Orchestrating a brighter world NEC

White Paper

－Towards the realization of AI drug development－

Comprehensive process workflow for the commercial use of personalized cancer vaccines

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Chapter 1
The Need and Potential for Establishing Comprehensive Process Workflow for Personalized Cancer Vaccines

The future of AI-driven cancer therapy

Expectations are growing for the practical application of personalized cancer therapies. Personalized neoantigen cancer vaccine therapy (”Personalized cancer vaccine therapy”), a form of tailor-made medicine designed to optimally address patient’s needs during cancer treatment, is attracting attention as the next breakthrough in cancer therapy.

Cancer immunotherapy, based on immune checkpoint inhibitors, has made a major impact in some diseases and continues to expand to into other indications, however the response rates to immune checkpoint inhibitors remain limited with about 20-30% of patients responding, leaving the medical need still largely unaddressed.

Personalized cancer vaccine therapy differs significantly from existing cancer therapies in that AI technology is at the center of the therapy design and manufacturing.

Personalized cancer vaccines target private neoantigens, which are genomic alterations specific to each tumor and differing from patient to patient. Advances in genome sequencing using next-generation sequencers and AI technologies for predicting neoantigens have made it possible to identify specific epitopes that can be recognized by the immune system. Hence, the accuracy of AI technologies for identifying neoantigens has a marked impact on patient outcome, and their robustness is critical for a large-scale clinical adoption of these therapies. Personalized cancer vaccine therapy and similar approaches open a new era in cancer care and can be expected to dramatically increase the response rate of cancer immunotherapy.

These high hopes have led innovative biotech and pharmaceutical companies to develop personalized cancer vaccines and some of these have been shown to improve clinical outcomes in various cancers in relatively small clinical trials. NEC also recognizes the potential of personalized cancer vaccines and is actively pursuing their practical application by developing its proprietary AI-driven neoantigen prediction technology as well as tools allowing up scaling of these approaches.

Necessity of establishing a comprehensive process workflow for the commercial use of Personalized Cancer Vaccines

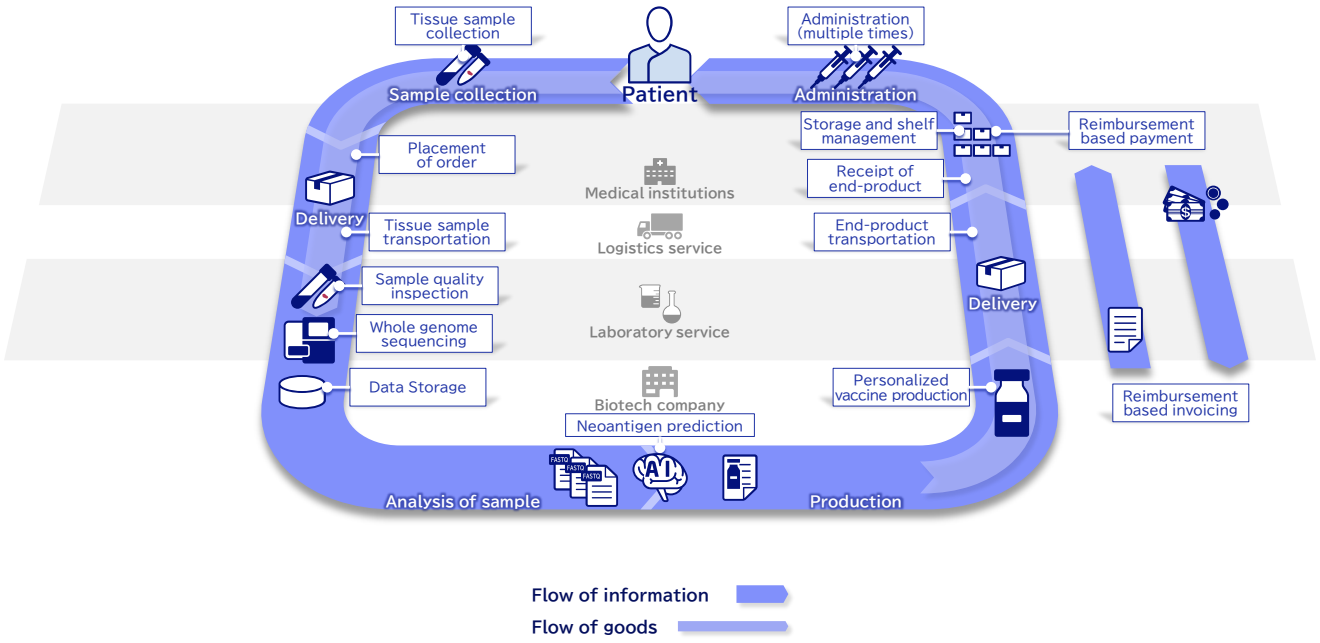


Fig. 1: Comprehensive process workflow for Personalized Cancer Vaccines

Identifying cancer-specific neoantigens that elicit robust immune responses in patients, swiftly designing and manufacturing vaccines, and effectively administering them to patients, are crucial steps to actually achieve high response rates in personalized cancer immunotherapy. Advanced AI technology plays a pivotal role in identifying these neoantigens. Concurrently, the development of personalized cancer vaccines necessitates a sophisticated blend of AI and Information and Communication Technology (ICT) capabilities. Personalized therapies designed based on patient data introduce new challenges over more classical approaches. Digitalization of the process will be critical to address these challenges and ICT systems offer an opportunity to meet the promises of a large-scale adoption of personalized therapy in cancer care.

