MARIS GROUP

Beijing Maris (CRO)
Beijing Shanpeng (SMO)
Maris HK
Maris TW
Maris Korea Branch

迈瑞生集团

北京迈瑞生 (CRO)
北京善芃 (SMO)
迈瑞生 香港分公司
迈瑞生 台湾办事处
迈瑞生 韩国支社

MARIS GROUP
迈瑞生集团

注册 · 咨询 · 服务

写在前面的话：

Preface：

我们是一群志同道合的人…

We are the team members have a common goal.

我们是一群 80 后 90 后的创业者…

We are entrepreneurs in 80s and 90s.

我们是一群热情有活力的年轻人…

We are a group of vigorous young people passions .

我们希望通过自己的辛勤工作帮助您的产品进入中国…

We hope your products can launch into Chinese market through our productive works.

我们希望通过自己的技术专长帮助您突破法规壁垒…

We hope to help you break if the barriers of regulations through our experienced techiques.

我们希望通过自己的沟通协调为您加速时间进程…

We hope to save time and cost for you through communication and coordination.

我们精通进口、国产医疗器械注册，IVD 产品注册以及化妆品注册；

We are dedicated to the registration imported and domestic for the device, IVD product and cosmetic.

我们擅长医疗器械临床实验和体外诊断试剂临床实验；

We are specialize in clinical trials of medical devices and IVD products.

我们可以做韩国、台湾、欧洲、美国医疗器械注册；

We can registrate medical devices for the client of Korea, Taiwan, the United States, Europe and so on.

随着我们的不断的学习和成长，我们能为您做更多…

As we get learning and growthing, continuously we can do much more for you…

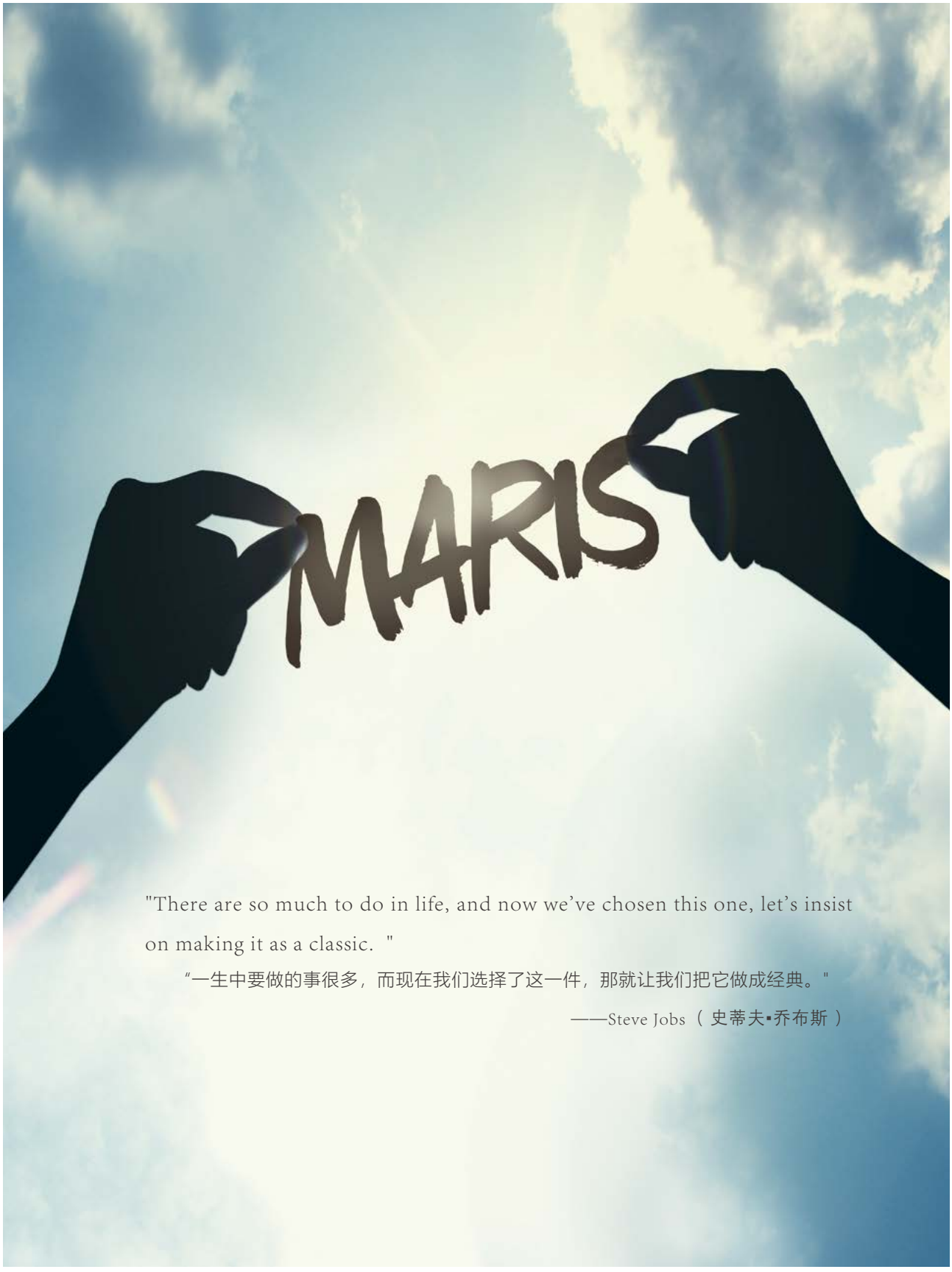
从 2008 年的 2 个人，到现在的近 100 人，我们有理由相信，我们可以做的比说的更好…

Since two people in 2008,nowadays we have over 100 employees, so that we have more confidence that we can do better than what we said.

we love maris !

