



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](http://www.nlsp.dk)

27 April 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.

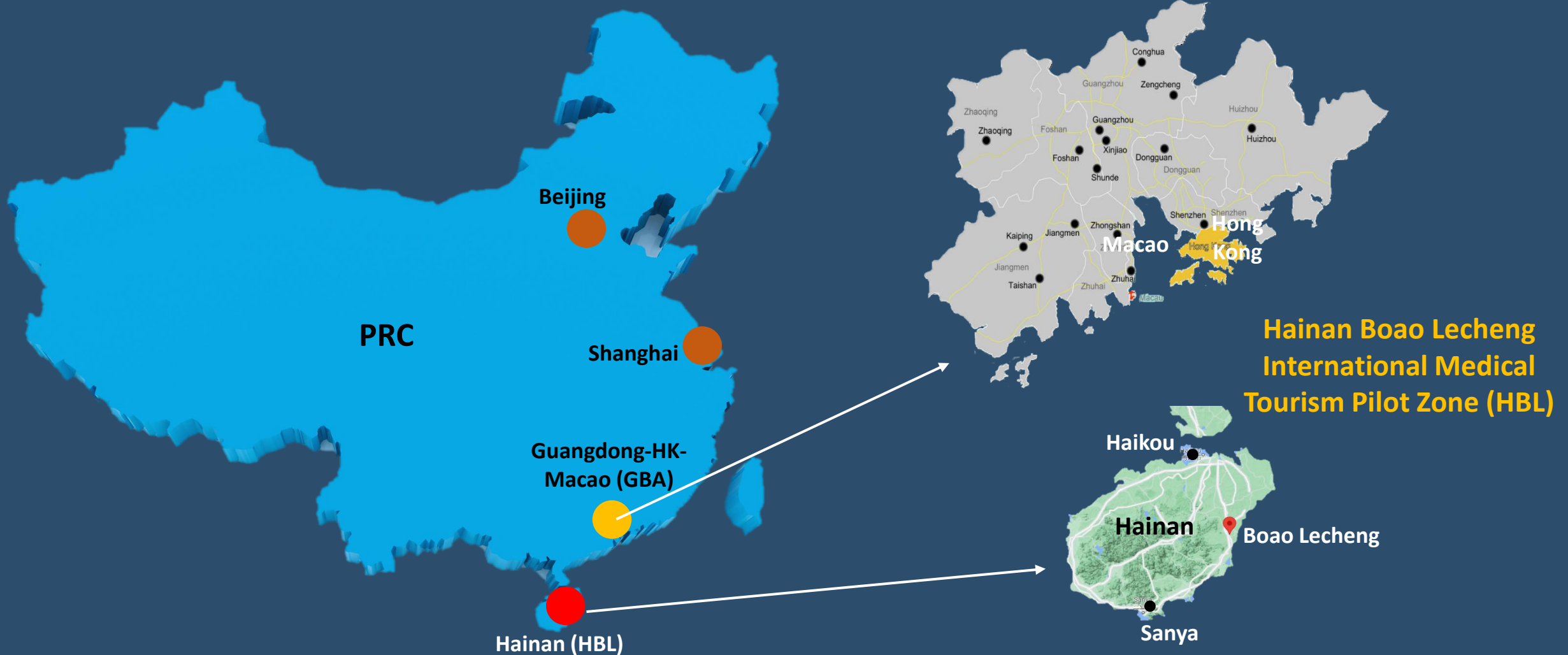




## NLSP – Purpose & Mission

- 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 **develop and access new sales opportunities** in China.

# NLSP – Geographical Area









# Hainan Boao Lecheng – Background

## 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 **29 private + 3 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 km<sup>2</sup> with 3 km<sup>2</sup> 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

## Fast-Track Approval

- Makes it easier and quicker to sell, register, import, and use **“innovative” medical products** in need by the hospitals at HBL.
- **Fast Review and Approval: 10 working days.**
- As of 1 April 2025, **473 medical products** have been approved by Hainan MPA for exclusive use at HBL.

## Main Criteria

1. Product cannot have been approved in mainland China but needs **CE/FDA/PMDA/ other inter. approval.**
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

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

- 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.

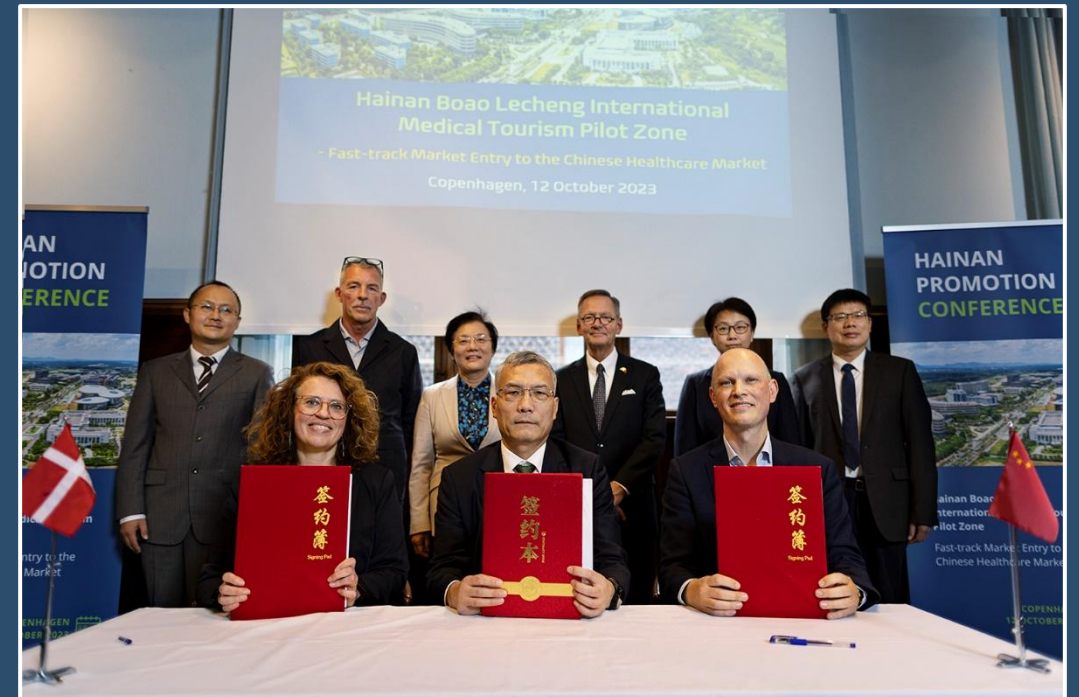


# NLSP – Strategic Cooperation Agreement

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

## 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

## 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 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 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:

- |                                |                                     |
|--------------------------------|-------------------------------------|
| ❖ Project Management           | ❖ CRO Identification and Selection  |
| ❖ Legal Advice & Assistance    | ❖ RWD Study Implementation          |
| ❖ IPR Protection               | ❖ NMPA Product Registrations        |
| ❖ Medical Expert Review        | ❖ Market Research                   |
| ❖ Hospital Matchmaking         | ❖ Contact to Potential Distributors |
| ❖ Contract Negotiations        | ❖ Contact to Potential Investors    |
| ❖ Fast-track Product Approvals | ❖ Company Set-up                    |

- 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  
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