In a classical setting the emphasis in advanced therapy delivery is on physical manufacturing capabilities, however, when it comes to personalized therapies, the underlying data infrastructure becomes an additional critical component. While great progress has been made in manufacturing operations following the advent of CAR-T cell therapies, part of the challenge related to the handling of large amount of genomic data remains to be tackled. It is necessary to ensure traceability not only in the physical flow of products, but also in the exchange of data in cyberspace, and to ensure that evidence storage is implemented. In addition, it is important to appropriately store and manage large amounts of genomic/medical increasingly complex manufacturing processes, required quality control process, and maintain

competitive of turnaround time (TAT). These intrinsic challenges are also confounded by external risks and threats in the cyberspace that must be mitigated. It is worth noting that these challenges will require the utilization of ICT technologies in diverse aspects. Collaboration with ICT companies or those possessing equivalent IT expertise is essential to realize this vision.

While these topics discussed are for cancer vaccines, it would also be applicable for other types of individualized therapies targeting neoantigen or other patient specific genomic features.

In order to build a comprehensive process workflow (*Fig. 1*) that satisfies the above issues from various perspectives, it is necessary to combine and implement not only AI technologies for identifying neoantigens but also a wide variety of ICT technologies to handle the complex data flow. The realization of a patient centric process workflow also opens new opportunities to facilitate real time data sharing across the relevant parties involved in patient care by facilitating timely decision making.

NEC will discuss several enablers that need to be considered in the comprehensive process workflow of such personalized cancer vaccines and introduce technologies that could address these enablers. Additionally, we attempt to envision how these technologies, have the potential to create further value beyond satisfying current needs.

Enablers of the comprehensive process workflow for Personalized Cancer Vaccines

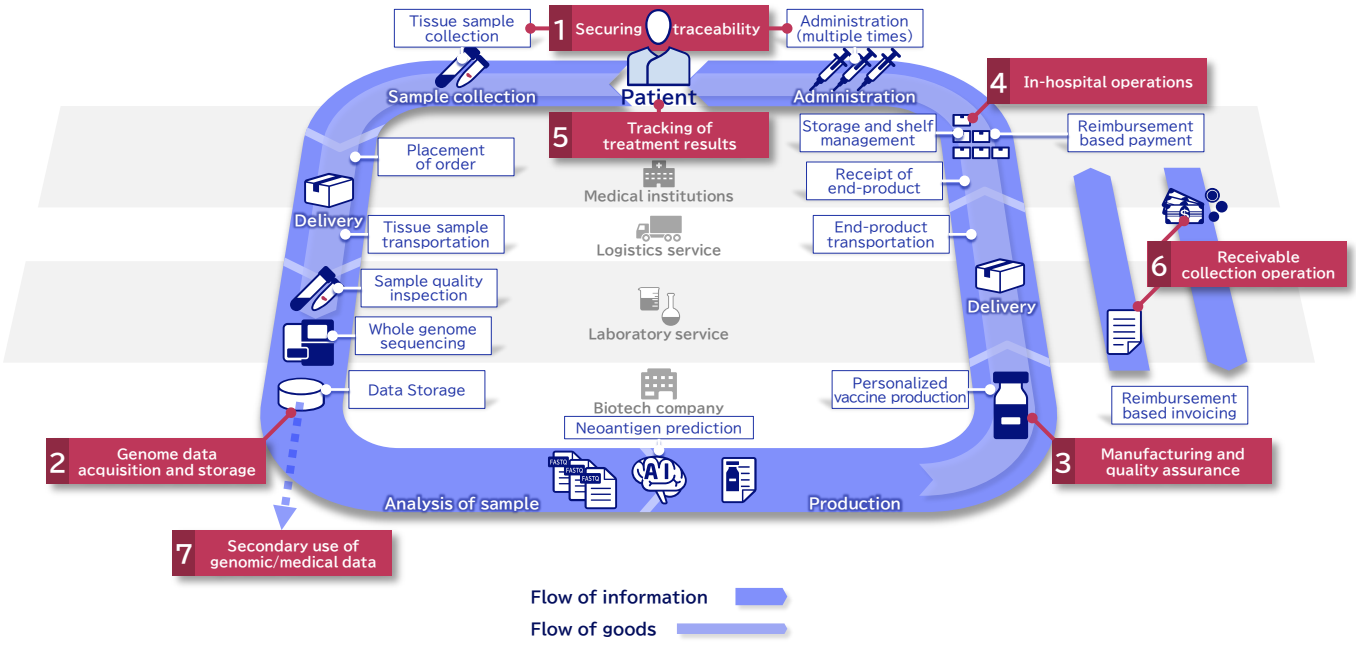
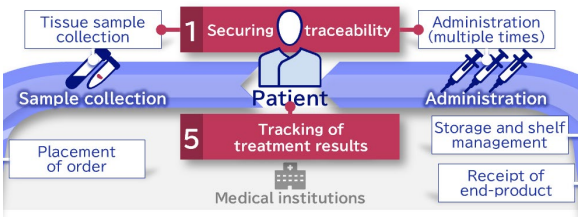


