Building Successful China Medtech Market Entry Strategies

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Part 1: Cisema presentation on Regulatory Strategy

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About Cisema

Regulatory affairs, quality assurance, clinical research,
product testing & safety certification services for **China** & **Hong Kong**

- Experienced **in-house and full-time team** of local, on-the-ground regulatory affairs & quality compliance specialists in our China offices.
- **Adding value** by accelerating your time to market in a cost-efficient, planned, strategic way. We do the work, so you can focus on your core business.
- Ensure you **maintain control** of your product registrations and retain unconstrained choice of distributor(s).
- Provide full-cost quotation from the beginning of the project, giving price **transparency and clarity** for budgeting and planning

20 years' experience

Sectors:

- Medical devices & IVDs
- Pharmaceuticals
- Cosmetics
- Health foods & supplements
- Industrial goods
- Consumer goods

100 employees worldwide | 12 offices

Agenda: Regulatory Strategy

- Recent trends
- Regulatory partnerships and pathways to achieve success in the market
- Key challenges
- Timeline & costs
- Is China localization required to compete?
- Top tips

Registration Trends: NMPA Approvals in 2022

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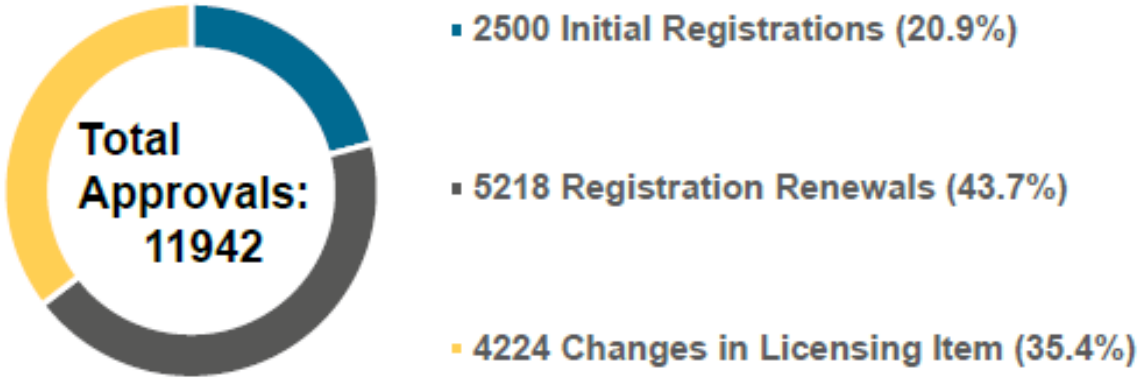
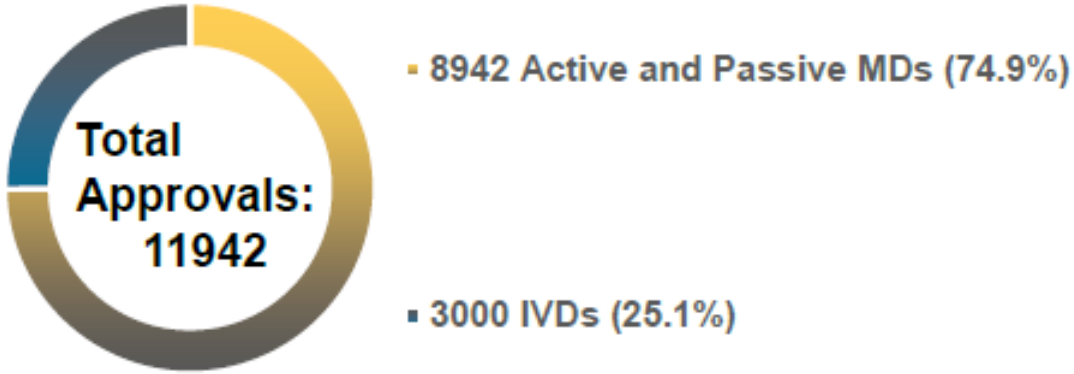
- NMPA handles applications and approvals for Domestic Class III and all overseas approvals