十年专注　成就品质

不忘初心　砥砺前行



"There are so much to do in life, and now we've chosen this one, let's insist on making it as a classic. "

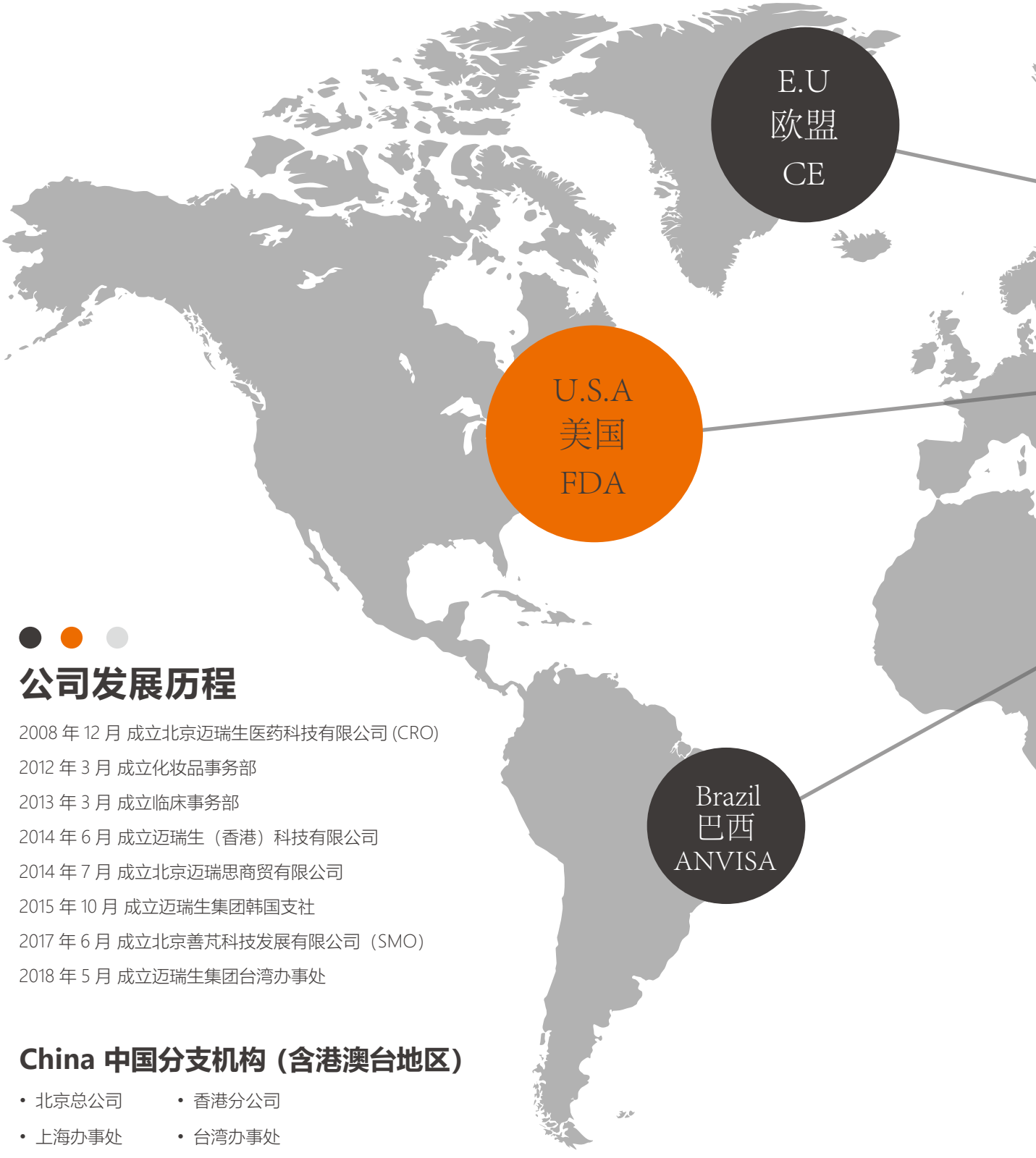
"一生中要做的事很多，而现在我们选择了这一件，那就让我们把它做成经典。"

——Steve Jobs（史蒂夫•乔布斯）

ABOUT MARIS:

Maris Group members consist of Beijing Maris Medical Technology Co., Ltd(CRO), Beijing Maris Trading, Beijing Shanpeng (SMO), Maris (Hong Kong),Maris (Taiwan),Maris (Korea) .Maris Group is dedicated to Regulatory Affairs consulting and registration business related to NMPA (National Medical Products) , formerly CFDA.Maris Group was founded in 2008 and its main business scope is focused on medical devices registration, medical devices clinical trials which also indude SMO service .and cosmetics registration. The key members of the firm have excellent personal capabilities, rich experiences in registration who are familiar with the NMPA regulatory system and application procedure. Besides, Maris has a fully mature and professional quality system (ISO9001&ISO13485) for registration task, which demonstrates more productive and efficient among the RA field.

