Chugai DX Meeting

DXグランプリ2022
Digital Transformation

DXプラチナ企業
2023-2025
Digital Transformation

September 29, 2023
Chugai Pharmaceutical Co., Ltd.

CHUGAI DIGITAL

Agenda

1. **Progress in CHUGAI DIGITAL**
   (Satoko Shisai: Executive Vice President, Head of Digital Transformation Unit)

2. Three Initiatives to Strengthen the Digital Platform
   (Keisuke Ohara, Head of IT Solution Department)
   (Kazumitsu Kanatani, Head of Digital Strategy Department)
   (1) Multicloud strategy/Cyber security strategy
   (2) Initiative toward utilization of generative AI
   (3) Initiative on healthcare × Web 3.0

3. Status of Progress in the Insight Business
   (Dr. Nobuya Ishii, Head of Science & Technology Intelligence Department)

Top Innovator 2030

◆ Realization of Chugai's "Envisioned Future" in 2030

Expectation from patients all over the world

With world-class drug discovery capabilities, patients around the world expect that "Chugai will surely create new treatments."

Attracting talent and players from around the world

Attract passionate talent from all over the world, and inspire players in globally to think they can create something new by partnering with Chugai

Role model for the world

Recognized for its ESG initiatives through its business activities, Chugai will become a global role model as a leader in resolving social issues

Our definition of "Top Innovator in the healthcare industry"

In collaboration with Roche, we will continue to place "innovative new drugs" at the core of our business, while aiming to become a leading innovator in the global healthcare field, where a diverse range of players, not limited to pharmaceutical companies, are taking on the challenge of innovation.

Growth Strategy to Become a Top Innovator 2030

CHUGAI DIGITAL

“Double R&D output” & “Launch global in-house products every year”

Global First-class Drug Discovery

- Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- Launch in-house global products every year by doubling R&D output
- Accelerating innovation opportunities by strengthening collaboration with leading global players and **leveraging digital technologies**

Futuristic Business Model

- Dramatic improvement in product / patient value by restructuring business model, having **digital utilization** as a core
- Improve productivity of entire value chain by leveraging digital technologies
- Commercialization of insight business with the aim of maximizing the value of pharmaceuticals and having a new business pillar

Key Drivers ▶ **DX** ▶ **RED SHIFT** ▶ **Open Innovation**

*RED: Research & Early Development

CHUGAI DIGITAL VISION 2030

CHUGAI DIGITAL

Transform our business by using digital technologies to make Chugai a top innovator in the provision of society-changing healthcare solutions

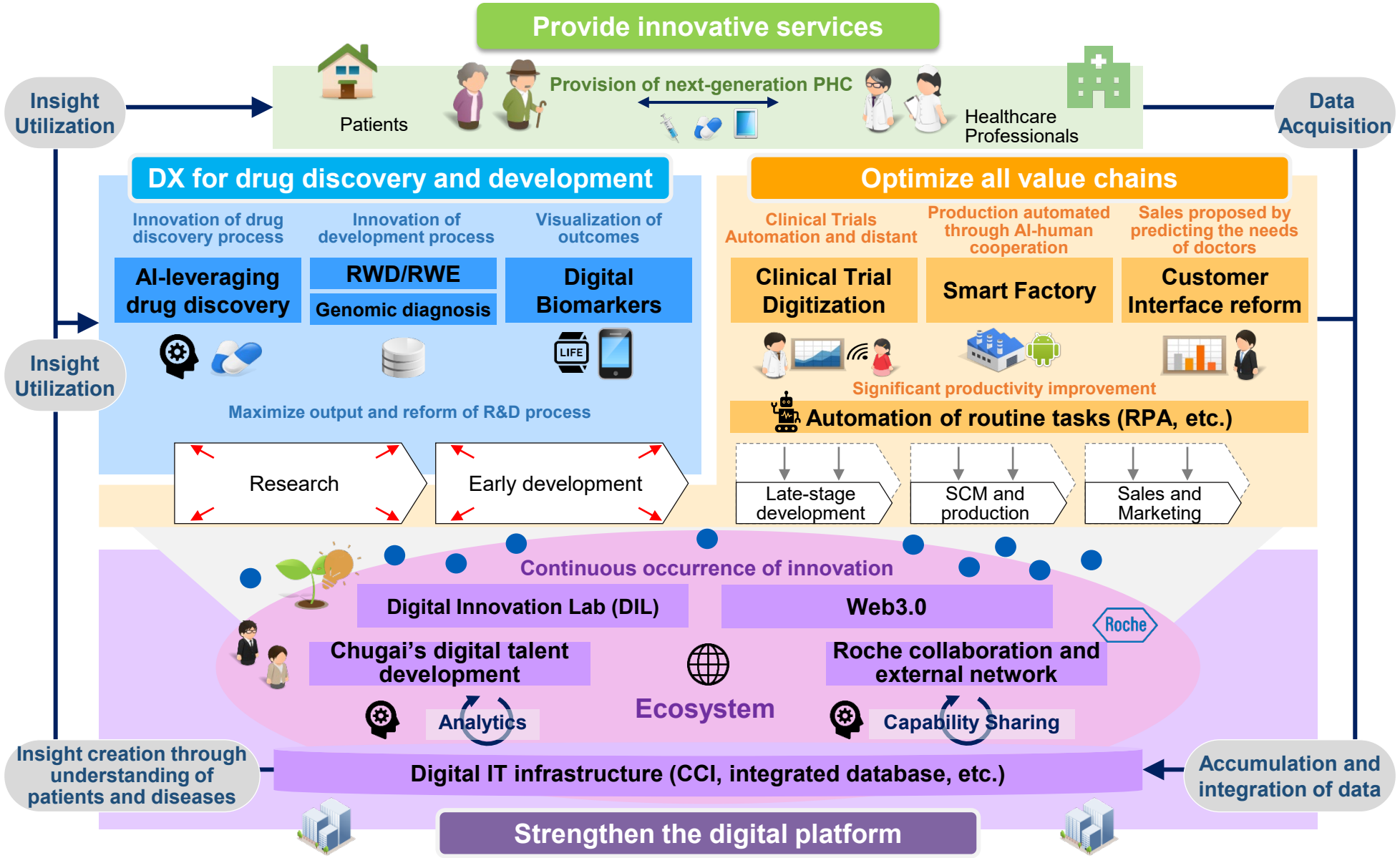
Transform our business

- Provide innovative drug products continuously by leveraging digital technologies.
- Greatly streamline all value chains.
- Create frameworks for providing innovative services.
- Change employee awareness and organizational structure and customs at Chugai.

Society-changing healthcare solutions

- Provide optimal personalized healthcare suited to individuals.
- Produce high QoL throughout life through ultra-early diagnosis, prevention, and treatment.
- Bring about social assurance programs sustainable even in shrinking and aging societies.

Overall Picture of CHUGAI DIGITAL VISION 2030



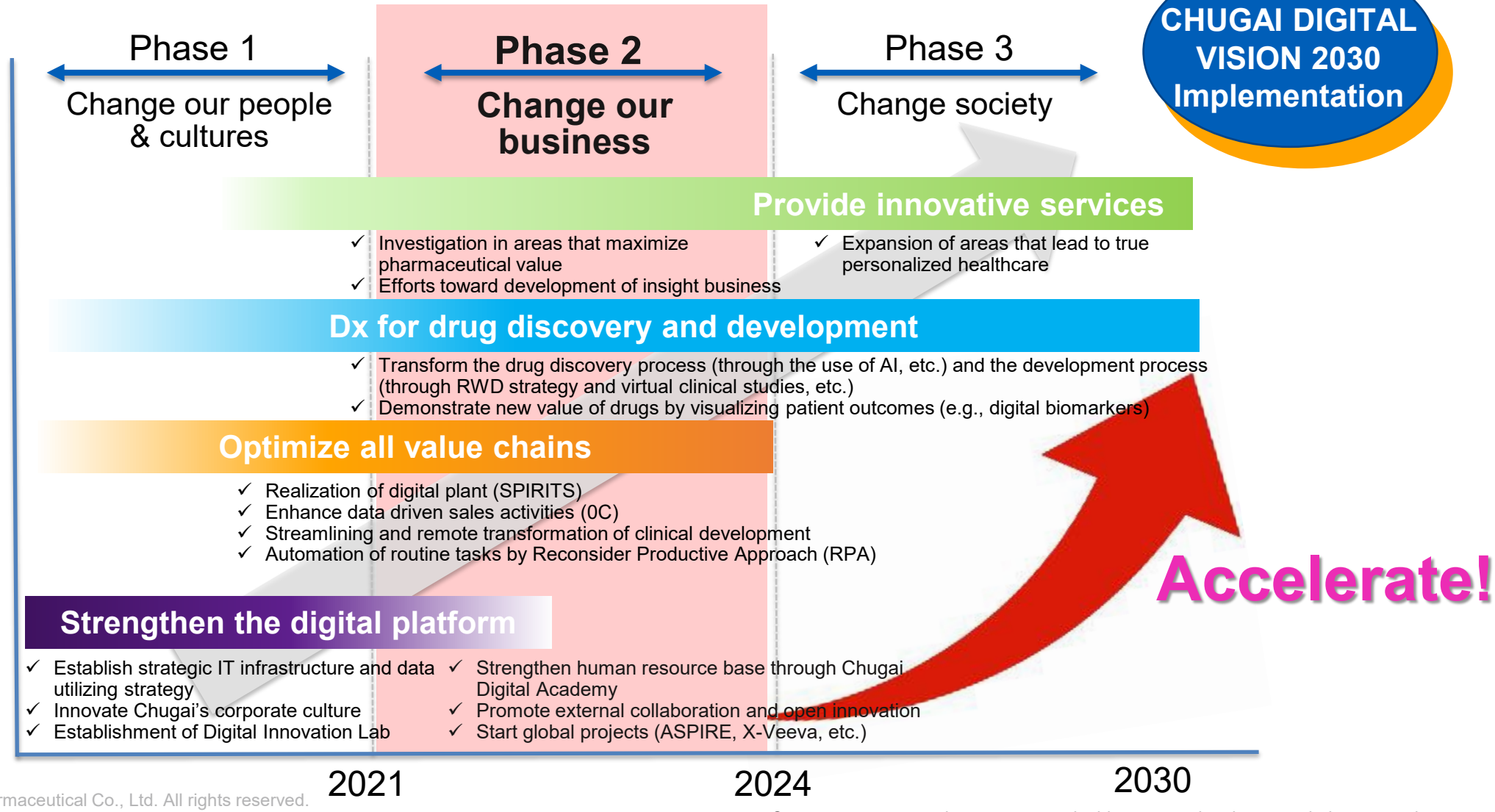
RWD: real world data, RWE: real world evidence
RPA: Reconsider Productive Approach, CCI: Chugai Cloud Infrastructure

Roadmap of Digital Transformation

TOP INNOVATOR TOP i 2030

CHUGAI DIGITAL

CHUGAI DIGITAL VISION 2030 Implementation



Key Achievements So Far (1)

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DX for drug discovery and development

- ✓ **Accelerate drug discovery research DX by utilizing AI, robotics, etc.**
  - ➢ Select candidate antibodies for development through the use of AI technology in generating antibody molecular sequences and optimization (MALEXA)
  - ➢ Improve molecular design and screening methods for small/mid-size molecules through AI technology
  - ➢ Improve productivity in pathology through the use of image analysis technology. Use quantitative evaluation to perform integrated analyses
  - ➢ Develop robots to support work in complex experiments
  - ➢ Promotion in development of Lab Automation System and digital infrastructure
- ✓ **Promote development of digital biomarkers**
  - ➢ Enter into new partnership agreement with Biofourmis for the continued development and practical clinical application of digital solutions to objectively evaluate pain in patients with endometriosis
- ✓ **Promote utilization of RWD in filing of regulatory application and internal decision-making**
  - ➢ Filing of regulatory application: Use of RWD as evaluation data and reference data in the filing package for HER2-positive colorectal cancer
  - ➢ Utilization in internal decision-making: to survey actual treatment status of diseases, investigate prognosis predictions, and consider clinical study design, etc.

Details to be explained today

Key Achievements So Far (2)

Optimize all value chains

✓ Promoting initiatives towards smart factories

- Equip Ukima Plant with the following functions.
  (1) Automation and visualization of work plan drafting
  (2) Efficient assignment and utilization of human resources throughout the entire plant
  (3) Use of smartphones to enable remote support and tamper-proof image recording tools
- Promote deployment to Fujieda Plant and Utsunomiya Plant

✓ Promote updating of customer engagement model

- Support sales, safety, and MA activities with a comprehensive platform that integrates customer databases and information on various solutions, and a decision-making support engine that utilizes AI. Accelerate improvement of operation results

✓ Digitization of clinical trials: Promotion of DCTs

- Start decentralized clinical trials (DCTs) incorporating visiting nursing and telemedicine into ordinary clinical trials in the US

✓ Promote Reconsider Productive Approach (RPA) efforts

- Initially aimed at reducing workload by 100,000 hours by 2023, but achieved 150,000 hours workload reduction by the end of 2022

Key Achievements So Far (3)

Strengthening the digital platform

✓ Operation of the Chugai Cloud Infrastructure (CCI)

- Unify the data provision functions in a multicloud environment (AWS/Azure/Google Cloud, etc.) to promote standardization, strengthen security governance, and achieve efficient integrated operations management
- While using AWS as the main platform, use Google for AI/machine learning, etc.

Details to be explained today

✓ Cyber Security

- Formulate a cyber security vision and clarify issues to enhance cyder security and countermeasures. In addition to raising the overall level of security, various risk-based initiatives will be implemented, and security checks and security monitoring of business partners will be enhanced.

Details to be explained today

✓ Acceleration of external collaborations and open innovation

- Establishment of CVC: Begin approach to digital AI technology to support drug discovery and translational research
- Digital Innovation Lab: Promoted more than 450 ideas and 80 PoCs in 3 years, and shifted more than 20 projects to actual development
- Innovation Pitch (C-DIP): A pitch event will be held on 9/22 (scheduled to be held within the year in October and December) with the aim of promoting collaboration with start-up companies and revitalizing the entire industry

Key Achievements So Far (4)

Strengthening the digital platform

- ✓ **Launch & promote ASPIRE project**
  - ➢ Introduction of state-of-the-art global standard processes and next-generation core business infrastructure (ERP), and promotion of company-wide operational process and organizational reforms
- ✓ **Promotion of data strategy**
  - ➢ Accelerate the establishment of a governance/control system whereby anyone who needs to use data can easily find and obtain that data thanks to the establishment of an environment in which the desired analysis can be performed conveniently, together with the FAIR + culture/system
- ✓ **Launch of Web 3.0 initiatives**
  - ➢ In October 2022, our company's philosophy on Web 3.0 was announced as a Point of View. We will aim for new innovations by utilizing "DAO," "DID," "NFT/FT," etc., based on blockchain technology
- ✓ **Promotion of utilization of generative AI**
  - ➢ ChatGPT: Company-wide use started in August after various risk evaluations and guidelines were formulated
  - ➢ Acceleration of utilization for more advanced operations and promotion of evaluation of various types of generative AI

Details to be explained today

Details to be explained today

DX Brand: Selected as Grand Prix and Platinum Company

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- The only pharmaceutical company selected for 4 consecutive years since 2020
- In 2022, Chugai was selected to receive the “DX Grand Prix” as “a company that leads the digital era in a manner that transcends the framework of its industry”
- In 2023, Chugai was selected for the “DX Platinum Company 2023-2025” as a company that has continued to pursue outstanding DX initiatives since the inception of the system

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   (Nobuya Ishii, Head of Science & Technology Intelligence Department)

