# 24th Intercollegiate Negotiation Competition Problem
## September 16 Version

1. Negoland is a developed country with a population of approximately 50 million people and a nominal GDP of about 850 billion US dollars. The country is known for its advanced science and technology and for the industries that make use of them. In particular, a large number of start-up companies that attract worldwide attention have emerged in fields such as IT and AI. Negoland is a society that respects the dignity of the individual and places importance on freedom of expression, freedom of thought, and freedom of religion. In education, it has placed emphasis on mathematics and foreign language education, as well as on fields such as engineering and economics that are useful for practical business. In addition, many companies are proactive in technological innovation, and a common corporate culture in Negoland is to take on new technologies and business opportunities actively and with speed, while managing risks to a certain extent.
2. The medical system of Negoland is based on a public basic insurance scheme that covers standard medical care and in which all citizens are enrolled. In addition, individuals may voluntarily join insurance provided by private companies. Some of these private insurance policies are able to cover the costs required for advanced medical care. The general tendency of Negoland's industries to proactively engage in technological innovation by utilizing advanced science and technology also applies to the medical field. Telemedicine using ICT technology and the utilization of AI in healthcare have spread throughout the country, and outcome-based payment of medical fees has also been approved in relation to certain advanced medical treatments. The Ministry of Health and Medical Care is responsible for supervision in the medical field. The Ministry of Health and Medical Care is actively working on the introduction and promotion of advanced medical care and is proceeding with the revision of laws and the publication of guidance for that purpose. Examples of laws and guidance related to the utilization of advanced medical care in Negoland as of the present are shown in Exhibit 1.
3. Arbitria is one of the world's leading economic powers, with a population of approximately 125 million people and a nominal GDP exceeding 4 trillion US dollars. The country has strengths in manufacturing such as automobiles, electronic devices, and precision machinery, and in recent years it has also been placing emphasis on fields such as renewable energy, robotics, and AI. While respecting the dignity of the individual, the society is rooted in a culture that values order and harmony. In education, importance has been placed on the enhancement of basic academic ability, with particular emphasis on mathematics and science subjects, and at the same time, human resource development has progressed in fields directly connected to practical societal needs, such as engineering, medicine, and economics. In terms of corporate culture, there is a tendency to place importance on long-term stability, while at the same time, in order to respond to international competition, the introduction of new technologies and efforts toward innovation are also being promoted, with an emphasis on the establishment of high standards with respect to quality control and safety.
4. The medical system of Arbitria is based on a public medical insurance scheme that covers the entire

population. Citizens are enrolled in multiple insurers (such as public insurance associations) according to their occupation and place of residence, and everyone can receive a certain standard of medical care with a relatively low burden. In addition, individuals may voluntarily join private insurance to cover advanced medical care and the like that are not covered by public insurance. In the country, aging of the population is rapidly advancing, and the efficient allocation of medical expenses and equalization of medical services have become major policy issues. On the other hand, the introduction of advanced technologies such as robotic surgery, AI diagnostic support, and telemedicine is also being actively considered. The supervisory authority in the medical field is the Ministry of Health and Medical Care. The Ministry, with regard to the regulation and formulation of guidelines concerning the use of advanced medical care and pharmaceuticals, has been gradually undertaking revisions of relevant laws and guidelines concerning the introduction of technology in order to secure the sustainability of the social security system as a whole while incorporating advances in science and technology. Examples of laws and guidance currently related to the utilization of advanced medical care in Arbitria are shown in Exhibit 2.

5. Red Corporation is a start-up company related to AI medical technology with its headquarters in Negoland. It has approximately 600 employees, most of whom are specialists in data science, medical informatics, and software engineering. Although the company is medium-sized, it is characterized by research and development capabilities and rapid market deployment, and it embodies the typical corporate culture and institutional environment of Negoland, namely “to adopt innovations quickly while accepting risks.” The core business of Red Corporation is the AI medical support tool “RedAid.” This tool, when patient symptoms and examination data are entered, has a mechanism by which AI cross-checks them against existing medical knowledge and presents diagnostic candidates and treatment plans. The final responsibility for clinical judgment lies with physicians, but the tool is expected to streamline the diagnostic process, and its use is anticipated particularly for young physicians and in busy hospitals. “RedAid” has already begun to be introduced in multiple hospitals within Negoland and is regarded as a successful case that was launched early into the market by utilizing the country’s sandbox system. Red Corporation is also developing a telemedicine platform business called “RedLink.” This service connects patients and physicians, or hospitals to each other, online, and makes diagnosis and consultation more efficient. Within Negoland, it has gradually spread as a foundation for regional medical care and international joint research, and Red Corporation is also considering expansion into overseas markets. An outline of the business of Red Corporation is shown in Exhibit 3.
6. Blue University is a prestigious private university corporation located in Arbitria, and it possesses both an educational division and an affiliated hospital division. It has received high evaluations domestically and internationally, particularly in the fields of medicine and pharmacology. The university has approximately 3,000 faculty and staff members, of whom 800 are researchers mainly in medicine and pharmacology. The affiliated hospital is a large-scale facility with more than 1,000 beds, and it plays the role as a core institution in regional medical care while also functioning as a center for advanced

clinical research. Blue University reflects the cultural characteristics of Arbitria and adheres to an attitude that prioritizes safety and reliability. When introducing new technologies, its basic policy is to undergo strict ethical review and clinical trials, and only after long-term safety has been confirmed does it proceed to full-scale introduction. In particular, with respect to AI technology and digital healthcare, it upholds a policy of giving utmost importance to the protection of patients' rights and the management of personal information, and thoroughly enforces this human-centered principle. In addition, in recent years Blue University has also been focusing on "medical tourism." By accepting patients from abroad and providing advanced medical services, it aims to enhance its international reputation and strengthen its financial base. The medical tourism division has been growing year by year, and in the future, it is also considering concepts to improve the convenience of foreign patients through the use of AI and ICT. An outline of the business of Blue University is shown in Exhibit 4.

7. The relationship between Red Corporation and Blue University began at the "Clinical AI Symposium" held in Japan in the autumn of 2023. At this international symposium, information exchange and discussions were conducted regarding the latest technologies and devices related to the use of AI in healthcare and examples of their clinical applications. Cases were introduced concerning the utilization of AI in improving the efficiency of triage in emergency outpatient care, reducing oversights in the cardiovascular field, and suppressing readmission rates for respiratory diseases. At this symposium, Red Corporation made a presentation introducing its AI diagnostic support tool, RedAid. The outline of the explanation distributed by Red Corporation concerning the functions and uses of RedAid is shown in Exhibit 5. In addition, Blue University made a presentation concerning the importance of clinical governance and ethical review (IRB/IEC). The summary of the presentation by Blue University is shown in Exhibit 6.
8. The participants from Red Corporation and the participants from Blue University listened to each other's presentations with interest. Red Corporation considered that if an internationally well-known university such as Blue University were to adopt RedAid, the recognition of RedAid would increase, and by making use of the data obtained through the utilization of RedAid by Blue University, RedAid could be further improved. On the other hand, Blue University thought that the introduction of RedAid could contribute to the advancement and streamlining of medical treatment. Therefore, it was decided that at a later date, a representative of Red Corporation would visit Blue University and provide a more detailed explanation regarding RedAid.
9. In November 2023, representatives of Red Corporation visited Blue University and discussed RedAid. In December of the same year, at the Data Governance Committee established within Blue University, technical staff of Red Corporation and persons responsible for the clinical and information divisions of Blue University sat together, and concrete verification work concerning RedAid was advanced. The minutes of the meeting that was conducted as the culmination of the verification work are shown in Exhibit 7.
10. Based on the agreement reached at this meeting, Blue University conducted more concrete technical verification at its internal Data Governance Committee, and at the beginning of 2024, a three-month

PoC (proof of concept) was carried out, and it was confirmed that RedAid demonstrated the functions expected in the environment of Blue University. The PoC report is shown in Exhibit 8. Following this, on April 1, 2024, Red Corporation and Blue University formally concluded a license agreement. The excerpts of the license agreement related to the present problem are shown in Exhibit 9. The excerpts of the model card of RedAid and the risk management plan that were provided by Red Corporation to Blue University at the time of the conclusion of this agreement are shown in Exhibit 10.

11. Immediately after the conclusion of the contract, however, a serious problem arose. On April 15, 2024, Red Corporation officially distributed an important update of RedAid (v3.3.0), introducing improvements that optimized the identification thresholds in the cardiovascular and respiratory modules and reduced the risk of false negatives. This distribution also reached Blue University. The notification of this update is shown in Exhibit 11.
12. On April 18, 2024, a case of patient death occurred in the emergency ward. In this case, a 62-year-old male patient who visited the hospital complaining of chest pain and dyspnea was judged as “low risk” by reference to the AI output of the old version v3.2.1, and inpatient observation was denied. On the following day, the patient suddenly deteriorated and returned to the hospital, but after being transferred to the intensive care unit, he died. The case record concerning this case is shown in Exhibit 12. In view of this case, Blue University suspended the use of RedAid from April 18 and conducted an internal investigation. The draft of the internal investigation report is shown in Exhibit 13. Based on this draft of the internal investigation report, Red Corporation and Blue University held consultations. The record of such consultations is shown in Exhibit 14.
13. Thereafter, this draft of the internal investigation report was leaked externally. The cause of the leak was that a staff member of Blue University mistakenly placed a draft of the internal investigation report in a file accessible to external persons on the university’s website. After one hour, a third party notified the university and it was deleted, but during this time the draft of the report appears to have been viewed or downloaded. Soon thereafter, information quickly spread on social media and in industry journals suggesting that RedAid might have defects. The descriptions in social media and industry journals are shown in Exhibit 15.
14. The report by an external expert appointed by agreement between Red Corporation and Blue University is shown in Exhibit 16. According to this report, it was clarified that no defects were recognized in RedAid after the update, and therefore Blue University resumed the use of RedAid from September 18.
15. Red Corporation asserted that it suffered enormous damage due to the leak of the draft internal investigation report and sent a document demanding compensation for damages to Blue University. This document is shown in Exhibit 17. In response, Blue University sent the document shown in Exhibit 18. Red Corporation and Blue University conducted negotiations concerning this matter, but as the negotiations remained at an impasse and were not resolved, Red Corporation filed a request for arbitration against Blue University. In response, Blue University sought dismissal of the claim of Red Corporation and also made a counterclaim demanding compensation equivalent to the consolation

money paid by Blue University, as explained in Exhibit 18. This case is referred to as the "RedAid Case."