北京迈瑞生医药科技有限公司、北京迈瑞思商贸有限公司、北京善芃科技发展有限公司、迈瑞生（香港）科技有限公司、台湾办事处、迈瑞生韩国支社隶属于 Maris 集团。Maris 集团专业从事 NMPA(国家市场监督管理总局，原 CFDA 已合并划归) 相关的法规咨询以及相关产品的注册业务。Maris 集团创立于 2008 年，业务主要发展方向为医疗器械注册、医疗器械临床试验、化妆品注册。团队主要成员个人能力优异，注册经验丰富，熟知 NMPA 法规体系及申报流程。Maris 具有十分成熟，专业的注册工作体系，并已取得 ISO9001 和 ISO13485 质量管理体系证书，与同行业中其它公司相比，更具规模与实力。



公司发展历程

2008 年 12 月 成立北京迈瑞生医药科技有限公司 (CRO)

2012 年 3 月 成立化妆品事务部

2013 年 3 月 成立临床事务部

2014 年 6 月 成立迈瑞生（香港）科技有限公司

2014 年 7 月 成立北京迈瑞思商贸有限公司

2015 年 10 月 成立迈瑞生集团韩国支社

2017 年 6 月 成立北京善芃科技发展有限公司（SMO）

2018 年 5 月 成立迈瑞生集团台湾办事处

China 中国分支机构（含港澳台地区）

- 北京总公司
- 香港分公司
- 上海办事处
- 台湾办事处
- 河北办事处
- 东北办事处

Korea 韩国支社

THROUGH TIMELINE

December 2008 Beijing Maris Medical Technology Co., Ltd. was established (CRO)

March 2012 Cosmetics Department was established

March 2012 Clinical Affair Department was established

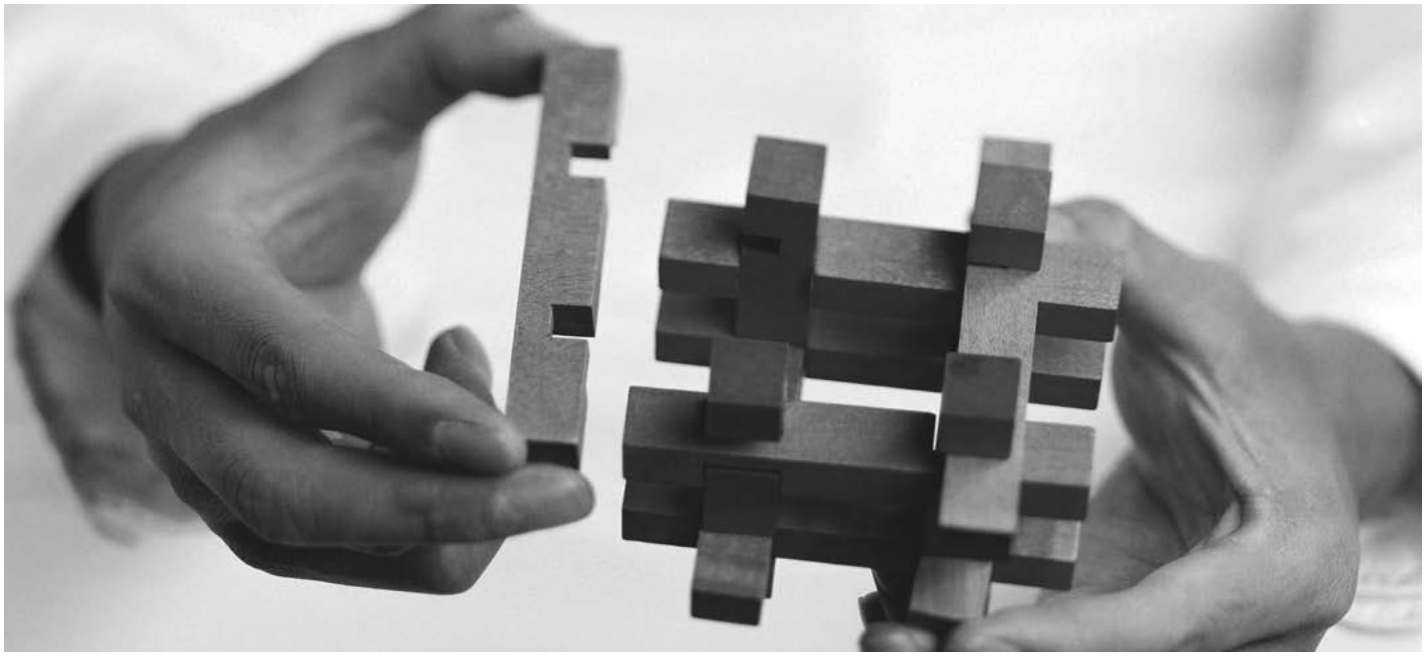
June 2014 Maris (Hong Kong) Technology Limited was established

July 2014 Maris Trading Co.,Ltd.was established

October 2015 Maris Group-Korea branch office was established

June 2017 Beijing Shanpeng Technology Development Co., Ltd. was established (SMO)

May 2018 Maris Group-Taiwan branch office was established



IVD Registration

Technical Requirement Drafting
Registration Strategy Designing
Submitted Document Compiling

体外诊断试剂注册

技术要求编写
注册方案设计
申报资料汇编

Medical Devices Registration

Imported/Domestic
Active medical Device/Non-Active medical Device
The Whole Category Registration Services

医疗器械注册

进口 / 国产
有源 / 无源
全品类注册服务

Clinical Trial/Clinical Evaluation

Clinical Trial Exemption Evaluation
Clinical Protocol Drafting
CRO&SMO

临床试验、临床评估

临床豁免评估
临床方案设计
CRO&SMO

Cosmetics Registration

Cosmetics Registration & Filing Service
Cosmetics Marketing Approval Evaluation Service
Cosmetics Chinese Responsible Officer Service
Cosmetics Customs Clearance Service
Cosmetics Trademark Registration Service
Cosmetics Customized Production Service
Cosmetics Market Promotion Service

化妆品注册

化妆品注册备案服务
化妆品上市风险评估服务
化妆品中国责任人服务
化妆品海关通关服务
化妆品商标注册服务
化妆品生产定制服务
化妆品市场推广服务

OUR SERVICE

Maris Group has been one of the leading providers in services of regulatory affairs, testing and for medical devices and cosmetics. Our company has established a good and stable cooperation relationship with a number of testing institutions, and has become a reliable RA partner for a large amount of imported and domestic manufacturers of medical device and cosmetics, assisted in launching products into Chinese market successfully and rapidly.