Overall Picture of CHUGAI DIGITAL and Security Risks

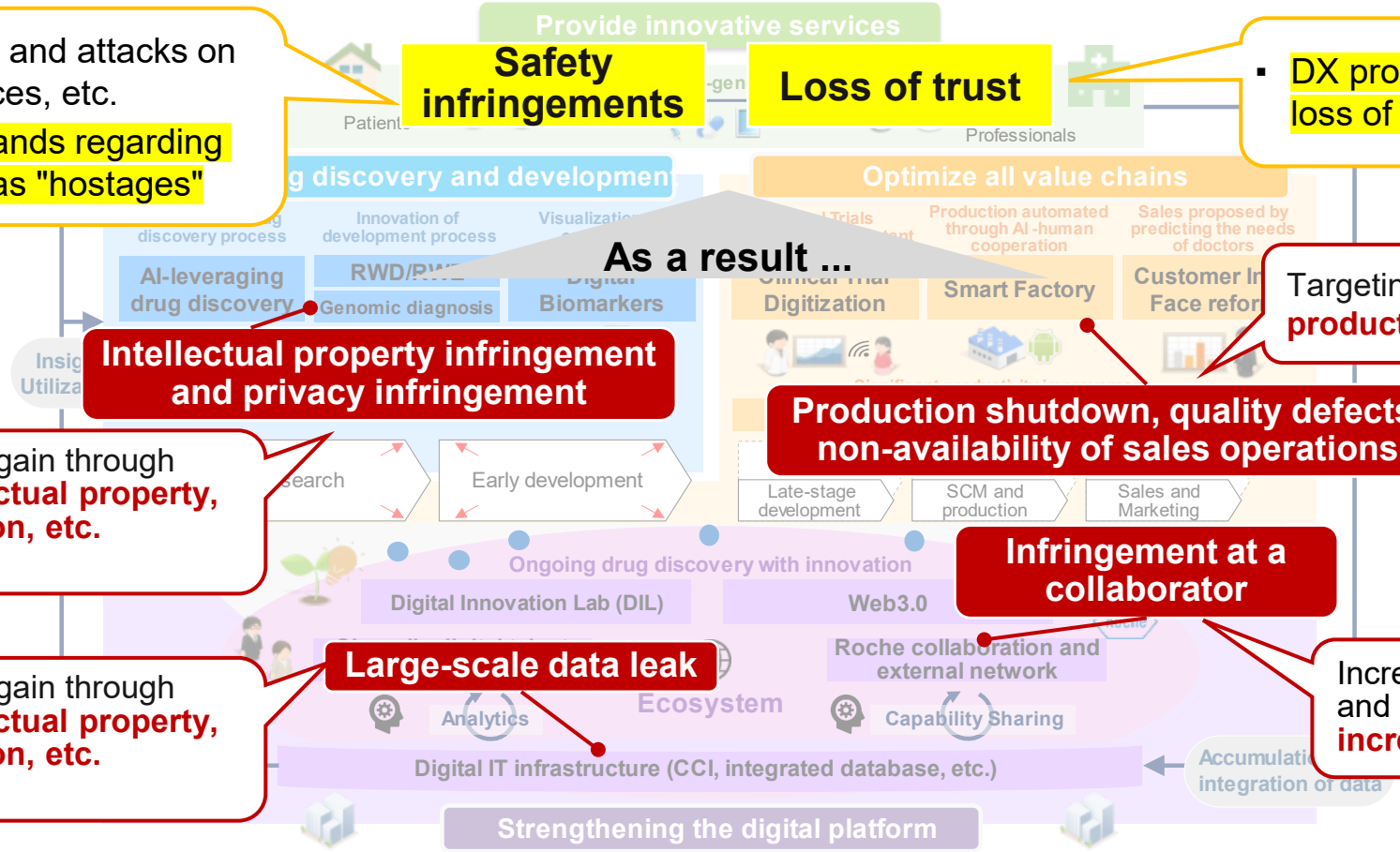
◆ **It will be essential to improve comprehensive security capabilities involving all business units**

■ Overall picture of CHUGAI DIGITAL security risks that could be targeted by attackers

- Data breaches and attacks on wearable devices, etc.
- Financial demands regarding patient safety as "hostages"

Safety infringements **Loss of trust**

- DX promotion itself is derailed by loss of trust on the part of stakeholders



Targeting monetary gain by **holding production and sales activities** “hostage”

Targeting monetary gain through **data theft of intellectual property, personal information, etc.** (Threats, direct sale)

Infringement at a collaborator

Large-scale data leak

Targeting monetary gain through **data theft of intellectual property, personal information, etc.** (Threats, direct sale)

Increasing and diversifying partners and business connections also **increases opportunities for attacks**

Cyber Security Vision

◆ Through internal and external environmental analyses, including CHUGAI DIGITAL VISION 2030, create a "vision and strategy" for cyber security by 2030

CHUGAI CYBER SECURITY VISION 2030

Become a cyber security leader to support the achievement of top innovator status in the healthcare industry

Organizational management

- ☐ Construct a companywide governance system with a robust monitoring/escalation and feedback loop
- ☐ Construct a system that supports business and enhances security by having business and IT coordinate while retaining high degrees of specialization

People/Culture

- ☐ Foster a security culture so that all employees throughout Chugai Global consider "Security First" to be a matter that concerns them personally
- ☐ Disclose a commitment to security in an outward-facing, proactive manner

Technology

- ☐ Construct a highly secure IT infrastructure base that enables secure use of data
- ☐ Achieve flexible and robust IT security to accommodate ecosystem expansion and change

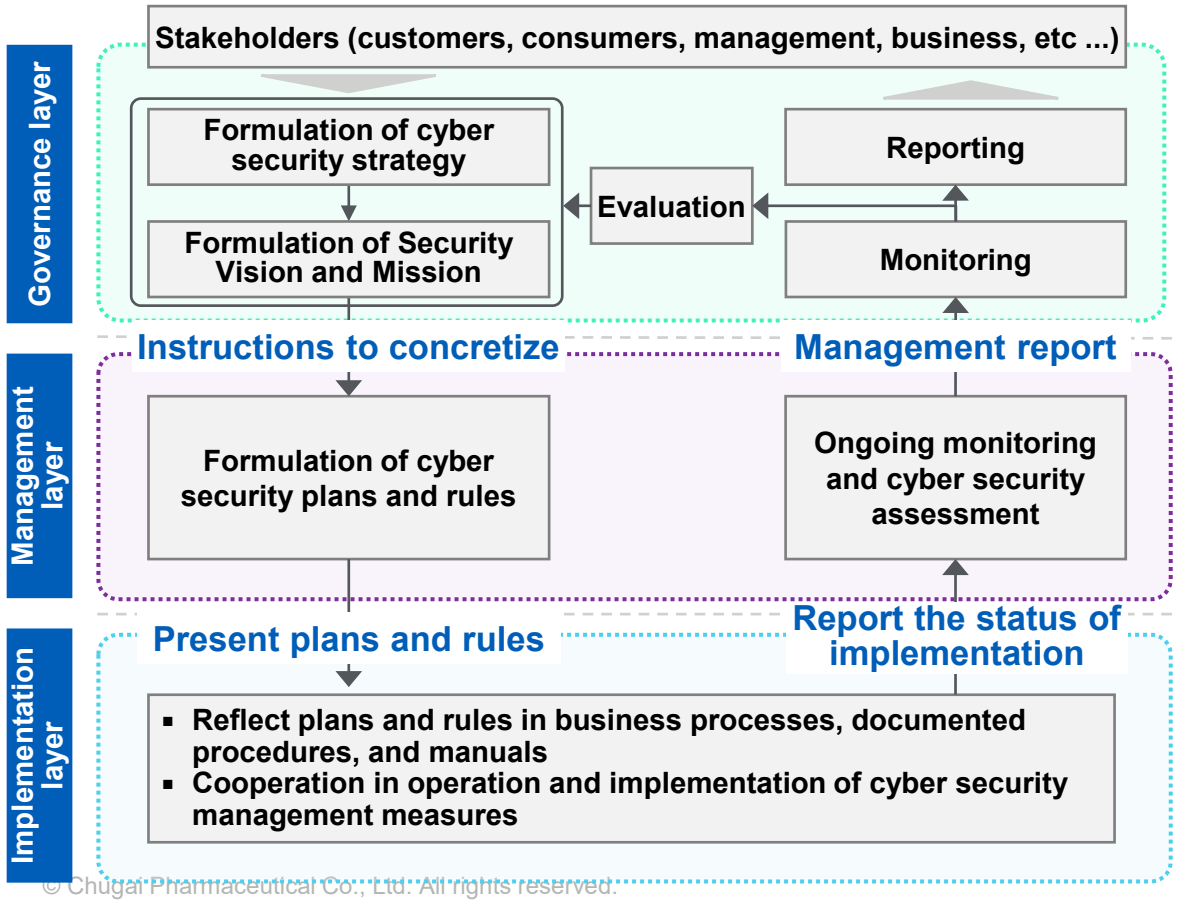
Establish a Cyber Security Management System

Organizational management | People/ Culture | Technology

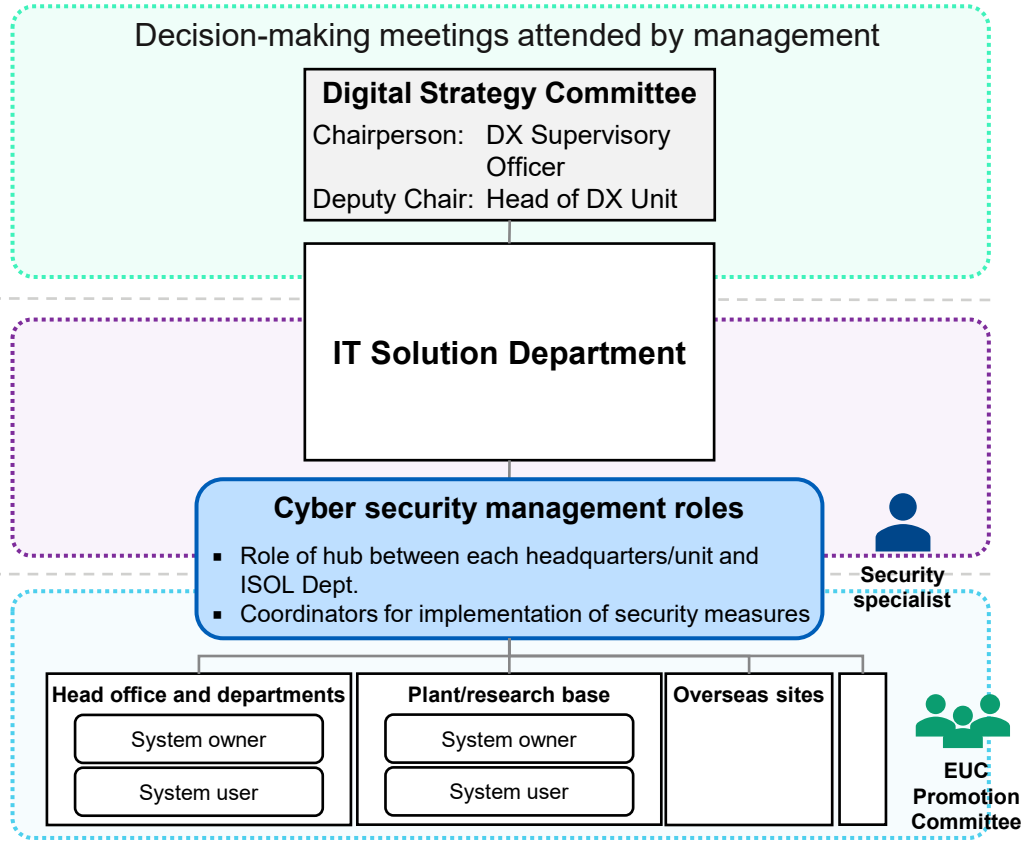
CHUGAI DIGITAL

- Construct a system to grasp security management information and implement vulnerability management in a timely and comprehensive manner
- Assign an officer to act as coordinator of the headquarters and bases and issue instructions and requests related to security
- Report the results of security monitoring to the management every quarter and connect them to additional improvement activities

Governance Cycle



Organizational chart of each layer



Approach to Security Issues

Organizational management | People/ Culture | Technology

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◆ **Gain a comprehensive grasp of information security issues by combining 2 approaches: “baseline ” and “risk-based”**

Baseline approach + **Risk-based approach**

- Create rules referring to best practices
- Regularly monitor compliance with rules
- Activities to correct gaps

Raise the overall security level

- Grasp risks specific to each case and system
- Grasp the latest trends in cyber attacks
- Implement individual measures for identified risks

Address residual risk in the baseline approach

Baseline Approach

Organizational management | People/ Culture | Technology

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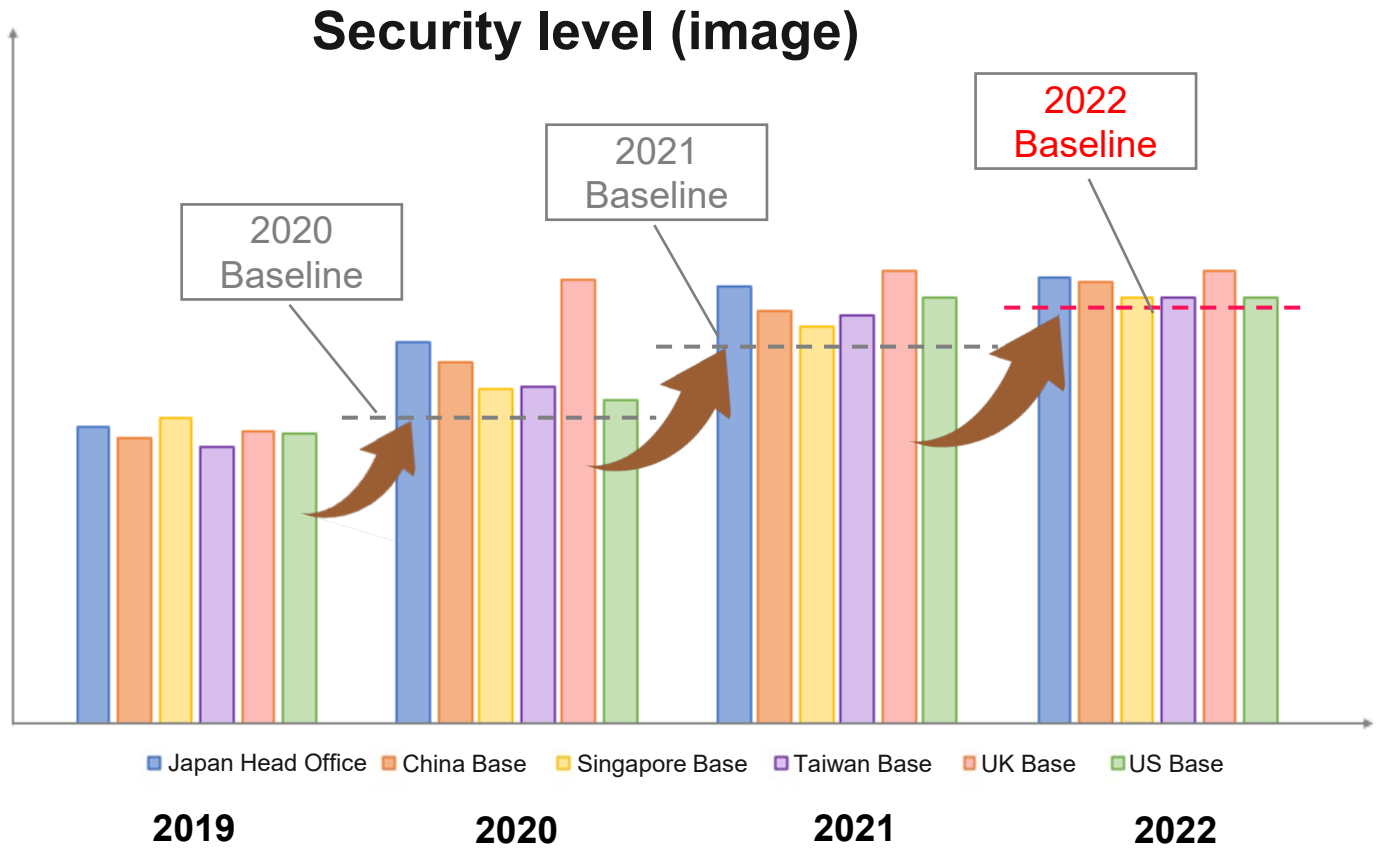
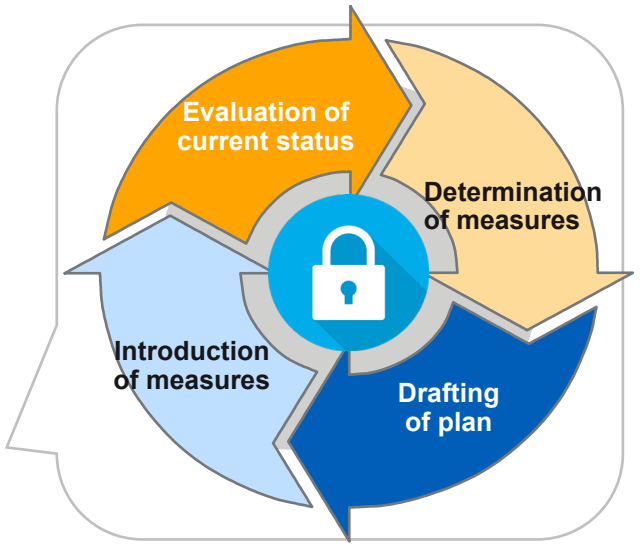
- Each site's security level is scored annually against the best practice collection
- Elevate the security level of the entire Group by establishing a baseline (security goals for each fiscal year) for plants, research laboratories, and overseas bases and planning and implementing various measures to achieve it





Risk-based Approach

Organizational management | People/ Culture | Technology

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- Combine multiple approaches to proactively grasp overall risk
- Take appropriate individual actions according to the identified risks in a planned manner

(1) Check security risks at the time of system planning and modification
(Catch up with cases in the budget drafting process)

(2) Conduct risk assessment for information assets
(Annual inventory of personal information ledger, occasional risk evaluation of human-derived data, etc.)