Fig. 2: Enablers of the comprehensive process workflow for Personalized Cancer Vaccines

Chapter 1
The Need and Potential for Establishing Comprehensive Process Workflow for Personalized Cancer Vaccines

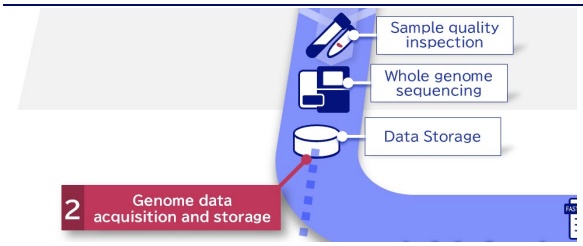
In the near future, given that many patients may receive personalized cancer vaccine therapies annually, it is clear that the process workflow for personalized cancer vaccines will be more complex and complicated than the traditional vaccine manufacturing process. Below we describe the key enablers of the process workflow (*Fig. 2*) , the challenges involved, and the ICT technologies that could address these challenges.

1 Securing traceability



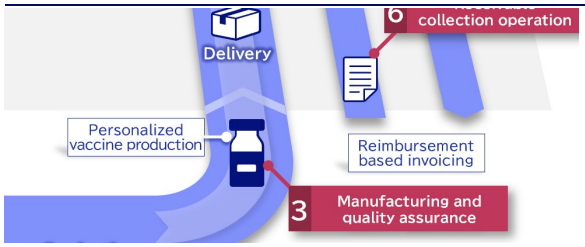
The most important aspect of personalized cancer vaccines is to ensure that vaccines manufactured based on information obtained from a given patient are administered to this same patient, and to ensure “chain of identity” from patient to patient. Therefore, logistical controls, such as the transfer of biological samples collected from patients and the transfer of vaccines, need to be strictly controlled. For example, the logistic flow can be managed to a higher level by using biometrics to record the validity of identity of third parties involved in product handling. Another important aspect is the need for a high level of traceability in the exchange of data and the maintenance of those trails, which means that not only logistics management but also the authenticity, integrity, and traceability of data exchanges must be ensured and the data that serves as a trail of such data must be securely maintained for a long period of time. For instance, if vaccines are manufactured based on falsified vaccine design data, not only will the product lose its efficacy for patients, but it might lead to potentially serious adverse events for the patients. In such unlikely event, an investigation may be performed based on audit trails to identify the source of the issue. While the implementation of digital signature technology and blockchain can be useful for improving traceability, including data exchanges, and for ensuring the maintenance of reliable trails, easy implementation without considering these technical features may not fully contribute to improving traceability. For example, the introduction of digital signatures is expected to improve the authenticity of data, but it may increase the volume of signed data and introduce new work procedures for obtaining such signatures. Sufficient considerations are needed to simplify the process when introducing digital signature and authentication technologies. On the other hand, the introduction of blockchain technology without sufficient consideration of its added value, it may come with a risk of increasing operational costs without actually contributing to the prevention of data tampering. These technologies need to be introduced appropriately after thorough assessment of their utility in any given setting.

2 Genome data acquisition and storage



How to protect and store large amounts of genome data are important aspects of personalized cancer vaccines. As genome data itself is patient sensitive data, strict management, and measures to protect against data leakage are essential. In addition to the technical aspects, it will also be necessary to take into consideration the legal requirements for genome data processing that differ from country to country and for processing such genome data across borders. Furthermore, since genome data and other data exchanged throughout the process workflow must be stored for a long period of time, it is necessary to address any compromise of cryptographic schemes. In other words, it is necessary to prevent existing cryptographic schemes from becoming vulnerable against hacking as the technology develops further. Moreover, it is necessary to take measures to prevent the loss or falsification of genomic data. Regarding encryption, it is necessary to implement measures from multiple perspectives, including the realization of advanced encryption and the introduction of PQC (Post quantum cryptography). In addition, applicable tamper detection mechanisms can be introduced into the data to facilitate recovery in the unlikely event of an incident. Storing genome data on a public cloud is a reasonable option to cope with cost and IT resource constraints associated with the large amount of data. However, one must ensure that countermeasures against data theft and browsing outside and beyond the network are implemented into these public cloud systems. Moreover, a mechanism is needed to prevent unauthorized data acquisition and viewing in public clouds. Alongside user management mechanisms based on strict access control and operation, it will be useful to introduce data protection technologies such as high-reliability network encryption and secure computation.