迈瑞生集团主要提供医疗器械、化妆品的注册、检测、临床试验等服务。公司已与多个检测机构建立了良好稳定的合作关系，并成为国内外众多医疗器械、化妆品厂商企业固定的注册合作伙伴，为其打开中国市场奠定了良好的基础。

细

10 年来，积累 1000 余项目的操作经验，总结出一套成熟完备的运营和管理体系，对于进口和国产医疗器械注册、临床试验有着独到的管理和执行经验，辅助以公司严格的质控 SOP，从而能够保证项目优质高效的完成。同时是行业内为数不多的拥有自己 SMO 服务的 CRO 公司，为客户注册备案提供一站式服务。

Detail-oriented: In the past 10 years, we have accumulated more than 1000 project experiences, and summarized a set of excellent and perfect quality system for operating and managing. We have unique management and execution experience for imported and domestic medical devices registration ， clinical trials, and assisted with the our strict quality control SOP, in order to ensure the high quality and high efficiency for completing the projects. It is also one of the only CRO companys who has its own SMO in order to provide one-stop service to customers in the inidustry.

作

深刻理解法律法规，在严格执行各类条款的同时，对于行业发展趋势有宏观的预判、能够结合产品的实际情况，帮助企业整体规划设计，指定最精准、最优化、最高效的注册方案。

Implement：Based on precise understanding of regulation and executing it，at the meantime according to the trend and the diversity of products of the industry，combined with the strategic design for enterprises，we can offer the most accurate, optimized and efficient registration and clinical proposal.

企业理念
Corporate philosophy

十年专注、精耕细作、优质高效、使命必达

A decade of focusing on consultation of CFDA regulations with high quality and high efficiency. Experts can solve problem frequently. And we won't stop until reach the goal.

精

Experts: Top experts in the industry work together to think out the perfect solutions.

精锐部队，团队全部来自行业内顶尖公司的人才，汇聚在一起迸发出新的智慧。

耕

Ploughing: Focus on high efficiency. In the industry, it has been established a good cooperative relationship with supervision department, laboratory, and a large amount clinical trial sites, which can effectively prejudge, avoid and solve problems that may occur during the product testing, registering, conducting clinical trial and other process.

唯有专注，才能高效。在行业内，与行业监管部门、检验机构、以及众多临床试验机构建立了良好的合作关系，可以有效预判、规避和解决产品检测、注册、临床等各个环节可能出现的问题。

MARIS CRO

Beijing Maris Medical Technology Co., Ltd. is a complex of professional CRAO (Contract Regulatory Affairs Organization) and CRO (Contract Research Organization). For most medical device legal manufacturers, partial or full appointment to CRO company is an inevitable choice for mature companies due to specialism, so that it becomes more professional, efficient, result-oriented, successful and lower costs. At present, the R&D and registration ability of Chinese medical device companies can be divided into five types: 1. strong R&D plus strong registration, 2. strong R&D weak registration, 3. weak R&D strong registration, 4. weak R&D andweak registration,5 almost no R&D and registration. Among them, first type is about 10% - 15%, the second, third and fourth ones are the overwhelming majority, are about 65% - 75%, and fifth one which is the non-R&D and non-registered companies is about 15% - 20%, or even higher. Some of medical device companies may not have R & D team members, or weak R&D abilities, besides may be lacking of sufficient R & D talents, awareness, idea and experiences. Perhaps no good facilities and conditions. In aspect of registration ability, a large majority of medical device manufacturer has less RA specialist, furthermore, who are not good at the updated regulations and guidance. Without registration experience and successful practice, it cannot provide sufficient support to R&D and sales department. So It is difficult, high-cost, or even impossible for a company to become a strong R & D with full regulatory experienced company. It is just why the CRO and CRAO which born for their missions. CRO is specialized in clinical research. CRAO dedicated to register medical device and regulatory affairs. The advantage of CRO and CRAO is that they already have professional team members, mature operation, valuable experience, rich resources, so that it can share resources and cost with customers.

MARIS CRO

北京迈瑞生医药科技有限公司是专业 CRAO（是“Contract Regulatory Affairs Organization”的缩写，即合同注册组织，指专业从事各种医药法规符合事务的服务机构）与 CRO 合同研究组织（CRO，Contract Research Organization）的综合体。

对于大多数医药或者器械公司而言，部分或全部委托 CRO 公司是现代专业分工的必然选择，这样更专业、更有效、更易得结果、更易成功和降低成本。就目前中国制药公司的研发与注册能力而言，可以分为：强研发强注册、强研发弱注册、弱研发强注册、弱研发弱注册、无研发和注册等五种类型。其中，第一种为，约 10%-15%，第二、三、四种占绝大多数，约 65%-75%，第五种，即无研发和无注册能力的公司，约 15%-20%，甚至更高。绝大多数医药或者器械公司没有研发团队，或力量薄弱，或根本没有懂研发的人才；没有现代研发的意识和理念；缺乏研发的经验；没有研发的设施和条件。在注册能力方面，绝大多数医疗企业缺少完备的注册团队，内部人员对法规和指南的要求了解不全、不深或甚少；没有注册经验，更不了解法规和指南以外的审评实践；没有意识和能力，根据法规和指南的要求和注册经验，规划和指导研发工作。一个公司想成为强研发强注册的公司是困难的、高成本的，甚至不可能的。正是在这种情况下，CRO 与 CRAO 应运而生。前者，专业从事器械研发；后者，专业从事器械注册及各种法规符合事务。CRO 与 CRAO 的优势在于，有着专业团队、专业运营、专业经验、专业资源，可以与企业客户共享资源、进行成本分担。

