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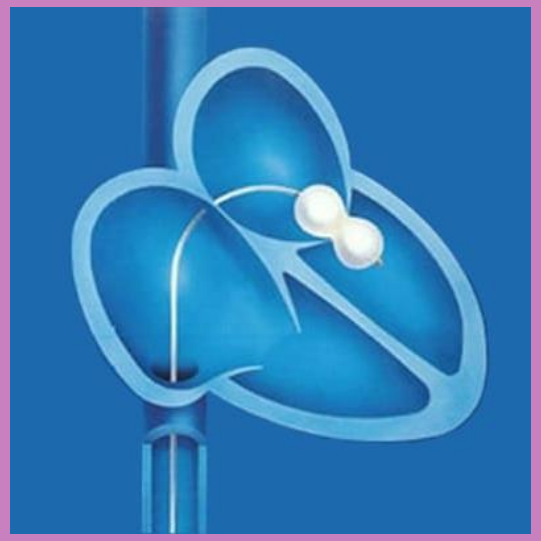
Medium-Term Management Program Project AP-G 2025

Pharmaceuticals and Medical Products Business

June 5th, 2023

Hirofumi Kobayashi
Senior Vice President
General Manager, Pharmaceuticals and Medical Products Division
Toray Industries, Inc.

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Overview of the Business

Product Lineup

Improve the quality of healthcare, reduce the burden on healthcare providers and contribute to health maintenance and longevity through Toray Group's innovative technologies and resources

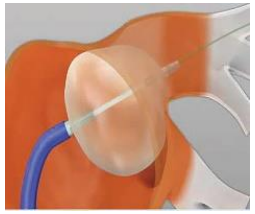
Major products which contribute to better medical care and longevity, foster public health

Pharmaceuticals & Medical Devices

Contact lenses

Pharmaceuticals

Dialyzers



Catheter

Extracorporeal circulation therapeutic columns

Dialysis machine
Integration system
DX/AI solution

New development
1. Diagnostics APOA2-i (Pancreatic cancer)
2. Nucleic Acid Drug "TRK-250"
3. New therapeutic columns to treat dialysis-related amyloidosis, ARDS etc.
4. Adhesion barrier (surgery and obstetrics)

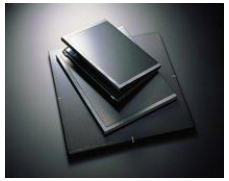
Advanced Materials

PP spunbond for hygiene products

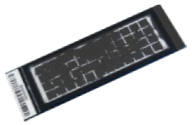
Disposable protective clothing

Functional materials for vital signs monitoring

X-ray CT cradle, Cartridge



Air filter



DNA chip

Fabrics for sportswear

TRK-950: Cancer antibody drug

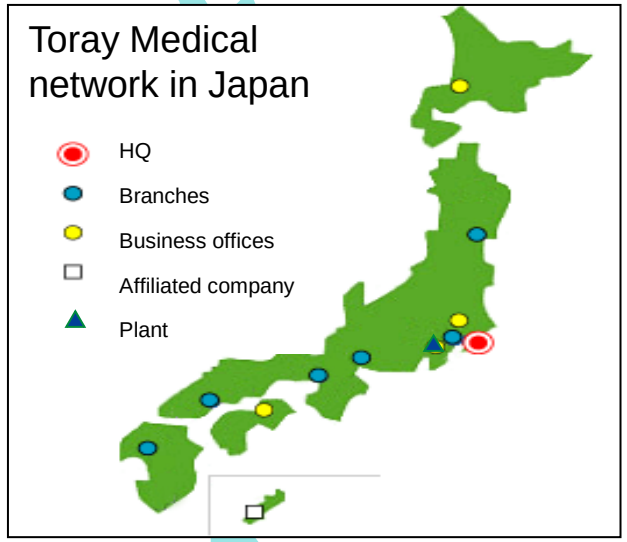
Global Network (Sales, Production and R&D)

Toray Medical (Qingdao) Co., Ltd.
(Dialyzer and dialysis machine)

- Production bases
- Sales bases

Shiga Plant : Optical products
Mishima Plant : Pharmaceuticals
Okazaki Plant : Medical devices and dialyzers
Seta Plant : Medical devices

Toray Medial Co., Ltd.
Shizuoka plant (Dialysis machine)



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Reviewing the Medium-Term Management Program, Project AP-G 2022

AP-G 2022 Result and AP-G 2025 Plan

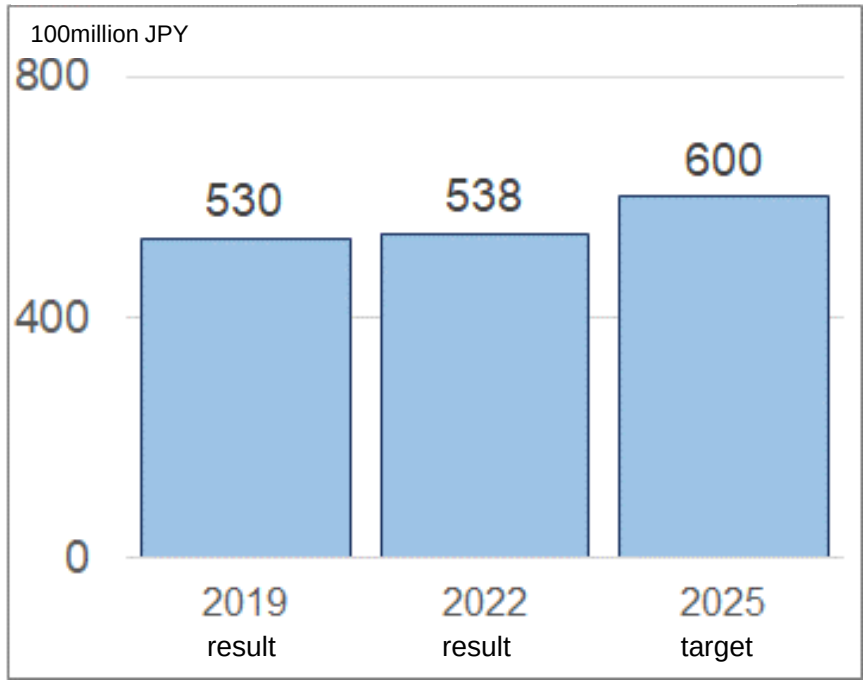
Business Environment

The business circumstances had been worse than the initial assumption due to disruptive impact from COVID-19 pandemic, soaring costs of raw materials and fuels caused by the prolonged war in Ukraine and exchange rate volatility