(3) Identify existential risks through regular penetration tests

(4) Continuous acquisition of information on the movements of advanced attackers
(Using threat intelligence)

Systematically implement individual measures for risks identified at each level

Respond appropriately to individual risks that cannot be grasped by the baseline approach (rules) alone

Business Partner Security Initiatives

Organizational management | People/ Culture | Technology

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- **Check response to the security risks of business partners from 2 viewpoints: "security system/maturity level" and "technical vulnerability"**
- **On a trial basis, implement for about 70 of our important business partners**

	Details of check	Frequency of checking
Check of security system and maturity level	• Confirmation of the status of acquisition of certification such as ISMS* • **Audit by our company, using checklist**	At the start of business + Periodically (e.g., annually)
Check of technical vulnerabilities	• **Use of security rating services** • Use of threat intelligence services • Use OSINT** to check from the perspective of attackers	Occasional checks, as needed (Routine continuous monitoring)

*ISMS: Information Security Management System
**OSINT: Open Source Intelligence

Business Partner Security Initiatives (Results)

Organizational management | People/ Culture | Technology

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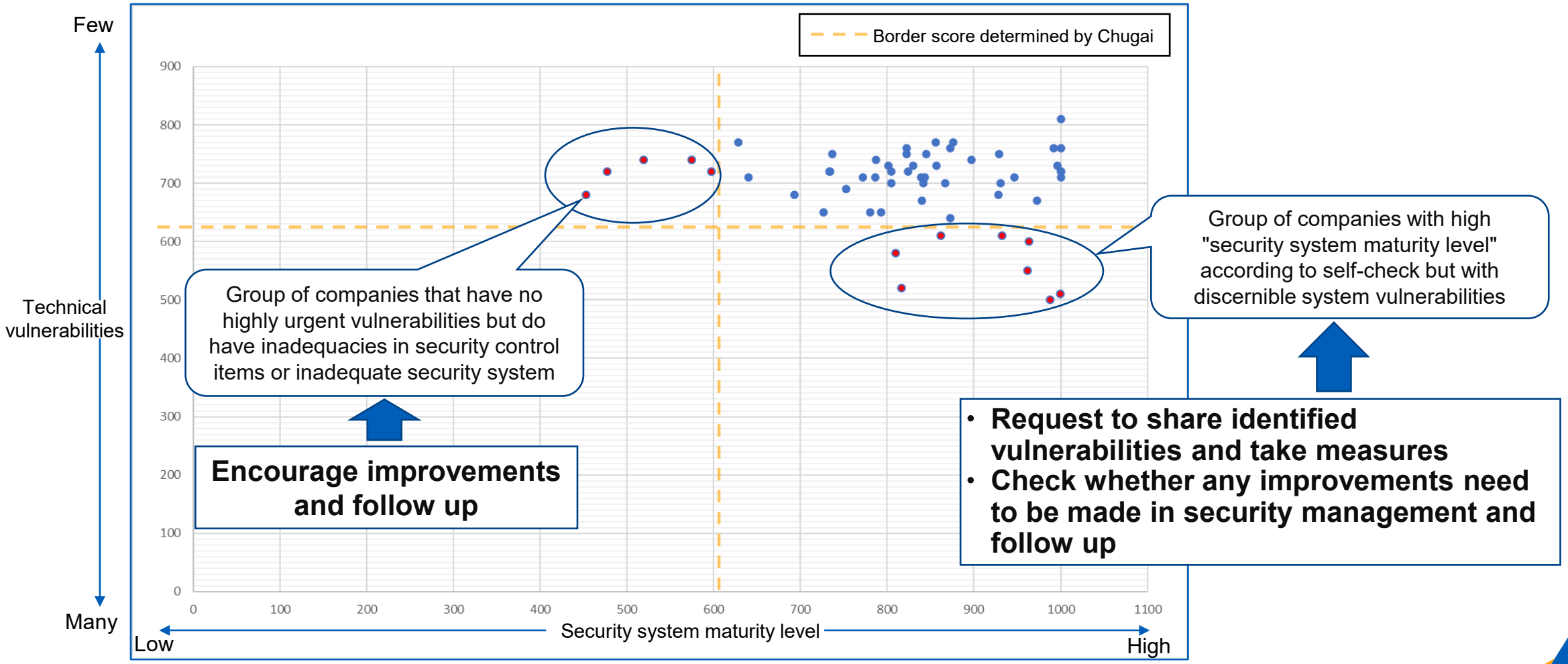
- Take action based on the results for "security system/maturity level" and "technical vulnerability"
- It will be necessary to establish a system for checking in cooperation with the business unit, risk management unit, procurement unit, and IT unit



Upgrading of Security Monitoring

Organizational management | People/ Culture | Technology

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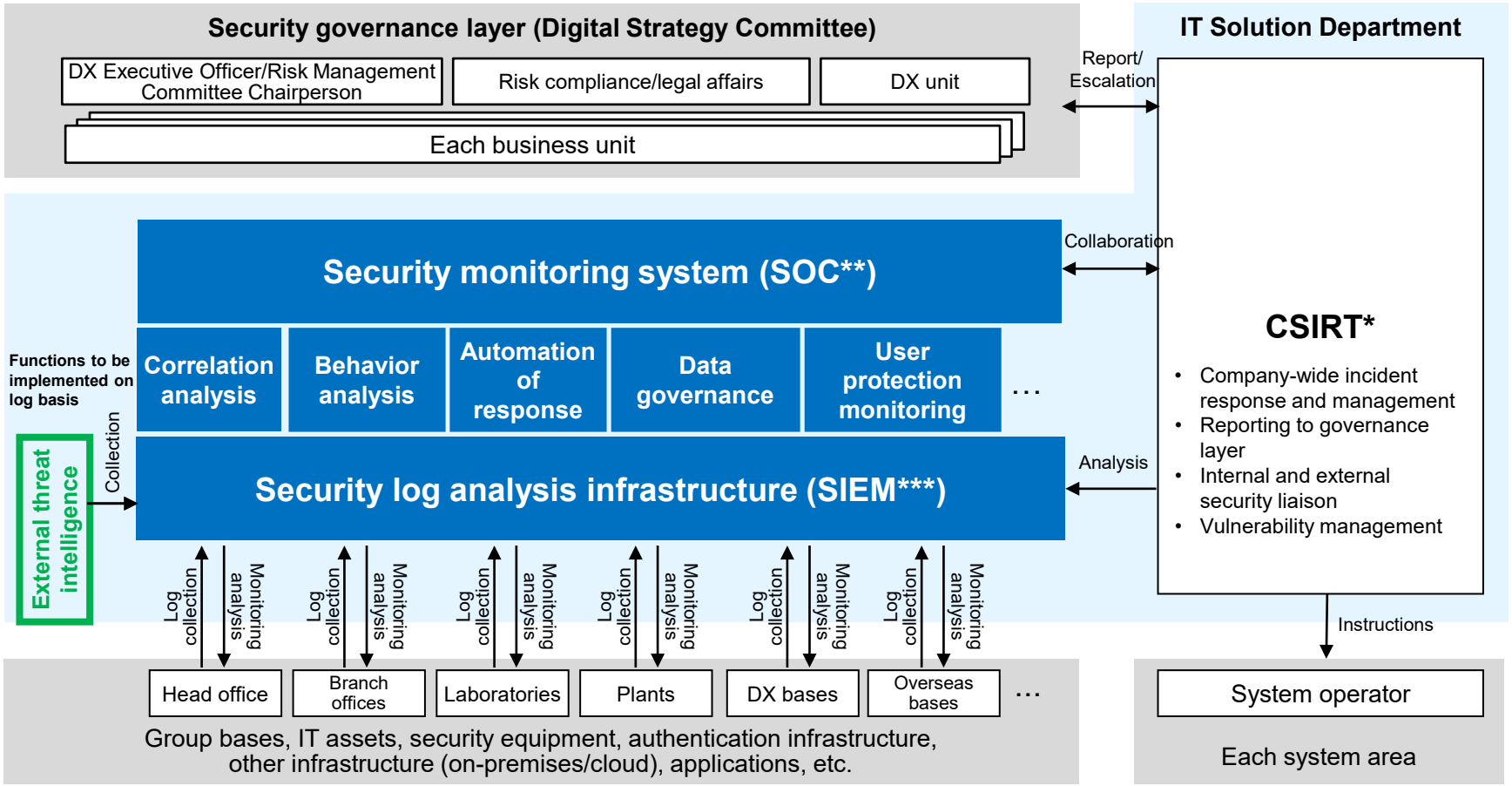
◆ Promote to upgrade SOC/SIEM that is central to proactive security response

Vision for security monitoring system

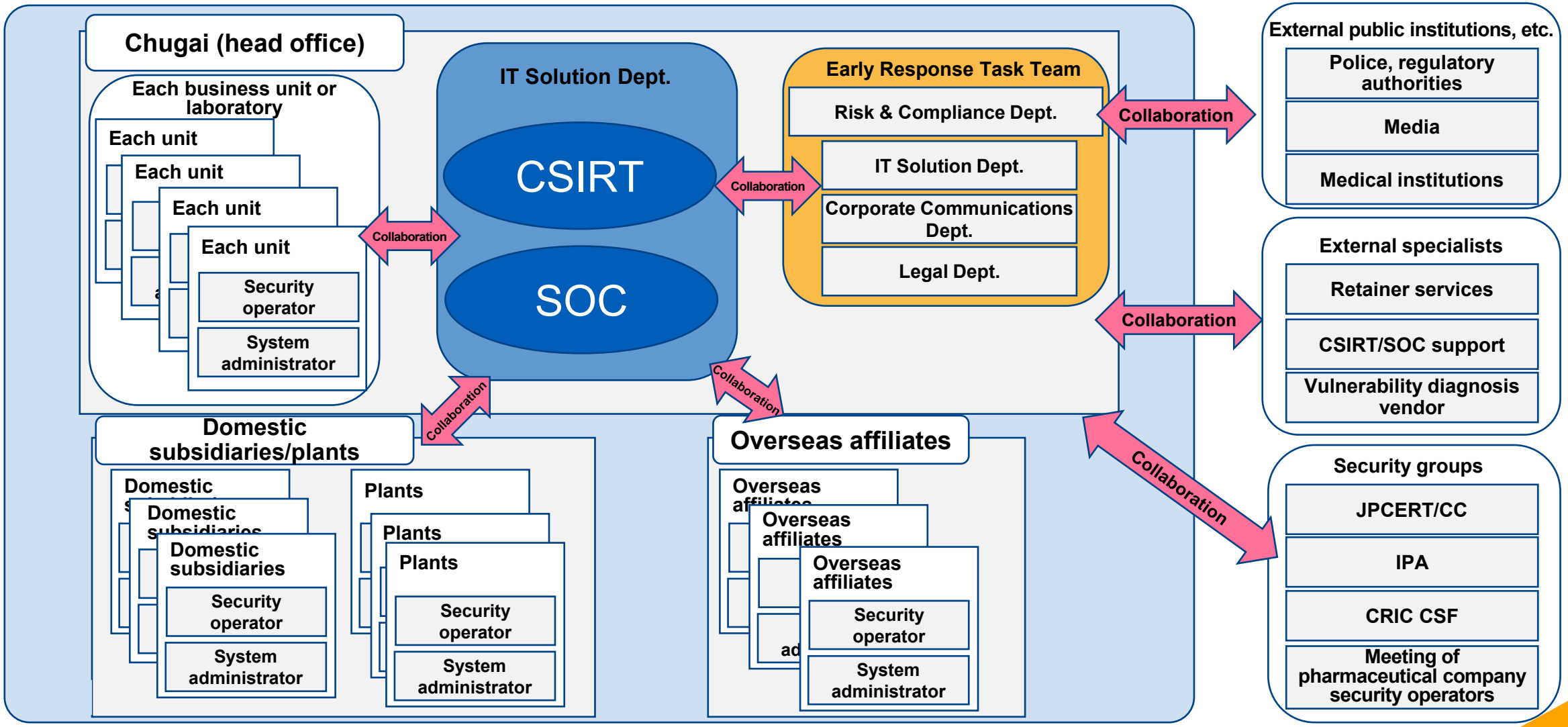


*CSIRT: Computer Security Incident Response Team
**SOC: Security Operation Center ***SIEM: Security Information and Event Management

Cyber Security Response System

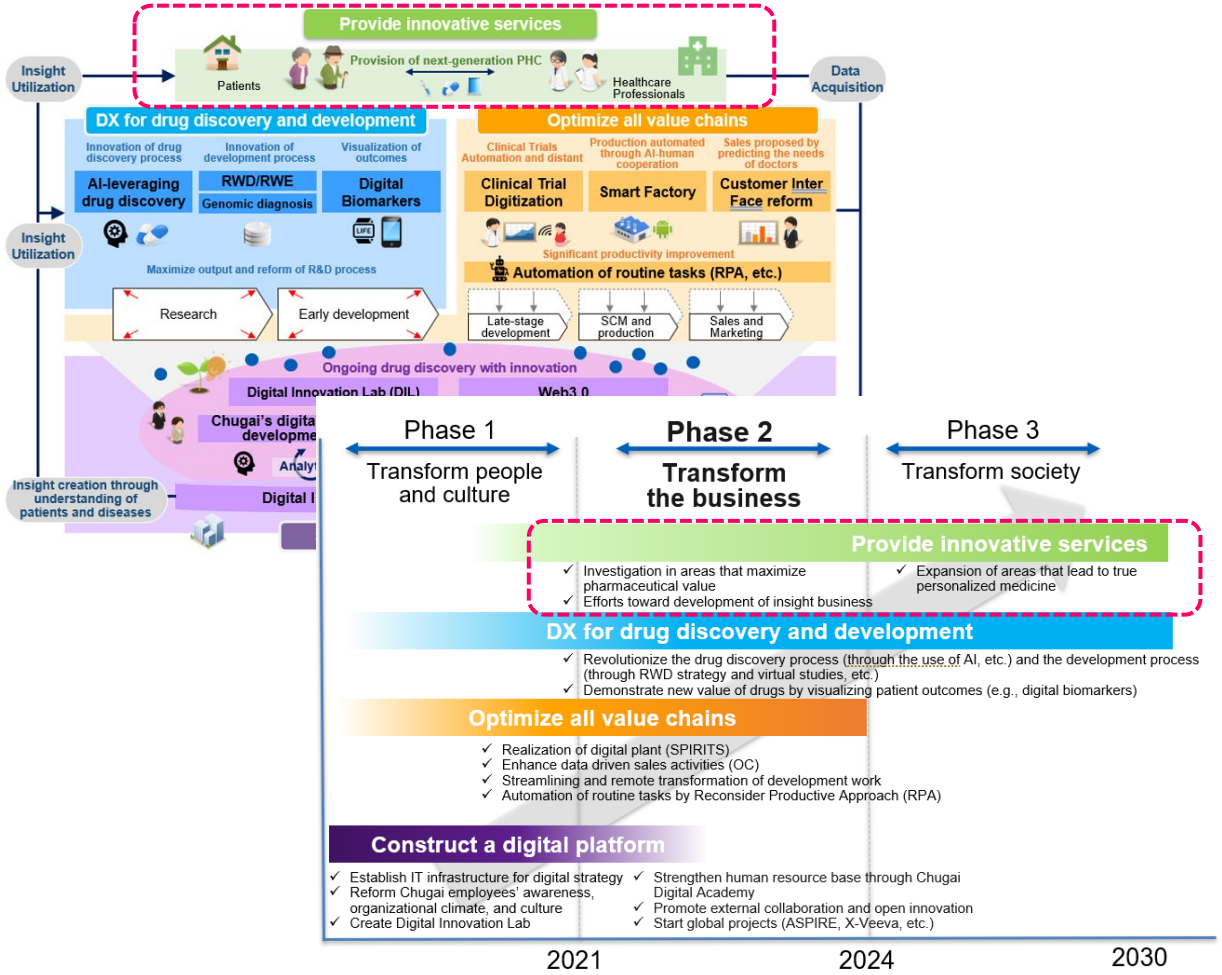
Organizational management | People/ Culture | Technology

- Cooperate and share information within and outside the company in preparation for emergency
- In the event of an emergency, promptly set up a task team for early response and take company-wide action with the aim of minimizing damage



Future Theme: Digital Service Security

- **It will be necessary to establish a security system that anticipates the provision of digital services to patients and healthcare providers (automatic drug delivery devices, digital biomarkers, smartphone applications, etc.).**



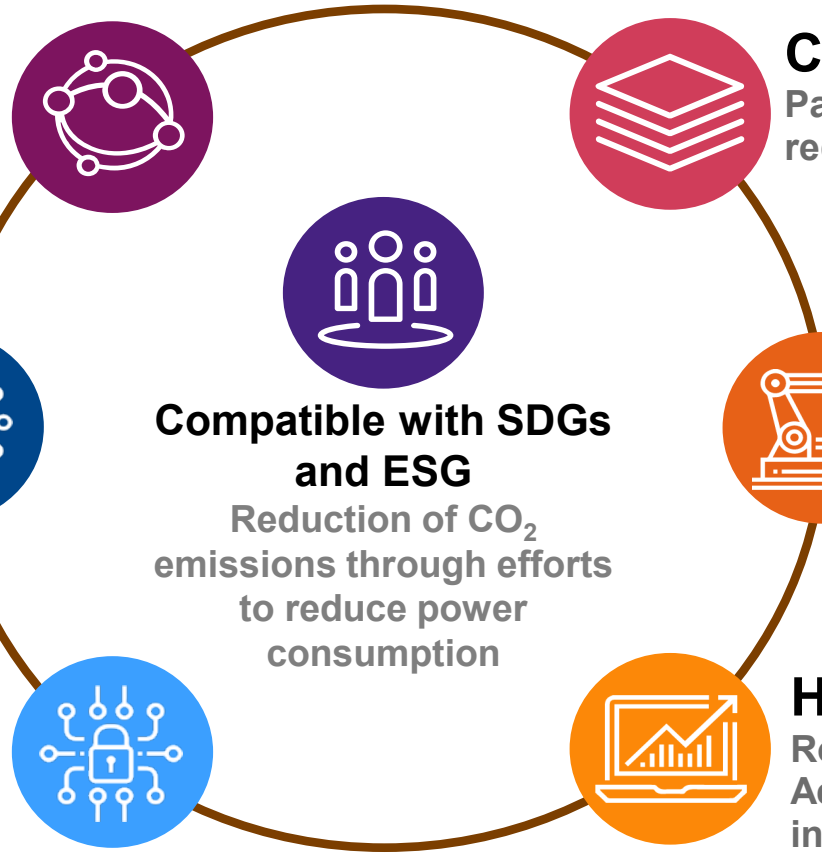
Evolution of DX

Our information protection is insufficient within the current in-house framework

We need to take measures from the perspective of the protection of users

Why will the Cloud be Necessary?