SMO COMPANY INTRODUCTION
SMO 公司介绍

The SMO (Site Management Organization) Operating Department of Beijing Shanpeng Technology Development Co., Ltd. was formally established in June 2017. It is dedicated to introduce the advanced international clinical trial management system and assisting researchers and research institutes in non-medical judgment affairs by providing high quality and efficient services for the growing number of clinical trials from clients around the world, improve the quality and promote the standardization process of clinical trials. Main Business: Responsible for the management of clinical CRC personnel throughout the country, providing coordination services for clinical trials and research, hospital research reports, questionnaires and other services. The Shanpeng SMO is dedicated to provide the best CRC service with a professional, solid and honest attitude.

北京善芃 SMO（site management organization）公司是 2017 年正式成立， 致力于引进国际先进的临床试验管理体系，通过提供临床试验相关的专业服务，协助研究者和研究机构临床中非医学判断类的事务性工作，为日益增长的、来自全球的临床试验提供优质高效的服务，提高临床试验质量和进度，推动临床试验规范化进程。主要业务：负责全国临床 CRC 人员管理，提供临床试验研究协调服务、医院调研报告、问卷调查等服务。

北京善芃 SMO 服务以客户利益为先，本着对客户负责的态度，专业、扎实、诚信做项目，为每位客户的每个项目负责，致力于提供最好的 CRC 进行中心驻地管理服务。

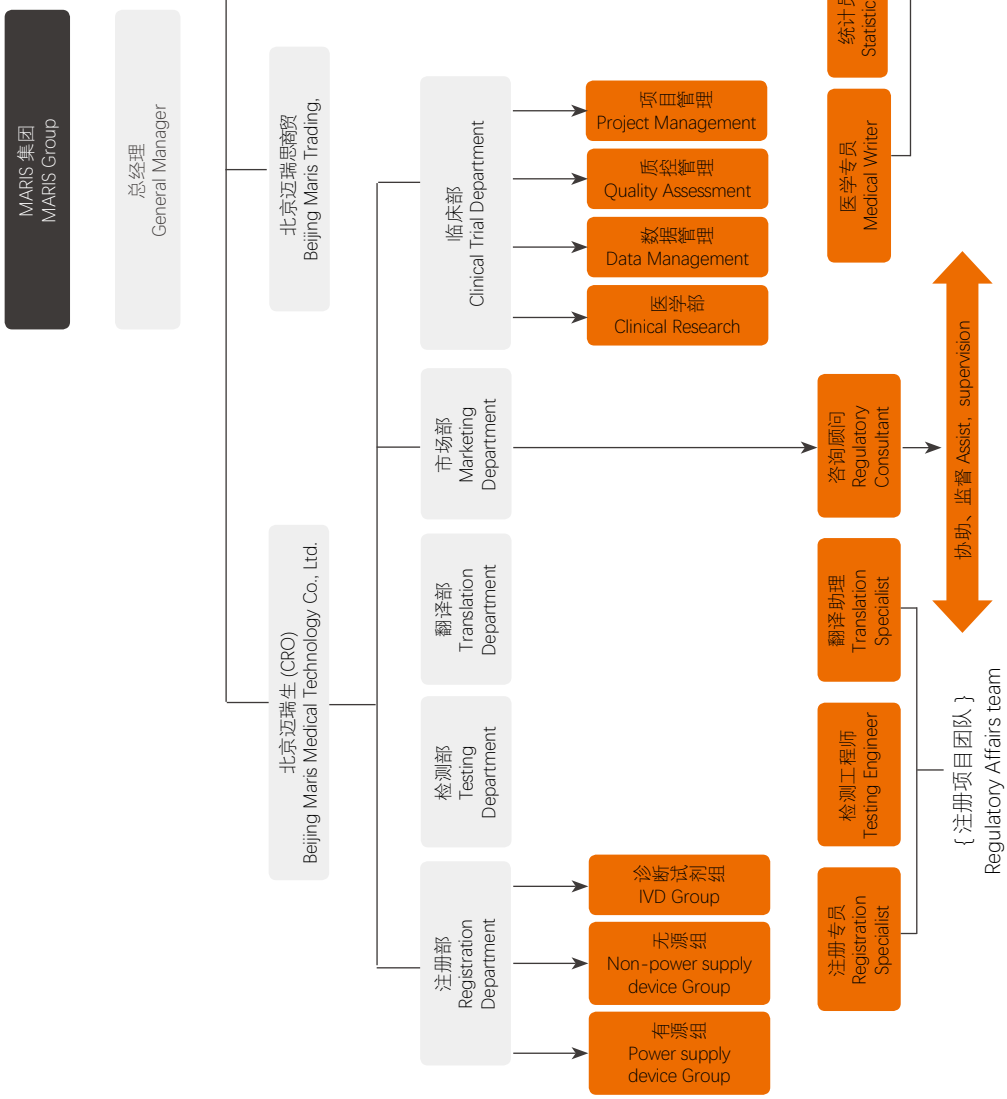
北京善芃 SMO 服务提供的 CRC 团队以护理、医学、药学、生物技术等专业背景为主，90% 以上为大学本科学历；剩余为研究生及以上学历，工作经验较为丰富，拥有多年市场经验；英语水平良好，88% 以上 CET-4 水平。熟悉 ICH-GCP、GCP 及医疗器械临床管理规范，并均通过了国家 GCP 考试并获得国家 GCP 证书，经过良好的 CRC 专业技能培训，熟悉医院环境，就医流程，CRC 的工作职责；熟悉 CRF 的填写；熟悉血样等标本的运送及实验室的要求；熟悉各种器械的使用，有较为丰富的器械临床试验经验，均为高素质的专业 CRC。

CRC PERSONNEL QUALIFICATIONS
CRC 人员专业素质

MARIS CRC 驻地
陆续扩增中 .....

