

COINS Social Implementation Strategy towards Realization of In-Body Hospitals

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Establish COINS' achievements and networks in the region and the world

Center of Open Innovation Network for Smart Health (COINS) Theme 6 is developing social infrastructure for the social implementation of the seeds developed in Themes 1-5. Dr. Tomohiro ANZAI, Assistant to Director-General, a member of Theme 6, Kawasaki Institute of Industrial Promotion Innovation Center of NanoMedicine (iCONM), Dr. Shintaro SENGOKU, Assistant to Vice-Director, Associate Professor, Department of Innovation Science, School of Environment and Society, Tokyo Institute of Technology and Wataru TAKAHASHI, Assistant to Vice-Director /Sub Leader of Innovation Support Group talked about COINS past achievements and future ambitions.

Tomohiro ANZAI

Assistant to Director-General, Kawasaki Institute of Industrial Promotion Innovation Center of NanoMedicine

He graduated Graduate School of Frontier Sciences, The University of Tokyo and obtained PhD. (Life Science). He joined in the Fast Track Initiative in 2006 after working for Arthur D. Little. In parallel to work as a venture capitalist, he served as a Project Associate Professor at The University of Tokyo, a visiting associate professor at Kyoto University, and the Cabinet Secretariat Medical Innovation Promotion Office. He was involved in the Innovation Center of NanoMedicine (iCONM) from the planning stage and is engaged in research and practice on social implementation in COINS.

Shintaro SENGOKU

Associate Professor, Department of Innovation Science, School of Environment and Society, Tokyo Institute of Technology

He graduated Graduate School of Science, The University of Tokyo and obtained PhD (Science). After working for McKinsey & Company, Fast Track Initiative, Inc. and Kyoto University, he became an associate professor at Tokyo Institute of Technology since 2014. Currently, based in King SkyFront, he works for iCONM, Tokyo Institute of Technology MIDL and "Development of cell manufacturing and processing system for industrialization of regenerative medicine" project of AMED, etc.

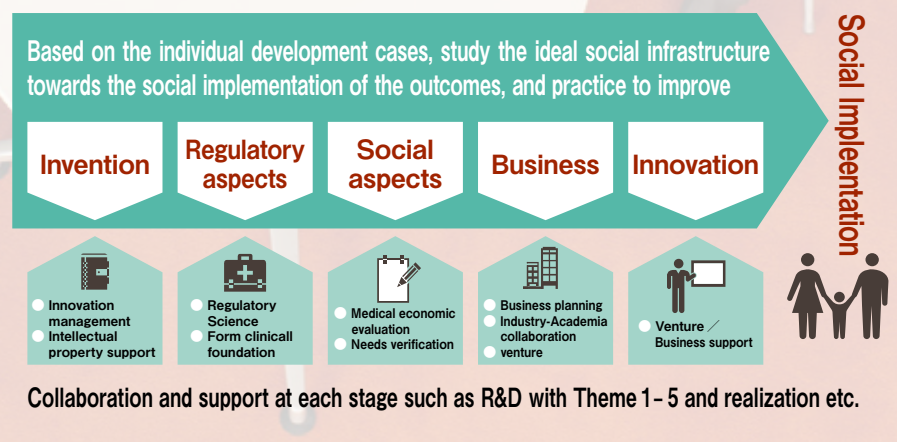


Wataru TAKAHASHI

Assistant to Vice-Director, Kawasaki Institute of Industrial Promotion Innovation Center of NanoMedicine
Sub Leader of Innovation Support Group

He graduated Graduate School of Science, Tokyo Institute of Technology in 1985 and obtained MA. He joined in Asahi Kasei Corporation in the same year. After working as a synthetic chemistry research director, a director of intellectual property department and a research promotion director at Asahi Kasei Pharma, currently he is working at iCONM from November 2017.

Figure 1 Road Map of social implementation and goal of Theme 6



The establishment of venture companies, management study for social implementation, etc. have been progressing

■ Please tell us about your work and relationship with COINS.

Anzai: I have been appointed as assistant to COINS Project Leader and the leader of Theme 6. I am currently working as a principal research scientist at the Kawasaki Institute of Industrial Promotion Innovation Center of NanoMedicine (iCONM) as well. In Theme 6, in order to realize the innovations from COINS, in parallel with support for the commercialization of seeds developed under Themes 1 to 5, we are working to develop the social infrastructure to advance each process for "social implementation", such as technology development, industry-academia collaboration, clinical development, commercialization, and social deployment, etc. (Figure 1)

Sengoku: I am in charge of education and research of Management of Technology (MOT) and Innovation Science at Tokyo Institute of Technology and I belong to Theme 6 at COINS. Now, I believe that it is my fate to be in King SkyFront because the research bases of the three projects, which are COINS, IT drug discovery from medium molecular-weight molecules where the Tokyo Institute of Technology and Kawasaki City collaborate on, and regenerative medicine that I worked on when I was working in Kyoto University, are all located at King SkyFront.

Takahashi: I was dispatch from Asahi Kasei Pharma to iCONM in 2017. I am using my experience in pharmaceutical research and R&D strategy.

■ What exactly does "social implementation" mean?

Anzai: The term "social return" was used in the Funding Program for world-Leading Innovative R&D on Science and Technology (FIRST) program "Nanobio First", the predecessor program of COINS, and the goal of academia was to return to society through research and development and industry-academia-government collaboration, but "social implementation" has been used since around 2010, hasn't it? The aim is not only to produce results but also to ensure effectiveness and safety of the technology, create medical and market values, as well as having the products that can be "implemented socially" only when the public widely uses it. As a research project from the university, the challenges are getting tougher. Determining whether research seeds will really be used in the marketplace is where universities have been weak at. Now they say that the research and development should be promoted in consideration of the creation of market value, so it became necessary for a team like Theme 6 to support the research promotion, market development, and commercialization in a bird's eye view.

Sengoku: The word implementation originally means to "full" or "fulfillment". In other words, we need things that properly fulfill the needs of society and established as part of the functions. It can be said that the social implementation has been

done if it does not always depend on subsidies from public funds, able to demonstrate its value, and circulates autonomously and economically. This is the difference between social implementation and "social return", which is sometimes regarded as temporary.

Takahashi: The social implementation that I experienced at the company was a cycle of marketing researched and developed drugs, supplying them to patients, and then researching and developing new drugs based on the benefits. When I came to iCONM, I found out that it started out as a venture to create employment and new business, and I am thrilled to be voluntarily involved.

■ What kind of activities are you involved in, and what are the results? Are there any social implementation features that are unique to COINS and King SkyFront?

Anzai: In the past, the research and development of medicine were based on the idea of "if you put it on the market, it will be sold widely". However, the technology elements have diversified, and the knowledge system is becoming more complex now. Interdisciplinary integration and industry-government-academia collaboration are becoming more important. It is crucial to create evaluation systems, regulations, and even the market itself to become the first runner in the world. In other words, we need to open up an unexplored land. Having that in mind from the start, we have created a research support team consisting of those with experience working in the private sector. Two venture companies have been created through the COINS research, each of which has raised over 500 million yen and hired more than ten researchers. Braizon Therapeutics now owns a research facility in LabCentral, Boston, USA, and has gained a foothold for entering the global market. AccuRNA is also planning to start a clinical trial for its nanomachine that has a payload of nucleic acid drugs. I think that the movement toward social implementation has been progressing beyond our initial assumptions.

