

Questionnaire on the development of new drugs

This survey is conducted to help us discuss the rules under which a pharmaceutical company uses patient information held by a hospital. Some of the questions may be difficult to respond to, but we would appreciate your candid views.

Thank you very much for your cooperation.

* This survey is conducted by the National Cancer Center Hospital using a grant from the Japan Agency for Medical Research and Development (“Research into the promotion of the clinical innovation network initiative by means of effective use of a disease registration system”).

Please answer each of the following questions regarding the process through which a new drug is developed.
Please choose the answer that is most applicable.

A-1 Have you heard of the term “clinical trial”?

1. Yes
2. No

A-2 Have you ever participated in a clinical trial?

1. Yes
2. No
3. Cannot remember

B-1 How much do you think it costs, in total, to develop a newly discovered drug candidate into a new drug to be used in treatment?

1. Less than 100 million yen
2. More than 100 million but less than 1 billion yen
3. More than 1 billion but less than 10 billion yen
4. More than 10 billion yen

B-2 How long do you think it takes to develop a newly discovered drug candidate into a new drug to be used in treatment?

1. Less than one year
2. More than one year but less than five years
3. More than five years but less than ten years
4. More than ten years

B-3 How many substances do you think must be investigated to develop a newly discovered drug candidate into a new drug to be used in treatment?

1. Approximately 10 substances
2. Approximately 100 substances
3. Approximately 1,000 substances
4. More than 10,000 substances

Now we would like to ask you about the system and structure of medicine and research that use patients' patient records.

Here, *patient record* refers to information that the doctor writes in the medical record when a patient seeks medical attention at a hospital, including information concerning diagnosis and treatment (e.g., disease name, treatment process, and test data).

Please choose the answer that is most applicable.

C-1 Are you aware that in Japan, various types of medical research are currently conducted using patients' patient records that is held by hospitals?

1. Yes, I am aware
2. No, I am not aware

C-2 Are you aware that in Japan, medical research is currently conducted using patient records held by hospitals without seeking the patients' consent?

1. Yes, I am aware
2. No, I am not aware

C-3 Are you aware that in Japan, there is currently no specific law regarding conducting medical research using patient records besides the Personal Information Protection Act?

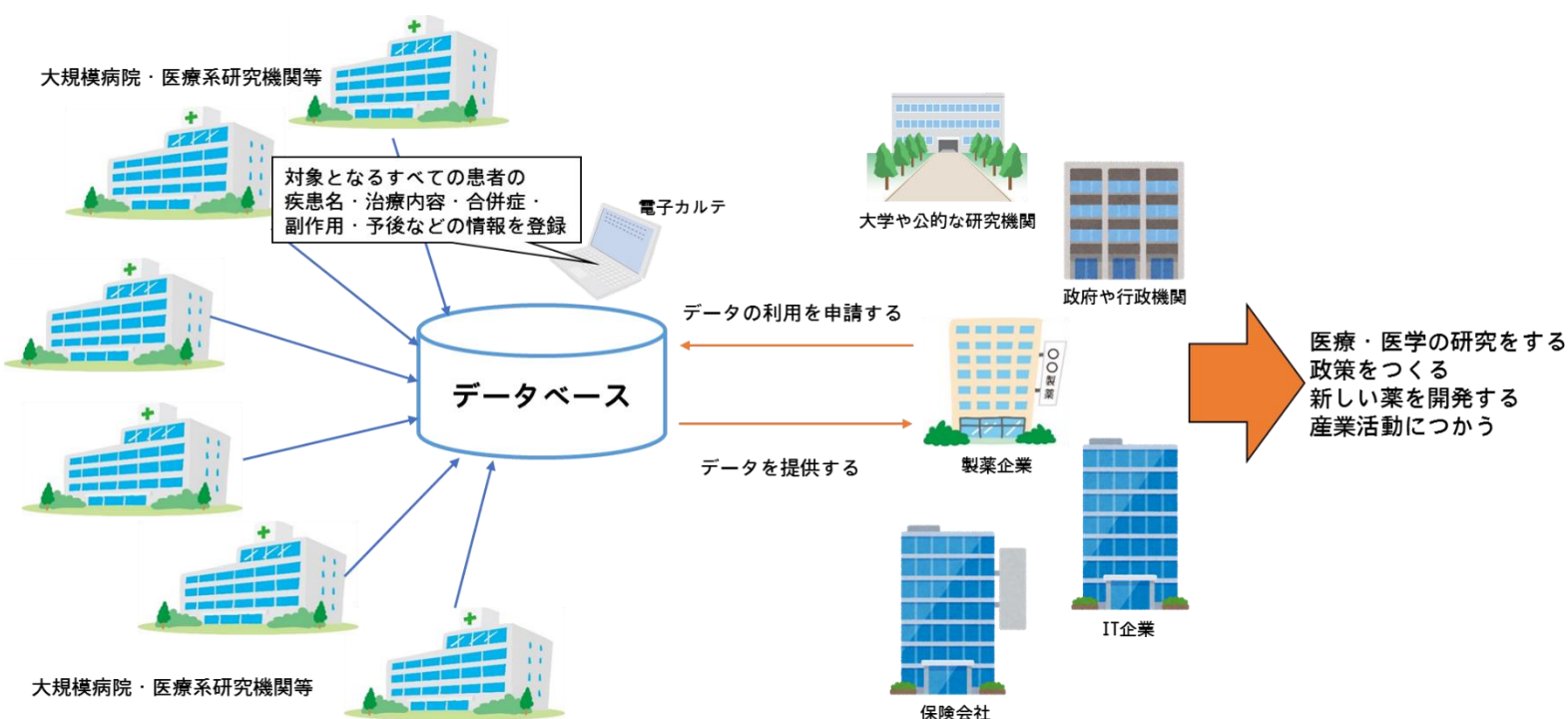
1. Yes, I am aware
2. No, I am not aware

