Medical Device and IVD Product Registration in Russia. Current Procedure.

医疗器械和IVD产品的俄罗斯注册 现行程序

深圳市领先医疗服务有限公司
Shenzhen Advanced Medical Services Co., Ltd

beAwire

Ruslan Kalachev 鲁斯兰·卡拉切夫
Development Director BeAWire
Moscow, Russia 俄罗斯，莫斯科

Session Agenda

会议议程

PART 1 Legislation Framework

PART 2 Classification Rules

PART 3 Registration Process Depending on Risk Class

PART 4 Documents From Manufacturer Side

PART 5 Basic Understanding of Pre-Clinical and Clinical Trials

PART 6 Successful Clinical Evaluation Strategy

PART 7 Declaration Issues

第一部分：立法框架

第二部分：分类规则

第三部分：基于风险类别的注册流程

第四部分：制造商需提供的文件

第五部分：临床前研究和临床试验的基本了解

第六部分：成功的临床评估策略

第七部分：声明问题

Legislative Framework 立法框架

Main regulatory documentation:
主要法规文件：

Federal Law #323- FZ 21/11/2011 (Bases of national healthcare safety). 联邦法律＃323- FZ （国家医疗安全基础）

Federal Law #210-FZ 27/07/2010 (Providing of public services).
联邦法律＃210-FZ（提供公共服务）

Order of RF Government #1416 from 27/12/2012 (Registration rules for Medical devices) with changes + order 4n with changes+2n+11n.
俄罗斯联邦政府＃1416号令（医疗器械注册规则），变更+4n号令，变更+ 2n + 11n号令

Order of RF Government #19 17/01/2002 (About “tax-free” for medical devices).RF政府＃19号令 （关于医疗器械的“免税”）

Federal law #532 from 31/12/2014 + Order of Russian Government #6 from 05/01/2015 (circulation of medical products – both of them)
联邦法律＃532 和俄罗斯6号政府令（医疗产品流通-器械和IVD）

Government control for all stages of medical device life-circle
政府对医疗器械全生命周期的各个阶段进行监控

Product Life-Circle into Russian Market
进入俄罗斯市场的产品的生命周期

Approval Stage
审批阶段

俄罗斯政府监管
Government
Surveillance
(Russia)

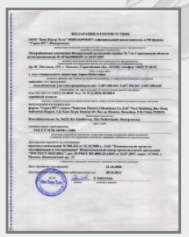
Medical Device into Russian Market
医疗器械进入俄罗斯市场

EEU政府监管
Government
Surveillance (EEU)

EEU Regulation (EAC MED)
欧亚经济联盟法规

MD Approved: 31.12.2021

Registration Certificate
注册证



DoC
GOST R

DoC
CU TR #20

EEU-欧亚经济联盟
EEU - Eurasian Economic Union

beowire

Regulatory Processes 监管程序

注册流程
Registration process

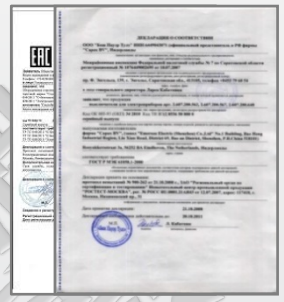
No expiry date
(see EEU regulation)
没有有效期（见欧亚经济联盟法规）

Notified Authority主管当局:
Roszdravnadzor - RZN (MoH/Russia)
+ expert centers (VNIIIMT or CMIIKEE)

Kind of approval批准类型:
State registration as
medical device (mandatory)医疗器械的国家注册（强制性）

Time: 6-18 months 周期：6-18个月

声明流程
Declaration process



DoC GOST R 俄罗斯标准化计量委员会符合性声明
3 years
DoC CU TR #20 关税联盟技术法规联盟符合性声明
5 years

Notified Body公告机构:
certification center in Russia
俄罗斯认证中心

Kind of approval批准类型:
Safety declaration 安全声明
(if applied for current product)

Time: 1-2 weeks

Chinese translation see next slide/中文翻译见下页

What is Medical Device (MD)? 什么是医疗仪器(MD)?

Regulation of Federal Service
ROSDRAVNADZOR

In Scope	«Medical device» («medical product» in the law) means any instrument, apparatus, appliance, software, material or other article used for medical purposes, alone or in combination with each other and with other accessories necessary for the application of these products to the destination, including special software and designed by the manufacturer
In-scope Regulations	• to prevent, diagnosis, treatment and rehabilitation of diseases, monitoring of the human body for medical research, restoration, replacement, modification of anatomical structures or physiological functions of the body, prevent or abortion pregnancy, • which does not achieve its principal intended action… by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means
Out of Scope	Cosmetics Custom-made product - for single patient (3D printed medical device) Pharmaceuticals

Chinese translation see next slide/中文翻译见下页

Extract from 323 FZ

What is Medical Device (MD)? 什么是医疗仪器(MD)?

Regulation of Federal Service
ROSDRAVNADZOR
联邦服务法规
联邦卫生和社会发展部

In Scope
在适用范围内

“医疗器械”（法律上为“医疗产品”）是指用于医疗目的的任何仪器，设备，器具，软件，材料或其他物品，单独或相互结合以及与应用这些产品所需的其他附件结合使用到目的地，包括专用软件并由制造商设计

In-scope Regulations范围内法规

●疾病的预防，诊断，治疗和康复，监测人体进行医学研究，恢复，更换，改变解剖结构或身体的生理功能，预防或终止妊娠
●它不是通过药理学，免疫学或代谢方法实现其主要的预期作用，或者有虽然有这些方式参与但是只是起辅助作用

Out of Scope
范围外

美容品
定制产品 - 适用于单个患者（3D打印器械）
药品

Extract from 323 FZ 摘自 FZ 323 号令

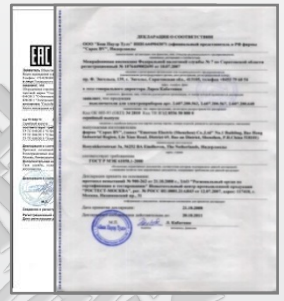
Classification Rules 分类规则

OKPD2 (earlier OKP) OKPD2(早期称为OKP)	Risk class 风险分类 (Order #4n)	命名法代码4号法令 Nomenclature code (Order #4n)
Base of tax-free system and national regulation, medical device classification is only a part of all product classification scheme	Mainly the same as in MDD 93/42 EEC 跟MDD大致相同	Unique code by RZN RZB 的独特代码
Used by Customs, hospital 海关和医院使用	Used by RZN RZN所使用	Used by RZN and hospitals RZN和医院使用

免税制度和国家法规的基础，医疗器械分类只是所有产品分类方案的一部分

Identify OKPD2 code: 识别OKPD2代码:
https://classifikators.ru/okpd

Registration Processes注册流程

注册**流程** **Registration process**	声明程序 **Declaration process**
	
No expiry date (see EEU regulation)	DoC GOST R 3 years DoC CU TR #20 5 years
Notified Authority: Roszdravnadzor - RZN (MoH/Russia) + expert centers (VNIIIMT or CMIIKEE)	Notified Body: certification center in Russia
Kind of approval: State registration as medical device (mandatory)	Kind of approval: Safety declaration (if applied for current product)
Time: 6-18 months	Time: 1-2 weeks

Chinese translation see next slide/中文翻译见下页

Registration Processes注册流程

注册流程
Registration process

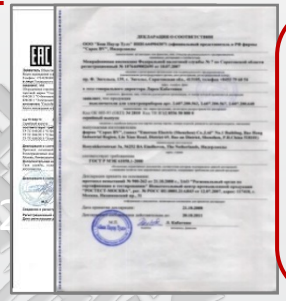
没有有效期
（见EE规定）

通知机关：Roszdravnadzor 医疗保健和社会发展领域的监督联邦服务 - RZN（卫生/俄罗斯）+专家中心（VNIIIMT或CMIIKEE）

批准种类：
国家注册为
医疗器械（强制性）

时间：6-18个月

声明程序
Declaration process



DoC GOST R
3 年
DoC CU TR
#20
5 年

公告机构：
俄罗斯认证中心

批准种类：
安全声明
（如果申请当前产品）

时间：1-2周

Registration from Zero-point 从零开始的注册

Registration Certificate 注册证书

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
от 26 июля 2016 года № РЗН 2016/4525

На медицинское изделие
Набор для анестезии стерильный одноразового использования AS-E/S

Настоящее регистрационное удостоверение выдано
[redacted]

Производитель
[redacted]

Место производства медицинского изделия
[redacted]

Номер регистрационного досье **№ РД-9189/51046 от 10.11.2015**

Вид медицинского изделия **299660**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции для медицинского изделия **94 3700**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 26 июля 2016 года № 7408
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

0018455

Product name
产品名称
Holder
持证人
Manufacturer
Factory Site
制造商地址
Classification
分类

Mandatory – for all medical devices and IVD products
强制性 - 适用于所有医疗设备和IVD产品

State registration 国家登记

Local Holder is not required – it could be manufacturer
不需要当地持有人 - 可以由制造商持有

No expiry date (see EEU regulation)
没有有效期（参见EEU法规）

No information about Authorized Representative in Russia (listed in TF and IFU)
没有俄罗斯授权代表的信息
（授权代表在在TF和IFU中列出）

Appendix to Registration Certificate 注册证书附录

Main criteria to identify quantity of submissions to use nomenclature codes*. Usual practice one code = one registration certificate (submission).
主要准则，以确定提交使用命名规则*的数量。通常做法 一代码= 一份注册提交证书(提交)。

Which devices could not be grouped together in main kit (submission)?*哪些器械不能作为一个注册单元进行申请呢
Intended use is different 预期用途不同
Kits and stand alone devices 套件和独立设备
Sterile and non-sterile 无菌和非无菌产
Disposable and non-disposable 一次性和非一次性产品
Implantable and non-implantable 植入和非植入产品
Portable and stationary 便携式和固定式产品
Drug eluting and without drug 载药和非载药产品
Etc.