Sengoku: What we are particular about is collaboration management. For example, at the start, we did not have the nanoscience and nanotechnology system in the interdisciplinary





collaboration, and the project started just as a result of the fusion of various disciplines. With so many different cultures, technical terms, communication methods, and research methods, sophisticated management is necessary for everyone to work together in a new direction. Industry-government-academia collaboration is also an important aspect. As for the regional collaboration, King SkyFront provides support from Kawasaki City, a city designated by government ordinance. When this collaboration comes to the point where the citizens of Kawasaki understand, agree, and cooperate with King SkyFront, we will be able to say that we have achieved a regional collaboration. Recently, many people have been interested in international collaboration, and it is important to plan how we can implement this inter-regional collaboration in this privileged location with Haneda Airport nearby, and as symbolized by the area's name, King SkyFront. Such connections cannot be divided into parts, and it is interesting to design and manage them together as a whole.

Anzai: To put it somewhat radically, COINS, iCONM, and King SkyFront consider the existing universities as negative case studies. For example, we are trying to destroy the walls that hinder research collaboration within the university, such as vertical division and frictions, by organizing research teams, designing and specifying buildings, operating experimental facilities, and creating new industry-government-academia collaboration regulations. At the beginning of iCONM, there were almost no buildings around us, and some people felt like working on a small remote island. However, it was important to have the location a little far from the city center to foster a strong sense of unity with the startup members. Before COINS, the University of Tokyo was the central base, which was virtually connected to other research bases. COINS was built based on the concept of advancing research on-site under the one roof.

Takahashi: King SkyFront designated as a special zone under the country's new growth strategy, and there are also institutions of Kawasaki City and Kanagawa Prefecture. It is also close to Tokyo and Fujisawa City, which has a Bio Park. The bridge that connects this area with Haneda Airport is scheduled to be completed next year, in 2020. In order to realize "in-body hospitals" using nanomachines in 2045, it is import-

ant to develop the underlying multi-field technologies, such as medical equipment and healthcare. We are gathering them. This place has the potential to become the core of innovation.

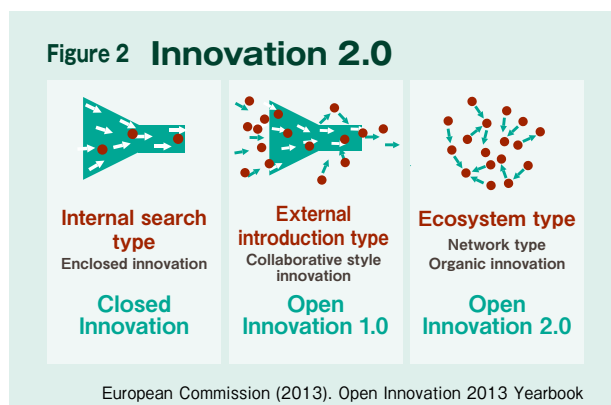
Anzai: Currently, the collaboration inside and outside the base has been progressing, but as Dr. Sengoku said, the main issue is to gain the understanding and support from the citizens of Kawasaki and develop their sense of ownership.

Takahashi: As an effort to improve our visibility to the citizens, we have been quite active sending out Twitter and Facebook posts since 2018. We can see that many people are watching us from the number of Facebook views. We also conduct crowdfunding to raise funds to advance the Drug Delivery System (DDS) for cancer and intractable diseases. The King SkyFront Network Council was established in 2018, and the Director General of iCONM, Dr. Kazunori Kataoka was appointed as Vice Chairman and has started various activities. Every year, we hold a "summer science event" that has been visited by more than 2,500 participants, mainly children. This council acts as the neighborhood association of King SkyFront. The number of companies and government agencies in King SkyFront, which used to be considered as a place to conduct mysterious experiments, has been increasing, and our network has expanded greatly.

Sengoku: There is a pub at Shin-Kawasaki that has been going to for about two years, and the owner once asked me, "Are you involved with King SkyFront? I heard that it's going to be big with companies such as PeptiDream opening their offices there." I explained that we are creating a new industry at the site of an automobile factory. The owner and other customers were interested in King SkyFront. There are SNS and communication at pub, so I think it is better to spread it gradually.

Anzai: What I have been feeling since when I was involved in promoting King SkyFront to various companies, we have progressed from the impression of being on a "remote island" to a place with large-enough land, improved access from the station and airport, and equipped to do animal experiments. We have become a vibrant place with a highly collaborative culture. I believe that the people working here, and all citizens will be proud if one of our researchers can win a Nobel Prize.

Sengoku: Tonomachi once succeeded in attracting a car factory. Kawasaki City became confident from such an intense success experience and is now taking on new challenges. We are equipped with world-class institutions and companies, including the first animal testing laboratory in Kawasaki City, the National Institute of Health Sciences, the university labo-



ratories, and many industry-leading venture companies. I would like to study how we can attract people.

Anzai: A place that used to be glittering in the past often becomes a lonely landscape after 30 years. So, the next issue that we have to tackle is how to design a base to nurture the next generation of entrepreneurs and young researchers and maintain the sustainability of the entire King SkyFront. To achieve this, together with promoting the regional metabolism, we believe that it is necessary to leave the conventional open innovation 1.0, where a base attracts and enlists excellent researchers and technology seeds from outside, and develop and evolve to open innovation 2.0 that has a networking mechanism among the bases in King SkyFront and among clusters in the region, where human resources, funding sources, and seeds people can enter and exit easily (Figure 2).

Sengoku: What we do not have right now are art and entertainment. Boston, which we talked about earlier, has research and education center for art, including the Berklee College of Music and the Contemporary Art Museum, both of which contribute to the revitalization of the region. I believe that we can use the advantages of our location in the Tokyo metropolitan area to explore collaborations with the surrounding art universities, art museums, and local art-related events.

I want to promote the support for global businesses, develop an environment for people to grow and collaboration within and outside the base.

Please tell us about your future ambitions.

Anzai: I would like to fully support business development in the global market to create examples of social implementation that can demonstrate our global presence. Next, I want to further promote networking of stakeholders, attract new companies and entrepreneurs, and develop social implementation research in order to attract people who take risks and aim for commercialization over their lives. For example, I think that how far a player in high-school baseball can go depends on

whether he is aiming for Koshien, the National Professional Baseball(NPB) in Japan, or the Major League Baseball(MLB). I would like to work as a "disliked role" to mentor researchers and innovators so that they can see the business from a high perspective and encourage them.

Sengoku: As a faculty member, I would like to cultivate excellent researchers and innovators and contribute in a way that is closely related to King SkyFront. The word nurturing is somewhat impertinent and can be interpreted to develop an environment that needs to be nurtured. iCONM has already attracted many overseas researchers, and I want to create even more places like it. Fortunately, I came here at an excellent time, and I have many connections, so I hope I can observe and see how this place develops for the next 20 years and talk about history. Not only by writing papers, but I also want to talk about it in a pub.

Takahashi: I will be retired soon, so as my final task, I would like to focus on coordination with the King SkyFront and other bases. I don't think this is a closed organization such as a university or a company, so I expect that we can do it.

Thank you.

(Interviewer: Science Writer Ayumi KOJIMA)



Initiatives to develop an ultrasonic therapeutic system combined with drugs and to create medical devices through social implementation and medical-engineering integration

Our team is promoting the research on sonodynamic therapy (SDT)^{*1} that combines nanomachine tumor accumulation and focused ultrasound targeting. This study embodies the "concept-driven" to minimize the dose of drugs and suppresses irradiation energy as much as possible and perform short-time minimally invasive treatments that do not damage the body. We believe that fostering a medical-engineering integration system is crucial for the social implementation of such new devices for medical treatment.



