

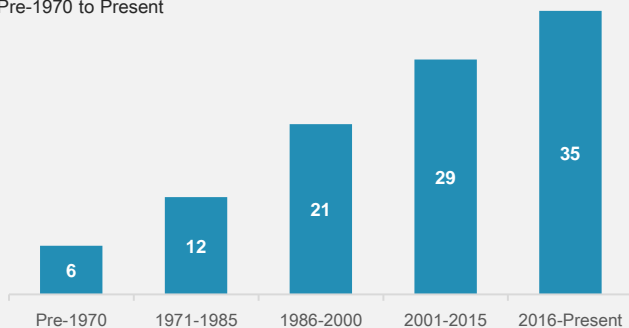
Developments In Treatment Of Epilepsy

A Deep-dive In Future Landscape

Epilepsy ranks as the fourth most common neurological disorder in the US and presents itself as seizures of generalized, focal and/or combined nature, as epileptic encephalopathy, or as a comorbidity. With the existing drug landscape only offering preventive care, there is a need for holistic therapies to treat epilepsy. The current pipeline, with promising New Chemical Entities (NCEs), attempts to address this need with a strong focus on rare encephalopathy-linked epilepsy as well as generalized and focal seizures.

CURRENT LANDSCAPE

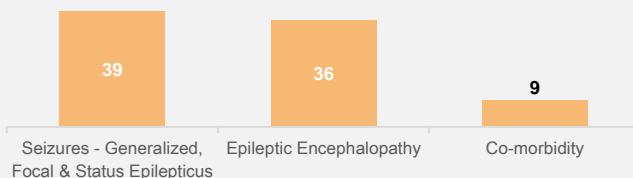
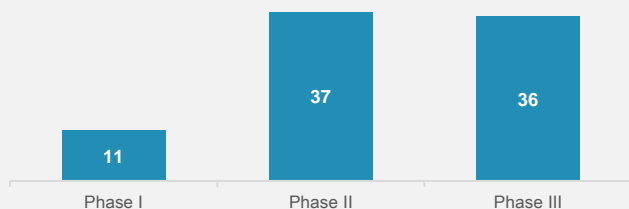
Number of FDA approved therapies for epilepsy
Pre-1970 to Present



- Current therapies include modulators of GABA_A receptors, Na⁺ channels, Ca²⁺ channels, AMPA receptors, and SV2A proteins.
- Since 2016, 3 medications have been introduced for orphan epilepsy indications: cannabidiol, fenfluramine, and ganaxolone.
- Two promising therapies were launched in 2020:
 - Fenfluramine: A 5HT-modulator, 56% reduction in seizure frequency, 9% cases reported freedom from seizures
 - Cenobamate: A GABA_A receptor and Na⁺ channels modulator, 93% reduction in seizure frequency, 21% cases reported freedom from seizures
- Existing therapies are preventive, providing only symptomatic relief.

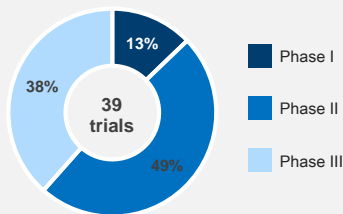
FUTURE LANDSCAPE

Since 2017, 84 clinical trials have been conducted, including promising NCEs such as Soticlestat (Takeda) and STK-001 (Stoke Therapeutics). Clinical activity has been observed for seizures (~46%), rare epilepsy (~43%), and associated comorbidities (~11%).

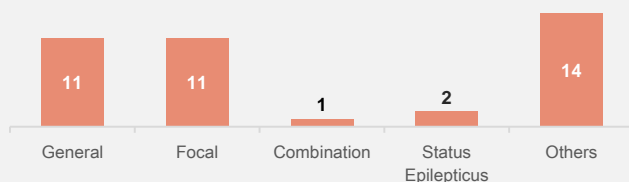


I. Seizures (Generalized, Focal, and Status Epilepticus)

About 39 trials focused on epileptic seizures, precipitated as generalized seizures, focal seizures, combined seizures, status epilepticus, and others.