C-4 Are you aware that pharmaceutical companies are legally obligated to keep records on the incidents of side effects occurring in patients using drugs that these companies have developed and sold?

1. Yes, I am aware
2. No, I am not aware

Currently in Japan, efforts are being made to build a database by collecting patient records from hospitals across the country to allow universities and companies to use data for various purposes.

When material is stored in the database, all information which can identify the patient, such as names and photos, is removed.



To what extent do you think it is useful for society to use patient records held by hospitals for the following purposes? Please choose the answer that is most applicable.

D-1 When universities and public research institutes use patient records to make scientific discoveries that lead to future development of medical treatment and medical science

1. I think it is very useful for society
2. I think it is useful for society
3. I do not think it is very useful for society
4. I do not think it is useful for society at all
5. I do not know if it is useful for society

D-2 When universities and public research institutes use patient records to produce research findings that lead to economic development in collaboration with companies

1. I think it is very useful for society
2. I think it is useful for society
3. I do not think it is very useful for society
4. I do not think it is useful for society at all

5. I do not know if it is useful for society

D-3 When the government and local authorities use patient records to draft policies regarding medical treatment and health

1. I think it is very useful for society
2. I think it is useful for society
3. I do not think it is very useful for society
4. I do not think it is useful for society at all
5. I do not know if it is useful for society

D-4 When pharmaceutical companies use patient records to develop or evaluate new drugs

1. I think it is very useful for society
2. I think it is useful for society
3. I do not think it is very useful for society
4. I do not think it is useful for society at all
5. I do not know if it is useful for society

D-5 When information technology (IT) companies use patient records to develop health-related applications (applications patients use on their smartphones to manage or promote their own health)

