drug, and the hospital gets paid for getting all the work done. But the intellectual property remains the property of the pharmaceutical company. This is really a big problem which remains unsolved. In my opinion, the academe should at least have a share on the intellectual property developed during the trial.

The third problem is the need to form a law for real interaction between academic people and the industry. There are a lot of projects which merged from the academe and which should use the academic system. In France there is facility now which helps people coming from academe to set up company. It is not very easy in France as it is in the United States where some people coming from universities can set up a small pharma and then come back. This is not yet solved in France even if there are some rules. This is a problem that needs to be solved to promote clinical research.

Masanori Fukushima

I agree with your 3 points—first, human protection in clinical trials, second, promotion of clinical research. As for the third issue on intellectual property, our center is actually a spin-off from the government. So we are now an independent institution. So we have to strengthen our intellectual property system, and now the university is moving to protect our intellectual property. Your last comment on conflict of interest of personnel affiliated to university or public institution, we have the same problem actually. We are in similar situation in terms of science, legal and ethics. So there is no question that we have to find intelligent solutions to these problems, and therefore we need to exchange our knowledge, ideas and thoughts, and so we need to have close and frequent interaction.