

R&D Day 2

The Future of Santen R&D

**Global R&D
Santen Pharmaceutical Co., Ltd.**

September 6th, 2019



Agenda



R&D Day2



Q&A session for DE-128 (MicroShunt)

Opening Remarks

Shigeo Taniuchi

President and Chief Operating Officer



Bringing the Joy of Sight

Naveed Shams, MD, Ph.D.

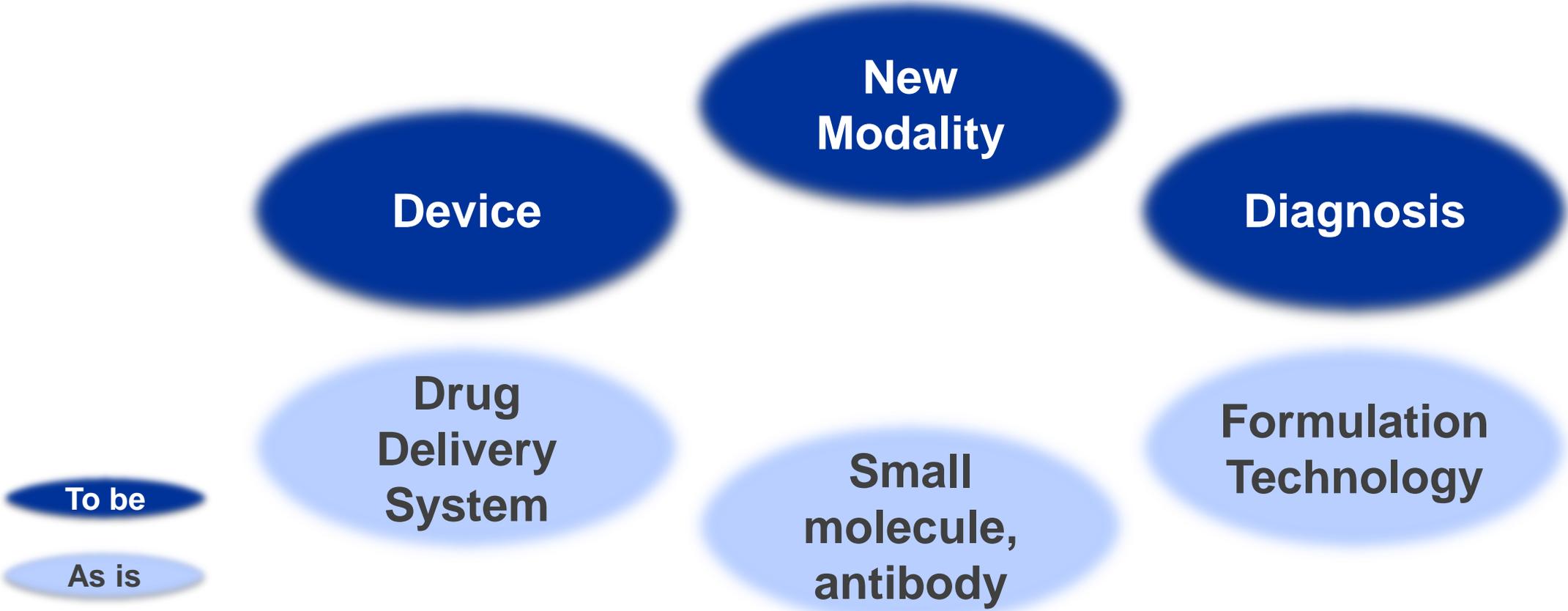
Senior Corporate Officer & Chief Scientific Officer,
Head of Global R&D