6 + 1 benefits of taking advantage of the cloud



Agility
Hundreds of thousands of servers can be deployed in minutes and shut down at any time

Cost reduction
Pay-as-you-go system that does not require an initial investment

Broad range of functions
Can utilize hundreds of state-of-the-art services, which are constantly evolving

Compatible with SDGs and ESG
Reduction of CO_2 emissions through efforts to reduce power consumption

Elasticity
No need for scale capacity forecast dependent on demand

Global-scale deployment
Deploy worldwide in just a few minutes

Higher security
Robust security by specialist organizations
Acquisition of various third-party international standards

Why is a Multi-cloud Strategy Necessary?

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Leveraging the advantages of multi-cloud

Niche services/ Strengths and weaknesses

A mixture of public cloud services that are carefully selected allows us to access **featured services** of the respective cloud vendors and **niche or advanced services** that are not available from other cloud services.

Mitigation of vendor lock-in and geopolitical risks

A mixture of public cloud services that are carefully selected can help mitigate or reduce the **risks of vendor lock-in**. These risks include potential **future price increases, service discontinuation by cloud vendors**, as well as **geopolitical risks that may lead to service outages and delivery delays**.

Managing the drawbacks of multi-cloud

Measures to simplify operations

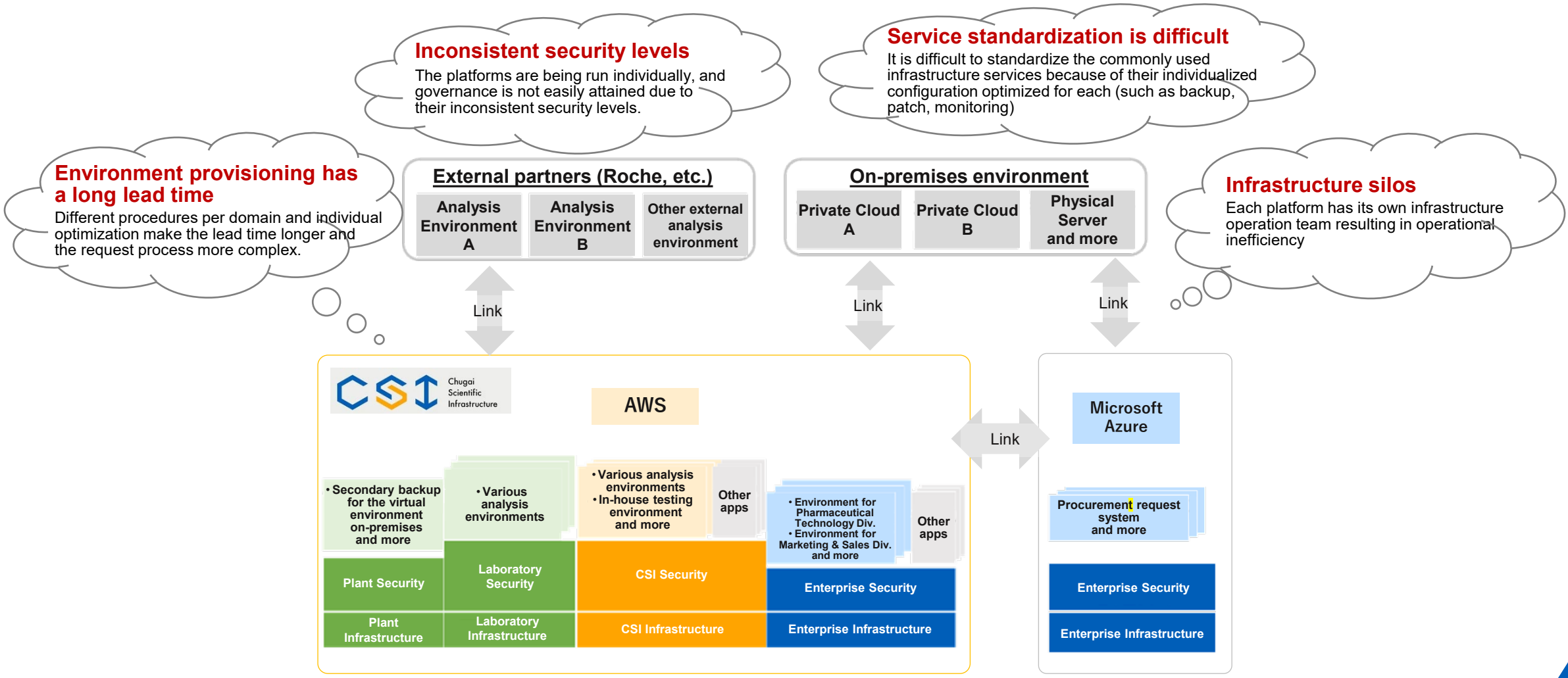
Multi-cloud environments are often criticized for their complexity and increased operational burdens. However, when **the same vendor handles both the design and operation**, it allows for standardized and consistent operations without adding unnecessary complexity.
Also, the use of **integrated automation management (IaC products)** allows us to reduce operational burdens.

Solution for increased costs

Multi-cloud environments do come with disadvantages, such as increased costs from not being eligible for volume discounts. However, by **taking advantage of the Roche Group's blanket policy**, we have reduced the costs.
Also, by adopting **the integrated cost management (FinOps products)**, we can collectively manage costs across multiple clouds, minimize expenses by adjusting, suspending, or deleting resources while comparing costs among cloud services.

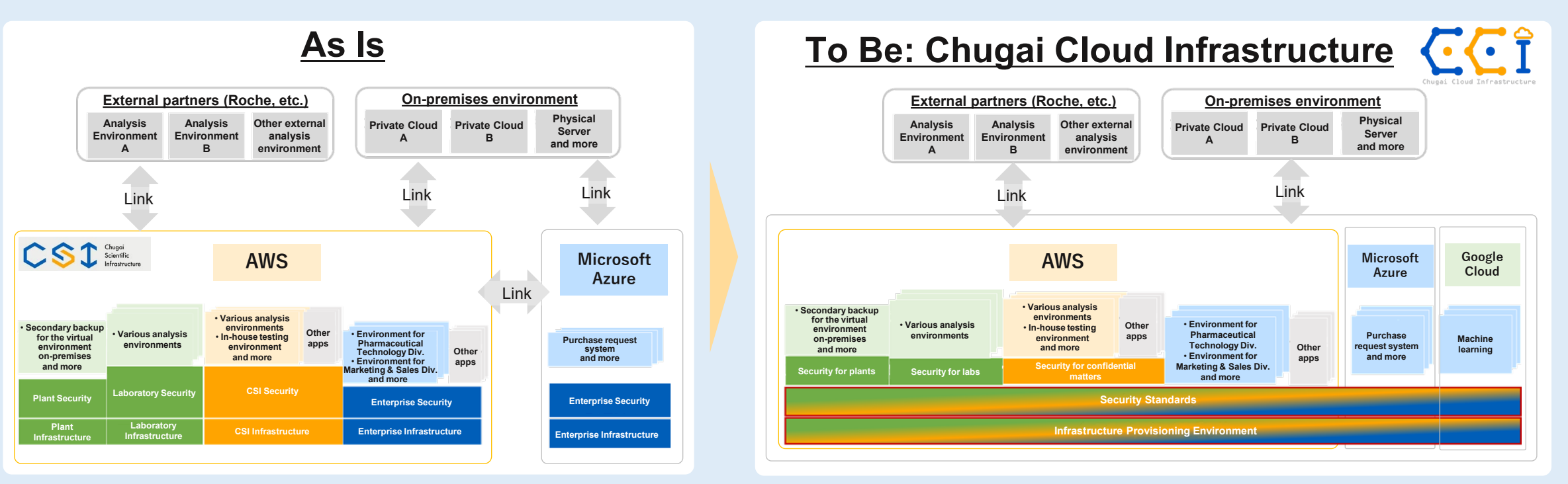
Utilization and Challenges of our Cloud Infrastructure

◆ **While we've pursued various measures for DX individually, further advancement of DX at an expedited pace should consider aspects like faster environment provisioning, enhanced security, standardized service utilization, and integrated infrastructure.**



Overview of the CCI (Chugai Cloud Infrastructure)

- Start building the next-generation Chugai cloud infrastructure (CCI) by utilizing the knowledge of CSI construction
- Efficiently integrate the enterprise system platforms that have been configured on third-party cloud environments
- Centralize cloud infrastructure features for enhanced standardization and security governance
- Continuously improve and extend functionality to keep pace with technological advancements



Integrated Cloud Infrastructure Services

Standardization of Cloud Security

Standardization of infrastructure-related Services

Usage Guidelines for the CCI (Chugai Cloud Infrastructure)

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◆ **Chugai Cloud Infrastructure (CCI) uses AWS as the main cloud platform, with Microsoft Azure and Google Cloud as the sub cloud platforms.**

Platform type	Platform concept
AWS Released in April 2023	✓**Main cloud platform** To be used as a main cloud platform for the entire company
Microsoft Azure	✓**Sub cloud platform** This platform is used for cases that specifically require Azure (e.g., ChatGPT, IoT, security analysis platform, etc.)
Google Cloud To be released in November 2023	✓**Sub cloud platform** This platform is used for cases that specifically require Google Cloud (e.g., AI, machine learning, Big Data analysis, etc.)

Effectiveness of the CCI (Chugai Cloud Infrastructure)

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Existing issues	Results achieved by CCI
Speed (Agility)	Environment provisioning that used to take one month to complete can be done in 2 to 3 business days
Governance (Security/Control)	Governance and speed achieved together through ‘Detective Control’
Growing operation costs	Operation cost reduction of 36% through consolidation and automation/self-service

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Promotion Policy for 2023

◆ **3 directions to be promoted for the time being**

Direction 1

Introduction of ChatGPT and promotion of its utilization

Direction 2

Promotion of utilization of generative AI (external solution) in each unit's operations

Direction 3

Generative AI utilization strategy for the creation of new value, and drafting of use cases

ChatGPT Utilization Status

◆ **Create infrastructure within the internal environment, confirm use cases through trials, and promote company-wide utilization from August onward after formulating guidelines**

Implementation status

◆ **Construct the Chugai version of ChatGPT on Azure and implement PoC from May onward, with the objective of investigating use cases and risks**

◆ **Start company-wide deployment in August after establishing rules and procedures**

Risk response

◆ **Identify the following 6 risks and formulate guidelines**

Infringement of intellectual property and copyrights	Biased output
Leakage of personal information and confidential data	Use for unintended purpose
Lack of credibility	Shadow AI

Examples of utilization

Preparation of meeting minutes and action list	UMN initial search
Creation of various scenarios	Extraction of information on laws and regulations
Questionnaire analysis	RWD tabulation efficiency
Proofreading of various regulatory documents	Code creation and programming explanation

Initial Use Cases

- **Promote various initiatives for tasks that can be done with Chugai's ChatGPT**
- **Develop a platform for utilizing internal and external data and encourage diverse usages of data beyond text**

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Use case details

Retrieval of paper and abstract summary

- Auto-search on scholarly paper databases using specific keywords
- Summarize the abstract of paper
- Share the abstract along with paper details (such as title, author, sources, abstract, link)

Streamlined programming

- Automatically generate code in Python or R to refine coding and streamline programming tasks
- Input error-containing code in Python or other languages and display suggestions to correct the identified error.
- Input code in Python, VBA, or other languages to identify the content and structure

Analysis of various text data

- Input survey results, including those from Google Forms, into GPT for analysis, which covers the entire process from comment aggregation/analysis to solution drafting
- Based on knowledge compiled internally along with written text for a task, create structured data (e.g., duration, root cause classification, impact, solutions, etc.)

Future usage

- Various internal data (Contract and privacy info needs strict control)
- Various external data
- Image and other non-text data

Idea Types Frequently Requested in ChatGPT and Direction of Realization

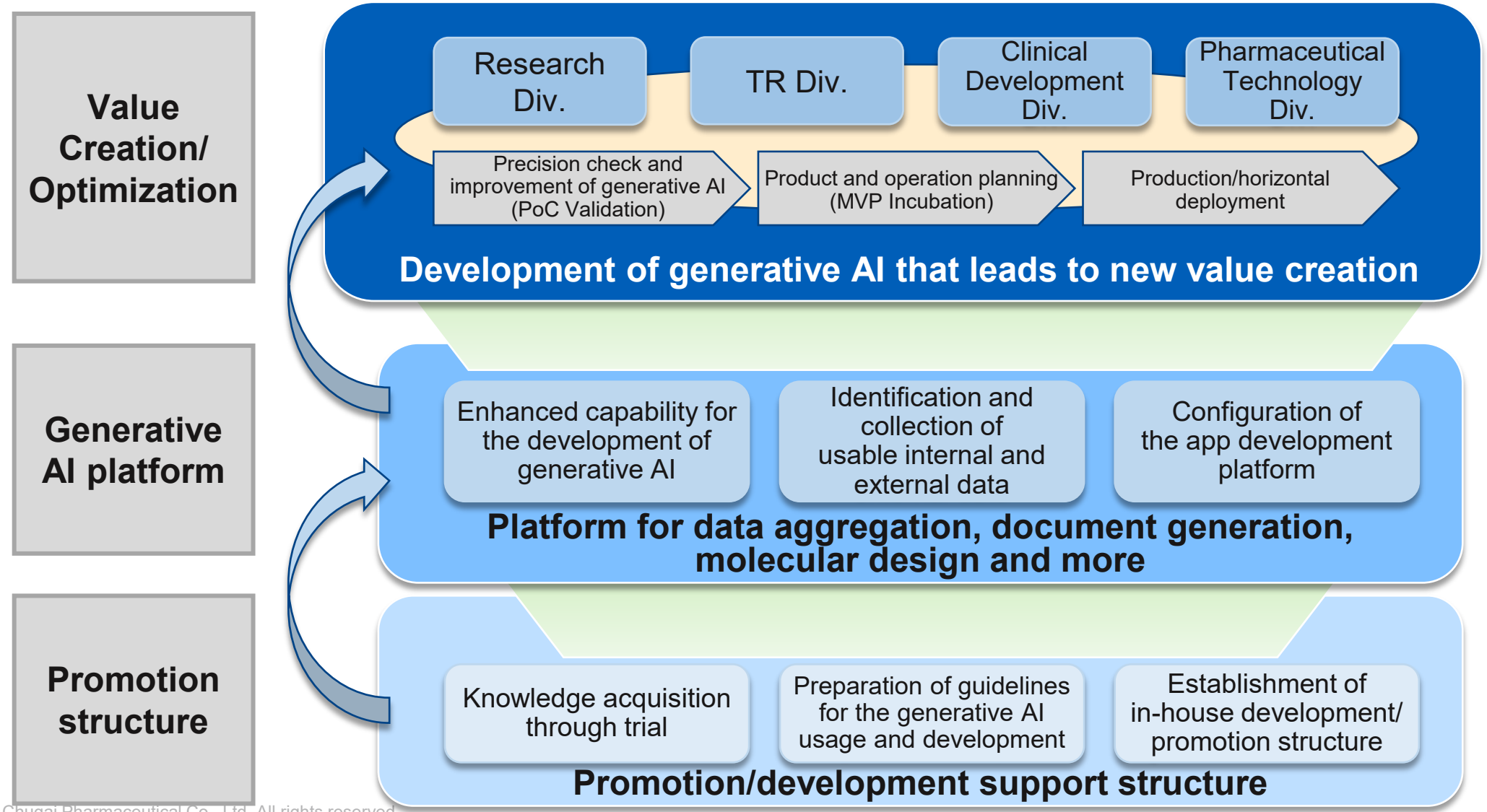
- **Promote utilization of ideas that can already be implemented**
- **Cognitive searches, etc., where the infrastructure is best considered by the entire company should be executed chiefly by DXU**