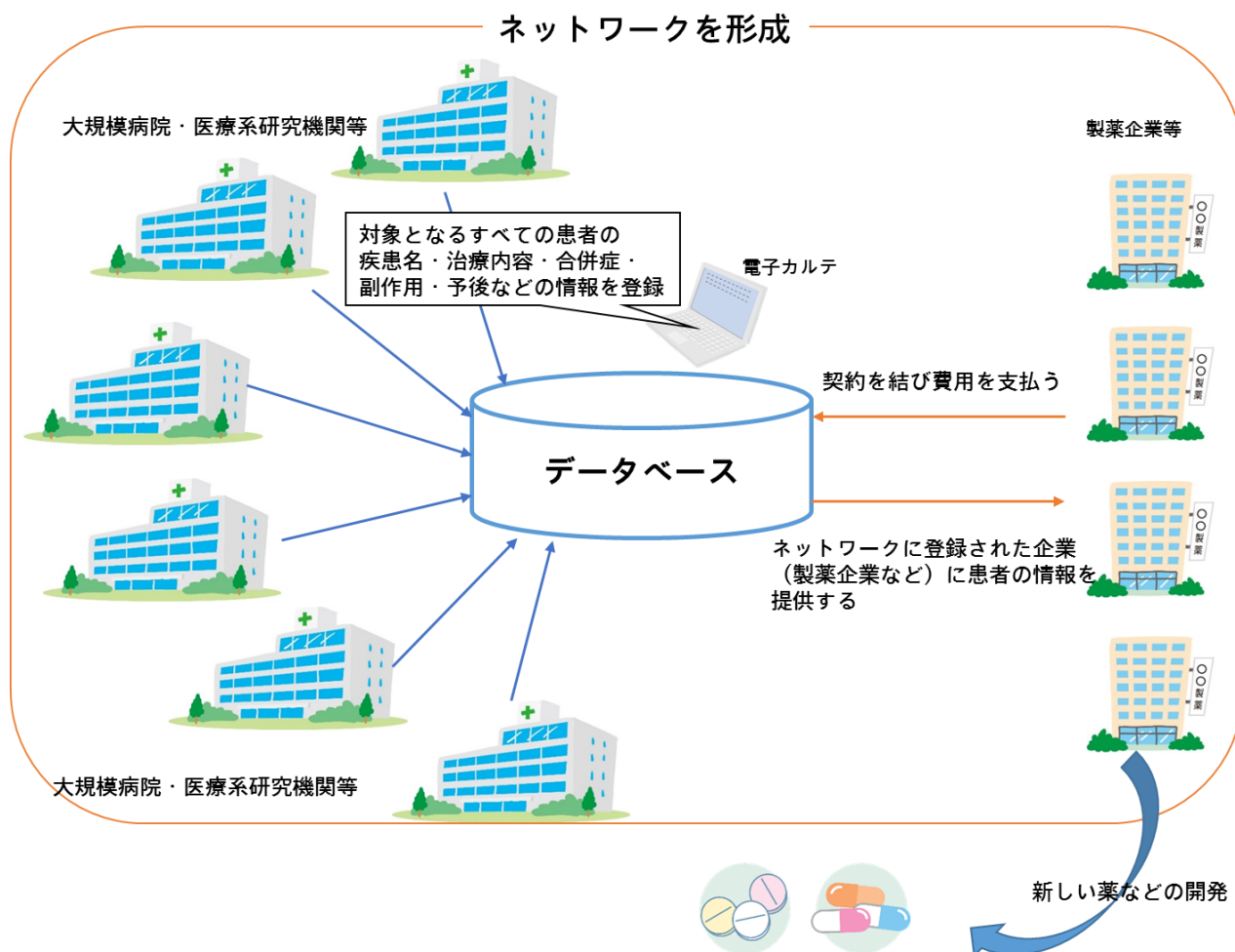
1. I think it is very useful for society
2. I think it is useful for society
3. I do not think it is very useful for society
4. I do not think it is useful for society at all
5. I do not know if it is useful for society

D-6 When insurance companies use patient records to determine the price of insurance products related to medical treatment and care

1. I think it is very useful for society
2. I think it is useful for society
3. I do not think it is very useful for society
4. I do not think it is useful for society at all
5. I do not know if it is useful for society

Currently, efforts are being made to build a system to facilitate the efficient use of patient records collected from hospitals across the country to allow pharmaceutical companies to better conduct clinical trials to develop new drugs and collect information regarding the safety of drugs presently in use (see the figure below). To what extent do you think the use of patient records by a pharmaceutical company is useful for society? Please choose the answer that is most applicable.

For your information, *clinical trials* are conducted in the process of developing a new drug and refer to research in which real patients are asked to take the drug being developed so that its safety and efficacy can be examined.



6.

