Nordic Life Science Platform
FAST-TRACK CHINA ENTRY

NORDIC LIFE SCIENCE PLATFORM

- Fast-track China Entry

- Medtech, Healthtech, Drugs, and Rehabilitation Equipment

www.nlsp.dk

20 June 2025

NLSP – China Entry Barriers

- Although China is the world's second largest market for both medical devices & drugs, many foreign companies hold back from doing business in China due to lack of market knowledge and both real and perceived entry barriers and therefore consider it too difficult and risky.

- This uncertainty and doubt include among others:

- ❖ Geopolitical tensions
- ❖ Language barriers
- ❖ Poor IPR protection
- ❖ Forced technology transfer
- ❖ Unfair local competition
- ❖ Growing protectionism
- ❖ Changing laws & regulations
- ❖ Complex registration & approval procedures
- ❖ Unclear procurement rules
- ❖ Unknown distribution channels

- To lower the entry barriers and reduce risks, NLSP presents a team of professionals with many years of know-how and experience from supporting foreign companies in China.

NLSP – Purpose & Mission

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- To give foreign life science companies a **more safe, efficient, and easier access** to the Chinese healthcare market by taking advantage of the preferential policies and opportunities at:

➢ Hainan Boao Lecheng International Medical Tourism Pilot Zone (HBL)

➢ Guangdong-Hong Kong-Macao Great Bay Area (GBA)

- To **match the demand** for innovative medtech, healthtech, drugs, and rehab. equipment by the hospitals at HBL and GBA **with the supply** of foreign life science companies to help them access and develop new sales opportunities in China.

NLSP – Geographical Area

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Guangdong - Hong Kong - Macao Great Bay Area (GBA)

Hainan Boao Lecheng International Medical Tourism Pilot Zone (HBL)











Hainan Boao Lecheng – Background

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National Medical Destination & Cluster

- On 10 September 2019, the State Council approved the **"Implementation Plan for Supporting the Construction of Boao Lecheng International Medical Tourism Pilot Zone"**.
- HBL granted **preferential policies and incentives** to create a world-class international medical destination & cluster for **advanced medical treatment, rehabilitation, R&D, and technological innovation** in China.

Status & Future Development

- Currently, a total of **30 private + 2 public general hospitals (Tier 3) are in operation** with another **10-15 planned or underway**.
- Total construction cost estimated at **RMB 100 billion (USD 14 billion)**.
- When completed by **2035**, it will cover 20 km2 with 3 km2 of constructed land, offer **12,000 hospital beds** and **employ 28,500 medical personnel.**
- In 2024, HBL received, **413,700 medical tourists** (+36.76%).

Hainan Boao Lecheng – Key Preferential Policies

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Fast-Track Approval

- Makes it easier and quicker to test, sell, register, import, and use **innovative drugs, medtech, and healthtech** in need by the HBL hospitals.
- **Fast Review and Approval: 10 working days.**
- As of 23 May 2025, **477 medical products** have been approved by Hainan MPA for exclusive use at HBL.

Main Eligibility Criteria

1. Product cannot have been approved in mainland China but needs **CE/FDA/PMDA/ ICH member registration.**
2. Product shall be **innovative** and cannot be replaced by an already approved predicate in mainland China.
3. Product shall be **used for a specific medical purpose** at designated hospital/medical institution.

Real-World Data Study

First place in China where it is possible to conduct **RWD Studies** of the use of medical devices and drugs imported under the fast-track approval procedure that can supplement the application for the **NMPA registration** and **accelerate the approval process** to sell in all of mainland China.

