The Role of Real-World Evidence in Regulatory Evaluation of Medical Devices – A Global Review

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Conflicts of Interest

- Lizheng Shi, PhD, MA, MsPharm, is the Endowed Regents Professor, Interim Chair and Director of the Health Systems Analytics Research Center in Tulane University, declaring no conflicts of interest.

- Dongyi (Tony) Du, PhD, MD, MS, is the Assistant Director at the Center for Devices and Radiological Health at the FDA, declaring no conflicts of interest. This speech reflects the views of the participant and should not be construed to represent FDA's views or policies.

- Mei Yang, PhD, MA, is the Vice President of innovative Healthcare Solutions Global in Happy Life Tech, a data science company providing research and solutions to pharmaceutical, biotech, and medical device companies and contract research organizations (CROs).

- Carol Bao, PhD, MA, is the Vice President of Global HEOR Strategy, Neuroscience, Eye Care and General Medicine at AbbVie, a biopharmaceutical company.

Panelist

Lizheng Shi, PhD, MA, MsPharm

Moderator
Endowed Regents Professor, Interim Chair, Director, Health Systems Analytics Research Center, Tulane University

Mei Yang, PhD, MA

Panelist
Vice President, innovative Healthcare Solutions Global, Happy Life Tech

Carol Bao, PhD, MA

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Dongyi (Tony) Du, PhD, MD, MS

Panelist
Assistant Director, Methods, Analysis and Infrastructure Team 1, DCEA1/OCEA CDRH/FDA

Agenda

Overview of real-world evidence (RWE) in regulatory evaluation of medical devices

Case 1: RWE test cases by the National Evaluation System for health Technology (NEST)

Case 2: Use of RWE to support regulatory decisions on devices in China and the Boao opportunity

Case 3: A successful Boao case - accelerated approval of XEN® in China using domestic RWE generated in Boao

The Role of Real-World Evidence for the Evaluation of Medical Devices in the Regulatory Environment and NEST Test Cases

Lizheng Shi, PhD, MA, MsPharm

History of the US Regulatory Evaluation of Medical Devices Using Real-World Evidence (RWE)

The United States

Aug. 2016

The FDA and the Medical Device Innovation Consortium (MDIC) established a Coordinating Center for NEST (NESTcc)

Dec. 2016

"21st Century Cures Act"

Aug. 2017

FDA Guidance: "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices"

