

# C PRESS

Special Talk

**Fumiaki Koizumi**

President, MercariMercari Inc.

Our Creative Service at CMIC

**CRA work in the Pioneering  
Period of the Job versus Now.**

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# People with Strong Wills Seize the Future:

Constantly Pursuing the Missions That Suit Every Passing Moment



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Work styles are currently at a turning point, with the spread of remote working alongside other changes. We can see a significant challenge in aligning the direction of an organization's mission with its people's own satisfaction in life and self-expression. What are the vital qualities that organizations and individuals need to pursue? Fumiaki Koizumi has served as a leader in Japan's Internet business, with the social media service Mixi in the 2000s and the flea market app Mercari in the 2010s. CEO Nakamura listened to his story.

**Nakamura** You're famous for playing a leading role in Mercari's rapid expansion. I'm embarrassed to say that I didn't know how much flea market services like Mercari had spread before I came to know you. I've been greatly looking forward to hearing your story, owing to how you created a completely new, game-changing service. Now, you're originally from Yamanashi, right?

**Koizumi** Yes. I was born here in Hokuto\*1 in 1980, and I grew up running around the plains. A neuroscientist once told me that my creativity originates from my experience playing in these plains when I was a child. I do agree that my current way of living has been greatly affected by the way I gained the attitude and habits to learn from nature as a child. Nothing beats nature when it comes to experiencing things for real.

**Nakamura** You grew up in a natural environment, but how did you get involved with the Internet?

**Koizumi** My first experience with a computer was in my first year of junior high school. My school had many Macs in the computer room, though they were uncommon at that time. I started by drawing graphics, and then I came to make games and other things too. I wasn't really much of a geek though. I was the captain of the soccer team.

**Nakamura** It's interesting how you didn't dive straight into geekdom.

**Koizumi** I liked fashion, so I naturally went on to link the Internet with fashion. Nike Air Max 95 sneakers were all the rage at the time. They were selling for over 10 times their regular price at one point, and they were a social phenomenon. As I watched the prices change for these products, I learned that there is a business

opportunity when supply and demand don't match. This really piqued my interest. The Internet began to spread around the time I started high school. I began buying products in Shinjuku and selling them like an agent within Internet communities for fashion lovers.

I think this might have prompted my desire to create a company related to the Internet one day.

### The Phase Where Ambition Changes to Mission Is the Most Fun

**Nakamura** I imagine that there must have been many hurdles in spreading a new service.

**Koizumi** Both Mixi and Mercari had many negative reactions at the start, but I believed that people would eventually come to use them.

As the business grew, there was a phase where the ambition we had at our founding to do it ourselves changed to become our mission. This phase was the most fun in the whole process.

**Nakamura** I found it hard to gather people when establishing my business. Did you have a similar experience?

**Koizumi** At the start, I was talking about my aspirations as much as I could. I was winning over people one at a time. I also reached out to people



\*1 This interview was held at the Nakamura Keith Haring Collection in Hokuto, Yamanashi.

over Twitter. It was like I was hitting on them online (laughter). I gradually got people to join me.

As the business made good progress, it proved bit by bit that we were not just speaking about a pipe dream, and so our network continued to grow.

### The World Needs Specialists with an Edge

**Nakamura** I started the company in a single room in an apartment too, so I had trouble gathering people. Young men in their prime didn't pay attention to me. Women and people past retirement age helped me out at the start. Looking back on it, we had diversity from the beginning.

Later, we sometimes had some strange but very smart people joining us. Those kinds of people saved us.

**Koizumi** When we started Mixi in the 2000s, there weren't many workers coming to the IT industry. But one person who did join us later became a key person at the company. This individual learned programming on his own in high school, and he came to our office one day at age 19 and asked us to hire him. He continued to distinguish himself from then on, and he became the Chief Development Officer six years later. It's pretty hard to hire talent like him after the company has grown large. I think it was only possible because we were in the venture phase.

**Nakamura** I can understand that. It happened because the company was still developing. Unique and very smart people have amazing energy, but it's



hard to integrate them in the team.

**Koizumi** The Mercari team used to have many people who had an edge but were also flawed in some way. I had a lot of trouble thinking how to bring them together as a team. But recently, I sometimes wish people actually had more of an edge. If you have people with ambitions of reaching the top, then it's easier to make a breakthrough if you encounter any issues.

**Nakamura** We are living in complex and tough times with the Japanese economy continuing to be stagnant, and with war and COVID-19 worldwide. At times like these, the world needs talented people who can pave the way forward.

### Seeking to Be the De facto Standard to Make Our Ideals a Reality

**Nakamura** The most important thing in the IT industry is to become the de facto standard\*2. Coming from the healthcare industry, this is a little hard for me to conceptualize. Could you tell

me about the mindset you have when managing your business?