Hainan Boao Lecheng – Other Preferential Policies

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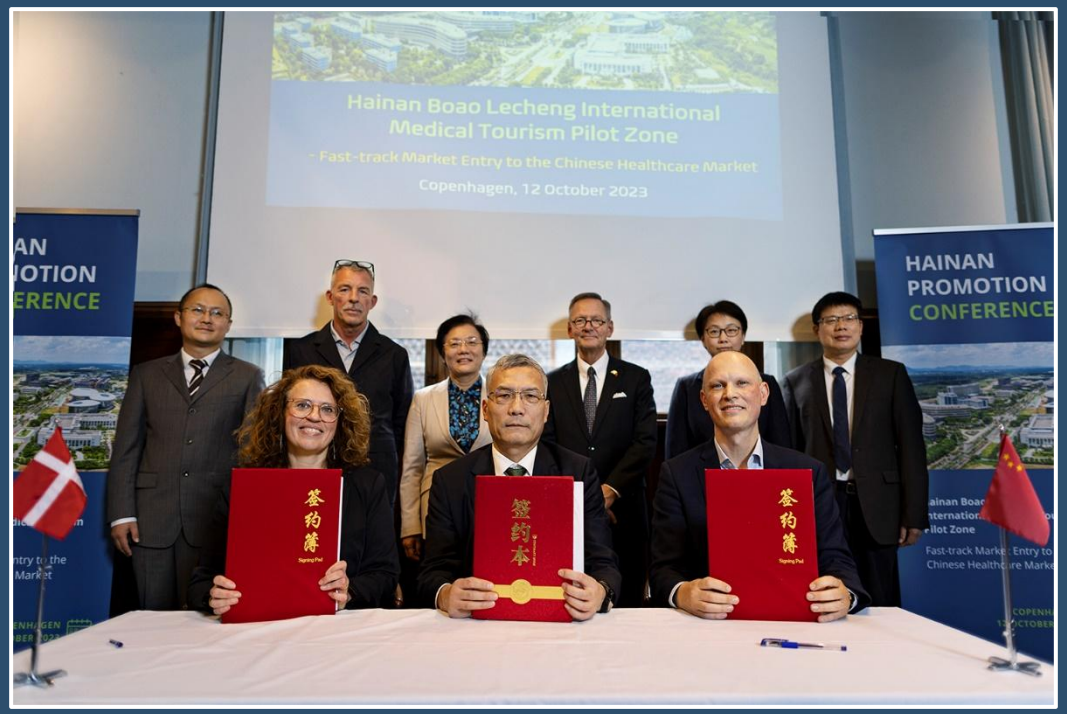
- Medical institutions with an independent registered entity at HBL are **exempt from import duties and import VAT** on medical devices and drugs.
- HBL allows the set-up of **wholly foreign-owned and JV medical institutions**.
- HBL allows **foreign doctors and nurses** to practice at the hospitals for three years.
- Products that have undergone a RWS at HBL can be included in the **national healthcare insurance reimbursement list**.

- Qualified medical institutions and foreign-invested enterprises at HBL can engage in the development and application of **human stem cells, gene diagnostics, and therapy technologies** for product registration and manufacturing.
- Overseas approved **Health Foods (dietary supplements) & Food for Special Medical Purposes** can be introduced and used at HBL without mainland China approval.

NLSP – Strategic Cooperation Agreement

On 12 October 2023, Nordic Life Science Platform, Danish Life Science Cluster, and the Lecheng Administration signed a Strategic Cooperation Agreement in Copenhagen, Denmark during a high-level medical delegation visit headed by Ms. XIE Jing, Vice Governor of Hainan Province.

Ms. XIE Jing, Vice Governor of Hainan Province.



From left to right: Ms. Diana Arsovic Nielsen, CEO of DLSC,
Mr. JIA Ning, Director of Lecheng Administration, and
Mr. Noam David Stern, Co-founder & Director of NLSP.

Great Bay Area – Background

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National Development Plan

- On 18 February 2019, the State Council published the latest **"Outline Development Plan for the Guangdong-Hong Kong-Macao Greater Bay Area"**.
- **GBA** is a designated geographical and economically integrated area including **HK, Macao**, and the nine mainland cities of **Dongguan, Foshan, Guangzhou, Jiangmen, Huizhou, Shenzhen, Zhaoqing, Zhongshan, and Zhuhai** in Guangdong Province.

Status & Future Development

- As of September 2024, the GBA consists of **45 designated hospitals** (Tier 3).
- Policy could potentially over time apply to many more hospitals in Guangdong.
- As of October 2024, **79 medical products** have been approved by the Guangdong MPA for exclusive use at the designated GBA hospitals.

Great Bay Area – Key Preferential Policies

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Fast-Track Approval

- Makes it **easier and quicker** to sell, register, import, and use medical devices and drugs in need by the designated hospitals without an NMPA approval for mainland China.