Already feasible	Streamline with ChatGPT and Microsoft Copilot	**Preparation of draft emails**	**Preparation of draft meeting minutes**	**Preparation of draft codes**
		Translation/proofreading	**Create drafts of recruitment guidelines and questions**	**Summaries of papers**
Handle by DXU + each unit	Enable with “Add your data” function	**Simplification of SOP search and document preparation**	**Confirmation of how to use systems, equipment, software, etc.**	**Responding to various inquiries (Chatbot)**
		Preparation of draft internal and external explanatory materials and educational materials		
Infrastructure to be considered by DXU	Realize by combining ChatGPT with other systems	**Cognitive searches**	**Collection of regulations and trends at other companies**	**Draft proposals for various applications and GxP documents, and proposals for modifications**

Cognitive search: A method of accurately and efficiently finding desired information for users through integrated search on various data
DXU: Digital Transformation Unit

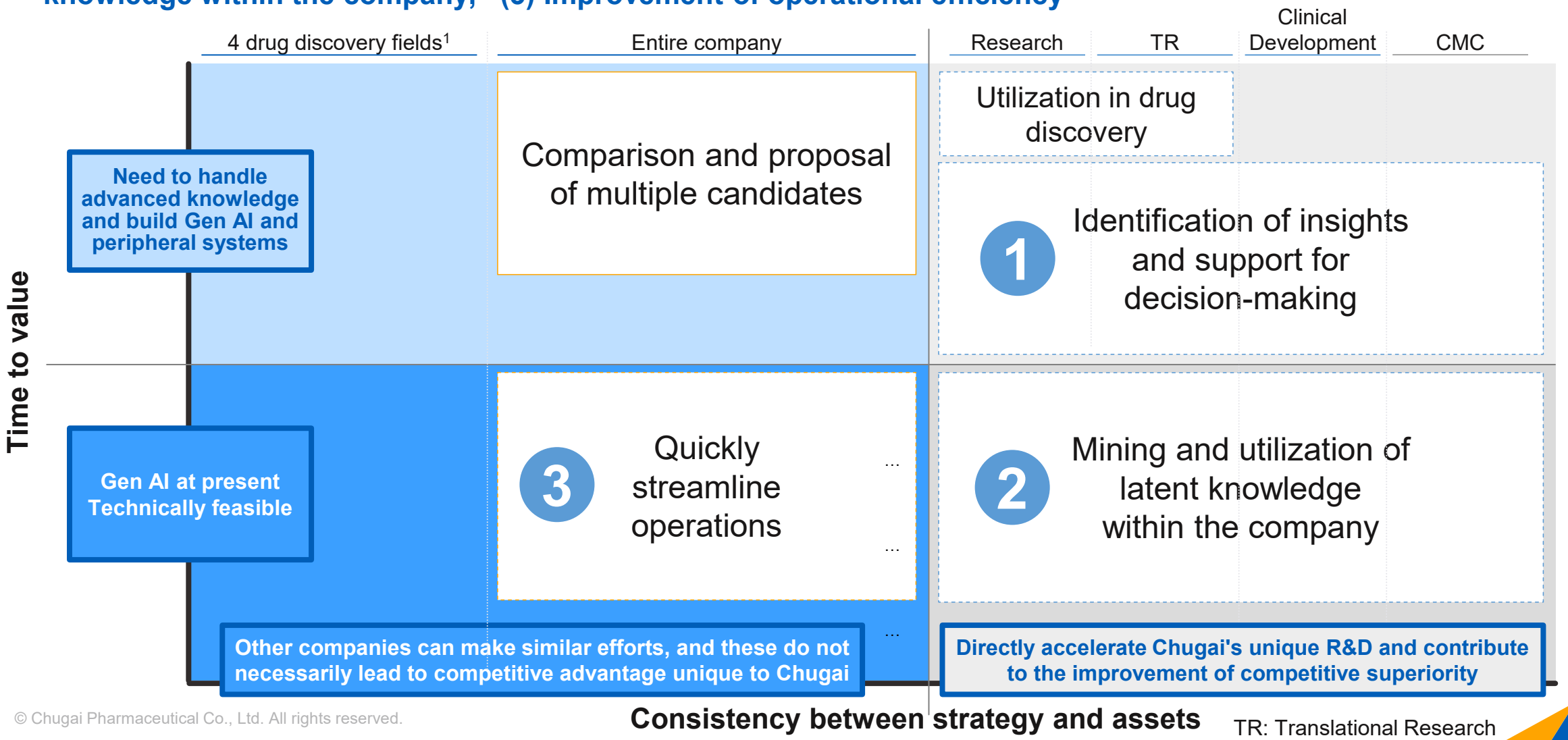
Organizing the Generative AI Development Structure

◆ **Promote the development of generative AI to expedite R&D upon organizing a well-structured developer team and the generative AI platform**



Our Focus in the Generative AI

- Organize the needs of each unit from the perspective of the technical area that leads to competitive advantage and time to produce results
- (1) “Identification of insights and support for decision-making,” (2) “Mining and utilization of latent knowledge within the company,” (3) Improvement of operational efficiency



TR: Translational Research

Direction of our Action to Extract Insights and Support Decision-making in R&D

◆ **We encourage utilization in R&D from the following perspectives:**

Research	TR	Clinical Development	CMC
Ensuring reusability of past findings	Structuring unstructured data Present structured evidence, regardless of whether it is unstructured RWD or simple charts.	Proposal of clinical study design and development plan	Generation of synthetic processes
Utilization for targeted molecule discovery	Study design assistance	Creation of clinical study documentation and FAQ	Creation of request form, report and review support
⋮	⋮	⋮	⋮

TR: Translational Research

Agenda

1. Progress in CHUGAI DIGITAL
   (Satoko Shisai: Executive Vice President,
   Head of Digital Transformation Unit)

2. **Three Initiatives to Strengthen the Digital Platform**
   (Keisuke Ohara, Head of IT Solution Department)
   (Kazumitsu Kanatani, Head of Digital Strategy Department)

   (1) Multicloud strategy/cyber security strategy

   (2) Initiative toward utilization of generative AI

   (3) Initiative on healthcare × Web 3.0

3. Status of Progress in the Insight Business
   (Dr. Nobuya Ishii, Head of Science & Technology Intelligence Department)

Changes in the Web

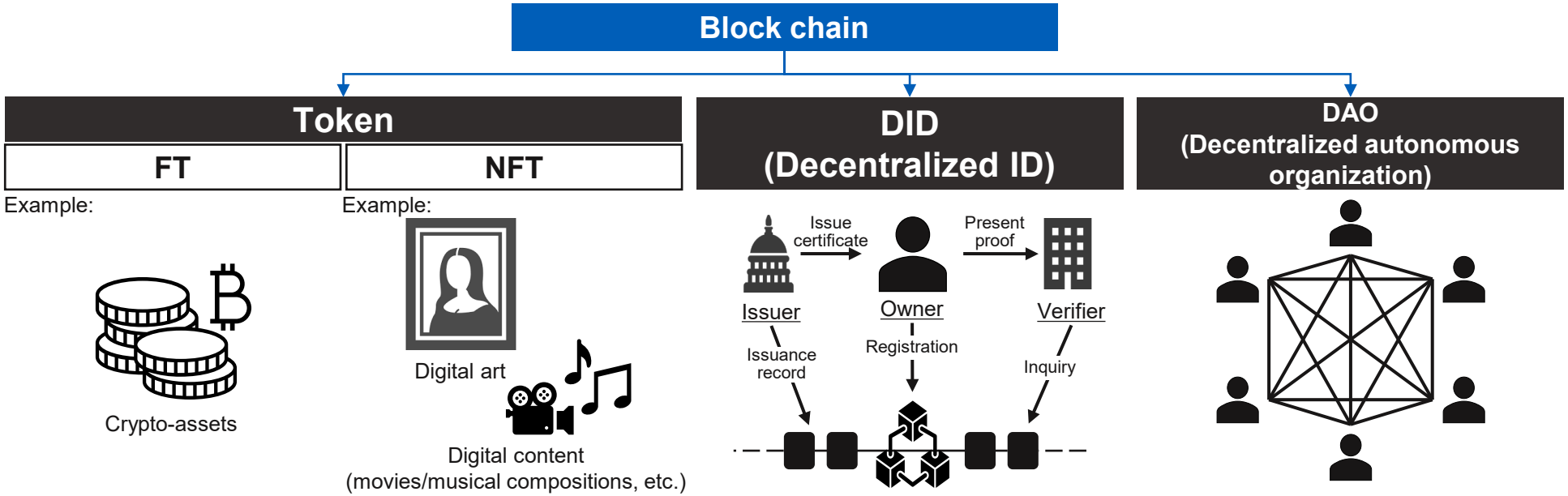
◆ **Web 3.0 is a new concept of the Internet since 2020. The key point is that data is distributed and managed by each system/individual, and that individuals directly connect with each other without relying on gigantic IT companies**

	Web 1.0	Web 2.0	Web 3.0
	Unidirectional	**Bidirectional**	**Multidirectional/ distributed**
			
[Timing]	1990s to early 2000s	Late 2000s to early 2010s	Early 2020s
[Flow of data]	Unidirectional from server to user	Bidirectional between server and user	**Distributed decentralized**
Key players	Web browser manufacturer	Giant platformers (e.g., GAFA)	**DAO**
Key services	Websites, etc.	SNS, etc.	**DeFi, NFT, etc.**
Primary platform	PCs	Mobile (Cloud)	**Metaverse**
Basic technology	HTML4.01	HTML5 (JavaScript)	**Blockchain, XR**

Source: Nikkei Cross Tech, https://xtech.nikkei.com/atcl/nxt/mag/nc/18/061500299/061500001/ (Japanese only) Accessed on 2023.9.28

Key Elements of Web 3.0 - Blockchain-related elements (FT, NFT/DID/DAO)

◆ **The main elements of Web 3.0, such as "DAO," "DID," and "NFT/FT," are based on blockchain technology**



- **"Fungible tokens"** represented by crypto-assets
- Secure digital value exchange
- Digital ticket or currency for which **it is possible to issue multiple copies of the same item**

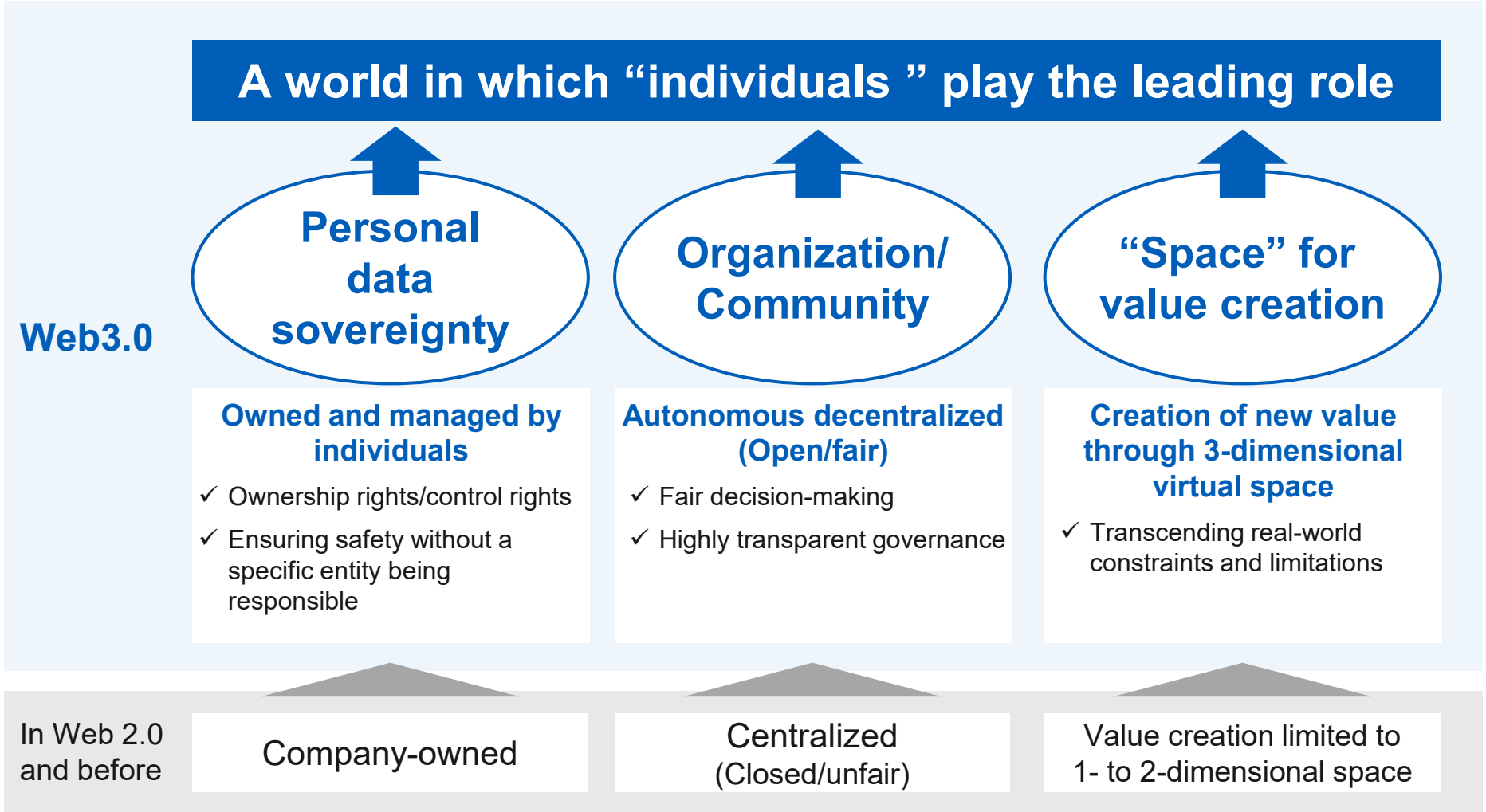
- A "**non-fungible token**" that demonstrates the uniqueness of a digital asset
- Digital one-of-a-kind article that **has a unique identification number and is difficult to tamper with**

- Easy to verify integrity and efficacy of proof with blockchain
- The **user possesses and ensures control rights** for attribute information.
- Possible to link to necessary information **to the extent permitted by the user**

- An organization with a distributed structure in which **authority/ responsibility does not focus on specific entities**
- Participants have an **equal voice**
- Aiming for incentives and common objectives, they **act independently through the decision-making process, including voting**

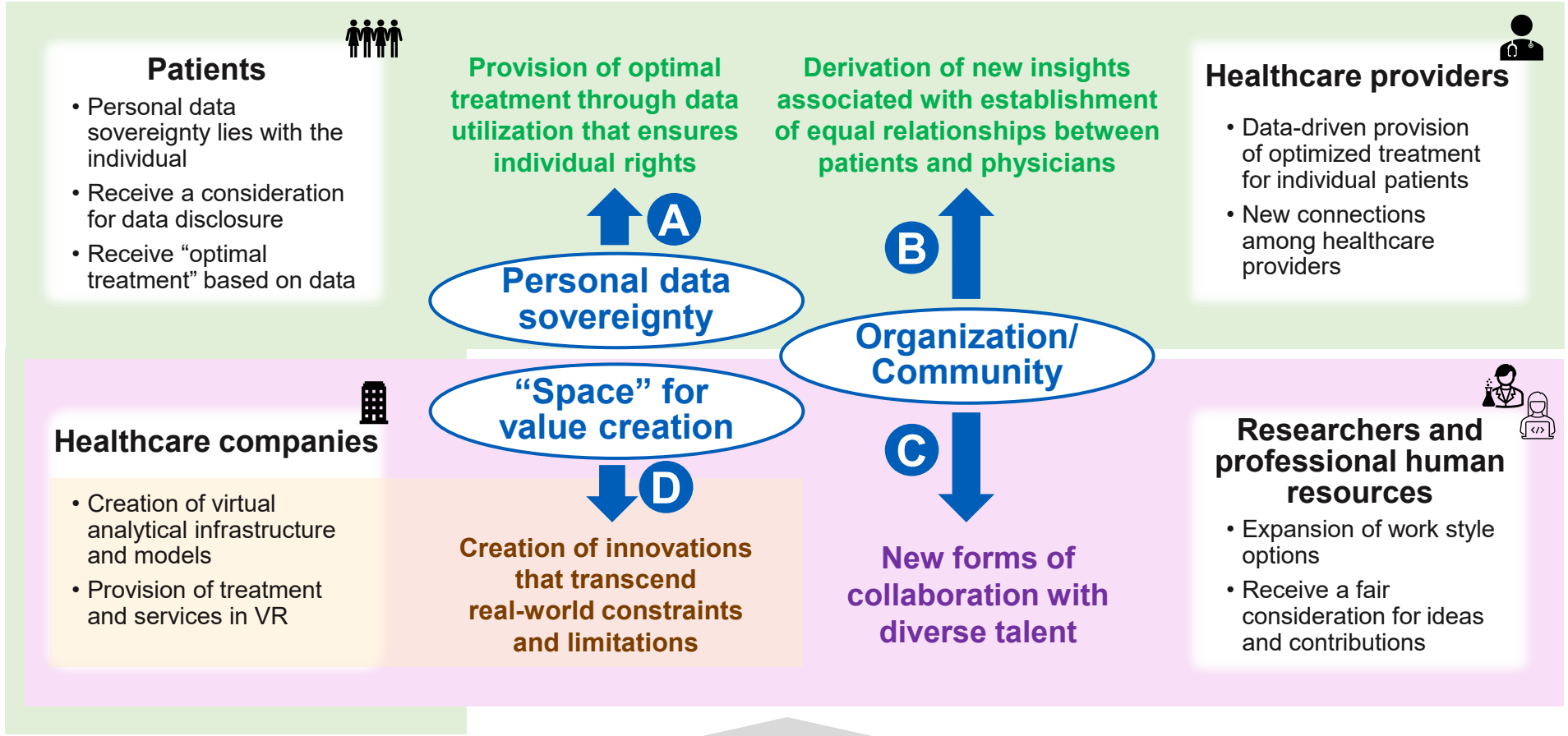
What is Web 3.0? (Chugai's Interpretation)