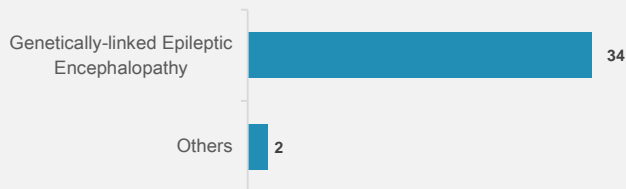
Investigation of treatments for **general and focal epilepsies** present the highest number of clinical studies



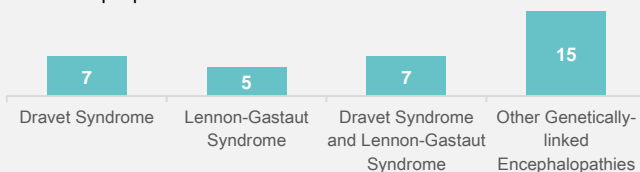
Total seven NCEs are under investigation for general and focal seizures, in addition to trials investigating brivaracetam, cenobamate, lacosamide, natalizumab, perampanel, etc.

II. Epileptic Encephalopathy

Out of the 36 clinical trials conducted on epileptic encephalopathy disorders, studies were largely focused on **genetically linked epileptic encephalopathy...**



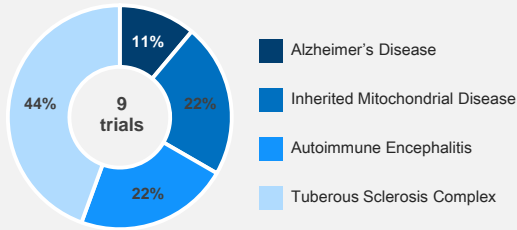
... within which the **Dravet and Lennox-Gastaut** syndromes were the most common epileptic disorders.



R&D in such orphan disease is primarily driven by increasing awareness of unmet patient needs, further supported by regulatory incentives such as grants, waivers, and market exclusivity.

III. Epilepsy as a Co-morbidity

Epilepsy co-exists with other neurological and genetic disorders. Alzheimer's disease independently contributes to epilepsy development, whereas epilepsy is a clinical representation in tuberous sclerosis complex, autoimmune encephalitis, and inherited mitochondrial disease



- NeuroPro Therapeutics, Inc. has conducted a Phase I trial to investigate NPT-2042 for Alzheimer-linked epilepsy.
- PTC Therapeutics, Inc. is conducting Phase III trials to investigate Vatiquinone's efficacy in inherited mitochondrial disease-linked epilepsy.
- UCB Pharma's rozanolizumab and satralizumab developed by Roche's Chugai Pharmaceuticals are under investigation for treatment of autoimmune encephalitis-linked epilepsy.
- Marinus Pharmaceuticals' ganaxolone and Jazz Pharmaceuticals' cannabidiol are under investigation for tuberous sclerosis complex-linked epilepsy.

Key Players from Epilepsy Pipeline

Clinical Trials

UCB Pharma	10
Marinus Pharmaceuticals	7
SK Life Science, Inc.	7
Zogenix International Limited, Inc.	6
Jazz Pharmaceuticals	5
Xenon Pharmaceuticals Inc.	5

Key players and clinical activity in epilepsy pipeline

- UCB Pharma is conducting one Phase I trial, four Phase II trials, and five Phase III trials, investigating brivaracetam in five trials and two novel medications.
- Marinus Pharmaceuticals investigated ganaxolone in all seven studies.
- SK Life Sciences is investigating cenobamate and carisbamate across the seven trials.
- Zogenix International Limited, Inc. investigated fenfluramine for Dravet and Lennon–Gastaut syndromes.
- Jazz Pharma and Xenon Pharma investigated two and one NCEs, respectively.

Right from understanding key issues to advising you through the right set of insights and recommendations, Aranca provides research, consolidation, and insightful analysis to aid in-depth understanding of therapy and effective decision-making.

HOW CAN ARANCA HELP?

- 01 Epidemiological Analysis:** Prevalence and diagnosis of diseases based on geography, gender, race and ethnicity, etc.
- 02 Diagnosis and Treatment Paradigm:** Analysis of diagnosis and treatment algorithm adopted in clinical practice
- 03 Current and Future Landscape:** Current treatments and latest pipeline landscape assessment for a particular therapy area
- 04 Humanistic, Economic Burden, and Unmet Need Analysis:** Impact of a disease on the patient's mental and economic well-being
- 05 Health Technology Assessment:** Analysis of various HTA decisions published by various countries

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