VIDEO: Patients Voice

Only available on site

Measures to Maximize Productivity

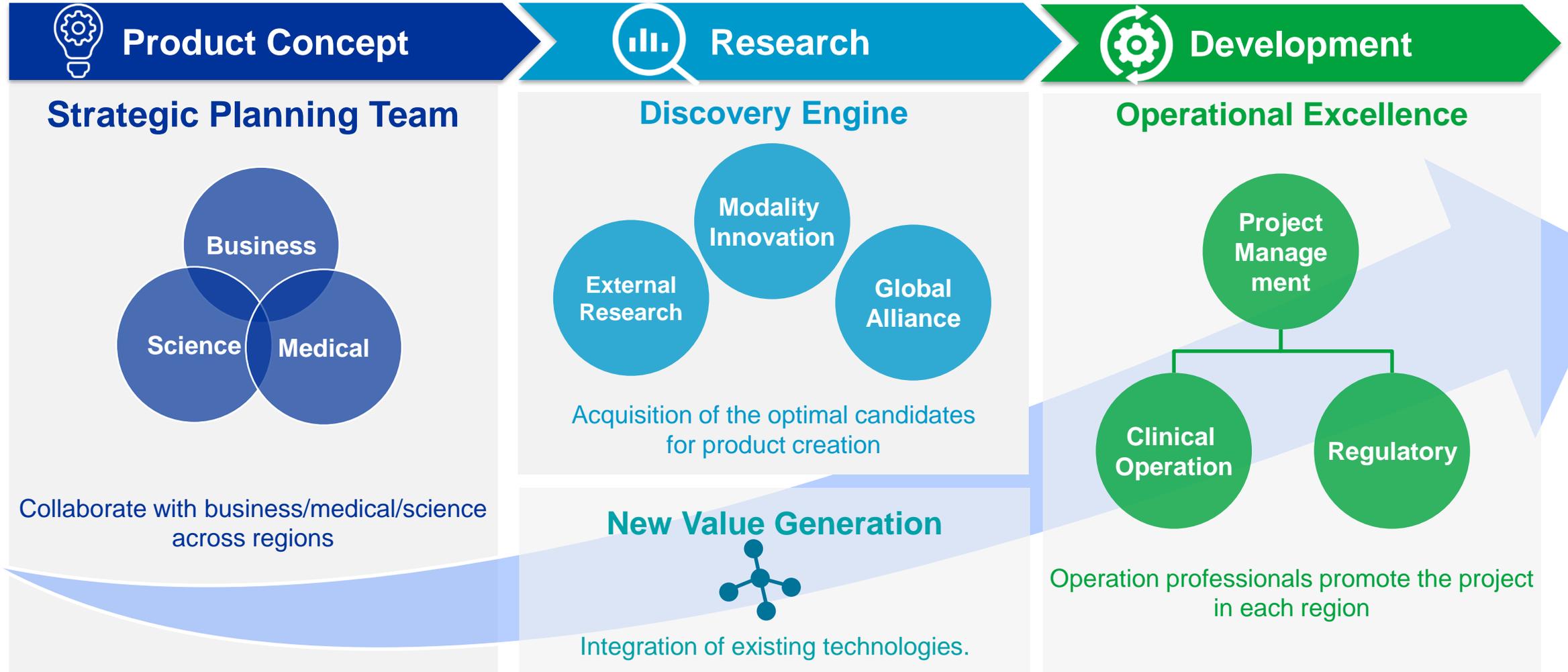


Our Approach



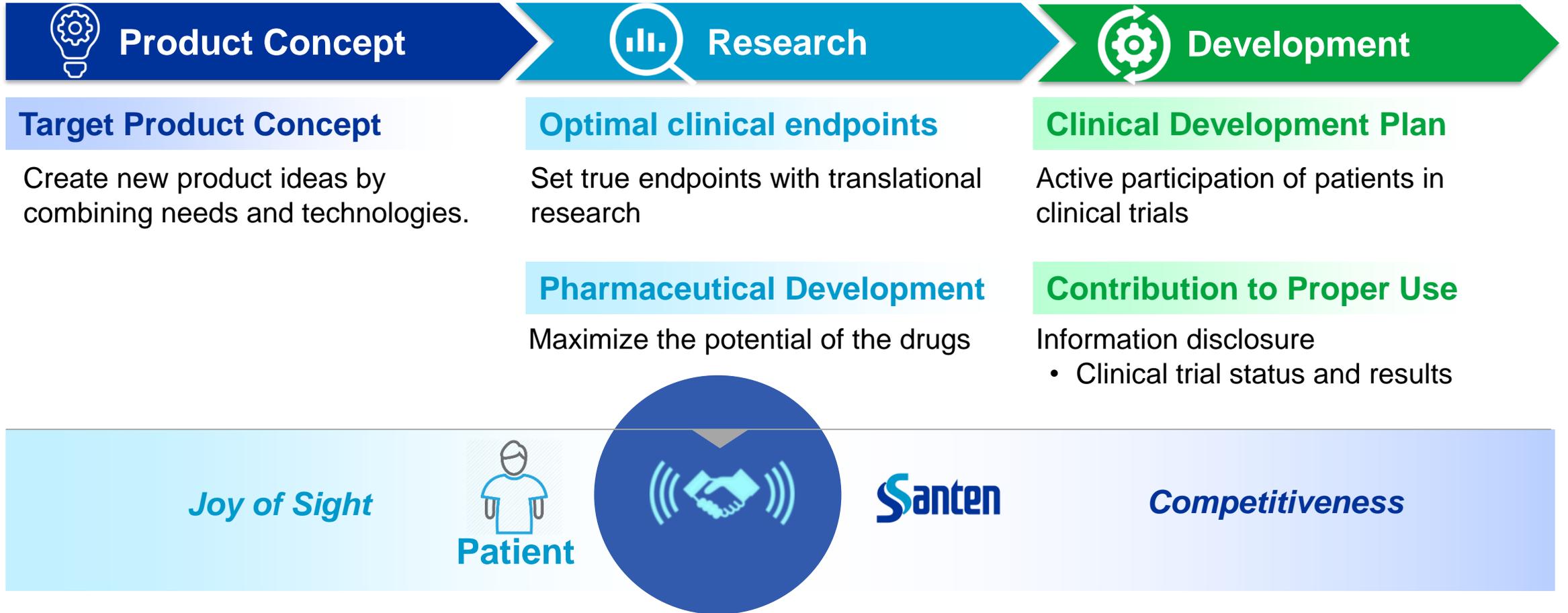
Our Synchronized Product Creation Process

Speed, Quality and Efficiency



Patient Centricity is Our Guiding Force

Throughout the Product Development Journey



This new approach will ensure we truly address patient needs!

R&D Leadership Team



Naveed Shams

Senior Corporate Officer
& Chief Scientific Officer,
Head of Global R&D



Reza Haque

Senior Vice President,
Head of Biomedical
Strategy & Research



Kenji Morishima

Corporate Officer,
Head of Pharmaceuticals &
Pharmacology
Representative, Asia R&D



Peter Sallstig

Senior Vice President,
Head of Product
Development
Representative, US R&D



Takeshi Matsugi

Head of R&D Strategic
Operations

Disease Area Strategy

Reza Haque, MD, Ph.D.

Senior Vice President,
Head of Biomedical Strategy & Research



We Can Enhance QoL for Patients Suffering from Various Eye Diseases



Addressing the needs of a changing world

Asia

Increasing Myopia Patients

Myopia progression
Pathologic myopia

Developing world

Reaching More Patients to Eye Care

Infectious disease

Developed world

Aging Society

Age related diseases (AMD, Glaucoma etc.)
Chronic illness (Dry Eye, DR/DME, etc.)

Genetic diseases

Improving Therapeutic Tech.