Nov. 2018

NESTcc Announced 8 RWE Test-Cases

Nov. 2019

NESTcc Announced 12 Additional RWE Test-Cases

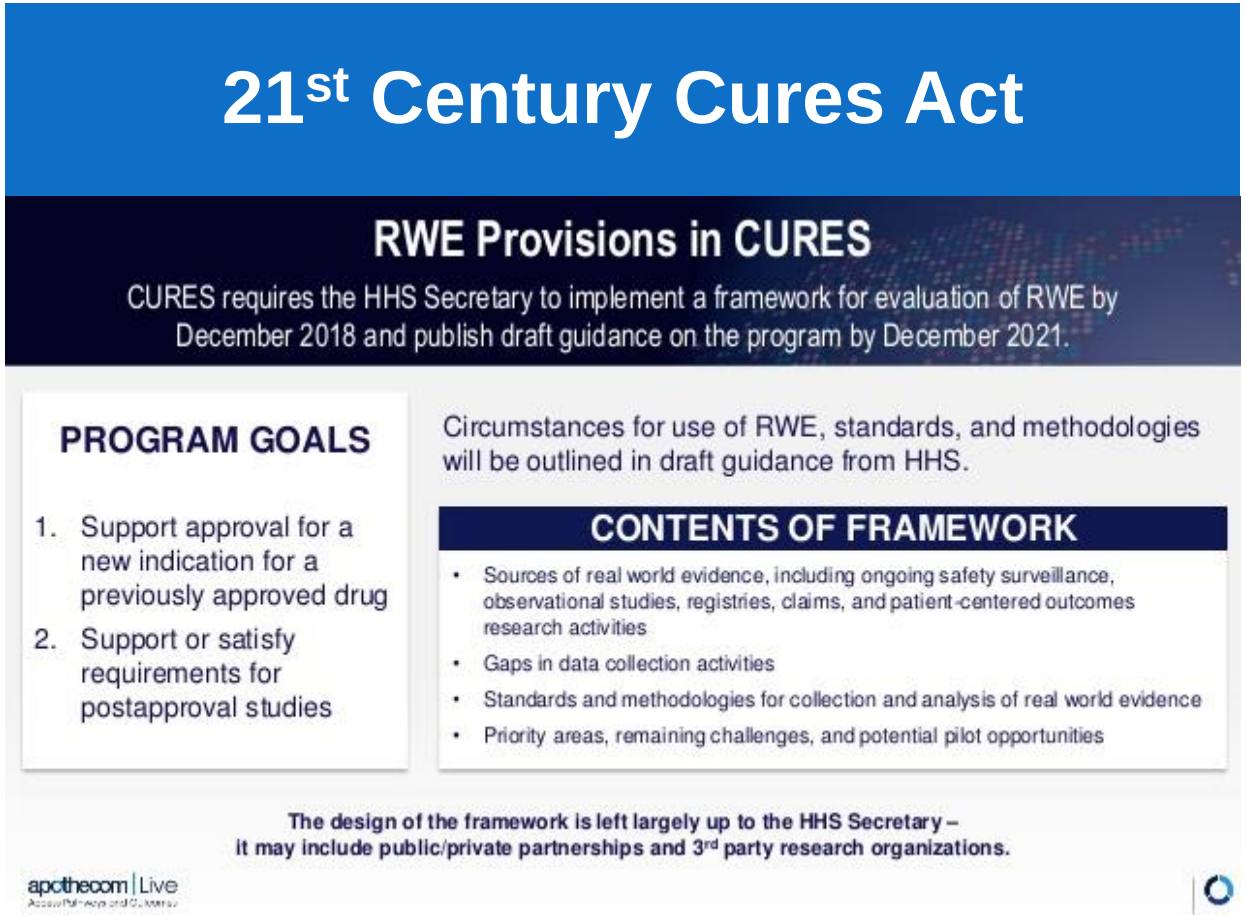
Feb. 2020

"NESTcc Methods Framework"; "NESTcc Data Quality Framework"

Mar. 2021

FDA/CDRH Report: "Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions"

The 21st Century Cures Act



Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

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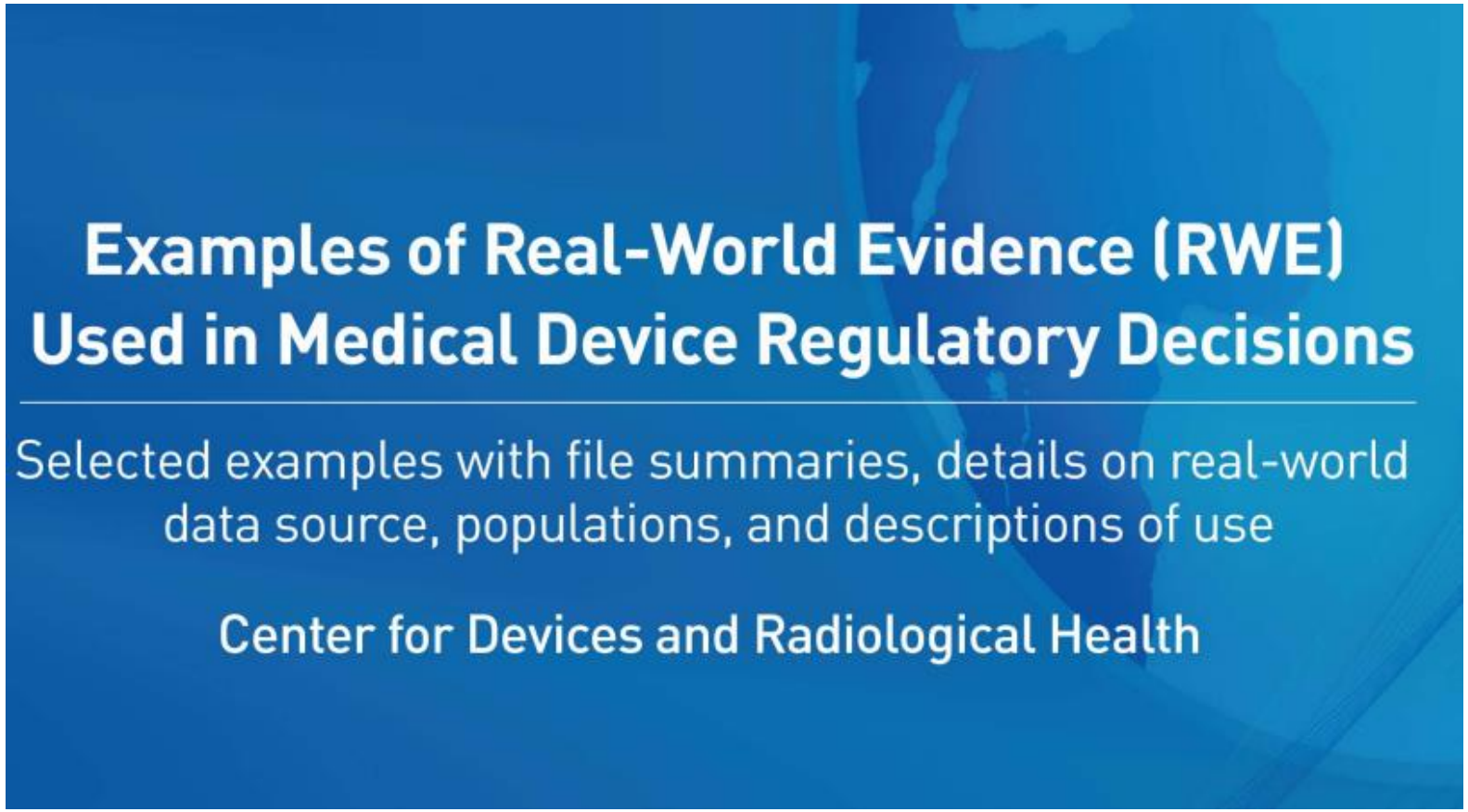
Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

CDRH Published 90 Examples Using RWE for Regulatory Submissions



National Evaluation System for Health Technologies (NEST)

NEST
Coordinating Center
An initiative of MDIC

Test-Cases

Overview

In November 2018, NESTcc announced eight Test-Case projects that reflect the diversity of types of medical devices available and the different uses of data in pre-market and post-market settings. In November 2019, 12 additional Test-Cases were announced.