Ken MASAMUNE

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One of the main objectives of medical device development is to ensure a safe and effective treatment that imposes the minimum burden on the patients. As the Theme 5 of COINS, our team is promoting research on sonodynamic therapy (SDT), which combines the tumor accumulation function of nano-micelles and the targeting function of focused ultrasound (Figure 1). After confirming that the treatment is safe on pet dogs with spontaneous tumors (Figure 2) [1], we have conducted clinical trials on 12 patients with unresectable intractable cancers (pancreatic cancer and biliary tract cancer) (Figure 3) [2]. Currently, to implement this treatment in society, we are evaluating the plans of Investigator-initiated clinical trials from various perspectives and exploring to implement them through an industry-academia collaboration system. At the same time, we are studying the mechanism of action of SDT to clarify the combined effects of nanomachines and ultrasound [3].

This SDT research project is only possible with the knowledge and actions of various medical professionals and engineers such as nanomachines, together with High-Intensity Focused Ultrasound (HIFU) treatment system with new energy output, as well as ultrasonic tomography and a robot positioning HIFU irradiation. So far, we have advanced from the stage of a basic exploratory experiment to the evaluation by pet dogs with spontaneous tumors and clinical research. Please refer to previous reports [4] for the technical aspects; here we describe the creation of a medical-engineering integration system that is an important social element.

Most studies on the development of medical devices so far have focused on "needs-driven" developments to meet the local needs of currently available treatments. Over the past few years, initiatives such as Stanford

Biodesign, which studies and implements needs-driven development methodologies, have been attracting much attention. However, research and development activities in one laboratory and one company are based on technology seeds, and many Japanese companies with top-level technology seeds are often limited to meet the medical needs and introduce their optimal seeds. Our research team invites and integrates human resources from various fields in medicine and engineering to create a medical and engineering integration system that promotes the foundation of research to realize open innovation that addresses new proposals on medical treatments and solves various prevailing issues. Figure 4 shows an example of a discussion among companies, surgeons, and engineering researchers in the project of domestic medical device creation infrastructure development supported by AMED that our research team is working on.

SDT embodies concept-driven development which aims to realize a minimally invasive treatment that is friendly to the human body by reducing the dose of drugs through an efficient DDS and reducing the irradiation energy using HIFU. Clinicians, pharmacists, researchers of HIFU irradiation research, developers of robots controlling irradiation focus, and animal treatment specialists need to come and work together. At the same time, we are building a business strategy plan that includes obtaining public approval for the social implementation and insurance coverage. Also, more costs are needed for higher phases of clinical trials after safety confirmation by early-phase clinical trials, and we are currently seeking any social implementations including venture companies.

Figure 1. Process of sonodynamic therapy (SDT)

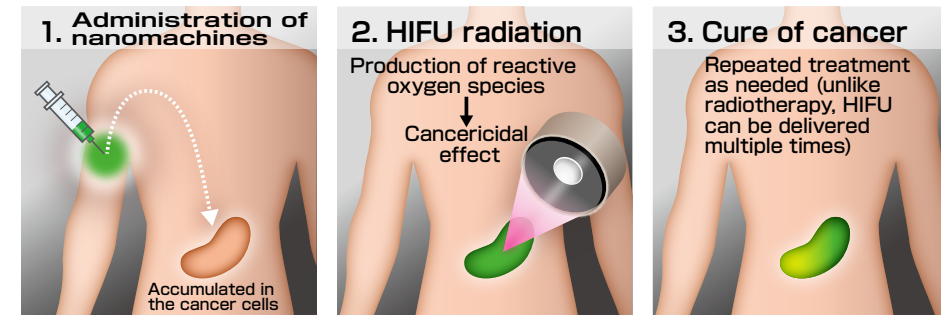
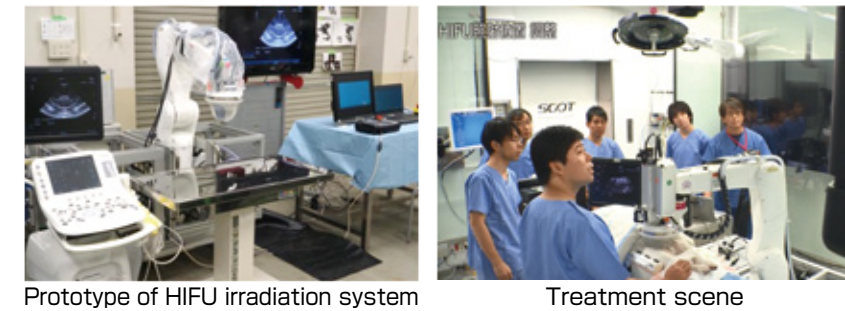
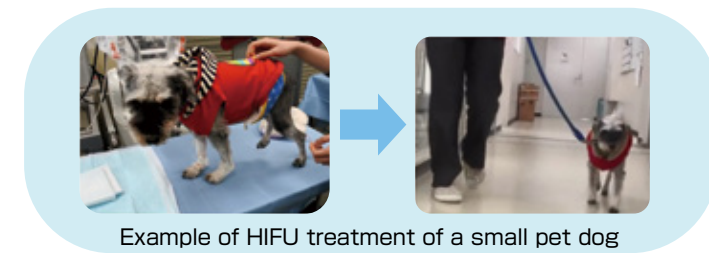


Figure 2. Japanese-made HIFU irradiation system (prototype) and treatment of pet dogs with spontaneous tumors



Prototype of HIFU irradiation system

Treatment scene



Example of HIFU treatment of a small pet dog

Figure 3. Clinical trial using SDT (Treatment on a patient with intractable cancer)



Figure 4. Cabinet Office Japan Agency for Medical Research and Development (AMED) "Infrastructure Development Project for the Creation of Medical Device in Japan"



Glossary

*1 SDT (Sonodynamic Therapy)

A new treatment method for minimally invasive treatment of the deep part of the body by combination of tumor accumulation of drugs and tumor targeting by focused ultrasound.

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Development of antibody/drug-conjugated micelles(ADCM)^{*1} Preparation of epirubicin-incorporated micelles conjugated with anti-Tissue factor antibody

ADCM is a next-generation micelle agent with an antibody that targets cancer cells added onto the surface of polymer micelles. Due to this property, the system is expected to have higher efficacy and safety than the first-generation micelle formulation that is currently in clinical development. So far, we have completed the formulation design and confirmed the efficacy of adding antibodies onto the micelle surface. In the next stage, we will identify the types of cancer that can be treated most effectively using human patient-derived cancer tissue transplantation model (PDX model), and proceed with the preparation of the studies that are essential for the start of clinical trials.



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Polymeric micelle preparations containing anticancer drugs circulate in the blood while bringing drugs and accumulate in cancer tissues and are therefore expected to improve the effectiveness and safety of the drugs, are under clinical development. NC-6300 (Epirubicin micelle), is one of them and is currently under Phase I/II clinical trial in the United States, conducted by NanoCarrier. In the Phase I part of the trial, Epirubicin-specific nausea/vomiting and myelotoxicity were observed. However, the trial also confirmed the decreased frequency of occurrence and decreased severity, and no clinically significant decline in cardiac functions has been observed even after long-term administrations. In terms of efficacy, 2 out of 2 cases of angiosarcoma enrolled in this study showed a partial response that resulted in a reduced tumor volume to 50% or less. A Phase II part plan for NC-6300 is currently being drafted.

We are now developing ADCM, a next-generation micelle preparation that adds antibodies targeting cancer cells onto the surface of micelles to further improve the ability of this polymeric micelle preparation to target cancer cells and achieve higher efficacy and safety (Figure 1). The Tissue Factor (TF) is selected as the target for antibodies added to the ADCM. TF is a target molecule that is overexpressed in many types of cancer since it is expressed not only in cancer cells but also in the tumor stroma, it is considered a promising target for antibodies. Also, it has been reported that in many types of cancer, higher

TF expression is correlated to a poorer prognosis. Targeting this molecule is expected to be useful for the treatment of refractory cancer. So far, we have completed the formulation design, and it has become possible to produce the antibodies with sufficient quality for use in clinical trials for antibody-added micelles. Figure 2 confirms that this ADCM system has improved efficacy as a result of antibody addition in a transplant model of a human gastric cancer cell line that highly expresses TF. The solid green line shows the results of the administration of Epirubicin micelles only. In contrast, antibody added Epirubicin micelles, indicated by the solid red line, clearly showed improved antitumor effects, including a decrease in tumor volume.