What could not be added in accessories?
Standalone devices
什么不能作为配件注册？独立器械

*exempt of kits 工具包除外

Main Composition 主要组成

Accessories 附件

Manufacturing Sites生产厂址

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 22 января 2018 года № РЗН 2018/6742

Лист 1

На медицинское изделие
Монитор матери и плода SRF618K9 с принадлежностями:
I. Состав:
1. Батарея литий-ионная аккумуляторная беспроводного преобразователя - не более 3 шт.
2. Батарея литий-ионная аккумуляторная оборудования - не более 2 шт.
3. Кабель ЭКГ (пятижильный, трехжильный) - не более 2 шт.
4. Манжета НИАД.
5. Метка движения плода.
6. Монитор.
7. Преобразователь SpO_2.
8. Преобразователь ТЕМП подмышечный.
9. Преобразователь ТЕМП ректальный.
10. Руководство пользователя.
11. ТОСО-преобразователь.
12. ТОСО-преобразователь беспроводной - не более 1 шт.
13. Трубка манжеты НИАД удлинительная.
14. УЗ-преобразователь - не более 3 шт.
15. УЗ-преобразователь беспроводной - не более 2 шт.
16. Шнур питания.
17. Электрод ЭКГ одноразовый - не более 30 уп. (50 шт. в уп.).
II. Принадлежности:
1. Гель ультразвуковой.
2. Диск с программным обеспечением.
3. Лента.
4. Предохранитель T2AL250V.
5. Термобумага.
III. Место производства:
1. Guangzhou Sunray Medical Apparatus Co., Ltd., 4/F No. 242 Tianhe Dong Road, 510620 Guangzhou, P.R. of China.
2. Guangzhou Sunray Medical Apparatus Co., Ltd., 38 Gaoke Road., Gaotang Industry District, GuangSnanEr Road, 510520 Guangzhou, P.R. of China.

Руководитель Федеральной службы по надзору в сфере здравоохранения **М.А. Мурашко**

0041529

Classification Rules 分类规则

OKPD2 (earlier OKP)	Risk class (Order #4n)	Nomenclature code (Order #4n)
Base of tax-free system and national regulation, medical device classification is only a part of all product classification scheme	Mainly the same as in MDD 93/42 EEC	Unique code by RZN
Used by Customs, hospital 海关和医院使用	Used by RZN RZN使用	Used by RZN and hospitals

免税制度和国家法规的基础，医疗器械分类只是所有产品分类方案的一部分

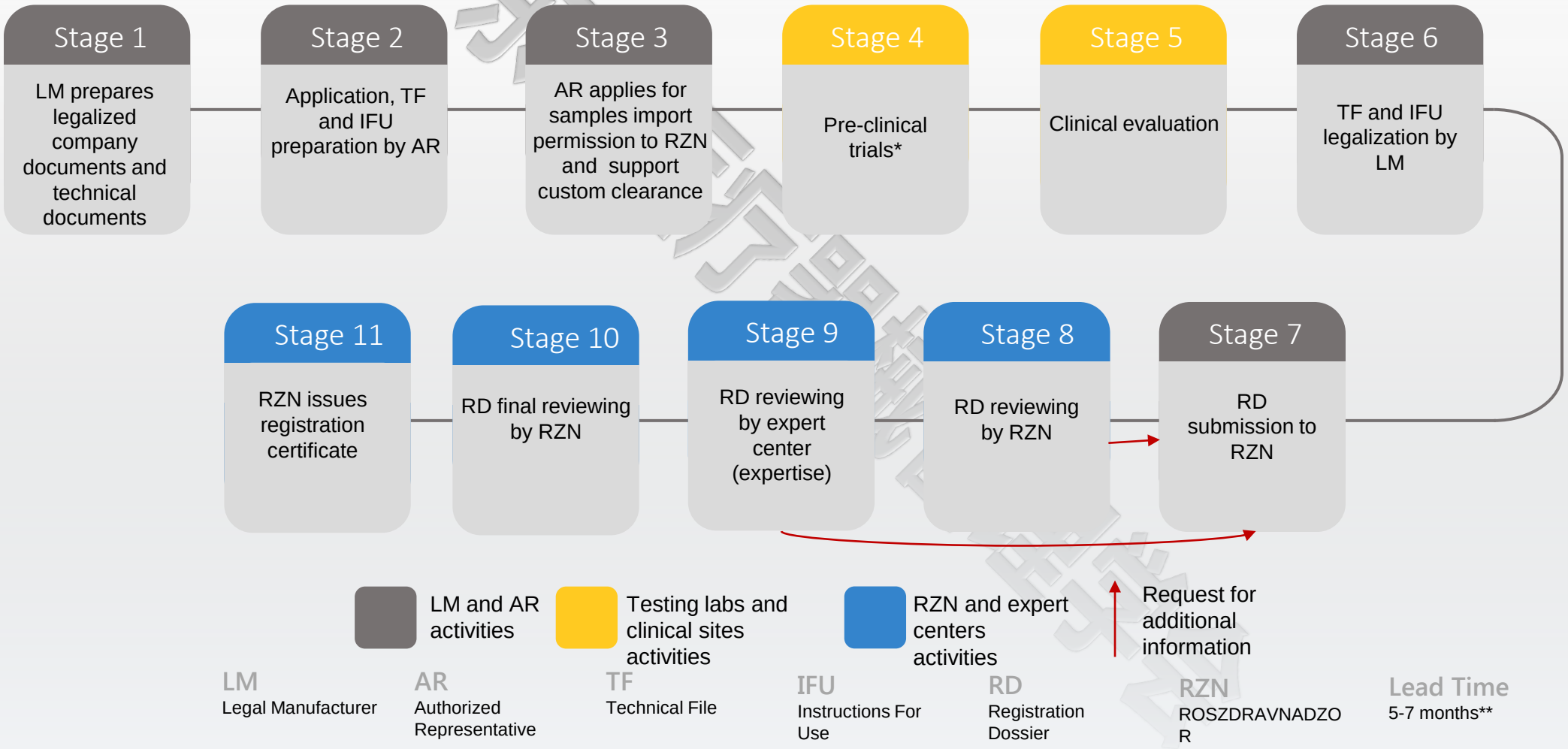
**检查您的产品是否为医疗器械：

**Check whether your product is medical device:

http://www.roszdravnadzor.ru/services/mi_reesetr

Main Registration Process (1 Risk Class)

主要注册流程（1类风险）

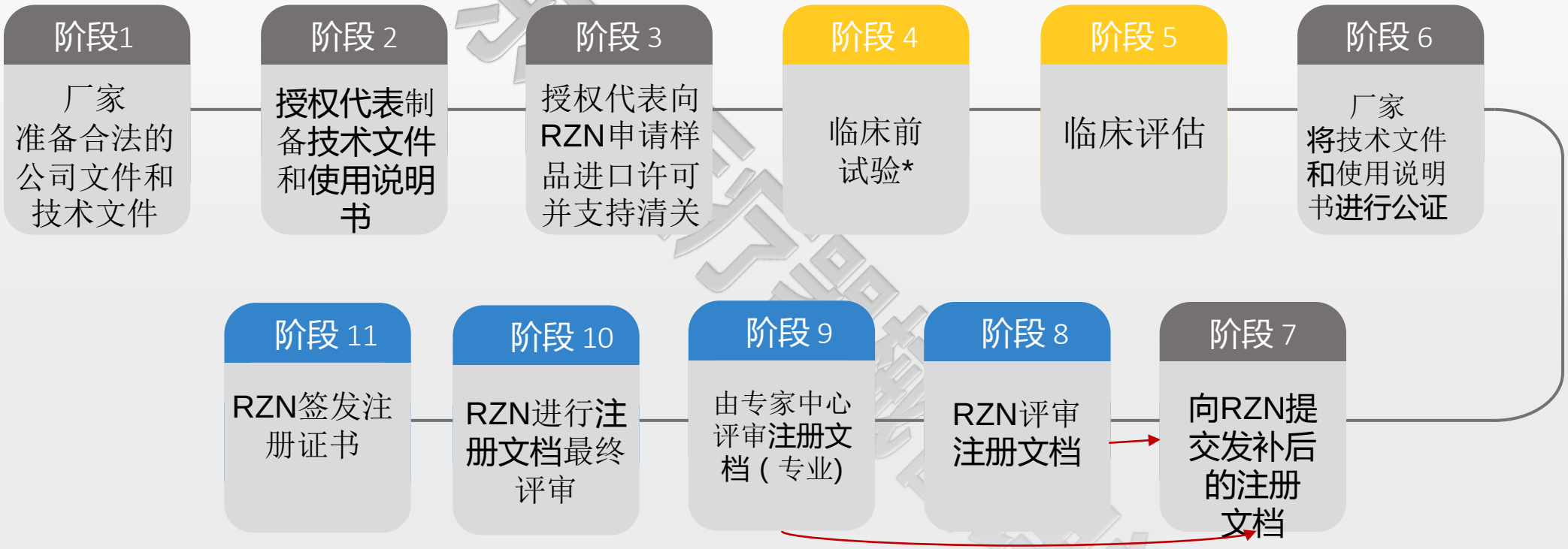


Chinese translation see next slide/中文翻译见下页

Pre-clinical trials* - biocompatibility, technical and measuring function testing on the base on accredited labs (depends on medical device type)

