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Single Day Event

From Vision to Reality: Patient Centricity in Pharma

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Disclaimer

- ✓ The views, thoughts, and opinions expressed in this presentation solely to the presenter, and not necessarily represent the official policy or position of the Astellas Pharm Inc..

Patient Centricity, what it means

Patient Centricity supports the development of innovative health solutions through a deep understanding of the patient experience, medical need and behavioral drivers of care.

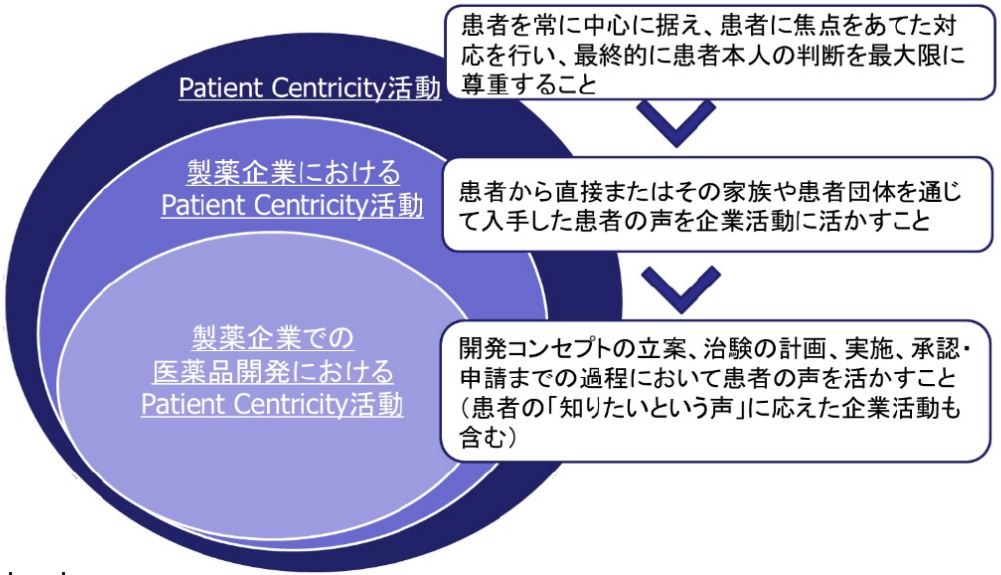
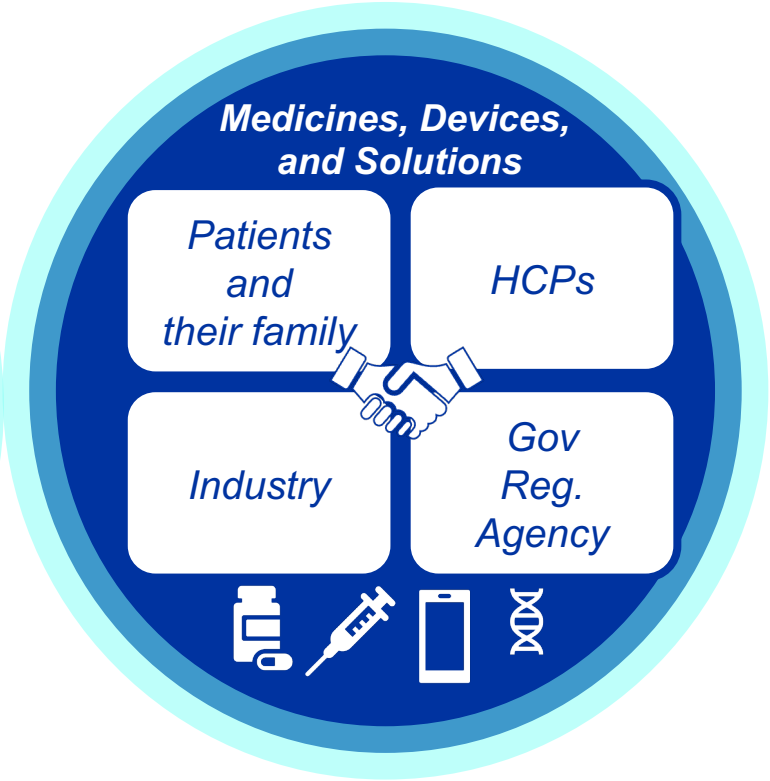


Figure from JPMA's guidebook
https://www.jpma.or.jp/information/evaluation/results/allotment/lofurc0000005m2b-att/patient_centricity2.pdf