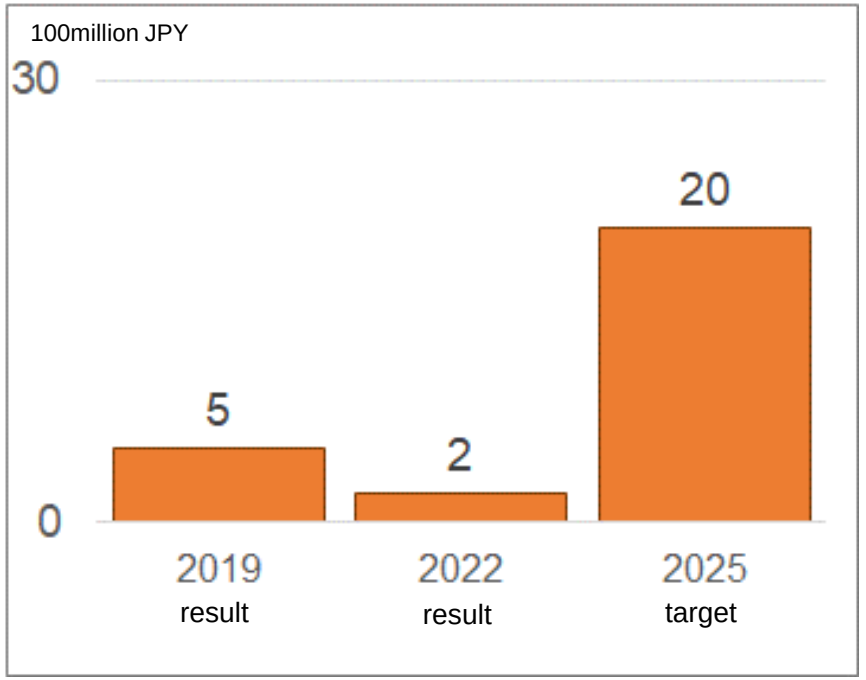
Priority Measures

Obtain additional indications in Japan for existing products, facilitate developments for global expansion, new products and improved products

Revenue (FY 2019 – FY 2025)



Core operating income (FY 2019 – FY 2025)



Achievement in AP-G 2022

- ✓ There has been unavoidable postponement of overseas clinical trials and launch of new products caused by disruptive impact from COVID-19 pandemic. However, the following has been achieved: a) the global expansion of existing products, b) development of additional indications and maximization of value, c) Implementation of solution business including dialysis machines, d) monetization of new technologies created through R&D activities, e) utilization of the existing technologies and intellectual properties
- ✓ Fulfilled the medical and hygiene needs from dialysis and other hospitals and the Government of Japan

Major achievement during AP-G 2022

	Products	Achievement
Pharma & Diagnostic	Development of In Vitro diagnostic test to measure APOA2(*1) Isoform concentrations	1. (Apr 2022) received positive results in clinical performance test 2. (Jun 2022) completed filing a manufacturing and marketing approval with the Ministry of Health, Labour and Welfare (MHLW)
	Global development of “TRK-820”(*2)	1. (Jul 2022) received positive results in Phase III clinical trial in China
	Global launch of BPS ((*3), PAH(*4))	1. (Sep 2022) received approval from China’s National Medical Products Administration (NMPA) for Careload™ tablets
	Nucleic Acid Drug “TRK-250”	1. (Jun 2022) received positive results in Phase I clinical trial in the U.S.
Medical Devices & Dialysis	Development of adhesion barrier “TRM-270C”	1. (Sep 2021) concluded Business Collaboration Agreement with ASKA Pharmaceutical Co., Ltd.
	Development of PMMA-based blood purification column	1. (Dec 2021) launched Filtryzer™ HDF, polymethyl methacrylate (PMMA) hollow fiber membrane-based hemodiafiltration device 2. (Dec 2022) launched Filtor™ (dialysis-related amyloidosis)
	Additional indication of Toraymyxin™	1. (Mar 2023) filed application for partial changes for IPF-AE
	Additional indication of HotBalloon™	1. (Oct 2021) obtained marketing approval of additional indications for a treatment of persistent atrial fibrillation, (May 2022) secured insurance coverages

*1: Apolipoprotein A2, *2: Antipruritic agent used only when sufficient efficacy is not obtained with the existing therapies or treatments,
*3: Beraprost sodium, *4: Pulmonary arterial hypertension

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Medium-Term Management Program, Project AP-G 2025

AP-G 2025 Basic Policy & Priority Measures

Slogan

Contributing to society through our products and services which protect human life and global environment

Basic Policy

- Utilizing the outcome/achievement during AP-G 2022 and improving probability of success in development, boost profitability and restore soundness of the business within FY 2025
- Realizing profitable and sustainable business foundation around FY 2030

Priority Measures

- Improve functions, obtain additional indications and develop overseas business of existing products
- Create maximum value utilizing exiting assets (tangible and intangible)
- Launch of the diagnostic business
- Identify growth areas, provide high value-added services utilizing DX/AI, strengthen solution proposals and expand business and product development in the oncology field.
- Develop environmentally friendly products
- Place top priority on quality, foster competitiveness led by innovative cost reduction technology

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Development of Diagnostics business for Pancreatic Cancer (completed filing a manufacturing and marketing approval with MHLW in June 2022)

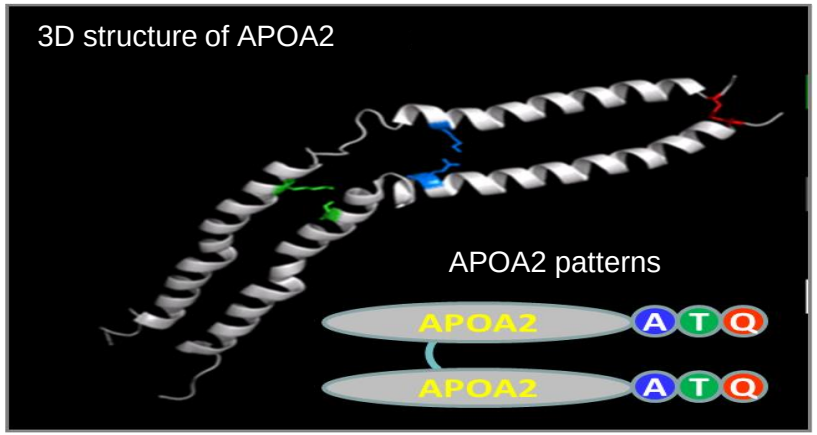
1. Pancreatic cancer statistics

[Japan] number of new cases 43,865 (FY 2019)
number of deaths 37,677 (FY 2020)

2. Difficulties in detection

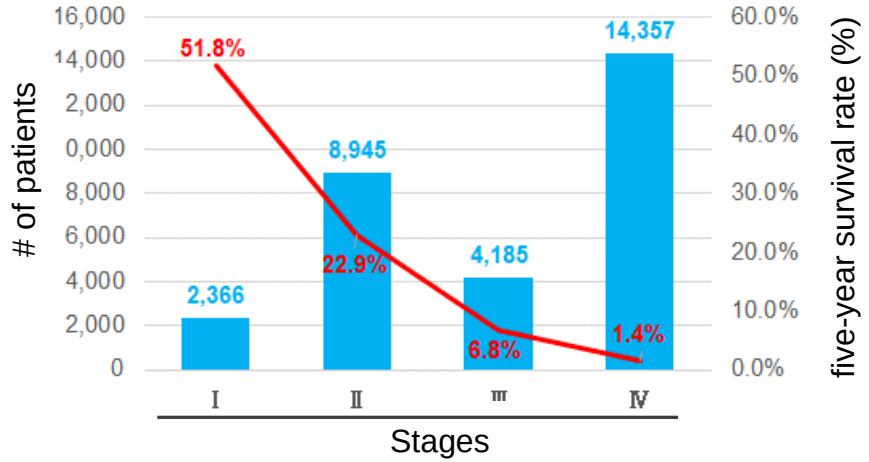
- No symptom in early stages and rapid progression
- existing biomarkers are not useful enough in early detection

