

# **Refractory Epilepsy Treatment Market - A Global and Regional Analysis: Focus on Treatment Type, Patient Type, Seizure Type, Distribution Channel, and Regional Analysis - Analysis and Forecast, 2025-2035**

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## **Abstracts**

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### Introduction of Refractory Epilepsy Treatment

Refractory epilepsy treatment utilizes an individual's distinct clinical, molecular, and lifestyle data to inform the diagnosis, treatment, and prevention of cancer, inherited diseases, and other complex conditions. Refractory epilepsy treatment represents a transformative shift in healthcare, moving away from the traditional one-size-fits-all approach to a more tailored and targeted therapeutic strategy. By leveraging advancements in genomics, molecular diagnostics, and data analytics, Refractory epilepsy treatment enables healthcare providers to craft personalized treatment plans based on an individual's genetic, environmental, and lifestyle factors. This approach not only promises to enhance the effectiveness of treatments but also reduces unnecessary trial-and-error, leading to better patient outcomes and reduced healthcare costs. As the field continues to evolve, large-scale population studies and cutting-edge technologies are paving the way for more accurate disease predictions, early diagnoses, and optimized therapeutic interventions.

### Market Introduction

The global refractory epilepsy treatment market is expected to witness substantial growth, projected to reach \$9,472.6 million by 2035. The global refractory epilepsy treatment market is experiencing consistent growth, driven by the increasing prevalence

of epilepsy and the limitations of conventional anti-seizure medications, which fail to control seizures in approximately 30–40% of patients. This significant unmet clinical need is transforming the market landscape, spurring demand for advanced treatment options such as neurostimulation therapies (including VNS, RNS, and DBS), surgical interventions, and innovative therapeutics like cannabidiol and next-generation anti-seizure medications. Growth is further supported by rising awareness, enhanced diagnostic capabilities, and broader healthcare access in emerging markets. Nonetheless, barriers such as high treatment costs, complex regulatory requirements, and uneven access to specialized care continue to hinder widespread adoption. As the field moves toward more personalized, device-integrated, and precision-targeted solutions, the refractory epilepsy treatment market stands at the forefront of urgent clinical need and evolving commercial potential.

Refractory epilepsy, also known as drug-resistant epilepsy (DRE), affects approximately 30% of all epilepsy patients, who do not respond adequately to at least two anti-seizure medications (ASMs). This condition represents a high unmet clinical need, driving both pharmaceutical and device innovation. Refractory epilepsy, affects roughly 30% of the global epilepsy population, representing a significant unmet medical need. This subset of patients fails to achieve seizure control despite trials of two or more anti-seizure medications (ASMs), driving demand for innovative therapies. The competitive landscape is diverse and rapidly evolving, spanning pharmaceutical, device, and emerging gene therapy sectors. Traditional ASMs, such as UCB Pharma's brivaracetam and SK Life Science's cenobamate, continue to advance with a focus on improved efficacy and tolerability, exemplified by cenobamate's clinical trials showing notable seizure freedom rates. Meanwhile, neuromodulation devices—like LivaNova's vagus nerve stimulation and NeuroPace's responsive neurostimulation system—offer alternative approaches targeting neural circuits, particularly for patients with focal epilepsy not amenable to surgery.

Additionally, cell and gene therapies, though still in early stages, promise transformative potential for rare genetic epilepsies such as Dravet syndrome, reflecting a shift towards precision medicine. Market growth is supported by regulatory incentives and increasing payer acceptance, particularly as real-world data validate the long-term benefits of these advanced therapies. Overall, the refractory epilepsy treatment landscape resembles a multi-modal transportation system navigating difficult terrain: conventional drugs serve broad populations but with limited efficacy, neuromodulation provides more precise control albeit at higher cost, and emerging genetic therapies hold the promise of a targeted, curative path for select patients.

