



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)

17 January 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:
  - ❖ Rising 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**, NLSP presents a team of experts in China and Denmark with many years of know-how and experience from supporting foreign companies in China.

## NLSP – Purpose & Mission

- To give Nordic/European 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 rehabilitation equipment by the hospitals at HBL and GBA **with the supply** of Nordic/European companies to **access and develop new sales opportunities** in China.



# NLSP – Geographical Area



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



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





# 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 **25 private + 3 public general hospitals (Tier 3)** are in operation with another 10-15 planned.
- 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 – Preferential Policies

## Fast-Track Approval

- Makes it easier and quicker to sell, register, import, and use “innovative” **medtech, healthtech, drugs, and rehabilitation equipment** in need by the hospitals at HBL.
- As of 1 January 2025, **450 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 medical institution.

## Real-World Data

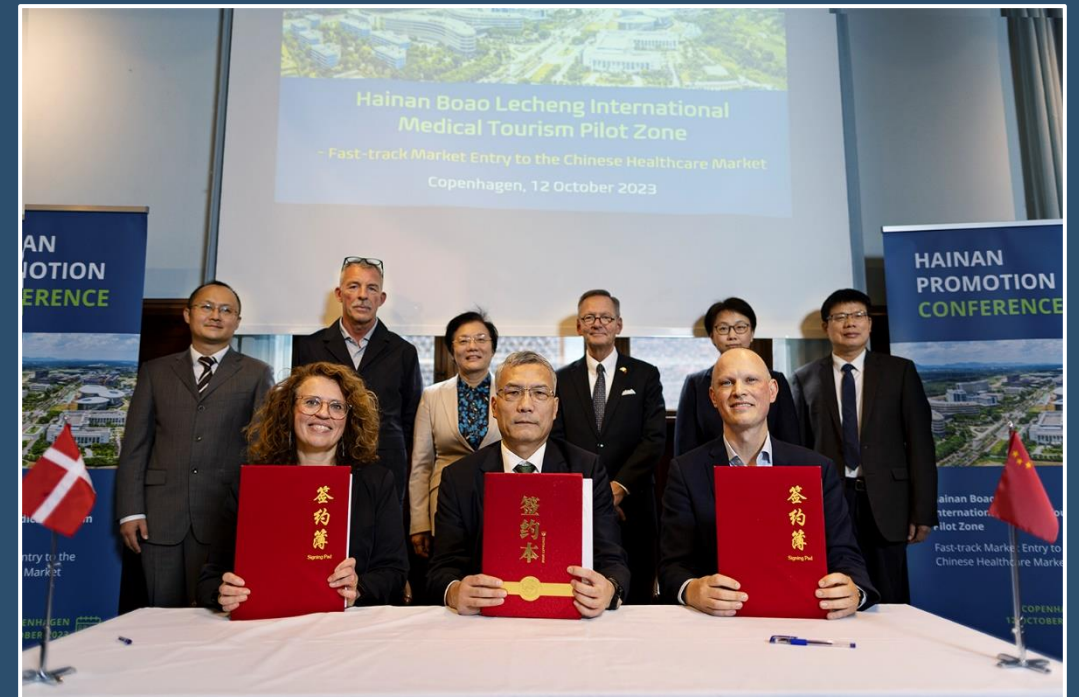
First place in China where it is possible to conduct **RWD Studies** of the use of medical devices and drugs imported under the fast-track approval procedure that can supplement the application for the **NMPA registration** and **accelerate the approval process** to sell in all of mainland China.

# 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 – 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:

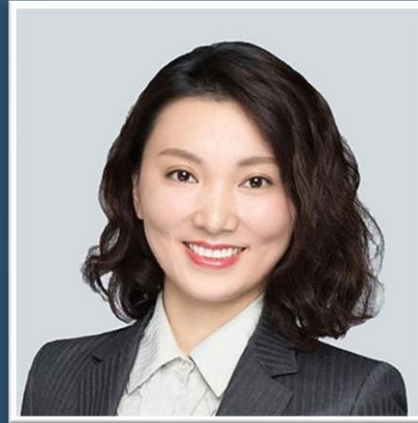
- ❖ Project management
- ❖ Legal assistance
- ❖ IPR protection
- ❖ Medical expert review
- ❖ Hospital matchmaking
- ❖ Contract negotiations
- ❖ Fast-track approvals
- ❖ CRO identification & selection
- ❖ RWD Study implementation
- ❖ NMPA filings
- ❖ Product registrations
- ❖ Market research
- ❖ Partner Search
- ❖ 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,  
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**Marcus Woldsen**  
BD & Project Manager,  
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