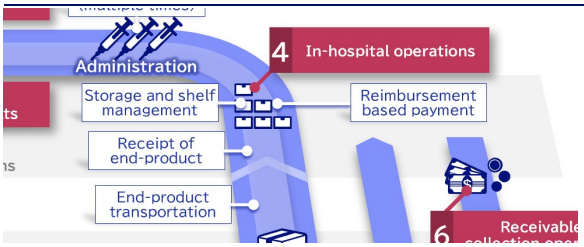
3 Manufacturing and quality assurance



It is clear that personalized cancer vaccine therapy and other types of individualized therapies such as Adoptive Cell Therapy or TCR therapy, which involve more complex operations than traditional vaccine manufacturing, with a risk to drive up TAT due to the complexity of the manufacturing and quality control processes. Also, a scalable and continually improved bioinformatic pipeline for the design of personalized cancer vaccines is also important to improve the response rate to neoantigen therapy. To reduce the burden on TAT in the manufacturing process, automation of manufacturing operations and testing processes are essential.

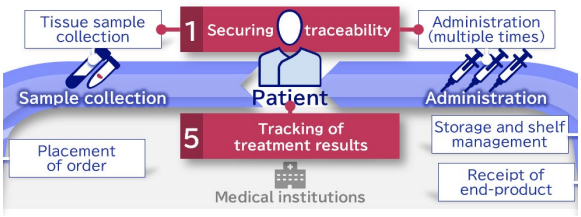
Automation of manual quality-related tests that would be useful for improving TAT of quality control processes, and the application of AI technologies to these automations can and should be fully considered. To achieve a robust bioinformatics pipeline, change-resistant software and quality control processes need to be implemented, for which the microservicization of software and the introduction of automated quality control processes would be essential requirements. In addition, processes where manual inspections are performed need to be made more efficient by introducing signature technologies that allow workers to sign without being aware of them. Furthermore, these manufacturing process information and quality control processes need to be analyzed, anonymized, and pseudonymized in real time, and need to be linked to subsequent operations and systems. A manufacturing process control system will be needed for this purpose. In addition, how to protect the neoantigen prediction algorithm and the AI algorithm for improving quality assurance efficiency to prevent leakage and tampering is also an issue that needs to be addressed. To protect these algorithms, along-side high-level cybersecurity measures and the use of data protection technologies, it will be necessary to introduce AI security technologies to ensure that the AI system has not been altered accidentally or by malicious intent to predict incorrect or unintended results.

4 In-hospital operations



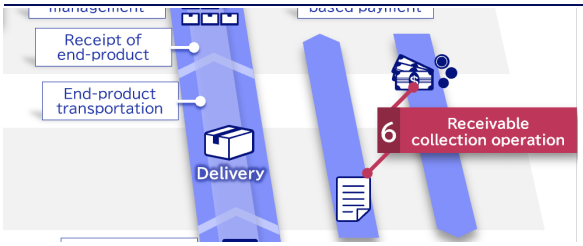
It is important to synchronize vaccine production with in-hospital operations in real time. Unlike regenerative medicine products, personalized cancer vaccines may need to be administered repeatedly. Therefore, it is assumed that manufacturing and shipping will continue after the first administration, and real-time linkage with the ordering and supply systems will prevent an increase in the TAT. Since the configuration of the ordering and receiving system and records of its operation, the method of inventory placement can be an important issue in the implementation of personalized cancer vaccines, and hence there is a need for the system to support multiple placement methods. In addition, to placing the orders and receiving orders, the diagnostic results of whether a personalized cancer vaccine is administered need to be linked to manufacturing sites in real time. Although some of these linkages have been realized in the system for CAR-T, many new issues remain, such as the need for more rigorous management of patient information which requires, and a more sophisticated and flexible system.