Rare Diseases

Strategies to Address Future the Unmet Need

| Disease Area | Strategy |
|-----------------------------|--|
| Glaucoma | <ul style="list-style-type: none"> • <i>DDS Rx Delivery</i> • <i>Improved Eye Drop Delivery</i> • <i>Continuous IOP-Monitoring Devices and Earlier Disease Progression Detection</i> • <i>Surrogate Biomarkers</i> • <i>Neuroprotection</i> |
| Retinal and Uveal Disorders | <ul style="list-style-type: none"> • Anti-VEGF (Adjunctive, <i>Long-Duration, Low Cost</i>) • <i>Therapy for Rare Disease</i> • <i>Cell Therapy</i> • <i>Gene Therapy</i> • <i>Stem Cell Therapy</i> |
| Myopia | <ul style="list-style-type: none"> • Prevention (<i>Superior</i>) • <i>Treatment for Pathologic Myopia</i> |
| Others | <ul style="list-style-type: none"> • <i>New MOA</i> • <i>New molecules</i> |

Glaucoma

Realize Neuroprotection with Partners



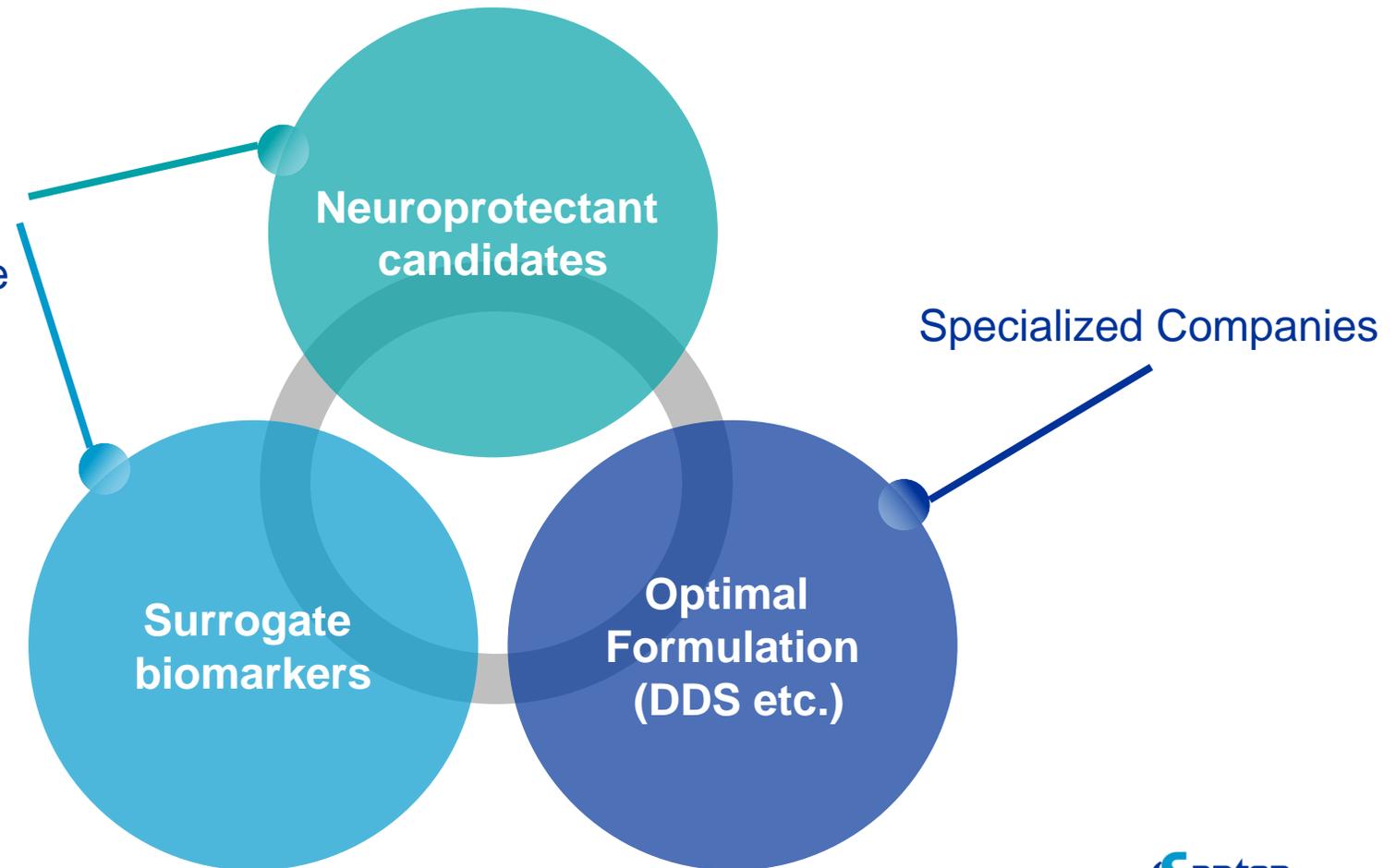
Tohoku University



University College of London

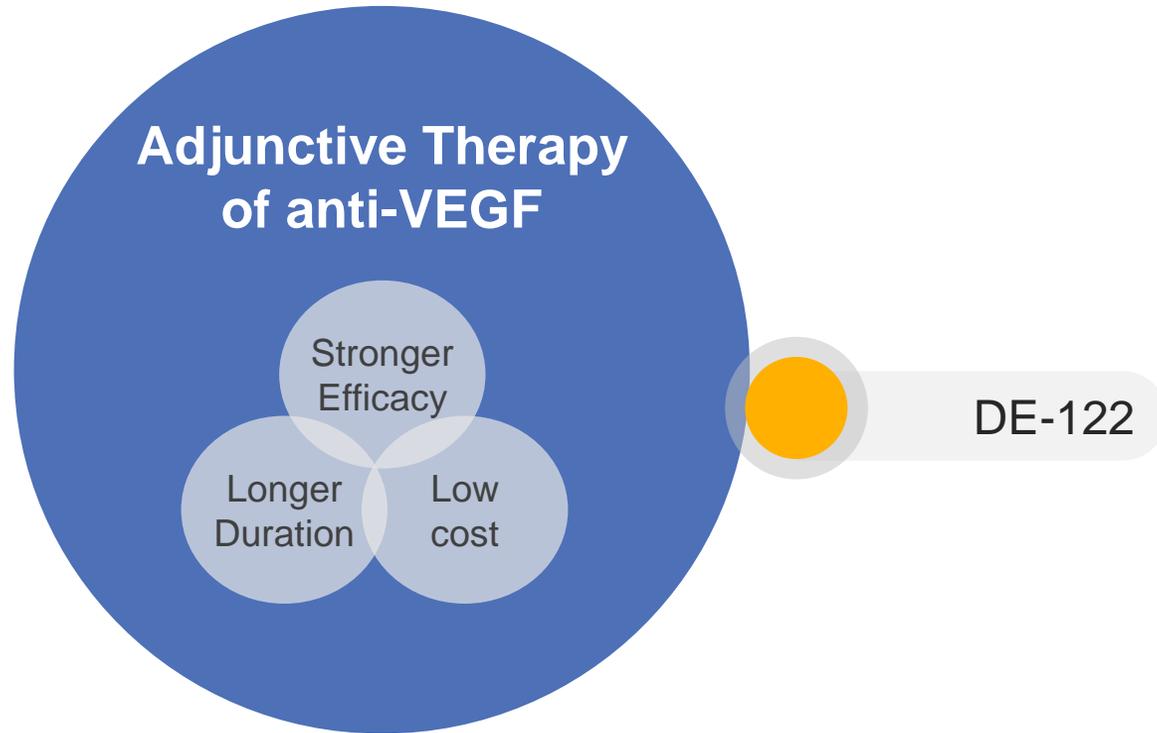


Singapore Eye Research Institute

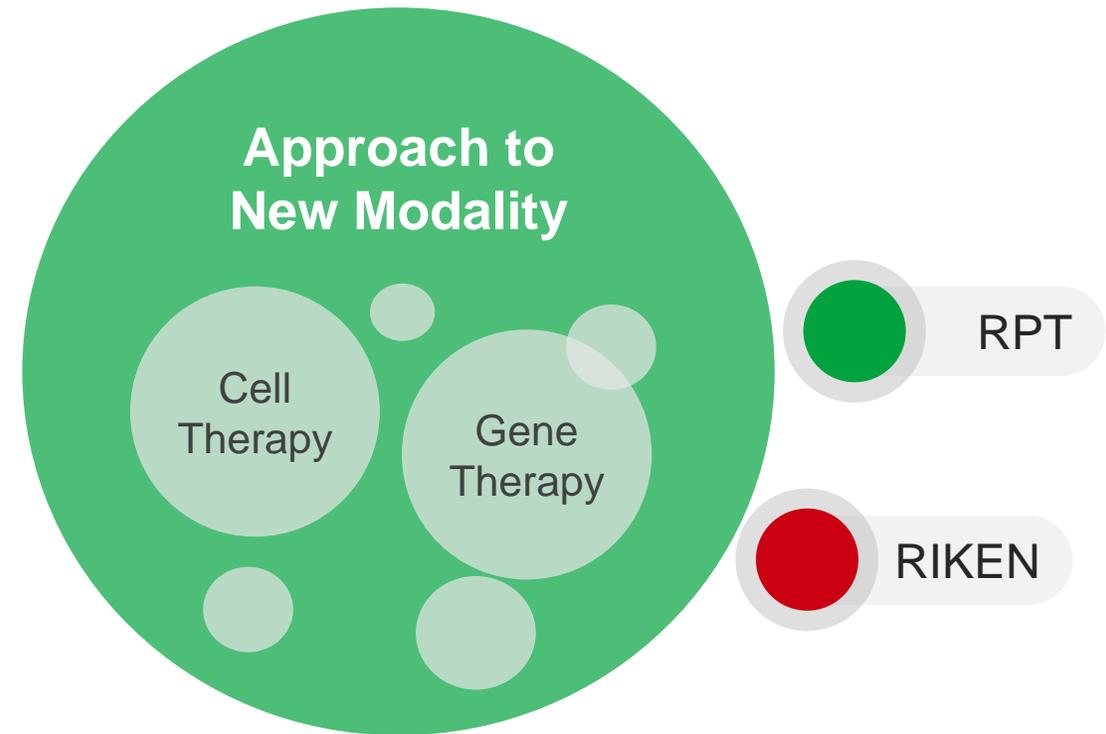


Retinal and Uveal Disorders

Improve dissatisfaction and burden of existing treatments

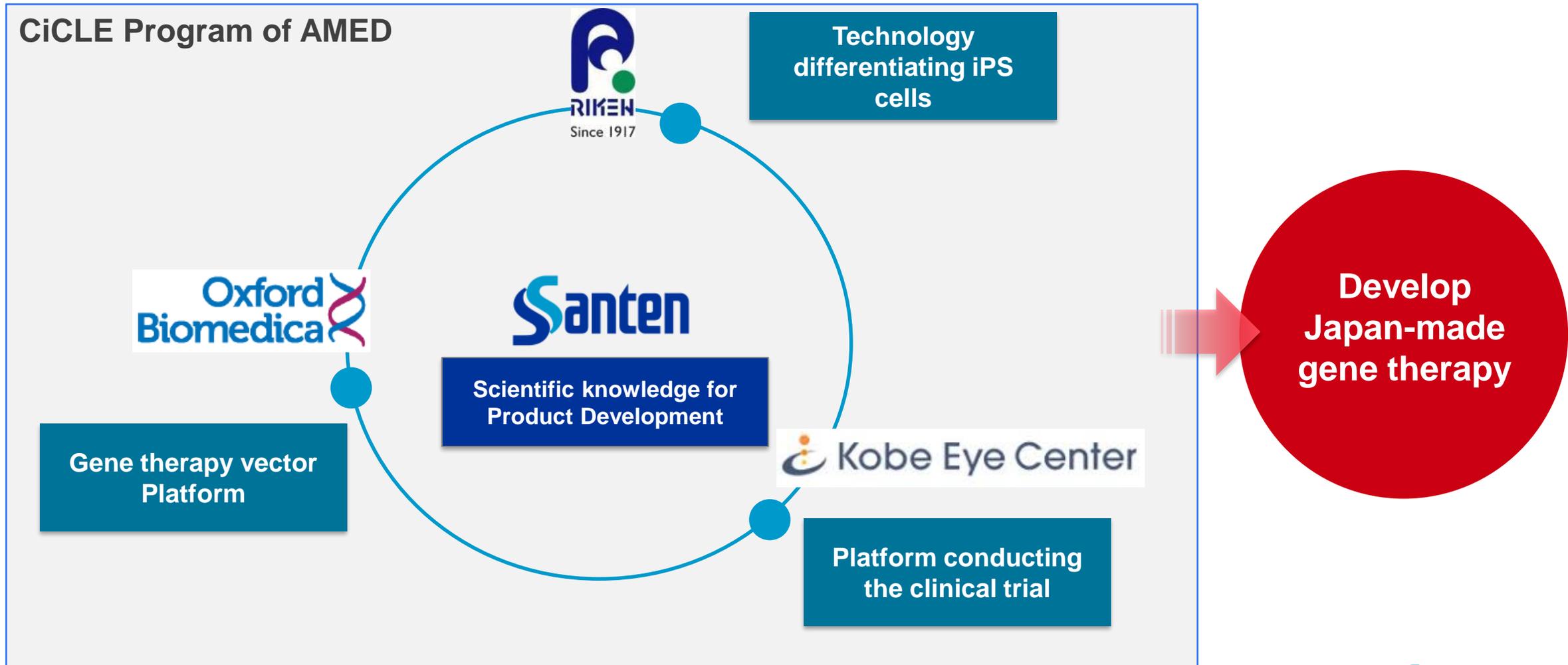