◆ **Web 3.0 will change ideas about the ideal states of "personal data sovereignty," "organization/community," and "'space' for value creation," and realize a world in which "individuals" play the leading role**



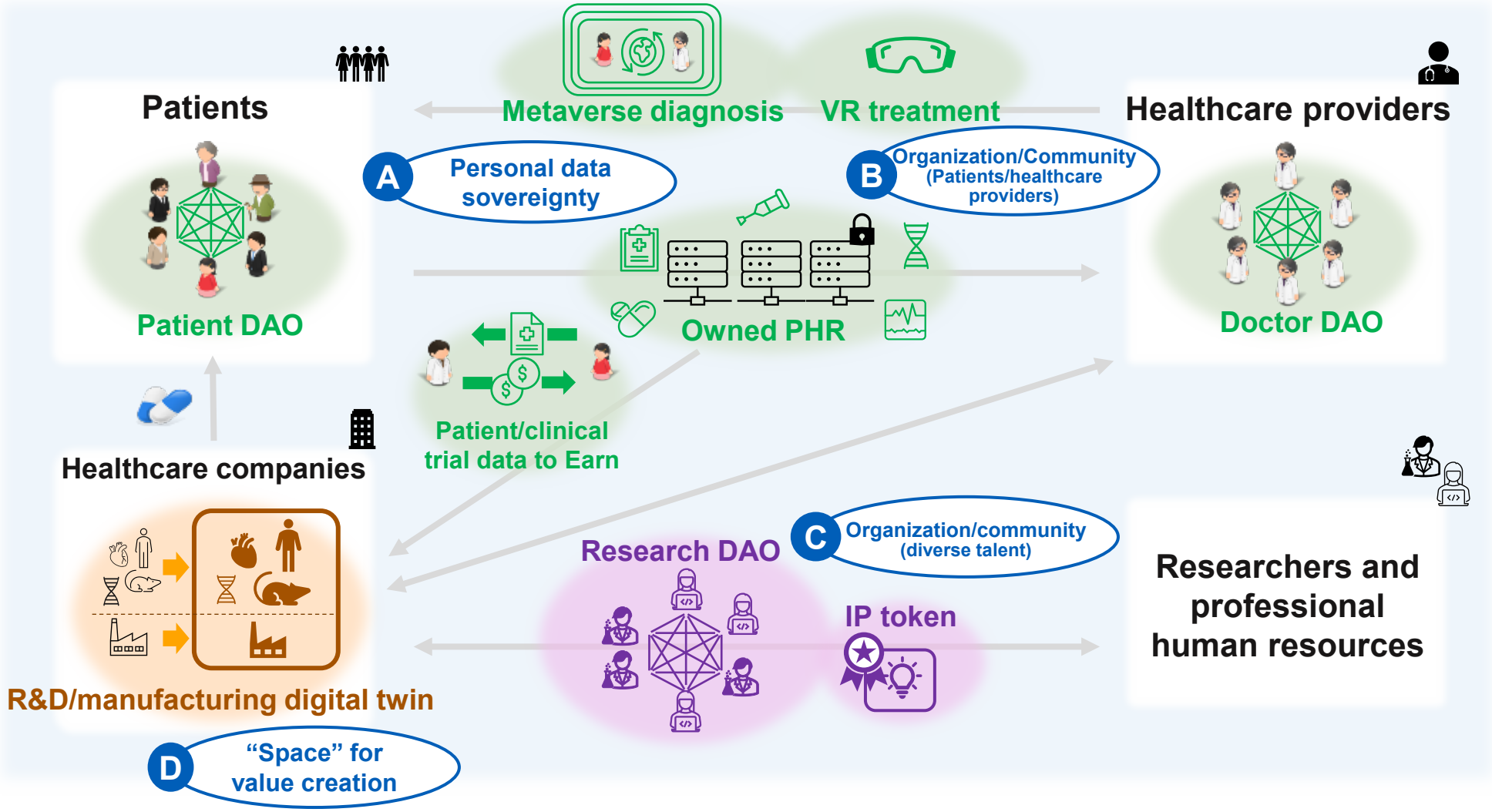
Healthcare Worldview Created by Web 3.0

◆ **Through Web 3.0, a world in which each stakeholder in the healthcare field will receive benefits is realized, and the values to be provided in that world can be broadly classified into 4 categories (A to D).**



Web 3.0 × Healthcare Worldview (realization image)

◆ Web 3.0 × Healthcare worldview will be realized through new use cases created by Web 3.0



Example of Realization Image: Research DAO

◆ **Accelerate innovation creation through formation of DAO mainly from collaboration/idea emergence and fair distribution toward the NFT-ization of IPs and contributions**

Issues

Rigorous protection and fair operation of intellectual property

- Protection of intellectual property through the utilization of digital evidence
- Visualization of contribution activities by token

Concern over understanding and handling of intellectual property related regulations (e.g., balance between work and research)

R&D and drug discovery DAO

Promotion of diversity in co-creation

- Promotion of diversity in research participants
- Encouragement of patient/company involvement

Because the organization operates autonomously, it is unclear where responsibility lies when a problem occurs

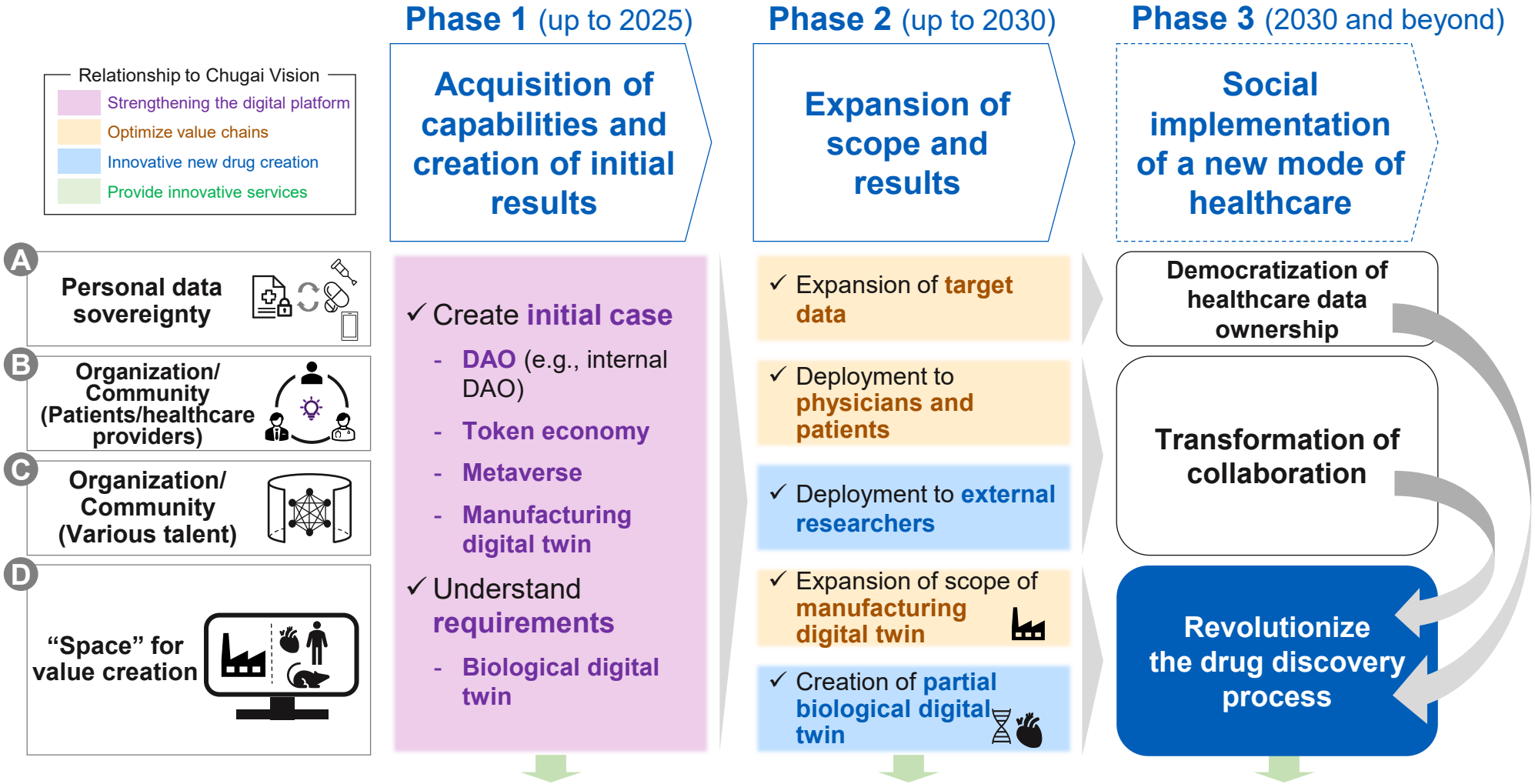
Acceleration of innovation creation

- Increase researcher motivation through fair incentives
- Insight creation through new collaboration

Incentive/rule design

Roadmap for Realizing Chugai's vision

◆ **First, we will strengthen our platform, expand applicable use cases by making the value chain more efficient, and ultimately promote the use of Web 3.0 toward crucial "revolutionization of the drug discovery process."**



Construction and Operation of Internal DAO

◆ **Construct internal DAO to promote understanding of DAOs and examine the possibility of business use**

Overview of DAO

Name of DAO	**LABORN**
Concept	***A "place" where each and every employee can play the leading role and demonstrate their personality and identity***
Objectives	✓ **Understand the ecosystem of DAOs and how they are perceived by users** ✓ **Explore potential for business use**
Specification/ design	✓ **Conduct discussions on a dedicated web application**

Points to verify

Is free and open communication promoted?

- **"Anonymity"** unfettered by department or position
- **"Visual design"** that supports the display of individuality and identity

Is it possible to display autonomous intent and visualize degree of contribution?

- **"Voting function"** that makes it possible to express one's own will
- **"Engagement score"** to quantify the actions of individuals, such as posting ideas or commenting

Verification of "valuation of ideas" through tokens

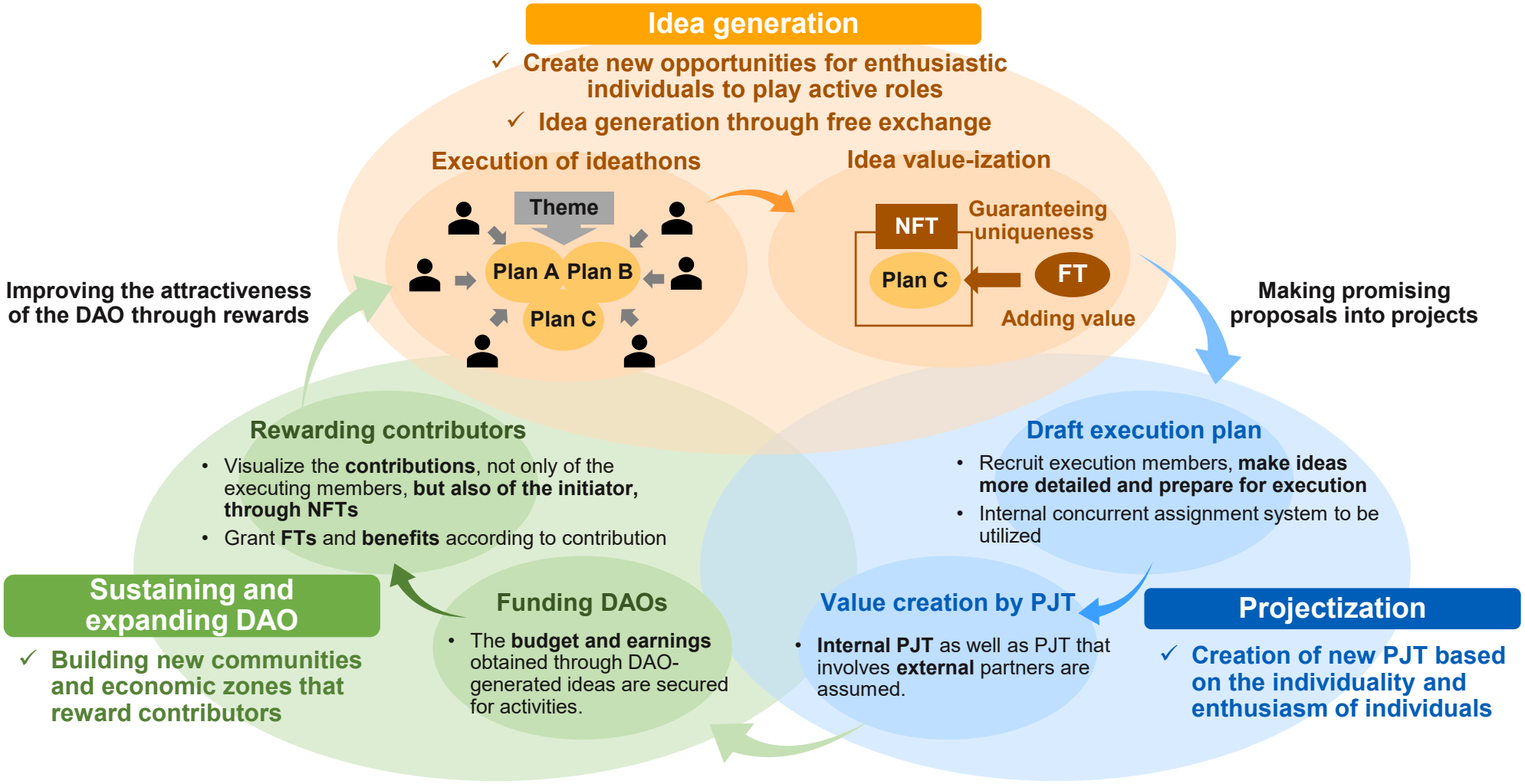
"**NFT-ization**" that manages promising ideas through BC

- **Issuing of "Chugai internal coin (FT)"** that assigns value to NFT-ized ideas

NFT: Non-Fungible Token

Concept of Deployment of Internal DAO

◆ **Aim to dynamize new value creation by making ideas spawned by DAO into projects**



Overview of LABORN Activities and Feel of Use

◆ **While enhancing the feel of use, posting ideas on specific themes and discussing them**

Examples of topics discussed

Ideas for utilization of ChatGPT and generative AI

Project drafting in Healthcare × Web 3.0

Sharing of issues and soliciting of improvement ideas

User's impression

- Because of anonymity, participation **without conjecture** is possible, and the **hurdles for posting are lowered**
- **I felt free to speak up**, and it was easy to make a comment at the “just an idea” level
- I felt good that I could make **proposals beyond the scope of my usual work**, and I could indicate that I agreed with other people's proposals.
- It was interesting because I was able to post **content that I wouldn’t have been able to talk about in my usual work**.