Registration Trends: NMPA New Approvals over time

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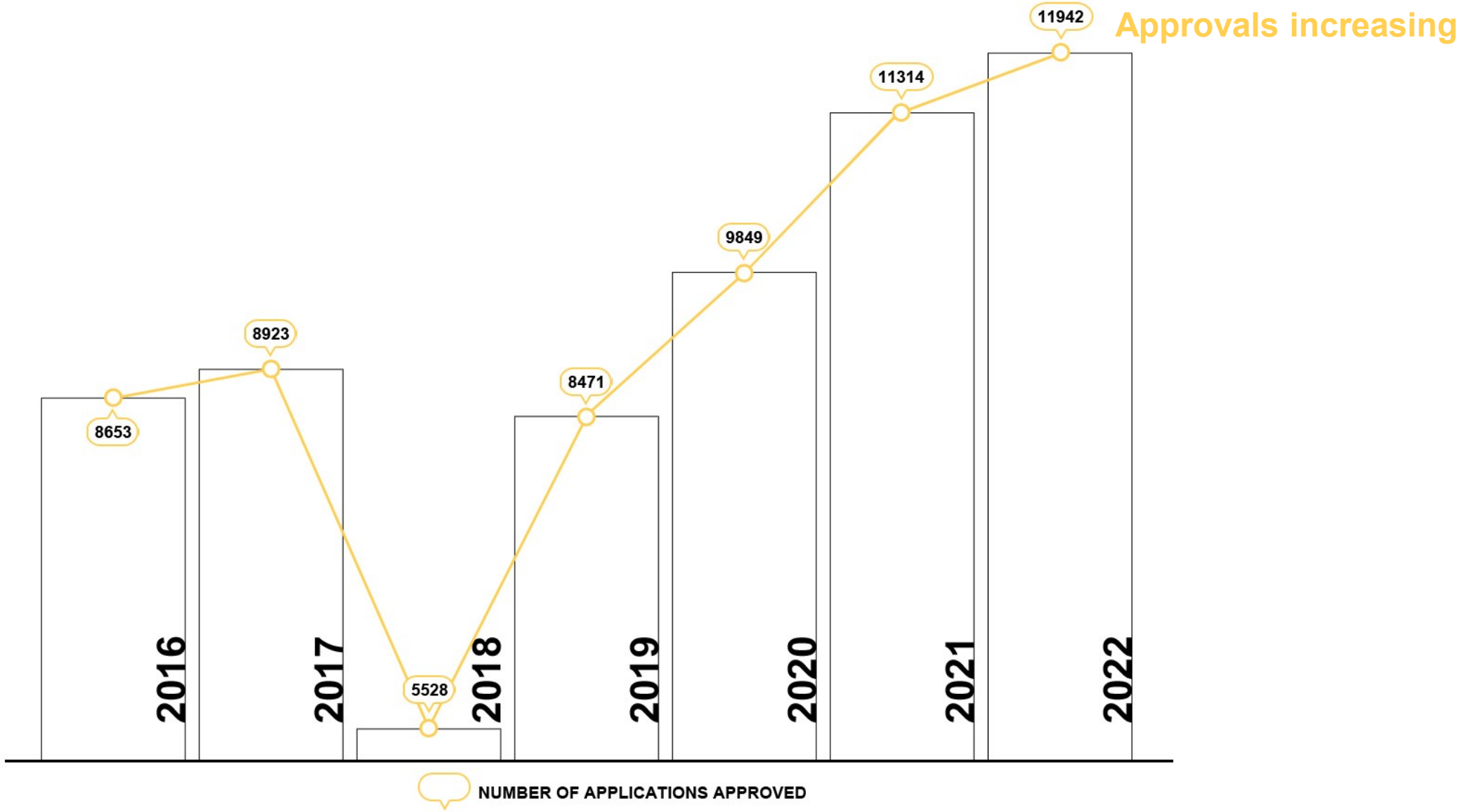