In the next stage, we plan to use a human patient-derived cancer tissue transplant model (PDX model). The PDX model is an abbreviation of Patient-Derived Xenograft, which is the transplantation of a patient's tumor tissue into an immunodeficient mouse to reproduce a tumor in the mouse. Compared to the Cell line-Derived Xenograft (CDX) model, in which a cancer cell line is transplanted into an immunodeficient mouse, the PDX model has a higher similarity to the construction of human clinical cancer, such as the construction of cancer stroma. Thus, PDX results are more likely to reflect the clinical results than those of CDX. We plan to identify the types of cancer that can be treated most effectively and to proceed with the preparation of the necessary tests for clinical trials.

Figure 1. Anti-cancer agent conjugated micelles (ADCM)

An anticancer drug (Epirubicin) is encapsulated inside in the inner core of the micelles, and antibody molecules are conjugated to the outer surface of the micelles.

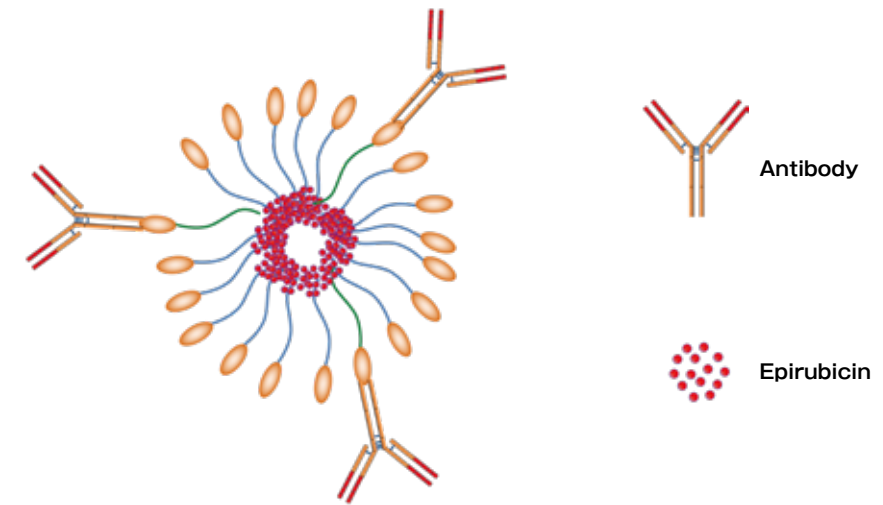
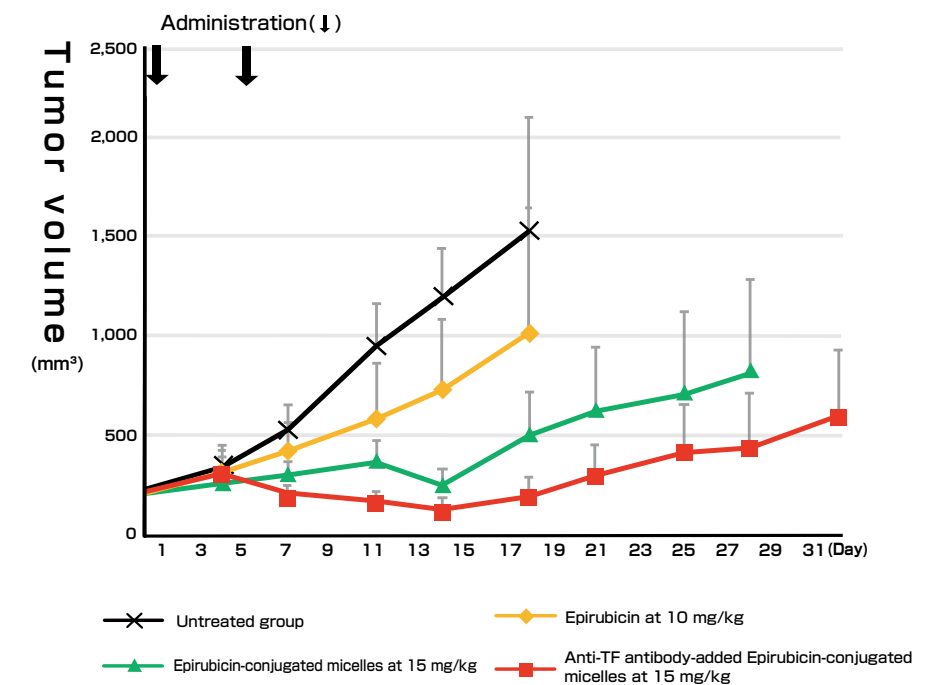


Figure 2. Anti-tumor effects of anti-TF antibody-conjugated Epirubicin micelles (ADCM)

Anti-tumor effect in a gastric cancer model with high-level expression of TF. The solid green line represents the change in tumor volume over time during the administration of the first generation Epirubicin-containing micelles. Comparatively, ADCM, which is a next-generation micelle indicated by a solid red line, has a significantly enhanced anti-tumor effect.



Glossary

^{*1} Antibody/drug-conjugated micelles(ADCM)

The micelle inner core contains an anticancer drug, and an antibody is added to the micelle outer shell to improve cancer directivity. ADCM stands for Antibody / Drug Conjugated Micelle.

Veterinary medicine as a spontaneous model of human disease: social implementation of mesenchymal stem cell therapy

In recent years, the movement to integrate humans and animals from a medical point of view with infectious diseases as the focus has been progressing at a global level. Under such circumstances, we believe that the same applies to cutting-edge medicine, and we are working on the shaping and implementation of social systems of regenerative medicine in veterinary medicine. A laboratory and hospital have been formed as an integrated base that targets pets living in the same environment as humans and provides regenerative medical treatment options.



Hirohiko TSUZUKI

Chief Scientist,
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FUJIFILM Corporation

In 2016, Fujifilm and Anicom Holdings (hereafter "Anicom"), a major pet insurance company, established Celltrust Animal Therapeutics Co., Ltd. (hereinafter "Celltrust") to develop and provide innovative and advanced medical technologies and services centered on regenerative medicine in the field of advanced veterinary care.

Celltrust has advanced production and quality control technologies that have been cultivated in the field of photographic film, technologies related to regenerative medicine, diagnostic imaging technology, analysis technology of blood chemical components, animal hospital network belonging to Anicom, as well as electronic medical record system, and by combining various types of medical information, the company is developing and commercializing innovative and advanced medical technologies and services centered on regenerative medicine in the field of advanced veterinary care. Furthermore, to disseminate the practical technologies and services, the company aims to build a new social system for advanced veterinary care through collaboration projects together with animal hospitals and pet insurance. To achieve this goal, the company established the Animal Regenerative Medicine Center Hospital (hereinafter "Center Hospital") in Yokohama in 2016. (Figure 1)

It can be said that pets are part of the family, and in the aging society, there has been much attention on how dementia can be suppressed through contact with pets. Along with the increase in the number of single-person households, family and partner pets are important members of society.

Based on the concept of One World One Health, there has been a global movement to capture human and animal medical care as one. At this moment, infectious diseases are the main focus. However, in the near future, cutting-edge medicine will become an

important field that can exist continuously as medical care for pets living in the same environment as humans. Engaging in the treatment of pets suffering from spontaneous occurrence rather than disease animal models will not only lead to the treatment of pets but will also be an effective study as a preliminary step in studies on human medical care. We are working to make this project a leading example in the social implementation of "In-body hospitals" hospitals.