5 Tracking of treatment results



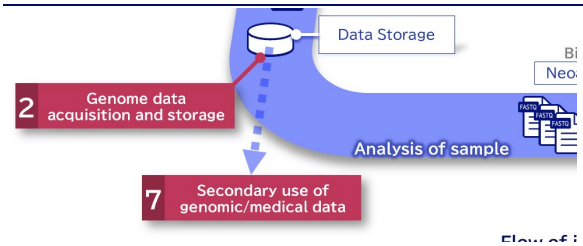
It is important for the value of personalized cancer vaccines to continuously improve the AI systems through learning with real world feedback. This requires efficient monitoring of therapeutic effects after the vaccine is administrated to patients, and the data should not be limited to the hospitals but also linked to the pharmaceutical manufacturer in order to further improve the manufacturing process and the analysis of genomic data. For example, the ability to monitor treatment effects and patient outcomes will optimize the number of vaccines manufactured and reduce TAT, leading to more efficient vaccine production. For pharmaceutical companies, observation and analysis of long-term effects will also increase the possibility of providing truly appropriate precision medicine. To efficiently collect information on the course of treatment described, there is a need to support information to and from a variety of Electric Medical Records. While it is possible to consider absorbing differences in data formats by processing data on the platform side, industry standardization of data formats and other measures are also possible. When sharing data outside the hospital, it will also be necessary to consider the introduction of data protection technologies such as secure computation and the application of advanced encryption technology.

6 Receivable collection operation



The post-launch reimbursement scheme for personalized cancer vaccines is not yet clear, and the reimbursement scheme generally differ across countries. Furthermore, the existing method of managing the administration status and treatment progress of each patient manually and recovering the investment is not realistic under the circumstances where personalized cancer vaccines have become widely available. Unless a system is established in which all organizations involved in the payment of personalized cancer vaccines, (such as medical institutions, pharmaceutical companies, and insurance companies), can access all the required information for each administration and measurement of treatment efficacy, there is a high possibility that the investment will not be recovered appropriately. For pharmaceutical companies manufacturing and selling personalized cancer vaccines, it is necessary not only to build a system to manage the manufacturing process workflow, but also to build a comprehensive system to appropriately handle such an investment recovery scheme, which requires the construction of a larger system than before.

7 Secondary use of genomic/medical data



While genomic data, biological data, and clinical data collected during personalized cancer vaccine therapy require strict management, additional analysis and combination of these data may bring highly effective cancer therapy. Especially in the process workflow of personalized cancer vaccines, a situation in which these data are expected to be processed internationally, there are hurdles to secondary use from a legal and regulatory perspective. However, there is a possibility to realize highly effective cancer treatment through additional analysis and combinations of these data. In addition, integrated analysis of such data and Real-World Data may lead to the discovery of new therapeutic medicines and diagnostic methods. If secondary use of such data, including genomic data, can be realized after appropriate measures are taken, the personalized cancer vaccine platform has the potential to become not only a platform for personalized cancer vaccines but also a new integrated platform for data-driven cancer therapy. Of course, there are legal and technical hurdles, technologies that enable analysis and computation without disclosing data to each other, such as secure computation technology and federated learning, are useful technologies to overcome these hurdles.

The Future of New Data-Driven Cancer Treatment Platforms

The process workflow for personalized cancer vaccines is described from enablers, including the challenges to be solved and some of the solutions. Establishing the comprehensive process workflow for a pharmaceutical company involves a wide variety of challenges and requires the implementation of numerous ICTs and security technologies. To establish a process workflow, one way is to collaborate with an ICT company that can implement end to end measures and build a comprehensive ICT platform. Furthermore, this ICT platform has the potential to become a new platform for cancer treatments (*Fig. 3*).

In particular, the integrated analysis of genomic data and data collected during the treatment process have the potential to provide new value:

- **Realization of the development of more advanced personalized cancer vaccines and diagnostic technologies based on analysis of treatment results.**
- **Accelerated development of new cancer drugs with and reduced development costs through the digitalization of clinical trials.**
- **Establishment of more precise medicine based on genome information-based patient stratification.**

and has the potential to provide new value.

Tailored cancer care is expected to advance significantly in the realm of medicine as a result of this added value provision made possible by expanded secondary use of data and the maturation of personalized cancer vaccine technology. An integrated ICT platform for cancer treatment will be at the center of this trend. In an environment where this cancer treatment platform is fully realized, the delivery of medical care may shift from a style in which physicians encourage patients to understand the standard of care to one in which treatment is tailored to the patient, under the oversight of the treating physician and based on a better understanding of patient-specific data.

The realization of personalized cancer vaccines will revolutionize cancer treatment and realize more patient-centered cancer care. At the same time, the ICT platform for managing the vaccine process workflow will be able to utilize a variety of data and function as the core of a platform that enables the provision of patient-centered cancer care.