**approximate term (from the date of documents and samples receiving by AR)

Main Registration Process (1 Risk Class)
主要注册流程（1级风险）



LM 法定制造商

AR 授权代表

TF 技术文件

IFU 使用说明书

RD 注册文档

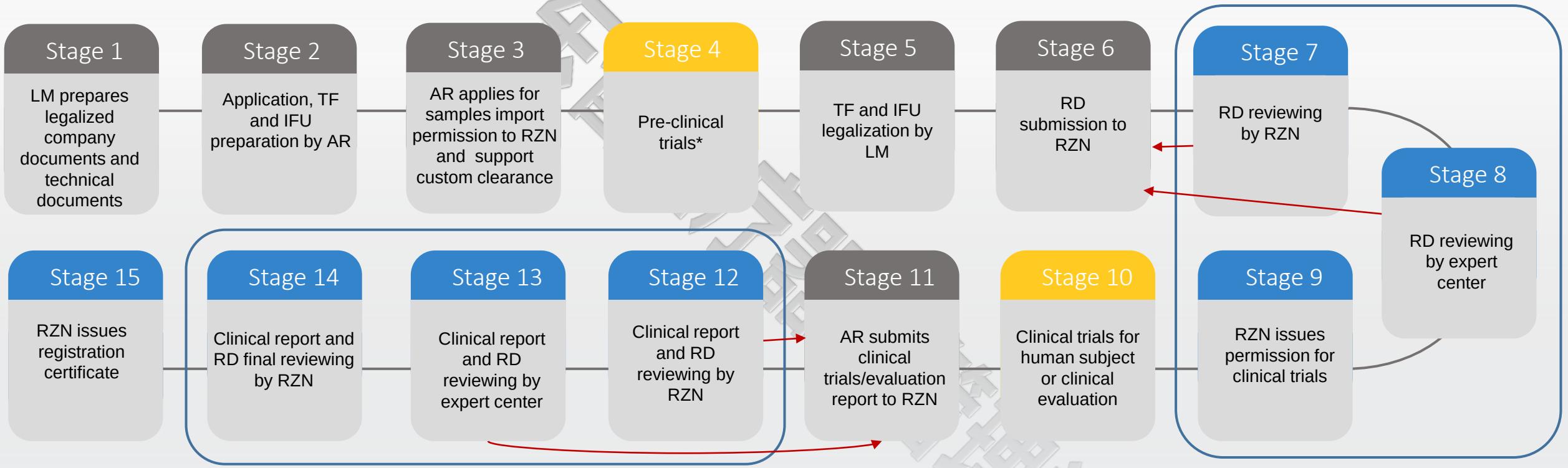
RZN ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务

Lead Time 周期 5 - 7个月**

临床前试验* - 基于认可实验室的生物相容性，技术和测量功能测试（取决于医疗器械类型）

**大致期限(自授权代表收到文件和样品之日起)

Main Stages of Registration Process
(2a, 2b, 3 Risk Class) 注册流程的主要阶段（2a，2b，3类）



LM
Legal Manufacturer

AR
Authorized Representative

TF
Technical File

IFU
Instructions For Use

RD
Registration Dossier

RZN
ROSZDRAVNADZOR

Lead Time
7-9 months**

Chinese translation see next slide/中文翻译见下页

RZN = Federal Service for surveillance in healthcare (ROSZDRAVNADZOR)- MoH structure

Pre-clinical trials* - biocompatibility, technical and measuring function testing on the base on accredited labs (depends on medical device type)

**approximate term (from the date of documents and samples receiving by AR)

Main Stages of Registration Process
(2a, 2b, 3 Risk Class) 注册流程的主要阶段（2a，2b，3类）

法定制造商和授权代表活动

测试实验室和临床机构活动

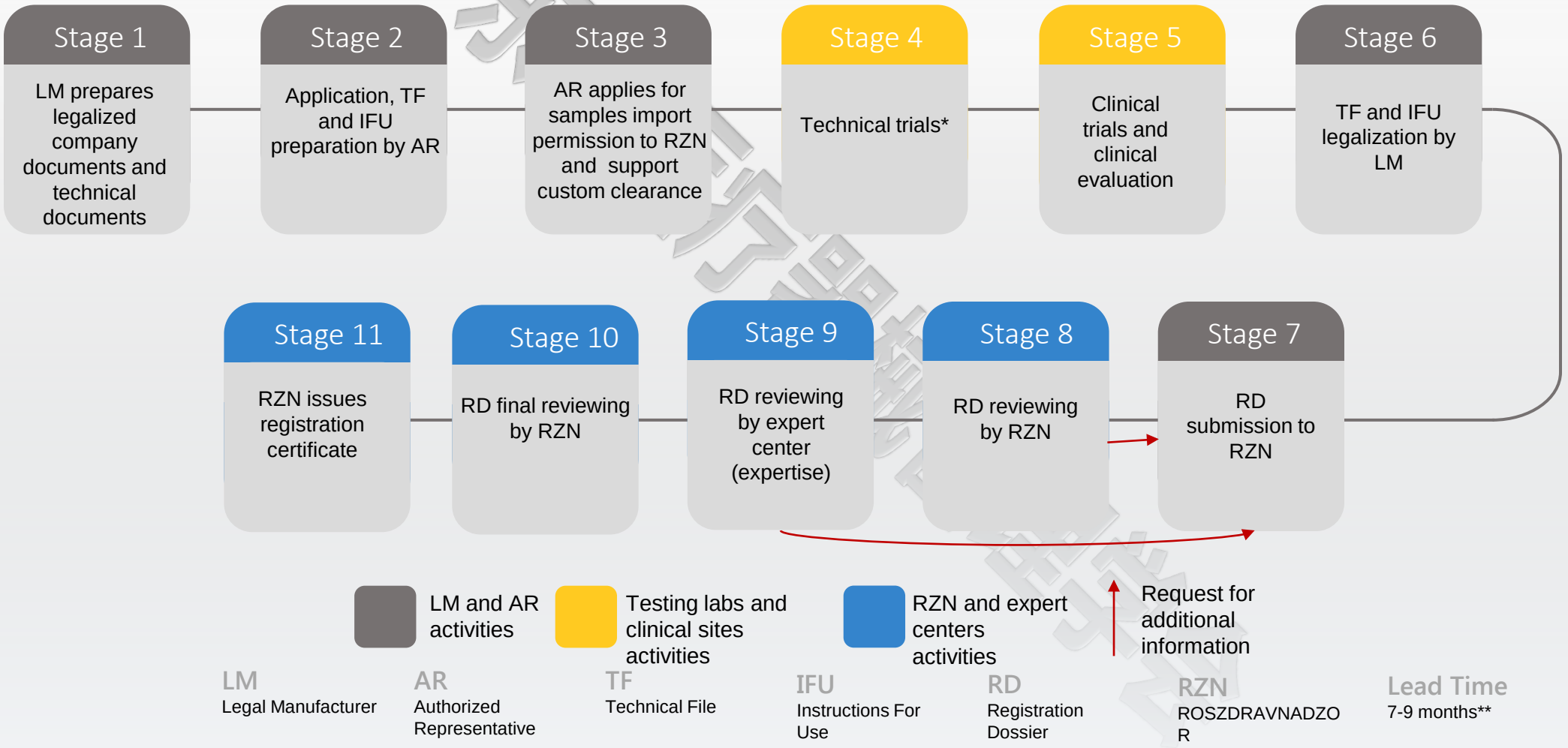
RZN和专家中心的活动

注册发补

LM	AR	TF	IFU	RD	RZN	Lead Time
法定制造商	授权代表	技术文件	使用说明书	注册文档	ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务	周期 7 - 9个月* *

RZN =联邦医疗保健监督局 (ROSZDRAVNADZOR)- MoH 架构
临床前试验* - 基于认可实验室的生物相容性，技术和测量功能测试（取决于医疗器械类型）
**大致期限(自授权代表收到文件和样品之日起)

Main Stages of Registration Process
(All IVD Products) 注册流程的主要阶段（所有IVD产品）

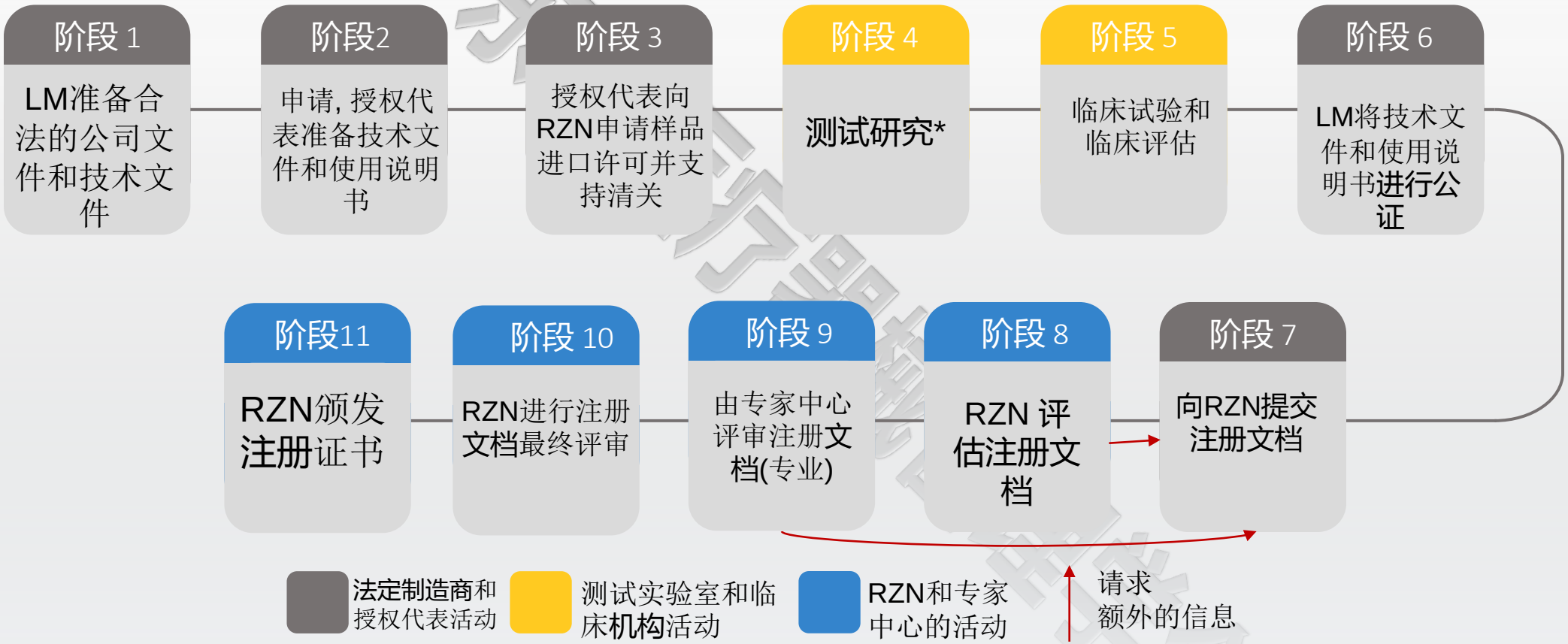


Chinese translation see next slide/中文翻译见下页

Technical trials*- for certain IVD products (tubes, strips, etc.) biocompatibility trials is strict requirement as well