Currently, Celltrust prioritizes the cell quality assurance in the practical application and dissemination of treatments using mesenchymal stem cells (hereinafter MSC)*1 in veterinary medicine and also working on the construction of a "new social system" that works in conjunction with various elements, such as accumulating scientific evidence, guaranteeing cell transport, treatment training, sharing of medical data, and utilization of private medical insurance. The Center Hospital has been developing canine fat-derived MSC treatment (Figure 2) and has already started the clinical medical treatment for keratoconjunctivitis sicca and chronic enteropathy (Figure 3). These diseases are immune-mediated, and MSCs are thought to cure the disease by suppressing the excessive response of the immune system. The company is also conducting clinical research on disc herniation, fractures, and arthritis. The use of MSC is expected to become a cell therapy treatment from the perspective of immune control, etc. It has also been approved in Japan as a product of regenerative medicine for the treatment of graft-versus-host disease (GVHD). However, because the mechanism of action of MSC is not fully understood, there are only a limited number of approved regenerative medicine products. We would like to demonstrate the effectiveness of this treatment against diseases in dogs, which may lead to the spread of MSC-based cell therapy in humans.

Figure 1.
Animal Regenerative
Medicine Center Hospital



Figure 2.
Image of MSC (stem cell therapy)

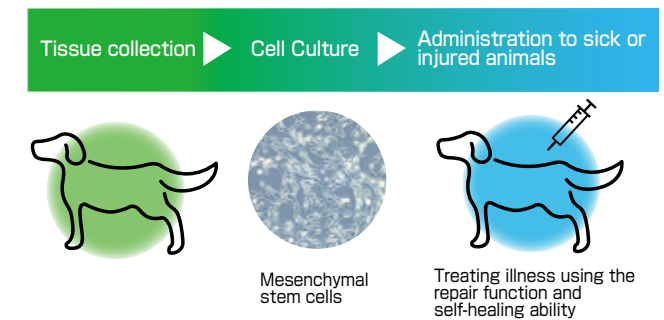
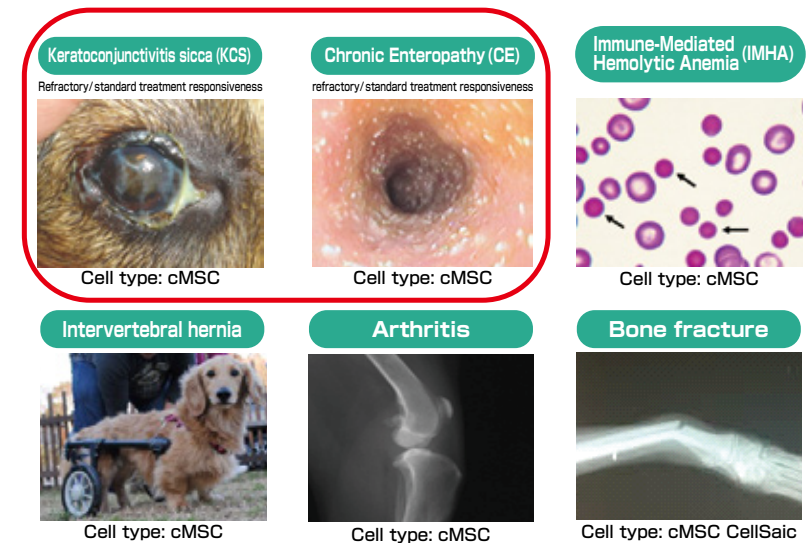


Figure 3. Diseases under development (the red frame shows the actual medical treatment)



Glossary

*1 Mesenchymal Stem Cell (MSC)

Stem cells that can be differentiated into three germ layers that can be collected from adipose tissue, bone marrow, etc. Due to its functions such as immune control and blood vessel induction, it is expected to be a cell for regenerative medicine.

Listen to
COINS'
Members

What we treasure



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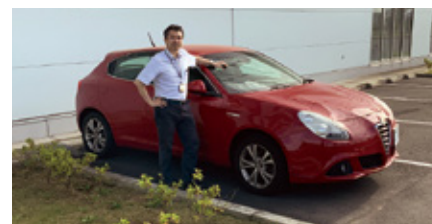
Research and development of new diagnostic equipment that holds the key to preventive medicine by making full use of nanotechnology (precision microfabrication technology)

Aiming for a new medical and healthcare business through exosome technology

Facilities for semiconductor manufacturing and precision machine manufacturing, which would not be normally achievable from the perspective of medical care, have been set up on the first floor of the Innovation Center of NanoMedicine (iCONM). Here, research is underway to develop innovative preventive diagnostic devices through the use of microfabrication technology (nanotechnology). Microfabrication in the semiconductor field is an advanced science and technology that enables the functions of mainframe computers, which were once only available to research institutions and large companies, to be stored in personal computers and smartphones. At the COINS project, with the goal

of reducing medical costs and extending healthy life expectancy by measuring exosomes and analyzing their inclusions (miRNA), we have been conducting research and developing nanoparticle analyzers and rapid cancer diagnostic devices using miRNA as a biomarker. Thanks to the use of iCONM's microfabrication facilities, we have confirmed the feasibility of innovative ideas in a short period of time while making actual prototypes, and our R&D has been progressing smoothly. At the end of last year (2018), we established a venture company, iXstream. The aim is to implement COINS project research results in society and create technologies and services that are useful for new healthcare, diagnosis,

and medical treatment. Although I have to switch my mind from daily research and education at universities to more practical activities, including studying business plans, the 40-minute drive from Tokyo to iCONM on the Metropolitan Expressway is a good time to switch my mind every day.



With his favorite car

Tetsuo YOSHIDA

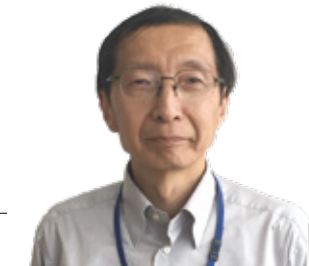
CSO / Director, Research Department, AccuRne, Inc.

Re-challenging a long-standing dream of "generating medicine from genes" in a venture company

About 35 years ago, as a undergraduate student in the Showa era, I was fascinated by the beauty of molecular biology and started my scientific life by studying cancer genes, which was an exciting topic. In the early Heisei era, when I entered a pharmaceutical company to apply molecular biology to drug discovery, I had a dream to make drugs from genes.

For 26 years, I was blessed with opportunities to engage in various drug discovery projects using state-of-the-art technologies, such as genome science, bioinformatics, and RNAi. However, unfortunately, I have not been able to develop medicines with my own hands due to my lack of abilities. Last year in September, I joined AccuRne Inc., a COINS venture company, and had the opportunity to engage in research aimed at nucleic acid medicine and mRNA medicine using the DDS developed by Dr. Kataoka, the COINS Research Leader, as the core technology. When I first moved to a venture company, I felt that I had been protected by the organization so far and got somewhat spoiled. In venture company, speed is everything. Without the ability to make decisions quickly, it is not possible to survive in such a fast-paced and competitive industry. Because of that, each person has massive authority and responsibility, and the pressure is strong. Still, the sense of achievement at the time of success is also (supposedly) highly rewarding. The practical application of nucleic acid medicine and mRNA medicine is the realization of my long-standing

dream of "making genes into drugs". It is not easy to engage in the rapidly-progressing world and bring out our achievements to the world. Nonetheless, with the satisfaction of being given a new challenge in this Reiwa era, while competing with rivals around the world, I would like to work hard every day together with great colleagues that I have made.