D-7 When a pharmaceutical company develops a new drug in Japan, it uses patient records to determine the number of patients diagnosed with the target disease and the areas in which they live (i.e., the disease's distribution)

1. I think this is very useful for society
2. I think this is useful for society
3. I do not think this is very useful for society
4. I do not think this is useful for society at all
5. I do not know if this is useful for society

D-8 When a pharmaceutical company develops a new drug, it uses patient records to look for patients to enroll in clinical trials

1. I think this is very useful for society
2. I think this is useful for society
3. I do not think this is very useful for society
4. I do not think this is useful for society at all
5. I do not know if this is useful for society

D-9 When a pharmaceutical company develops a new drug and would like to confirm its efficacy by comparing the patients who use it and those who do not, it utilizes patient records to collect data on people who do not use the new drug

1. I think this is very useful for society
2. I think this is useful for society
3. I do not think this is very useful for society
4. I do not think this is useful for society at all
5. I do not know if this is useful for society

D-10 A pharmaceutical company uses patient records to collect data concerning side effects and other information regarding a drug that is currently used in treatment

1. I think this is very useful for society
2. I think this is useful for society
3. I do not think this is very useful for society
4. I do not think this is useful for society at all
5. I do not know if this is useful for society

E-1 Do you think that when an insurance company uses patient records held by hospitals in determining the price of insurance products related to medical treatment and care, it should seek to obtain patient consent? Please choose the answer that is closest to your view.

1. Any policy will suffice.
2. It should be able to use patient records without patient consent.
3. Each patient should be given a leaflet or information sheet which clearly states that his or her patient records could be used, and a system should be in place that allows patients who do not want their patient records used to contact the person in charge.
4. As the purpose for each use of patient records is determined, it should be communicated widely through the hospital's web page or message board and a system should be in place that allows patients who do

not want their patient records used to contact the person in charge.

5. First, consent should be obtained regarding the possible use of patient records, and later, as the purpose of each use is determined, it should be communicated widely through the hospital's web page or message board. A system should be in place that allows patients who do not want their patient records used to contact the person in charge.
6. Each time the purpose of using patient records is determined, the insurance company should contact patients and seek consent by explaining how the information would be used.
7. Regardless of providing notice to patients, patient records should not be used.

[If Response 1, 2, 3, or 4 was chosen in E-1, please proceed to E-5.]

E-2-1 Please answer if you chose Response 5 in E-1. Why do you think so? Please choose the two statements that are most applicable.

1. How patient records are used should be decided by the patient himself/herself
2. I would want to know how the information would be used by an insurance company
3. I am unsure about how the hospital manages patient records
4. I would like to have an opportunity to receive an individualized explanation regarding the planned future use by medical professionals

If only one option applies, or if there is no applicable option, please write your response in the space below.

Other ()

E-2-2 Please answer if you chose Response 6 in E-1. Why do you think so? Please choose the two statements that are most applicable.

1. How patient records are used should be decided by the patient himself/herself
2. I would want to know how the information would be used by an insurance company
3. I am unsure about how the hospital manages patient records
4. I cannot be persuaded to contact the person in charge
5. I would like to have an opportunity to receive an individualized explanation regarding the planned future use by medical professionals
6. Finding where research outlines are published seems difficult

If only one option applies, or if there is no applicable option, please write your response in the space below.

7. Other ()

E-3 Please answer if you chose either Response 5 or 6 in E-1. Under what conditions do you think an insurance company should be allowed to use patient records without being required to obtain patient consent? Please choose all that apply. If you think an insurance company should not be allowed to use

patient records without patient consent, please choose **Response 10 only**.

1. A system is established that prevents the insurance company from using patient records obtained from the hospital for other purposes
2. Patient records are processed in such a way that the patient cannot be traced from the data
3. There are stricter penalties when the insurance company uses patient records for other purposes
4. The insurance company stores patient records safely
5. It is clear that patient records are used for purposes that are useful for society
6. An independent committee including ordinary citizens and lawyers examines the purpose of use
7. Governmental institutions or regulatory authorities conduct an audit on how patient records are used
8. Make any use of patient records to advertise for a specific product or to promote sales illegal under any circumstance
9. Place an upper limit to the size of economic benefits the insurance company can obtain from using patient records
10. Regardless of provisions, the insurance company should not use patient records if patients do not provide consent
11. Other ()

E-4 Please answer if you chose Response 10 in E-3. Why do you think so? Please choose the statement that is most applicable.