**Koizumi** The phrase "winner takes all" is common in the IT industry, so I always stay aware of the potential dangers. You might see rivalries between strong parties at the start, but people, property and information end up coming to the organization with the most power, so that organization becomes the standout leader.

In the 18 months after Mercari was established, we raised a total of 4.3 billion yen in funding. We worked with high start-up costs to make something good, carry out promotions, and win customers. I was scared that I would be unable to take care of my team if we did not take first place, so I was working as hard as I could to succeed. I stopped drinking liquor despite my love for it, and I was working until morning every day. I kept telling myself that I could drink as much as I liked once we had come out on top.

To tell you the truth, I was more relieved than elated when I could see we had become the

\*2 A protocol that has come to be recognized as an industry standard following competition between companies in the market. This is a standard for all intents and purposes



de facto standard. Some 20 competitors had joined the market at the start, but there were only one or two left at the end.

**Nakamura** That is completely different from the industry that I am in. Nobody would imagine a single entity winning everything in the world of new drug development or science. It takes at least 10 years to develop one new drug, so it takes perseverance. Decentralized activity is essential to prevent research from stagnating. We strive to make competition. That's why you see many new bio ventures. My mindset is based on an approach for maintaining diversity through this kind of metabolism.

However, we are currently making a healthcare communication channel called harmo based on electronic medicine notebooks, and we need this to become the de facto standard. This is a completely different approach from my mindset, so I am not strong in this area. I have called on younger employees to exert efforts in this regard.

**Koizumi** We seem to be polar opposites at first glance, but in fact we both want to make society better. We just have different approaches. It is more convenient for society if there is one integrated service, and Mercari seeks to create a world where people don't throw things out, so in that sense, it is better for it to be a de facto standard.

**Nakamura** I think your approach is truly amazing in the way you capture everyone's needs and create an ecosystem to make society better.

### It Is Crucial to Retain a Feel for Things on the Ground

**Nakamura** If someone makes a good drug it will spread across the world instantly, so there is always a sense of fear within the drug industry because you cannot avoid international competition.

**Koizumi** I went through a hitch like that once too myself, actually. We built Mixi as a de facto standard within

Japan during the heyday of flip-phones in a partially isolated environment. However, I feel Mixi was slowly driven out by Twitter and Facebook when smartphones came on the scene.

In light of this experience, I strongly focused on the competition being global with Mercari, and on entering a world where only one platform reigns supreme. We even branched out into America.

**Nakamura** Once a company grows to a reasonable size, it can get enough income from domestic business. Companies like these tend to prioritize bolstering their foundation in the domestic market, and so they lag behind in going international. And if they do seek to go overseas once they reach that stage of growth, they tend to only think of buying a company in America. But I don't think that's the right way to do it. How do you perceive the idea of going international?

**Koizumi** We also have requests from investors to acquire overseas competitors. However, you can't tell if you are doing business correctly if you don't have a feel for the kind of customer base there is and the kind of commercial practices that are there. It would be fine if you jump in first and start business, and then decide whether M&As are appropriate, but I wouldn't approve of making a decision only based on due diligence\*<sup>3</sup> materials. I want to jump in myself, learn through that process, and build a strategy step by step.

**Nakamura** You can't convince anyone if you don't have a feel for things on

the ground. Nowadays, you need to know what is actually happening.

### Desire to Continue as a Mission-driven Company

**Nakamura** As we see a turning point in workstyles within the present day, it is more important than ever for companies to share details with every employee about the absolute core areas that are non-negotiable.

**Koizumi** I always talk about our mission until I am blue in the face—about what the company stands for and the future we want to create. I want the company to be mission-driven, and I feel it was able to grow in such a short time because of this mission-driven approach.

I am actually in the middle of replanning our mission in line with our 10th anniversary, so we are returning to discussions on the vital qualities we need to pursue.

**Nakamura** We are seeking to go beyond just curing diseases, and to think about what we can do to make society a better place where everyone can live according to their own will. We have incorporated this mindset into our Creed\*<sup>4</sup>. We have a morning meeting at CMIC to which all employees are welcome to join. At this meeting, I always ask people to revisit our ideals and to be courageous in taking on new challenges.

**Koizumi** I feel that we have entered a

phase at which we need to launch an app to enrich the lives of people in their working and regular lives, and to further realize a recycling society. It is crucial to keep rethinking your relationship with society as the company grows.

### Creating the Future through the Sheer Power of Aspirations

**Nakamura** If you place focus on individuals living their own lives to the fullest, it is essential for people to feel fulfilled with their lives. It is also crucial to respect each other. If you respect others rather than trying to force your values on them, the world will be a better place, and you will see new technologies appear as well.