We conduct research aiming the realization of nucleic acid medicine and mRNA with COINS's DDS technology.



The Eagle Bar in Cambridge, where the DNA double helix was born.

Philip M.C. DAVY

Director, Business Development
Braizon Therapeutics, Inc.

Improve lives with innovation and partnership

Developing new drugs to treat brain and spinal cord (central nervous system) disorders is very difficult, but it is especially important in an aging society. Pharmaceutical companies have made large R&D investments in drug discovery in this area. However, very few of these programs lead to successfully approved drugs, which significantly increases the expense to Pharma companies and patients. The blood-brain barrier (BBB), the biological barrier between blood and brain, is literally a major barrier to the development of new drugs for nervous system disorders.

I joined Braizon Therapeutics, Inc. in April 2018. Around that time, I had the opportunity to learn about the research by members of the Innovation Center of NanoMedicine and the COINS research network.

The fascinating developments in challenging areas were very impressive. The technology for delivering drugs to the brain beyond the BBB, developed by members of COINS, was incredible!

Polymer micelle nanoparticles enable many different new types of medicine to be designed, such as biological medicine that normally cannot enter the brain. Combining glucose-ligand nanoparticles with glycemic control delivers drugs specifically and effectively to the brain, this is a very elegant solution to a difficult problem. Pharmaceutical companies and biotechnology companies are naturally starting to pay a great deal of attention to this innovative technology to bring their new drugs to the brain. Based on this technology, Braizon has the opportunity to develop new drugs for nervous system diseases for which

treatment has not been possible to date. We are confident that Braizon will be able to improve the lives of many people in the future with strong partnerships and a great team.



Members of Team Braizon in spring 2019



We aim to change lives around the world with powerful innovations in central nervous system drug delivery technology.



Research on better health and disease treatment centered on ALA from the viewpoint of biochemistry and analytical chemistry.

Urara OTA

Manager, Kawasaki Research Institute,
Division of Pharmaceutical Research,
SBI Pharmaceuticals Co., Ltd.

Toward a new stage with unrestrained ideas

Do you know what ALA (5-aminolevulinic acid) is? ALA is a naturally-occurring amino acid that can be found in various foods and is produced daily in our bodies.

ALA is metabolized into porphyrin in the body, which then forms heme with iron. Heme plays essential roles in the human body, such as energy production. Recent studies have also reported the beneficial effects of ingesting ALA with iron in enhancing mitochondrial functions.

I learned about ALA when I was in a laboratory that researched a genetic disease called porphyria. In this disease, the process of metabolizing ALA to heme is

genetically inhibited, causing metabolites such as porphyrins to accumulate in the body. Porphyrin accumulation causes damage to the skin and the like. ALA is known as a marker for diagnosing abnormal heme metabolism, and people had been looking at ALA based on the perspective that its level must remain low in the body. When it was shown that the administration of ALA in a subject with normal heme metabolism could improve health, I felt that the scales have fallen from my eyes. Looking at things one-sidedly will not lead to new ideas, and it was a valuable experience to realize that a multifaceted perspective and flexible

thinking are crucial in challenging ourselves to give the best efforts. Afterward,

I have been blessed with knowing many different people, and I have been involved in the work of delivering ALA in health, cosmetics, and pharmaceutical products to the world. I would like to make the best use of my experiences and work towards the realization of this project as soon as possible.

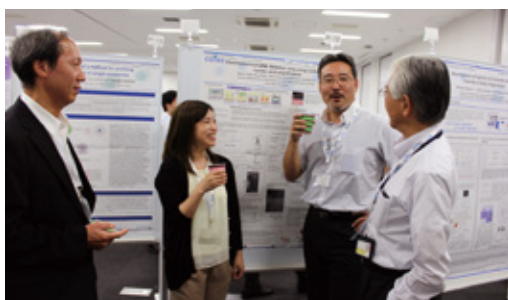


Science event from last year

12th General Meeting ~In the phase III, harvesting results and sowing for the future~

Friday, June 14, 2019, 12th COINS General Meeting was held at the main conference room at Life Science & Environment Center (LiSE). We have entered the final phase III of COI (fiscal 2019-2021) this year, and along with promotion of social implementation, strengthen efforts for post-COI are expected. In this general meeting, each institution presented its goals and plans towards the end of COI based on the results achieved up to date and talked about the world of 2045 which aims to transform into a smart life care society in panel discussions. Everyone shared vision and direction. 30 posters were presented in the poster session and there was an active exchange of opinions. Moreover, the nearby facility tour and lecture were organized. In the Medtronic Innovation Center,

there was an explanation by the person in charge about the medical technology and services developed by the company and the lectures were given by the Ministry of Health, Labor and Welfare and AMED lecturers on venture promotion measures and intellectual property support systems. We had feedback from Mr. Toshio Asano, advisor (Asahi Kasei Corp.), Dr. Tatsuhiro Imamura, professor (Juntendo Medical School), Mr. Hiroshi Misawa (Medical Technology Association of Japan). Dr. Haruhiko Manabe, Assistant Visionary Leader, JST gave us valuable comments that he would like us to work on a specific design to realize an in-body hospitals. The meeting was very meaningful to strengthen further solidarity towards the harvest of results in the phase III and the leap to post-COI.



Poster session



General meeting

Topics July 2018 - June 2019

- 7. 9. 2018 [Activity] COINS Seminar #34 was held.
Speaker: Toshio NAGAE, Pharma Business Consultant, PeptiDream Inc., Director, Human Metabolome Technologies, Inc.
Title: Maximize business value of Japanese drug discovery / DDS in global markets, challenges and solutions
- 7.11. 2018 [News] iCONM Director-General, Dr. KATAOKA appeared on TV program. He talked about the potential of in-body hospitals for Cancer. TV Asahi group [Shinichi Hatori Morning Show]
- 7.18. 2018 [News] iCONM Director-General, Dr. KATAOKA appeared on TV program. He talked about the potential of in-body hospitals for Cancer. TV Asahi group [Shinichi Hatori Morning Show]
- 7.18. 2018 [Award] Dr. Akira MATSUMOTO, Associate Professor, Tokyo Medical and Dental University was received 2nd Japan Bioindustry Association Award for Young Scientists. His research title was "Development of "electronics-free" and totally synthetic artificial pancreas".
- 7.20. 2018 [Activity] iCONM Director-General, Dr. KATAOKA (COINS Research Leader) gave talk at Kawasaki Institute of Industrial Promotion Ceremony of Celebrating 30th Anniversary and it was introduced on Kanagawa Shimbun and Nihon Keizai Shimbun.
- 7.22. 2018 [News] AccuRna, Inc. was featured in the episode of the highly acclaimed TV series, Innovations TV with Ed Begley, Jr., via CNBC, USA.
- 8.10. 2018 [Appoint] Dr. Kazunori KATAOKA, Director General of Innovation Center of NanoMedicine (iCONM) was awarded the honorary doctorate (Doktor der Naturwissenschaften ehrenhalber; Dr. rer. Nat. H. C.) from Johannes Gutenberg University (Mainz University) in Germany.
The honorary doctorate of Mainz University is awarded to researchers who have globally achieved exceptionally high level of performance. This time, Dr. KATAOKA's research titled "Development of Polymer Therapeutics and Their Application to Cancer Treatment" was highly appreciated in the Faculty of "Chemistry, Pharmaceutical Science and Earth Sciences" and it was the first time in eight years for the Faculty to be awarded.
- 8.30 ~ 8.31. 2018 [Activity] COINS exhibition was held on "JST Fair 2018 - Future Industry Creation with Science and Technology" organized by JST.

