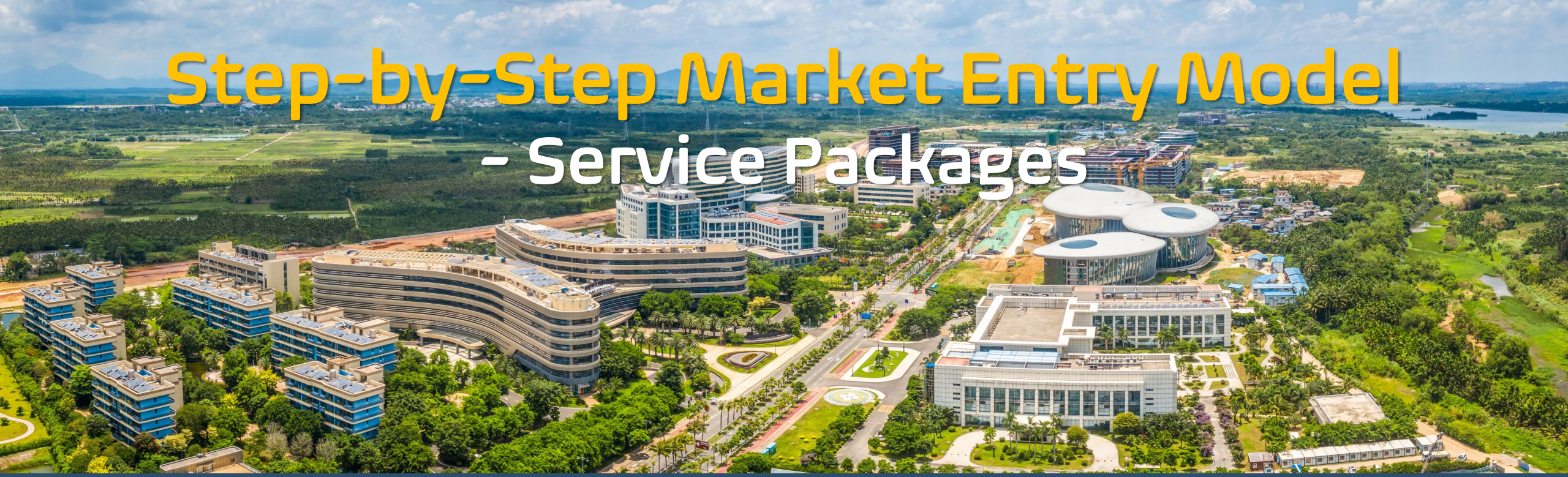
# Step-by-Step Market Entry Model

## - Service Packages



Nordic Life Science Platform
FAST-TRACK CHINA ENTRY

# NORDIC LIFE SCIENCE PLATFORM

## - Fast-track China Entry

NLSP Partners:

Danish Life Science Cluster

INNOVATION CENTRE DENMARK

www.nlsp.dk

9 July 2024

# What is Nordic Life Science Platform?

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- The **Nordic Life Science Partners ApS (NLSP)** gives Nordic life science companies within medical devices, drugs, and rehabilitation equipment 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)**.
- Through NLSP, Hainan Boao Lecheng serves as a **gateway and stepping-stone** to the rest of the Mainland China market.
- NLSP has gathered a team of experts with many years of know-how and practical experience from advising and assisting Nordic (medical) companies entering and operating in China.
- NLSP is a **one-stop service platform** that reduces the challenges and time to market by offering companies expert advice and supporting services, and by utilizing our local partners in China.
- NLSP delivers a **Step-by-Step Market Entry Model** that supports companies all the way but also gives them the option to pause after each step of the process to decide their next move into the Chinese market.
- To explore the market opportunities in China further, NLSP has formed a Partnership with the Danish Life Science Cluster and Innovation Centre Denmark in Shanghai.

