

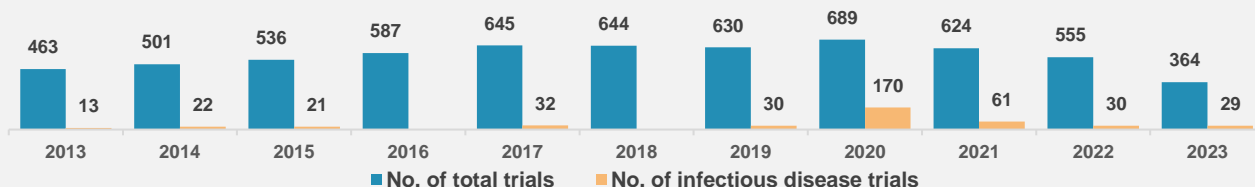
PRECISION AND PERSONALIZED MEDICINE TRIALS

CLINICAL TRIAL LANDSCAPE OVERVIEW

In 2020, precision and personalized medicine trials reached a peak, primarily driven by an increase in infectious disease trials in response to COVID-19. Oncology emerged as the dominant therapy area with 5,395 trials, constituting 47% of all precision and personalized medicine trials; however, this proportion has decreased by more than half over the past two decades. Phase II trials consistently outnumbered other phases, representing 64% of all precision and personalized medicine trials since 2013.

PRECISION AND PERSONALIZED MEDICINE TRIALS BY YEAR

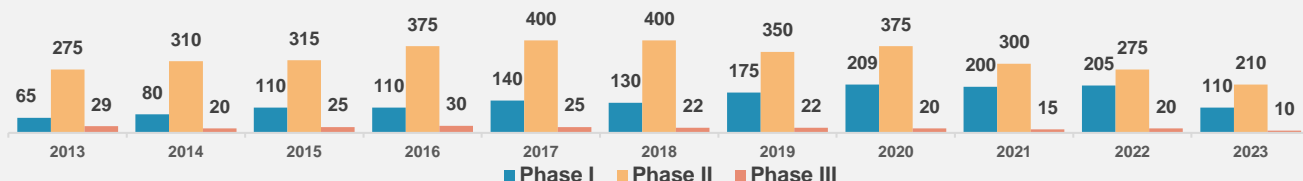
Precision medicine trials grew steadily from 2013 to 2017, peaking in 2020 after Zolgensma and Kymriah FDA approvals. Despite a low in 2022, the trials show an evolving trend. Notably, infectious disease trials surged from 5% in 2017 to 25% in 2020.



- Precision medicine trials steadily grew from 2013 to 2017, peaking in 2020 after a dip in 2019 due to pandemic disruptions.
- Notably, 2019–20 showed the highest year-on-year growth after FDA approval of Novartis's Zolgensma, similar to the trend in 2016–17 after Kymriah received FDA approval.
- Overall, 2022 recorded a seven-year low, highlighting the evolving nature of these trials.
- Before the 2020 peak, infectious diseases accounted for 5% of trials in 2017; however, in 2020, they surged to 25% of all precision medicine trials.

PRECISION AND PERSONALIZED MEDICINE CLINICAL TRIALS BY YEAR AND PHASE

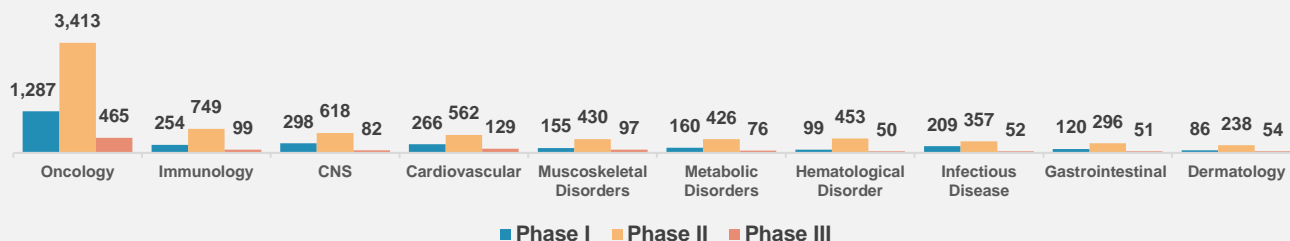
Phase II trials, typically the most numerous, saw their first decline in 2019, briefly recovering in 2020 but trending downward since 2021.



- Phase II trials have consistently outnumbered all other phases.
- Phase II trials declined for the first time since 2013 in 2019. Although they briefly recovered in 2020, they have been on a downward trend since 2021.

TOP THERAPY AREAS IN PRECISION AND PERSONALIZED MEDICINE CLINICAL TRIALS

Oncology leads precision medicine trials at 47%, driven by the first approved gene therapy Gencidine. Oncology and dermatology both have eight marketed precision medicines globally, followed by cardiovascular with seven.



- Oncology is the leading therapeutic area, accounting for 47% of all precision and personalized medicine trials.
- Oncology's leadership position was aided by the approval of the first gene therapy, Shenzhen SiBiono Genentech's Gencidine (recombinant human p53 adenovirus), which was marketed in 2003 for the treatment of various cancers.
- Oncology and dermatology both have eight marketed oncology precision and personalized medicines worldwide. They are followed by cardiovascular with seven medicines.

Catalytic Trial Events Using Cell and Gene Therapies in Precision and Personalized Medicine

Key Companies	Type of Therapy	Therapy Area	Upcoming Catalytic Trial Events		
			Phase I	Phase II	Phase III
AVROBIO	Cell Therapy	Genetic Disorders		● ●	●
		Metabolic Disorders		●	●
Infectious Disease		●			
CNS		●	●		
Genetic Disorders			●		
CNS			● ●		
Infectious Diseases					
Respiratory Disorders		● ●			
Cardiovascular Disorders		●			
SAREPTA THERAPEUTICS		Gene Therapy	Genetic Disorders	●	
Roche	Gene Therapy	Musculoskeletal Disorders	●		●
Gene Therapy	Genetic Disorders	●	●	●	
Spark	Gene Therapy	Metabolic Disorders		●	
CANDEL THERAPEUTICS	Gene Therapy	Hematological Disorders		●	●
	Oncology		● ● ●		

● Number of trials

- In 2023, precision and personalized medicine clinical trials focused on genetic disorders, with ongoing, new, or upcoming gene therapies expected to conclude, begin, or release results.
- Sarepta Therapeutics was at the forefront, with six catalytic events conducted by the end of 2023.
- AVROBIO was also a frontrunner, featuring five catalytic events conducted by the end of 2023.
- The central nervous system (CNS) takes center stage in precision and personalized medicine clinical trials, with a focus on cell therapy.

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

HOW CAN ARANCA HELP?

01

Market Assessment: Disease burden/disease landscape, diagnosis and treatment paradigm, humanistic and economic burden

02

Current and Future Landscape: Current treatments and latest pipeline landscape assessment for a particular therapy area

03

Strategic Initiative Analysis: Understanding key market trends in terms of M&As, funding, deals and other pertinent strategic initiatives

04

Health Technology Assessment (HTA): Analysis of various HTA decisions published by various countries

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