

Clinical Research – The Best of 2023

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Mini-Review

In recent years, clinical research has been improving by leaps and bounds. Although it is true that there were a couple of years in which the development of new molecules was noticeably reduced due to the uncertainty of the change in patent protection time, today clinical research has improved its levels of global investment, especially with the entry of the Asian continent. The field of clinical research is little known, even among healthcare professionals, but it plays a critical role in driving medical progress and improving global health. Clinical research is the foundation of modern healthcare and drives innovation and medical advances that can change people's lives. Whether scientific research pioneers new treatments or improves existing treatments, the importance of clinical research cannot be underestimated. The field of clinical research is dynamic and rapidly evolving. Therefore, keeping up to date with the latest trends and developments is essential for professionals in this field. As patients, healthcare providers, and pharmaceutical companies increasingly recognize the important role of evidence-based practice, the need for rigorous and ethical clinical research continues to grow. By systematically collecting data and evidence, clinical research contributes

to the development of best practices and evidence-based guidelines, thereby shaping the standard of care for various medical conditions. The clinical research process is guided by rigorous scientific methods, ensuring that results are reliable and repeatable. Researchers follow strict protocols and ethical standards to protect the health of clinical trial participants and maintain the integrity of research results.

This commitment to methodological rigor and ethical behavior enhances the credibility and impact of clinical research on healthcare practice. This affects the entire spectrum of medical advances, from diagnostic tools to therapeutic interventions. These advances have expanded and improved the lives of countless patients, highlighting the profound impact of clinical research on global health outcomes. The Clinical Research creates the knowledge and tools so that healthcare professionals can understand better the diseases, prevent, cure or rehabilitate patients and in that way, improve health levels worldwide. During 2023, the FDA Center for Drug Evaluation and Research (CDER) approved 55 new medications, presentations and indications, which are detailed below: Table 1. This is the result of years of research that manages to bear fruit for global benefit. This work continues and clinical trials continue.

Table 1: Novel Drug Approvals for 2023 | FDA.

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
55.	Wainua	eplontersen	12/21/2023	To treat polyneuropathy of hereditary transthyretin-mediated amyloidosisDrug Trials Snapshot
54.	Filsuvez	birch triterpenes	12/18/2023	To treat wounds associated with dystrophic and junctional epidermolysis bullosaDrug Trials Snapshot
53.	Fabhalta	iptacopan	12/5/2023	To treat paroxysmal nocturnal hemoglobinuria
52.	Ogsiveo	nirogacestat	11/27/2023	To treat adults with progressing desmoid tumors who require systemic treatmentDrug Trials Snapshot
51.	Truqap	capivasertib	11/16/2023	To treat breast cancer that meets certain disease criteria
50.	Ryzneuta	efbmalenograstim alfa-vuxw	11/16/2023	To treat neutropeniaDrug Trials Snapshot
49.	Augtyro	repotrectinib	11/15/2023	To treat ROS1-positive non-small cell lung cancerDrug Trials Snapshot
48.	Defencath	taurolidine, heparin	11/15/2023	To reduce the incidence of catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter
47.	Fruzaqla	fruquintinib	11/8/2023	To treat refractory, metastatic colorectal cancerDrug Trials Snapshot
46.	Loqtorzi	toripalimab-tpzi	10/27/2023	To treat recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies
45.	OmvoH	mirikizumab-mrkz	10/26/2023	To treat ulcerative colitis
44.	Agamree	vamorolone	10/26/2023	To treat Duchenne muscular dystrophyDrug Trials Snapshot
43.	Bimzelx	bimekizumab	10/17/2023	To treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapyDrug Trials Snapshot
42.	Zilbrysq	zilucoplan	10/17/2023	To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive
41.	Velsipity	etrasimod	10/12/2023	To treat moderately to severely active ulcerative colitis in adults
40.	Rivfloza	nedosiran	9/29/2023	To lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney functionDrug Trials Snapshot
39.	Pombiliti	cipaglucosidase alfa-atga	9/28/2023	To treat late-onset Pompe diseaseDrug Trials Snapshot
38.	Exxua	gepirone	9/22/2023	To treat major depressive disorder
37.	Ojjaara	momelotinib	9/15/2023	To treat intermediate or high-risk myelofibrosis in adults with anemia
36.	Aphexda	motixafortide	9/8/2023	To use with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myelomaDrug Trials Snapshot
35.	Veopoz	pozelimab-bbfg	8/18/2023	To treat patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease
34.	Sohonos	palovarotene	8/16/2023	To reduce the volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva
33.	Elrexfio	elranatamab-bcmm	8/14/2023	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapyDrug Trials Snapshot
32.	Talvey	talquetamab-tgvs	8/9/2023	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior therapies
31.	Izervay	avacincaptad pegol	8/4/2023	To treat geographic atrophy secondary to age-related macular degeneration
30.	Zurzuvae	zuranolone	8/4/2023	To treat postpartum depression Press ReleaseDrug Trials Snapshot
29.	Xdemvy	lotilaner	7/25/2023	To treat Demodex blepharitis
28.	Vanflyta	quizartinib	7/20/2023	To use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteriaDrug Trials Snapshot
27.	Beyfortus	nirsevimab-alip	7/17/2023	To prevent respiratory syncytial virus (RSV) lower respiratory tract diseasePress ReleaseDrug Trials Snapshot
26.	Ngenla	somatrogon-ghla	6/27/2023	To treat growth failure due to inadequate secretion of endogenous growth hormoneDrug Trials Snapshot