3. Changes of APOA2 isoform levels with progression of pancreatic cancer

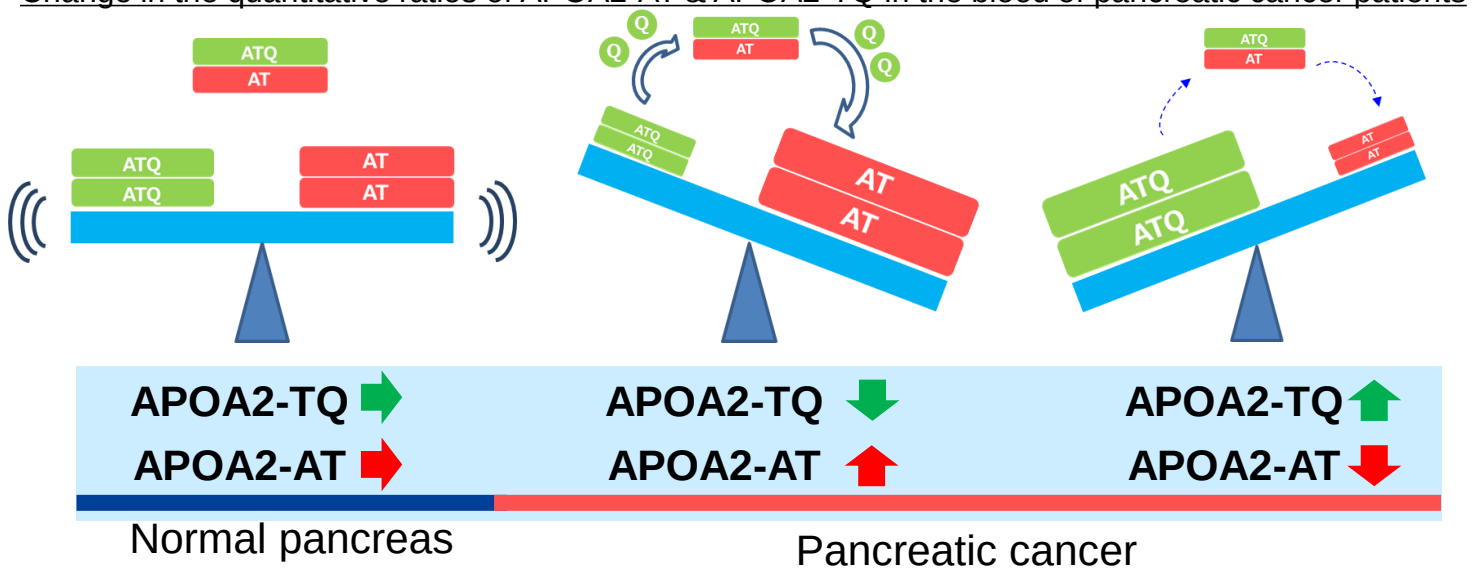


Quantitative ratios of APOA2-AT & APOA2-TQ change in the blood of pancreatic cancer patients
Honda, et al., PLos ONE 7(10): e46908, 2012

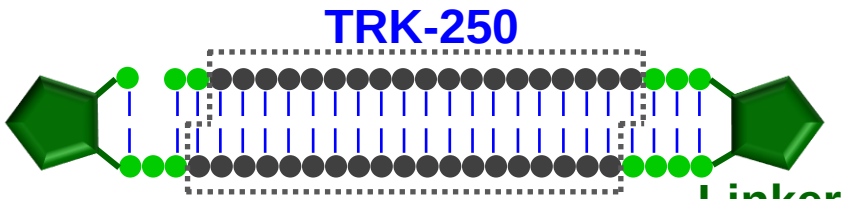
Early detection of pancreatic cancer can dramatically improve 5-year survival rate



Change in the quantitative ratios of APOA2-AT & APOA2-TQ in the blood of pancreatic cancer patients



Development of “TRK-250” for Patients with Idiopathic Pulmonary Fibrosis



A single strand long-chain nucleic acid with a unique molecular structure

- Improved biostability
- Direct local administration to the lung by a nebulizer

Selectively suppresses the expression of a key growth factor involved in lung fibrosis

- showed effectiveness in studies conducted in an animal model
- received Orphan Drug Designation from FDA

Result of Phase 1 clinical trial in the USA

Weekly administration by a nebulizer to IPF patients

- **Safety: showed good tolerability**
- **Pharmacokinetics: no systemic exposure (potential side effects expected to be low)**

Global Licensing: Further development will be conducted by/with prospective business partner

Development of Adhesion Barrier “TRM-270C”

Strategic Open Innovation

- ✓ Has been developing the product since 2012 in collaboration with Nanotheta Co., Ltd., a Waseda Univ. initiated startup, applying its polymer nanosheet technology.
- ✓ In 2021 concluded Business Collaboration Agreement with ASKA Pharmaceutical Co., Ltd., a specialty pharmaceutical company that focuses on obstetrics and gynecology.

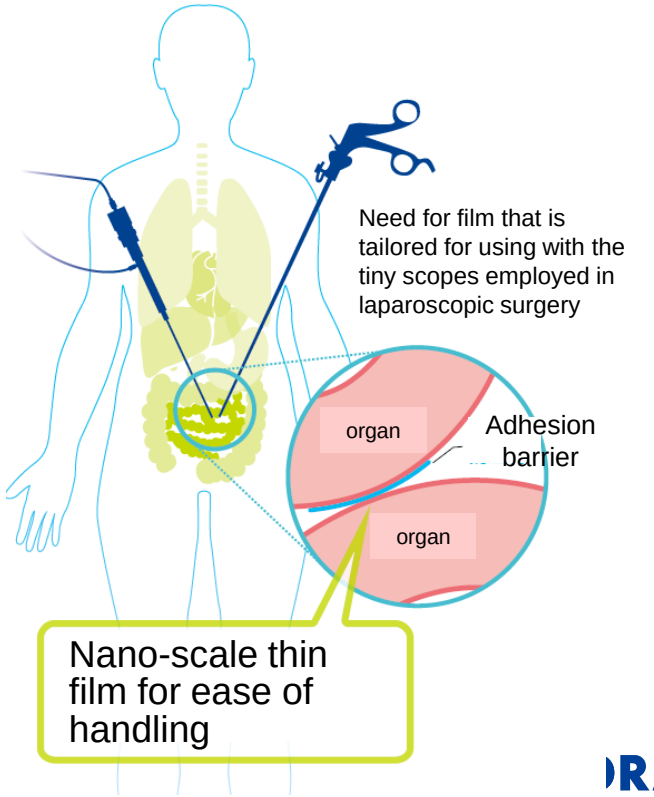
Technologies in TRM-270C

By utilizing a laminated structure consisted of resins with different properties, provide the necessary handling at laparoscopic surgery and robot-assisted surgery which has increased in recent years.

