Health Products Regulatory Conference

Regulatory Roadmap: Key Initiatives Explained

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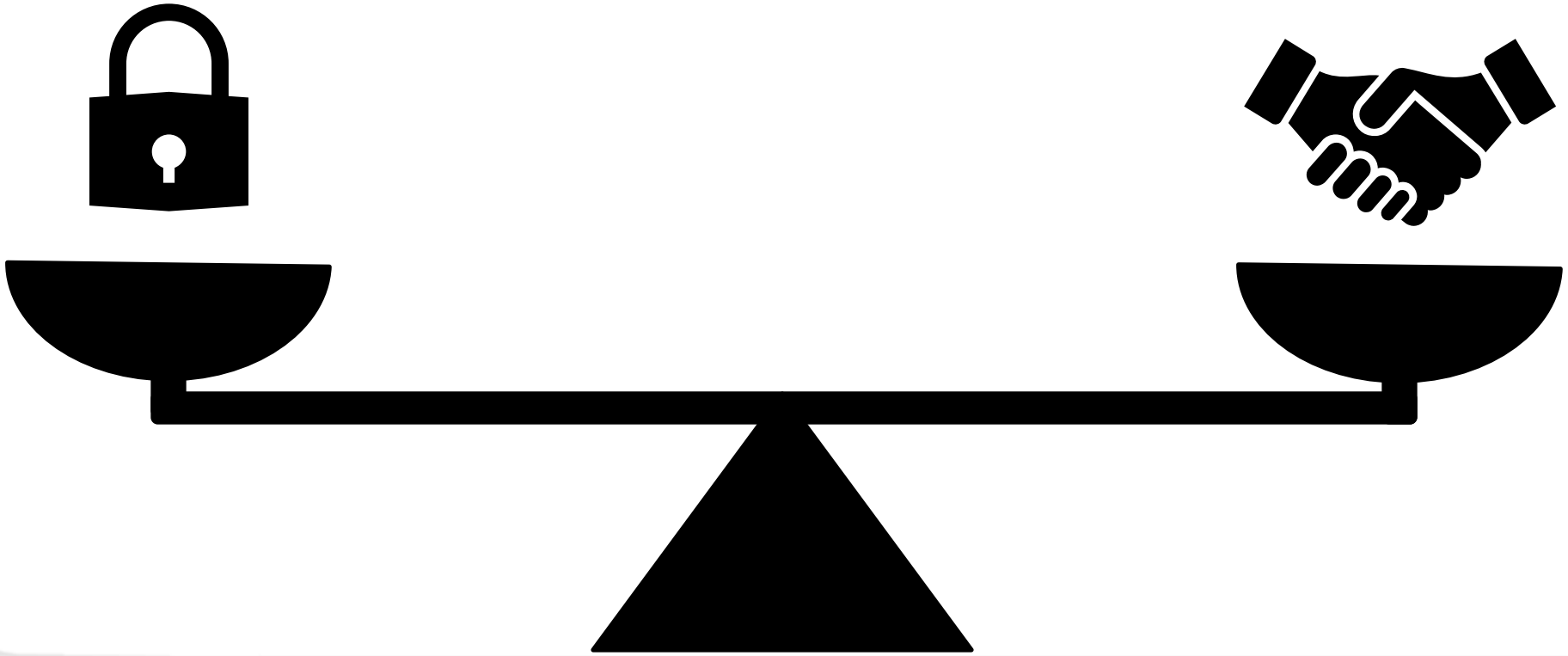
Health Sciences Authority (HSA)