16. Thereafter, another trouble arose between Red Corporation and Blue University. Since around 2023, Blue University had been making preparations with the aim of internationally disseminating its own country's medical standards and becoming a hub for medical tourism in the Asian region. As part of this effort, it planned to introduce an "AI diagnostic support system for medical tourism," in which foreign patients would input their symptoms online before visiting the hospital, and AI would determine the risk in advance. By this means, appropriate pre-triage of visiting patients would become possible, unnecessary travel could be prevented, and patients could also be provided with reassurance.
17. Blue University also turned its attention to Red Corporation, which had gained worldwide recognition in this field. Red Corporation had already deployed the AI diagnostic support tool "RedAid" in multiple countries, and RedAid was also able to provide functionality suitable for medical tourism. Therefore, from December 2024, negotiations were conducted between Red Corporation and Blue University concerning technical feasibility and contractual conditions. Although the RedAid Case had previously occurred between Red Corporation and Blue University, at that time it had already been clarified by the investigation of external experts that no defect was recognized in RedAid, and Red Corporation and Blue University agreed to treat the matter concerning medical tourism separately from the RedAid Case while resolving the RedAid Case through arbitration. The record of such consultations is shown in Exhibit 19. On February 1, 2025, the "Special Agreement on AI Diagnostic Support for Medical Tourism" was concluded. This special agreement is shown in Exhibit 20.
18. After the conclusion of the contract, Red Corporation determined that in order to satisfy the performance requirements demanded by Blue University, i.e., multilingual support in more than ten languages, real-time processing of high-resolution images such as CT/MRI, and connection capacity to withstand simultaneous access of more than 500 cases, it would have to partially use its own contracted high-performance cloud servers in Negoland. When Red Corporation reconfirmed this point with Blue University, a response was received from the Head of the IT Division of Blue University. The exchange between Red Corporation and Blue University regarding this matter is shown in Exhibit 21.
19. From July 15, 2025, Blue University began the use of RedAid related to medical tourism. However, on August 15, 2025, the Audit Division of Blue University, as part of an internal audit, investigated the utilization status of the RedAid system and confirmed that part of the patient data was stored in cloud servers within Negoland. The Audit Division immediately reported to the upper management of the university, and the issue became a major concern throughout the entire university. In response, the IT Division explained that "it was an operational measure to meet performance requirements, and we did not anticipate that it would become such a serious issue." The excerpt of the audit results by the Audit Division is shown in Exhibit 22. Based on the audit results, Blue University, on August 20, sent a formal notice to Red Corporation, ordering the immediate cessation of cross-border data transfers and the return of all data to within Arbitria. This notice is shown in Exhibit 23. In response, Red Corporation replied on August 22 as shown in Exhibit 24. Furthermore, on August 25, Red Corporation

again sent a notice to Blue University as shown in Exhibit 25. In response, on September 5, Blue University replied as shown in Exhibit 26.

20. On September 7, Blue University made a voluntary report to the Personal Information Protection Commission of Arbitria. Based on the notification made by the Personal Information Protection Commission of Arbitria to Blue University, on September 12 Blue University sent the document shown in Exhibit 27 to Red Corporation, and on September 13 the document shown in Exhibit 28 was sent from Red Corporation to Blue University.
21. Therefore, Blue University filed a request for arbitration against Red Corporation, demanding that the cross-border transfer be stopped, that the services under the special agreement on medical tourism of RedAid be continuously provided, and that the penalty which Blue University had been forced to pay under the Personal Information Protection Law of Arbitria be compensated by Red Corporation. At the same time, Blue University filed an application for interim measures ordering that the cross-border transfer be stopped no later than November 30, and that, until the arbitral award is rendered, services be continuously provided. This case is referred to as the "Tourism Case."

＜Round A＞

22. Red Corporation and Blue University agreed to consolidate and hear both the "RedAid Case" and the "Tourism Case," and as a result of consultations with the arbitrators, it was decided to conduct an oral hearing on November 15. It was also agreed, as a result of organizing the issues together with the arbitrators, that the issues to be heard on November 15 would be those shown in Exhibit 29.

＜Round B＞

23. The present negotiation is to be conducted between Red Corporation, an AI medical technology company located in Negoland, and Blue University, a prestigious private university in Arbitria. In relation to Round B, the background information set forth in Paragraphs 1 through 7 of this Problem shall apply, but the problem text from Paragraph 8 onwards shall not apply.
24. Red Corporation intended to further improve the accuracy of its core product, the AI medical support tool “RedAid,” in particular so that it could also respond to rare diseases, elderly patients, and patients with multiple complications. However, it lacked the large-scale and diverse clinical data required for this purpose. Therefore, it came to have a strong interest in collaboration with Blue University, which is internationally renowned and possesses abundant clinical data. On the other hand, Blue University, in order to further enhance its international presence, sought to conclude a joint research agreement with a company possessing high technological capability. In addition to the publication of academic results and the securing of research funds, it also wished to connect this to the advancement of medical treatment in the clinical field, and thus felt attraction to partnership with Red Corporation, which has strengths in AI medical technology.
25. As a result of discussions between the representatives of both parties, two projects came to be seen as possible areas of collaboration. The parties met at an international symposium held in Japan in the spring of 2025, and the decision was made to actively proceed with consultations focusing on the two projects described below.
    1. Negotiation of a Joint Research Agreement
        ① The creation of a framework for joint research aimed at improvement of RedAid;
        ② The attribution of ownership of intellectual property rights and method of publication of research results; and
        ③ The determination of the scope of data provision and sharing of costs.
    2. Introduction of the telemedicine platform “RedLink”
        ① Proposal as a new business to be promoted by Red Corporation;
        ② Merits in regional medical collaboration and formation of international networks; and
        ③ Risk management such as regulations on cross-border transfer of patient data, use of cloud services, and the allocation of burden and responsibility of physicians
26. The minutes of the meeting at which the representatives of both parties gathered and discussed these projects are shown in Exhibit 30. Based on the discussions on that occasion, negotiations will be held on November 16 to decide further details of the two projects. From Red Corporation, the Vice President, the Chief Technology Officer, the Head of the Legal Department, and others are scheduled to participate in the negotiations, and from Blue University, the Vice President, the Head of the Clinical Governance Division, the Head of the Legal Department, and others are scheduled to participate.

**Exhibit 1**

## Examples of Laws and Guidance in Negoland

1. **Medical Device Act**

- **Outline of the System**
  For the clinical use and sale of new medical devices, approval of the Ministry of Health and Medical Care is required. Applications must be accompanied by detailed materials such as clinical trial data, manufacturing processes, and quality control systems.
- **Normal Approval Process**
  Review normally requires about 12 to 18 months. However, mechanisms have been established to utilize online review tools and electronic applications between applicants and the regulatory authority, and the efficiency of review is high.
- **Advanced Framework**
  A "sandbox system" has been introduced. For devices that are recognized by the Ministry of Health and Medical Care as advanced medical devices, the review period is shortened to about 6 to 9 months, and they may be conditionally placed on the market. Clinical use is permitted in limited markets (rare diseases, urgent medical needs, etc.) while additional data is collected at the same time.
- **Characteristics**
  A large number of start-up companies have been utilizing this system to introduce AI diagnostic devices and remote monitoring devices. While a certain degree of failure and risk is tolerated, the environment is such that improvements progress rapidly through quick feedback.

2. **Personal Information Protection Act**

- **Outline of the System**
  Medical records, test values, images, genetic information, disease history, insurance claim information, and the like are subject to special regulations as "medical personal data." The collection and use of such data requires the consent of the individual, but use for research and development is permitted on the condition that it does not cause undue harm to the individual.
- **Cross-border Transfer**
  With respect to anonymized data, cross-border transfer is possible without the consent of the individual. With respect to non-anonymized data, the consent of the individual is required. Even transfer to countries whose level of personal information protection is not equivalent to that of Negoland is possible if certain protective measures are taken by contract.
- **Research Use**
  Use of data for AI learning and international joint research is positively encouraged. Data sharing with cloud service providers and overseas research institutions is widely permitted.

- **Characteristics**

  Negoland's policy is to prioritize "the promotion of innovation through the use of data," and although the protection of personal information is necessary, regulation tends to be flexibly interpreted so as not to become a factor hindering innovation.

3. **Guidance on AI in the Medical Field (Ministry of Health and Medical Care)**

- **Responsibilities of Developers**

  In the development of medical devices using AI, it is necessary to prepare a "model card" describing the purpose of use, intended users, outline of training data, known biases, performance and limitations, and security vulnerabilities. However, the level of description is relatively concise, and "ensuring transparency" is emphasized over detailedness.

- **Response of Medical Institutions**

  The decision whether or not to actually use it in the medical field is made by medical institutions with reference to the model card. After introduction, medical institutions are under a duty of effort to monitor whether performance deterioration occurs.

- **Clinical Judgment**

  As a general rule, physicians bear final responsibility, but diagnosis or treatment decisions by AI alone are also permitted within the scope judged by medical institutions as acceptable risk.

- **Characteristics**

  Depending on the judgment of medical institutions, AI can be utilized with flexibility not only as "assistance" but also as a "quasi-autonomous tool."

**Exhibit 2**

## Examples of Laws and Guidance in Arbitria

1. **Pharmaceuticals and Medical Devices Act**

- **Outline of the System**
  This is the basic law regulating the approval and distribution of pharmaceuticals and medical devices; and for the sale of new medical devices, the approval of the Ministry of Health and Medical Care is essential.
- **Normal Approval Process**
  Review normally requires more than 18 months. The materials to be submitted for review are voluminous, and in addition to clinical trial data, long-term safety and details of the manufacturing process are also emphasized.
- **Advanced Framework**
  For advanced medical devices, there is the "Sakigake Designation System" (review within about 12 months) and the "Conditional Early Approval System" (approval within about 9 months with conditions such as being limited to use in restricted cases), but their scope of application is limited and the number of cases of use is few. A broad early introduction system such as a sandbox does not exist.
- **Characteristics**
  A culture of "not allowing failure" exists in administration in general, and is reflected in the system. Market introduction of new technologies is slower, but the basic policy of the government is to prioritize citizen safety and reliability.

2. **Personal Information Protection Act**

- **Outline of the System**
  Medical data (medical records, test values, images, genetic information, disease history, insurance claim information, and the like) is regarded as "sensitive personal information" and is subject to particularly strict regulation. In collection and use, specification of the purpose of use and obtaining the consent of the individual are mandatory.
- **Cross-border Transfer**
  Transfer of medical data is permitted only to countries that have been certified by the personal information protection authority of Arbitria as having systems of personal information protection equivalent to that of Arbitria, and when transferring, it is necessary to make contractual arrangements with the related parties necessary to realize the protection of the personal information. Negoland is not included in the scope of the above certification.
- **Research Use**
  What may be used for AI learning or international joint research is limited to information that does

not identify the individual (information processed so that identification of the individual is impossible, and information that does not identify the individual unless collated with other information). In the case of use of overseas cloud services or cross-border transfer for joint research with overseas research institutions, it is necessary to obtain the consent of the individual in each case.

- **Characteristics**

  The level of personal information protection is strict even from an international perspective, and while it supports citizens' sense of security, there are also criticisms that it lacks flexibility for research and business operators.

3. **Guidance on AI in the Medical Field (Ministry of Health and Medical Care)**

- **Responsibilities of Developers**

  In the model card, it is required to describe in detail the biases of the training data, the performance limitations, the failure modes, and the security measures. The level of description is not formalized but requires a level at which practical verification is possible.

- **Response of Medical Institutions**

  Before introducing medical devices using AI, medical institutions are obligated to conduct strict validation from clinical, technical, and operational perspectives, and to record the details of such validation. After introduction, they are also obligated to conduct performance monitoring and re-evaluation at least once a year.

- **Clinical Judgment**

  All final responsibility in clinical practice must always be borne by physicians or other professionals. Diagnosis or treatment decisions solely by AI are prohibited.

- **Characteristics**

  The basic idea is that AI is positioned only as an "auxiliary tool," and the human-centered principle is thoroughly enforced.