Visualization of contribution

➢ Calculate individual contribution by **engagement score** and display ranking on site

Next Step

- For the internal DAO, define and promote projects initiated by DAO
- For the external DAO, proceed with the work/system requirement design and configuration in preparation for the first phase of operation

	Action in FY2023	Action in FY2024 and beyond
Internal DAO (LABORN)	Planning and execution of the first project Planning and execution of the second project FT-related policy design (Linking benefits/distribution to individuals, etc.) UI improvements	✓ Company-wide deployment ✓ Continuation of LABORN as new communication space
External DAO (Development of new services, drug discovery, etc.)	Organization and structure planning System requirement definition, system design/configuration Work requirements definition and design Seek involvement of community members Formulation of the DAO operation policy (Legal positioning of DAOs and tokens, handling of IP and privacy data, etc.) Seek availability of new external DAO	✓ Start the first phase of external DAO operation ✓ Design and plan the second phase operation

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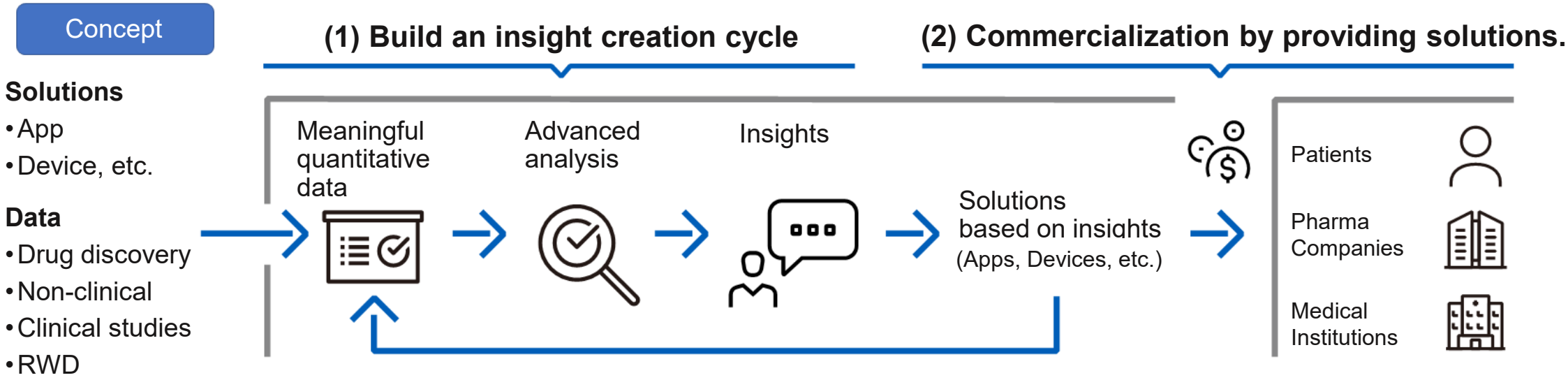
3. **Status of Progress in the Insight Business**
   (Dr. Nobuya Ishii, Head of Science & Technology Intelligence Department)

Insight Business

- **Business aiming to provide sustainable medical solutions to improve the value of providing drugs, etc. to patients and other stakeholders**

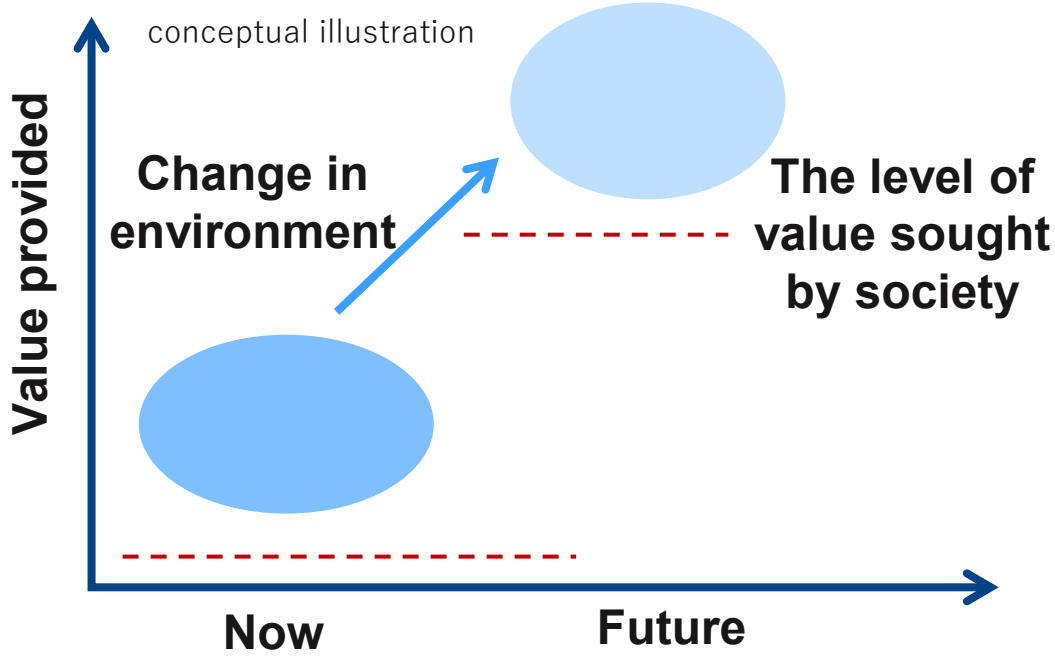


From the new special website on growth strategy “TOP I 2030”

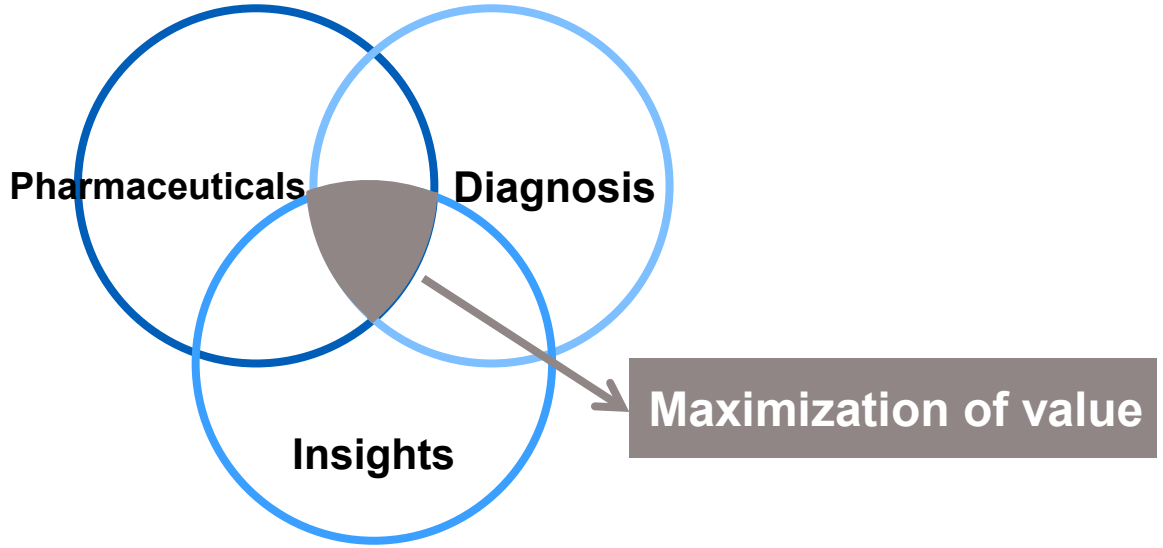
Why Take On the Insight Business?

The core business of Chugai is to **provide innovative pharmaceuticals**, and that remains unchanged. However, as a response **to an era in which we are being called upon to provide value that goes beyond the "creation of innovative drugs**," we are working on **improving the value proposition by providing solutions that utilize insights** obtained from the analysis of various data.

The desired increase in value

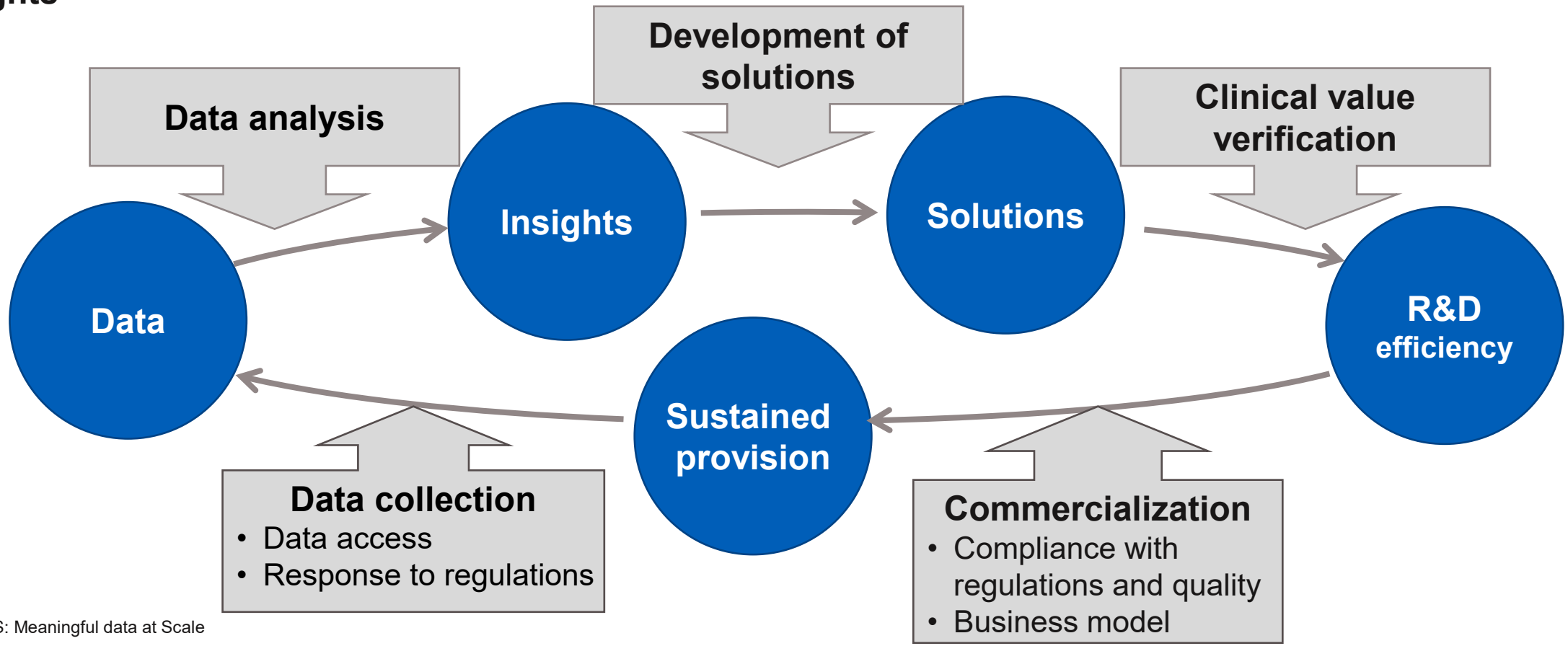


Maximization of value through drugs + α



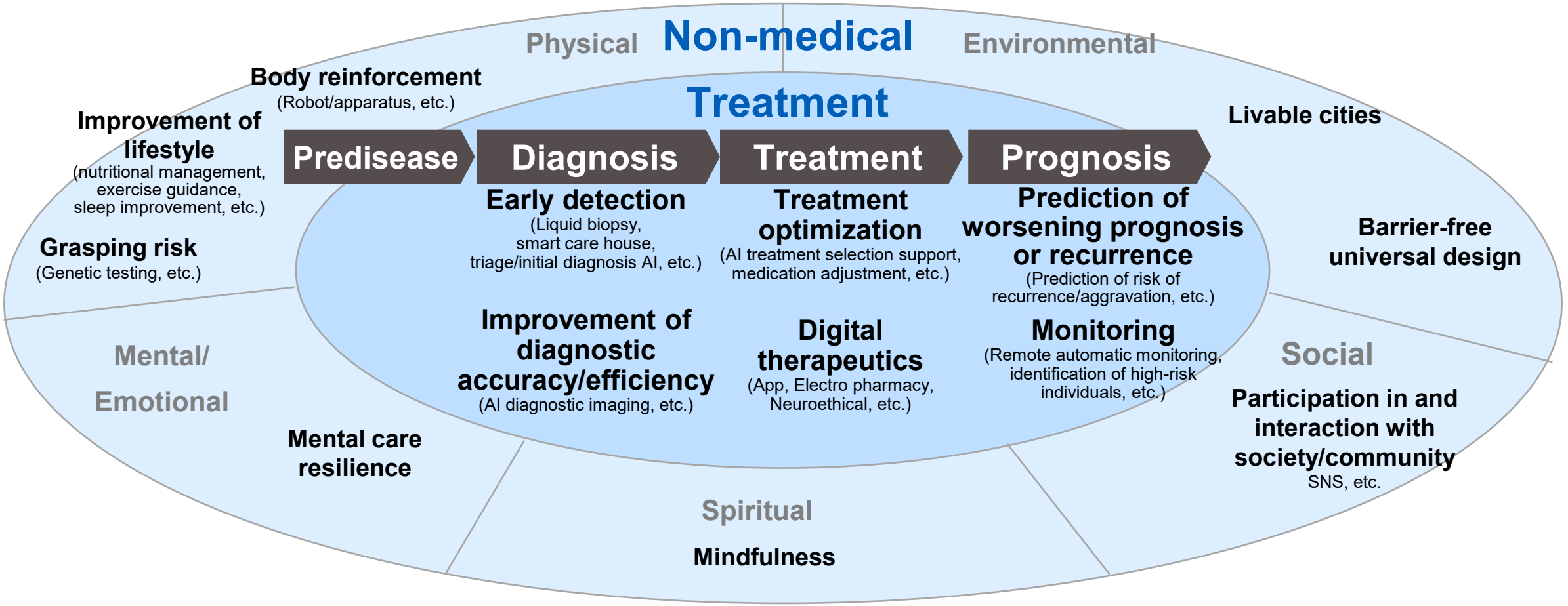
Insight Business Value Cycle Model

Develop insights obtained from in various businesses such as pharmaceutical R&D activities into solutions to reaprocesseslize a value cycle that leads to (1) maximization of pharmaceutical value, (2) simultaneous generating MDAS* through continuous data acquisition, and (3) creation of new insights



*MDAS: Meaningful data at Scale

Expected Areas where Insight Business to be Rolled Out



*Created based on Global wellness institute What is Wellness? (https://globalwellnessinstitute.org/what-is-wellness/, accessed September 28, 2023)

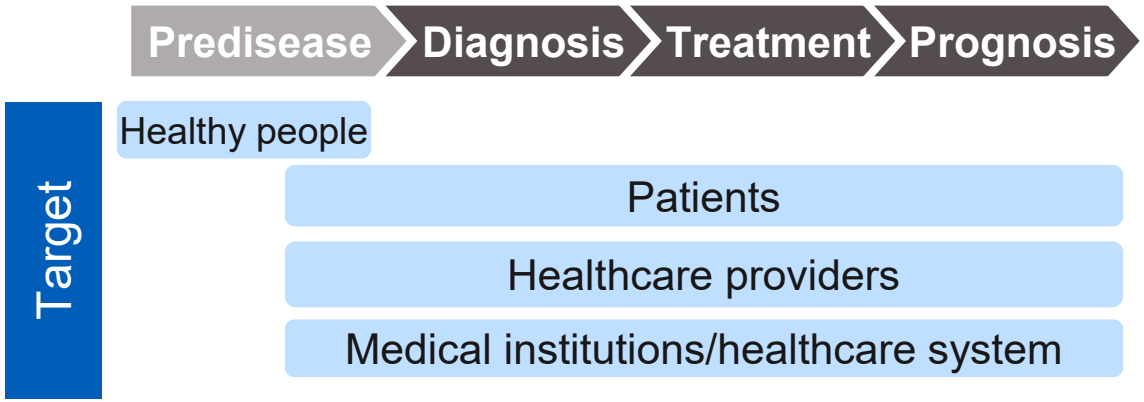
Scope of Efforts in the Insight Business

Basic principles

- Focus on patients and pain in medical institutions/systems, considering Chugai's competitive advantage and synergy with the pharmaceutical business
- Deployment of solutions from Roche in Japan
- Development of solutions related to products created by Chugai, utilization in clinical development, and post-launch deployment

Direction of approach

- Decision support
  - Clinical (healthcare providers, patients): CDS
  - R&D (for companies, including Chugai): RDS
- Remote Patient Monitoring (RPM)
  - Clinical (healthcare providers, patients)
  - R&D (for companies, including Chugai)

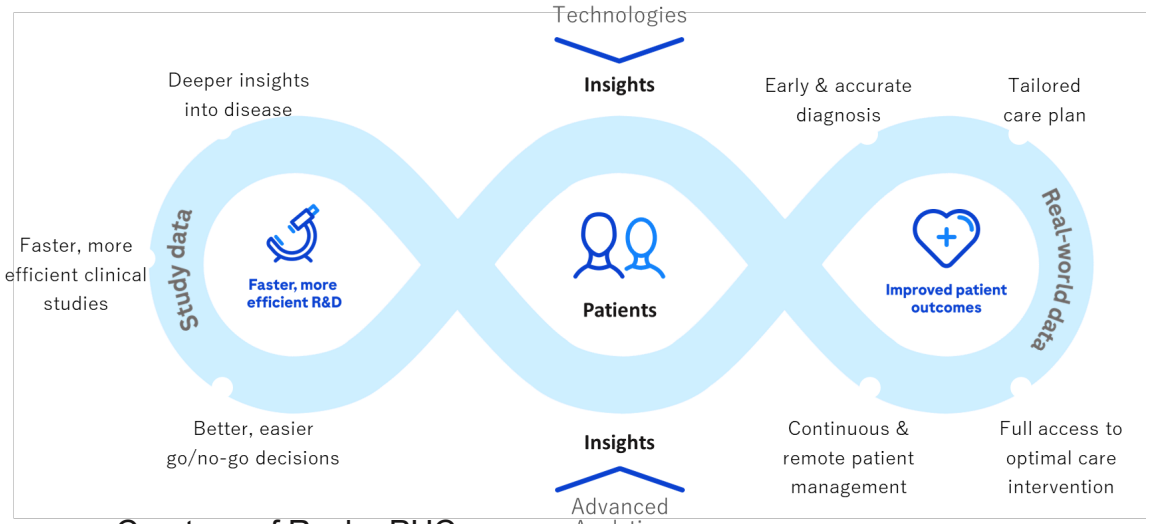


CDS: Clinical Decision Support; RDS: R&D Decision Support

Efforts toward Integrated Solutions at Roche

What is an integrated solution?