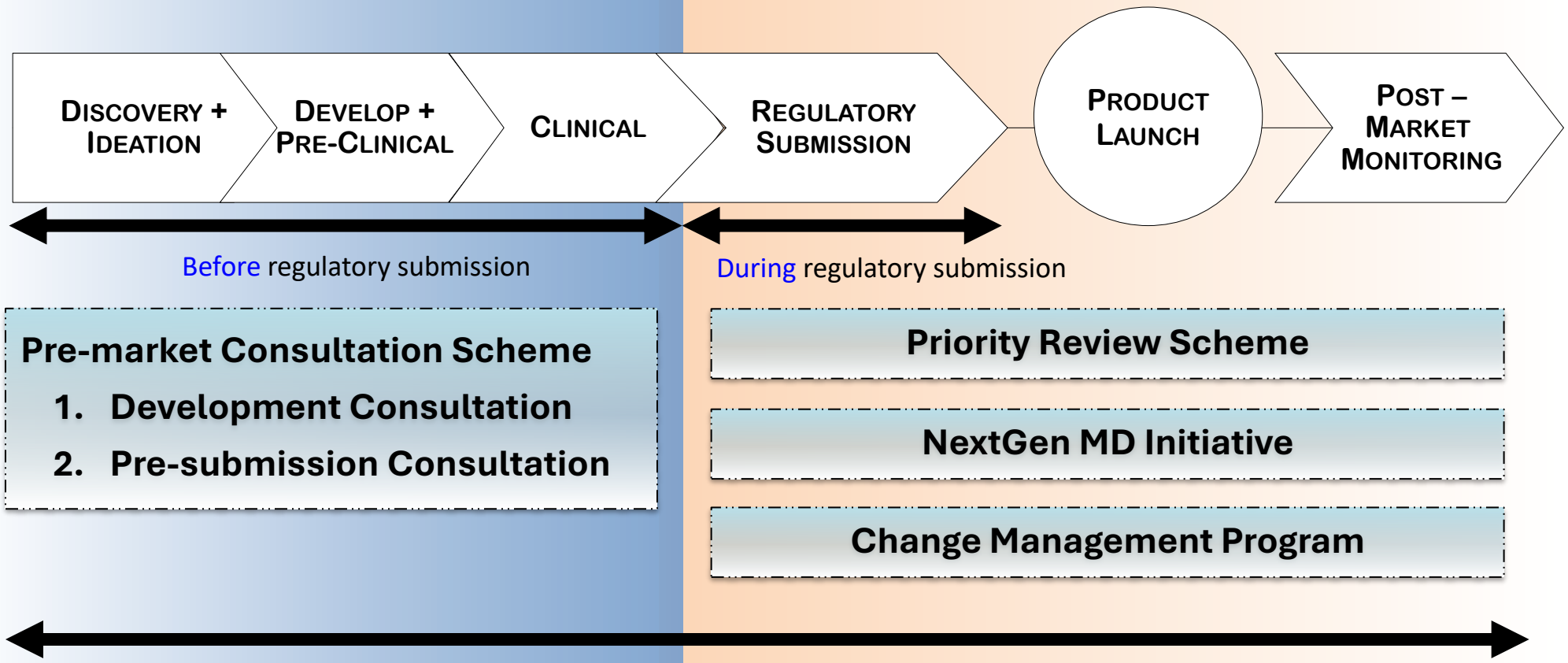
Gatekeeper

Enabler



Key Takeaway

Supporting innovation and facilitating device approvals across the product lifecycle while maintaining high safety standards



Regulatory Initiatives in Supporting Innovation

Pre-market Consultation Scheme: Early guidance on regulatory alignment during development or pre-registration submission phase

Priority Review Scheme: Accelerated evaluation for breakthrough technologies. Facilitates timely access for devices that address unmet clinical needs

Since 2017, we have supported ~250 consultations & 140 priority review applications, through which market access of innovative devices was facilitated

Pre-market Consultation Scheme

1 Development Consultation

RESEARCHERS & DEVELOPERS

For regulatory advice during development phase

2 Pre-submission Consultation

MEDICAL DEVICE COMPANIES

For regulatory inputs on submission dossier prepared for product registration

DISCOVERY + IDEATION → DEVELOP + PRE-CLINICAL → CLINICAL → REGULATORY SUBMISSION → PRODUCT LAUNCH → POST – MARKET MONITORING

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Priority Review Scheme

Medical devices* to be registered via FULL Evaluation Route → **Route 2**

1 **Falls under 1 of the 5 healthcare focus areas**

- Cancer
- Diabetes
- Ophthalmic diseases
- Cardiovascular diseases
- Infectious diseases