# Step-by-Step Flow Chart

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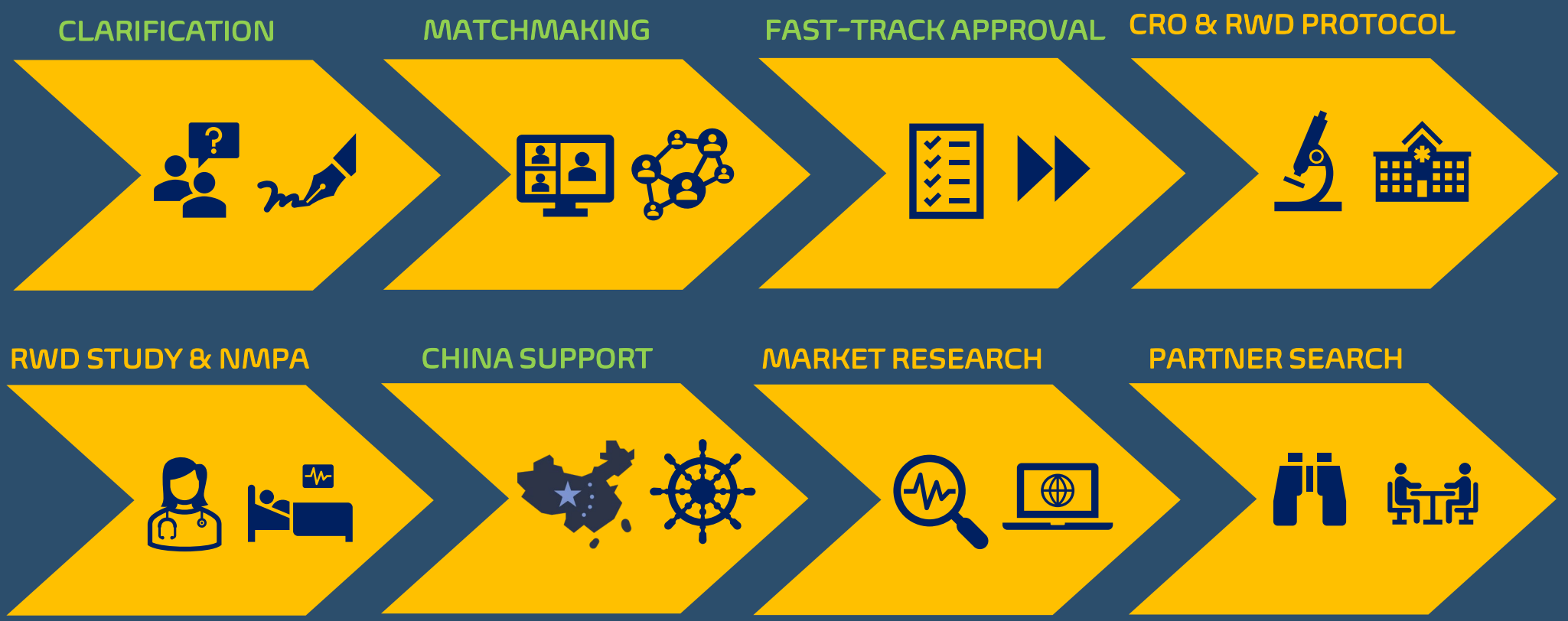

# What is Hainan Boao Lecheng International Medical Tourism Pilot Zone?

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- Special medical zone in Hainan, China that has been granted preferential policies and incentives to create a world-class international medical destination and cluster for advanced medical treatment, professional rehabilitation, medical R&D, and technological innovation in China.
- When fully developed, Hainan Boao Lecheng (HBL) is planned to cover 22 km2 with 3 km2 of constructed land.
- Currently, 25 private hospitals/medical centres (Tier 3) are in operation with 3 new opening in 2024, and 10 more planned. Total construction cost est. at RMB 100 billion.
- When completed, HBL will provide 12,000 hospital beds, employ 28,500 medical personnel incl. 3,500 R&D staff, and by 2025 provide 1.5 million medical consultations per year.
- Offers a special fast-track approval procedure that makes it easier and quicker to sell, register, and import "innovative" medical devices and drugs in "urgent" need by the hospitals at HBL that are not yet registered in China.
- Criteria: 1) Product cannot have been registered in China but needs CE/FDA/PMDA approval, 2) Product shall be innovative and cannot be replaced by an already approved predicate in China, and 3) Product shall be used for a specific medical use at HBL medical institution applying for its use.
- First place in China where you can conduct Real-World Data studies of the use of medical devices and medicines imported under the fast-track approval procedure that can supplement the application for the NMPA registration and accelerate the approval process to sell in Mainland China.

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# "CLARIFICATION"

## STEP A: (ONLINE) INTRODUCTION MEETING

- Introduction to the Nordic Life Science Platform.
- Introduction to Company and medical product(s).
- Brief information about China's healthcare market.
- Brief introduction of preferential policies and overview of hospitals at HBL.
- Provide general information and advice about IPR protection in China.
- General time schedule and cost overview.
- Q&A, align expectations, and next step.

## STEP B: SERVICE AGREEMENT & NDA

- Define service scope, deliverables, and schedule.
- Determine service fees, costs and payment terms.
- Prepare proposal according to needs and requirements.
- Conclude and sign service agreement with NDA.