Effective use of new modality to approach diseases for which there is no treatment



Rare Ocular disease

Develop Novel Gene Therapy with Partners



Myopia

Expand therapies to Asia where great UMN is exists, from two perspectives of prevention and treatment



× **Asia**



No.1 Company for Myopia Market



First Therapy for Pathologic Myopia

Keratoconjunctival Disorders

Handling the global/regional UMN's of each disease carefully utilizing new technologies



Pharmaceutical Development

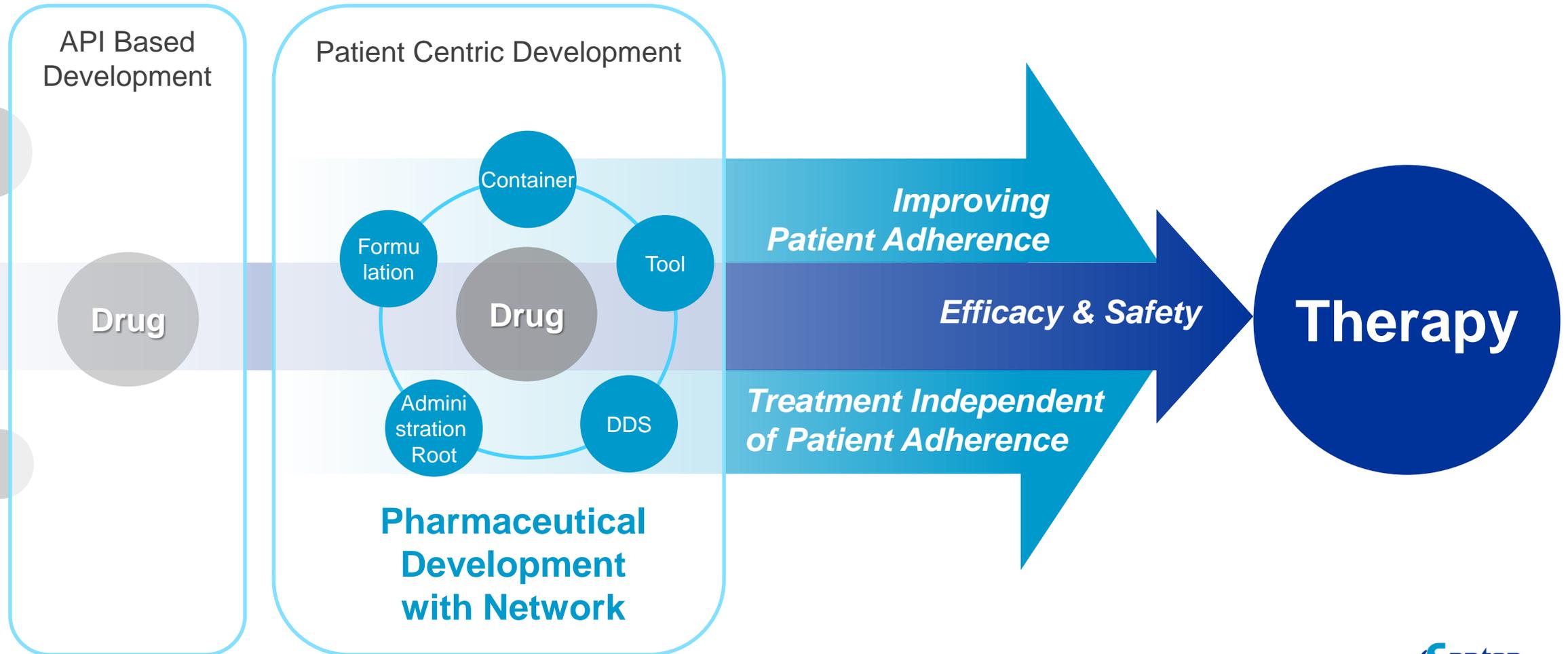
Kenji Morishima

Corporate Officer,
Head of Pharmaceuticals & Pharmacology
Representative, Asia R&D