+

2 **Designed & validated to meet unmet clinical needs**

Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis

OR

Represents a breakthrough technology that provides a **clinically meaningful advantage** over an existing legally marketed technology

→ **Route 1**

⌛ Turnaround time (TAT) for Priority Review Scheme is **35% shorter** than a standard full route

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** Exclude devices incorporating registrable medicinal products*

NextGen MD Initiative: Supporting Iterative Device Development

Opt-in initiative, for devices with no prior reference agencies approval

Recognizes that medical devices often undergo numerous iterations. Next generation devices typically rebranded but share common characteristics & validation data with their predecessors

An initiative for next generation devices to tap on previously reviewed **identical** dataset by HSA for the predecessor devices from the **same legal manufacturer**

Benefits:

- Streamlined evaluation when common characteristics and validation data are shared
- Access market more efficiently while maintaining robust safety and performance standards

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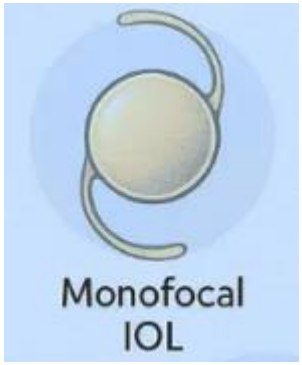
How it works?

Registered intraocular lens (IOL)



DEVICE ITERATIONS

- Similar materials
- Same manufacturing & sterilization site

Rebranded next generation IOL

Shares identical dataset as the registered IOL that was previously reviewed by HSA

Change application

Pre-market registration

Full route

If eligibility criteria is met:

- Registration process can be streamlined
- HSA will leverage on the data that was previously reviewed for the registered device

SaMD Change Management Program (CMP): Supporting Iterative Device Changes

- Optional regulatory pathway, can be integrated with product registration or change notification
- Enables timely implementation of pre-specified changes* post-approval without individual change applications, while maintaining safety standards
- Built on trust in manufacturers' robust quality management system
- Annual declaration of implemented pre-specified changes

*** *Pre-specified changes***: *Upcoming anticipated changes (e.g., improvement in existing features) that would otherwise require a new change application*

Scan to access GN-37 for more information

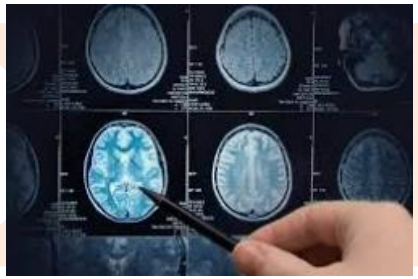
How it works? Product registration + CMP