**Exhibit 3**

**Outline of Red Corporation**

- **Establishment:** 1975
- **Head Office:** Negonego City, Negoland
- **President:** Hiromi Red
- **Status:** Joint-stock company under the laws of Negoland (unlisted)

**Trends in Sales and Profits (Unit: Million USD)**

| Fiscal Year | Sales | Operating Profit | Net Profit | Remarks |
|---|---|---|---|---|
| 2022 | 120 | 12 | 8 | Period of trial introduction of "RedAid" in domestic market |
| 2023 | 160 | 18 | 12 | Expansion of use through utilization of sandbox system |
| 2024 | 200 | 25 | 17 | Start of overseas expansion, strengthening of cloud collaboration |

**Performance by Business Division (FY2024)**

| Division | Sales (Million USD) | Characteristics |
|---|---|---|
| AI Medical Support Tool "RedAid" | 120 | Core business. Introduced into hospitals domestically and internationally for diagnostic assistance and treatment planning support. |
| Data Analysis / AI Learning Services | 40 | Contract research utilizing anonymized data and analysis for pharmaceutical companies. |
| Telemedicine Platform "RedLink" | 40 | Online medical consultation support service between patients and physicians. Market is expanding. |

**Exhibit 4**

**Outline of Blue University**

- **Establishment:** 1900
- **Location:** Abuabu City, Arbitria
- **Chairperson:** Lin Blue
- **Status:** School corporation under the laws of Arbitria (unlisted)

**Trends in Sales and Profits (Unit: Million USD)**

| Fiscal Year | Sales | Operating Profit | Net Profit | Remarks |
|---|---|---|---|---|
| 2022 | 600 | 55 | 35 | Stable revenue from university hospital and educational business |
| 2023 | 640 | 60 | 38 | Medical tourism showing an expanding trend |
| 2024 | 680 | 65 | 42 | Increased revenue through international patients and enhanced education |

**Performance by Business Division (FY2024)**

| Division | Sales (Million USD) | Characteristics |
|---|---|---|
| University Hospital (Clinical Revenue) | 300 | Core of regional medical care. Introduction of AI is experimental. |
| Research Activities (Grants and Joint Research Income) | 120 | Stable income based on public funding and industry-academia collaboration. |
| Medical Tourism | 80 | Attracting international patients with advanced medical care and reassurance. |
| Educational Activities (Enrollment Fees and Tuition) | 180 | Includes tuition for undergraduate and graduate programs, and income from accepting international students. |

**Exhibit 5**

## Explanatory Document of the Outline of RedAid

Red Corporation

1. **Basic Functions**
   - Diagnostic Support: When the patient's symptoms, vital signs, and examination results (such as blood tests, image data, etc.) are entered, it presents likely disease candidates.
   - Probability Presentation: Indicates the estimated probability of each disease in numerical values so that physicians can quantitatively grasp the risks.
   - Evidence Display: Presents grounds based on medical literature and guidelines and provides support for diagnosis.
   - Alert Function: When there is a high risk of missing a serious disease, it displays a warning and prompts immediate response.

2. **Supplementary Functions**
   - Triage Support: Assists in prioritizing serious patients in emergency outpatient departments and similar settings.
   - Prediction of Risk of Readmission: Based on past data, predicts the possibility of readmission and strengthens follow-up.
   - Multilingual Support: Assists interviews with foreign patients in multiple languages.
   - Learning Function: Continuously improves performance using anonymized data (supports federated learning and use of synthetic data).

3. **Intended Uses**
   - Emergency Outpatient: Used to promptly identify serious patients among many visiting patients.
   - Cardiovascular Field: Reduces the risk of missing diseases that would be fatal if overlooked, such as myocardial infarction and arrhythmia.
   - Respiratory Field: Severity assessment of pneumonia and chronic obstructive pulmonary disease (COPD), and management of risk of readmission.
   - Second Opinion: Can be referred to by physicians when reinforcing judgment in complex cases.
   - Medical Tourism: Conducts interviews and provides medical support for overseas patients in multiple languages, supporting international provision of medical care (it is necessary to conclude a special agreement for medical tourism separately).

4. **Characteristics**
   - Human-in-the-Loop (HITL) Principle: The final judgment must always be made by a physician. AI

does not autonomously determine diagnoses or treatments.

- Safety and Transparency: Equipped with a model card and risk management plan, clarifying performance, limitations, and security precautions.
- Flexible Introduction Forms: Compatible with in-hospital server operation and cloud operation, and can be designed in accordance with personal information protection systems of each country.

5. **Information Held by Red Corporation and Rights Thereof**
    - Red Corporation does not acquire or possess individual patient data directly related to medical treatment (such as medical records, images, test values, etc.). These are retained by the utilizing institution as the managing entity, and the system is designed so that Red Corporation cannot access them.
    - For the operation and improvement of RedAid, Red Corporation generates and retains the following types of information:
        - System Log Information: Access history, frequency of use, error logs, operating rate, response time, etc. (processed so as not to include information that can identify individuals).
        - Aggregated Metadata: Statistically organized information such as the number of uses by medical department, time zones of use, number of images processed, etc. (utilized for improvement of work efficiency in each medical institution and for enhancement of the functions of RedAid).
        - Anonymized / Synthetic Data (if agreed with the medical institution): Data statistically processed and generated by removing personal identifiability, for the purpose of learning and performance verification (it is not possible to restore individual data).
    - This information is an indispensable resource for the continuous improvement of RedAid and the development of new functions, and Red Corporation holds rights to them and manages them as intellectual property. However, in the utilization of such information, it is always limited to a scope that complies with contractual provisions and applicable laws and does not harm the interests of the utilizing institution.

**Exhibit 6**

## Summary of Presentation by Blue University

### Title

Challenges of Data Governance and Clinical Governance in the Introduction of Clinical AI — Practical Considerations in the Fields of Emergency, Cardiovascular, and Respiratory Care

### Abstract

In recent years, concrete issues have become evident in clinical settings, such as improving the efficiency of triage in emergency outpatient care, preventing the overlooking of severe cases in the cardiovascular field, and reducing the rate of readmission in respiratory diseases. This presentation examines the governance and ethical requirements when introducing AI diagnostic support technology to address these issues.

Blue University emphasizes the principle of "Human-in-the-Loop (HITL)" in the utilization of AI, stating that the final clinical judgment must always be made by a physician. Furthermore, the use of AI requires the approval of the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) before proceeding to clinical use, and from the perspective of ensuring transparency, it positions the disclosure of the model card and risk management plan (RMP) as indispensable. In addition, with regard to the management of patient data, it establishes as fundamentals the anonymization, domestic storage, and limitations of the purpose of use, and points out the importance of developing an external third-party organization audit system.

This presentation demonstrates the basic stance of Blue University, which emphasizes safety, reliability, and accountability while incorporating the benefits of technological innovation, and deepens the discussion on institutional design and governance for the sustainable utilization of clinical AI.

**Exhibit 7**

**Blue University Data Governance Committee Meeting Minutes**

**Date:** December 15, 2023

**Place:** Blue University, Data Governance Committee Meeting Room

**Participants:**

・Blue University: Chairperson of the Data Governance Committee, Head of the Clinical Governance Division, Head of the Information Systems Division, Committee Members

・Red Corporation: Chief Technology Officer (CTO), Head of Medical AI Division, Legal Counsel

**Agenda**

1. Contribution of the introduction of RedAid to the advancement of medical care at Blue University
2. Handling of data and restrictions on cross-border transfer
3. Utilization of federated learning and synthetic data
4. Documentation requirements (model card and risk management plan)
5. Reporting system and supervisory framework

**Discussion and Matters Agreed**

1. **Advancement of medical care at Blue University through the introduction of RedAid**
   - The committee confirmed a shared recognition that the introduction of RedAid would greatly contribute to the advancement of medical care at Blue University.
   - In particular, it was evaluated that RedAid's diagnostic support function and alert function are effective for the major issues pointed out by Blue University at the symposium (① improvement of triage efficiency in emergency outpatient care, ② prevention of overlooking in the cardiovascular field, ③ reduction of readmission rate for respiratory disease patients).
   - Furthermore, in the medical tourism promoted by Blue University, it was confirmed that RedAid's multilingual interview and post-operative remote follow-up functions would enhance the quality of response to international patients and contribute to improving the overall competitiveness of the university.
   - The committee reached agreement that RedAid's technology is not limited to mere diagnostic assistance, but could become a foundation supporting the university's advancement strategy in the aspects of clinical governance, educational system, and international development.

2. **Data Handling**
   - It is a principle that data including personal information shall not ever be taken outside the country.
   - It was confirmed that all learning shall be carried out by the federated learning method.

3. **Federated Learning and Synthetic Data**
    - Both parties confirmed that by introducing federated learning, AI can be improved without taking data outside, thereby achieving highly accurate diagnostic support while protecting patient information.
    - It was conditionally approved to use synthetic data supplementarily in fields where the number of cases is insufficient.

4. **Documentation (Model Card and RMP)**
    - Red Corporation shall prepare and provide to Blue University a model card that describes the following:
        - Intended purpose and scope of use
        - Performance indicators (sensitivity, specificity, limitations, etc.)
        - Known biases and failure modes
        - Security vulnerabilities and countermeasures
    - In addition, Red Corporation shall prepare a Risk Management Plan (RMP) and provide it to Blue University when updated.

5. **Supervision and Transparency**
    - Blue University shall request the regular disclosure of the model card and RMP.
    - Both parties shall hold joint review meetings every quarter to confirm progress and compliance status.

**Conclusion**

- Agreement was reached that RedAid would greatly contribute to solving the clinical issues raised by Blue University and to the advancement of medical care including the medical tourism strategy.
- Federated learning shall be adopted as the basic method, and synthetic data shall be supplementarily used when necessary.
- Preparation and disclosure of the model card and RMP shall be mandatory requirements.
- Regular joint reviews shall be conducted to ensure safety and transparency.

**Exhibit 8**

**Subject:** RedAid Proof of Concept (PoC) Result Report
**Date of Preparation:** March 31, 2024
**Prepared by:** Blue University Data Governance Committee, Red Corporation Technical Division

1. **Background**

Based on the discussions at the Clinical AI Symposium in the autumn of 2023, Blue University and Red Corporation conducted a PoC over three months from January to March 2024 in order to verify the effectiveness and safety of the AI diagnostic support tool “RedAid.” This trial targeted the emergency outpatient department, the Department of Cardiology, and the Department of Respiratory Medicine.

2. **Trial System**

- Lead Institution: Blue University (clinical setting)
- Cooperating Institution: Red Corporation (technical support, training, operational monitoring)
- Target Departments: Emergency Outpatient, Cardiology, Respiratory Medicine
- Number of Target Patients: 1,200 cases total

3. **Verification Items and Methods**

(1) **Performance Aspects**

- Measurement of alert response time (in seconds)
- Statistical evaluation of sensitivity and specificity
- Analysis of rates of false negatives and false positives

(2) **Operational Aspects**

- Status of compliance with the Human-in-the-Loop (HITL) principle
- Training for physicians and nurses and degree of establishment
- Preservation of operation logs and AI outputs and auditability

(3) **Safety and Governance Aspects**

- Confirmation of anonymization and domestic storage of personal information
- Implementation test of federated learning
- Degree of utilization of the model card and risk management plan (RMP)

4. **Results**

**Emergency Outpatient**

- Average alert response time: shortened from 2.3 seconds to 1.4 seconds
- The rate of overlooking severe cases statistically significantly decreased

**Cardiovascular Field**

- Sensitivity: improved from 85% to 91%

- The rate of escalation to senior physicians improved

**Respiratory Field**

- The readmission rate showed an improving trend, from 12% to 9% over three months

**Operational Aspects**

- The HITL principle was observed, and no cases were confirmed in which AI alone made judgments
- The training participation rate of physicians and nurses was over 95%
- All logs were preserved, and an auditable state was maintained

**Safety and Governance**

- No cross-border transfer of individual data occurred, and anonymization processing was confirmed
- Learning updates through federated learning succeeded
- The model card and RMP were referenced in the clinical setting and functioned as a foundation for accountability

## 5. Conclusion

It was confirmed that RedAid is effective in improving the efficiency of triage in emergency outpatient care, preventing the overlooking of severe cases in the cardiovascular field, and reducing the readmission rate for respiratory diseases. Furthermore, it was demonstrated that RedAid satisfies the HITL principle and requirements of data governance, and can be operated without impairing safety and transparency in the clinical setting of Blue University.