NESTcc's Test-Cases include projects along the 510(k) and premarket approval regulatory pathways, across nine disease areas, and throughout the medical device Total Product Life Cycle (TPLC). Test-Case concepts were solicited from stakeholders across the ecosystem, including health systems, government organizations, non-profit patient organizations, and medical device manufacturers.

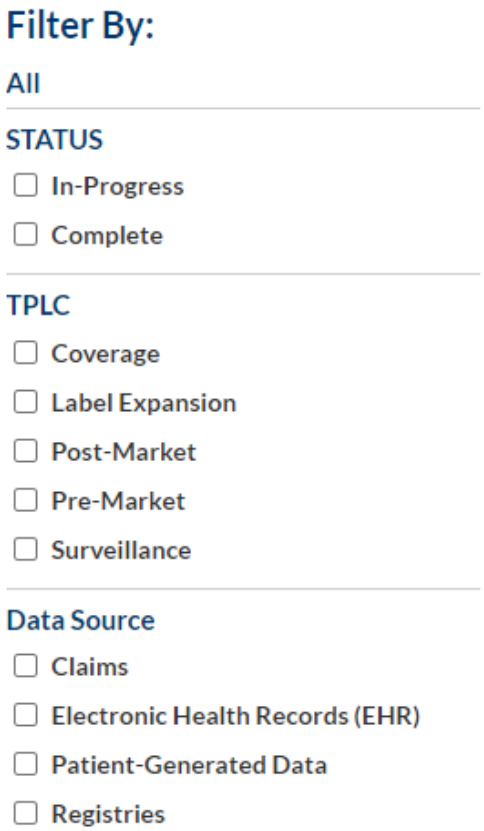
✓ Objective 1

Explore the feasibility for medical device ecosystem stakeholders to work with Real-World Data (RWD) sources and NESTcc's initial set of Network Collaborators.

✓ Objective 2

Help identify areas where NESTcc could play a role in reducing transaction costs (e.g., contracting, Institutional Review Board [IRB], data sharing agreements, publication policies).

Test-Case Snapshots



Interim Report of the RAND Independent Assessment of the NESTcc Test-Cases

Using Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices

Interim Report on Lessons from the National Evaluation System for health Technology Coordinating Center (NESTcc) Test-Cases

Justin W. Timbie, Thomas W. Concannon, Alice Y. Kim, Lawrence Baker, Grace Gahlon, Rosemary Li

Independent assessment of the NESTcc Test-Cases: RAND interim report - NESTcc

Key Lessons Learned from RAND Interim Assessment of the Test Cases

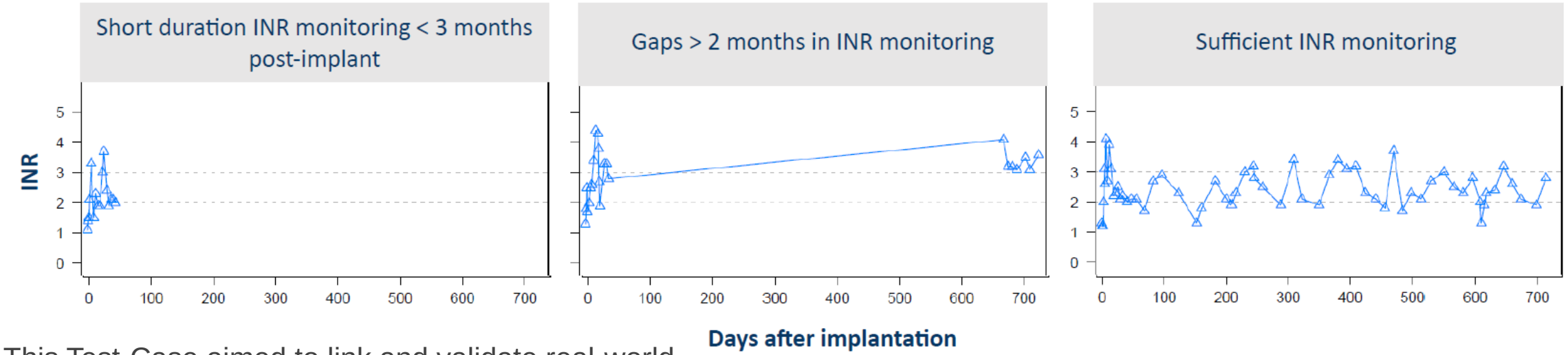
- **Research and Data Challenges**
  - Variation in data formats and data generation practices
  - Extraction of RWD elements
  - Lack of long-term follow-up
  - Data completeness.
  - Difficulties in identifying devices, study population, and small sample size
  - Granularity and reliability of coding systems.
  - Data sharing and data privacy

- **Keys to Success**
  - Robust data sources: CDM, NLP, Use of existing registries, Use of manufacturer data
  - Multidisciplinary team
  - Cross validation in results by different RWD.

