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CASE STUDY

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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/>.



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