Based on the results of this PoC, both parties recommend proceeding to the conclusion of a license agreement for April 1, 2024.

**Exhibit 9**

License Agreement

Red Inc. (hereinafter referred to as "Licensor") and Blue University (hereinafter referred to as "Licensee") hereby agree as follows with respect to the use of the AI diagnostic support tool “RedAid.”

**Article 1 (Purpose)**
The purpose of this Agreement is to set forth the terms and conditions for the use of RedAid, in order to ensure patient safety and improve clinical efficiency.

**Article 2 (Grant of License)**
The Licensor grants to the Licensee a non-exclusive, non-transferable license to use RedAid within the Licensee’s hospital facilities.

**Article 3 (Consideration)**
The Licensee shall pay the Licensor an annual license fee of USD 600,000.

**Article 4 (Training)**
The Licensee shall conduct sufficient training for its personnel prior to the commencement of use.

**Article 5 (Updates and Notifications)**
(1) The Licensor shall provide software updates on a regular basis.
(2) The Licensee shall promptly apply such updates to all terminals and notify and train its personnel accordingly.
(3) The Licensee shall submit written confirmation of the completion of such updates and training.

**Article 6 (Safe Operation Obligation)**
The Licensee shall operate RedAid in a safe manner at all times and shall immediately apply any emergency patches provided by the Licensor.

**Article 7 (Allocation of Responsibility)**
RedAid is a diagnostic support tool and does not replace the physician’s final judgment. The Licensor shall endeavor to improve the performance of the tool, while the Licensee shall remain responsible for clinical decision-making.

**Article 8 (Term and Termination)**
This Agreement shall be valid for three (3) years and shall automatically renew unless either Party notifies

the other Party of its intention to terminate at least twelve (12) months in advance.

**Article 9 (Confidentiality of Technical Information)**

(1) The Licensee shall treat as strictly confidential all technical information disclosed by the Licensor in connection with RedAid, including but not limited to its performance, specifications, architecture, and algorithms.

(2) The Licensee shall not disclose, publish, or provide such information, whether directly or indirectly, to any third party without the prior written consent of the Licensor, except where disclosure is strictly required by law or a competent regulatory authority.

**Article 10 (Restriction on Anonymized and Synthetic Data)**

(1) Unless and until the Licensee gives its prior written consent, the Licensor shall not generate, retain, or utilize anonymized data or synthetic data derived from the Licensee's patient information or related medical records.

(2) The Licensor's rights to retain information shall be limited to:
(i) system log data (e.g., access history, error logs, system availability); and
(ii) aggregated metadata (e.g., usage volume, response times, performance statistics),
provided that such data does not identify or enable the re-identification of any individual patient.

(3) For the avoidance of doubt, any general rights of the Licensor to anonymized or synthetic data described in RedAid's product documentation shall not apply under this Agreement unless explicitly approved in writing by the Licensee.

**Article 11 (Governing Law and Arbitration)**

This Agreement shall be governed by UNIDROIT Principles for International Commercial Contracts 2016. Any disputes arising out of or in connection with this Agreement shall be finally settled by arbitration under the UNCITRAL Arbitration Rules. The seat of arbitration shall be Japan. The arbitral tribunal may seek expert opinions on purely technical matters.

Date: April 1, 2024

| **Red Corporation:** | **Blue University:** |
|---|---|
| By: _____ | By: _____ |
| Name: Hiromi Red | Name: Lin Blue |
| Title: President | Title: Chancelor |

**Exhibit 10**

**Excerpt of Model Card (RedAid v3.2.1)**

- **Product Name:** RedAid – Clinical Support Version (Not compatible with Tourism)
- **Version:** v3.2.1 (Provided April 2024)
- **Developer:** Red Inc.

**Purpose**

- Improvement of triage efficiency in emergency outpatient care
- Prevention of overlooking serious diseases in the cardiovascular field
- Prediction of risk of readmission of patients with respiratory diseases

**Intended Users and Use Environment**

- Emergency physicians, cardiologists, pulmonologists
- Clinical nurses working in hospitals (for triage assistance)
- Environment: On-premise servers within hospitals / domestic cloud servers, electronic medical record-linked terminals

**Overview of Training Data**

- Clinical images (CT, X-ray) collected within Arbitria and structured data derived from electronic medical records
- Anonymized case data from joint research with partner hospitals in Negoland (stored domestically under contract, no cross-border transfer)

**Performance**

- Sensitivity of emergency triage: 90% (conventional average 82%)
- Diagnostic accuracy for differential diagnosis in the cardiovascular field: AUC 0.87
- Prediction accuracy of readmission in the respiratory field: 70% (conventional 65%)

**Limitations / Failure Modes**

- Increased false detection rate when image data are missing or of low resolution
- Tendency for predictive performance to decline in elderly patients and cases with multiple complications
- Use of AI output for final diagnosis is prohibited; physicians must always confirm

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**Excerpt of Risk Management Plan (RMP) (April 2024 Version)**

- **Target Product:** RedAid v3.2.1
- **Applicable Laws:** Arbitria Medical Device Act, Personal Information Protection Act, Guidance of the Health Authority

**Risk Identification**

1. Risk of non-application of updates
    - If old versions remain in clinical practice, risk of misdiagnosis increases.
2. Risk of excessive reliance

    - Physicians may misunderstand AI output as the final judgment.
3. Risk concerning data protection
    - Individual data must not be transferred abroad. No use of overseas cloud servers.

**Risk Mitigation Measures**

- Update management: Regular distribution + obligation to report completion of switchover.
- Education: Thorough enforcement of the Human-in-the-Loop principle in training for physicians and nurses.
- Data protection: All individual data are to be stored and processed on servers within Arbitria. Cross-border transfer is contractually prohibited.

**Monitoring and Review**

- Annual review by external experts.
- In the event of occurrence of clinical incident reports, risk assessment must be immediately re-implemented.

**Exhibit 11**

Subject: Application of RedAid v3.3.0 Critical Update (Urgent Request for Action)
Sender: Red Inc. (Red Corporation)
Recipient: Blue University, Medical Information Systems Division / Clinical Governance Division

We would like to extend our sincere gratitude for your continued cooperation in the use of RedAid.
We hereby officially release RedAid v3.3.0. This update is intended to improve the detection performance of serious diseases in the cardiovascular and respiratory fields, and includes important modifications to correct residual risks of false detection (in particular, the high false negative rate) present in the previous version (v3.2.1).

【Main Modifications】

1. Adjustment of identification thresholds in the cardiovascular module
    - Approximately 20% reduction of false negative rate in the detection of myocardial infarction and arrhythmia.
2. Optimization of algorithm in the respiratory module
    - Strengthening of accuracy of early warnings concerning pneumonia and pulmonary embolism.
3. Improvement of system stability
    - Strengthening of session management at the time of large-scale access.
    - Expansion of log storage and audit functions.

【Obligation of Application】

In accordance with Article 5 of the License Agreement between us, this update must be promptly applied to all terminals.

- Deadline for application: April 25, 2024
- Within 10 days after completion of the switchover, please submit to us a report of completion of the switchover.

【Risks in Case of Non-application】

In the event the old version (v3.2.1) continues to be used, the reliability of diagnostic support in clinical settings will decline, and there is a risk of affecting patient safety. This may also lead to liability for violation of the contractual obligation of safe operation; therefore, please be sure to complete the update by the deadline.
Detailed technical documents and educational materials concerning this update can be downloaded from the dedicated portal. Remote support by our technical staff is also available if necessary.
We kindly request your reliable application within the deadline.

**Exhibit 12**

**Case Record (Emergency Case X, April 18, 2024)**

**Patient Information**

- Age: 62 years
- Sex: Male
- Chief Complaint: Chest pain, dyspnea
- Vital Signs at Time of Visit: BP 138/82, HR 104, $SpO_2$ 93%, Temperature 37.2℃

**System Used**

- AI Tool Used: RedAid
- Version: v3.2.1 (old version, terminal not updated)

**AI Output**

- Determination Result: “Low risk (hospitalization not necessary)”
- Differential Diagnoses Presented: Mild heart failure, nonspecific chest pain
- Recommended Action: Outpatient follow-up possible

**Clinical Course**

- Attending Physician’s Note: “Outpatient management based on AI output. Symptoms showed a tendency to improve.”
- Additional Examination: Electrocardiogram (no abnormal findings), blood test (only mild elevation)
- Escalation to Senior Physician: Not performed
- CT Examination: Not requested

**Outcome**

- On the morning of the following day, the patient suddenly deteriorated at home. Emergency transport and return to hospital.
- Admitted to the intensive care unit but went into cardiac arrest and died.

**Exhibit 13**

**Blue University Internal Investigation Report (Draft)**

**Case of Death of Patient X**

Date of Preparation: July 2, 2024

Prepared by: Blue University In-Hospital Accident Investigation Committee

**Overview of the Case**

Patient X (62-year-old male) visited the emergency outpatient department on April 16, 2024, complaining of chest pain and dyspnea. Because an old version of RedAid (v3.2.1) remained on the emergency outpatient terminal, the attending physician referred to its output and judged it as "low risk." Hospitalized observation was not implemented, and the patient suddenly deteriorated at home the following day and, after returning to the hospital, died.

**Course of the Investigation**

- **Terminal Status:** The emergency outpatient terminal ID3421 was not updated and was running v3.2.1. Automatic updating was off, and there was no sufficient system to centrally manage update status.
- **Influence of AI Output:** The output of the old version RedAid indicated "low risk" and directly led to the decision to avoid additional examinations (such as CT).
- **Problem of Notification:** Although an update notice had been issued by Red Corporation, the switchover procedures and confirmation methods were not sufficiently specified.

**Findings of the Committee**

- The direct cause of this case was misjudgment due to the use of the old version. However, the very fact that such a defect resulting in a fatal accident occurred simply because the old version was used is unacceptable for an AI diagnostic support system.
- That is, it cannot be denied that RedAid may have some kind of structural defect. A design in which safety is significantly impaired depending on the update status is fundamentally problematic.
- Furthermore, as to whether there was a fundamental defect in the algorithm itself, it cannot be determined by this committee's investigation alone.

**Provisional Conclusion**

- This case is highly likely to have involved not only operational deficiencies and lack of education but also potential structural defects in the very design of RedAid.
- To reach a final conclusion, it is necessary to conduct an independent re-investigation by external experts and verify whether there are defects in the core of the algorithm.

- The final attribution of responsibility concerning this case should be reconsidered based on the results of such external investigation.

**Exhibit 14**

**Date:** July 5, 2024
**Place:** Blue University, Main Conference Room
**Participants:**

- Red Corporation: Chief Technology Officer (CTO), Head of Legal Department, Head of Medical AI Division
- Blue University: Hospital Director, Head of Clinical Governance Division, Deputy Head of Legal Department, Chairperson of Accident Investigation Committee

**Opening of the Consultation**

Blue University, Hospital Director:
"Today, based on the draft report of the Internal Investigation Committee concerning Case X, we would like to exchange opinions with your company. This draft report is provisional, and we intend to make revisions after hearing your company's opinion and then formulate the final version."