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# "MATCHMAKING"

## STEP A: INITIAL CONTACT & FEEDBACK

- Online meeting with Company to discuss specific product indication(s), hospital selection process, and requirements.
- Company to complete "Medical Product Search Form" in English (with Chinese translation).
- Company to prepare "Product Sales Presentation" in English according to Guideline (with Chinese translation).
- Organize and hold online Q&A meeting about medical product between Company and local NLSP partner(s).
- Reviewed Medical Product Search Form and Product Sales Presentation to be shared with relevant partner hospital(s).
- Follow up with partner hospital(s) for feedback on product inquiry.
- Organize and hold online introduction and Q&A meeting between Company and interested hospital(s), if any.
- Send report to Company with findings and suggestions for next step(s).

**Estimated Timeline:** From 4-6 weeks (from sharing documents)

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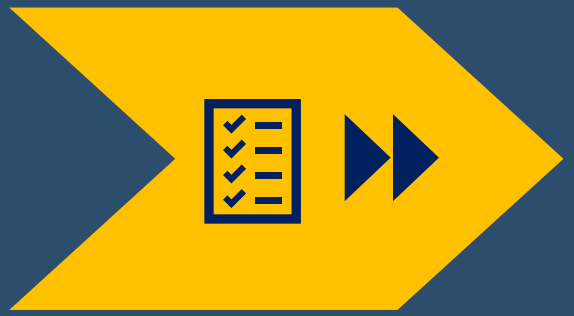
# "MATCHMAKING"

## STEP B: NEGOTIATIONS & AGREEMENT

- Online meeting with Company to present the Fast-track Approval Process and prepare for the sales negotiations with the partner hospital.
- Organize and join online meeting to initiate sales negotiations between Company and partner hospital.
- Assist Company to conclude the commercial terms with the partner hospital to be included in the sales contract to be signed with the appointed eligible logistic agent (medical trading license).
- Organize and join online meeting between Company and appointed logistic agent about the procurement, payments, import, customs clearance, bonded warehouse, and delivery of the medical product.
- Contact and follow-up with the HBL Administration (medical zone), if needed.
- Online meeting to discuss the findings and suggestions for the next step(s).

**Estimated Timeline: From 3-6 weeks**



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# "FAST-TRACK APPROVAL"

## FAST-TRACK APPROVAL PROCESS

- Provide Company with a detailed checklist for the Fast-track Approval procedures and List of Materials to be collected.
- Assist Company to collect, organize, and deliver the required registration documents with certified Chinese translations to the Partner Hospital that will submit the application and relevant documents in the Boao Lecheng E-Tracking System
- Provide guideline to Company to prepare the Chinese presentation for the Hainan MPA approval meeting.
- Assist Company during scheduled online approval meeting with the Hainan MPA and joined by the partner hospital.
- Follow-up on the signed sales contract between Company and appointed logistic agent to ensure that the delivery of the HBL approved medical product is on schedule.
- Company shall deliver the required (online) training to the partner hospital in the use of the medical product.
- Online meeting to discuss findings and next step(s).

**Estimated Timeline: From 8-12 weeks**

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# "CRO & RWD PROTOCOL"

## CRO APPOINTMENT & RWD STUDY PRE-COMMUNICATION

- Online meeting with Company to discuss search and selection criteria for CROs operating in Hainan.
- Identify, contact, and recommend CRO(s) with the required experience from RWD studies at Hainan Boao Lecheng.
- Organize and facilitate online meeting(s) for initial talks between Company and proposed CRO(s).
- Assist Company to appoint and conclude agreement with selected CRO for supporting RWD Study process.
- Assist Company to determine RWD cooperation model with partner hospital and appointment of Principal Investigator.
- Support the organizing of kick-off meeting for RWD Study and strategy discussions for clinical development.
- Assist in collecting and organizing supporting documents and data for RWD Study Protocol development.
- Assist with project management, coordination, and communication during RWD Protocol development and completion.
- Assist in collecting, organizing, and reviewing supporting documents and technical information for the "Pre-communication Application Form for Clinical RWD at Hainan Boao Lecheng".
- Assist with the preparation for the regional ethics committee review and approval.
- Support Company in Pre-communication meeting with the "Hainan Institute of Real-World Data" at HBL.