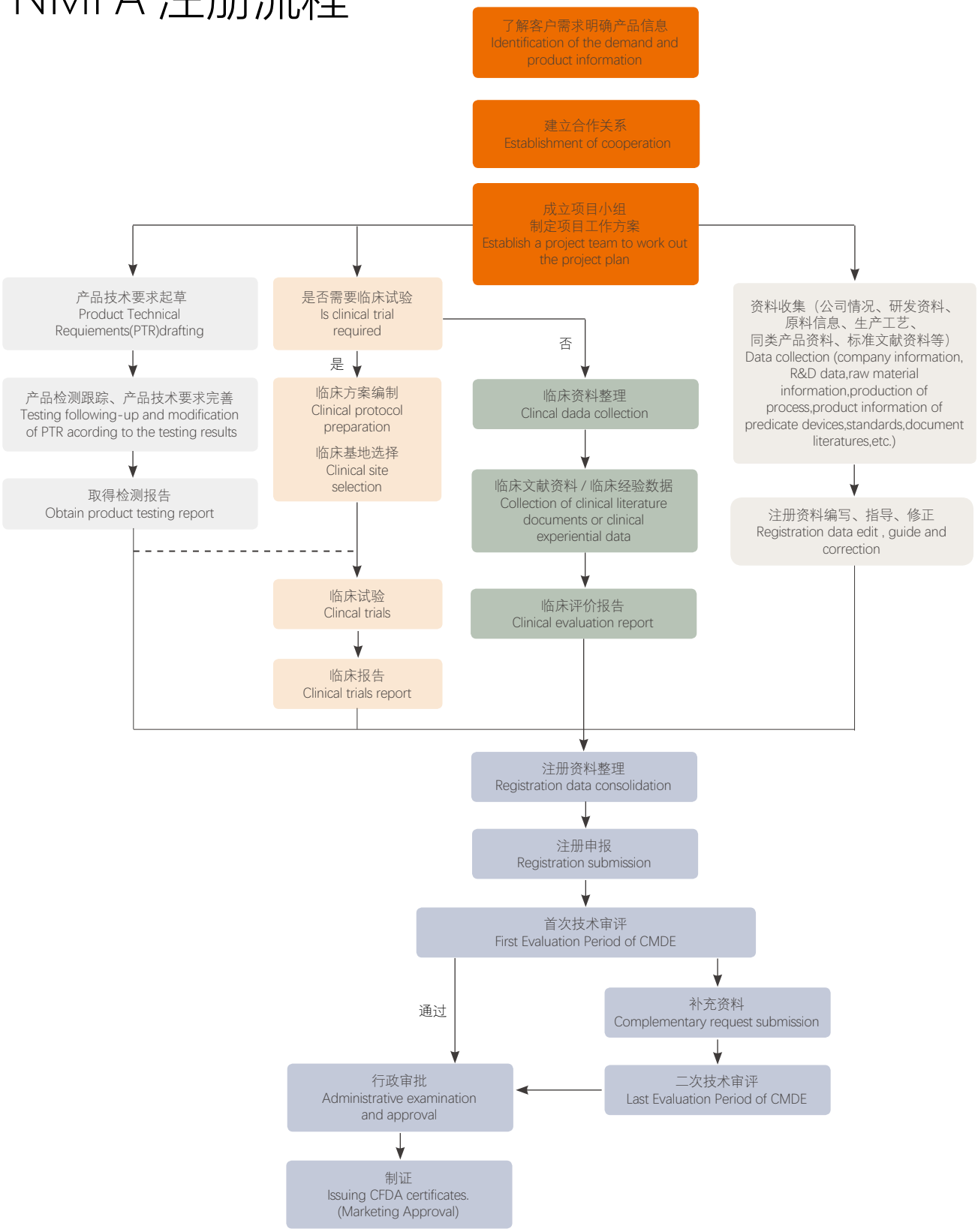
Our SMO has a group of CRC who are mainly with nursing, medicine, pharmacy, biotechnology and other professional backgrounds. More than 90% of them have bachelor's degree. The rest are graduate students or doctoral students with rich working experience and many years of market experience. The English level is good and 88% of them have at least CET-4 level. Familiar with ICH-GCP, GCP and clinical management standards of medical devices, and have passed the national GCP examination and obtained the GCP certificate, after CRC professional skills training, familiar with the hospital environment, medical procedures, CRC work responsibilities; familiar with filling in the CRF; familiar with blood samples and other specimens delivery and laboratory requirements; familiar with the use of various instruments, There are relatively rich experience in clinical trials of medical devices and they are all high qualified professional CRC.