SaMD

Regulatory approval

Access to market

Annual declaration



SMDR

SHARE

Planned improvements

- ☐ New features
- ☐ Improve existing features

Product registration

\+

CMP

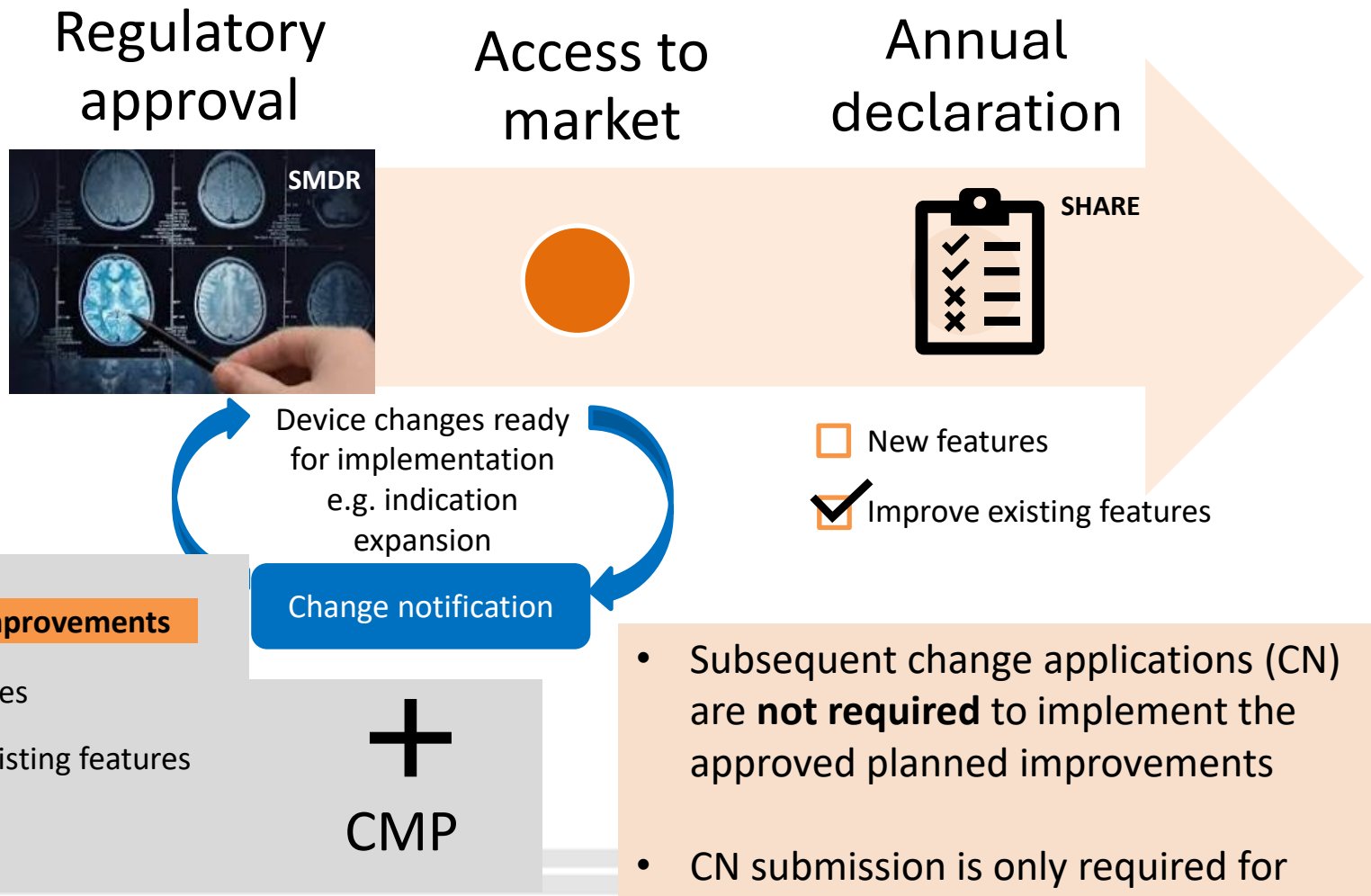
Device improvements ready for implementation

Change notification

- ☐ New features
- ☑ Improve existing features

- Subsequent change applications (CN) are **not required** to implement the approved planned improvements
- CN submission is only required for changes outside the scope of CMP, or changes to the approved CMP

How it works? Change Notification + CMP



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Singapore Health Product Access & Regulation E-system (SHARE)

VISION: A **unified and integrated transformative digital platform** synergising health product regulatory related services through the product lifecycle that delivers value to stakeholders while protecting and advancing national health and safety.