What is needed to create future medicines, medical devices and solution

*The **collective engagement, insights, analysis and solution delivery from these teams** maximizes patient VALUE by enabling evidence-based decision-making and prioritization through all stages of research, development and utilization.*



Changes in the relationship between patients and pharmaceutical companies

Trend toward "patient-centered medical care" →Significant impact on the relationship between patient groups and pharmaceutical companies

In the past,

- Mainly indirect relationships involving healthcare professionals
- Rarely collected "patient voice" throughout the drug life cycle.
- "Voice of medical staff" has been emphasized rather than "voice of patients"

In recent years,

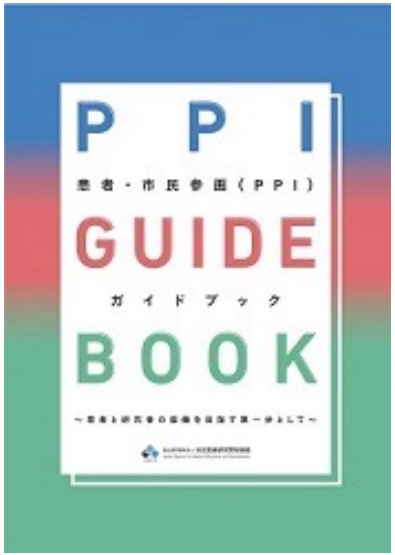
- There have been increasing opportunities for direct relationships between patients and pharmaceutical companies, such as dialogue, interaction, and collaboration between them.

Trends : Patient centricity in Japan

Active patient involvement in planning, designing or evaluating clinical trials and relevant education are proposed in multiple government plans. eg.

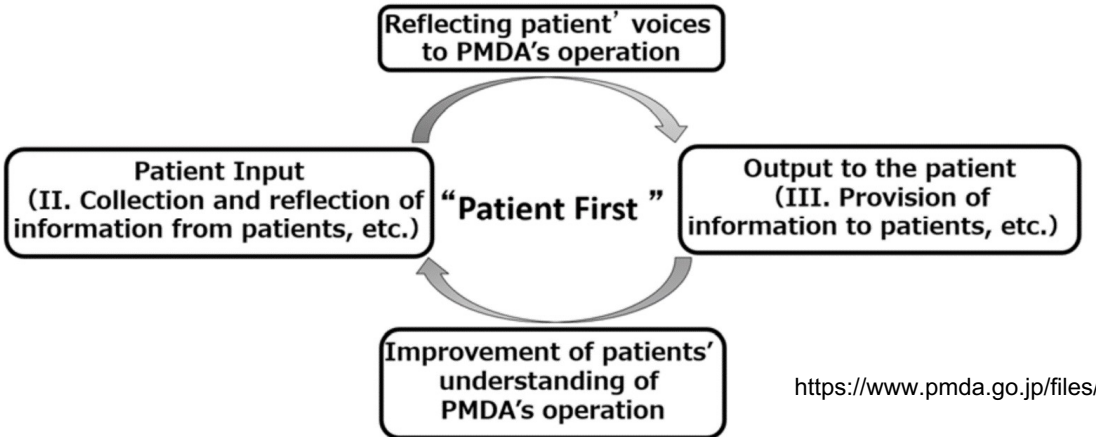
- The Plan for Promotion of Medical Research and Development by the Headquarters for Healthcare Policy, July 22, 2014
- Basic Plan to Promote Cancer Control Programs, Oct 2017

AMED published the PPI Guidebook, Apr 2019



Patient centricity Trends in regulatory agency

- EMA established the Patients' and 4 Consumers' Working Party (PCWP)
- FDA has established the Clinical Trial Transformation Initiative (CTTI), the Patient Engagement Collaborative (PEC) and the Patient-Focused Drug Development (PFDD) guidance with patients.
- PMDA established Patient Centricity Working Group, May 2019 and publishes "Patient Participation Guidance", Sep, 2021



https://www.pmda.go.jp/files/000243407.pdf

Patient centricity activities at JPMA

Patient Cooperation Committee

Builds better relationships with patient groups and actively exchanges opinions with them, and disseminates information and executes policies that reflect the patients perspective.