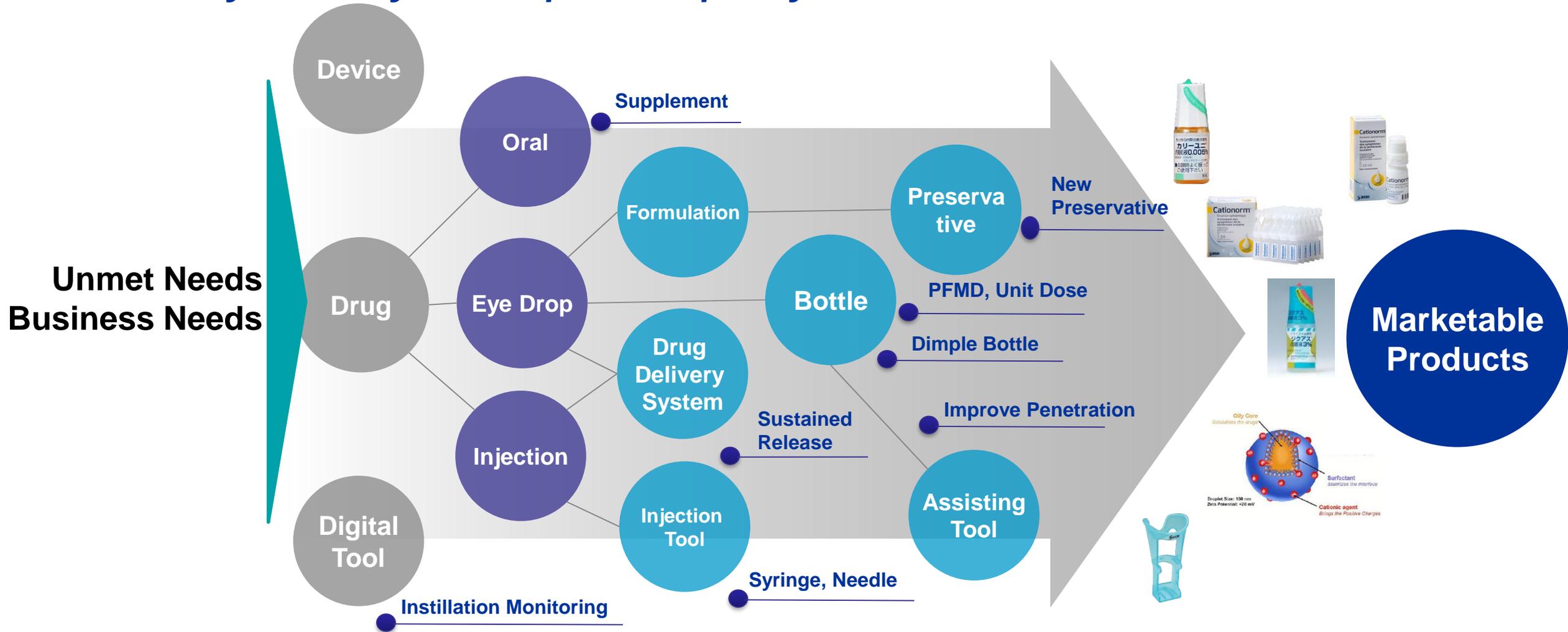
Maximize the Potential of the Drugs

Based on Solid Knowledge and Experience in Ophthalmology



Become Total Solution Provider in Ophthalmology

Go Beyond Eye Drop Company



Providing joy to patients by creating new product value.

100% focusing on ophthalmology, that's exactly why we can do it.



謹啓 まいまい寒さを感ずる頃でございますが、貴社には
 益々ご繁栄のことと存じ、お喜び申し上げます。
 さて、この年が明けたばかりで、いろいろと準備中ですが、白濁症との
 診断をうけた日、4回診察をうけていただきましたが、眼薬をお使い
 いただき、仰ぐとおり、おかげで思っていたよりも、最近おさま
 貴社のカリニューニ点眼液が改良された使いやすくなり、私としては
 画期的な改善をうけたことを喜んでいます。
 われを申しあげなく、一筆、お礼を申し上げます。

敬 啓

“使用優秀賞”
 カリニューニ点眼液 2006年
 下半分の四部の工夫が、眼に光を
 とし、眼が抱えやすくなり、
 貴社の努力と、おかげで、
 私共、今後に期待を込めて
 ありがとうございます。

「お客様の声」

| | |
|--|-------------|
| ご記入日 | 平成18年 2月 2日 |
| 白内障の点眼液の容器が 変わりとても使い易くなり 助かっています 他の容器も変わってほしい位 です。 | |
| | |
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| | |

Product Development

Peter Sallstig, MD, MBA

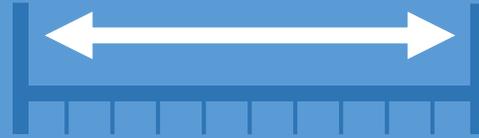
Senior Vice President,
Head of Product Development
Representative, US R&D



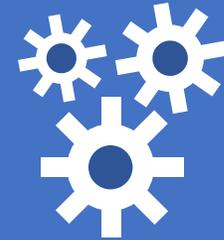
A New Approach to Product Development



Increased predictability through accurate, science- and evidence-based study designs, plans, and budgets



Shortened timelines through faster study start-up and timely patient enrollment and trial completion



Optimized clinical operations and data collection

Ensure Competitive Advantage in Ophthalmology

Optimized Product Development



**Launch on Time
Higher PTS
Value Generation**



Operational Excellence

- Product development in an appropriate region based on accumulated knowledge and experience in Ophthalmology
- Continuous high quality communication with investigators
- Optimized clinical operations and project management in each region

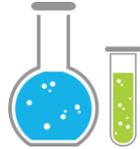


Establishment of Robust Global Development Platform

- Deep understanding of the science
- Collaboration with Thought Leaders (KOLs) in Ophthalmology
- Credible relationship and communication with regulatory authorities

Key Focus Areas of Immediate Improvements

Better leverage of in house-know how and historical data fuels enhancement of core strength in product development



Social media campaigns, site and patient-support tools, study websites, on-site enrolment managers, patient and investigator apps, digital listening.