A Brief NEST Test Case: Development of RWE Related to Mechanical Heart Valve Replacement

Subject Characterization | INR Management

Subjects' INR follow-up could be divided into three patterns:

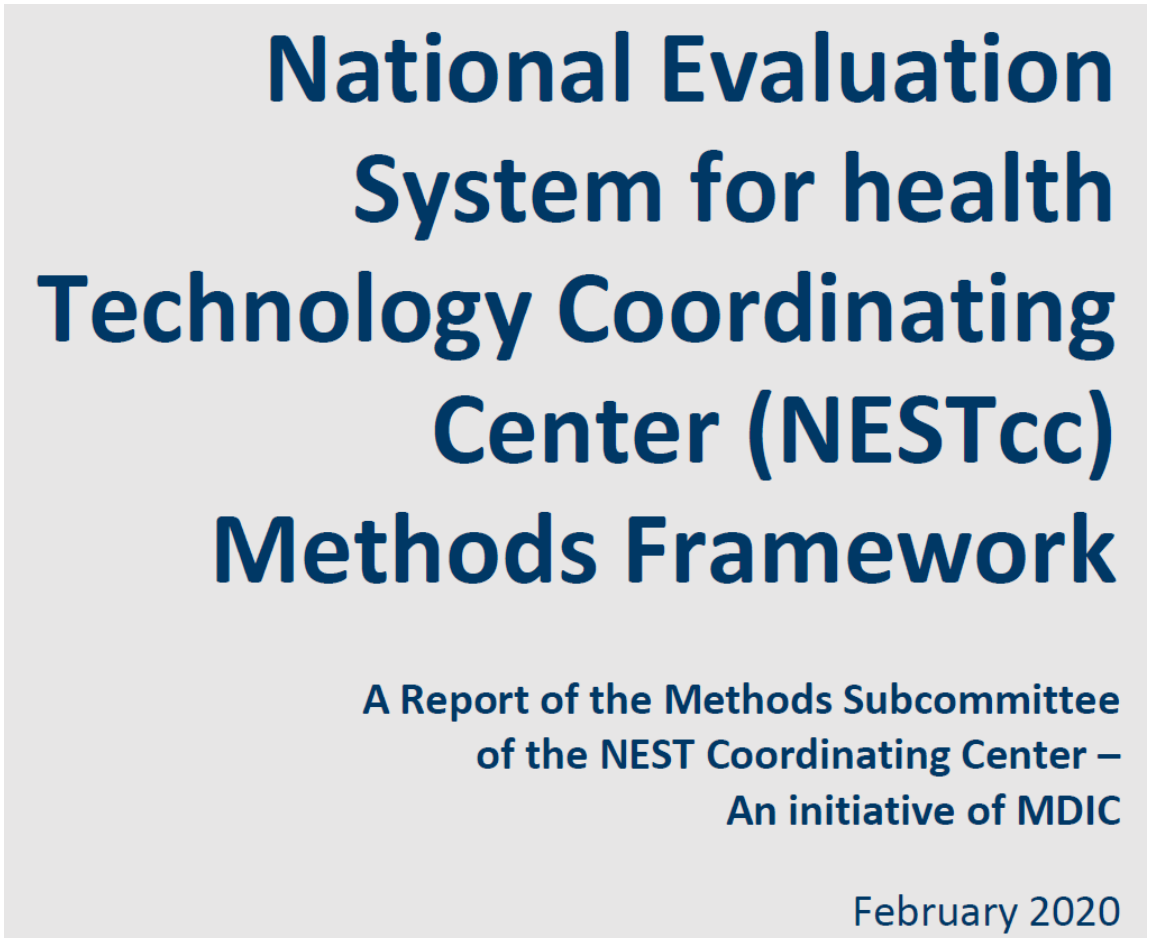


This Test-Case aimed to link and validate real-world EHR data from two sites with a manufacturer implant registration database.

Source: Vanderbilt University Medical Center

Note: Each graph depicts data of one anonymous patient selected for illustration purposes.

Methods Framework and Data Quality Framework



It’s Time for a Poll

- Have you tried using RWE for regulatory pathway in your country?
  - Yes
  - No

It’s Time for a Poll

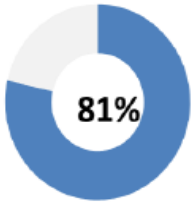
- How confident are you about the future of RWE use in medical device accelerated approval in your country?
  - Very confident
  - Somewhat confident
  - Not confident
  - Don’t think it will happen

Take-Home Message

Data Standards

Stakeholder Engagement

FDA'S THERAPEUTIC AREA STANDARDS PROJECT



Of the 54 TAs prioritized, 44 have started with 21 of those completed as of Feb 2017

Duke | MARGOLIS CENTER *for* Health Policy

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Guidances

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers

Draft

Draft Use of Electronic Health Record Data in Clinical Investigations

Demonstration Projects

Electronic Source Data in Clinical Investigations

Use of Electronic Informed Consent

Happy Life Tech

Use of real-world evidence to support regulatory decisions on medical devices in China

Mei Yang, PhD

Background

Introduction of Medical Devices of Their Registration Process in China

- **Medical devices** are defined as instruments, equipment, appliances, in vitro diagnostic products, materials, and other similar items used directly or indirectly on the human body (e.g., software).
- In China, the **National Medical Products Administration (NMPA)** reviews and decides whether to approve the registration applications based on safety, effectiveness, and quality assessments.

Three Classes and Registration

Class I Devices

- ***Low-risk*** devices that require general control, such as bandages, exam gloves.

Class II Devices

- ***Intermediate-risk*** devices that require strict control, such as suture needle and electrocardiograph.

Class III Devices

- ***High-risk*** devices that require special strict control, such as implantable pacemaker.

- Applicants should provide relevant materials to the NMPA for records
- The NMPA reviews the applications, and issues "***Medical device registration certificate***" after approval.

Special Registration Program

Three types of devices could be prioritized:

- ***Innovative devices***: for imported innovative devices, overseas market approval is not required*;
- Devices for ***urgent and unmet clinical needs***;
- Devices for ***public health emergencies***.

