Chugai Introduced Medidata eConsent for obtaining informed consent for clinical trials as part of company-wide DX promotion

AIMING TO STREAMLINE TRIALS AND REALIZE A PATIENT-CENTERED APPROACH THROUGH DIGITAL TECHNOLOGY

- Introduced eConsent in their domestic trial to promote DX and propel patient-centered
- Evaluated affinity with EDC and Medidata's flexible implementation process
- Obtained a certain level of understanding from the clinical trial site and the subjects regarding benefit of eConsent
- Progress can be grasped by visualizing the subject's understanding and consent acquisition status, and informed consent can be obtained efficiently

CHUGAI PROMOTES DIGITALIZATION IN CLINICAL TRIALS IN RESPONSE TO COMPANY-WIDE DIGITAL TRANSFORMATION STRATEGY

In October 2019, Chugai launched its Digital Strategy Department to promote DX across its divisions and its working on digitalization. One of the three basic strategies of the "CHUGAI DIGITAL VISION 2030" is "DxD3: Digital transformation for Drug Discovery and Development". Along with considering and implementing the use of various methods and tools in both the research and development processes, the use of digital technology is also advancing in the clinical trial phase. As one of these efforts, implementation of IT technology for the informed consent process was considered. The Clinical System and Informatics Group of the Biometrics Department of the Clinical Development Division is responsible for promoting the study and implementation of IT systems related to clinical trials. Ms. Hitomi Kitaura, who is in charge of comparing and reviewing systems at Chugai, explains, "In some cases, when implementing a system, each clinical trial is handled individually, but our department is in charge of understanding and managing systems across trials."

Chugai has now introduced eConsent for obtaining informed consent in a Phase 1 study for healthy adults for the first time in the company's domestic trials. In introducing the system, Chugai evaluated, compared, and reviewed the systems of various companies in mid-2021, and started obtaining consent using Medidata eConsent by Medidata in October of the same year. Medidata eConsent is an application of Medidata Clinical Platform, and it allows customers to use it easily like using EDC.

About Chugai Pharmaceutical Co., Ltd.

Chugai Pharmaceutical (Headquarters: Tokyo, Japan) is an R&D-oriented pharmaceutical company with strengths in antibody engineering technology and other proprietary drug discovery technologies.
Chugai is an R&D-oriented pharmaceutical company with strengths in antibody engineering technology and other proprietary drug discovery technologies. As an important member of the Roche Group and a listed company on the prime market of the Tokyo Stock Exchange, Chugai is committed to the discovery of innovative drugs to meet unmet medical needs under independent management.
For more information about Chugai Pharmaceutical, please visit https://www.chugai-pharm.co.jp/.

AIMING TO MEET GLOBAL STANDARDS AND ACHIEVE PATIENT CENTRICITY, CHUGAI STEERED TOWARD THE INTRODUCTION OF ECONSENT

Ms. Kitaura explains how eConsent was adopted, "We would like to digitalize our clinical trials in order to achieve the DX that we are promoting, and the trend toward the introduction of distributed clinical trials (DCT) due to the COVID-19 pandemic also encouraged us to adopt eConsent." Until now, explanation for patients, informed consent, and outcome reporting had all been done in-person and on paper, but the pandemic made it difficult for patients to come to the clinical trial sites. Therefore, DCT, which allows patients and sites to do some or most of the processes remotely, has attracted attention, and such circumstances have provided a tailwind for the company's digital promotion. The underlying concept is that of "Patient Centricity," which has become more prevalent than ever in recent years –Chugai has also been focusing on how Patient Centricity should be adopted to clinical trials. "We believe that digitalization will make clinical trials more efficient and allow us to deliver drugs to patients faster. Also, by understanding the true needs of patients, we will be able to develop drugs and treatments that are truly meaningful for patients," explains Ms. Kurata Masako, Group Manager of the Clinical System and Informatics Group at Chugai.

That Chugai is a member of the Roche Group is another reason for the introduction of eConsent. The Roche Group has already been using electrical consent (eConsent) globally for several years, and Roche had mentioned the possibility of introducing it in Japan in the past. In response to it, Chugai initiated a challenge of using eConsent to follow the global tide and to identify the possibility of eConsent in Japan in terms of regulations and operations, since there are differences in the regulatory situation or concerns about the process.

