

Cancer Gene Panel Test handled by Chugai
Pharmaceutical Co., Ltd.

Explanation Document on Procedures for Requesting Sequence Data

Innovation all for the patients



CHUGAI PHARMACEUTICAL CO., LTD.



Roche Group

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1. Introduction

This document describes the procedure for requesting sequence data obtained in the process of the following cancer gene panel test you have received, which is handled by Chugai Pharmaceutical Co., Ltd.

Product Name
FoundationOne® CDx Cancer Genomic Profile

Procedures for requesting sequence data are established in accordance with the Act on the Protection of Personal Information. Applicants applying for the provision of sequence data are requested to read this document carefully before applying.

2. Request for Genomic Data

There are two types of genomic data created in the course of a test that can be requested.

1. Analysis data

Data containing your genetic mutation information, etc. in the form of a XML file

2. Sequence data

String representation of your DNA Data in the form of a BAM file

1. In case of request your analysis data

Please contact the medical institution where you had the test.

2. In case of request your sequence data

Since the sequence data are owned by Foundation Medicine, Inc. (“FMI” hereinafter) in the United States, Chugai will handle the procedures with FMI on behalf of you. This document explains the details of the procedure.

All of the above data is provided for research use only, and is neither considered to be part of the cancer gene panel test you have received, nor intended for actual clinical use, including the predicting efficacy of treatment.

Notes

Viewing sequence data requires specialized software and genetic information analysis expertise. Please note that it is not intended to be operated or viewed on a general Personal computer. The provision of proprietary software is not included in this request, and such software may not be provided by our company.

3. Application and Provision Method of Sequence Data

After the report on your test result is completed, the Applicant or Proxy may request sequence data through this procedure.

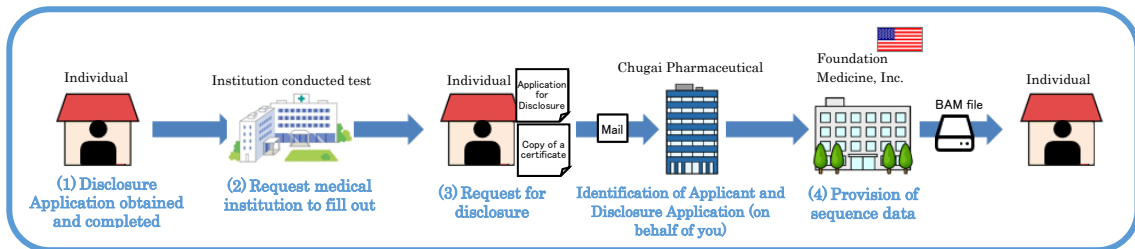


Figure 1: Application flow diagram of sequence data

Application for disclosure of sequence data (Figure 1: (1)-(3))

Please access "Handling of personal information" on the Chugai Pharmaceutical website to obtain the form of Application for Disclosure of Sequence Data.

Handling of personal information: Application procedures for disclosure, etc.:

<https://www.chugai-pharm.co.jp/english/rule/Privacy/index.html#sec07>

Please fill out the needed items on (A) Application for Disclosure of Sequence Data, attach (B) Documents for Identification of the Applicant, and send them to the following the contact.

2-1-1, Nihonbashi Muromachi, Chuo-ku, Tokyo 103-8324

Personal Information Protection Promotion Secretariat, Chugai Pharmaceutical Co., Ltd.

(1) Application for Disclosure of Sequence Data

Please fill out the Applicant section and sign. Also, ask Healthcare professionals in a medical institution ordered your test on the Medical Institution section. In addition, if the application is made by proxy, please fill out the Proxy section in addition to the Applicant section and sign by both the Proxy and Applicant. Provided, however, that only if it is difficult for the Applicant to sign, consent of the Applicant is deemed to have been obtained with the signature of Proxy.

Supplementary information

FMI will leverage the "JRF No." to identify your test, written by your Healthcare professionals in a medical institution.

(2) Documents for Identification of the Applicant

Application Pattern	Document to be Prepared
Request by Applicant	One copy of driver's license, passport, or an original copy of the certificate of residence * Answer to the application for disclosure, etc. will be sent to the address indicated on the copy of an official certificate. Please note in the case of an address change.
Application by Proxy	Request by a statutory agent of a minor or an adult ward Please fill out the Proxy section and enclose the following documents in addition to the above Documents for Identification of the Applicant. <ul style="list-style-type: none">• One copy of family register• One copy of driver's license, passport, or an original copy of the certificate of residence of the Proxy
	Request by authorized agent Please fill out the Proxy section and enclose the following documents in addition to the above Documents for Identification of the Applicant. <ul style="list-style-type: none">• One authorization letter signed and sealed by the Applicant URL: https://www.chugai-pharm.co.jp/english/rule/Privacy/files/proxyForm.pdf• One copy of a seal registration certificate of the Applicant• One copy of driver's license, passport, or an original copy of the certificate of residence of the Proxy

Supplementary information

Personal information obtained through this process will only be leveraged for the required procedure, and as soon as this procedure is completed, documents for identification of the individual shall be destroyed.

Provision of sequence data (Figure 1: (4))

Approximately one month after identification of the Applicant, FMI will send a storage medium containing sequence data directly to the address indicated on the copy of a public certificate. However, in case we cannot send the data physically, we may contact you via the email address you provided regarding how to retrieve sequence data.

4. Contact for Inquiries

If you have any questions, please contact the following the Chugai Personal Information Inquiry Form.

Chugai Personal Information Inquiry Form:

<https://www.chugai-pharm.co.jp/enquete/q28/>