- Generic term for a non-product-dependent solution that leads to improvement of the value delivered to patients through a patient journey
  - Early + accurate detection
  - Timely diagnosis
  - Remote disease monitoring
  - Individually tailored care/interventions



Courtesy of Roche PHC

Examples of efforts

- Remote monitoring of patients with multiple sclerosis (MS) via smartphone app
- Remote monitoring of patients with ophthalmologic diseases via smartphone app
- Remote monitoring of cancer patients via smartphone app
- Support for analysis of radiological images and pathological images of cancer patients

Javier Garcia Palacios, Global Head of Personalized Healthcare Integrated Solutions in Roche @ ViVE 2023

Efforts in the Insight Business at Chugai

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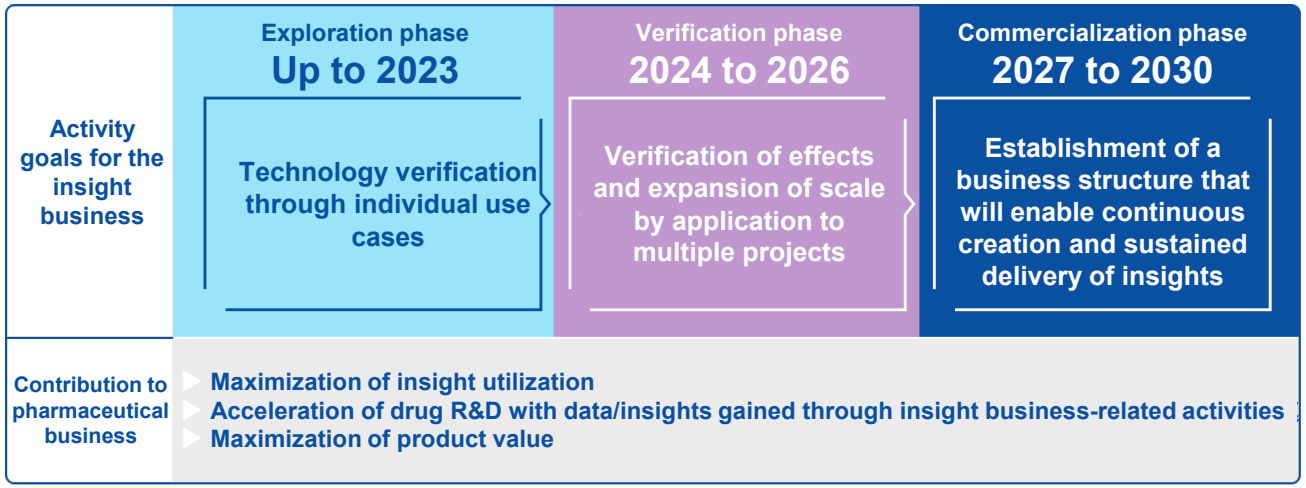
TOP I 2030: One of the growth foundation reforms

- With the goal of establishing a business system for the insight business by 2030, we will work on verifying technologies and effects through individual use cases, reexamine our internal system, and establish a model for collaboration with external parties.



Examples of efforts

	Decision-making support	Remote monitoring
Endometriosis	• Diagnostic imaging	• Pain
Cancer	• Foundation medicine business • Prognosis prediction • Early diagnosis	• Adverse events/ prognosis
Hemophilia		• Asymptomatic hemorrhage • Motor function
Eye diseases		• Eye function

Example of Efforts in the Insight Business: Endometriosis

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What is endometriosis?

- 10% of adult women are affected
- A disorder in which tissue similar to the "endometrium" covering the inside of the uterus forms outside the uterine cavity
- One of the causes of infertility. Frequency of occurrence is low, but can be one of the risk factors for ovarian cancer
- Major symptoms include pain due to adhesion and inflammation and worsening of menstrual pain. Major treatment methods include hormone therapy and other pharmacotherapy, as well as surgery (nonradical)
- Issues:
  - Non-invasive diagnostic imaging
  - Quantitative evaluation of pain

Predisease > Diagnosis > Treatment > Prognosis

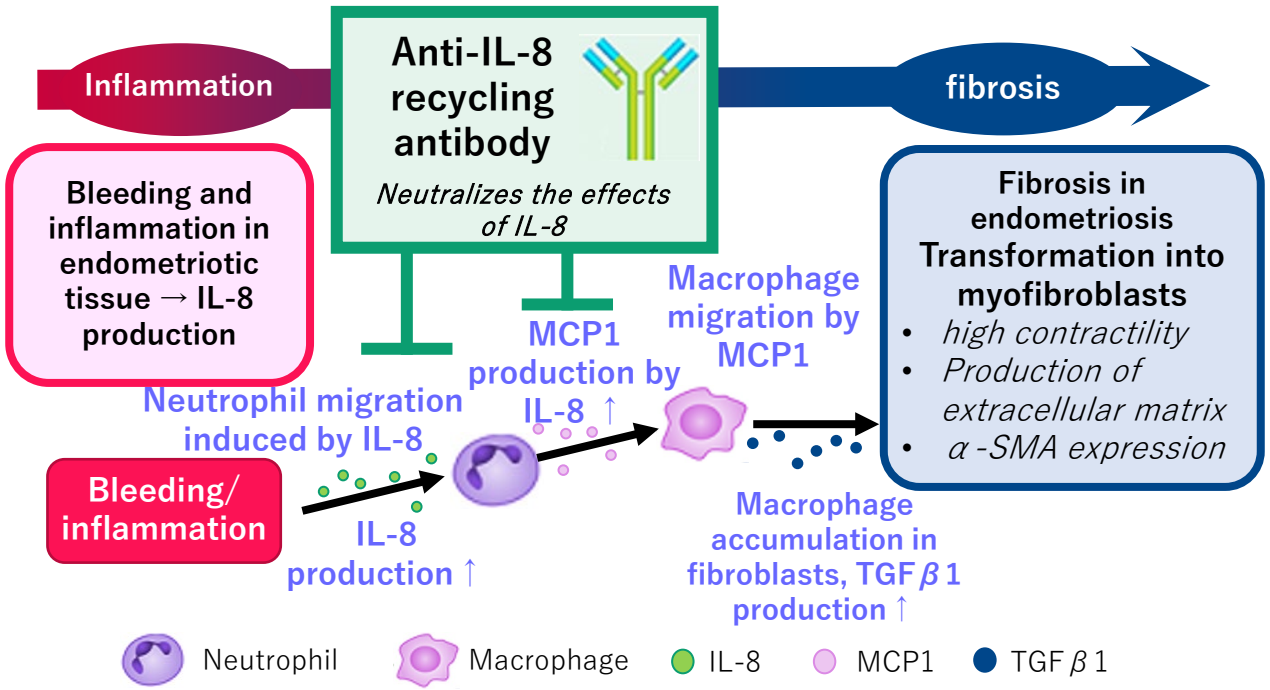
#1 Diagnostic imaging

#2 Pain measurement

#3 Virtual Care Platform

Anti-IL-8 recycling antibody

- Currently under development for endometriosis



Mode of action of anti-IL-8 recycling antibody

Drawing from Sci. Transl. Med. 15(684):eabq5858 Figure S5

Efforts in the Insight Business, Case #1

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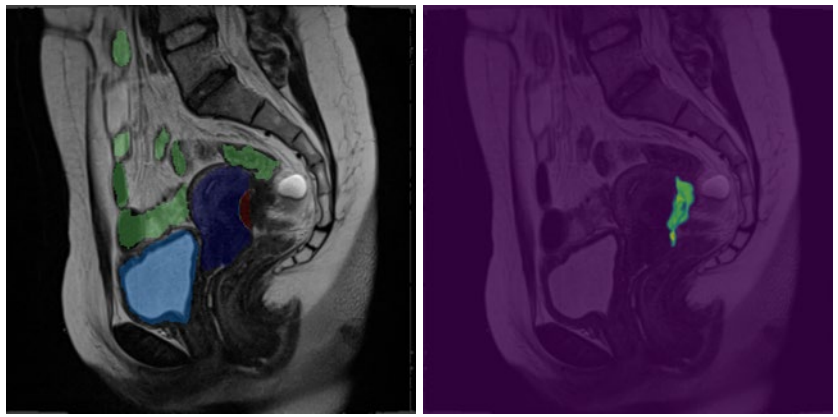
Issues in imaging diagnosis of endometriosis

- Current diagnosis: Definitive diagnosis by endoscopy, which is highly invasive, is required. Diagnostic imaging is difficult to adjudicate, and evaluation differs greatly among evaluators.
- Variability in efficacy assessment in clinical studies

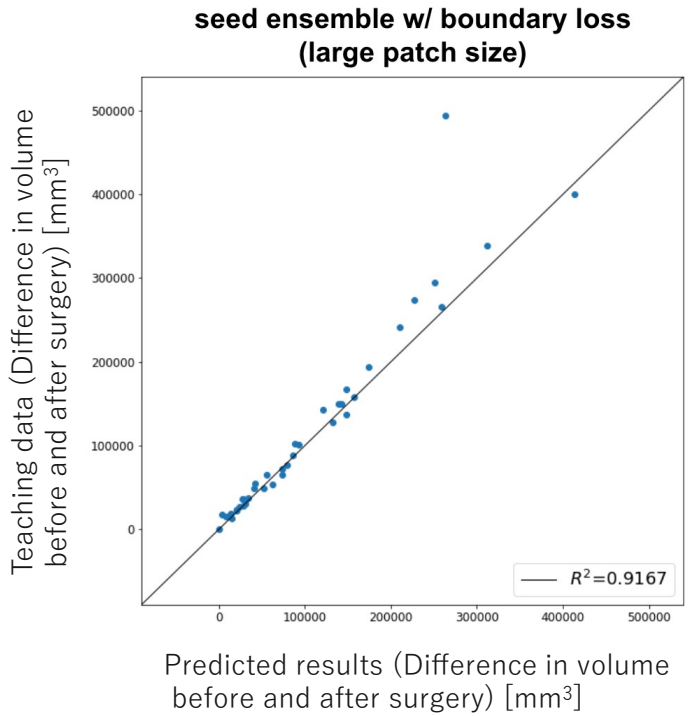
(a) Lesion detection (b)



(a) Segmentation results of lesions (reddish brown), uterus (blue), bladder (light blue), and rectum (green) using the algorithm
(b) Areas with high prediction uncertainty (lesion and its surroundings tend to have high prediction uncertainty)

Efforts

- Efforts to develop models for detecting pelvic organ and nodal lesions by artificial intelligence (collaboration with Preferred Networks)



Results of a prespecified exploratory analysis of a clinical trial targeting endometriosis patients

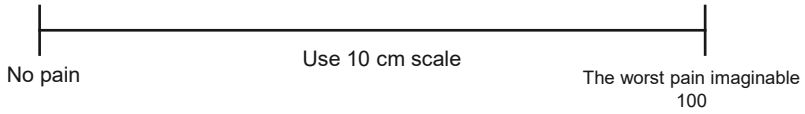
Provided by Preferred Networks

Efforts in the Insight Business, Case #2

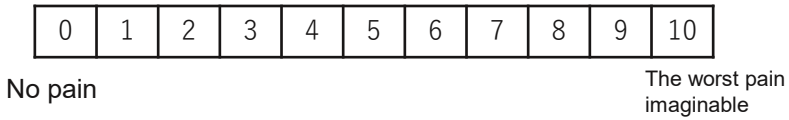
Issues in pain measurement

- Large variation in subjective evaluation
- Variability in efficacy assessment in clinical studies

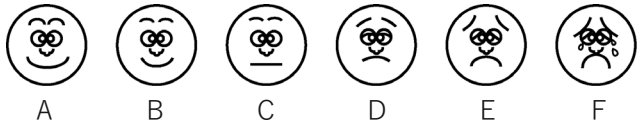
(1) Visual analog scale (VAS)



(2) Numeric rating scale (NRS)



(3) Face rating scale (FRS)



Japan Chronic Pain Information Center https://itami-net.or.jp/download (Access: September 26, 2023)
Created by Chugai Pharmaceutical with reference to and citation of pain education content data for medical education.

Efforts

- Development of continuous pain measurement technology using digital devices (collaboration with Biofourmis)
- Mechanism of pain in endometriosis: autonomic nerves
  - Vitals related to autonomic nerve pain: heart rate fluctuation, skin conductance

Objective Pain Measurement Using a Wearable Biosensor and a Mobile Platform in Patients With Endometriosis

ClinicalTrials.gov Identifier: NCT04318275

Wearable Biosensor

Empatica's E4

Mobile Platform

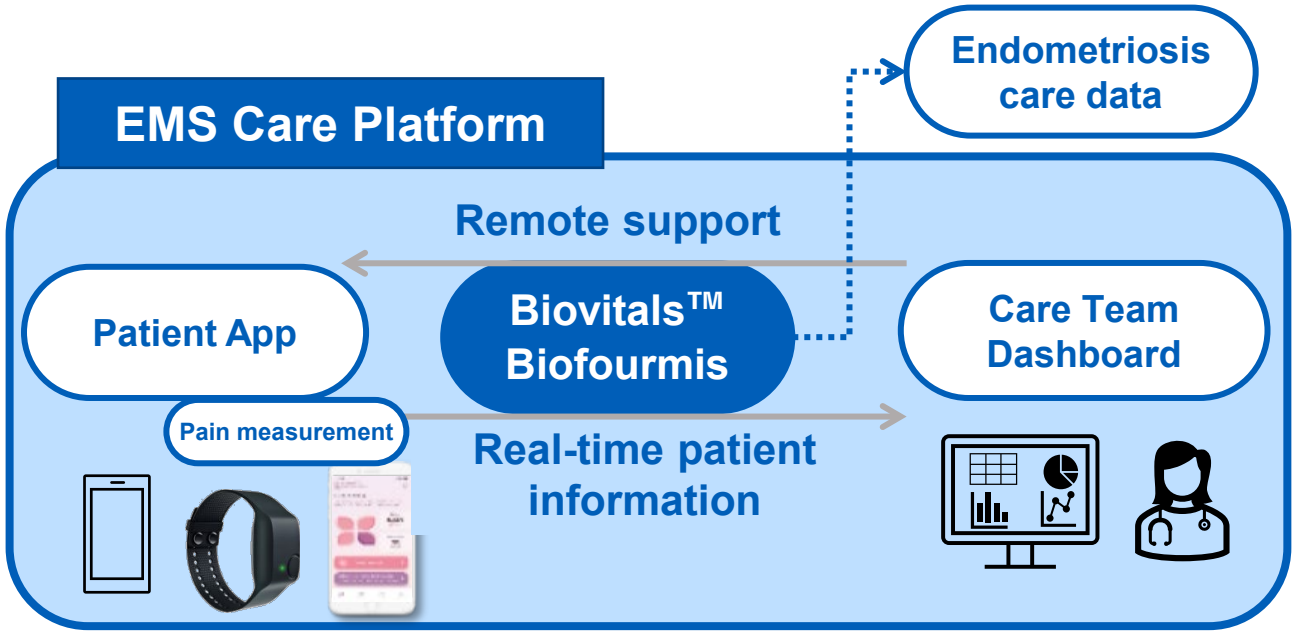
Biofourmis's Biovitals™ Platform
Pain Algorithm
Biovitals® Pain Index
Mobile app
Femme Rhythm™ App

The E4 wristband
https://www.empatica.com/research/e4/
(Access: September 27, 2023)

Efforts in the Insight Business, Case #3

Issues in the delivery of solutions

- Need to build access infrastructure to deliver solutions to patients and medical institutions



Efforts

- Efforts to deliver solutions through the virtual care platform that Biofourmis provides to medical institutions
  - Development of a virtual care platform that enables real-world pain measurement
  - Small-scale provision of virtual care for patients with endometriosis in the U.S.
  - Find insights from data gathered from platform to support Chugai R&D on endometriosis and post-launch activities for the endometriosis drug candidate under development

Published at 10th Annual Mobile Tech In Clinical Trials
https://theconferenceforum.org/conferences/mobile-in-clinical-trials/2023-agenda/ (Access: September 26, 2023)
"Scaling Mobile Technologies and Digital Biomarkers to Personalize Therapy Development"

Future Issues

- **Regulatory compliance (medical device regulations, personal information protection, etc.)**
  - Acquire capabilities to appropriately protect personal information and comply with various regulations depending on where the solution is deployed (Japan, overseas)
- **Involvement of relevant stakeholders (patients, healthcare professionals/medical institutions, etc.)**
  - From the solution development stage, we consider the benefits to various stakeholders and build solutions that can provide services sustainably.
- **Knowledge accumulation**
  - Improve efficiency by accumulating knowledge through creating solution development examples.

Summary

- Aiming to commercialize an insight business that realizes the provision of sustainable solutions based on insights to further improve the value provided by pharmaceuticals.
- By developing solutions from insights obtained from pharmaceutical R&D activities and other business processes, we aim to realize a value cycle that leads to (1) maximization of pharmaceutical value, (2) simultaneous construction of MDAS* through continuous data acquisition, and (3) creation of new insights

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CHUGAI DIGITAL

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