MAIRS 组织架构


MARIS 集团
MARIS Group
总经理
General Manager
北京善芃 (SMO)
Beijing Shanpeng (SMO)
北京迈瑞思商贸
Beijing Maris Trading.
北京迈瑞生 (CRO)
Beijing Maris Medical Technology Co., Ltd.
CRC 经理
CRC Team
协调员经理
LCRC
高级协调员
SCRC
协调员
CRC
监查员
CRA
项目经理
Project Manager
质控员
QA/QC
统计员
Statistician
医学专员
Medical Writer
{ 临床项目团队 }
Clinical Affairs team
临床部
Clinical Trial Department
项目管理
Project Management
质控管理
Quality Assessment
数据管理
Data Management
医学部
Clinical Research
市场部
Marketing Department
咨询顾问
Regulatory Consultant
翻译部
Translation Department
翻译助理
Translation Specialist
检测部
Testing Department
检测工程师
Testing Engineer
注册部
Registration Department
注册专员
Registration Specialist
诊断试剂组
IVD Group
无源组
Non-power supply device Group
有源组
Power supply device Group
协助、监督 Assist、supervision
{ 注册项目团队 }
Regulatory Affairs team

NMPA REGISTRATION WORKFLOW

NMPA 注册流程



CLINICAL TRIAL PROCESS
临床试验流程

试验准备
clinical trial preparation

1. 检索同类产品信息 Search similar product information
2. 检索国内外文献及资料 Search domestic and foreign literature and data
3. 制定项目时间计划 Make a project schedule
4. 撰写临床试验方案框架 Draft the framework of clinical trial protocol
5. 动物实验（如有） Animal trial (if need)
6. 筛选临床试验机构 Screening clinical trialsites
7. 拟定临床试验方案 Develop clinical trial protocol
8. 组织召开方案讨论会 Organize and convene the seminar of clinical trial protocol
9. 中心立项 Project Approval by Sites
10. 准备伦理资料及上报 EC preparation and submission
11. 伦理批准 EC approval
12. 人类遗传学备案（进口医疗器械） Filing in Genetic Office & Local FDA（Imported instruments）
13. 签署临床试验协议 Agreements of Sites
14. 高风险产品审批 High risk listed products approval
15. 临床试验备案 Clinical trial filing
16. 试验样品管理及临床资料配送 Data archiving and sample recovery
17. 临床试验操作培训 Clinical trial operation training
18. 确定项目管理计划及质量管理计划 Validating the project management plan and quality control plan

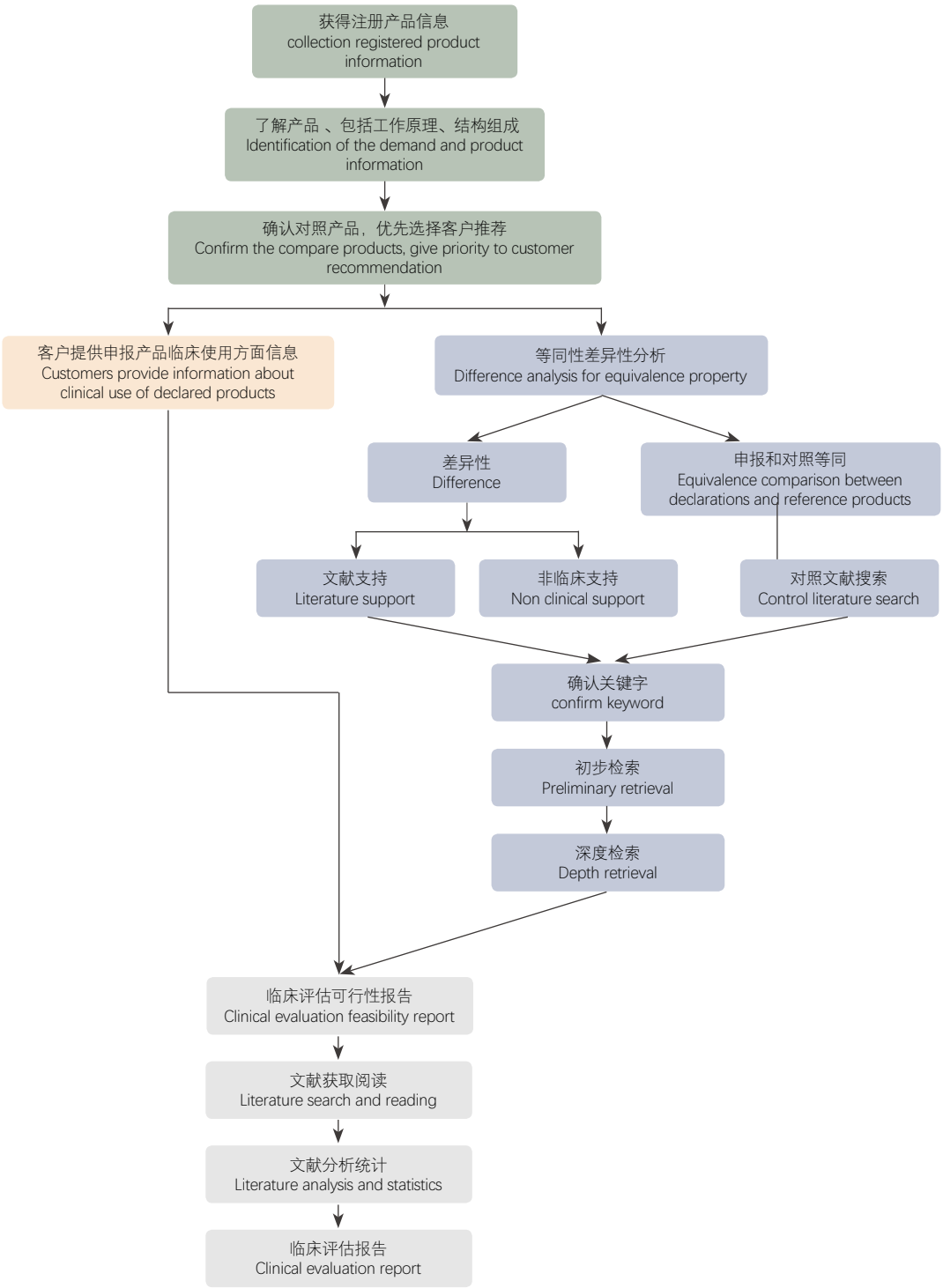
试验启动
start-up clinical trial

19. 组织项目启动会 Project Kick-off Meeting
20. 首例病例入组 Enrollment Period
21. 首例质量监察 First case quality monitoring
22. 临床监察、CAR/CRC 服务 Clinical monitoring
23. 中期讨论会（如需） Medium-term Seminar (if needed)
24. 数据管理和统计 Data management and statistics analysis
25. 完成病例入组 Completion of case enrollment
26. 完成全部病例随访 Cases followed up