Ongoing Process

Have been conducting clinical trial in gastroenterology and organizing coming trial in obstetrics and gynecology to obtain approval in Japan

Polymer nanosheet on skin



Policy & Measures (Dialysis Business)

Basic Policy

- Dialyzers

  Pursue profitability and high probability of market penetration by the best possible combination of target countries/regions, variety of products, additional indications, and value-added products

- Dialysis Machines

  Accelerate growth by developing new products/functions and solution proposal

Priority Measures

- Adding value to the dialyzers business

  Appeal protein adsorption performance of PMMA and clinical improvement
  Promotion of development of environmentally friendly columns (including downsizing)

- Advancement of overseas business models

  Improvement in the functions of dialysis equipment and maintenance platforms and collaboration with other companies

- Strengthen the ability/functions to propose dialysis total solutions

  Proposal of dialysis management system, energy conservation, reduction of dialysate, enhancement of proposal capabilities utilizing DX/AI

- Enhance cost reduction

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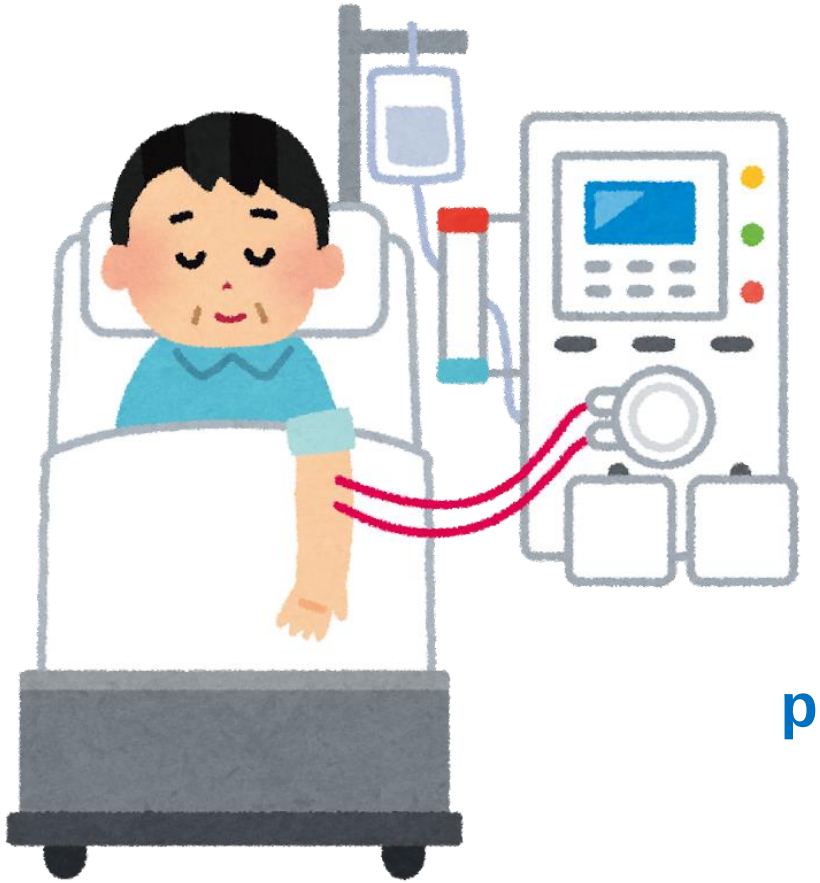
Policy & Measures (Dialysis Business)

Example: Prediction model of intradialytic hypotension



Optimizing treatment for dialysis patients

AI suggests to the patient the appropriate:

- type of membrane
- amount of fluid removal
- amount of blood flow

Reduce the burden on patients and healthcare providers using optimized treatment by AI prediction

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Policy & Measures (Dialysis Business)

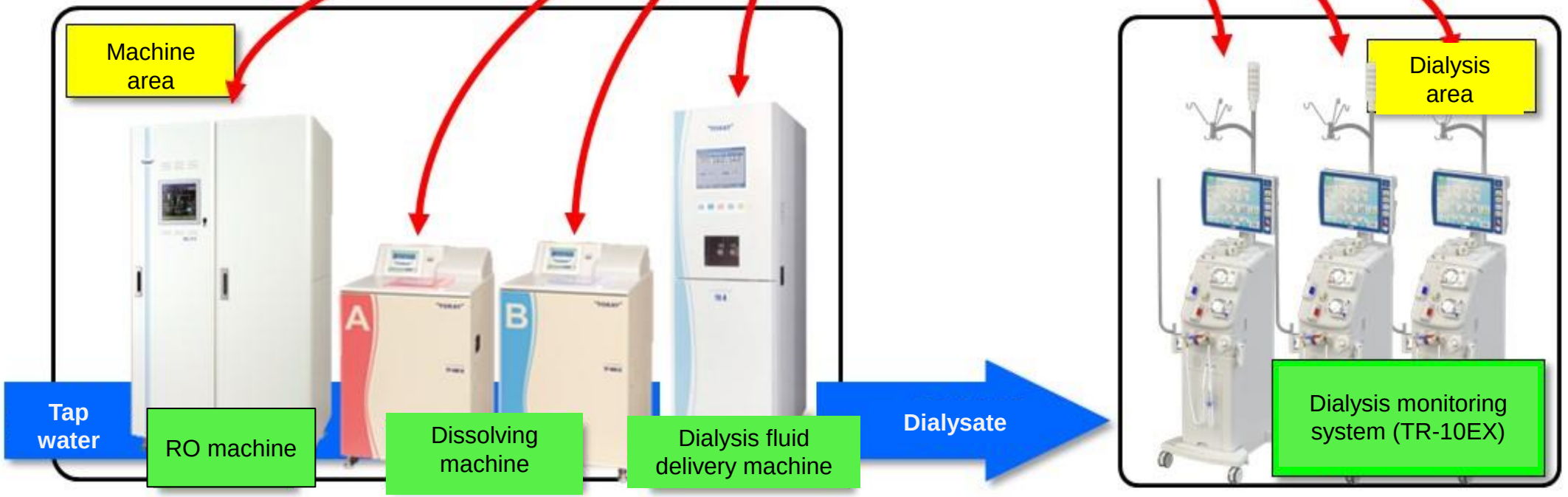
MICS (Patient monitoring System)

DMACS(Dialysis Machine Advanced Communication System)

First in industry

Machine area

Dialysis area



Toray is the only manufacturer in Japan to provide full range of dialysis related equipment including RO machines and dialysis machines.

Policy & Measures (Dialysis Business)

Development of PHR System

PHR：Personal Health Record, Lifespan electronic health record

[Our Vision]

Provide safety and QOL(Quality of Life) of dialysis patients, through our unique dialysis machines and dialysis monitoring system (*).

[Backgrounds]

1. Increasing dialysis patients in need of nursing care due to aging
2. The healthcare budget in dialysis center is expected to be reduced due to decreasing number of dialysis patients in Japan
3. Provision of healthcare service by several experts, close coordination with community-based integrated care systems

[Ongoing Activities]

We will build PHR system to keep patient's personal health record and the linkage with dialysis monitoring system which will help patients to realize better QOL and to decrease a risk of becoming a care recipient.