*Otherwise, proof of overseas market approval is required for imported devices

References:
1. National Medical Products Administration. What are medical devices? [updated 10/25/2017. Available from: https://www.nmpa.gov.cn/xxgk/kpzhsh/kpzhshylqx/20171025134201114.html.
2. The State Council of the People's Republic of China. Regulations on the supervision and administration of medical devices. [updated 3/18/2021. Available from: http://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm.
3. Guangdong Medical Products Administration. What are the classification standards and methods for medical devices? [updated 10/21/2020. Available from: http://mpa.gd.gov.cn/dawenku/ylqx/content/post_3107270.html.
4. National Medical Products Administration. Solicitation of comments on the draft of "Regulations on Medical Device Registrations". [updated 3/26/2021. Available from: https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20210326094015179.html.

Guideline

国家药品监督管理局
National Medical Products Administration

In 2020, the NMPA issued a draft guideline on the "**Use of real-world data to support clinical evaluation for medical devices**".

Data Quality

The guideline emphasizes the **quality of RWD**; two key elements of RWD quality assessment are:

- ***Data relevance*** mean if data are sufficient for answering all the clinical questions relevant to a given research objective.
- ***Data reliability*** relies on the accuracy of data collection.

Data Sources

- Electronic medical records (EMRs) from hospitals
- Healthcare claims data
- Personal health records
- Medical device registries, etc.

Examples of RWE Used in Regulatory Decisions

The guideline suggests that **RWE** derived from RWD could support clinical evaluation throughout the **lifecycle** of a medical device, some examples are:

- ***External control group*** for single-arm trial
- ***Modification of indications*** and contraindications
- Postmarket research as ***condition of approval***
- ***Long-term safety and effectiveness*** evaluation of high-risk medical devices
- ***Postmarket surveillance studies***
- Clinical evidence for the ***same type*** of medical devices
- Clinical evaluation of medical devices for ***rare diseases***
- ***Supplementary data***, etc.

Reference:
1. National Medical Products Administration. Use of real-world data to support clinical evaluation for medical devices. 2020. p. 1-13.

Challenges and Potential Solutions

Challenges

Limited data accessibility and data sharing

- EMR systems are disconnected
- No public access to the medical claims data from the national social insurance system, which covers over 95% of the Chinese population

The accuracy, completeness, and consistency of data

- Lack of systematic technical guidance for data collection or data quality control
- Data quality and completeness vary by hospitals and regions
- Lack of device-specific outcomes in EMRs, e.g., calibration records, unique device identifiers

Gap between the limited research capacity and the great demand

Potential Solutions

- Develop policies to increase data access and sharing, strengthen privacy protection, and improve ethical approval process
- Establish a national integration and data sharing platform

- Develop systematic technical guidance
- Improve data quality by the type of data (e.g., EMRs, claims data, registries)

- Develop rigorous academic programs and foster the next generation of talents and leaders in the field of RWE research

References:
1. Zhang L, Wang H, Li Q, Zhao M-H, Zhan Q-M. Big data and medical research in China. BMJ. 2018;360:j5910.
2. Sun X, Tan J, Tang L, Guo JJ, Li X. Real world evidence: experience and lessons from China. BMJ. 2018;360:j5262.
3. Wang Z. Data integration of electronic medical record under administrative decentralization of medical insurance and healthcare in China: a case study. Israel journal of health policy research. 2019;8(1):24.
4. Liu B. Review of the problems and future development of hospital information system in the era of big data. Technology and Economic Guide. 2018;26(25):194-213.

Hainan Boao Pilot Zone: A Unique Opportunity for Innovative Medical Devices to Gain Accelerated Approval in China

2018

Chinese government authorities issued a series of policies to guide the **use of RWE** in accelerating the **market approval** of **innovative drugs** and **medical devices**.

June 2019

The **"Hainan Boao Lecheng International Medical Tourism Pilot Zone"** was initiated by the NMPA and the Hainan Provincial Government.

Sep 2019

The "Implementation Plan" specified that qualified **RWD** collected in **Boao Lecheng** could support **registration application** of innovative **drugs** and **medical devices**, which have been **approved abroad**, and meet **urgent** and **unmet** medical needs in China.

March 2020

XEN® was **approved** in China as the **first medical device** using **domestic RWE** (generated in **Boao**) for registration.

2021

The **"Boao Lecheng Real-World Data Platform"** went live, which could be used to collect RWD and generate RWE for various researches