- 9.10. 2018 [Activity] COINS Seminar #35 was held.
Speaker: Dr. Shin KWAK, Visiting Scientist, University of Tokyo, Graduate School of Medicine
Title: ALS-targeted therapy and biomarker development
- 9.25. 2018 [Activity] COINS Seminar #36 was held.
Speaker: Dr. Kazuo KURIHARA
Professor, New Industry Creation Hatchery Center (NICHe), Tohoku University
Title: Surface Forces Measurement for Materials Science, Applications for Polymer Brush and Gel
- 10. 3. 2018 [Activity] COINS Seminar #37 was held.
Speaker: Dr. Ulrich S. SCHUBERT, Professor of Organic-/Macromolecular Chemistry, Friedrich Schiller University Jena
Title: New pharmacopolymers and nanoparticles for applications in nanomedicine
- 10.15. 2018 [News] Dr. Kazunori KATAOKA (Director General, iCONM, Professor, The University of Tokyo) and Sub Theme2 Leader, Dr. Yasutaka ANRAKU (Assistant Professor, The University of Tokyo and a guest researcher at iCONM)'s research was introduced on Nipponkeizai Newspaper.
- 10.19. 2018 [News] Dr. Kazunori KATAOKA (Director General, iCONM, Professor, The University of Tokyo)'s article "Enhanced intracellular Delivery of siRNA by Controlling ATP-Responsiveness of Phenylboronic Acid-Functionalized Polyion Complex Micelles" published in Macromolecular Bioscience was one of the journal's top 20 most downloaded recent papers amongst articles published between July 2016 and June 2018.
- 10.28. 2018 [News] COINS member Dr. Takahiro OCHIYA (National Cancer Center Research Institute)'s group and their research was introduced on Nihon Keizai Shimbun.
- 10. 29. 2018 [Activity] COINS Seminar #38 was held.
Speaker: Dr. Weibo CAI
Vilas Distinguished Achievement Professor, University of Wisconsin - Madison, USA
Title: Molecular Imaging, Image-Guided Drug Delivery, and Theranostics
- 11.16 - 11.17 [Activity] 5th COINS Retreat was held at Shonan Village Center.
- 11. 28. 2018 [Activity] Research Leader, Kazunori KATAOKA (Director General of iCONM, Professor, The University of Tokyo) has been named a 2018 Highly Cited Researcher in

Clarivate Analytics (Web of Science) meaning that research ranks among the top 1% most cited works in the corresponding field.

- 11.30-12.1. 2018 [Activity] 1st COI Retreat in Kawasaki was held.
- 12. 4. 2018 [News] Research Leader, Kazunori KATAOKA (Director General, iCONM, Professor, The University of Tokyo)'s Lecture was introduced on Zaikai magazine (Vol.4 Dec.).
TM Topics No. 184 / From TM Study meeting
Dr. Kazunori KATAOKA, Director of iCONM Center, etc. gave a lecture on nanotechnology and technological singularities "Possibilities that nanomachines diagnosis and treat inside the body toward cancer and Alzheimer's disease"
- 12. 7. 2018 [Activity] COINS Seminar #39 was held.
Speaker: Dr. Yan LEE
Associate Professor, Department of Chemistry, Seoul National University (SNU), Korea
Title: β -acid amide-based materials: charge-conversion chemistry and new polymeric materials
- 12. 7. 2018 [News] COINS member Dr. Satoshi UCHIDA (Visiting Scientist, iCONM, Project Associate Prof., The University of Tokyo)'s research was introduced on UTokyo Research.
"Designing immunostimulatory double stranded messenger RNA with maintained translational activity through hybridization with poly A sequences for effective vaccination"
- 12. 13. 2018 [Appoint] COINS Newsletter "NanoSky Vol.6" was published.
Contents: "Fascinating! World's first mRNA therapeutics", Development of basic technology of cancer vaccine using a new formation of mRNA medicine, etc.
- 12.14. 2018 [Activity] 5th COINS Symposium was held at Kawasaki City Industrial Promotion Hall.
- 1. 7. 2019 [Activity] COINS Seminar #40 was held.
Speaker: Mr. Seiji YANO
Professor, Cancer Research Institute of Kanazawa University
Title: Circumvention of targeted drug resistance in CNS metastasis
- 1.7. 2019 [News] The article about COINS was introduced Weekly Igakukai Newspaper.
Future cancer treatment with DDS research (Vol. 3304)
- 1.18. 2019 [Activity] COINS Seminar #41 was held.
Speaker: Dr. Xiaoyuan (Shawn) CHEN
Senior Investigator, National Institutes of Health (NIH)
Title: Reactive Oxygen Species Goes Beyond Photodynamic Therapy
- 1.18. 2019 [News] COINS member, Akira MATSUMOTO (Associate Professor, Tokyo Medical and Dental University) and his research group's paper has published on Advanced Function Materials. It was adopted as a back cover and Video abstract. "Glucose - Responsive Insulin Delivery: Microneedle - Array Patch Fabricated with Enzyme - Free Polymeric Components Capable of On - Demand Insulin Delivery"
- 1. 22. 2019 [Appoint] Research Leader, Dr. Kazunori KATAOKA (Director General, iCONM, Professor, The University of Tokyo)'s interview movie was launched on bt cn asia, internet TV of Singapore.
(1/21) Part 1: Nanomedicine in neurodegenerative diseases like Alzheimer's
(1/28) Part 2: The future of nanomedicine for everybody
- 1.22. 2019 [News] COINS member, Dr. Akira MATSUMOTO, Associate Professor, Tokyo Medical and Dental University and his research group's paper was published. "Blood sugar control with boronic acid gel Tokyo Medical and Dental University Diabetes Patch"
- 1.25. 2019 [News] The article of a research "Development of smart artificial on-skin pancreas" conducted by Dr. Akira MATSUMOTO (COINS theme 4), Department of Bioelectronics, Institute of Biomaterials and Bioengineering, Tokyo Medical and Dental University was introduced in The Science News. "Persistence and blood glucose level responsiveness is over one week Trial production of Microneedle-Array Patch with Enzyme-Free Polymeric Components"
- 1.26. 2019 [News] The article of Dr. Kazunori KATAOKA, iCONM Director-General was carried in Newton magazine. "Deliver drugs to the targeted organs! "Polymer micelle"
- 1. 30. 2019 [Activity] 11th COINS General meeting was held.
- 2. 5. 2019 [Award] The team of Prof. Yoshihiro MURAGAKI (COINS member), Tokyo Women's Medical University and his team received the Minister of Health, Labor and Welfare Award in 1st Japan Innovation Award. This was widely reported in the website of Cabinet Office, Ministry of Health, Labor and Welfare.
"Tokyo Medical and Dental University and DENSO, etc. received "Minister of Health, Labor and Welfare Award".
- 2.14. 2019 [News] Theme2 Leader, Dr. Yasutaka ANRAKU (Assistant Professor, The University of Tokyo and a Visiting Scientist at iCONM)'s talk session (held on last Dec.) was introduced on NATIONAL MUSEUM OF EMERGING SCIENCE AND INNOVATION website.
"Become naturally healthy without medical care? - Medical revolution with "in-body hospitals" [First part]"
- 2.14. 2019 [News] The article regarding Dr. Kazunori KATAOKA, Director-General was published in Yomiuri Shimbun.
[We are in the future (2) Realization of nanomachines
- 2. 22. 2019 [Award] Dr. Yasutaka ANRAKU, Assistant Professor, The University of Tokyo

(COINS Theme 2 Leader) received Dean's Award of Graduate School of Engineering, The University of Tokyo. This award is given annually to five faculty members who have done extremely good works.