Basic principles drive POC/POM trials criteria. Usage of more new technology,

We are Addressing Changing Ophthalmic Treatment

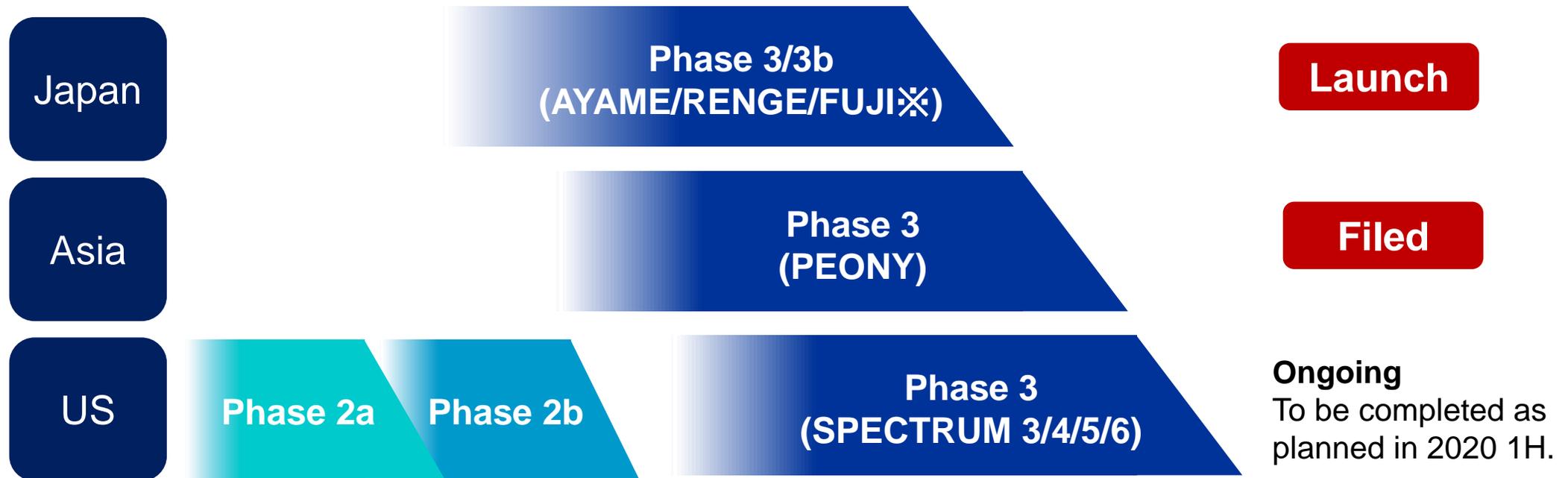
| Disease Area | Pipeline |
|------------------------------|---|
| Glaucoma | <p><i>IOP Lowering</i></p> <ul style="list-style-type: none"> ‣ <i>New agent</i> ‣ <i>Compliance (MIGS)</i> ‣ <i>Territory Expansion</i> |
| Retinal and Uveal Disorders | <p><i>Anti-VEGF (Adjunctive) Therapy for Rare Disease</i></p> |
| Myopia | <p><i>Prevention</i></p> |
| Keratoconjunctival Disorders | <p><i>Improve Usability (Line Extension) Territory Expansion</i></p> |

Launching Where the Need is Greatest

Applying the Learnings to Future Markets

Case Study: Development Strategy for DE-117

- Development in Japan, which is the fastest to launch, then Asia
- Leverage knowledge experienced in previous regions
- Differentiation study for value maximization in Phase 3 (FUJI study)

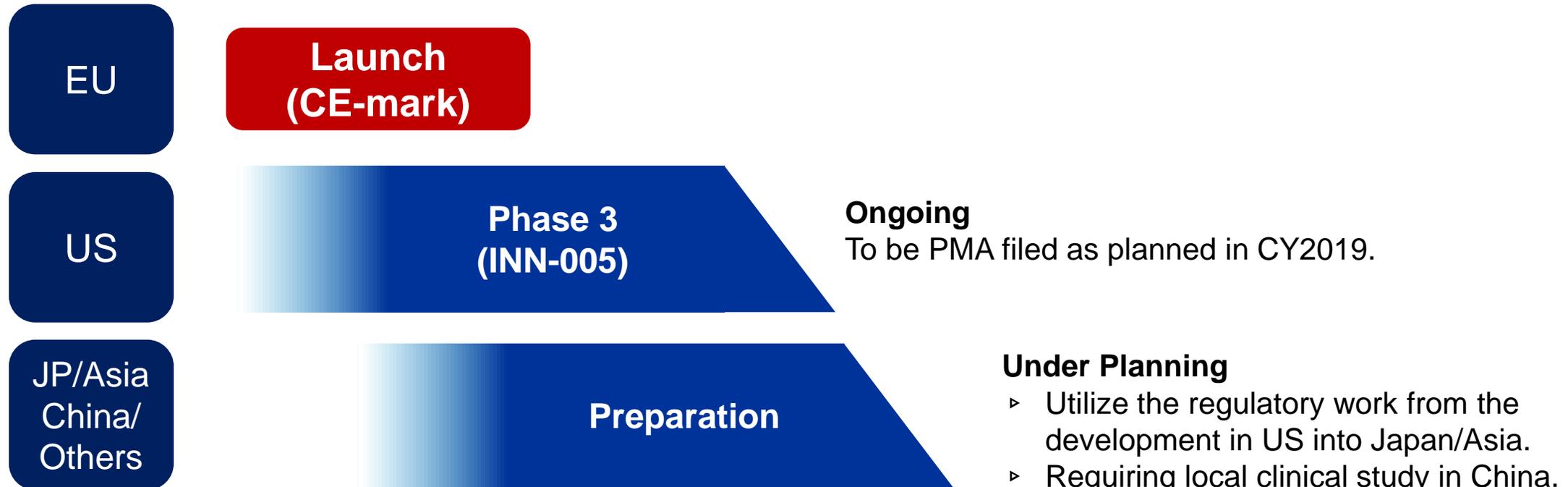


※FUJI study: Safety and Efficacy of DE-117 in subjects With POAG or OH who are Non-/Low-responders to Latanoprost