**approximate term (from the date of documents and samples receiving by AR)

Main Stages of Registration Process
(All IVD Products) 注册流程的主要阶段（所有IVD产品）

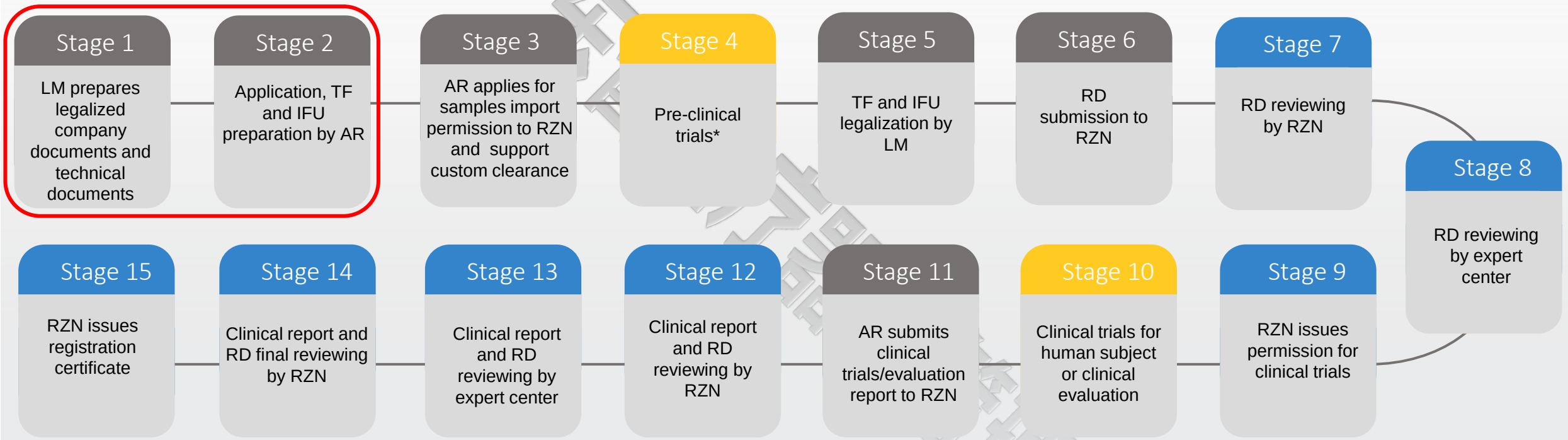


LM 法定制造商　AR 授权代表　TF 技术文件　IFU 使用说明书　RD 注册文档　RZN ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务　Lead Time 周期 7 - 9个月* *

技术试验* - 对于某些IVD产品（管，条等），生物相容性试验也是严格要求

**大致期限（自授权代表收到的文件和样品之日起）

Documents Preparation Stage文件准备阶段



LM and AR activities

Testing labs and clinical sites activities

RZN and expert centers activities

LM Legal Manufacturer

AR Authorized Representative

TF Technical File

IFU Instructions For Use

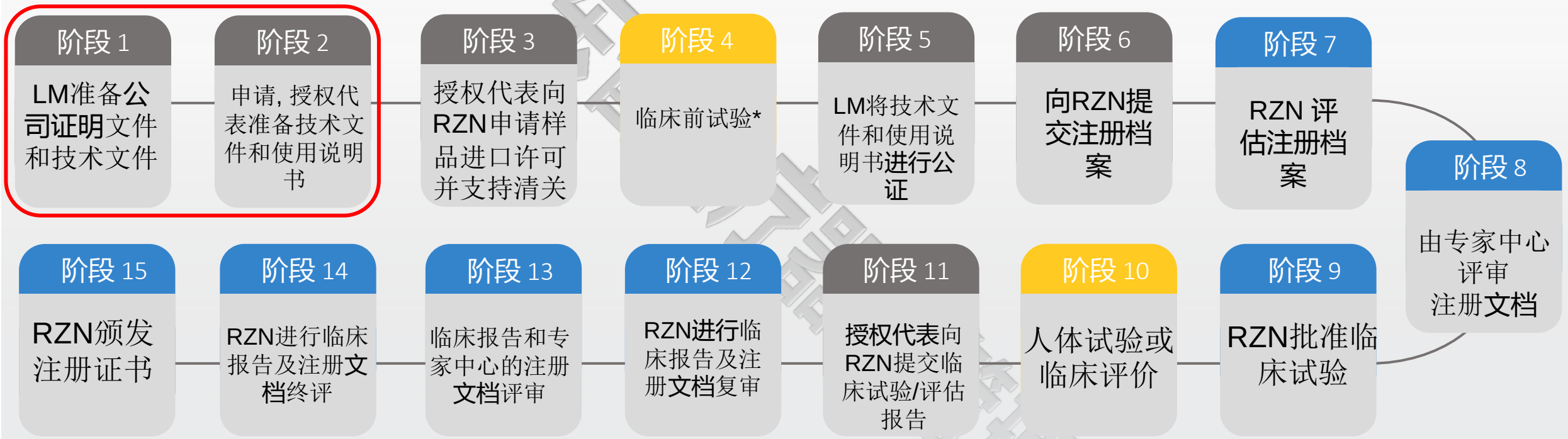
RD Registration Dossier

RZN ROSZDRAVNADZOR

Lead Time 7-9 months**

Chinese translation see next slide/中文翻译见下页

Documents Preparation Stage文件准备阶段



法定制造商和授权代表活动

测试实验室和临床机构活动

RZN和专家中心的活动

LM 法定制造商

AR 授权代表

TF 技术文件

IFU 使用说明书

RD 注册文档

RZN ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务

Lead Time 周期 7 - 9个月* *

Documents from Manufacturer Side (Main List)

制造商方面的文件（主要清单）

Company documents

Power of attorney (PoA - to provide registration process)
Manufacturer business license (BR - evidence that manufacturing company is registered as legal entity)
ISO 13485 (or another document about QMS or manufacturing license in country of original)
CE certificate + declaration of conformity (MDD 93/42/EEC or another applicable directive or state registration in country of origin)

Technical documents

Technical specification (including risk management file, clinical review, etc.)
User manual (IFU)
Photos (all models and accessorizes, all reference numbers)

公司文件

授权书（PoA - 授权进行注册）
制造商营业执照（BR-制造公司注册为法人实体的证据）
ISO 13485（或关于质量管理体系或原产国制造许可证的其他文件（如生产许可证）
CE证书+符合性声明（MDD 93/42 / EEC或其他适用指令或原产国的注册证）

技术文件

技术规范（包括风险管理文件，临床评审等）
用户手册（IFU）
照片（所有型号和配件，所有参考号码）

*通过链接检查技术文件要求和IFU的（11号 MoH法令）：
www.beawire.files.wordpress.com/2017/03/11n-from-10-03-2017.pdf

FFQ About Dossiers
(Documents from Manufacturer Side – Registration Process)
FFQ关于注册文档（制造商方面的文件 - 注册流程）

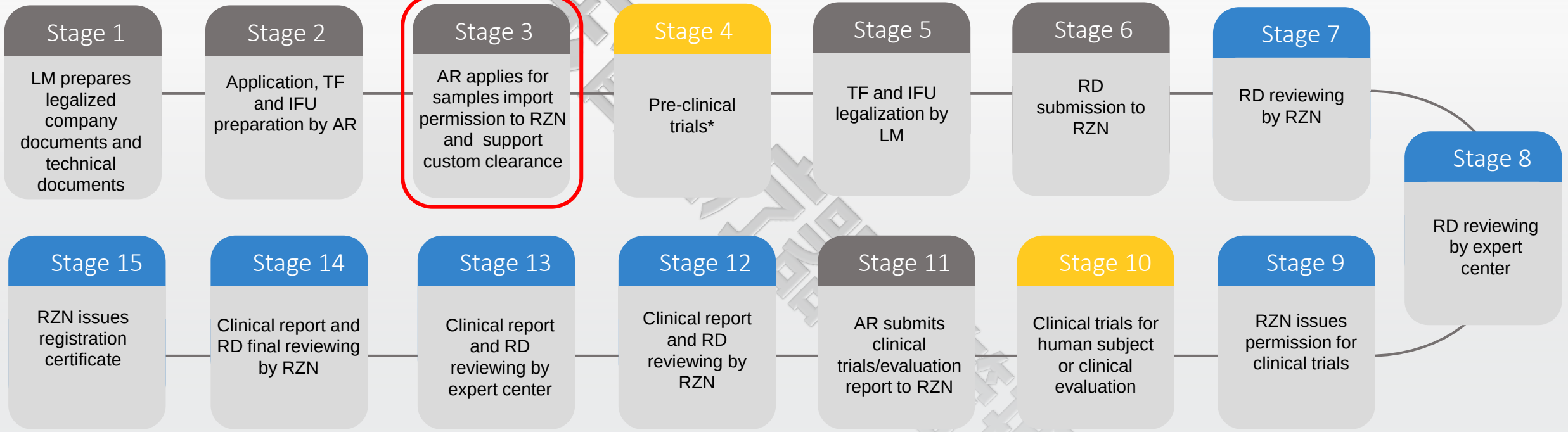
Common Problems	Why it is happened	How to solve
Documents from manufacturer side are not legalized	Manufacturer didn't do it before. Legalization process is long (especially when Russian Embassy involved)	Provide documents legalization – there are no ways to avoid this process
Manufacturer has no ISO 13485 certificate for factory site	Manufacturer has ISO 9001 Product is not a medical device in country of origin	ISO 9001 is acceptable also for all medical devices Manufacturing license is acceptable
Manufacturer couldn't provide risk management file or (and) clinical review	Product is not a medical device in country of origin. Manufacturer has no CE mark (and technical file for CE mark)	Could be prepared for registration process by BW team Same documents could be used if manufacturer prepared them separately

