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**STEPS TO FACILITATE INNOVATION FOR DEVICES INTENDED TO
TREAT OPIOID USE DISORDER**

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ABSTRACT

The opioid epidemic presents a significant public health challenge, necessitating innovative approaches for effective treatment. Devices intended to treat Opioid Use Disorder (OUD) have emerged as promising solutions, offering potential advantages over traditional methods. This involves analyzing existing identifying gaps, and pinpointing areas where innovative devices can bring substantial improvements. Navigating regulatory pathways is critical to ensure the safety and efficacy of innovative OUD treatment devices. Rigorous clinical trials are fundamental to establish the safety and efficacy of OUD treatment devices. Addressing the opioid epidemic requires innovative approaches, and devices intended to treat OUD offer promising solutions. The stakeholders can collaborate to develop, validate, and implement effective and safe devices that transform OUD treatment, ultimately improving patient outcomes and public health. **Objective:** To comprehend a medical device for treating opioid use disorder in US

Keywords: Clinical Trial, Disorder, Medical devices, Opioid Use Disorder

INTRODUCTION

The US is facing a serious problem with opioid overdoses. The Agency has been working hard to reduce unnecessary use of opioids, prevent opioid addiction, and help people with opioid addiction. The Center for Devices and Radiological Health (CDRH) is also involved in addressing this issue. They are focused on helping with this emergency situation within the country.

One way they're doing this is by designing and conducting studies to test devices that can treat opioid addiction. These studies aim to show if these devices are safe and effective. The information from these studies helps the FDA decide if these devices can be trusted to work as intended in treating opioid addiction. So, by following these principles and conducting proper studies, we can make progress in treating opioid addiction [1].

DISCUSSION

Opioid Use Disorder (OUD) is a problem where people struggle with using opioids in a harmful way, causing them distress or problems in their life. This can happen when they use opioids too much and it affects their health, emotions, relationships, or thinking. This disorder can come from misusing prescription painkillers or using illegal drugs. The opioid epidemic is a very serious health crisis in the US, with many people dying from

opioid overdoses. To tackle this issue, the FDA has already done things to limit people's exposure to opioids, stop more cases of opioid addiction, and help those who are already addicted.

As part of their efforts, the FDA started a challenge in 2018 to encourage the development of new medical devices, tests, and digital health technologies (like phone apps) that can help deal with the opioid crisis. The goal is to prevent and treat opioid addiction using innovative approaches [2].

Overdose Prevention Framework Priorities [2]

- Promoting primary prevention by preventing inappropriate prolonged prescribing and unnecessary initial prescription drug exposure.
- Promoting harm reduction through research and instruction.
- Promoting the creation of treatments for substance use disorders that are supported by evidence.
- Defending people from illicit, misdirected, or fake drugs that pose an overdose danger.

List of Applicants Selected for the Challenge

Many people responded to the FDA's challenge to create devices for preventing and treating opioid addiction. They got over 250 applications from different companies that make medical devices. After looking at all the applications carefully and using specific

criteria, the FDA chose eight participants for the challenge. These participants have made medical devices that can do things like predict the risk of opioid addiction, detect when someone has taken too much opioids, give out medication, and offer other ways to manage pain instead of using opioids [3].

Table 1: Applicants Selected for the Challenge

Company	Product Name	Category
Algomet Rx, Inc.	Rapid Drug Screen	Monitoring
Avanos	Withheld Per Company Request	Other
Brainsway, Ltd	Brainsway Deep Transcranial Magnetic Stimulation (DTMS) Device	Opioid Use Disorder Therapy
CognifiSense, Inc.	Virtual Reality Neuropsychological Therapy (VRNT)	Pain Therapy
iPill Dispenser	iPill Dispenser	Medication Dispensing
Masimo Corporation	SafetyNet Opioid System	Overdose Therapy
Milliman	Opioid Prediction Service	Diagnostic
ThermoTek, Inc.	NanoTherm™ and VascuTherm™ Systems	Pain Therapy

FDA Opioids Action Plan [4]

Table 2: FDA Action Plan

Category	Action Plan	Outcome
Expand use of advisory committees.	Before the FDA approves any new opioid medication that doesn't have built-in features to prevent abuse, they will gather a group of experts to discuss it. Also, before they approve any new drug application for using opioids in children, they will get advice from a committee that focuses on children's health. If there are new kinds of opioid medications designed to be abuse-resistant, the FDA will also ask a special committee for advice if there are unique concerns.	Experts from outside and the public get to give their opinions before the FDA approves any new opioid without abuse prevention features, and they also get expert advice on how to label opioids for use in children.
Develop warnings and safety information for immediate-release (IR) opioid labeling.	The FDA is working on updating the labels for immediate-release opioids to include more warnings and safety details, similar to what they did for extended-release opioids in 2013.	Providing doctors with improved information about the dangers and safe prescription practices
Strengthen postmarket requirements	There isn't enough solid evidence about using opioid medications for a long time, especially the extended-release/long-acting ones, the FDA is making drug companies gather information after the drugs are on the market to see the long-term effects	Getting more solid proof about the serious dangers of misusing and abusing opioids for a long time, as well as understanding factors that predict opioid addiction
Update Risk Evaluation and Mitigation Strategy (REMS) Program	ER/LA opioids are currently covered by a REMS program, which compels sponsors to pay CME providers to conduct low- or no-cost CME courses on how to utilize these medications properly. After taking into account the suggestions of the advisory group and reviewing the current standards, the FDA will amend the REMS program requirements for opioids	To reduce inappropriate opioid prescriptions, more prescribers should get training on pain management and safe opioid drug prescription.

Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder [5]

Clinical Study Design

The study's general plan is to develop features for important OUD device investigations. Pivotal OUD device studies should be carefully controlled and planned to produce genuine scientific evidence that indicates clinically significant results due to the significant uncertainty caused by subjective outcomes, placebo effects, concurrent therapies, and potential bias, among other things.

A. Patient Population and Assignment to Treatment and Control Groups: CDRH advises sponsors to specify the population the device is meant to treat by setting precise inclusion and exclusion criteria that easily translate to clinical practice when developing a pivotal OUD device trial. To prevent the introduction of biases, participants in the control group are given a fake control for gadgets.

B. Recording Medication Use: Each drug, the dose, the length of use, dose adjustments, and drug initiation or discontinuation after enrollment in the study has initiated should be documented by the researchers. Participant diaries, pill counts, random or routine toxicological drug tests for prescribed and

non-prescribed drug use, as well as other SUD therapy drugs can all be used to measure participant adherence to treatment regimens for OUD and other SUDs.

C. Appropriate Study Length and Evaluation: It is advised to conduct pivotal OUD device trials with a minimum 6-month treatment period.

D. Participant Retention and Preventing Missing Data: A key OUD device study should put a lot of effort into maximizing participant retention and minimizing missing data by making sure that treatment plans and follow-up schedules are followed.

Clinical Outcomes: An improvement in how a study participant feels, functions, or survives, such as a decrease in hospitalizations or improvements in everyday living, including the ability to resume work, school, and other activities, is regarded by the FDA as a clinically meaningful benefit. Sponsors should identify the clinical objectives of the device for the target patient population and align the objectives with the desired indications for use, a relevant definition of a clinically significant benefit, and the choice of effectiveness outcomes when choosing primary outcomes for pivotal OUD device studies.

1. Change in Drug Use Pattern

2. Change in OUD Disease Status Using DSM-5-TR Diagnostic Criteria
3. Reduction in Adverse Outcomes of OUD
4. Patient-Reported Outcome Instruments

SUMMARY AND CONCLUSION

The opioid epidemic is a significant and complex public health challenge that demands novel and effective solutions for treatment. The emergence of devices designed to address Opioid Use Disorder (OUD) holds promise as a way to overcome the limitations of traditional methods. To successfully combat this epidemic, a comprehensive understanding of the struggles faced by individuals dealing with OUD is crucial. This necessitates a thorough evaluation of current treatment approaches, identification of gaps in care, and recognition of areas where innovative devices can make substantial contributions.

Navigating the regulatory landscape is of paramount importance in ensuring the,

- safety and
- efficacy

of these groundbreaking OUD treatment devices. Rigorous clinical trials are essential to establish the validity and reliability of these devices, establishing a foundation of evidence-based practice. By addressing the opioid epidemic with innovative approaches,

including the implementation of OUD treatment devices, the potential is to bring about transformative changes in manage and overcome of OUD.

To achieve success, collaboration among stakeholders is vital. By working together, researchers, healthcare professionals, policymakers, and technology developers can collectively develop, validate, and implement these novel devices. This collaborative effort can lead to the creation of effective and safe solutions that revolutionize OUD treatment, ultimately improving both patient outcomes and public health on a broader scale. In the face of the opioid epidemic, embracing innovation through advanced treatment device offers a beacon of hope in the pursuit of a healthier and safer future for those affected by OUD.

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Conflict of interest

The authors declared that there is no conflict of interest.

REFERENCES

- [1] The Federal Register [Internet]. [cited 2023 Aug 30]. Available from: <https://www.federalregister.gov/docu>

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- [ments/2023/07/28/2023-15968/clinical-considerations-for-studies-of-devices-intended-to-treat-opioid-use-disorder-draft-guidance](https://www.fda.gov/oc/announcements/2023/07/28/2023-15968/clinical-considerations-for-studies-of-devices-intended-to-treat-opioid-use-disorder-draft-guidance)
- [2] Center for Drug Evaluation and Research. Food and Drug Administration Overdose Prevention Framework [Internet]. FDA; [cited 2023 Aug 30]. Available from: <https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework>
- [3] Center for Devices and Radiological Health. FDA Innovation Challenge: Devices to prevent treat opioid use disorder [Internet]. FDA; [cited 2023 Aug 30]. Available from: [innovation/fda-innovation-challenge-devices-prevent-and-treat-opioid-use-disorder](https://www.fda.gov/about-fda/cdrh-innovation/fda-innovation-challenge-devices-prevent-and-treat-opioid-use-disorder)
- [4] Center for Drug Evaluation and Research. FDA Opioids Action Plan [Internet]. FDA; [cited 2023 Aug 30]. Available from: <https://www.fda.gov/drugs/information-drug-class/fda-opioids-action-plan>
- [5] Center for Devices and Radiological Health. CDRH opioid use disorder guidance [Internet]. FDA; [cited 2023 Aug 30]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-considerations-studies-devices-intended-treat-opioid-use-disorder>
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