**Summary of the Meeting**

Blue University, Head of Clinical Governance Division:

> "This problem originated from the fact that a major update was announced immediately after the conclusion of the contract. The contract was concluded on April 1, and only two weeks later, on April 15, v3.3.0 was released, which aimed to significantly reduce the false negative rate. Does this not mean that the old version v3.2.1 failed even to meet the level stated in the model card provided at the time of contract conclusion, that is, that it had defects contrary to the model card?"

Blue University, Deputy Head of Legal Department:

> "Moreover, this was the first update, and hospital staff were unfamiliar with the update procedures. The emergency outpatient department requested remote support from your company on April 16, and response was scheduled for April 17. However, the problem case occurred at night on April 16. In other words, the fact that misdiagnosis occurred in the state before application of the update was not negligence of the university but was because the old version had defects contrary to the explanation in the model card."

Blue University, Chairperson of Accident Investigation Committee:

> "Furthermore, the emergency physician in charge of this case was not informed of the existence of the update. If the obligation of update is imposed on the university, your company has responsibility for dissemination and education. Was this not also lacking?"

Red Corporation, CTO:

> "It is admitted that the old version had certain limitations and that improvements were made in v3.3.0. However, it was also clearly stated in the model card that there was a 'risk of false detection and possibility of false negatives,' and it was not that defects were concealed. Article 5 of the License Agreement stipulates that application of updates to all terminals promptly is the obligation of the university. The fact that the old version remained and was used in Case X is the responsibility of your institution."

Red Corporation, Head of Medical AI Division:

> "What I wish to emphasize further is that RedAid is not a device to replace diagnosis but an auxiliary device. From the PoC up to the conclusion of the contract, we thoroughly explained the Human-in-the-Loop principle. It was a misjudgment of the physician to take the AI output at face value and decide discharge."

Blue University, Head of Clinical Governance Division:

> "Our physician used AI only within the originally intended scope. If it appears that there was excessive reliance, that was because your company did not sufficiently explain 'to what extent it can be trusted.' Above all, the fundamental cause of the accident was that the old version demonstrated performance not in line with the model card, and your company cannot escape responsibility."

**Conclusion**

- Blue University emphasized that the old version v3.2.1 did not meet the performance level described in the model card - in effect had defects - and that both dissemination and education were insufficient.
- Red Corporation, while admitting the limitations of the old version, argued that they were within the range specified in the model card, and that the university's operational responsibility for failing to apply the update and the physician's misjudgment were the direct causes of the accident.
- The views of both parties remained at an impasse.
- It was decided that consultations would continue concerning the draft internal report and that the final version would be formulated.

**Exhibit 15**

**SNS Post**

“Internal report of Blue University leaked! It states that RedAid has a ‘structural defect’ that causes fatal accidents when the old version is used. The university committee points out that it cannot be denied that there may be fundamental problems in the algorithm. Is it really acceptable to continue using such a tool?”

*This was posted by a medical journalist in Arbitria, and it was quoted by medical journalists in various countries.*

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**Industry Journal Article**

**Industry Journal Article (July 2024 Issue)**

**Headline:** “Possibility of Structural Defect in RedAid — Blue University Accident Investigation Draft Points Out”

A draft by the in-hospital accident investigation committee concerning a patient death accident that occurred at Blue University Hospital was leaked. The draft included strong wording stating that, while the use of the old version RedAid (v3.2.1) led to misjudgment and was one of the causes of the death, “defects that cause fatal accidents due to the use of the old version are not acceptable, and RedAid should be regarded as having a structural defect.” Furthermore, it was stated that, as to whether fundamental defects exist in the algorithm, an independent re-investigation by external experts is necessary.

This description spread rapidly on social media, and criticism spread that “entrusting life to AI is dangerous.” Multiple medical institutions decided to postpone or cancel contracts for the introduction of RedAid, and the credibility of Red Corporation has been seriously affected. Among industry stakeholders, discussions have been intensifying once again regarding how to secure the safety of AI medical devices and the way update management should be conducted.

**Exhibit 16**

**Date:** August 31, 2024
**Prepared by:** Medical AI Evaluation Center (Independent Third-Party Organization)
**Subject:** RedAid Diagnostic Support Tool (Old Version v3.2.1 and Latest Version v3.3.0)

1. **Purpose of Verification**

This verification aimed to clarify whether there existed serious defects in the old version of RedAid (v3.2.1) in connection with Emergency Case X, and to evaluate the status of improvements in the latest version (v3.3.0).

2. **Methods of Verification**

- Reproduction experiments using past case data (provided by Blue University)
- Comparison of algorithm identification threshold settings and misjudgment rates
- Performance evaluation tests between versions (v3.2.1 and v3.3.0)
- Review by external clinical experts (cardiology and emergency medicine)

3. **Results of Verification**

(1) **Regarding the Old Version v3.2.1**

- It was confirmed that the thresholds for risk assessment in cardiovascular diseases were set insufficiently, and there was a tendency to misjudge some cases as “low risk.”
- In cases similar to the present accident (Emergency Case X), erroneous output recommending against hospitalized observation was reproduced, and it is judged that defects existed which could directly lead to fatal accidents.

(2) **Regarding the Latest Version v3.3.0**

- Threshold settings were revised, and the misjudgment rate significantly decreased.
- In reproduction experiments, similar cases were judged as “recommend hospitalized observation,” and it was confirmed that the defects had been resolved.

(3) **Existence of Structural Defects**

- No fatal structural defects were recognized in the overall design of the algorithm.
- The deficiencies in the old version were limited problems relating to threshold settings, and they have been improved by the update.

4. **Conclusion**

- The old version v3.2.1 had defects and could have misled clinical judgment.
- In the latest version v3.3.0, such defects have been resolved.
- No fatal problems were recognized in the fundamental structure of the algorithm itself.
- For prevention of recurrence, it is desirable that confirmation of the status of application of updates

and thorough user education continue in the future.

**Exhibit 17**

**Date:** September 10, 2024
**To:** Blue University
**From:** Red Corporation
**Subject:** Concerning RedAid

Our company has been providing to your university the AI diagnostic support tool “RedAid” based on the “RedAid License Agreement” dated April 1, 2024 (hereinafter referred to as this “Agreement”).
Article 7, Paragraphs 1 and 2 of this Agreement clearly stipulate that information concerning the performance, specifications, algorithms, etc. of RedAid shall be treated as confidential and shall not be provided, disclosed, or leaked to third parties without the prior consent of our company.
However, the internal accident investigation report draft of your university, prepared on July 2, 2024, was leaked externally, and in it there was a description stating that “there may be fundamental defects in the algorithm of RedAid.” This description is contrary to the facts, and as a result of the outside leakage, it spread widely through SNS and industry journals and the credibility of our company was seriously damaged.
Because of this, our company lost contract negotiations with multiple hospitals and research institutions, and suffered great damage including lost profits. Specifically, our company’s damage is as follows:

- Lost profits due to cancellation or postponement of contracts: USD 2,400,000
- Estimated loss of new contract opportunities due to damage to credibility: USD 1,800,000
- Additional expenses for public relations and crisis response: USD 200,000
- Total amount of damages: USD 4,400,000

In view of the above, our company hereby claims damages against your university for the above amount. Please make payment to the designated account of our company within 30 days after receipt of this document.
If a sincere response is not made, our company intends to take appropriate legal measures based on the Agreement.

**Exhibit 18**

**Date:** September 20, 2024
**To:** Red Corporation
**From:** Blue University
**Subject:** Concerning RedAid

Our university has received your payment request dated September 10, 2024, but we cannot accept your claim. The reasons are as follows.

**No Breach of Confidentiality Obligation**
The internal investigation report draft does not directly disclose information about the algorithms or specifications of RedAid, but is merely a provisional internal study report. It does not fall under the leakage of "confidential information" as defined in Article 9 of the License Agreement.

**Nature of the Leakage**
The external leakage of the report draft was not intentional by our university but was due to unforeseen circumstances. The prohibition in the Agreement targets "acts of disclosing to third parties without permission," and this case cannot be regarded as a contractual violation.

**Implementation of Patient Compensation**
In the case between April 16 and 17, the patient, who was a prominent corporate executive with an annual income of USD 3,000,000, died. In view of the significant social impact, our university has already paid USD 2,000,000 as consolation money to the bereaved family. This expenditure was made in consideration of the influence of the defects remaining in the old version of RedAid.

Note: The payment of USD 2,000,000 in compensation to the bereaved family has been proven by receipts and other documentation, and there is no dispute between the parties.

**Request for Refund Due to Suspension of Use of RedAid**
After the accident, our university was forced to suspend the use of RedAid until the results of verification by external experts were obtained. Accordingly, for the five months from April 18 to September 18, our university did not receive services commensurate with the fees paid under the Agreement. Although the usage fee for one year had already been paid in lump sum, the usage fee corresponding to the said period should be refunded. After the external expert's report confirmed the elimination of defects in the latest version, use has been resumed.

In light of the above, our university denies your company's claim, and demands: (i) reimbursement for the

burden of USD 2,000,000 consolation money paid to the patient's bereaved family; and (ii) refund of USD 250,000, corresponding to five months of prepaid usage fees for the suspension period.

**Exhibit 19**

**Date and Time:** March 15, 2025

**Place:** Blue University, Main Conference Room (with online connection)

**Participants:**

**Blue University**

- Head of IT Division
- Representative of Clinical Governance Division
- Deputy Head of Legal Division

**Red Corporation**

- Chief Technology Officer (CTO)
- System Design Manager

**Contents of the Meeting**

Blue University, Head of IT Division:

> "First, let me restate our requirements. For international medical tourism, we require support for at least 10 languages, and the ability to process high-resolution images such as CT and MRI in real time. We also anticipate that, at peak times, more than 500 patients may access simultaneously. Moreover, the fundamental level-up of medical tourism using your system is scheduled to begin in July 2025."

Red Corporation, CTO:

> "Thank you. We understand the requirements. However, to be honest, with only the existing cloud servers or on-premise facilities within Arbitria, it may not be possible to withstand real-time processing. Especially for image analysis, there is a high risk that delays may extend to several minutes."

Blue University, Representative of Clinical Governance Division:

> "Delays of several minutes would be fatal in clinical practice. We would not be able to fulfill accountability to patients. Does your company have a solution?"

Red Corporation, System Design Manager:

> "Yes. If we partially use the high-performance cloud servers with which we have a contract in Negoland, the problem of processing speed can be solved. However, this means that part of the patient data will be stored abroad. How data protection is handled in the contract terms will be important."

Blue University, Deputy Head of Legal Division:

> "As you know, the Personal Information Protection Act of Arbitria in principle prohibits cross-border transfers. There is even a precedent where a major hospital was subjected to administrative sanctions for using an overseas cloud server. The contract must include an explicit provision prohibiting cross-border transfers."

Red Corporation, CTO:

> "We understand. However, to secure performance, the use of an overseas cloud service is in practice indispensable. In that case, would this not cause contradictions between the contract terms and the actual operation?"

Blue University, Head of IT Division:

> "Certainly, in terms of contract provisions, it must be written strictly. However, Arbitria law also has exceptions. If it is for improvement of the quality of medical care or for international joint research, there are cases where the authorities allow certain operations. It would be self-defeating if the clinical sites could not function."