References:
1. The State Council of the People's Republic of China. Decisions made by the State Council regarding temporary revisions of relevant provisions in the "Regulations for the Implementation of the Drug Administration Law of the People's Republic of China" in the International Medical Tourism Pilot Zone in Boao Lecheng, Hainan. 2018 [Available from: http://www.gov.cn/gongbao/content/2019/content_5355468.htm.
2. The State Council of the People's Republic of China. Decisions made by the State Council regarding suspended implementation of relevant provisions in the "Regulations on the Supervision and Administration of Medical Devices" in the International Medical Tourism Pilot Zone in Boao Lecheng, Hainan. 2018 [Available from: http://www.gov.cn/zhengce/content/2018-04/08/content_5280499.htm.
3. The State Council Information Office of the People's Republic of China. Notice by the People's Government of Hainan Province regarding the temporary provisions of regulations on clinically urgently needed imported drugs in the International Medical Tourism Pilot Zone in Hainan Boao Lecheng. 2019 [Available from: http://www.scio.gov.cn/xwfbh/xwbfbh/wqfbh/39595/41683/xgzc41696/Document/1664324/1664324.htm.
4. The People's Government of Hainan Province. Notice by the People's Government of Hainan Province regarding "Temporary Provisions of Regulations on Urgently Needed Imported Medical Devices in the International Medical Tourism Pilot Zone in Hai-nan Boao Lecheng". 2020 [Available from: https://www.hainan.gov.cn/hainan/fzfzsx/201805/81829f8a42084f06bd5fdc00f0cd1e0f.shtml.
5. Hainan Medical Products Administration. The People's Government of Hainan Province and the National Medical Products Administration discuss medical products' reform and development. 2019 [Available from: https://amr.hainan.gov.cn/himpa/sytpxw/201906/t20190624_2609504.html.
6. The State Council of the People's Republic of China. Notice of the "Implementation Plan of the International Medical Tourism Pilot Zone in Hainan Boao Lecheng" by the National Development and Reform Commission and three other national organizations. 2019 [Available from: http://www.gov.cn/xinwen/2019-09/17/content_5430452.htm.

Hainan Boao Pilot Zone: RWD Collected within and outside of the Pilot Zone for Innovative Medical Devices

Happy Life Tech

Boao Lecheng is currently the only region in China authorized to use innovative medical devices, which have been approved abroad but not in China yet.

Category	Data Sources	Collection Method	Information Collected
Medical data outside of Boao Lecheng	Patients' local medical institutions	Proactive collection	Past medical history, past diagnoses and treatments, compliances, other follow-up data, etc.
Medical data within Boao Lecheng*	**Medical institutions in Boao Lecheng**	**Routine collection**	**Symptoms, diagnoses, imaging, lab results, prescriptions, other medical information, etc.**
		Proactive collection	**Adverse events, patient-reported outcomes, etc.**
Data from past research of medical devices	Medical device manufacturers	Proactive collection	Overseas registration information, published data, etc.
Data collected from other devices or innovative platforms	Wearable devices	Routine collection	Heart rate, blood pressure, sleeping status, daily activities, etc.
	Innovative medical device tracing platform	Routine collection	Product tracing and monitoring across entire lifecycle of a medical device
	"Lecheng Health" smartphone app	Routine collection	Patient recruitment, patient registration, appointments, on-line consultation, product compliance, self-reported adverse events, etc.

Note: *Main data routinely collected

Reference:
1. Ren Yan YM, Yao Chen, Liu Yanmei, Jia Yulong, Sun Xin. Exploration of framework for real world data studies on special innovative medical products in Boao Lecheng. China food and drug administration magazine. 2011(11):14-20.

Hainan Boao Pilot Zone: Real-World Study Types

Difference between RWS in Boao and other regions

Real-world studies in Boao are **different** from those in other regions:

- Access to the medical devices is limited to the **pilot zone**
- Patients are from different regions with **diverse background**
- **Uneven quality of evidence** from overseas registration and post-market surveillance exists.

Types of Real-World Studies Considered

- **Observational study**: can be prospective (with little or low-quality RWD), retrospective (with large amount of high-quality RWD), or ambidirectional (with some high-quality RWD)
- **Single-arm trial with external control**: external control group could be historical control (e.g., previous RWD or clinical trial data) or parallel control (e.g., a patient registry)
- **Single-arm trial or cohort study** comparing to **objective performance criteria** (OPC)*: feasible for some rare or life-threatening diseases without any treatment in China
- **Pragmatic clinical trial**
  - Both the intervention and control groups receive medical devices in Boao
  - The intervention receives medical devices in Boao, while the control group receives SOC locally

Note: *OPC refers to a numerical target value derived from guidance, expert opinions, historical data and so on.

References:
1. Yao Minghong JY, Ren Yan, Liu Yanmei, Zou Kang, Lin Kai, Zhu Ning, Sun Xin. Real-world data studies of medical products in the context of special healthcare policy: study designs and key considerations. Chin J Epidemiol. 2021;42(7):1306-11.
2. Health Affairs. Improving access to medical devices: the use and evolution of objective performance criteria. [updated 7/26/2018. Available from: https://www.healthaffairs.org/do/10.1377/hblog20180726.907775/full/.

Hainan Boao Pilot Zone: Future

Future of Boao Pilot Zone

- **Build comprehensive databases** consisting of data from EMRs, patient-reported outcomes, follow-ups, etc., for **specific diseases**, which can be utilized for disease management, medical device evaluation, policy reform, etc.

- "**Boao Lecheng Real-World Data Research Center**": develop talents and build an outstanding RWD research ecosystem in the pilot zone

- Construct the **"Hainan Real-World Data Platform"** in two steps:
  - Develop the "**Boao Lecheng** Real-World Data Platform"
  - Establish the "**Hainan** Real-World Data Platform", integrating data sources across the entire Hainan Province (e.g., EMRs, insurance claims, registries), which can be used for decision-markings on **medical device registration**, **reimbursement**, and health policy, etc.