- "JPMA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Groups".
- Transparency guideline
- Advisor board meeting and Seminar by Patient Organizations

Clinical Evaluation Expert Committee

- Patient Centricity Guidebook and Communication Guidebook
- Questionnaire Survey on Patient centricity
- Seminar on Patient centricity

Questionnaire survey on activities based on Patient Centricity (2019, JPMA Clinical Evaluation Subcommittee)

Survey item	2016	2019
I feel that it is necessary that trained patient representatives to participate and express their opinions at drug approval review meetings and meetings between pharmaceutical companies and regulatory agencies (such as the FDA), as is done in other countries.	**85 % (47/55)**	**96 % (53/55)**
Incorporating the concept of Patient Centricity into corporate vision	**55 % (30/55)**	**65 % (36/55)**
Patients have been invited to give in-house lectures, and drug development staff have taken measures such as directly confirming the opinions and requests of patients.	**31 % (17/55)**	**44 % (24/55)**
Have made efforts such as drug development staff experience the daily lives of patients through patient groups and hospitals	**18 % (10/55)**	**24 % (13/55)**
Experience in setting items and procedures after listening to the patient's voice when creating a clinical trial protocol	**4 % (2/55)**	**20 % (11/55)**

Clinical Research Professional No.80, 81 p16 ~

PATIENT engagement in Medicine lifecycle (examples)

Research

Concept creation

Natural history
Biomarker
exploration

Providing
bio samples

Development

Hearing opinions on
study plan/design

Clinical trial
material review

Result semination
(Seminar, HP, etc.)

Real world

Material creation for
patients

Disease
awareness

Patient Journey

PMS, IIS cooperation

Ecosystem

Patient support
program

Public open Forum

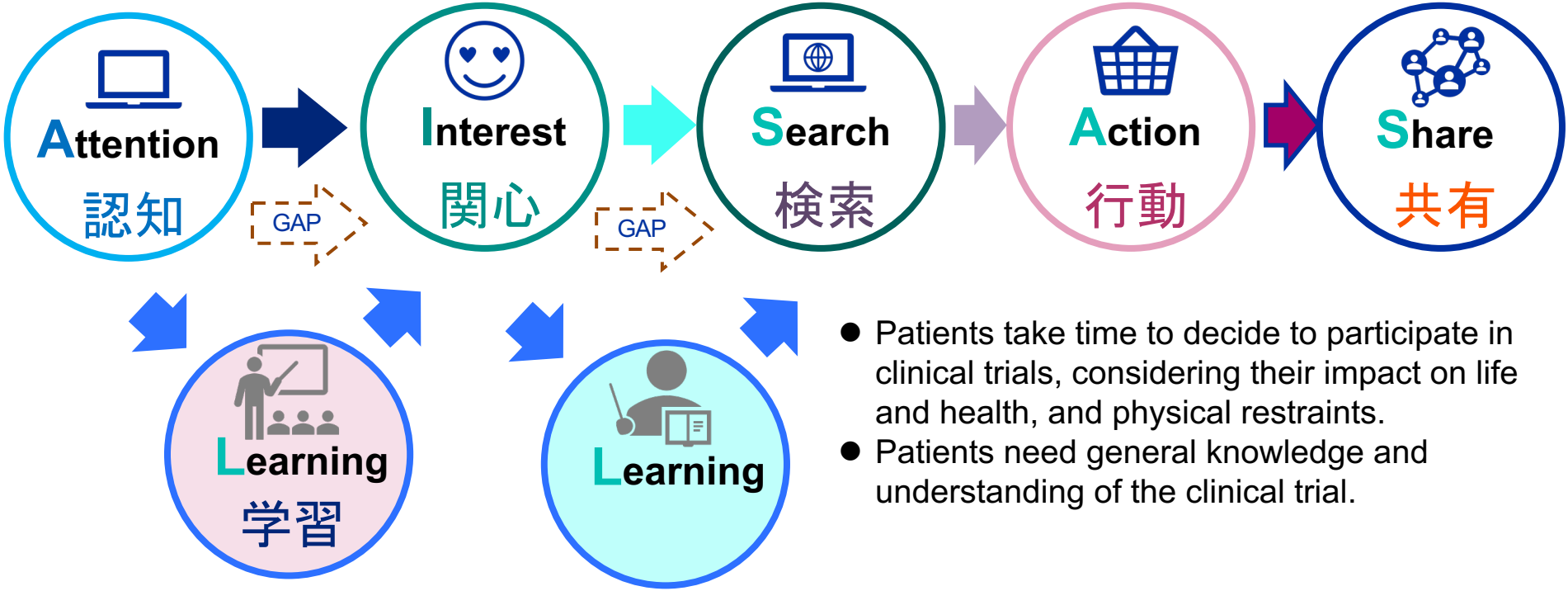
Donation activities
Social contributions

Question

What is the position of a patient in your work?