Global Need Requires Global Approach

Case Study: Development Strategy for DE-128

- Learn and experience from any commercialization activities Europe under CE-mark
- Realized the maximum value through PMA process in the biggest market, US
- Utilize all knowledge/data in the following countries, Japan, Asia and China



Protecting World's Vision through Patient Centric R&D

Bring the Joy of Sight



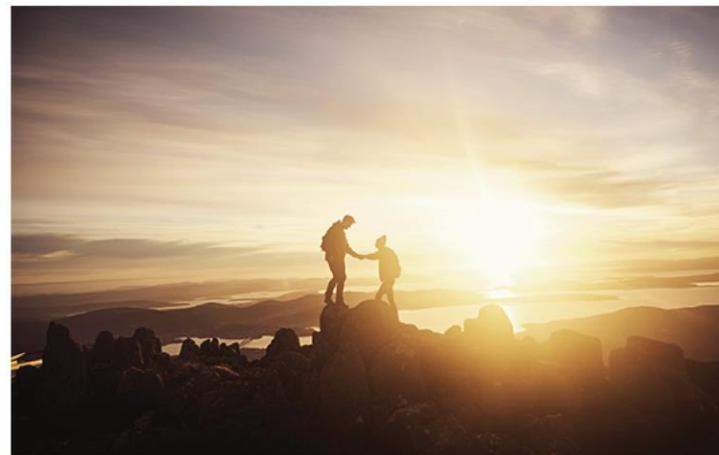
Fulfilling Unmet Worldwide



**Unique competitive advantage
by excelling in product development capability and globalization of opportunities**



**VISION
EVERY
DAY.**



Q&A Session



A Clear Vision For Life™

Q&A session for DE-128 (MicroShunt)



Santen Pharmaceutical Co., Ltd.

September 6th, 2019

VIDEO: MicroShunt

VIDEO: Trabeculectomy

Only available on site

Value Proposition & Our Objective

First FDA approved minimally invasive stand alone procedure for mild, moderate, and severe stage open angle Glaucoma, that lowers and sustains IOP under 15 mmHg, and completely eliminates eye drop medications in most patients.

Value Proposition: Addressing Unmet Need

Patients with Mild, Moderate & Severe Glaucoma

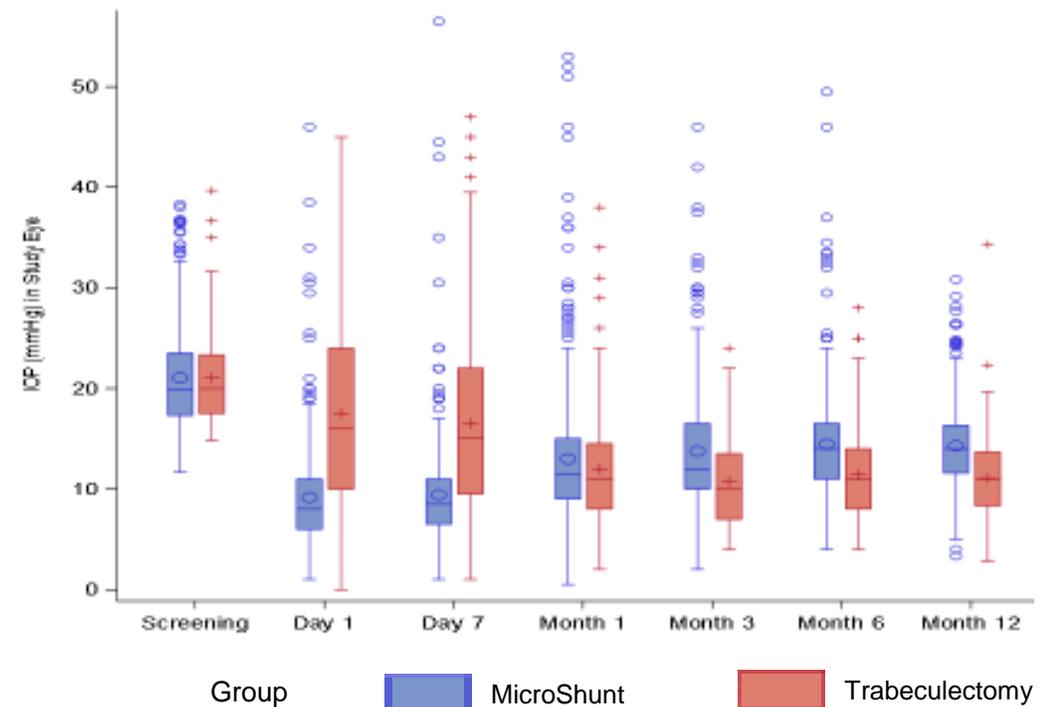
Trabeculectomy:

High Treatment Burden for the Patient, Caregivers, and Physicians leading to poor quality of life:

- Unpredictable effectiveness & safety outcomes in the near term post operation leading to repeated visits to the Clinic and multiple interventions
- Procedure-related adverse effect such as hypotony, on recovery of vision & progression of Lens Opacities
- Higher cost of care

Micro Surgical Approach using MicroShunt:

Intraocular Pressure (mmHg) in Study Eye by Visit by Device



Q&A Session