THE REASONABLE PROCESS AND FLEXIBILITY WERE DECISIVE FACTORS OF MEDIDATA ECONSENT

Chugai evaluated the process and flexibility of Medidata in a short timeframe of two and a half months from system implementation to Go Live. The ICF needed to be approved by the Institutional Review Board (IRB), the actual materials and content had to be prepared in advance, and also since obtaining consent is the first process in a clinical trial, sponsor needed a smooth introduction in a short period of time so as not to impact the start and overall schedule of the trial.

Product experts and project management from Medidata provided support as a single team. The fact that they were able to efficiently respond to questions about functionality and make the necessary preparations before the start of the trial in parallel led to a smooth implementation. "In fact, we had considered eConsent in the past, but had to abandon it because we could not meet the schedule for starting the test. Medidata was flexible enough to accommodate our expected timing, so we were able to go live without incident," said Ms. Kitaura.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, 2,000+ customers and partners access the world's most trusted platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: FR0014003TT8, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at www.medidata.com and follow us @Medidata.

The other reason Chugai achieved to implement in a required timeline is that the company had video explaining consent. Since Chugai had been considering the use of eConsent for the study for some time, they had created their own video before they planned the implementation.

Additionally, system compatibility and functionality with Medidata Rave EDC was a key factor of their decision because Rave EDC is already widely used in clinical trials.

ACHIEVED VISUALIZING SUBJECTS' COMPREHENSION LEVEL AND THE PROGRESS OF CONSENT, AND PATIENT FRIENDLINESS SIMULTANEOUSLY

Generally, the introduction of a new tool or system requires acceptance by sites conducting clinical trials, but Chugai has received a certain level of understanding as DCT has become popular, and there have been no negative reactions to it. Chugaihad conducted interviews with several sites regarding eConsent prior to the introduction of this system, and many of them expressed interest in electrical consent rather than paper. As well as sites, through the survey Chugai conducted regarding the reaction of the subjects also gave positive feedback such as "It was easier to read than paper" and "eConsent is enough to do informed consent as the same as I do with paper." The visibility of the documents and the ability to easily identify the signature line were also highly evaluated about the video itself.

Unlike the company's original plan, paper-based consent was also used in this study, but Chugai took this as a good opportunity to compare paper and eConsent, which was also a positive experience for the company. Ms. Kitaura added, "This was Phase 1, so we were targeting healthy adult subjects who were relatively familiar with digital technology, but it was good to get a good impression of eConsent in comparison to paper. Another benefit of implementing eConsent was the ability to visualize the status of the consent acquisition process, as the dashboard functionality allows the user to check the progress and comprehension of the subjects. Although there are still improvements to be made in the use of the tool and its benefits still need to be emphasized, this experience has given us confidence that eConsent can be used for trials in Japan."

CONSIDER USING ECONSENT IN FUTURE CLINICAL TRIALS CONTINUOUSLY DEPENDING ON THERAPEUTIC AREA AND DURATION

"We are sure the benefits of eConsent is that the common parts of trials can be summarized in a video and can be used for general purposes, and progress can be managed on a dashboard, but we received the feedback that it takes longer time to have done the entire informed consent process. In the case of Phase 1 like we did for this time, we need to adjust the process because multiple subjects can be gathered and be explained at the same time, and everyone can proceed in the same way – rather than explaining to each one. This is the first time we have experienced this, so there are many things that need to be improved in the future, and I would like to be able to feel the benefits of digitization more." Ms. Kitaura says. Regarding the future use, she added, "It is necessary to consider various things such as the target therapeutic area, the characteristics of the trial, the IT literacy of the sites and the patients when we plan to execute trials with eConsent." She showed a positive stance toward continued use of the eConsent, as she certainly sees the path to eConsent trials. In the future, they plan to work on further enhancing video content and improving the process.

In many trials, since informed consent process by paper is not a major problem, it's a bit difficult to change all trials to eConsent studies drastically for now. But Chugai will continue to challenge the status quo with the use of eConsent by leveraging their experience. Regarding eConsent in local clinical trials, clear guidance from the regulatory authorities is awaited. It is hoped that adoption of eConsent to local trials will be accelerated by the establishment of regulatory compliance in Japan, following Europe and the United States. In addition, Chugai is considering the use of DCT platform and sensor devices, showing a glimpse of how Chugai will lead the industry in digitalizing all aspects of clinical trials.