Trends: Top 5 Registered Product Types Class II & III

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2020	2021	2022
1. Dental Instruments	1. Medical Imaging Equipment ▲	1. Medical Imaging Equipment
2. Medical Imaging Equipment	2. Passive Implantable Devices ▲	2. Passive Implantable Devices
3. Passive Implantable Devices	3. Dental Instruments ▼	3. Infusion, Nursing & Protective Equipment ▲
4. Neurological & Cardiovascular Surgical Instruments	4. Neurological & Cardiovascular Surgical Instruments	4. Dental Instruments ▼
5. Ophthalmic Devices	5. Ophthalmic Devices	5. Neurological & Cardiovascular Surgical Instruments ▼

Pathways to register medical devices in China

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Mainland China

NMPA Standard Application

- Standard route requires home-country approval (e.g., CE, FDA, UK CA)
- Clinical Evaluation Report or Clinical Trial required

- NMPA Priority Review
- NMPA Emergency Approval
- NMPA Conditional Approval

NMPA Innovative Medical Device Application

- NMPA Innovative Medical Device Application: approved or not
- Requires China patent

Alternative pathways

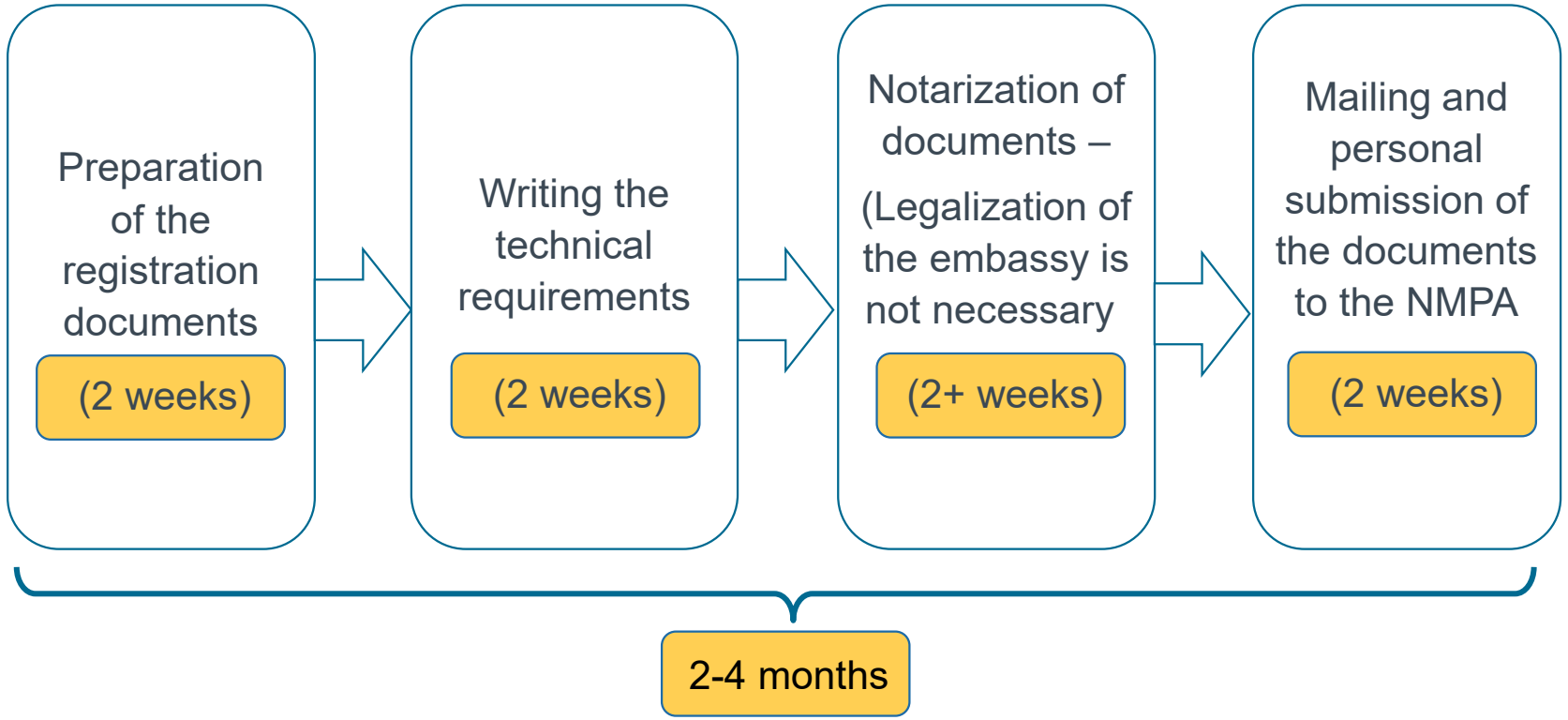
Hong Kong & Greater Bay Area

- Registration is voluntary at present
- Clinical data collected in Hong Kong is considered as overseas data; whereas clinical data in GBA is not
- Hospital sponsor in GBA req.
- Home country approval req.

Hainan Boao Lecheng International Medical Tourism Pilot Zone

- Requires home country approval (e.g., CE, FDA, UK CA)
- Hospital sponsor

Class I Filing Process



- If they are complete and meet the formal requirements, the certificate for the filing with NMPA stamp will be issued immediately.