Enhance patient satisfaction

Ease the burden on medical care providers

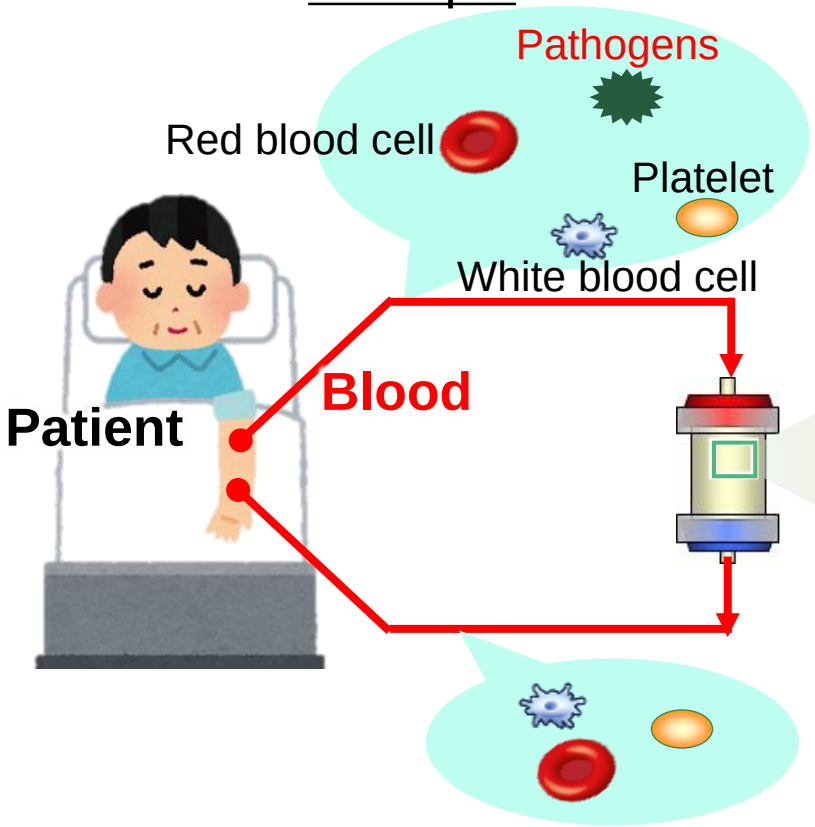
Improve efficiency

*: Dialysis monitoring system: computer system that assists safety and efficiency during dialysis treatment by connecting electronic health record, machines and other peripheral devices. MiracleDIMCS UX is available for sale by Toray Medical Co.,Ltd.

Extracorporeal Blood Purification

Treatment intended to remove pathogens from blood through extracorporeal circulation

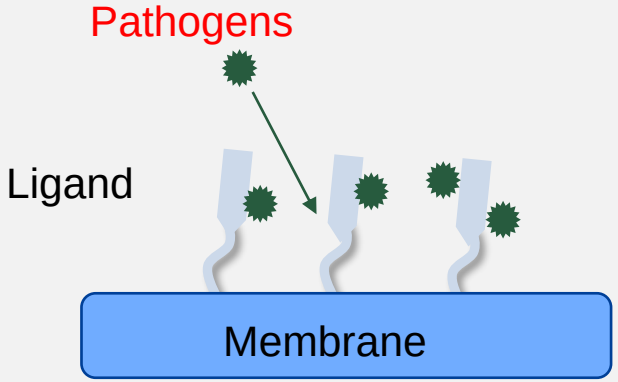
Example



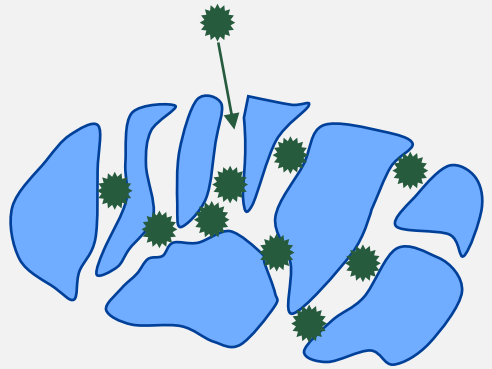
Principle of adsorption column

Adsorbed on ligand*

*compound to elevate adsorptiveness



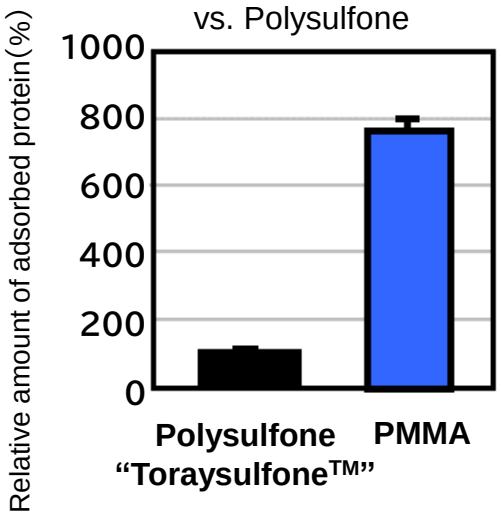
Adsorbed in porous structure (ex: activated carbon)



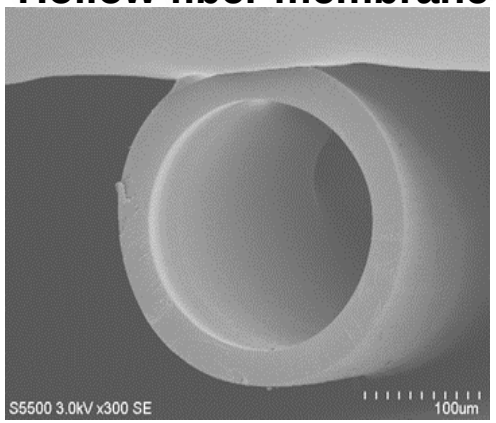
Expansion of applications in dialysis technology ：PMMA adsorption membrane technology

Dialyzers

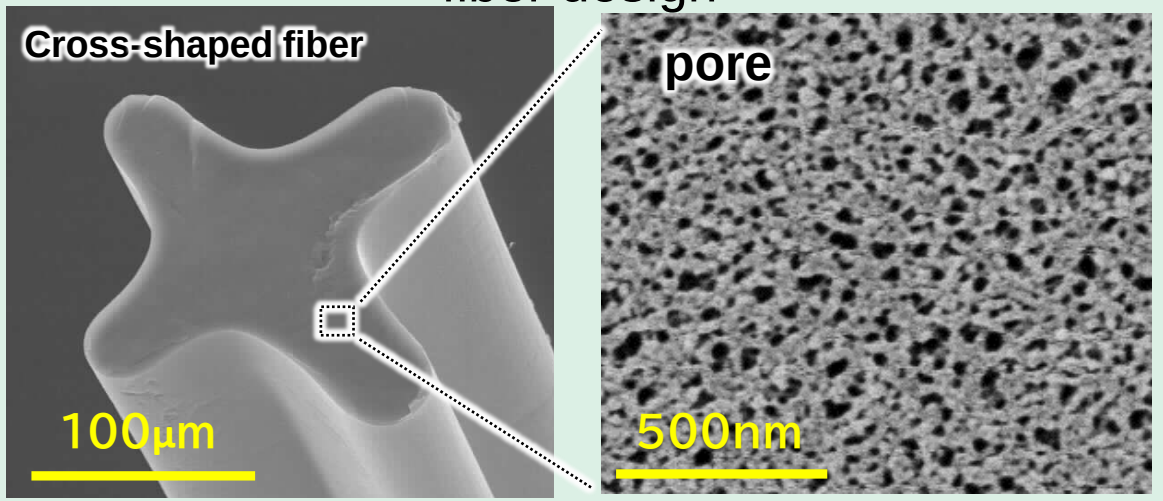
Type of membrane	Features
Polysulfone membrane  (Since 1995)	Major membrane with high permeability and separation
PMMA membrane  (Since 1976)	Highly biocompatible, especially suitable for the elderly