Blue University, Deputy Head of Legal Division:

> "However, that is only an 'exception.' Ultimately, it cannot be guaranteed how the supervisory authorities will judge. We, as the university, are in the position of bearing the risk, so in the contract we should clearly stipulate prohibition of transfer, and leave room to consult later if necessary."

Red Corporation, CTO:

> "Understood. As for the contract provisions, we will state 'prohibition of cross-border transfer,' while in terms of operation we will consider the design on the premise of the university's understanding that exceptions may exist."

Blue University, Representative of Clinical Governance Division:

> "From a clinical perspective, securing processing speed and accuracy is the top priority. If legal and IT can make adjustments on that basis, I agree."

Blue University, Representative of Clinical Governance Division:

> "Medical tourism is directly connected to patient trust and the university's brand. Even a single system outage would cause us to lose international credibility. Therefore, it is necessary that the service be stably continued for at least three years. We want to absolutely avoid any suspension in the middle."

Red Corporation, CTO:

> "We understand that point. Our company also assumes long-term cooperation, and we promise to continue provision for three years without fail. Regarding subsequent renewal, shall we make it in the form of consultation and agreement between the parties?"

Blue University, Head of IT Division:

> "Yes, that is acceptable. In the contract, let us clearly state continuation of provision for three years, and provide for a consultation clause concerning renewal thereafter."

**Additional Matters for Confirmation (Summary of Discussion)**

In fact, the specifications required by Blue University were at a very high level:

1. Multilingual interface in the mother tongue of patients (support for at least 10 languages)
2. Real-time processing using high-resolution images such as CT and MRI

3. Concurrent connection processing capability so that even if hundreds of people access simultaneously, no delays occur

It was pointed out that in order to satisfy all of these, reliance on only on-premise facilities within Arbitria and domestic cloud servers would be insufficient, and that there was a high possibility that processing capacity would not keep up and response time would expand to several minutes.
Red Corporation strongly insisted that in order to meet such high specifications, the “exception” of using overseas cloud servers is indispensable.

**Conclusion**

- The contract shall clearly stipulate “prohibition of cross-border transfer of patient data.”
- Red Corporation emphasized the necessity of using overseas cloud servers in order to meet performance requirements.
- Blue University, Head of IT Division, mentioned the “possibility of exceptions being permitted.”
- Both parties shared the understanding of “prohibition in contract, but with room for adjustment in operation.”

**Exhibit 20**

Addendum to RedAid License Agreement

Medical Tourism Services

This Addendum (“Addendum”) forms an integral part of the RedAid License Agreement dated April 1, 2024 (the “Main Agreement”) between Red Corporation (“Provider”) and Blue University (“Licensee”). This Addendum shall be interpreted in accordance with the provisions of the Main Agreement.

**Article 1 (Purpose and Scope)**

1. This Addendum applies to the use of RedAid in connection with medical tourism services.
2. Medical tourism services covered by this Addendum include:
   (i) Pre-travel symptom input and risk assessment;
   (ii) Provision of second opinions;
   (iii) Post-operative remote follow-up;
   (iv) Multilingual support for international patients.

**Article 2 (Revenue Sharing)**

1. Licensee shall collect package fees and other revenues from medical tourism patients.
2. Such revenues shall be shared as follows: 70% to Licensee, 30% to Provider.
3. Revenue sharing shall be based on verifiable reports subject to audit, as mutually agreed by the Parties.

**Article 3 (Additional Obligations)**

1. Provider shall:
   (i) Ensure multilingual functionality in at least ten (10) languages;
   (ii) Establish a dedicated support line for international patients;
   (iii) Maintain modules for pre-travel assessment and post-operative follow-up.

2. Licensee shall:
   (i) Obtain explicit informed consent from international patients regarding the use of AI diagnostic support;
   (ii) Ensure that all clinical judgments and treatment decisions remain the responsibility of qualified medical professionals.

**Article 4 (Data Management)**

1. Patient Data relating to patients shall be stored and processed exclusively within Arbitoria, in accordance with Article 5 of the Main Agreement.
2. Provider may use anonymized and aggregated data for product improvement, subject to Licensee's oversight.
3. Licensee shall supervise such use to ensure compliance with applicable laws and ethical standards.

**Article 5 (Additional Fees and Remuneration)**

1. In consideration of the services under this Addendum, Licensee shall pay Provider an additional annual fee of USD 600,000.
2. In the event that urgent technical measures are required to ensure the quality of the service and/or to comply with relevant laws and regulations, the Parties shall negotiate in good faith regarding the allocation of associated costs.

**Article 6 (Adjustment of License Fees in Case of Cost Increases)**

1. If the Provider incurs a substantial and reasonable increase in costs directly attributable to:
   (i) compliance with changes in applicable laws or regulations;
   (ii) technical requirements expressly requested by the Licensee; or
   (iii) unforeseeable technical measures necessary to ensure the continued provision of the RedAid system,
   the Provider may request a reasonable increase of the license fee. Upon such request, the Parties shall in good faith negotiate and agree on the adjusted license fee.
2. Any adjustment under this Article shall be limited to the portion of costs reasonably and proportionally related to the continued provision of the services under this Agreement.

3. The Provider shall submit documentation evidencing the relevant cost increase, and the Parties shall endeavor to reach an agreement within thirty (30) days from the date of such submission.

**Article 7 (Risk Allocation)**

1. Licensee shall bear responsibility for any medical errors or malpractice.
2. Provider shall be responsible for damages caused by system failures, security breaches, or other technical defects attributable to RedAid, subject to the liability cap in Article 11 of the Main Agreement.
3. In the event of reputational damage relating to international patients, the Parties shall coordinate and

issue joint public communications.

**Article 8 (Minimum Term of Service for Medical Tourism Program)**

1. The Provider shall ensure the continuous and stable provision of RedAid services for medical tourism purposes for a fixed term of three (3) years commencing from the Effective Date of this Special Agreement.
2. During this three-year period, the Provider shall not suspend or terminate the provision of services except in cases of force majeure or material breach by the Licensee.
3. Upon the expiration of the three-year period, the Parties shall, in good faith, enter into negotiations to renew or extend the Agreement under mutually agreed terms.

**Article 9 (Termination)**

1. This Addendum shall enter into force on the same date as the Main Agreement and remain in effect for the duration thereof.
2. Either Party may terminate this Addendum independently, upon six (6) months' prior written notice, without prejudice to the validity of the Main Agreement.
3. Termination of this Addendum shall not affect the continuation of the Main Agreement.

**Article 10 (Miscellaneous)**

1. Matters not specifically provided for in this Addendum shall be governed by the Main Agreement.
2. In case of inconsistency between this Addendum and the Main Agreement, the provisions of this Addendum shall prevail.

**Article 11 (Governing Law and Arbitration)**

This Agreement shall be governed by UNIDROIT Principles for International Commercial Contracts 2016. Any disputes arising out of or in connection with this Agreement shall be finally settled by arbitration under the UNCITRAL Arbitration Rules. The seat of arbitration shall be Japan. The arbitral tribunal may seek expert opinions on purely technical matters.

IN WITNESS WHEREOF, the Parties have caused this Addendum to be executed by their duly authorized representatives.

February 1, 2025

Red Corporation (Provider)

By: _____

Title: Chief Technology Officer

Blue University (Licensee)

By: _____

Title: Chancelor

**Exhibit 21**

**Email (1)**
**Date:** March 8, 2025
**Subject:** Concerning RedAid Performance Requirements and Use of Overseas Cloud Server
**Sender:** Red Corporation CTO
**Recipient:** Head of IT Division, Blue University

Today, I am contacting you to request important confirmation regarding the performance requirements for the expansion of RedAid for medical tourism.
As was mentioned at the recent technical meeting, to meet the level required by your university, namely:
• Multilingual interface for 10 or more languages
• Real-time processing of high-resolution images such as CT and MRI
• Processing capacity in which no delay occurs even with access on the scale of 500 people simultaneously, we consider that relying only on existing on-premise facilities and domestic cloud servers within Arbitria has a high possibility of reaching the limit of processing capacity. In particular, for real-time processing of high-resolution images, analysis of mother-tongue interview text by international patients, and processing of session-management data required for simultaneous connections, unless we partially utilize a high-performance cloud server located in Negoland, there is a fear that we cannot guarantee the level required by the clinical setting.
Of course, the medical record proper of the patient and identifying information such as name and address, as well as genetic information, are outside the scope of cross-border transfer; all of these will be retained within Arbitria. Only data that are absolutely necessary to secure processing performance will be transferred to an overseas cloud server.
Accordingly, we would like to ask for your views on the following:
• For the success of the campaign, should performance requirements be given top priority, or should the contract wording be interpreted strictly?
• As the university, would you tolerate the possibility of “operational exceptions” in view of coordination with the supervisory authority?
While complying with the contract, our company would like to confirm the university’s official intentions so that we can provide stable services in line with the university’s requests.
We apologize for the trouble, but we would appreciate your prompt reply.

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**Email (2)**
**Date:** March 10, 2025
**Subject:** Re: Confirmation Concerning RedAid Operation (Coexistence of Cross-Border Transfer Prohibition Clause and Performance Requirements)
**Sender:** Head of IT Division, Blue University

**Recipient:** Red Corporation CTO

Thank you for your email.
Our university also considers it extremely important, for the international medical tourism campaign scheduled to start in July 2025, that RedAid realize the required performance requirements—multilingual support, real-time processing of high-resolution images, and 500 or more simultaneous connections. If performance is insufficient, it is certain that there will be a serious impact on the smooth implementation of the campaign.
Regarding the clause prohibiting cross-border transfer, we fully recognize the legal risk. Therefore, the other day we conducted an informal sounding with the competent department of the authority. As a result, we received the answer that “if the purpose is improvement of the quality of medical care, there is a high possibility that it would fall under an exception; however, to obtain an official decision, a written inquiry is necessary.”
For this reason, we cannot assert immediately that full use of an overseas cloud server is acceptable, but we expect there is room for the application of an exception. Our university has also begun to consider proceeding with the formal inquiry procedure.
In addition, we consider it desirable that your company also conduct additional confirmation from technical and legal perspectives, and that, while sharing information between us, we search for the optimal response. First, we would like to proceed with preparations in parallel and make adjustments so as to meet the timing of the campaign.

**Exhibit 22**

**Blue University Audit Division Internal Audit Report (Excerpt)**

**Date:** August 15, 2025
**Prepared by:** Blue University Audit Division
**Subject:** Operational Status of RedAid System for Medical Tourism

- **Purpose of Audit**
    - To confirm the status of patient data processing in the RedAid system and to verify whether it complies with the contract and the Personal Information Protection Act of Arbitria.

- **Audit Results (Major Findings)**

1. **Confirmation of Overseas Cloud Server Use**
    - It was confirmed that, in the operation of RedAid, part of the data was stored and processed on cloud servers located in Negoland.
2. **Types of Data Transferred Abroad**
    - The following information was transferred to the overseas cloud server:
        - High-resolution image data such as CT and MRI (for real-time analysis)
        - Interview text input by international patients in their mother tongue (for multilingual translation and analysis)
        - Session management information necessary for simultaneous connections (for load handling of access by about 500 persons)
    - Although these were used in a limited manner for the purpose of securing processing performance, the contract explicitly stipulates “prohibition of cross-border transfer,” and therefore serious doubts arise concerning compliance.
3. **Information Not Transferred Abroad**
    - On the other hand, it was confirmed that the following information was not transferred abroad:
        - Main body of patients’ medical records (electronic medical record entries)
        - Direct identifying information such as names and addresses
        - Genetic information
4. **Evaluation Concerning Compliance with Contract and Laws**
    - Use of overseas cloud servers is highly likely to be inconsistent with the contract provisions (prohibition of cross-border transfer), and carries the risk of contravening the Personal Information Protection Act of Arbitria. The possibility of sanctions or fines by the authorities cannot be denied.