References:
1. Ren Yan YM, Yao Chen, Liu Yanmei, Jia Yulong, Sun Xin. Exploration of framework for real world data studies on special innovative medical products in Boao Lecheng. China food and drug administration magazine. 2011(11):14-20.
2. Ren Yan LY, Liu Mimi, Lin Youhai, Lin Kai, Tan Jing, Wang Wen, Li Ling, Liu Yanmei, Jia Yulong, Yao Minghong, Zou Kang, Chen Wei, Qu Jia, Sun Xin. Exploration and practice of real-world data studies on innovative medical products in Boao Lecheng: analysis based on Chinese first case of approved medical device using domestic real-world data. Chinese journal of evidence-based medicine. 2020;20(10):1117-23.

Summary

- **Using RWD to support regulatory decision-making** for medical devices is still in an **early stage** in China.
- **Limitations**:
  - The **NMPA guideline** needs to be **refined**: e.g., specify how to conduct real-world studies meeting regulatory standards as the FDA or the EMA, recommend early dialogues with the NMPA
  - Some **hurdles** in conducting **real-world studies**: e.g., disconnection across hospitals, lengthy ethical approval process, lack of key outcomes for medical devices in EMRs, etc.
- **Opportunities**:
  - **Favorable policy environment**: the NMPA approved RWD research for over ten medical devices (two received approval by January 2021) and three drugs in the Boao pilot zone by December 2020
  - **High-level of digitalization** and **innovative new technologies** (e.g., cloud computing and machine learning)

References:
1. European Medicines Agency. Guideline on registry-based studies draft. 2020. p. 1-33.
2. U.S. Food and Drug Administration. Use of real-world evidence to support regulatory decision-making for medical devices. 2017. p. 1-24.
3. The State Council Information Office of the People's Republic of China. Press release in Hainan: the approval of laser cataract “Catalys” machine. 2021 [Available from: http://www.scio.gov.cn/xwfbh/gssxwfbh/xwfbh/hainan/Document/1698216/1698216.htm.

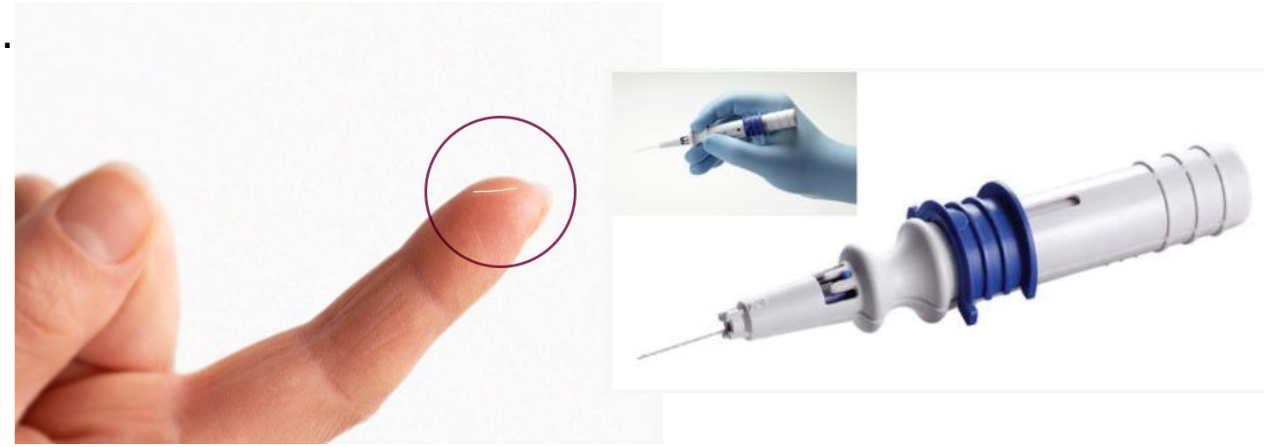
A successful Boao case - accelerated approval of XEN® in China using domestic RWE generated in Boao

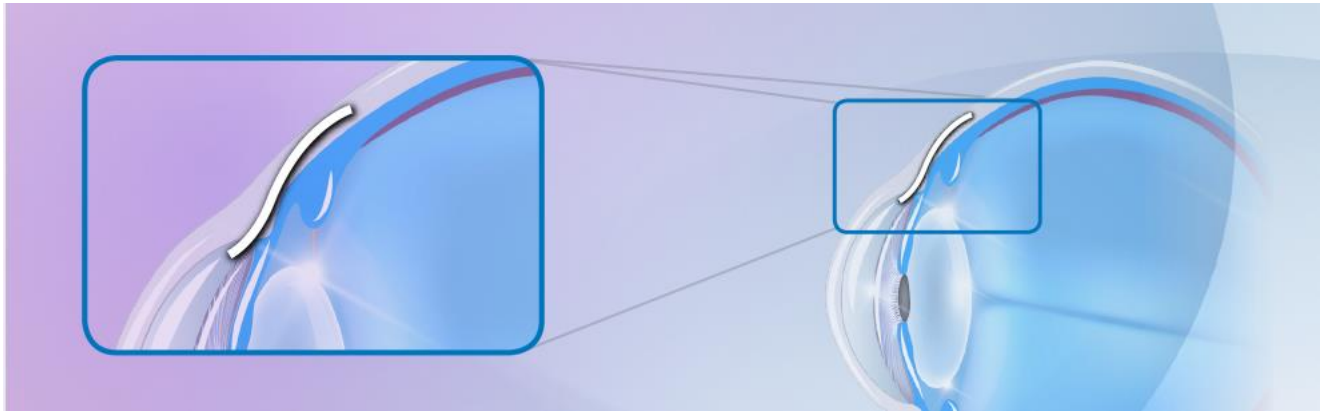
Carol Bao, PhD

Brief Overview of XEN®

The XEN® Gel Stent is a surgical implant designed to lower high eye pressure in open-angle glaucoma patients where previous surgical treatment has failed and/or medications alone were insufficient (also known as refractory glaucoma).