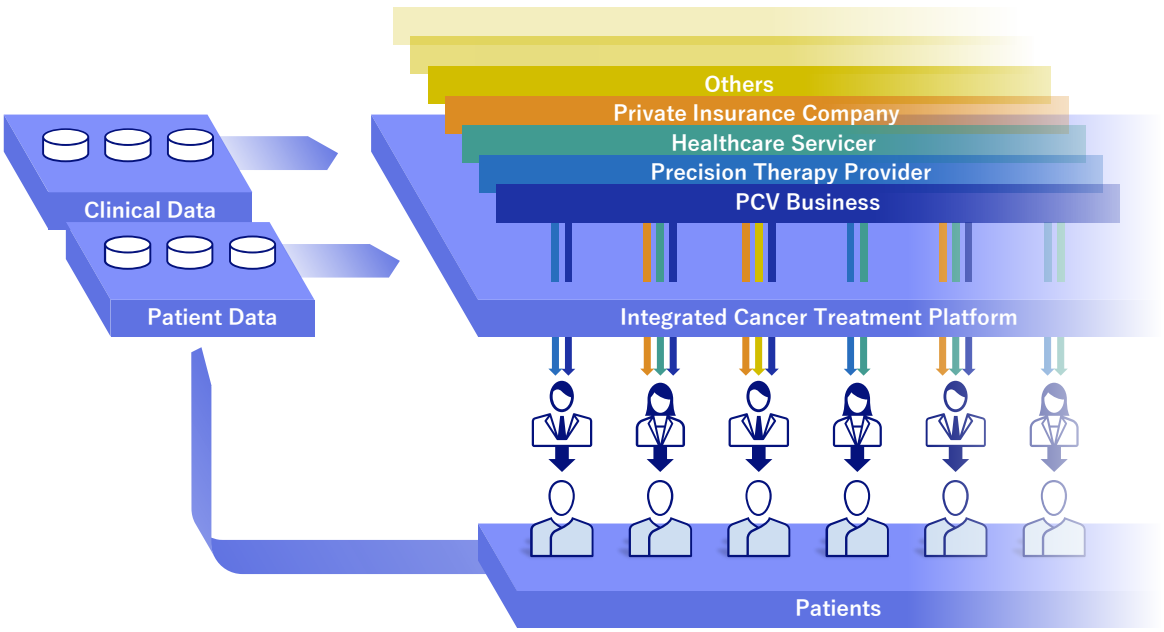


Fig. 3: Integrated platform for cancer treatments

Chapter 2:
NEC's technologies and initiatives that can contribute to the realization of personalized cancer vaccines