Hollow fiber membrane



For treatment of amyloidosis: adsorptive material & fiber design



porous structures adsorb pathogenic proteins (Ligand-free)

- ✓ **Possible to develop compact, high-performance column which is patient (the elderly and children)-friendly**
- ✓ **Ligand-free structure technology can be applied to various development easily**

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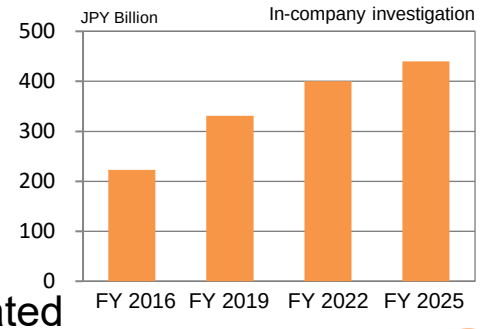
HotBalloon™ Ablation System

Backgrounds

- Increasing patients of Atrial fibrillation due to advance of aging
- Definitive care for atrial fibrillation, which is a risk factor of cerebral infarction, heart failure and dementia, is needed

Global ablation market



CAGR (FY 2016→FY 2022)
10%+

Market size (FY 2022)
Japan: JPY 33billion
Overseas: JPY 367billion

Growing market worldwide

About HotBalloon™

- The world's first hot balloon system, in which the interior of a balloon is heated using a radio frequency energy (launched in 2016). A flexible, compliant balloon allows for firm contact with a variety of anatomical configurations and may lead to lower recurrence rates
- Secured insurance coverage to treat persistent atrial fibrillation in Japan in May 2022, following the approval for paroxysmal atrial fibrillation
- Investigator-initiated clinical research to assess the effectiveness against persistent atrial fibrillation scheduled to begin in June 2023

HotBalloon™

Ongoing Development and Future Plans

- Launch of better operable 2nd generation product which succeeds to the 1st generation's level of safety and effectiveness
- Further develop the products in order to address the needs in clinical environment
- "Future model" development is aiming for exceptional quality in safety, effectiveness and operability

*Surface temperature: temperature of interior fluid

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Long-term Vision

Long-term Vision

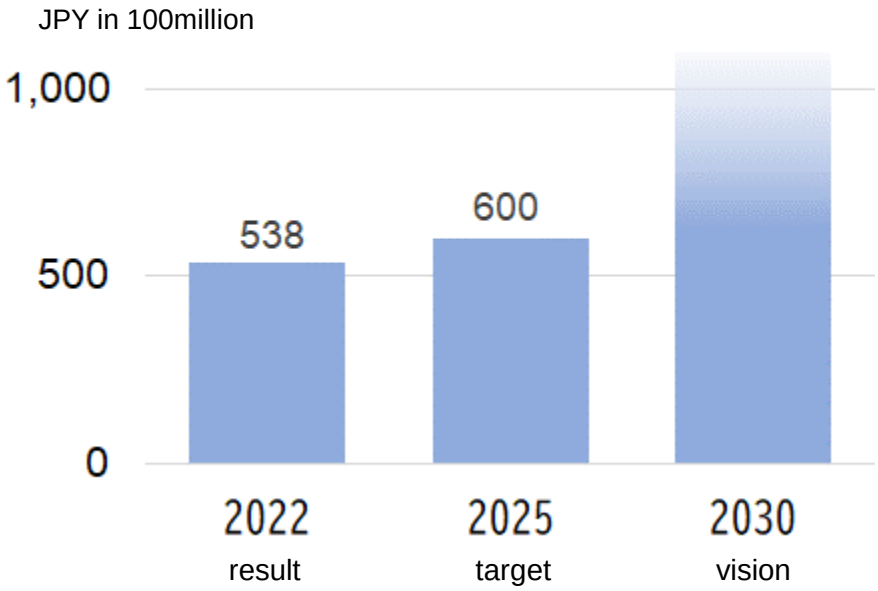
Long-term Vision

Pursue business expansion and high-profitability by means of global launch of Diagnostic business and existing products, getting additional indications, developing eco-friendly products, introducing new products and solution service proposal

Key Drivers

- Produce synergetic effect among Pharmaceuticals, Diagnostic business and Medical Devices
  - Licensing nucleic acid drug “TRK-250” patent rights and the positive results in Phase 1 clinical trial in the U.S.
  - Acceleration of activities leveraged by networks and technologies gained through Remitch development.
  - Apply NANODESIGN™ technology and diagnostic business knowledge
- Raise competitiveness of blood purification business and development of eco-friendly products
  - High-performance, compact and recyclable design
- DX/AI solution business
  - Support better QOL of dialysis patients and less burden on healthcare providers.
  - Sophistication of diagnosis, Diagnostics Test + imaging AI
- Generating a new business with maximizing value out of existing assets and intellectual properties

Financial target



Core Technologies and Value Creation with Pharmaceuticals, Diagnostic business and Medical Devices

▶ Get maximum value out of the assets and external collaborations

1. Diagnostic business: APOA2-i

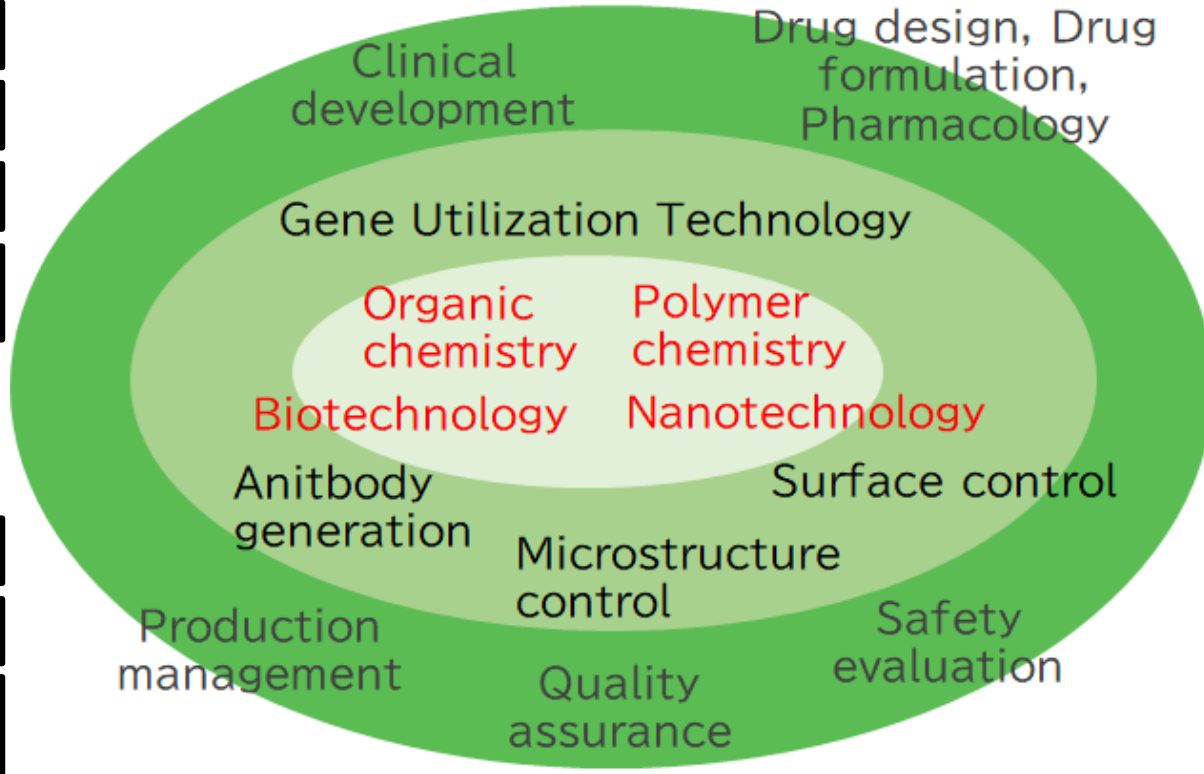
Collaboration with National Cancer Center