**Koizumi** The debate on diversity tends to focus on superficial aspects like gender, but it would be better to focus on diversity in areas closer to the heart of things.

**Nakamura** The essence of diversity is found within us. The key is to have the power to take on challenges and accept other people for who they are.

**Koizumi** To me, diversity and inclusion means that everyone has a place where they feel comfortable, that everyone can express themselves, and that the direction of their self-actualization is aligned with the company's mission. This applies to society in general, not just companies.

**Nakamura** However, society in recent years has changed, in the sense that people get attacked if they say something that doesn't match others' opinions. We need to make society a place where people can voice many different opinions; otherwise our business will not go well, and it will be no fun, either. That is diversity in its genuine sense.

**Koizumi** I feel it is more important than ever to hold onto your own opinion despite a flurry of other views. While younger people are more familiar with social media, I have noticed in particular that many have been attacked for their views online and tend to see communication as something constrictive as they fear expressing opinions that differ from others. It is extremely important to hold onto your own opinions.

**Nakamura** Do you have any advice for younger people, or for people looking to start a company?

**Koizumi** First of all, they need to have a strong will. Both you and I have created a future for ourselves through the sheer power of our aspirations, right? There is more fear in our current chaotic and unpredictable times, but I think people should believe in themselves and aim to be optimistic. The most important thing is to maintain a strong will and discover something.

**Nakamura** Thank you for taking the time to talk with me today.

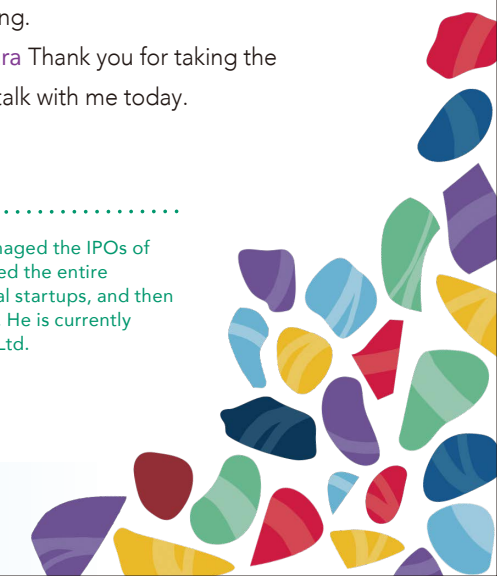


\*3 Preliminary surveys on the status of a company's management and finances

### PROFILE Fumiaki Koizumi .....

Born in Yamanashi Prefecture in 1980. After graduating from the School of Commerce at Waseda University, he managed the IPOs of Internet-focused companies such as Mixi and DeNA at Daiwa Securities SMBC. He joined Mixi in 2006 and supervised the entire Corporate Division as Director, Executive Officer, and CFO. After leaving the company in 2012, he supported several startups, and then joined Mercari, Inc. in December 2013. He became Director in March 2014, and then President & COO in April 2017. He is currently Director and President of the company while also maintaining a role as President/CEO of Kashima Antlers F.C. Co., Ltd.

\*4 CMIC's CREED is CMIC Group's corporate philosophy, and was established in 2016





# CRA

Clinical Research Associates'

Work in the **Pioneering Period of the Job** versus **Now**

Clinical Research Associates (CRAs) are responsible for supporting the smooth progress of clinical trials and ensuring the reliability of data. They work in a wide range of areas from contracting with clinical trial sites, to preparing for clinical trials, promoting subject enrollment and monitoring. While the essence of the work has not changed, the approach used has changed dramatically over the past 30 years.

## Now

In some cases, consulting and clinical departments at CROs support the creation of protocols.

They propose site selection in cooperation with a site management organization (SMO).

They convene an Institutional Review Board (IRB) at the trial site to obtain approvals for the clinical trial.

### IRB



They negotiate with the trial site and sign a clinical trial agreement.



They hold a study meeting to explain the details of the clinical trial to all parties involved. They discuss the details with the clinical investigators/Clinical Research Coordinators (CRCs) until all questions are answered.



Review and understanding of the protocol

Investigation of medical institutions and physicians

Preparation for Clinical Trials

Approval by the Institutional Review Board (IRB)

Signing of a contract

Signing of Clinical Trial Agreement

Little was known about CROs and CRAs, which often led to suspicion...

During the Pioneering Period

"CRO? Why is the manufacturer not coming?"



Many facilities were not accustomed to clinical trials, and it was not easy to gain their understanding about our business and have them sign contracts.



Supporting site personnel unfamiliar with clinical trials

"What should I do?"



Preparation for Clinical Trial Start-Up and Promotion of Subject Enrollment

Explanation of clinical trial contents

Delivery of investigational products

Promotion of subject enrollment



A clinical trial cannot begin without the participation of subjects. CRAs work closely with the clinical investigators and CRCs to increase the participation rate of clinical trials.