25.	Rystiggo	rozanolixizumab-noli	6/26/2023	To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor- or anti-muscle-specific tyrosine kinase antibody-positiveDrug Trials Snapshot
24.	Litfulo	ritlecitinib	6/23/2023	To treat severely patchy hair lossDrug Trials Snapshot
23.	Columvi	glofitamab-gxbm	6/15/2023	To treat diffuse large B-cell lymphoma, not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapyDrug Trials Snapshot
22.	Inpefa	sotagliflozin	5/26/2023	To treat heart failureDrug Trials Snapshot
21.	Posluma	flotufolastat F 18	5/25/2023	To use with positron emission tomography imaging in certain patients with prostate cancerDrug Trials Snapshot
20.	Paxlovid	nirmatrelvir, ritonavir	5/25/2023	To treat mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19Press ReleaseDrug Trials Snapshot
19.	Xacduro	sulbactam, durlobactam	5/23/2023	To treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complexPress Release
18.	Epkinly	epcoritamab-bysp	5/19/2023	To treat relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma after two or more lines of systemic therapyDrug Trials Snapshots
17.	Miebo	perfluorhexyloctane	5/18/2023	To treat signs and symptoms of dry eye disease
16.	Veozah	fezolinetant	5/12/2023	To treat moderate to severe hot flashes caused by menopausePress Release
15.	Elfabrio	pegunigalsidase alfa-iwxj	5/9/2023	To treat confirmed Fabry disease
14.	Qalsody	tofersen	4/25/2023	To treat amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation
13.	Joenja	leniolisib	3/24/2023	To treat activated phosphoinositide 3-kinase delta syndromeDrug Trials Snapshots
12.	Rezzayo	rezafungin	3/22/2023	To treat candidemia and invasive candidiasis
11.	Zynyz	retifanlimab-dlwr	3/22/2023	To treat metastatic or recurrent locally advanced Merkel cell carcinoma
10.	Daybue	trofinetide	3/10/2023	To treat Rett syndrome
9.	Zavzpret	zavegepant	3/9/2023	To treat migraine
8.	Skyclarys	omaveloxolone	2/28/2023	To treat Friedrich's ataxiaDrug Trials Snapshots
7.	Filspari	sparsentan	2/17/2023	To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progressionDrug Trials Snapshot
6.	Lamzede	velmanase alfa-tycv	2/16/2023	To treat non-central nervous system manifestations of alpha-mannosidosis
5.	Jesduvroq	daprodustat	2/1/2023	To treat anemia caused by chronic kidney disease for adults on dialysis for at least four monthsPress ReleaseDrug Trials Snapshot
4.	Orserdu	elacestrant	1/27/2023	To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapyDrug Trials Snapshot
3.	Jaypirca	pirtobrutinib	1/27/2023	To treat relapsed or refractory mantle cell lymphoma in adults who have had at least two lines of systemic therapy, including a BTK inhibitorDrug Trials Snapshot
2.	Brenzavvy	bexagliflozin	1/20/2023	To improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exerciseDrug Trials Snapshot
1.	Leqembi	lecanemab-irmb	1/6/2023	To treat Alzheimer's diseasePress Release