Chinese translation see next slide/中文翻译见下页

FFQ About Dossiers
(Documents from Manufacturer Side – Registration Process)
FFQ关于档案（制造商方面的文件 - 注册流程）

常见问题	为什么会这样	怎么解决
来自制造商方的文件 没有**进行公证**	制造商之前没有这样做过。 **公证**程序很**久** （特别是当 俄罗斯大使馆参与**时**）	提供**公证后的**文件 - 没有办法 避免这个过程
制造商不能**提供**ISO 13485证书	**该产品在**制造商**原产国不是器械，** 有iso9001**证书**	对于所有器械来说，ISO 9001证书 是可以接受的 制造许可证也是可以接受的
制造商不能 提供风险管理 文件或（和）临床**评估文件**	产品**在原产国**不是**器械**。 制造商没有CE标志 （以及**申请**CE标志的技术文件）	可以由BW团队在注册过程中如果制 如果造商单独准备了其他相关文件， 也可以用

Permission for Samples Import and Custom Clearance Stage样品进口许可及清关阶段



LM and AR activities

Testing labs and clinical sites activities

RZN and expert centers activities

LM
Legal Manufacturer

AR
Authorized Representative

TF
Technical File

IFU
Instructions For Use

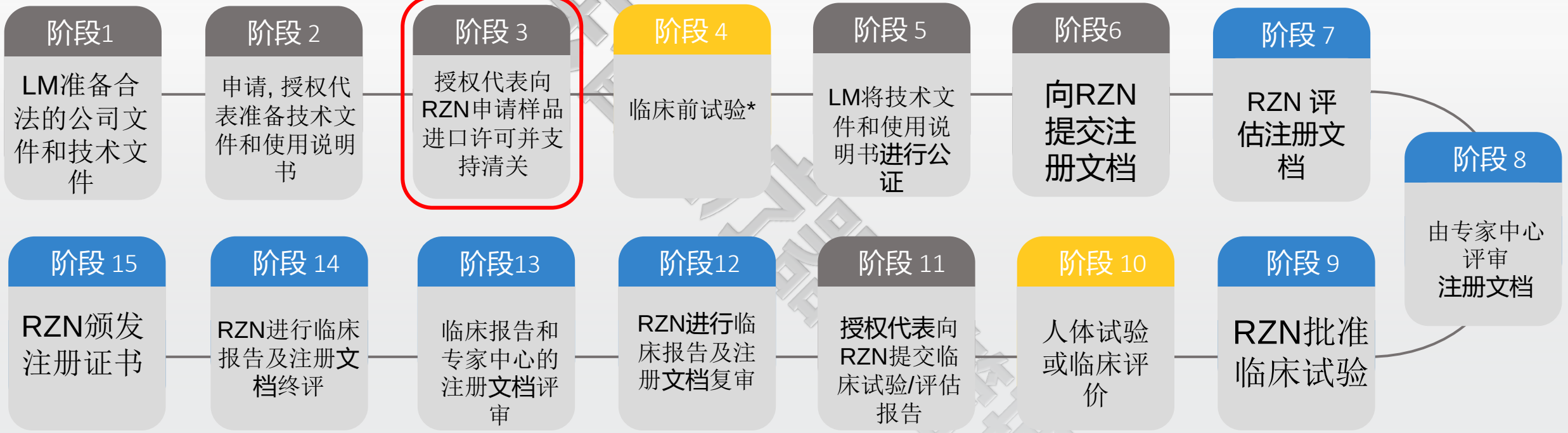
RD
Registration Dossier

RZN
ROSZDRAVNADZOR

Lead Time
7-9 months**

Chinese translation see next slide/中文翻译见下页

Permission for Samples Import and Custom Clearance Stage样品进口许可及清关阶段



法定制造商和授权代表活动

测试实验室和临床机构活动

RZN和专家中心的活动

LM 法定制造商

AR 授权代表

TF 技术文件

IFU 使用说明书

RD 注册文档

RZN ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务

Lead Time 周期 7 - 9个月* *

Permission for Samples Import and Custom Clearance

样品进口及海关清关

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6
LM sends samples info which will be shipped (lot, ref, manuf. date, expire date) to AR and PoA original	AR signs a contract with testing lab and applies for samples import permission to RZN	RZN issues permission for samples import*	LM sends samples, AR pays custom fees and arrange custom clearance	Custom check compliance and issue CCC	AR arrange samples delivery to the testing labs

LM and AR activities

RZN and expert centers activities

LM
Legal Manufacturer

AR
Authorized Representative

PoA
Power of Attorney (from LM to AR), will be used for registration process

CCC
Customs Cargo Declaration

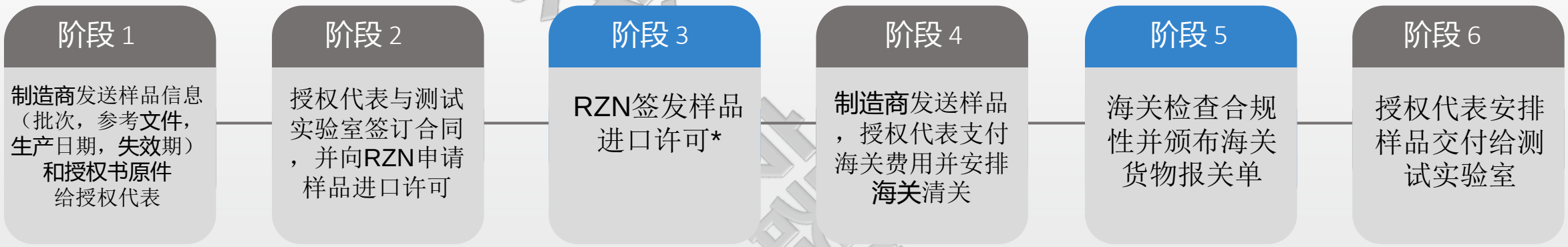
Lead Time
4 weeks**

Chinese translation see next slide/中文翻译见下页

*Check issued permissions for samples import
www.roszdravnadzor.ru/services/importmed

**approximate term (from the date of documents and samples receiving by AR)

Permission for Samples Import and Custom Clearance
样品进口及海关清关



法定制造商和授权代表活动

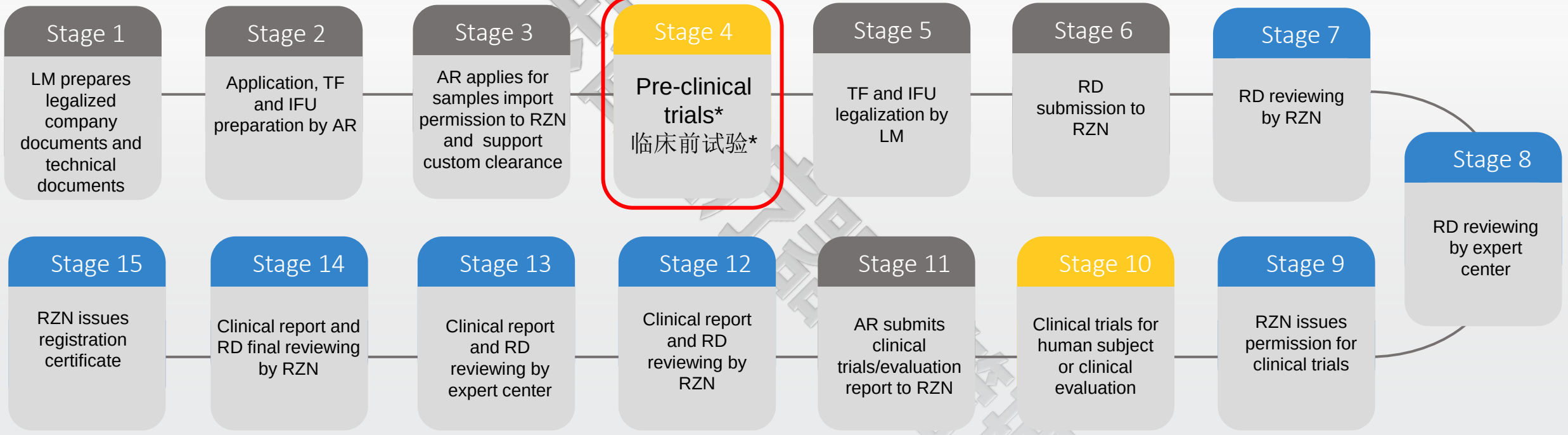
RZN和专家中心的活动

LM	AR	PoA	CCC	Lead Time
法定制造商	授权代表	授权书(（由制造商提供给授权代表，授权注册）	海关货物报关单	4 weeks** 周期 4周**

*检查已经颁发的样品进口许可证
*Check issued permissions for samples import
www.roszdravnadzor.ru/services/importmed