The delivery of investigational products has become mainly outsourced to transportation and logistics companies.

We had to review all source documents in person or match source documents to CRFs (Source Document Verification—SDV).



Transporting investigational products was part of the CRA's job.



Subject enrollment was done by fax.

Clinical Trial Conduct and Monitoring



Paper CRFs were collected, and data entry was done in-house.

Electronic Data Capture (EDC)

The system collects data electronically: Clinical trial sites enter clinical trial data directly into PCs or other devices.



Clinical Trial Termination Procedures

Adverse event handling

Inquiry handling

Review of Case Report Forms (CRFs)

An appropriate action is taken, such as confirming the seriousness of the event with the clinical investigator if an adverse event is detected.



The clinical investigator is contacted if inconsistent data is found in a CRF.

Clinical trials are monitored as to whether they are conducted in compliance with good clinical practice (GCP) and protocols. The data in the source documents is checked as whether they have been accurately entered into EDC. Sampled data may be monitored (Risk Based Monitoring; see next page) instead of surveying all cases.



In international joint clinical trials, the case report form (CRF) checks and confirms responses are all carried out in English.



In this issue, we will introduce  
of the CMIC Group.

## the current CRA operations

### Q. How has CRA work evolved over the past 30 years?

A. In the pioneering days, the term "monitor" was used instead of CRA (Clinical Research Associate), and many physicians and medical institutions were not familiar with CROs (Contract Research Organizations) and were not familiar with clinical trials either. The need for CROs increased dramatically with the implementation of the new GCP Ministerial Ordinance in 1997, which clarified the legal basis for CROs. Comparing then and now, it is fair to say that it has become much easier to conduct clinical trials because medical institutions have a better understanding of not only GCP and their roles to be performed in clinical trials but also the roles of CRAs and CRCs (clinical research coordinators) in clinical trials. The most significant change in CRA's operations is a shift to an electronic data-capturing process (EDC) from the one based on paper CRFs (case report forms). In the past, CRA's work required visiting medical institutions several times a week, and it was said that one had to like traveling to do the job. Today, with the rise of remote interviewing, which has been rapidly implemented due to the COVID-19 pandemic, there has been a shift to a variety of work styles that combine home and office work with business travel. In anticipation of changes to clinical trials, CMIC's clinical trial monitoring operations have evolved significantly over the past 30 years. CMIC, which has the largest number of CRAs in Japan at 1,100, will continue to lead clinical trial monitoring by proactively taking action to respond to changes in the clinical trial environment, such as the introduction of Decentralized Clinical Trials (DCT) and the adoption of concomitant drug error checking using harmo®.

**\*harmo®:** A medical information collaboration system (<https://www.harmo.biz/>) based on an electronic medication registry that allows patients to manage medication information centrally, easily and reliably, and share and utilize this information with medical professionals.

### Q. What is RBM?

A. Risk Based Monitoring (RBM) is a more efficient and effective monitoring method based on the concept of improving the quality of clinical trials by focusing on how to manage and prevent problems, rather than deal with them after they have occurred. Until now, 100% data reconciliation has been mandatory, and the main task of monitoring has been to find and solve problems by doing so. Due to the increasing scale of trials and the diversity of participating countries, the method in which all data is verified is time-consuming and costly, but it does not reduce the incidence of quality problems in clinical trials. As such, improvements in this area have been sought. Advances in information technology have also helped the adoption of RBM, as CRFs have shifted to EDC, i.e., from paper to electronic media. This environment enables us to check data in advance. Since the establishment of CMIC's RBM, CMIC has supported more than 10 studies in a wide range of fields and at various development phases, meeting all kinds of needs, including monitoring-led RBM and data management-led RBM. We have already received manufacturing and marketing approval for a project in which CMIC's RBM was implemented. The company has also signed a pilot agreement in May 2021 with Lokavant, which provides solutions for an efficient implementation of RBM using machine learning and has started a joint project.

### Q. Are there any changes in our clients?

A. More and more clients, including domestic and foreign venture companies, are looking to CMIC to guide them through the entire development process. In these cases, our work begins with an introduction to Japanese pharmaceutical regulations. There are an increasing number of international joint clinical trials, etc., where English is required for data collection (CRFs), queries to CRFs\*, provision of materials and Q&A, meetings, and more. In addition, there are an increasing number of overseas companies that do not have offices in Japan among our clients. CMIC serves as an in-country clinical-trial caretaker (ICCC) to carry out various procedures necessary to request clinical trials on behalf of such overseas companies in order to market pharmaceutical products in Japan. In order to respond to these various changes, the CRA works as part of a project team.

**\*Queries:** Inquiries issued to clinical trial institutions due to the finding of inconsistencies in CRF data.