- 2. 26. 2019 [News] Dr. Keiji ITAKA, Professor, Tokyo Medical and Dental University, laboratory (head of iCONM Itaka lab.) had a press release announcing the research paper published in Molecular Therapy - Nucleic Acids titled "Treatment of intervertebral disk disease by administration of messenger RNA encoding a cartilage-anabolic transcription factor".
- 3. 5. 2019 [Activity] COINS Seminar #42 was held.
Speaker: Dr. Joachim O. Rädler, Full Professor, Faculty of Physics and Center for NanoScience, Ludwig-Maximilians-University
Title: Single Cell Time-Lapse Imaging on Micro-Arrays- transfection kinetics, apoptosis and cell migration
- 4. 1. 2019 [News] The interview of Dr. KATAOKA, iCONM Director General (COINS Research Leader) iCONM was posted in monthly magazine "Themis". April 1 issue
"Dr. Kazunori KATAOKA, Director of iCONM challenges Cancer & Alzheimer's Disease Eradication with micelles"
- 4. 3. 2019 [Appoint] COINS SDGs promotion video has been completed. This is request from JST.
We are proactively contributing to the achievement of the SDGs goal 3 of "Good health and well-being". "In-body hospitals" change the future - Good health and well-being - What is the SDGs?
The 2030 Agenda for Sustainable Development (the 2030 Agenda) is a set of international development goals from 2016 to 2030, which was adopted by the UN Sustainable Development Summit held in September 2015 building on the success of Millennium Development Goals (MDGs).
- 4. 9. 2019 [Award] Dr. Nobuhiro NISHIYAMA, Principal Research Scientist / Head of Nishiyama Laboratory, KAWASAKI INSTITUTE OF INDUSTRIAL PROMOTION Innovation Center of NanoMedicine (iCONM) (Professor, Institute of Innovative Research, Tokyo Institute of Technology) was awarded. Award title: "Study on development and medical application of nanomachines based on polymer design"
- 4.16. 2019 [Activity] COINS Seminar #43 was held at Kawasaki King SkyFront Tokyu REI Hotel.
Part1
Speaker: Mr. Kazuomi IWATANI
Manager, Intellectual Property Division
Japan Agency for Medical Research and Development (AMED)
Title: "The briefing session of support program by Intellectual Property Division of AMED"
Part2
Speaker: Dr. Hiroatsu NOHARA
Associated Researcher, Affiliation: Lest-CNRS / Aix-Marseille University
Title: "French medical cluster: the case of "Oncopole" in Toulouse"
- 4.23. 2019 [News] There was a press conference by Dr. Kazunori KATAOKA, Director General, iCONM / Professor, The University of Tokyo and Dr. Kanjiro MIYATA, COINS Theme 1 leader (Associate Professor, The University of Tokyo / Visiting Scientist, iCONM). They succeeded in developing the Nucleic Acid Medicine-loaded Nanomachine, a technology that can stably protect nucleic acid drugs that are prone to deactivation in the bloodstream and deliver them to intractable cancers such as pancreatic cancer and brain tumors. This research result was published in "Nature Communications (UK scientific journal)" on Wednesday, April 24, 2019.
Research title: In vivo rendezvous of small nucleic acid drugs with charge- matched block cationomers to target cancers
The articles regarding this matter were introduced on some newspapers.
Nippon Keizai Shimbun online, Nikkan Kogyo Shimbun online, Alpha Galileo, Science X, e cancer, Kyodo News, Jiji Press
- 4. 26. 2019 [News] Vice-Director, Mr. Hirokazu IWASAKI appeared on TV program on TVK [NEWS Harbor] and talked about "in-body hospitals" and iCONM.
- 4.29. 2019 [News] Dr. Kazunori KATAOKA, Director General (Professor, The University of Tokyo) appeared on TV program "Sukkiri" and introduced "Future medical care" at the Jaguar YOKOTA's corner.
- 5.14. 2019 [Activity] COINS Seminar #44 was held.
Speaker: Dr. Hiroyuki FUJITA, Professor, Tokyo City University, Advanced Research Lab.
Title: "MEMS Technology and Applications to Biomedical Field"
- 5. 30. 2019 [Appoint] Professor Kazunori KATAOKA, Director General of iCONM, was recommended to become an Honorary Member of the Society of Polymer Science, Japan.
- 6. 3. 2019 [News] AccuRna, Inc. one of the participating institutions announced that they will start clinical trials for breast cancer treatment with siRNA based nucleic acid medicines later this year.
AccuRna starts triple negative breast cancer (TNBC) treatment with nucleic acid medicines. | The Chemical Daily
- 6. 5. 2019 [Activity] Dr. Kazunori KATAOKA, Director General (Professor, The University of Tokyo) gave a talk at Link-J Networking Reception UCLA Health : Partnering with Industry to Advance Healthcare that was held on 5/16. He talked about the academic exchange with UCLA that lasts for more than a decade.

We are actively using crowdfunding.

When we visit the shrines and temples, we often see notices calling for donations for repairs and those who donate can leave names on the tile. In this way, even if it is a small amount of donation, if many supporters gather, it will become a large amount of money. It is becoming. Along with the spread of the Internet, this crowdfunding is becoming an important way to raise funds that support social contribution activities. More importantly, many people will get to know the specific contents of the activity and will become easier for them to understand. The reason we challenge crowdfunding is that in addition to raising student participation fees, to increase the understanding of esoteric research and its purpose, and to commit to help society in the future. iCONM also took on two challenges last year in research aimed at treating refractory cancer. This year, we succeeded challenging with a research aimed at the fundamental treatment of the intractable disease called cystic fibrosis.



We had 49 people supported us. Thank you.
Wenqian YANG

Details are here ↓



COINS Seminar Report Pick up! ~Learn latest trends of medical service and science~

《COINS seminar #43》

COINS Seminar #43 was held on Tuesday, Apr. 16th at Kawasaki King SkyFront Tokyu REI Hotel. The seminar, it has been divided into two parts. In the first part, we had lectures by Mr. Kazuomi IWATANI (Manager, Intellectual Property Division, Japan Agency for Medical Research and Development (AMED)), Title: "The briefing session of support program by Intellectual Property Division of AMED".

In the second part, we had lectures by Dr. Hiroatsu Nohara (Associate Researcher, Affiliation: Lest-CNRS / Aix-Marseille University), Title: "French medical cluster: the case of "Oncopole" in Toulouse".

We had a discussion and mixer after the seminar, all participants and speakers had enjoyed active discussion at stylish and open space.

《COINS seminar #44》

COINS Seminar #44 was held on Tuesday, May. 14th at iCONM. In this seminar, we had lectures by Dr. Hiroyuki FUJITA (Professor, Tokyo City University, Advanced Research Lab.), Title: "MEMS Technology and Applications to Biomedical Field".

We had a discussion and research mixer after the seminar, all participants and speakers had enjoyed active discussion.



Mr. Kazuomi IWATANI



Dr. Hiroyuki FUJITA



Dr. Hiroatsu NOHARA and the seminar venue

Editor's Note

NanoSky vol.7 will be the last issue of the six themes aiming to realize "In-Body Hospitals".

The contents include research activities, business models, and introductions of ventures originating from COINS with the goal of Theme 6 "Social system for implementation of the results into society". As we enter Phase III, our initiatives will accelerate to realize the "in-body hospitals" in 2045, the focus is on the COINS social implementation strategy for the realization of in-body hospitals.

In the "Talking about Theme 6", the establishment of new venture companies according to the business potential of intellectual property based on research results and the networks including the Tonomachi district, the Keihin coastal area and the Tokyo metropolitan area and the cooperation between clusters are promoted, and activities for fostering venture companies that transmit to the world are introduced.

With the change of editorial system, I will be the editor-in-chief from this month issue. The next issue will be a novel style that is not bound by the theme frame. Please don't miss it.

(Editor-in-chief Miyako YOKOYAMA)