**大致期限(自授权代表收到文件和样品之日起)

Pre-clinical Trials Stage临床前试验阶段



LM and AR activities

Testing labs and clinical sites activities

RZN and expert centers activities

LM Legal Manufacturer

AR Authorized Representative

TF Technical File

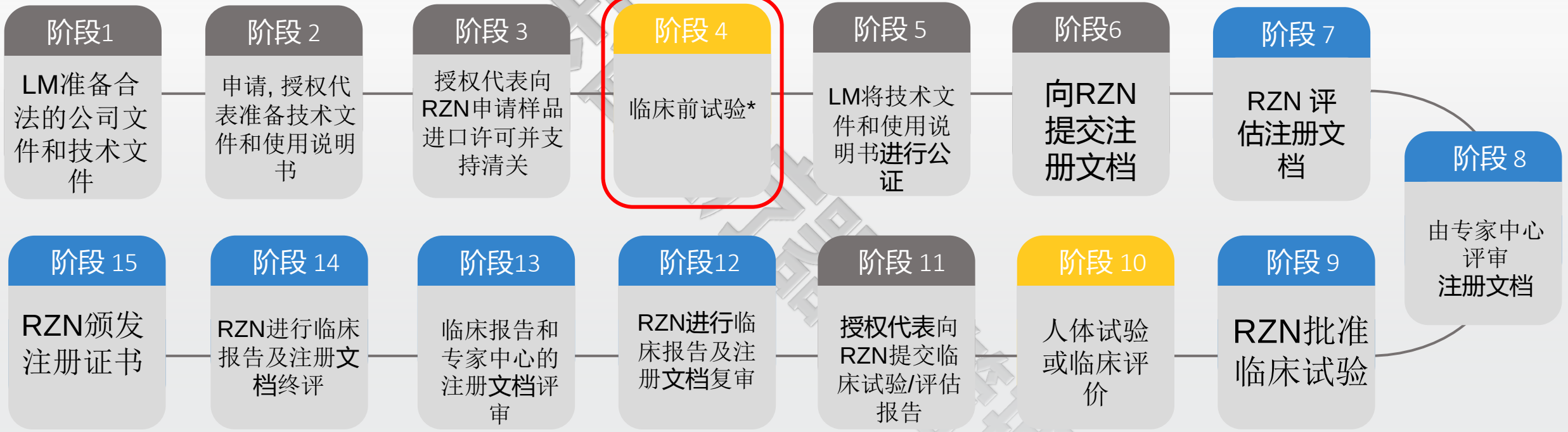
IFU Instructions For Use

RD Registration Dossier

RZN ROSZDRAVNADZOR

Chinese translation see next slide/中文翻译见下页

Pre-clinical Trials Stage临床前试验阶段



法定制造商和授权代表活动

测试实验室和临床机构活动

RZN和专家中心的活动

LM 法定制造商

AR 授权代表

TF 技术文件

IFU 使用说明书

RD 文档

RZN ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务

Lead Time 周期 7 - 9个月* *

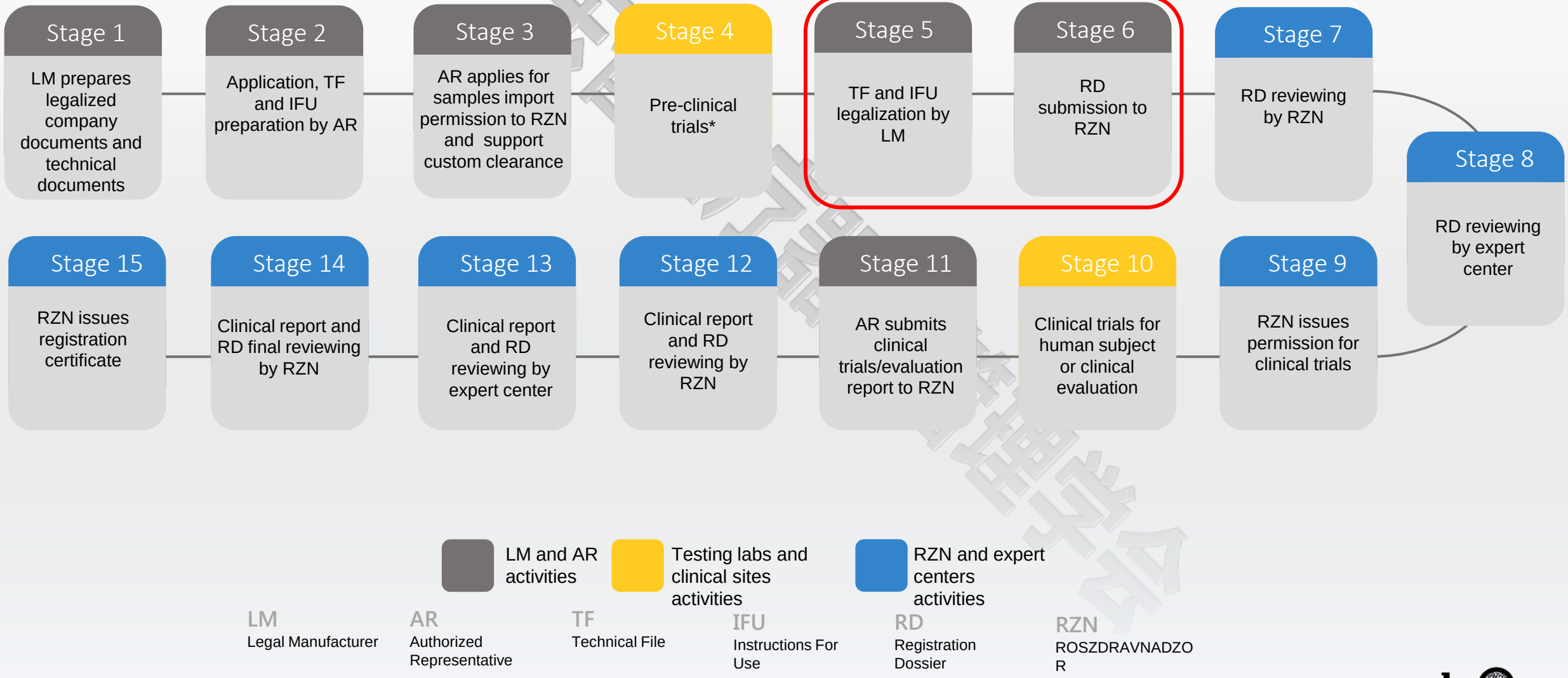
Pre-clinical Trials 临床前试验

Technical trials 技术试验	Safety + functional tests + EMC 安全+功能测试+ EMC
Toxicological testing 毒理学测试	ISO 10993 group of standards (for all surfaces which could be touched by patient or user)ISO 10993系列标准（适用于与患者或用户表面接触的产品）
Measuring function testing 测量功能测试	If medical device falls under order 89n - specific tests 如果医疗设备属于89n法令要求的特定测试

Pre-clinical Trials (Specific Points)
临床前试验（特定要点）

- Clear list of applicable standards for groups of medical devices (technical trials) – not exist
  清楚的医疗器械组（技术试验）适用标准清单 - 不存在
- Both expert centers (VNIIIMT and CMIIKEE) have own meaning about applied standards and dossier properties 两个专家中心（VNIIIMT和CMIIKEE）对应用标准和**文档特性**都有自己的定义
- A lot of national Russian standards (which are not harmonized) – must be applied for medical device (GOST R 50444-92 as most popular example)
  很多俄罗斯国家标准（**非协调标准**） - 医疗器械**必须要采纳**（GOST R 50444-92**是**最常见的例子）
- Specific requirements for labeling 标签的**特殊**要求
- Registration requirements could be changed each 6 months (officially and non-officially)
  注册要求可以每6个月更改一次（正式和非正式）