- Drug consumer
- End user
- Beneficiaries
- Stakeholder
- Clinical trial subjects
- Provider of biological sample
- Analysis target to generate data
- Partners who create medicine together

Lack of general knowledge and understanding of clinical trials for many patients



- Patients take time to decide to participate in clinical trials, considering their impact on life and health, and physical restraints.
- Patients need general knowledge and understanding of the clinical trial.

Examples: communication starts from in-house Patient's lecture meeting

「患者とともに、治療薬を」アステラス製薬開発本部にて患者会講演

2020年2月3日（月）、アステラス製薬株式会社にて開発本部の約200名のみなさまに向け、妹尾みどり事務局長が講演をさせていただきました。

同社開発本部では疾患や患者に対する正しい知識を身につけ、今後の業務に生かすことを目的として社内向け患者会講演が開催されており、今回は同社から助成などを受けてきた当会へ講演依頼を頂き、事務局長として妹尾みどりがお話させていただく運びとなりました。

当日は妹尾みどりの妹で理事長の旗野あかねを患者の一例として紹介し、疾患の原因や症状の説明、患者と家族が困っていること、広く一般社会と同社に期待することなどを話しました。

https://dm-family.net/achievement/2020032301/

Each department invites people who have experienced disease to continuously hold lectures and exchange opinions.

One Conversation after meeting

Astellas employee:
"Generally, no matter how much money and time it takes, a drug candidate cannot be a product without efficacy, safety and product validity, etc.."

Patient:
"Really ?! I need to understand more on general knowledge on clinical development ."

Webinar program for patients

国際筋強直性ジストロフィー啓発の日記念

INTERNATIONAL Myotonic Dystrophy Awareness Day SEPTEMBER 15

astellas × DM family

希少疾患・難病の新薬開発を進めるために

Introduction to the general knowledge of medicine development,
Such as “Clinical trials are required to be approved as a drug.”, ”Preclinical studies are conducted prior to clinical trials.”, etc.

(obtained permission to use from the DM-family)

Examples of utilization of natural history research data

- Identify target patients in drug development

- Develop or identify clinical outcome assessments (COAs)

- Develop or identify biomarkers

- Use natural history data as a control group

What is "value co-creation“ in medicine development?

Not only the pursuit of **value-in-exchange or functional value,**

but also understanding of **values-in-context or –in-use** is important.

"value co-creation“ in medicine development

Seeds
Evidence

→

Medicine (material)

→

Benefit (value)

Knowledge / skills
medicinal chemistry, safety, pharmacology, formulation technology, IP strategy, commercial production, biomarkers, study design, etc.

Input for value creation

Knowledge / skills
Appropriate target patients
appropriate usage
Demonstrate the expected effect

industry-customer value co-creation

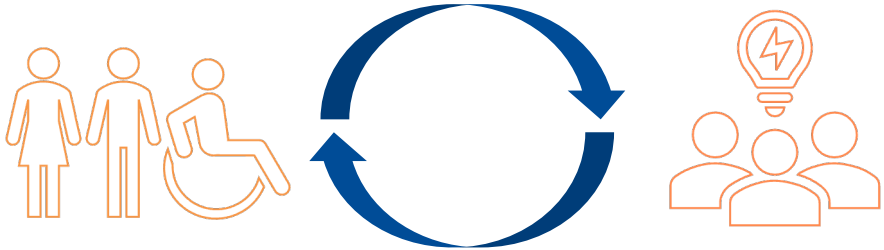
Inclusive innovation in medicine’s lifecycle

Innovation that leaves no one behind（＊），

1. targets people who live with a disease,
2. is intended to benefit these people,
3. is an outcome that is accessible to these people,
4. and is a reality that is beneficial to these people

And also,

5. these people are also included in all stages of medicine’s lifecycle
6. and the participation of these people all stages of medicine’s lifecycle is taken as given.



＊modified from https://www.cyberdyne.jp/company/Event_detail.html?id=11595

Avatar robot café at Nihonbashi

(posted with permission from the store and individual patient to use photo)

An experimental cafe where people who have difficulty going out due to intractable diseases such as ALS or severe disabilities operate the avatar robot **"OriHime"** remotely and work as a service staff.