**Estimated Timeline: From 14-28 weeks**

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# "RWD STUDY & NMPA"

## RWD STUDY IMPLEMENTATION & NDA SUBMISSION

- Assist in collecting, organizing, writing, and reviewing the required documents and information according to the Pre-IND (Investigational New Drug) guidelines for the communication with the NMPA, Centre for Drug Evaluation (CDE).
- Assist in the communication between Company, partner hospital, and CRO with the Hainan MPA for pre-review before submitting the Pre-IND application.
- Assist in applying for the Pre-IND meeting with the CDE for RWD Study Protocol approval and feedback meeting.
- After RWD Study Protocol approval, assist in the preparation of the study implementation and initial communications between the involved parties to ensure alignment of the information and action plan.
- Assist in coordinating the implementation of the RWD Study Protocol and give timely updates to Company of the progress and milestones such as patient recruitment, enrolment status, data collection, and medical product usage.
- Assist in the communication between Company, partner hospital, and CRO during RWD collection and analysis.
- Assist in coordinating the submission of the new medical product application and related communication with the CDE for NMPA approval.

**Estimated Timeline: From 12-18 weeks**

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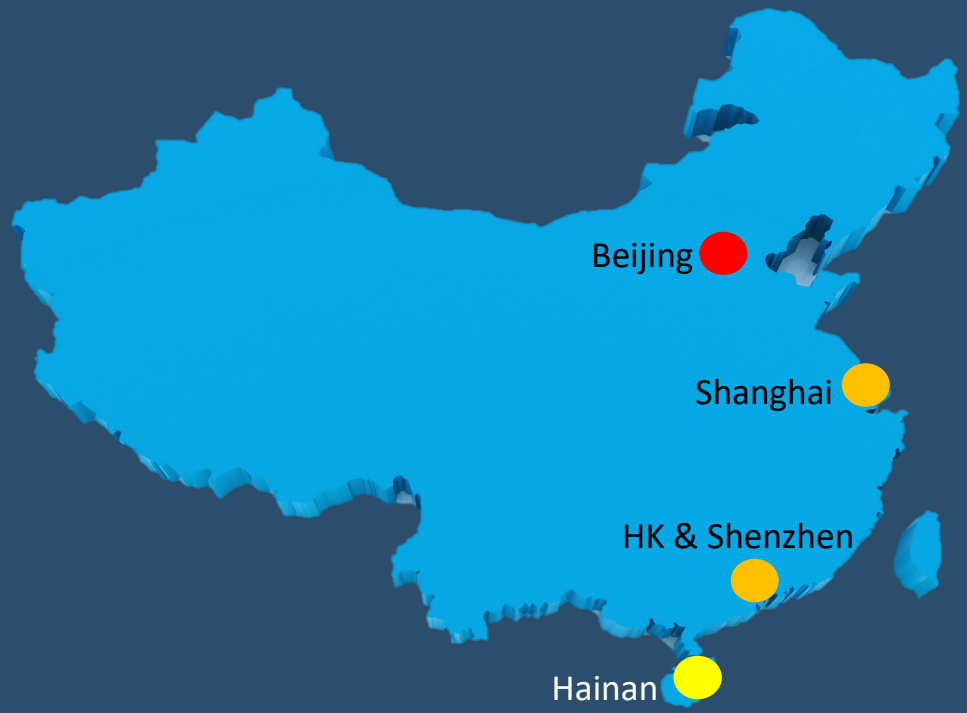
# "CHINA SUPPORT"

## LEGAL SUPPORT & SERVICES

- Market research (Mainland China)
- Partner search (distributor/agent)
- Legal and business advice
- IPR filings and registrations
- Assist with contract negotiations
- Contract reviewing & drafting
- NMPA applications, registrations, licenses and certificates
- Sales & Distribution Channels
- Incorporation/Company set-up
- Other




**Estimated Timeline:** Case-by-Case

# Nordic Life Science Partners ApS

## - Expert Advise & Support

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Co-founder & Owner,
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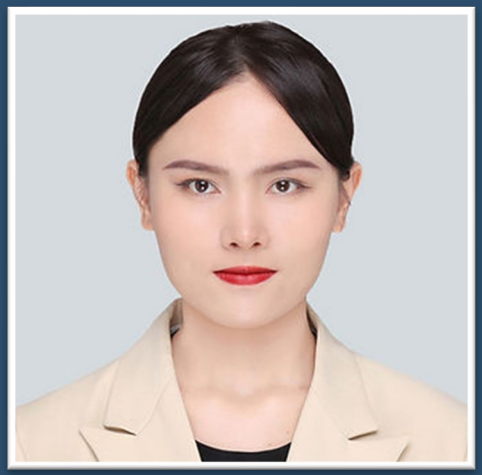

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