## Industrial Impact

Refractory epilepsy treatment is reshaping the healthcare industry by enabling personalized treatments that significantly improve patient outcomes. For instance, the use of genetic profiling in oncology has led to the development of targeted therapies such as Herceptin for breast cancer, which is specifically designed to treat patients with HER2-positive tumors. In addition to improving individual patient care, Refractory epilepsy treatment is driving innovation across the healthcare ecosystem, particularly in drug discovery and clinical trials. The pharmaceutical industry is leveraging genomics to discover new drug targets, as seen in the development of the breakthrough drug Kymriah, a CAR-T therapy for leukemia, which was developed through the identification of genetic markers specific to the disease. Clinical trials are also becoming more targeted, with companies such as Novartis and Pfizer using genomic data to stratify patient populations and improve trial efficiency. Moreover, the integration of refractory epilepsy treatment into population health management is evident in initiatives such as Geisinger Health System's MyCode Community Health Initiative, which offers genomic sequencing to patients to improve preventive care and early disease detection. This growing application of refractory epilepsy treatment has not only improved individual treatment outcomes but has also helped to optimize healthcare delivery systems, reduce costs, and accelerate the development of new therapies.

## Market Segmentation:

### Segmentation 1: By Treatment Type

#### Pharmacological

##### Drug Class

First-Generation Drugs

Second-Generation Drugs

New and Emerging Drugs

Combination Drugs

#### Non-Pharmacological

## Surgical and Neurostimulation Devices

Resective Surgery Devices

Laser Interstitial Thermal Therapy (LiTT)

Stereotactic EEG

Deep Brain Stimulation (DBS)

Vagus Nerve Stimulation (VNS)

## Consumables

Electrodes/Leads

Batteries and Pulse Generators

Surgical Tools and Kits

External Accessories

Pharmacological treatment remains the leading segment due to the widespread use of anti-epileptic drugs (AEDs) as the first-line approach for managing refractory epilepsy. The segment holds a market share of 90.60% in 2024 with a CAGR of 6.87% during the forecast period 2025-2035. Continuous advancements in drug formulations, coupled with the increasing availability of next-generation AEDs with improved efficacy and fewer side effects, are expected to drive growth in this segment through 2035.

## Segmentation 2: By Patient Type

Adult

Paediatrics

Based on patient type, the global refractory epilepsy treatment market was led by the paediatrics segment, which held a 59.6% share in 2024. The paediatric population is

projected to dominate the refractory epilepsy treatment market due to a higher prevalence of epilepsy among children compared to adults. Additionally, improved diagnosis rates, a growing aging population, and higher healthcare awareness in adult groups contribute to the rising demand for effective treatment solutions.

### Segmentation 3: By Seizure Type

Focal

Generalised

Based on seizure type, the global refractory epilepsy treatment market was led by the focal segment, which held a 61.4% share in 2024. Focal epilepsy is expected to lead the market as it accounts for a significant proportion of refractory epilepsy cases. Its complex and variable presentation often makes it resistant to standard therapies, driving the need for advanced treatment approaches, including newer pharmacological options and neuromodulation techniques.

### Segmentation 4: By Distribution Channel

Hospital Pharmacy

Retail Pharmacy

Online Pharmacy

Based on distribution channel, the global refractory epilepsy treatment market was led by the hospital pharmacy segment, which held a 45.7% share in 2024. Hospital pharmacies are anticipated to dominate the distribution channel due to their access to specialized medications and advanced treatment infrastructure. The rising number of hospital-based treatment protocols and the preference for inpatient care in severe cases of refractory epilepsy further support this segment's growth.

### Segmentation 5: By Region

North America

U.S.

Canada

Europe

Germany

U.K.