- employment for people who are unable to move but want to work,
- use technology to overcome the issues that hinder people's participation in society.

"Co-creation type drug discovery"
COVID-19 Medicine / vaccine research and development

What is the driving force?

- There was understanding, hope, and request from the beneficiary patients and society.
- Interest in vaccines, medicines, and clinical trials has increased.
- All humans have a sense of ownership

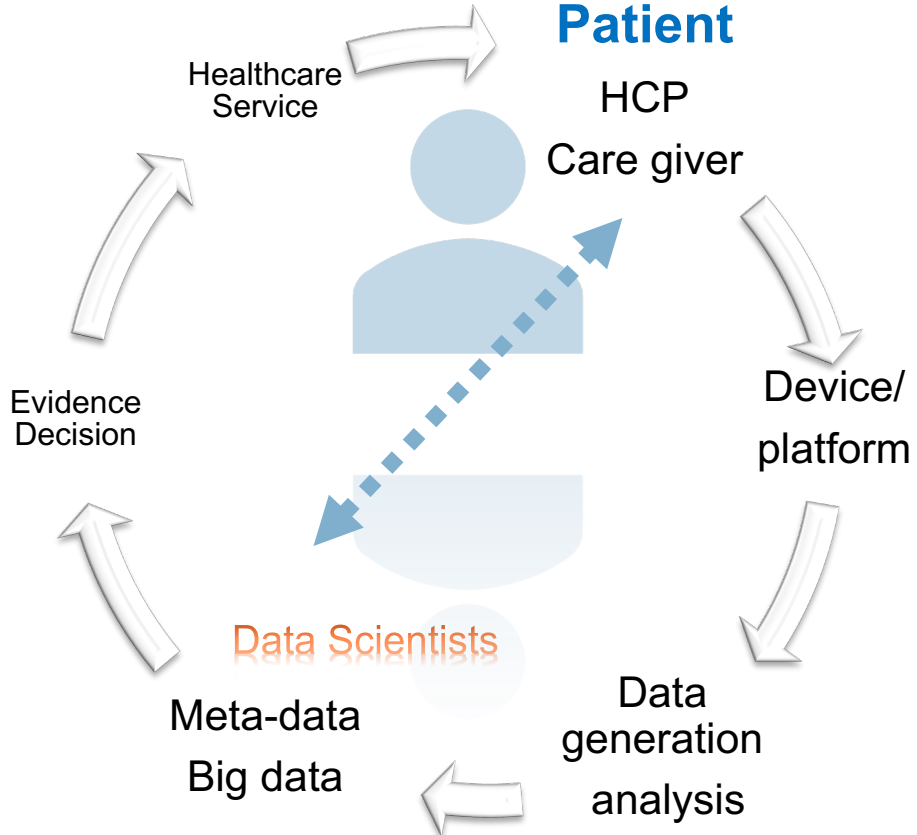
コロナワクチン開発の進捗状況（国内開発）＜主なもの＞

	基本情報	取り組み状況	目標（開発者から聞取り）	生産体制の見通し	研究費
①塩野義製薬 感染研/UMNファーマ ※組換えタンパクワクチン	ウイルスのタンパク質（抗原）を遺伝子組換え技術で作成し人に投与	第Ⅰ/Ⅱ相試験を開始（2020年12月） アジュバントを変更した製剤による第Ⅰ/Ⅱ相試験を開始（2021年８月） 第II/III相試験を開始（2021年10月）	第Ⅲ相試験を2021年度内に開始の意向。	2021年末までに3000万人分の生産体制構築を目標 生産体制等緊急整備事業で223億円を補助	• AMED（R１年度）100百万円　感染研 • AMED（R２年度一次公募）1,309百万円　塩野義 • AMED（R２年度二次公募）
②第一三共 東大医科研 ※mRNAワクチン	ウイルスのmRNAを人に投与 人体の中でウイルスのタンパク質（抗原）が合成される	第Ⅰ/Ⅱ相試験を開始（2021年３月） 第Ⅱ相試験を開始予定（2021年11月） ブースター用試験を開始予定（2022年１月）	第Ⅲ相試験を2021年度内に開始の意向。	生産体制等緊急整備事業で60.3億円を補助	• AMED（R１年度）150百万円　東大医科研 • AMED（R２年度二次公募）