Submission 提交



LM
Legal Manufacturer

AR
Authorized Representative

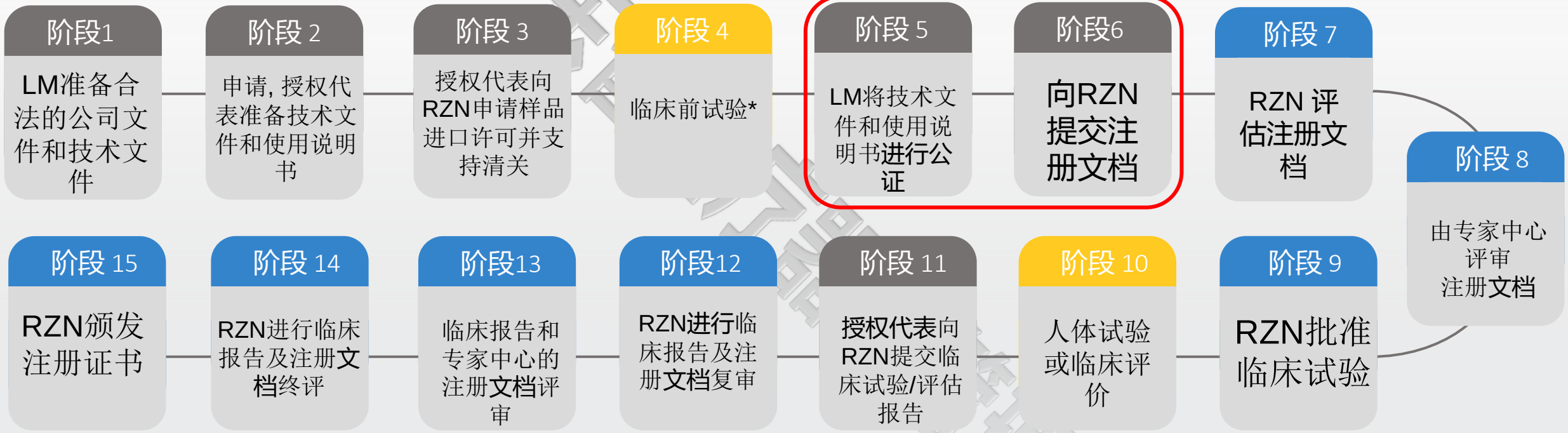
TF
Technical File

IFU
Instructions For Use

RD
Registration Dossier

RZN
ROSZDRAVNADZOR

Submission 提交



法定制造商和授权代表活动

测试实验室和临床机构活动

RZN和专家中心的活动

LM 法定制造商

AR 授权代表

TF 技术文件

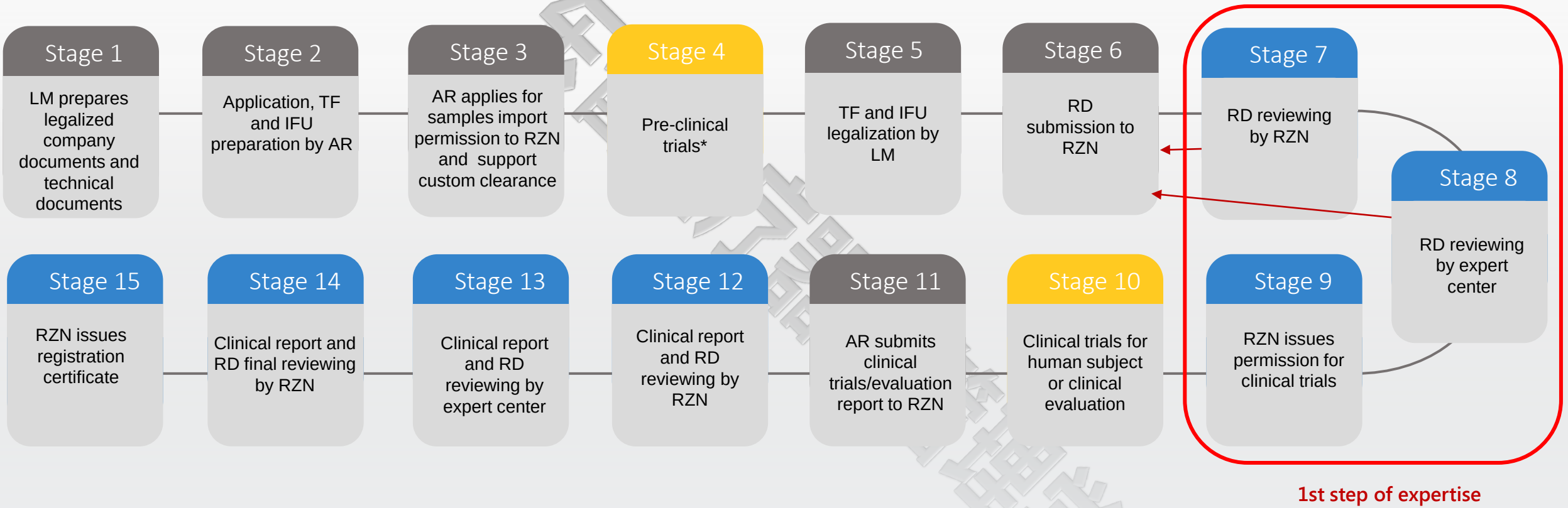
IFU 使用说明书

RD 注册文档

RZN ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务

Lead Time 周期 7 - 9个月* *

1st Step of Government Expertise 政府专家意见的第一步



LM Legal Manufacturer

AR Authorized Representative

TF Technical File

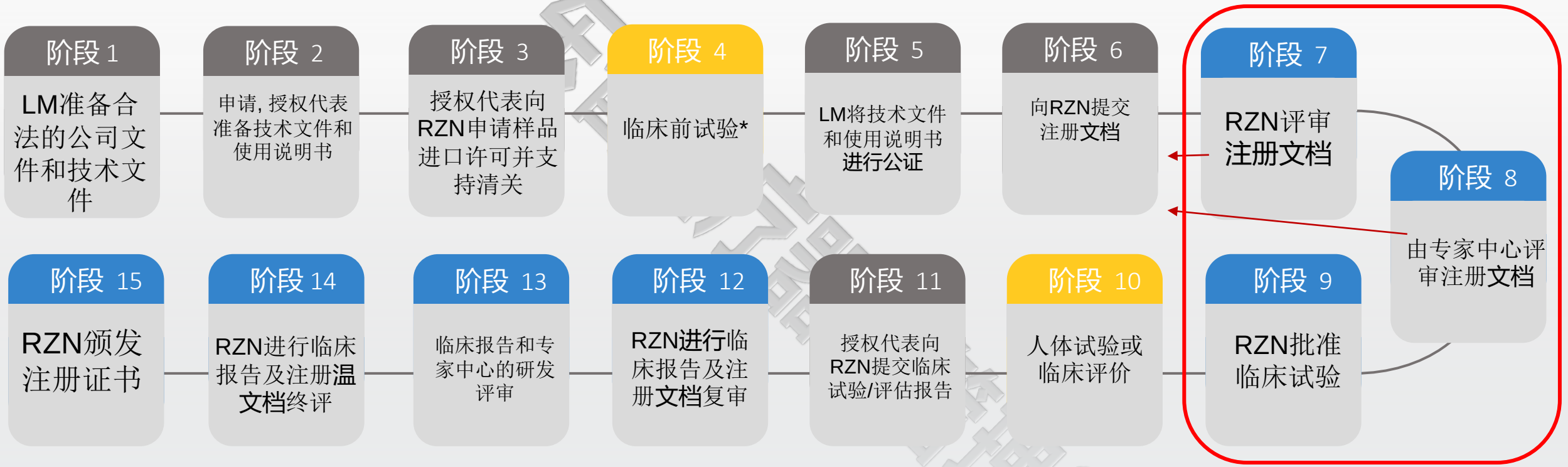
IFU Instructions For Use

RD Registration Dossier

RZN ROSZDRAVNADZOR

Chinese translation see next slide/中文翻译见下页

Main Stages of Registration Process (2a, 2b, 3 Risk Class) 注册流程的主要阶段（2a，2b，3风险级）



1st step of expertise
第一步专家评审

法定制造商和授权代表活动

测试实验室和临床机构活动

RZN和专家中心的活动

请求额外的信息

LM 法定制造商

AR 授权代表

TF 技术文件

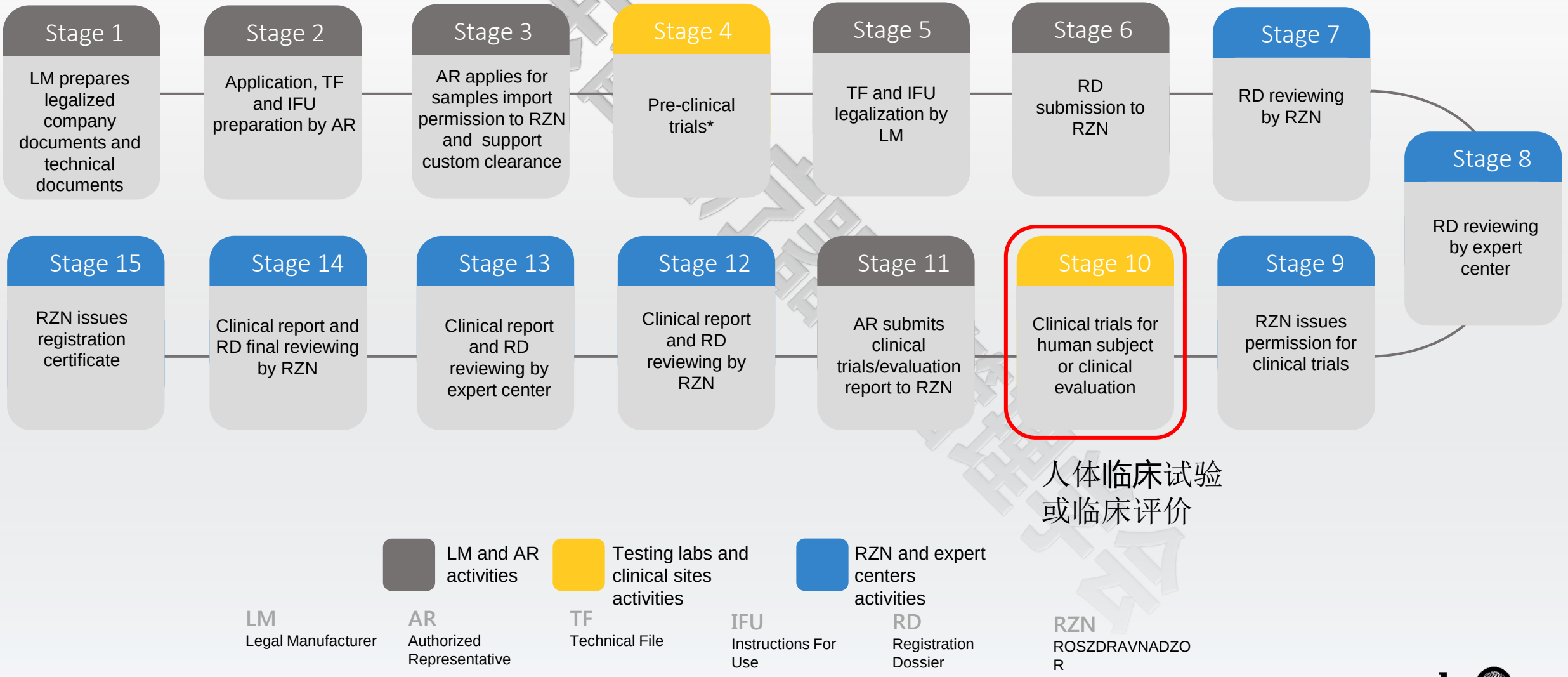
IFU 使用说明书

RD 注册档案

RZN ROSZDRAVNADZOR 医疗保健和社会发展领域的监督联邦服务

Lead Time 周期 7 - 9个月* *

Clinical Trials Stage临床试验阶段



Clinical Trials Definition in Russian Law

俄罗斯法律中的临床试验定义

Clinical trials (part of conformity assessment)
临床试验（**符合性评估**的一部分）

Clinical evaluation on the of accredited clinical site
认可的临床机构出具的临床评估报告

GOST R 56429- 2015

Clinical investigations for human subject in the accredited clinical site
在认可的临床**机构**进行**人体**临床研究

GOST R ISO 14155-2014

210 accredited clinical sites with different accreditation scope
210个具有不同**认可**范围的**临床机构**

通过链接**查询获得认可的**临床机构
Check accreditation of clinical site by link:
www.roszdravnadzor.ru/services/clinicaltrials

When Clinical Investigations for Human Subject is Required? (By Moh Decree № 2n)什么时候需要人体临床试验？

（根据Moh № 2 号法令）

一款新型医疗设备
A new type of medical device

应用新的复杂或独特或特殊的疾病和病症的预防，诊断和治疗方法，以及应用新的和复杂的医疗技术
Application of new complex or unique or special methods of prevention, diagnosis and treatment of diseases and conditions, and the application new and complex medical technologies

如果临床评估**没法正面**医疗器械的性能和安全性
If the clinical evaluation do not verify the performance and safety of medical device

Clinical investigations for human subject in the accredited clinical site
在获得认可的临床机构进行人体临床试验

When Clinical Evaluation is Enough?