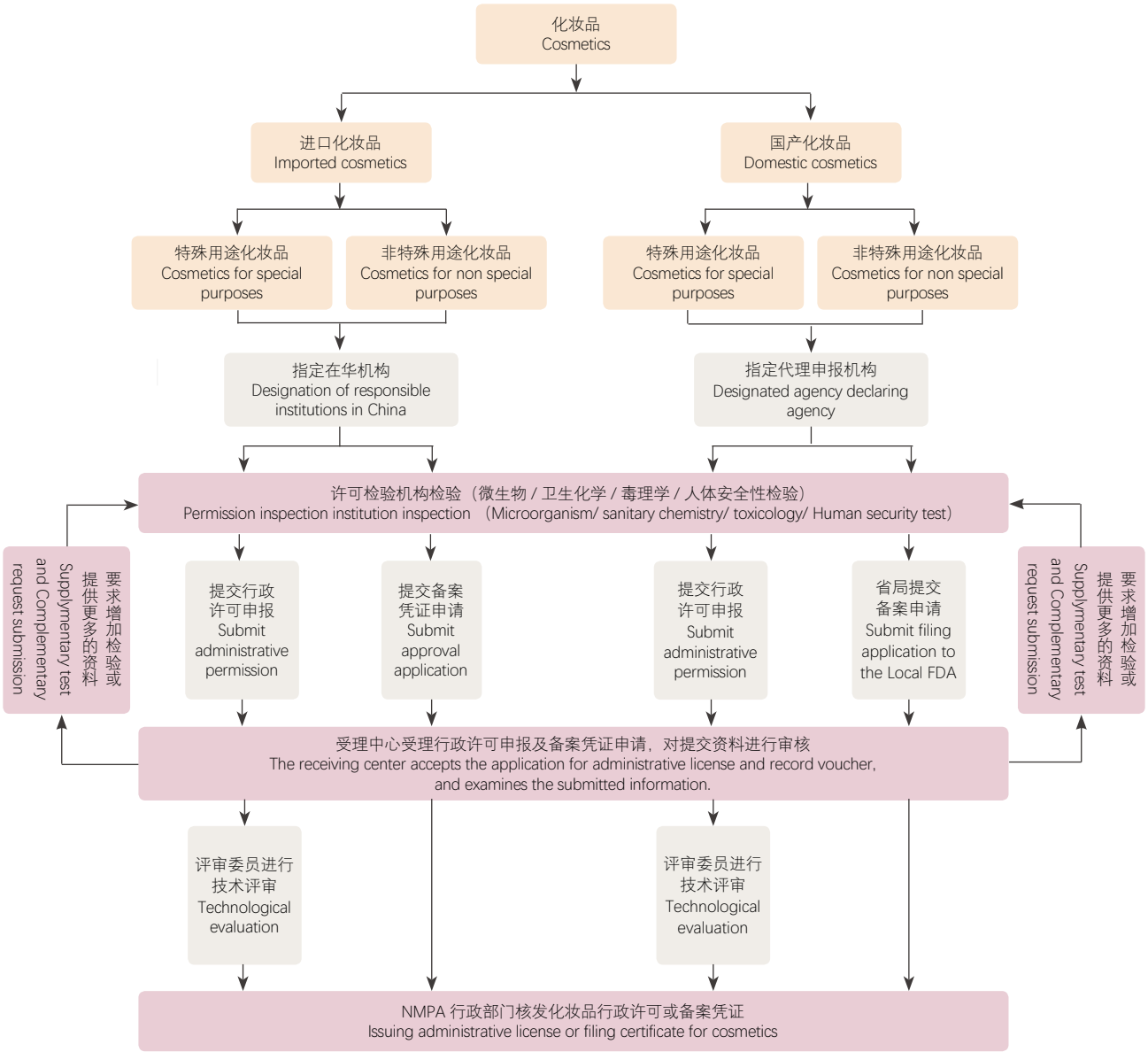
试验关闭
Close clinical trial

27. 数据整理及录入 Data compilation and collection
28. 数据答疑 Data Q & A
29. 数据统计及报告 Data statistics and reports
30. 编写总结报告 Drafting the conclusion report
31. 召开项目总结会 Conclusion meeting
32. 总结报告签字盖章 Validating conclusion report
33. 剩余样品及临床资料收回 Data archiving and sample recovery
34. 研究单位资料归档备案 Shutting Down Sites
35. 移交注册 Preparing Dossier for Submission to CFDA

CLINICAL ASSESSMENT PROCESS
临床评估流程



COSMETIC REGISTRATION PROCESS
化妆品注册流程



化妆品分类 Cosmetics classification

特殊用途化妆品	育发类、健美类、美乳类、染发类、烫发类、防晒类、除臭类、美白祛斑类、脱毛类				
非特殊用途化妆品	发用类	护肤类	彩妆类	指（趾）甲类	芳香类
	例如： 洗发液 护发素 发膜	例如： 洗面奶 乳液 面膜	例如： 胭脂 口红 眼影	例如： 洗甲水 指甲油 护甲霜	例如： 香水 古龙水 精油

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