France

Italy

Spain

Rest-of-Europe

Asia-Pacific

Japan

India

China

Australia

South Korea

Rest-of-Asia-Pacific

Latin America

Brazil

Mexico

Rest-of-Latin America

## Middle East and Africa

Egypt

South Africa

Rest-of-Middle East and Africa

The refractory epilepsy treatment market in the North America region is expected to witness a significant growth rate during the forecast period, marked by a high disease burden, advanced healthcare infrastructure, and a strong focus on innovation. The market is expected to witness notable growth over the next five years due to increasing R&D investments, rising patient awareness, and improved diagnostic capabilities. Key developments include the FDA's recent approval of Cenobamate by SK Life Science, which has demonstrated effectiveness in treatment-resistant seizures, and the ongoing late-stage development of promising candidates such as XEN1101 by Xenon Pharmaceuticals. Leading companies are actively pursuing novel mechanisms of action and personalized medicine approaches to improve efficacy and minimize side effects. Additionally, strategic initiatives like expanded patient assistance programs and public-private research collaborations are expected to enhance access and accelerate innovation.

### Recent Developments in the Refractory Epilepsy Treatment Market

In June 2024, EpilepsyGTx, a U.K.-based biotechnology company, secured USD 10 million in seed funding led by the UCL Technology Fund, with participation from Health Technology Holding. The funds have been allocated to finalize preclinical studies and prepare for a first-in-human Phase 1/2a clinical trial of their lead gene therapy candidate, EPY201, aimed at treating focal refractory epilepsy.

In October 2023, NeuroPace introduced significant enhancements to its RNS System aimed at streamlining epilepsy care. These updates include an upgraded nSight Platform for improved data review, 'Simple Set Programming' to expedite clinic workflows, and a newly FDA-approved, portable Tablet Remote Monitor with wireless connectivity for seamless patient data transmission.

In June 2023, SK Biopharmaceuticals announced that its partner, Paladin Labs, received approval from Health Canada to market and distribute XCOPRI (cenobamate tablets) for adjunctive therapy in managing partial-onset seizures in adults with epilepsy who are not satisfactorily controlled with conventional therapy. Paladin Labs plans to commercially launch XCOPRI in Canada in December 2023, collaborating with Canadian health agencies to ensure patient access.

In Feb 2023, LivaNova introduced the SenTiva DUO, an implantable pulse generator (IPG) featuring a dual-pin header designed to deliver Vagus Nerve Stimulation (VNS) therapy for individuals with drug-resistant epilepsy. This advancement allows patients with legacy dual-pin systems to upgrade to the latest VNS technology without requiring lead replacement, offering customizable and automated therapy options to enhance seizure control.

## Demand –Drivers, Challenges, and Opportunities

### Market Demand Drivers:

Increasing prevalence of drug-resistant epilepsy and ever expanding pipeline of novel therapeutics: Refractory epilepsy is defined by the International League Against Epilepsy (ILAE) as the failure to achieve sustained seizure freedom after adequate trials of at least two appropriately chosen and tolerated anti-epileptic drugs (AEDs). Individuals with this form of epilepsy face greater health complications, increased risk of injury or sudden death (SUDEP), and significantly reduced quality of life. The rising prevalence of this epilepsy further amplifies the burden on healthcare systems.

According to UChicago Medicine, an estimated 65 million people worldwide live with epilepsy, and among those, 30-40 percent, roughly 20-26 million individuals, have drug-resistant or medically refractory epilepsy, meaning they fail to achieve sustained seizure control despite trials of two or more appropriate antiseizure medications. In the U.S. alone, there are over 2 million people with refractory epilepsy, and in India, where 10-12 million people have epilepsy, approximately 30-40 percent (3-4 million) are estimated to be drug-resistant, underscoring a substantial and growing treatment gap worldwide.