Class II & III Registration Process

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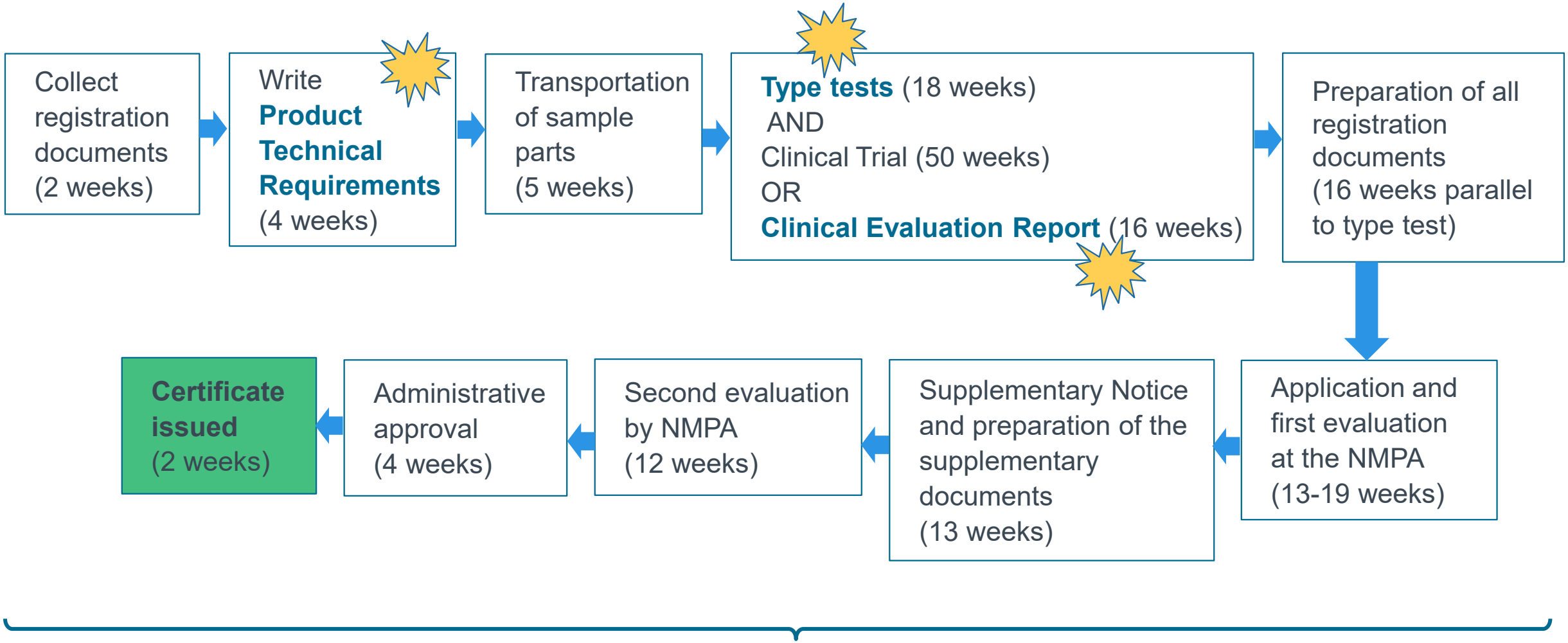
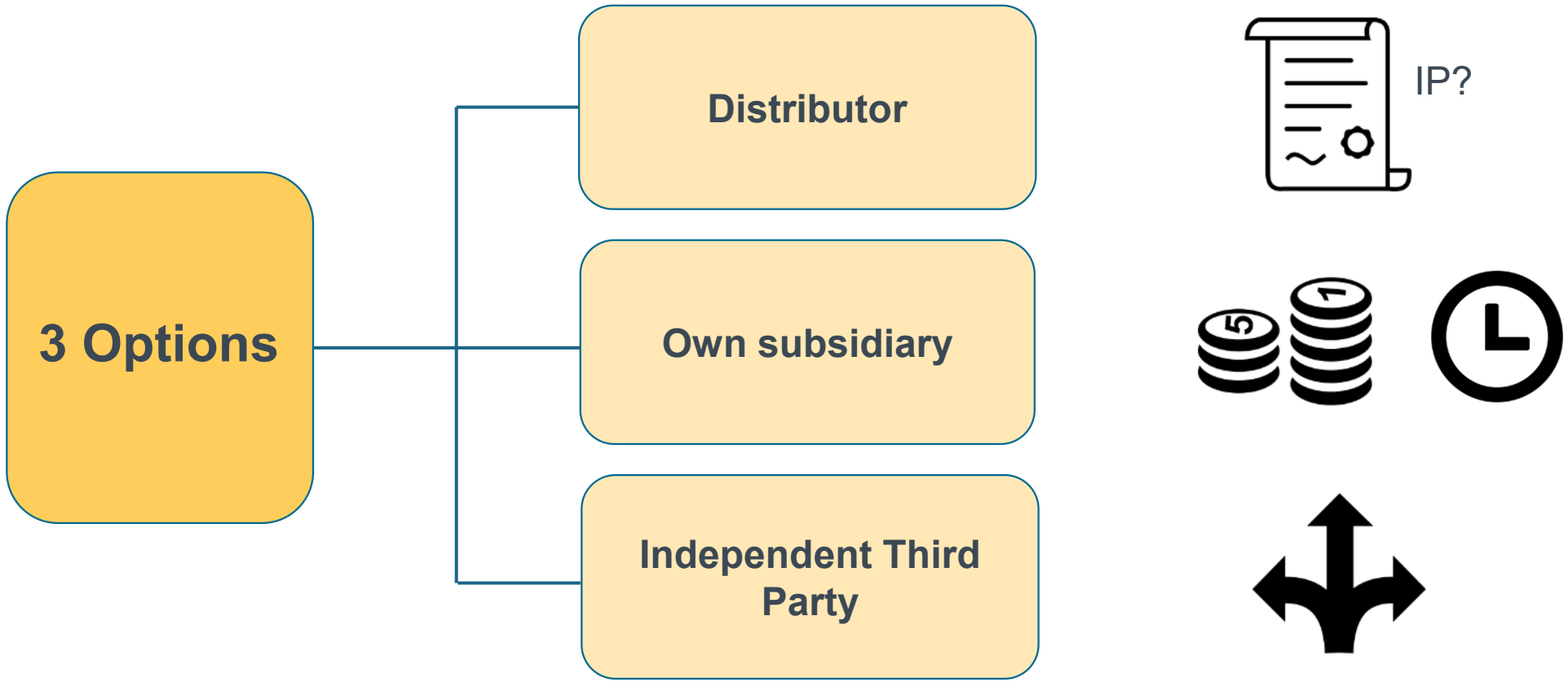