- **Conclusion**

The RedAid system, in order to meet performance requirements, used overseas cloud servers, and as a result, part of the data was transferred abroad. With regard to consistency with the prohibition provisions of the contract and with domestic laws and regulations, there exists a serious risk. Immediate corrective measures should be taken concerning this matter, and if necessary, self-reporting to the supervisory authority should be considered.

**Exhibit 23**

**Date:** August 20, 2025
**Subject:** Corrective Demand Concerning Violation of Cross-Border Transfer Prohibition Clause
**Sender:** Head of Legal Division, Blue University
**Recipient:** CTO, Red Corporation

As a result of an internal audit conducted by the Audit Division of our university, it has been found that part of the patient data in the RedAid system was stored in a cloud server located abroad (cloud server within Negoland). This constitutes a violation of the obligation of prohibition of cross-border transfer explicitly stipulated in Article 5 of the contract.
Accordingly, we hereby demand the following from your company:

- Immediately cease the use of the overseas cloud server.
- Transfer and store all patient data within Arbitria.
- Present evidence of corrective measures taken within 30 days.

**Exhibit 24**

**Date:** August 22, 2025
**Subject:** Response Concerning Corrective Demand
**Sender:** CTO, Red Corporation
**Recipient:** Head of Legal Division, Blue University

Our company received an explanation from your university's Head of IT Division at the time of contract negotiations that "cross-border transfer may be exceptionally permitted," and we have conducted operations based on that understanding.
If cross-border transfer is to be stopped immediately, it will become impossible to satisfy the initially agreed performance requirements (multilingual support, real-time processing of high-resolution images, and more than 500 simultaneous connections), and we will not be able to guarantee stable operation of the system. In such case, it may become difficult to continue the provision of the service itself.

**Exhibit 25**

**Date:** August 25, 2025
**Subject:** Additional Explanation Concerning Alternative Measures
**Sender:** CTO, Red Corporation
**Recipient:** Head of Legal Division, Blue University

Upon reconsideration within our company, it has been found that there do exist alternative measures without cross-border transfer. However, these require the following urgent measures:

- Procurement of dedicated GPU servers
- Securing of international dedicated communication lines
- Optimization of algorithms

These measures will involve additional costs of at least USD 3,000,000. Please refer to the attached estimate for further details. Yellow Corporation is an independent and reliable company, and it has objectively calculated how much cost would be incurred. For example, in the case of emergency measures within one month, an additional cost of USD 5,000,000 would arise. It is impossible for our company to bear this burden, and unless your university bears the costs, it will be difficult to continue provision of the current service.

<Attachment>
**Date of Issue**: August 25, 2025
**Issuer**: Yellow Corporation (Independent IT Infrastructure Provider)
**Addressee**: To Red Corporation

**Subject**
Estimate of Additional Costs in Connection with Compliance with the Prohibition of Cross-Border Transfer in the RedAid System

**Scope of Estimate**
This estimate calculates the costs required for additional measures necessary for Red Corporation to operate the RedAid Medical Tourism System **without any cross-border transfer of patient data**. The calculation is premised on meeting the performance requirements indicated by Blue University:
(i) multilingual support in at least 10 languages,
(ii) real-time processing of high-resolution images such as CT and MRI, and
(iii) processing capacity enabling simultaneous access by more than 500 users without delay.

**Breakdown of Costs**
1. **Procurement of Dedicated GPU Servers**

- GPU cluster (10-rack redundant configuration) capable of high-resolution image analysis
- Includes procurement, installation, and first-year maintenance
- **USD 1,200,000**

2. **Securing of International Dedicated Lines (Domestic Termination)**
   - Bandwidth sufficient to withstand simultaneous connections by 500 users (including redundant lines)
   - Installation and initial contract costs
   - **USD 800,000**
3. **Algorithm Optimization and Software Modification**
   - Adaptation of cloud-dependent components for domestic environment
   - Parallel processing, cache optimization, and modification of language-processing modules
   - **USD 500,000**
4. **Enhancement of Security and Audit Systems**
   - Introduction of encryption devices, access control, audit logs, and notification systems
   - Includes external compliance audit
   - **USD 400,000**
5. **Personnel Costs and Emergency Response Costs**
   - Establishment of a 24-hour system with 20 additional engineers
   - Premium pricing for urgent delivery
   - **USD 600,000**

**Total Estimated Amount**

- **Normal implementation (3–4 months): USD 3,500,000**
- **Emergency implementation (within several weeks): USD 5,000,000**

**Remarks**

- This estimate is calculated based on Yellow Corporation's independent technical evaluation.
- In the case of emergency implementation, significant additional costs will be incurred for procurement, installation, and securing personnel, resulting in higher costs than under normal implementation.
- The above amounts do not include taxes, maintenance costs from the second year onward, or costs of modifications resulting from future regulatory changes.

**Exhibit 26**

**Date:** September 5, 2025
**Subject:** Further Rebuttal Concerning Additional Cost Burden and Cross-Border Transfer
**Sender:** Head of Legal Division, Blue University
**Recipient:** CTO, Red Corporation

**Regarding Additional Costs**
As to the additional cost of USD 3,000,000 – 5,000,000 presented by your company, our university has absolutely no obligation to bear this. Under the contract, the provision of RedAid is the obligation of your company, and continuation of service without cross-border transfer is the natural premise. Therefore, our university cannot bear additional costs.

**Regarding Opinion of Law Firm**
Our university consulted the most reputable law firm in Arbitria concerning this matter. As a result, we received the opinion that cross-border transfer may constitute a serious violation under the Personal Information Protection Act of Arbitria, and may be subject to administrative disposition or a large fine by the supervisory authority. We also received advice that, if cross-border use is voluntarily stopped and corrective measures are promptly taken, the risk can be greatly mitigated. The opinion of the law firm is attached.
In accordance with the opinion of the law firm, our university intends to make voluntary notification of the present situation to the Personal Information Protection Commission on September 7.

**Our University's Demand**
Accordingly, our university strongly demands that your company immediately stop the use of overseas cloud servers, and transfer and store all patient data within Arbitria.

**Notice of Claim for Damages**
If your company does not stop overseas use and, as a result, our university suffers damages due to administrative disposition or patient response, our university intends to claim compensation for such damages against your company based on the contract and applicable laws.

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**(Attached Document)**
**Legal Opinion**
**Client:** Blue University
**Request:** Risk Assessment Concerning Suspicion of Violation of Cross-Border Transfer Prohibition Clause
**Prepared by:** Lex & Partners Law Firm (Arbitria)
**Date:** September 4, 2025

1. **Recognition of Facts**

(1) Blue University has introduced the AI medical support system “RedAid” of Red Inc. of Negoland, and has utilized it for international patient care including medical tourism.

(2) The contract clearly stipulates that “cross-border transfer of patient data is prohibited,” but it was found that, in order to meet performance requirements (multilingual support, real-time processing of high-resolution images, and more than 500 simultaneous connections), Red Corporation partially utilized a cloud server located in Negoland.

(3) Cross-border transfer was confirmed in the internal audit conducted by the Audit Division of the university on August 15, 2025, and was reported to the senior management of Blue University.

(4) At present, whether cross-border transfer is formally reported to the supervisory authority is a critical matter of judgment.

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2. **Legal Evaluation**

(1) **Personal Information Protection Law of Arbitria**

Arbitrian law, in principle, prohibits cross-border transfer of medical information, and stipulates that in case of violation, a sanction of “up to 4% of total revenue” may be imposed (Article 45 of said law). In past cases, a major hospital that used an overseas cloud server was subjected to a fine equivalent to about 3% of sales and to an order to stop data transfer.

(2) **Effect of Voluntary Notification**

According to the authority’s guidelines (“Guidelines on Data Protection Enforcement,” 2023), if a business operator voluntarily reports a violation and promptly takes corrective measures, it will be considered as a factor for mitigation of sanctions.

- Concealment → Possibility of maximum sanction being applied
- Voluntary notification → Possibility of strict warning or substantial reduction of fine

(3) **Evaluation under Contract**

Cross-border transfer is also “prohibited” under the contract, and therefore, if violation is recognized, breach of contract by Red Corporation can be pursued. However, since there is a history that the university suggested the possibility of an exception, the other party is likely to argue that “the operation was based on reasonable expectation.”

3. **Risk Estimation**

According to the estimation of our law firm, the following applies:

(1) **Sanctions**

- If concealed and discovered: 2–4% of annual revenue of USD 600 million → USD 12–24 million
- If voluntarily reported and corrected: 0.5–1% → USD 3–6 million

(2) **Civil Litigation (Patients)**

- If concealed and discovered: risk of class action → about USD 10 million

- If voluntarily reported: lower level of consolation money → about USD 2 million

(3) **Claims under Contract (with Red Corporation)**

- If concealed and discovered: lost profits + response costs → more than USD 6 million
- If voluntarily reported: mainly response costs → USD 1–2 million

(4) **Overall Comparison**

| **Scenario** | **Sanctions (USD)** | **Civil Litigation (USD)** | **Contractual (USD)** | **Total Risk Amount (USD)** |
|---|---|---|---|---|
| Concealed & Found | 12–24 million | about 10 million | about 6 million | 28–40 million |
| Voluntary Report | 3–6 million | about 2 million | about 1–2 million | 6–10 million |

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4. **Conclusion**

(1) Immediate cessation of cross-border transfer and voluntary reporting to the authority is the measure that most reduces risk.

(2) If voluntary notification is made, fines may be reduced by more than 75%, and in civil litigation and contractual liability it will be evaluated as a “sincere response,” with compensation amounts being greatly reduced.

(3) On the other hand, if concealed and discovered, there is a risk of sanctions and damages on the scale of up to USD 40 million.

(4) Therefore, it is strongly recommended that Blue University immediately stop cross-border transfer and voluntarily report to the Personal Information Protection Commission.

**Exhibit 27**

**Date:** September 12, 2025
**To:** President and Representative Director, Red Corporation
**From:** President, Blue University

Dear Sir,
Our university made a voluntary report concerning this cross-border transfer to the Personal Data Protection Commission of Arbitria on September 7, 2025, and received a response letter dated September 10, 2025 (attached).
According to the said response, this cross-border transfer has been recognized as a violation of the Personal Information Protection Act, and an order has been issued to stop cross-border transfer by November 30, 2025.
Accordingly, we hereby notify your company as follows:

1. **Immediate Suspension of Cross-Border Transfer**
    - Immediately stop the cross-border transfer of data concerning patients through the use of RedAid, and process and store the data domestically.
2. **Continuation of Service Provision**
    - Under the contract, your company bears the obligation to continue provision of RedAid for three years, and interruption of service provision on the grounds of suspension of cross-border transfer will not be permitted.
3. **Compensation for Sanctions**
    - The sanctions imposed in this matter (USD 1,000,000, or in the case of noncompliance with conditions, USD 6,000,000 + USD 10,000 per day) are attributable to your company, which carried out the cross-border transfer, and shall be compensated in full by your company.

We demand prompt performance.