According to the Global Data Pharmaceutical Intelligence Center, 22,338 clinical studies were initiated in 2023. The main indication was oncology, followed by the central nervous system. Of the trials initiated in 2023, the majority (36%) were Phase II trials. Also in 2023, 7,183 clinical trials ended, with 6,234 completing and 777 terminated

[1-5]. During the first half of 2024, the FDA is already approving 21 new drugs and indications: Table 2.

My recognition to all the scientific and administrative staff in the field of clinical research, who carry out such commendable work and benefit the entire world with their efforts.

Table 2: Novel Drug Approvals for 2024 | FDA.

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
21.	Ohtuvayre	ensifentrine	6/26/2024	To treat chronic obstructive pulmonary disease
20.	Piasky	crovalimab-akkz	6/20/2024	To treat paroxysmal nocturnal hemoglobinuria
19.	Sofdra	sofpironium	6/18/2024	To treat primary axillary hyperhidrosis
18.	Iqirvo	elafibranor	6/10/2024	To treat primary biliary cholangitis in combination with ursodeoxycholic acid
17.	Rytelo	imetelstat	6/6/2024	To treat low- to intermediate-1 risk myelodysplastic syndromes
16.	Imdelltra	tarlatamab-dlle	5/16/2024	To treat extensive stage small cell lung cancer
15.	Xolremdi	mavorixafor	4/26/2024	To treat WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis)Drug Trials Snapshot
14.	Ojemda	tovorafenib	4/23/2024	To treat relapsed or refractory pediatric low-grade glioma
13.	Anktiva	nogapendekin alfa inbakicept-pmln	4/22/2024	To treat bladder cancer
12.	Lumisight	pegulicianine	4/17/2024	To use as an optical imaging agent for the detection of cancerous tissue
11.	Zevtera	ceftobiprole medocaril sodium	4/3/2024	To treat certain bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumoniaPress Release
10.	Voydeya	danicopan	3/29/2024	To treat extravascular hemolysis with paroxysmal nocturnal hemoglobinuria
9.	Vafseo	vadadustat	3/27/2024	To treat anemia due to chronic kidney disease
8.	Winrevair	sotatercept-csrk	3/26/2024	To treat pulmonary arterial hypertensionDrug Trials Snapshot
7.	Duvyzat	givinostat	3/21/2024	To treat Duchenne muscular dystrophy in individuals aged 6 years and olderPress ReleaseDrug Trials Snapshot
6.	Tryvio	aprocitentan	3/19/2024	To treat hypertensionDrug Trials Snapshot
5.	Rezdiffra	resmetirom	3/14/2024	To treat noncirrhotic non-alcoholic steatohepatitis with moderate to advanced liver scarringPress Release
4.	Tevimbra	tislelizumab-jsgr	3/13/2024	To treat unresectable or metastatic esophageal squamous cell carcinomaDrug Trials Snapshot
3.	Letybo	letibotulinumtoxinA-wlbg	2/29/2024	To temporarily improve the appearance of moderate-to-severe glabellar linesDrug Trials Snapshot
2.	Exblifep	cefepime, enmetazobactam	2/22/2024	To treat complicated urinary tract infectionsDrug Trials Snapshot
1.	Zelsuvmi	berdazimer	1/5/2024	To treat molluscum contagiosumDrug Trials Snapshot

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