Expected registration time frame: About 18 months for class II and 21 months for class III without clinical trials

Costs and timelines for standard process

- Application fee payable upon submission for new NMPA medical device or IVD filing/registration:
  - Class I: ¥ 0
  - Class II: ~USD30,000 (¥ 210,900)
  - Class III: ~USD44,000 (¥ 308,800)
- Timelines according to experience:
  - Class I: ~4 months
  - Class II: ~18 months
  - Class III: ~21 months
- Additional fees to take into consideration:
  - **Type tests**
  - Importation
  - Notarization
  - Translation

NMPA legal agent – 3 Options



Is China ‘localization’ required to compete?

- For high-end medical devices, foreign companies remain as dominating market players in China.
- Headwinds:
  - Buy “Made in China” & localization trends
  - Bidding platform practical difficulties
- Tender bidding platform operation -> despite their insistence, not necessary for distributor to be local agent.

Options to localize production in China

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Market Authorization Holder (MAH)

- Establish own entity in China to act as MAH
- Find Chinese partner as OEM
- OEM produces samples
- Local registration of MD (certificate transfer)
- MAH receives product approval & sales license
- OEM starts to produce
- MAH starts to sell

VS

Wholly foreign-owned enterprise (WFOE)

- Find location for factory
- Create WFOE and build factory
- Produce samples
- Local registration of MD (certificate transfer)
- WFOE receives product approval and sales license
- WFOE starts to produce and sell

Hong Kong Listing

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- Voluntary system for product safety approvals of medical devices and IVDs
- Advantages to listing your product for tender wins and market adoption
  - Source: New Procurement Requirement of the Department of Health for Medical Devices
- Law changes on the horizon that may make listing mandatory

Key points:

- Require a **Local Responsible Person** (LRP) in Hong Kong
- Classification of product according to Hong Kong standards
- Submission dossier for listing with the Hong Kong Medical Device Administrative Control System (MDACS)
- Post-approval requirements
- Enables subsequent **Greater Bay Area applications** and registration
- Real-world data for eventual Mainland China registration

Top Tips

- Start regulatory and feasibility discussions early
- Evaluate the various pathways to market
- Understand in-China testing requirements:
    1. Conduct internal validation tests in advance according to Chinese testing standards
    2. Consider whether education on product usage possible for test lab consultant, if relevant
- Don’t treat China like just another export market
- Don’t rely on your distributor only
- Think long-term and stay objective

Cisema Services Overview for MedTech in China

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Pre-Registration

- Regulatory Pathway
- Feasibility Studies
- Clinical Trial Protocol Design
- CRO China Clinical Trials

Registration

- NMPA Legal Agent
- NMPA Filing of Class I
- NMPA Registration of Class II & III incl. CER writing
- Hong Kong Listing
- Type Testing Support
- Labelling Support

Post-Registration

- Post-Market Surveillance
- Advise on “Made in China” minimum production step
- Analysis of MAH vs OEM pathways for localization
- Overseas factory inspections
- GMP, QMS, SOP adaptation
- Certificate localization in China
- China audits

Cisema around the World

Follow up whitepaper or other information available by email or website request:
https://www.cisema.com/en/knowledge/free-know-how/

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Enabling Compliance in China

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