什么时候临床评估就够了？

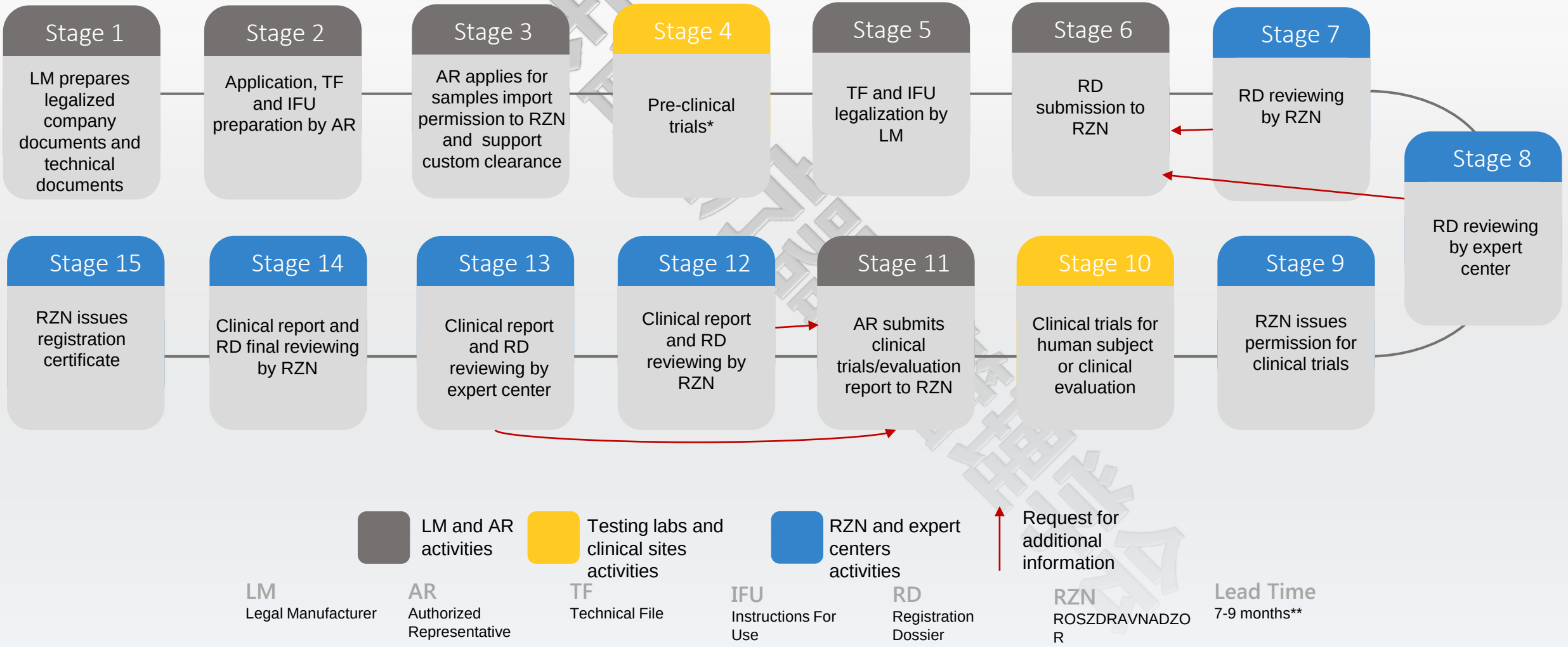
在俄罗斯市场注册的可对比（通用）器械	风险管理文件（ISO 14971）+俄罗斯境外的上市后监督信息	科学文章+临床评论
Comparable (generic) device registered in Russian Market	Risk management file (ISO 14971) + Post Market Surveillance information outside Russia	Science articles + clinical review

Clinical evaluation on the base of accredited clinical site
获得认可的临床机构出具的临床评价报告

Key Points for Successful Clinical Evaluation Report
成功的临床评估报告的要点

- Compliance of information in clinical evaluation report with information in Technical File and IFU　临床评估报告中的信息与技术文件和IFU中的信息一致
- Scientific articles and investigations with human which verify performance and safety
科学文献和人体试验用于验证产品性能和安全性
- Chosen comparable device registered in Russia before has same features
选择在俄罗斯注册的具有相同的特点的可对比器械
- Clinically relevant corrective actions (adverse events, recalls, suspensions)
临床相关的纠正措施（不良事件，召回，暂停销售）
- Experienced accredited clinical site for effective coordination
与经历丰富的临床机构进行有效的合作
- All additional data providing requested by clinical site.
给临床机构提供其所要求的所有额外数据。

Request for Additional Information发补信息



LM Legal Manufacturer

AR Authorized Representative

TF Technical File

IFU Instructions For Use

RD Registration Dossier

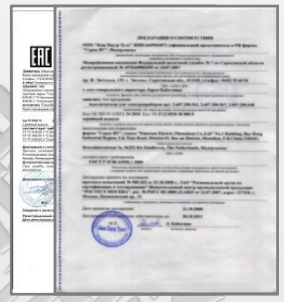
RZN ROSZDRAVNADZOR

Lead Time 7-9 months**

IVD Registration Process (Specific Points)
IVD注册流程（特定要点）

- High risk classification (no specific classification rules for IVD)
  高风险分类（IVD没有特定的分类规则）
- Big quantity of registration certificates (each reagent must be registered separately as usual) – on the base on classification rules (Order #4n)
  大量的注册证书（通常每个试剂必须单独注册）- 基于分类规则（＃4n法令）
- Clinical trials (Clinical evaluation + Clinical investigation)
  临床试验（临床评估+临床调查）
- Clinical trials for close system could be provided only together for all devices (despite of quantity of approval processes)
  器械系统的临床试验只能是系统里面的所有器械一起提供（尽管有大量的审批程序）
- Biocompatibility trials are not required for biggest part of products
  大部分产品不需要生物相容性试验

Declaration Processes 声明流程

Registration process	Declaration process
	
No expiry date (see EEU regulation)	DoC GOST R 3 years DoC CU TR #20 5 years
Notified Authority: Roszdravnadzor - RZN (MoH/Russia) + expert centers (VNIIIMT or CMIIKEE)	Notified Body: certification center in Russia
Kind of approval: State registration as medical device (mandatory)	Kind of approval: Safety declaration (if applied for current product)
Time: 5-9 months	Time: 1-2 weeks

Chinese translation see next slide/中文翻译见下页

Declaration Processes 声明流程

注册流程
Registration process

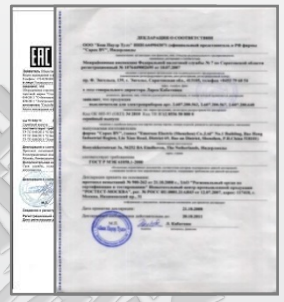
没有有效期
（见EEU规定）

通知机关：
Roszdravnadzor - RZN（卫生/俄罗斯）
+专家中心（VNIIIMT或CMIIKEE）

批准种类：
国家注册为
医疗器械（强制性）

时间：5-9个月

声明程序
Declaration process



DoC GOST R
3 年
DoC CU TR
#20
5 年

公告机构：
俄罗斯认证中心

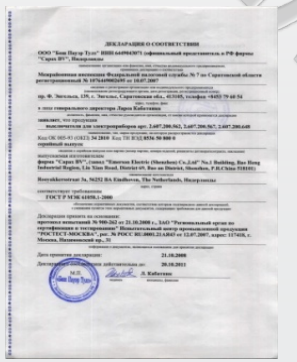
批准种类：
安全声明
（如果当前产品适用）

时间：1-2周

| Declaration Processes – GOST R　声明流程 - GOST R

Type of procedure depends on OKP classification
(according to order of RF government #982 from 01/12/2009)
流程类型取决于OKP分类
（根据RF政府令＃982 2009年12月1日起）

Declaration of Conformity
符合性声明



Certificate of Compliance
合格证明书

强制性
- 取决于OKP类
声明
3年有效期
需要当地持证人

Mandatory
– depends on OKP class
Declaration
3 years validity
Local Holder required

Voluntary
Certification
3 years validity
Local Holder is not required

自愿性
证书
3年有效期
不需要当地持证人

Declaration Processes – EAC MARK 申报流程 - EAC 标志

Type of procedure according to CU TR 020\2011
(electromagnetic compatibility – only for electrical medical devices)

Declaration of Conformity

Mandatory –
if medical device is electrical product
Declaration
5 years validity
Local Holder required

Declaration process – GOST R and CU TR

NB = Notified Body.
Testing – in accredited lab (test reports from registration process could be used).
Declaration registration (local confirm draft and sign, after that it is issued by notified body).
Lead time – 1-2 weeks.

Application 申请 → Testing 测试 → Declaration registration by NB 向NB申请符合性声明的注册

Chinese translation see next slide/中文翻译见下页

| Declaration Processes – EAC MARK 声明流程 - EAC 标志

根据CU TR 020 \ 2011的程序类型
（电磁兼容性 - 仅适用于电子类医疗器械）

产品符合性声明

强制要求-如果医疗器械是电气产品

声明

5年有效期

要求当地持证人

声明程序- GOST R和CU TR

公告机构。

测试-在认可的实验室(可以使用注册过程中的测试报告)。

声明注册(当地确认草案并签字后，由公告机构出具)。

周期： 1-2周。

EAC

Application 申请 > Testing 测试 > Declaration registration by NB 由公告机构发布声明 注册证

THANK YOU
感谢!

beawire.com
info@beawire.com

Ruslan.Kalachev@beawire.com
+7(499)281-67-68 (ext. 101)
+7 (968)968-11-84 (cellphone, WhatsApp, WeChat)

深圳市领先医疗服务有限公司
Shenzhen Advanced Medical Services Co., Ltd

beawire

扫一扫上面的二维码图案，加我微信

本课件由深圳市领先医疗服务有限公司进行翻译，仅供学习参考。