③アンジェス 阪大/タカラバイオ ※DNAワクチン	ウイルスのDNAを人に投与 人体の中で、DNAからmRNAを介して、ウイルスのタンパク質（抗原）が合成される	2020年６月、９月に第Ⅰ/Ⅱ相試験を開始し、その後、2020年12月に第Ⅱ/Ⅲ相試験を開始したが、期待する効果を得られず。 高用量製剤での臨床試験（第Ⅰ/Ⅱ相試験相当）を開始（2021年８月）	高用量製剤の開発に注力。	タカラバイオ・AGC・カネカ等が生産予定 生産体制等緊急整備事業で93.8億円を補助	• 厚労科研（R１年度）10百万円　大阪大 • AMED（R２年度一次公募）2,000百万円　アンジェス • AMED（R２年度二次公募）
④KMバイオロジクス 東大医科研/感染研/基盤研 ※不活化ワクチン	不活化したウイルスを人に投与（従来型のワクチン）	第Ⅰ/Ⅱ相試験を開始（2021年３月） 第II/III相試験を開始（2021年10月）	第Ⅲ相試験を2021年度内に開始の意向。	生産体制等緊急整備事業で60.9億円を補助	• AMED（R２年度一次公募）1,061百万円　KMバイオロジクス • AMED（R２年度二次公募）
⑤VLP セラピューティクス ※mRNAワクチン	ウイルスのmRNAを人に投与 人体の中でウイルスのタンパク質（抗原）が合成される	第Ⅰ相試験を開始（2021年10月）	第II/III相試験を2021年度内に開始の意向。	生産体制等緊急整備事業で143.4億円を補助	• AMED（R２年度二次公募）

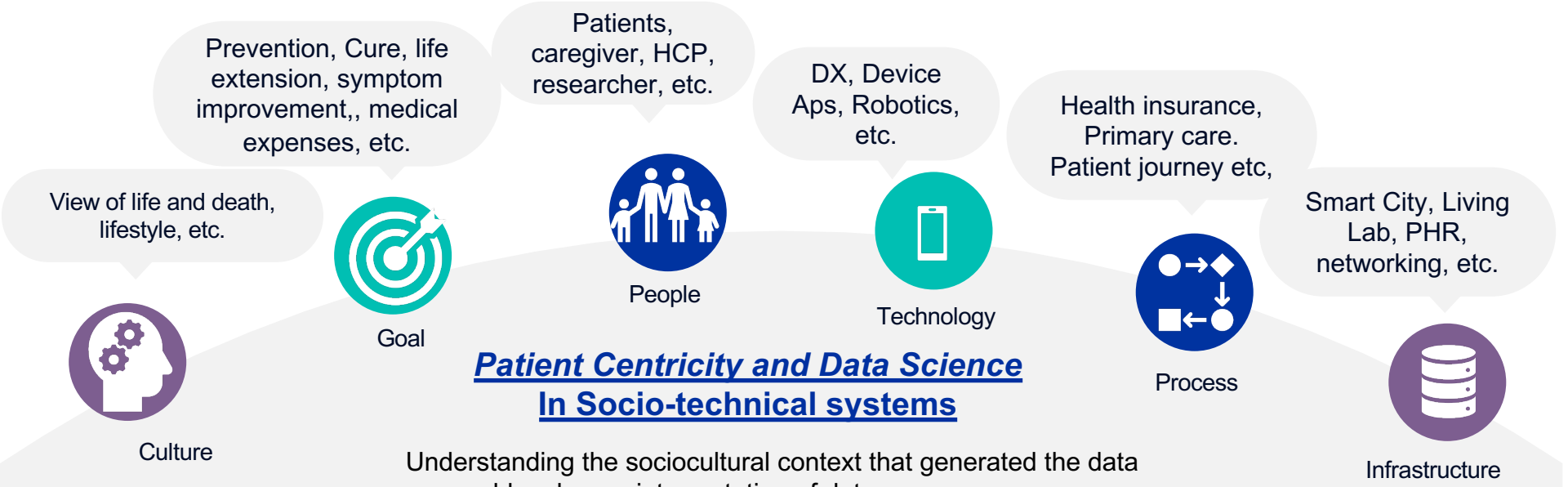
※生産体制等緊急整備事業で採択された企業を掲載

Ref Data (as of Nov-6)from https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000121431_00223.html

Is “patient centricity” the furthest process for data scientists ?