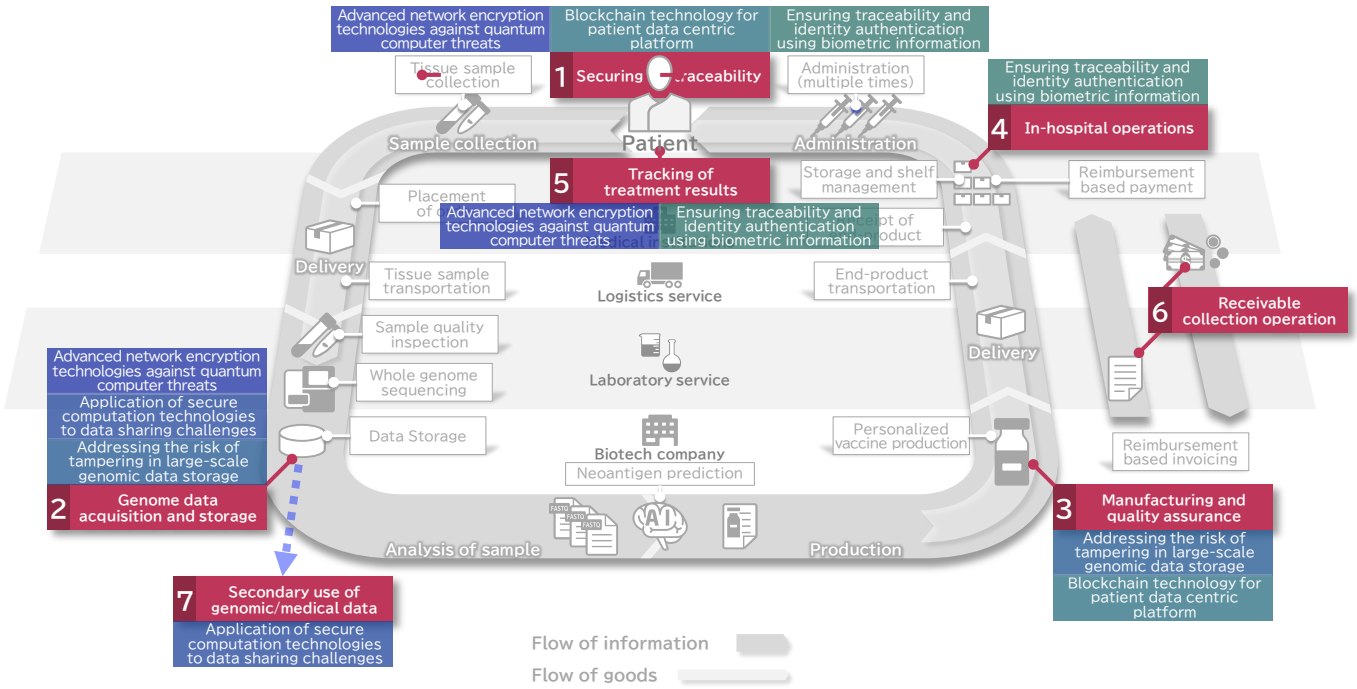


Fig. 4: Advanced ICT technologies for the comprehensive process workflow

Advanced network encryption technologies against quantum computer threats

In the comprehensive process workflow of personalized cancer vaccines, in which various players other than vaccine manufacturers play diverse roles and exchange sensitive information such as genome data and medical information. For instance, access from hospital staff would be assumed, as it can be envisaged that clinical feedback can be obtained from patient in order to update vaccines over time in case of evolution of the disease. Hence, there is a need to transfer data via a highly reliable and secure network. In addition, there is a high possibility that long-term system operation will be required, and in such cases, the network and system must consider the emergence of new risks, such as the realization of quantum computers. Classical cryptographic methods are going to be subject to increasingly powerful attacks made possible by the gain in computational power offered by quantum computers. Such risk in the field of genomic medicine is associated with unacceptable consequences on patient safety and privacy. Therefore, one of the challenges posed to large scale clinical deployment of genomic medicine at large and personalized vaccine in particular is to implement cryptographic technologies that are resistant to quantum computers. Regulators have already taken steps towards addressing these issues and, for instance, in the U.S. the implementation of PQC for National security systems will be required in 2035 for cases where a public key cryptography is used. It is highly likely that similar

approaches will also be dictated by health regulators for patient sensitive data. In order to respond to the stringent network security requirements and, future risks, NEC has devised a more secure communication environment for data exchange by utilizing network software with quantum resistant cryptographic algorithm developed in-house. This software realizes new network encryption by utilizing multiple encryption algorithms that are unlikely to be broken by a large-scale quantum computer. In addition, this software is implemented to enable key sharing using quantum cryptography in the future, a theoretically unbreakable encryption method, providing the ability to mitigate future risks. NEC is currently validating, using this software in an actual clinical trial and is actively working on a new network encryption technology that will enable data transfer with a high level of security.

Applicable areas:

< Securing traceability, Genome data acquisition and storage, Tracking of treatment results >

Application of secure computation technologies to data sharing challenges

In storing and utilizing large-scale genomic data and clinical data, it is more cost-effective and scalable to use public clouds instead of conventional on-premises environments, however, when utilizing a public cloud, protecting the data becomes an issue. At the same time, expanding the secondary use of data is also necessary for the complete realization of personalized cancer vaccines. NEC is developing multiple secure computation technologies which could be leveraged to address these concerns.

Secure computation technology is a generic term for technologies that guarantee confidentiality during computation, and several schemes have been proposed, including secure Multi-Party Computation (MPC)[1] and homomorphic encryption, etc. NEC is actively developing secure computation technologies and has already demonstrated that it can be used for genome data.[2] Guaranteeing confidentiality during computation can provide additional data protection against cloud-based attackers, as opposed to data confidentiality with simple data encryption, which requires decryption during computation. It also enables data analysis while keeping the data itself confidential for users with limited access, thereby making it possible to utilize the data for a wider range of users. In order to increase the possibility of value creation through the utilization of such data, it is necessary to adopt and implement secure computation technology suitable for each use case. NEC has researched, developed, and implemented multiple methods of secure computation technology, including the MPC and homomorphic encryption, and will be able to introduce secure computation technologies in an appropriate combination in the area of personalized cancer vaccines.

Applicable Areas:

< Genome data acquisition and storage, Secondary use of genomic/medical data >

[1] https://www.nec.com/en/global/solutions/secure-computation/index.html
[2] https://www.nec.com/en/press/201907/global_20190723_03.html

Addressing the risk of tampering in large-scale genomic data storage

A large amount of intermediate data, including genomic data, will be generated during the manufacturing process, and ensuring their integrity will also be an important aspect. This is because corruption or falsification of genomic data or vaccine design data could lead to potentially catastrophic consequences.

For such data, it is useful to introduce tamper detection technologies. Moreover, if tamper detection technologies can identify the tampered areas, the severity of the impact on patients can be evaluated. NEC's tamper detection technology is very suitable for requirements of a personalized cancer vaccine. For example, when applied to genomic data, it can detect whether an attacker has inserted an incorrect mutation that may cause side effects to patients, and when applied to vaccine design data, it can detect whether an attacker has altered vaccine sequences that may cause side effects to patients. NEC tamper detection technology can detect tampering on single datapoints, as well as datasets, such as databases, and is applicable to data of various sizes and formats.