Key Features of SHARE

Meet Albert

Key Takeaway

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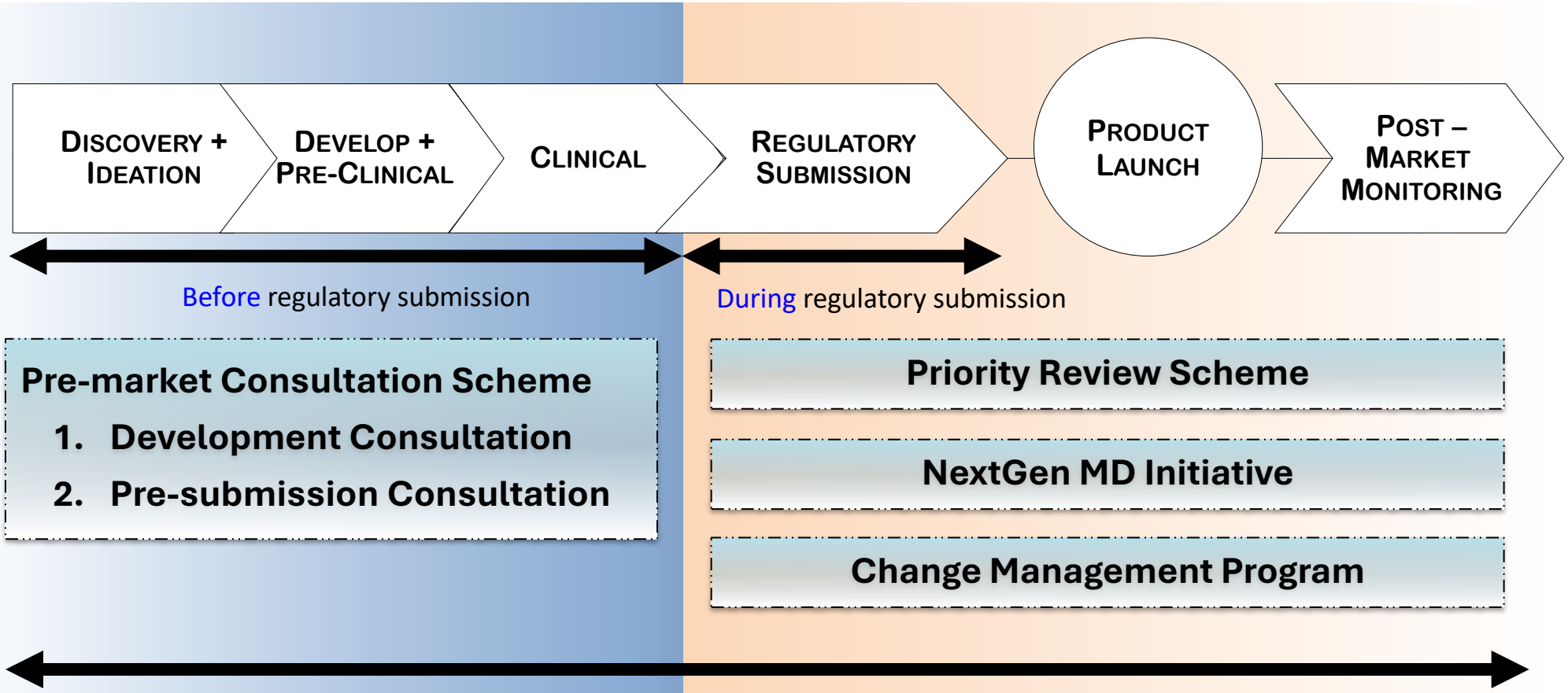

Regulatory Leverage

International Recognition as a Reference Authority

Thailand
(Population: 71.7M)
- Time savings: Reduced from 150 to 60 working days
- Covers: Class B, C, D (including IVDs) devices

Hong Kong
(Population: 7.5M)
- Covers: Class B, C, D (including IVDs) devices
- Accepts HSA approval to qualify for listing by Hong Kong Medical Device Division

Philippines
(Population: 114.9M)
- Time savings: Reduced from 90-180 to 30 working days
- Covers: Class B, C, D (including IVDs) devices

WHO
- Recognized as a WHO Stringent Regulatory Authority (SRA)
- Accepts HSA approval as evidence for abridged prequalification assessment by WHO
- Covers: high risk (Class C & D) IVDs

Australia
(Population: 27.2M)
- Recognized as a Comparable Overseas Regulator for faster registration pathways
- Covers: Class B, C, D (including IVDs) devices

Malaysia and Singapore Launch 6-Month Pilot of Medical Device Regulatory Reliance Programme

1. In Malaysia: Devices registered with HSA may undergo a verification route (abridged review pathway) through MDA's Conformity Assessment Body (CAB). The review is expected to take 30 working days, compared to 60 working days under the full conformity assessment route. The device will then be registered within 30 working days.
2. In Singapore: Devices registered with MDA will benefit from an abridged review pathway, achieving up to 30% shorter review times across all Class B to D medical devices.

Scan for more information

Thank you