Socio-technical systems that generate data

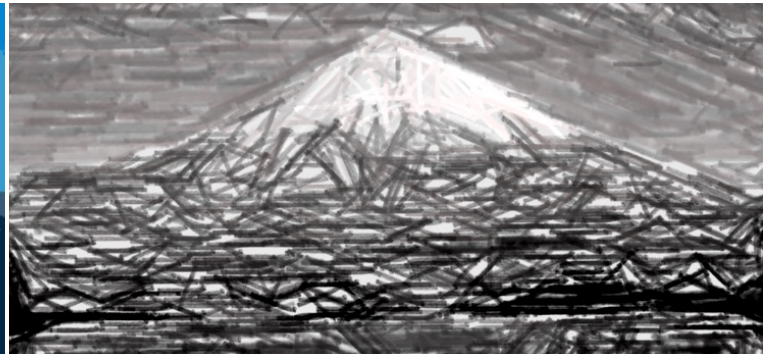


Patient Centricity and Data Science
In Socio-technical systems

Understanding the sociocultural context that generated the data

- enables deeper interpretation of data
- utilization and improvement of the technology
- Influences decision-making in medicine development and business.

Real vs prototype



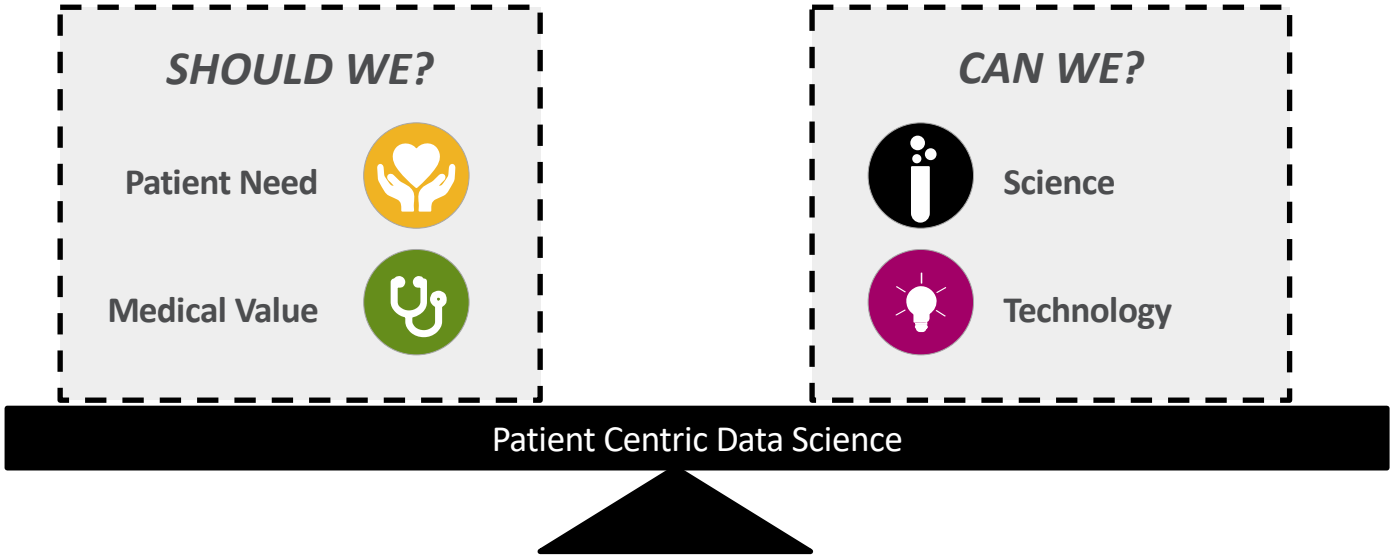
Patient centricity in Data-driven Healthcare System

Healthcare system Transformation

Data Provider-User	→	Partner	Data Sharing, Increasing data literacy, Improving transparency, etc.
Engagement	→	Co-creation	Co-planning, Explanation on the results, Improving data access, etc.
Data obtained from hospital and in clinical study, etc.	→	Life-course data	Creating an easy-to-use platform, Not burdensome tech in daily life, Incentive for user, etc.
Physician's subjective judgment	→	ePRO Digital Biomarker, etc.	Patient-Friendly Design Data robustness Tech literacy, etc.

Patient needs

Balance science and technology with value for patients and healthcare providers



The Global Healthcare Data Science Community

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