Applicable Areas:

< Genome data acquisition and storage, Manufacturing and quality assurance >

Blockchain technology for patient data centric platform

Blockchain technology is already being used in many industrial domains, and there are cases where it is being used to ensure traceability, especially in the supply chain due to the difficulty of tampering with the information written on the blockchain. NEC has a proven track record of introducing blockchain to supply chains across various industries, including the construction of ICT platform using blockchain technology to ensure the traceability of agricultural products in the Indian market[3] . In addition, NEC has engaged in the development of blockchain technology for enterprise applications[4] from early on, and has pioneered its own high-performance blockchain technology, making NEC unique in its high development capabilities in addition to its utilization. This blockchain technology is a blockchain infrastructure that is fully compatible with blockchain technology (Hyperledger Fabric), which is widely used as open source, and has a unique high-speed consensus algorithm. It is an effective technology for ensuring the traceability of personalized cancer vaccines as a blockchain infrastructure that combines high performance and scalability.

Blockchain technology can be applied not only to ensure traceability of data and logistics between companies, but also to patient-centric data utilization infrastructure. For instance, it could be used to an application infrastructure that allows patients themselves to self-sovereignly manage the scope of data sharing. Data linkage and sharing are essential in the production of personalized cancer vaccines, but they must

be implemented with the consent of patients. To achieve this goal, it would be efficient to provide an application that can confirm the patient's consent on a case-by-case basis. However, managing patient consent data obtained from applications in a centralized database may not be transparent enough for patients. When this information is managed in a single database, it is easy for an administrator to tamper with these consents and in the worst case, it could action remain difficult to detect when a process deviates from the scope of the consent. In contrast, the introduction of decentralized management using blockchain can enhance resistance against tampering and deviations, thereby improving reliability. Specifically, it is possible to prevent tampering by storing the history of the individual's consent signatures on the blockchain. In addition, by posting the process information of the manufacturing flow to the blockchain, multiple companies and the patients themselves can monitor whether they are deviating from the predetermined manufacturing flow and whether they are disclosing unnecessary data. Building a system that understands the scope of patient data disclosure and sharing allows for a more reliable vaccine production process.

Applicable areas:

< Securing traceability, Manufacturing and quality assurance >

[3] https://www.nec.com/en/global/sdgs/innovators/project/article14.html
[4] https://www.nec.com/en/global/solutions/blockchain/nec-activities-on-blockchain.html

Ensuring traceability and identity authentication using biometric information

For personalized cancer vaccines, it is an essential requirement that the vaccine be created from and administered to the same patient from whom the biological samples were collected from. However, for personalized cancer vaccines with process workflow that move back and forth between cyber and physical space, it is difficult to mitigate the possibility of data and vaccine mismatches.

One solution to this issue is authentication and signature based on the patient's biometric information. An example of application would be performing authentication of patient ID using biometric information, such as facial recognition. it is possible to link the vaccine to the patient. Another way to utilize biometric information is to use a digital signature based on the patient's biometric information (biometric signature). The signature of the patient is obtained before administration and verified at the time of administration, simplifying the authentication at the time of administration. NEC has its own proprietary biometric signature technology, which enables the use of biometric signatures to link individualized cancer vaccines to patients and can be used to improve the safety of personalized cancer vaccines.

Applicable areas:

< Securing traceability, In-hospital operations, Tracking of treatment results >

Notes

- **Post Quantum Cryptography(PQC)**

  A cryptographic scheme that can remain secure when large-scale quantum computers are realized. Implementation may be considered in the medical field, where sensitive data needs to be protected, in order to address future risks.

- **Multi Party Computation(MPC)**

  It is one of the protocols of secure computation. This protocol allows data to be distributedly randomized and to be processed by multiple servers in a coordinated manner, thereby increasing confidentiality, so that even if one server is hacked, the original data cannot be retrieved because only randomly distributed data can be retrieved. This ensures the security of sensitive data such as genome data and medical data.

  NEC Secure Computation
  https://www.nec.com/en/global/solutions/secure-computation/index.html

- **Homomorphic Encryption**

  This is a cryptographic technique that allows calculations to be performed while data is encrypted. This makes it possible to obtain calculation results while keeping the data itself confidential. This makes it possible to provide only analysis results to users who cannot directly provide genome data or medical data, thus enabling a wider range of users to utilize the data.

- **Quantum Computer**

  A computer that uses quantum properties to perform computational processing, and is expected to demonstrate extremely higher computational performance than conventional computers in certain fields.

- **Blockchain**

  It is a decentralized system in which records called blocks are connected in chronological order like a chain so that they can be processed and recorded in a decentralized manner. To tamper with a single block, it is necessary to tamper with that block and the blocks connected behind it, making it difficult to tamper with the data. This makes it useful for protecting sensitive data such as medical data.

- **Hyperledger Fabric**

  A blockchain framework developed at the Linux Foundation and used widely for enterprise blockchain platforms.

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