The increasing number of patients diagnosed with medication-refractory epilepsy across Africa has emerged as a key driver for the regional and global refractory epilepsy

treatment market. "Surgery for Medication Refractory Epilepsy in Africa: A Review of Seizure Freedom Outcomes", published in 2024, systematically reviews epilepsy surgery programs across Africa. Analyzing eight studies representing seven unique patient cohorts, the review found that 60–100% of patients achieved seizure freedom within a year post-surgery, alongside improvements in quality of life and reduced depression severity. These outcomes are comparable to those reported in higher-income regions, demonstrating the feasibility and effectiveness of establishing refractory epilepsy surgery programs in Africa. Given here is a graphical representation of the number of patients undergoing various surgical procedures for medication-refractory epilepsy in Africa. CAH, corticoamygdalohippocampectomy; SAH, selective amygdalohippocampectomy.

Some of the other driving factors include:

Growing Impact of Orphan Drug Development and Role of Addvcacy Group and Awareness Programs

Emerging Treatment Modalities in Refractory Epilepsy

Note: All of the above factors will be evaluated in detail in the report.

Market Challenges:

**Financial Constraints on Patient Access:** The financial constraints on patient access are a significant challenge for the refractory epilepsy treatment market, particularly because many patients with refractory epilepsy often require a combination of therapies, including newer medications, advanced surgical options, or devices like Vagus Nerve Stimulation (VNS) or Responsive Neurostimulation (RNS). These treatments can be prohibitively expensive, creating financial barriers for patients and limiting market growth. AEDs, especially those approved in recent years for refractory epilepsy, often come with high price tags. Although they may offer effective seizure control, their cost can be a burden for both healthcare systems and patients, especially in developing countries or where insurance coverage is limited.

Some of the other factors challenging the market growth include:

Under diagnosis of patients who meet the criteria of drug-resistant epilepsy (DRE)

Note: All of the above factors will be evaluated in detail in the report.

#### Market Opportunities:

**Advances in Neuromodulation Devices in Refractory Epilepsy Treatment Market:** Neuromodulation has emerged as a transformative approach for managing drug-resistant epilepsy (DRE), offering hope to patients unresponsive to conventional antiseizure medications. Recent advancements in both invasive and non-invasive neuromodulation technologies have significantly enhanced seizure control, improved patient outcomes, and expanded therapeutic options. These advancements not only enhance patient outcomes but also expand the therapeutic landscape, positioning neuromodulation as a central component in the management of refractory epilepsy. The integration of cutting-edge technologies and personalized treatment approaches underscores the market's dynamic evolution and its commitment to addressing the complexities of drug-resistant epilepsy.

Some of the other factors creating an opportunity for market growth include:

Shift from neo-adjuvant approaches driven by diagnostic advancements

Note: All of the above factors will be evaluated in detail in the report.

#### Market Trends:

**Integrating Advanced Imaging for Enhanced Diagnostics and Treatment:** The trend in Refractory Epilepsy Treatment is shifting toward delivering high-quality, personalized care through the integration of advanced imaging technologies, genomics, and AI-driven solutions. This approach enhances the accuracy and effectiveness of diagnoses and treatment plans by offering a multi-dimensional understanding of diseases such as cancer. Radiomics and AI are transforming clinical decision-making by providing actionable insights from medical images, enabling a deeper understanding of tumor heterogeneity and patient-specific factors. Additionally, cloud-based platforms and biophysical modeling are allowing for real-time analysis and personalized treatment simulations, further improving clinical outcomes. As these technologies evolve, the demand for high-quality, tailored therapies is expected to rise, offering better results than traditional methods.

Some of the other emerging trends in the market include:

### Emerging Targeted Therapy for Refractory Epilepsy Treatment

Note: All of the above trends will be evaluated in detail in the report.

How can this report add value to an organization?

**Product/Innovation Strategy:** The report offers in-depth insights into the latest technological advancements in refractory epilepsy treatment, enabling organizations to drive innovation and develop cutting-edge products tailored to market needs.

**Growth/Marketing Strategy:** By providing comprehensive market analysis and identifying key growth opportunities, the report equips organizations with the knowledge to craft targeted marketing strategies and expand their market presence effectively.