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**<Attached Document>**
**Date:** September 10, 2025
**To:** President, Blue University
**From:** Personal Data Protection Commission of Arbitria (APDPC)
Dear Sir,
Concerning the voluntary report submitted by your university on September 7, 2025, our Commission has conducted an examination. As a result, we hereby determine as follows:

1. **Recognition of Violation of Law**
    - This case is recognized as a violation of the “provisions prohibiting cross-border transfer of personal data” under the Personal Information Protection Act of Arbitria.

2. **Order of Corrective Measures**
    - To completely stop cross-border transfers and store all data within Arbitria by November 30, 2025.
3. **Measures for Protection of Patient Rights**
    - To take all possible measures to ensure that no infringement of patient rights arises due to the said transfer. In the event that infringement of rights is recognized, provide appropriate and prompt compensation.
4. **Amount of Sanctions**
    - If the above corrective measures are complied with, the sanction shall be USD 1,000,000.
    - If cross-border transfer is not stopped by December 15, 2025, the sanction shall be USD 6,000,000, and in addition, as long as cross-border transfer continues, an additional sanction of USD 10,000 per day shall be imposed.

We request your university’s prompt response.

**Exhibit 28**

**Date:** September 13, 2025
**To:** President, Blue University
**From:** President and Representative Director, Red Corporation
We have received your university's notice dated September 12, 2025. We hereby state our company's position as follows:

**Concerning Suspension of Cross-Border Transfer**
Our company is preparing to suspend cross-border transfer in accordance with the instructions of the Arbitrian authorities. However, if cross-border transfer is suspended, additional costs on the order of USD 1,000,000 will arise due to alternative measures (procurement of dedicated GPU servers, installation of dedicated lines, etc.). There is no reasonable grounds for our company to bear this cost alone; we consider that it should be borne by your university.

**Concerning Sanctions**
This cross-border transfer was carried out with the understanding of your university, based on explanations received during the contract negotiation process from your Head of IT Division and other related persons that "it may be exceptionally permitted." Therefore, the sanctions imposed are not ones that our company should bear, and there is no reason for our company to compensate your university.

**Concerning Continuation of Service**
We respect our contractual obligations and will continue the provision of RedAid. However, please understand that unless an arrangement is made concerning the burden of additional costs, it will be difficult to continue provision under the current specifications and functions.

**Exhibit 29**

**RedAid Case**

1. **Arbitral Award Sought by Red Corporation**

That Blue University shall pay Red Corporation USD 4,400,000.

2. **Arbitral Award Sought by Blue University**

(1) That the claim of Red Corporation be dismissed.

(2) That Red Corporation shall pay Blue University USD 2,250,000.

3. **Issues in Dispute**

(1) Does Blue University bear liability for non-performance of obligation toward Red Corporation due to the leakage of Blue University's internal investigation report? If liability for non-performance is borne, what is the amount of compensation?

(2) Is Red Corporation obligated to compensate Blue University for USD 2,000,000 that Blue University paid to the bereaved family?

(3) Is Red Corporation obligated to return to Blue University USD 250,000, being the usage fee corresponding to the period in which Blue University suspended the use of RedAid?

**Tourism Case**

1. **Arbitral Award Sought by Blue University**

(1) That Red Corporation shall not transfer abroad, outside Arbitria, patient-related data through the use of RedAid's medical tourism service.

(2) That Red Corporation shall provide Blue University, until the expiration date of the license agreement, RedAid's medical tourism service with the same specifications and functions as are currently being provided.

(3) That Red Corporation shall compensate Blue University for sanctions imposed under the Personal Information Protection Act of Arbitria (USD 1,000,000, or USD 6,000,000 + USD 10,000 per day).

**Application for Provisional Measures**

(1) That Red Corporation shall, no later than November 30, 2025, stop the transfer abroad of patient data through the use of RedAid.

(2) That Red Corporation shall, until an arbitral award is rendered, continue to provide Blue University with RedAid service with the specifications and functions currently being provided.

2. **Arbitral Award Sought by Red Corporation**

(1) That the claim of Blue University be dismissed.
(2) That, in the event that Red Corporation is obligated to continue provision of RedAid's medical tourism service to Blue University after stopping the transfer abroad of patient data, that Blue University shall pay Red Corporation the costs associated with continuing the service while stopping cross-border data transfer (estimated at USD 3,000,000 to 5,000,000)..

3. **Issues in Dispute**

(1) Is Red Corporation obligated, in the provision of RedAid's medical tourism service, to continue provision of the service with the current specifications and functions to Blue University after stopping the transfer abroad of patient data ? If obligated to provide the service, is Blue University obligated to pay Red Corporation the cost associated with continuing the service while stopping cross-border data transfer ?
(2) Should the provisional measures sought by Blue University be granted?

**Exhibit 30**

**Minutes of the First Preliminary Meeting**

- **Date and Time:** Friday, October 18, 2025, 15:00–17:00 (Japan Time)
- **Location:** Online meeting (Zoom)
- **Participants:**
    - **Red Corporation:** Business Development Manager, RedAid/RedLink Product Lead, Legal Counsel, Data Privacy Officer
    - **Blue University:** Manager of International Strategy Office, Head of Medical Information Division, Staff of Legal Office, Clinical Representative (Professor of Internal Medicine)
- **Record:** Summary of key points with mutual consent

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**Agenda 1: Recognition Concerning Medicine and AI**

Red Corporation and Blue University confirmed that they share the following recognitions:

- The utilization of AI in the medical field is attracting attention. The role of AI in diagnostic support, image analysis, triage, etc., is expanding year by year, and regulatory authorities in various countries are showing a stance of supporting its introduction. On the other hand, issues such as lack of explainability, existence of bias, and risks of unexpected outcomes remain significant, and social debate and regulatory development are in a transitional stage.
- Differences exist between the legal systems and cultures of Negoland and Arbitria. Negoland has established a system to introduce innovative technology in a limited manner through a sandbox system, to accumulate demonstration, and to gradually spread it. If anonymized data is used, cross-border transfer is relatively easy, creating an environment favorable for international joint research in AI. Arbitria, by contrast, takes time in approval reviews, and cross-border transfer is restricted to countries recognized as ensuring personal data protection equivalent to Arbitria. AI is limited to assisting clinical judgment, and in principle independent AI diagnosis or treatment decisions are not permitted. While both countries share the prioritization of patient safety and rights, there is a large gap in the scope of permissible risk and in the speed of introduction.
- Ethical and social perspectives are also important. When using AI, it is necessary to clearly inform patients that it plays a supplementary role and to appropriately obtain informed consent. It is also strongly required socially to establish monitoring systems to prevent promotion of discrimination or bias, and to establish systems to stop immediately and respond manually in the event of abnormality or malfunction. Regarding data security, minimum technical and organizational measures such as encryption, access control, audit logs, and notification obligations in the event of breach are essential.
- While AI introduction may reduce physicians' burden, if operation is complicated it may conversely increase burden; therefore, the quality of UI and UX is extremely important. In

addition, continuous monitoring after introduction, detection of performance degradation and data distribution changes, and re-training as necessary are indispensable. Furthermore, accumulation of successful cases is essential for building trust, while conversely, a major failure poses the risk of loss of social credibility.

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**Agenda 2: Joint Research Agreement (Enhancement of RedAid)**

**Red Corporation's Position**

Red Corporation emphasized that high-quality clinical data held by Blue University is indispensable for realizing an AI medical support tool capable of dealing with rare diseases, elderly patients, and cases with multiple complications. It requested that the contract recognize the use of federated learning as the basic method of data utilization, the use of synthetic data generated within the university, and the use of aggregated metadata within the scope contributing to product improvement. Regarding publication of results, it expressed the intention to actively support publication in anonymized form, after completion of intellectual property application and rights acquisition, and prior review by both parties. Regarding ownership of intellectual property, it proposed that general functions belong to Red Corporation, while Blue University's specific operational know-how and derivative functions belong to the university. As for contract term, it explained that it wishes first to conduct a one-year PoC, evaluate its results, and then proceed to extension or full contract.

**Blue University's Position**

Blue University made clear that while it recognizes the significance of international joint research, it prioritizes protection of patient safety and the university brand. As for data, it stipulated as a fundamental principle that data be stored in the domestic region with encryption keys managed solely by the university, and that cross-border transfer or external analysis of individual records be prohibited. It indicated that there is room to allow for utilization of synthetic data if generated and used within the university. Regarding publication of results, it responded positively to Red Corporation's proposal of joint review and anonymization after filing of applications. As to intellectual property, it accepted that general functions belong to Red Corporation, but insisted that university-specific knowledge and derivative functions belong to the university, and that if reuse by others is conducted, prior notice and confidentiality obligations should be imposed. For contract period, it showed a stance to start with a short-term PoC and examine extension year by year depending on results.

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**Agenda 3: Introduction of Telemedicine Platform "RedLink"**

**Red Corporation's Position**

Red Corporation explained that it wishes to utilize RedLink widely, including outpatient follow-up, pre-

and post-operative consultations, preliminary triage for international patients, and second opinions. Regarding service quality, it proposed a final target of SLA 99.9%, starting from 99.5% at the initial stage and improving step by step. Regarding security, it presented specific measures such as multi-factor authentication, encryption, annual vulnerability inspection, and provision of audit logs. On the other hand, it strongly emphasized the necessity of securing by contract the right to utilize aggregated metadata, federated learning, and synthetic data within the university for product improvement. Regarding contract term, it originally desired a medium-term three-year contract, but stated it could also accept starting with a one-year contract in consideration of the university's circumstances, evaluating results and then extending. However, if termination for convenience is allowed, a clause for amortizing or apportioning initial costs should be included. Regarding fees, it desired to base them on a fixed fee, with pay-per-use set for additional modules. It also insisted on introducing a small element of performance-based fees. Furthermore, if possible, it added that it would like to be granted limited exclusivity in certain medical departments or target countries.

**Blue University's Position**

Blue University, while appreciating that telemedicine contributes to regional medical cooperation and international expansion, reiterated the importance of regulation and risk management. It stated that patient data must be stored domestically, with encryption keys managed solely by the university, as an absolute condition, and cross-border transfer would not be permitted at all. Regarding metadata utilization, it indicated that limited acceptance is possible if purposes of use are specified and prior approval obtained. It expressed intention to begin with a one-year PoC contract and judge renewal depending on results. Regarding termination for convenience, it required six months' prior notice, and demanded that data return, deletion, and provision of audit trails be specified as exit conditions. Regarding allocation of responsibilities, it stated that clinical judgment would be borne by the university, while defects in the platform or infringement of intellectual property should be compensated by Red Corporation. As to liability cap, it presented a standard of 1–3 times the annual contract amount, and noted the possibility of additionally requiring insurance coverage. Regarding exclusivity contracts, it declared a general rejection, but indicated that there may be room for consideration only if limited to certain departments or target countries.

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**Closing**

- Both parties agreed in principle on the direction of "gradual introduction" and "renewal after evaluation of results" for all projects.
- On the other hand, key issues such as scope of data utilization, timing of result publication, fee structure, liability cap, and permissibility of exclusivity were left to future detailed discussions.
- Both parties recognized "protection of university brand" and "product improvement and accumulation of achievements" as critical points, and agreed to present concrete draft clauses by the next meeting.

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**Next Meeting**

- **Date and Time:** Sunday, November 16, 2025, 12:00–14:00 (Japan Time)
- **Location:** Blue University (in person, planned)
- **Agenda:**
    1. Confirmation of draft clauses of joint research agreement (data utilization, intellectual property, result publication)
    2. Details of RedLink contract conditions (SLA, termination conditions, liability cap)
    3. Others