- Core Technology: new biomarker & biotechnologies
- Component Technology: antibody generation
- Backbone: expertise in gastroenterology (liver, gallbladder and pancreas)
- DX/AI: clinical development & AI supported imaging diagnostics (external collaboration)

2. Medical Devices: Blood purification columns

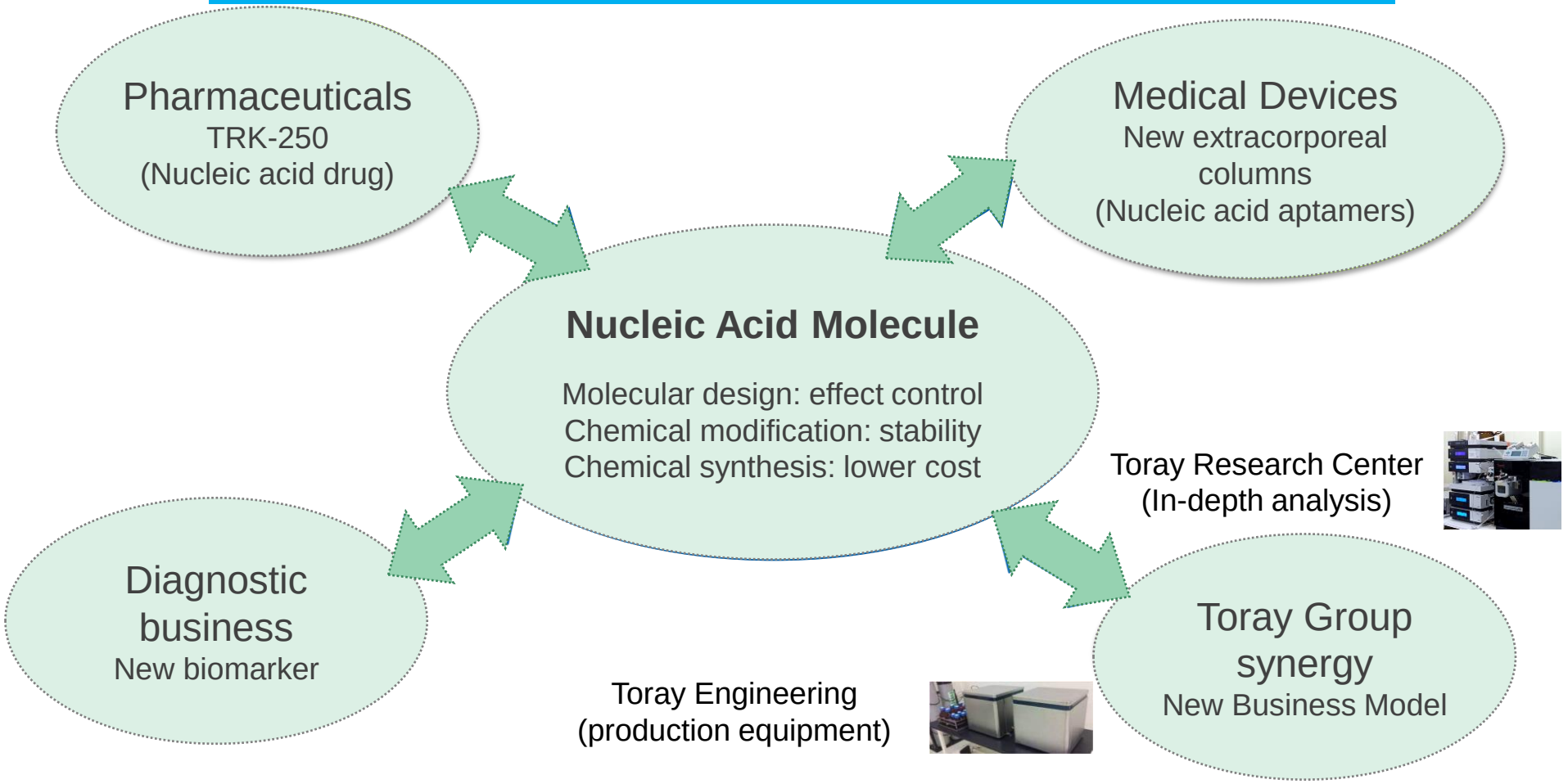
External collaboration including AMED and investors

- Core Technology: polymer chemistry & nano technologies
- Component Technology: processing of fiber, membrane and surfaces
- Backbone: blood purification and machine business in dialysis and intensive care
- DX/AI: integrated system on dialysis equipment & biological monitoring



Synergetic effect among Pharmaceuticals, Diagnostics and Medical Devices by nucleic acid molecule

Evolution of core technology in various business areas



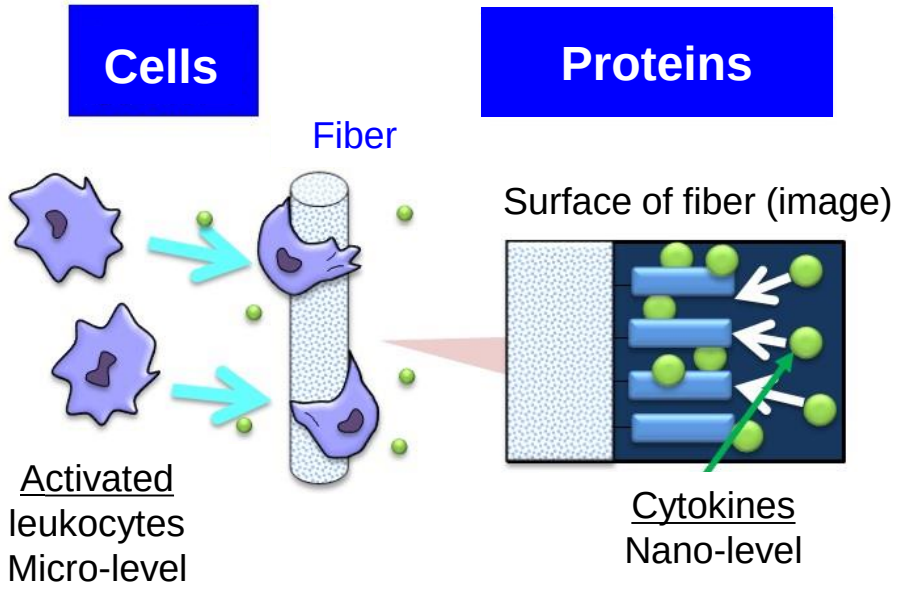
Utilize Toray Group's products, technologies and expertise to develop nucleic acid-based business

External Collaboration & Long-term Vision: Evolution of Blood Purification column

Blood purification to Treat acute pulmonary disease

Funding from Development Bank of Japan Inc.