**Competitive Strategy:** The report includes a thorough competitive landscape analysis, helping organizations understand their competitors' strengths and weaknesses and allowing them to strategize effectively to gain a competitive edge in the market.

**Regulatory and Compliance Strategy:** It provides updates on evolving regulatory frameworks, approvals, and industry guidelines, ensuring organizations stay compliant and accelerate market entry for new Refractory Epilepsy Treatment solutions.

**Investment and Business Expansion Strategy:** By analyzing market trends, funding patterns, and partnership opportunities, the report assists organizations in making informed investment decisions and identifying potential M&A opportunities for business growth.

Methodology

Key Considerations and Assumptions in Market Engineering and Validation

The base year considered for the calculation of the market size is 2023. A historical year analysis has been done for the period FY2022-FY2023. The market size has been estimated for FY2024 and projected for the period FY2025-FY2035.

The scope of this report has been carefully derived based on interactions with experts in different companies across the world. This report provides a market study of applied sciences, precision diagnostics, digital health and information technology, and precision therapeutics products of the refractory epilepsy treatment market.

The market contribution of the precision therapeutics anticipated to be launched in the future has been calculated based on the historical analysis of the products.

Revenues of the companies have been referenced from their annual reports for FY2023 and FY2024. For private companies, revenues have been estimated based on factors such as inputs obtained from primary research, funding history, market collaborations, and operational history.

The market has been mapped based on the available refractory epilepsy treatment solutions. All the key companies with significant offerings in this field have been considered and profiled in this report.

#### Primary Research:

The primary sources involve industry experts in Refractory Epilepsy Treatment, including the market players offering products and services. Resources such as CEOs, vice presidents, marketing directors, and technology and innovation directors have been interviewed to obtain and verify both qualitative and quantitative aspects of this research study.

The key data points taken from the primary sources include:

Validation and triangulation of all the numbers and graphs

Validation of the report's segmentation and key qualitative findings

Understanding the competitive landscape and business model

Current and proposed production values of a product by market players

Validation of the numbers of the different segments of the market in focus

Percentage split of individual markets for regional analysis

## Secondary Research

### Open Sources

Certified publications, articles from recognized authors, white papers, directories, and major databases, among others

Annual reports, SEC filings, and investor presentations of the leading market players

Company websites and detailed study of their product portfolio

Gold standard magazines, journals, white papers, press releases, and news articles

Paid databases

The key data points taken from the secondary sources include:

Segmentations and percentage shares

Data for market value

Key industry trends of the top players of the market

Qualitative insights into various aspects of the market, key trends, and emerging areas of innovation

Quantitative data for mathematical and statistical calculations

## Key Market Players and Competition Synopsis

Profiled companies have been selected based on inputs gathered from primary experts, as well as analyzing company coverage, product portfolio, and market penetration.

Key players in the refractory epilepsy treatment market include major global pharmaceutical companies offer a range of antiepileptic drugs (AEDs), including traditional drugs like carbamazepine and phenytoin, as well as newer medications such as cenobamate (Xcopri) and clobazam (Onfi). Specialty companies focus on rare and severe forms of epilepsy, including syndromes like Dravet syndrome and Lennox-Gastaut syndrome. Biotech companies are working on developing novel compounds that target ion channels involved in seizure activity. Small molecule therapies are being developed to offer better intervention during acute seizure events. Research into epilepsy syndromes is yielding promising results for disorders with unique sensitivities to light and other triggers. Other companies are working on GABA-A receptor modulators and other innovative drug targets to improve epilepsy treatment. Companies with a focus on refractory conditions also work on therapies targeting status epilepticus and related complications.

Some prominent names established in this market are:

Teva Pharmaceuticals Industries Ltd.

Janssen Global Services, LLC

SK Biopharmaceuticals

UCB S.A.

Novartis AG

NeuroPace, Inc.

LivaNova PLC

GSK plc.

Eisai, Inc.

Biocodex-SP

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