- Hydrophilic tube porcine gelatin
- Length: 6 mm, preload in an injector
- Placed just under the conjunctiva to create a small channel in the eye to drain fluid





Challenges for XEN® in the Regulatory Pathway of China

Background

- **XEN**® has been approved in more than 30 countries to treat Glaucoma.
- Glaucoma is the most common irreversible blinding disease in the world and is impacting **22 million** patients in China.

US Clinical Study Design

- US study design was based on ANSI Z80.27-2014 and guidance for industry and for FDA reviewers/staff “Aqueous shunts – 510(k) submission”.
- Sample size (65 subjects): FDA guidance, minimum of 50 subjects at 12 months.
- Single arm:
  - A control arm is not mandatory requirement for 510(K) clearance from FDA.
  - The clinical results were compared to other commercially available glaucoma device.
- Primary endpoint: IOP reduction ≥20% on the same or fewer number of medications than at baseline

Challenges with XEN® in China

- No guidance for clinical trial for glaucoma implantable device in China
- Intrinsic factors: ethnicity, race, age, gender, etc.
- Extrinsic factor: social environment, natural environment and culture, etc.
- Working mechanism, anatomical structure.
- Limited literature on impact of above factors on outcomes
- Only 3 Asian subjects were enrolled and completed the US study. No difference in IOP-lowering and safety comparing to the overall study population.

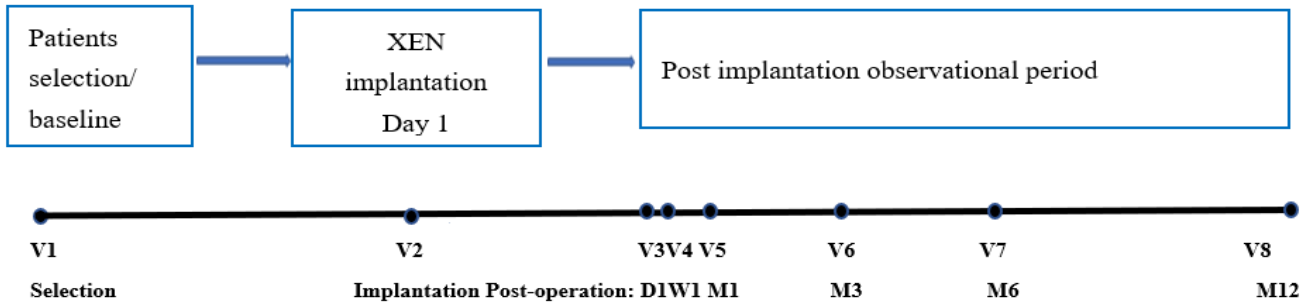
XEN® : Collaboration with Hainan Super Hospital to Collect Local RWD as a Bridging Strategy

Strategy

- Conducted the small sample size in Hainan Super Hospital to bridge the ethnic difference between Chinese and Caucasian population to demonstrate the safety and effectiveness in Chinese population.

Project

- Invited via US Chamber of Commerce to participate in Hainan Accelerated Access Path
- Early engagement with China RWE KOL: Professor Sun Xin, Sichuan University, China
- Collected real-world data for the evaluation of the safety and IOP-lowering effectiveness of XEN in Chinese patients with refractory glaucoma who were authorized to be treated with XEN in Hainan Boao Super Hospital (N=65 pts)
- Feb 24th, 2020: Provided the interim results (N=24 patients) at the CMDE Panel meeting with success: Await 6 month results & promise to continue recruitment & FU of patients till 12 months



XEN® : First Medical Device Approved through Accelerated Pathway in China using Local RWE

Outcome

- The real-world evidence data collection in Hainan Province enabled the assessment of ethnic differences to treatment with XEN®
- XEN® was approved by the NMPA within **five months** since its application for registration, which was at least **7 times faster** than the approval process for previous imported innovative medical devices (three to five years).
  - In *April 2019*, XEN® entered China, and received the permission to be used in Boao.
  - In *May 2019*, the first glaucoma surgery using XEN® was conducted successfully in Boao Super Hospital.
  - On *March 26, 2020*, XEN® was approved in China as the first medical device using domestic RWE for registration.

博鳌超级医院引入艾尔建XEN完成首例青光眼微创手术

Allergan艾尔建 前天

海南博鳌，2019年5月26日 ---- 全球领先的制药企业艾尔建今天在此宣布，其研发
眼治疗新利器XEN®入驻海南博鳌超级医院并完成中国的首例植入手术。此次微创植
鳌超级医院国际眼视光眼科中心、温州医科大学附属眼视光医院梁远波教授带领的
补了我国青光眼微创手术治疗领域的空白。

Word Cloud

- What's the biggest challenge you can think of using RWD/RWE for regulatory submissions in your country?

  Please type in one short answer.

Panel Discussion

1. What are the challenges in using RWD/RWE for regulatory submissions from your experiences? How to overcome these challenges?

2. What could RWD/RWE be used for regulatory purposes?

3. What are your advices to companies when they plan to use RWE to support regulatory submissions?

4. Will the FDA consider RWD/RWE from outside of the US or vice versa? Why and why not?

Q & A

Contact Information

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