1. I do not think that an insurance company can safely store data
2. It is not fair that if patient records are provided to an insurance company, it could be tampered with to benefit the company
3. There may be disadvantages for the patients and/or their families in the future (e.g., leaking patients' medical histories)
4. Even if name and address are removed from patient records, an individual could still be identified
5. There may be disadvantages for groups of people with certain characteristics (e.g., those with specific illness might be denied insurance coverage)
6. There is no law for penalizing insurance companies, even if they wrongfully use patient records
7. Other ()

E-5 Currently, efforts are being made to build a system to allow patient records to be used widely in society. As part of these efforts, a law has been passed that allows organizations which are accredited by the government (accredited organizations) to collect patient records from a hospital and provide it to pharmaceutical companies and research institutions after processing it in such a way that the individual patient cannot be traced.

Do you think when a hospital provides patient records to an accredited organization, it should seek the patient's consent? Please choose the statement that is most applicable.

1. Any policy will suffice.
2. A hospital should be able to provide patient records to an accredited organization without the patient's consent.
3. A hospital should publish the relevant details on its message board or web page so the patient can view them beforehand. If this has been done, the hospital should be able to provide patient records to an accredited organization.
4. A hospital should inform the patient of the relevant details beforehand by means of a leaflet. If the patient does not refuse for his or her data to be released, then the hospital should be able to provide patient records to an accredited organization.
5. A hospital should contact the patient beforehand and explain the details face-to-face. If the patient provides consent after the consultation, then the hospital should be able to provide patient records to an accredited organization.

E-6 **Please answer if you chose Response 5 in E-5.** As in Response 4 in E-5, the law stipulates: "A hospital should inform the patient of the relevant details beforehand by means of a leaflet. If the patient does not refuse for his or her data to be released, then the hospital can provide patient records to the accredited organization."

Do you think the law should be amended to adopt the policy expressed in Response 5 (e.g., to provide that "A hospital should contact the patient beforehand and explain the details face-to-face. If the patient provides consent after the consultation, then the hospital can provide patient records to an accredited organization,") in the near future? Please choose the statement that is most applicable.

1. Very much so
2. I think so
3. I do not think so
4. I do not think so at all
5. I do not know

F 【Face sheet: 7 questions】

Last, please tell us about yourself

F-1 How old are you?

Years old

F-2 Please tell us your gender (Please choose only one)

1	Male	2	Female
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F-3 What was your household income last year (annual income/before deduction)? (Please choose one)

- | | |
|---|--|
| 1 Less than 3 million yen | 6 More than 10 million but less than 12 million yen |
| 2 More than 3 million but less than 4 million yen | 7 More than 12 million but less than 15 million yen |
| 3 More than 4 million but less than 6 million yen | 8 More than 15 million but less than 20 million yen |
| 4 More than 6 million but less than 8 million yen | 9 More than 20 million but less than 30 million yen |
| 5 More than 8 million but less than 10 million yen | 10 More than 30 million yen |

F-4 How many people are currently in your household, including yourself? If someone is living somewhere else temporarily, please exclude them. If you live on your own, please choose “1 person.” (Please choose one).

1. 1 person
2. 2 persons
3. 3 persons
4. 4 persons
5. 5 or more persons

F-5 Have you visited the hospital (including being hospitalized) within the past year? (Please choose one)

- | | |
|---|---|
| 1 I am in the hospital now | 4 I have visited the hospital in the past year |
| 2 I have visited the hospital in the past three months | 5 I have not visited the hospital in the past year |
| 3 I have visited the hospital in the past six months | |

F-6 Do you have any family members who have been hospitalized for more than a week in the past year? (Please choose one)

1 Family member(s) currently hospitalized	4 Family member(s) hospitalized in the past year
2 Family member(s) hospitalized in the past three months	5 No one was hospitalized in the past year
3 Family member(s) hospitalized in the past six months	

F-7 What is the highest level of education you have completed? (Please choose one)

- 1 Junior high school
- 2 High school (junior high school, under the old system)
- 3 Technical college/specialist college
- 4 Junior college
- 5 University (high school, under the old system)
- 6 Graduate school