Main Eligibility Criteria

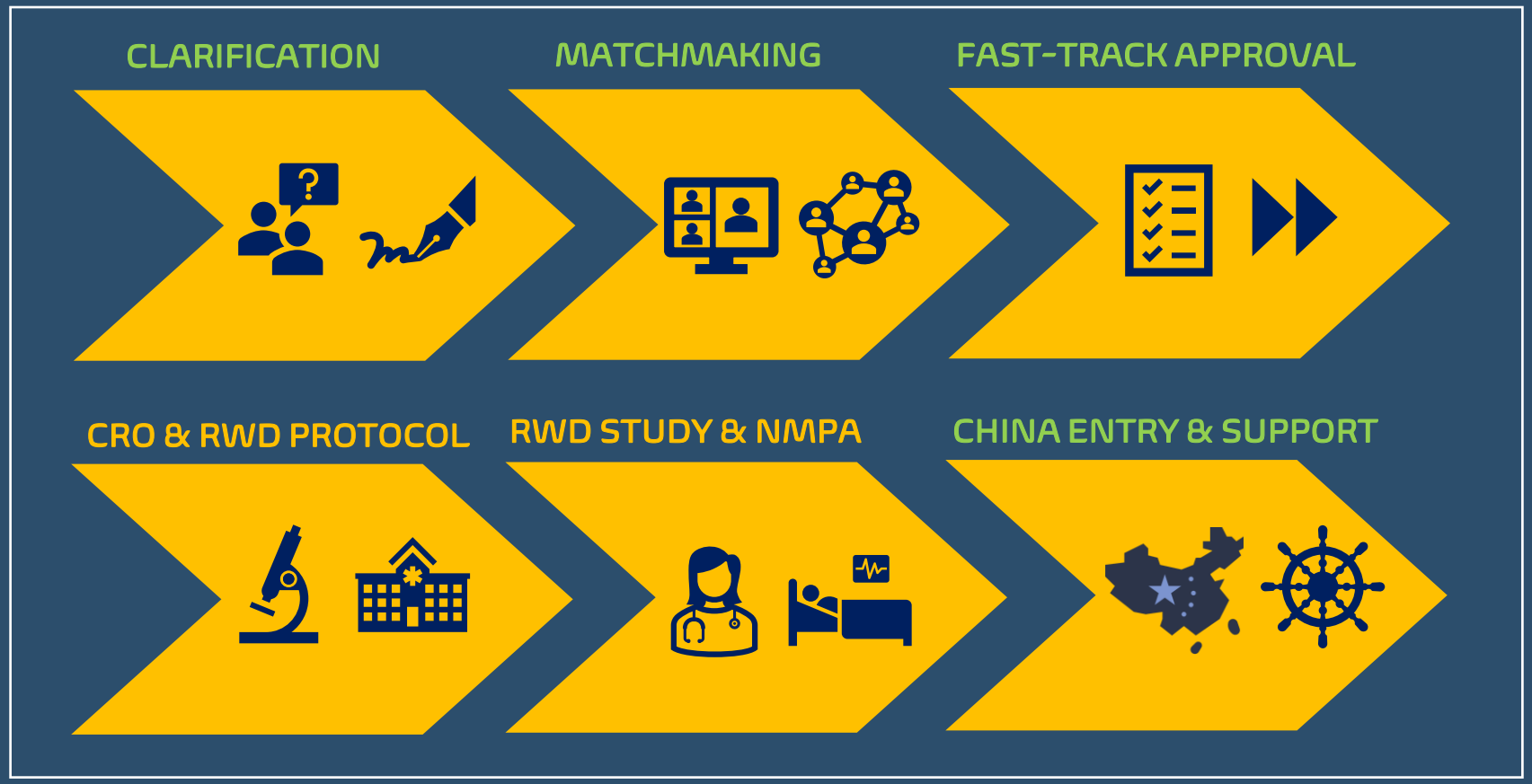
1) Product cannot be replaced by a similarly approved product in mainland China.
2) Product needs **HK or Macao** registration.
3) Product needs to have been procured and used by a public hospital in **HK or Macao**.
4) Product shall be used for a specific medical purpose at designated GBA hospital.

Real-World Data Study

- GBA also offers the opportunity to conduct Real-World Data Studies that can supplement the application for the **NMPA registration** and accelerate the approval process to sell in all of mainland China.

NLSP – Step-by-Step Market Entry Model

- NLSP delivers a **Step-by-Step Market Entry Model** that supports companies all the way from exploring, entering, and/or expanding in the Chinese healthcare market with the option to stop after each step of the process to determine the next step.



NLSP – One Stop Service Platform

- NLSP reduces the challenges and time-to-market by offering expert advice and supporting services that are part of the different steps in the process such as:

- ❖ Project Management
- ❖ Legal Advice & Assistance
- ❖ IPR Protection
- ❖ Medical Expert Review
- ❖ Hospital Matchmaking
- ❖ Contract Negotiations
- ❖ Fast-track Product Approvals
- ❖ CRO Appointment & RWD Study Pre-communication
- ❖ RWD Study Implementation & New Medical Product Application
- ❖ NMPA Product Registrations
- ❖ Contact to Potential Distributors
- ❖ Contact to Potential Investors

- NLSP cooperates closely with the hospitals at HBL & GBA and Chinese national distributors of medical products that can open doors to the mainland China market.

NLSP – Expert Advise & Support

Noam David Stern
Co-founder & Director,
China & Denmark

Daisy Du
Legal Advisor
China

Sharon Xu
Medical Project Manager,
China & Germany

Peter Ølbye
Co-founder & Advisor,
Denmark

Marcus Woldsen
BD & Project Manager,
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