Targeting pneumonia-induced ARDS in the case of COVID-19



Micro-level control of fiber surface structure Activated leukocytes	Immobilized Ligand Target proteins

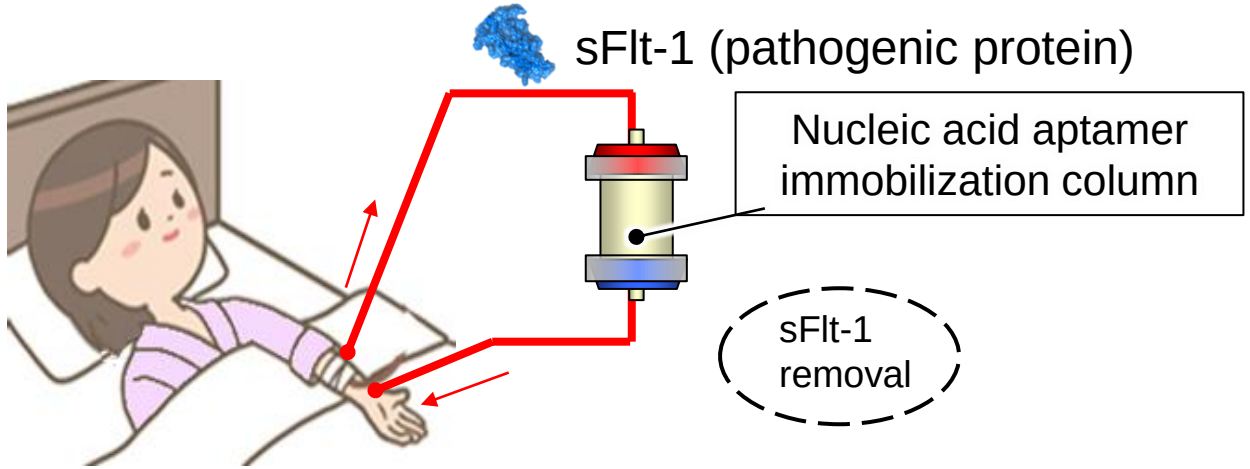
Blood purification against pregnancy hypertension

Development of sFlt-1 adsorption columns

Extracorporeal circulation can provide safe treatment to the pregnant patient who is difficult to use pharmaceuticals

Obtained funding through R&D support program provided by Japan Agency for Medical Research and Development (AMED)

Industry-academia collaboration



World's first treatment to every bedside!

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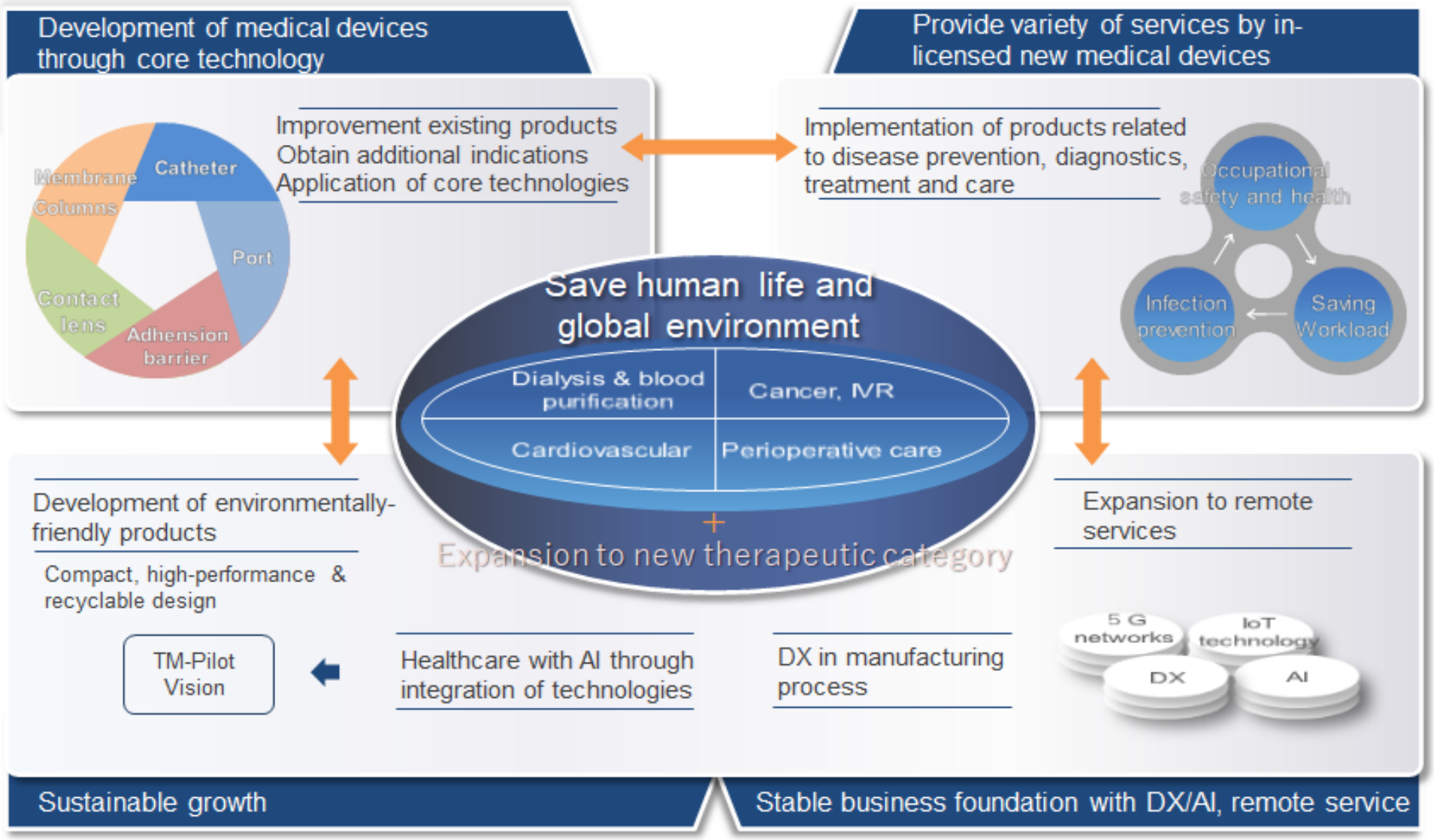
Solution Map for Medical Device Business

Contributing to society through our products and services which protect human life and global environment



Descriptions of predicted business results, projections and business plans contained in this material are based on assumptions and forecasts regarding the future business environment, made at the time of publication.

Information provided in this material does not constitute any guarantee concerning the Toray Group’s future performance.

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