# Clinical Trial Success & Dropout Analysis

# **Insights Report**

## **Overview**

This project analyzes clinical trial data sourced from <u>ClinicalTrials.gov</u> to identify patterns influencing trial success and dropout rates. The dataset covers multiple therapeutic areas, study phases, sponsors, and regions providing a comprehensive view of global clinical research activity.

A total of <u>542</u> trials were examined, spanning from <u>2000</u> to <u>2025</u>. The objective was to understand how factors such as trial phase, sponsor type, study status, duration, and yearly trends impact the likelihood of trial completion or discontinuation.

The insights derived from this analysis aim to support better trial design, patient retention strategies, and sponsor-level decision-making in the clinical research process.

# **Key Insights**

## A. Clinical Trial Distribution by Phase & Status

- Observation 1: Phase 2 trials account for the largest proportion of studies in the dataset, indicating that the majority of clinical research activity is focused on this stage of development.
- Observation 2: The state of **Missouri** hosts the highest number of trials, suggesting regional concentration of clinical research activity in this area.

## **B.** Clinical Trial Distribution by Study Status

- Observation 1: The three highest categories are Recruiting, Active Not Recruiting, and Completed together account for the largest proportion of all clinical trials shown. Specifically, Recruiting has the highest number of trials (around 158), followed closely by Active Not Recruiting (around 145), and then Completed (around 128). This indicates a strong focus on trials that are either in progress or have reached their conclusion.
- Observation 2: The number of trials that have been **Terminated** is substantial (around <u>83</u>), representing the fourth-largest category. This is significantly higher than trials that are **Suspended** (around <u>6</u>) or in an **Unknown** status (around <u>8</u>), suggesting that a major reason for a trial not being active or complete is its formal termination.

#### C. Distribution of Trial Duration

- Observation 1: The distribution is not symmetric; it clearly peaks between approximately **1,500** and **2,000 days** (about 4 to 5.5 years), which represents the most frequent trial duration. The distribution then has a long tail extending toward the right (longer durations), indicating that while most trials fall within the **1,000** to **3,500 days** range, a few trials last for very long periods, extending up to or beyond **8,000 days** (over 21 years).
- Observation 2: The vast majority of trials are clustered within a relatively narrow window. Specifically, the four tallest bars, which range from about 1,000 days to 2,500 days (approximately 2.7 to 6.8 years), collectively contain the highest concentration of the total number of clinical trials. The frequency of trials drops off significantly past the 3,500-day mark, showing that very long durations are relatively rare.

#### **D. Dropout vs Completion Rates**

Observation 1: The overall success (completion) and challenge (dropout) rates differ widely among the top sponsors. For example, the **University of Washington** has the highest recorded dropout percentage (around 70%), resulting in a very low completion percentage (around 15%), making it the least successful in terms of participant retention/completion. Conversely, the **Mayo Clinic** has a high completion rate (around 45%) with no visible dropout percentage, suggesting high participant retention or a data recording difference.

Observation 2: Several cancer-focused institutions have relatively high completion percentages compared to their dropout percentages. For instance, the M.D. Anderson Cancer Center, Dana-Farber Cancer Institute, and Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins all show completion rates that are equal to or greater than their dropout rates (or have a notably high completion rate overall), indicating generally effective trial execution or participant engagement among these specialized centers.

## **E.** Yearly Trend (Initiation vs Completion)

Observation 1: The vast majority of both initiated (blue line) and completed (orange line) trials are clustered at the right end of the graph, corresponding to the year 2000 and beyond. Both metrics show a dramatic, near-vertical increase starting around the year 2000, with the peak number of initiated trials (around 65) and completed trials (around 90) occurring in the latest recorded year. This suggests a massive and recent acceleration in clinical trial activity.

Observation 2: Before the sharp rise around the year 2000, the data points for "Initiated Trials" are consistently low, near zero. However, the "Completed Trials" line shows much higher and more variable numbers in the earliest years (e.g., around 70, 38, 26, and 18), while simultaneously declining to near zero by the year 2000. This pattern suggests either that data recording was sporadic in early years or that a large number of older trials were completed before the start of the massive initiation phase seen after 2000.

## **Summary of Insights**

The analysis reveals a research landscape currently dominated by **Phase 2 trials**, with key activity clustered geographically in regions such as **Missouri**. The overall pipeline is robust, with the majority of trials categorized as **Recruiting**, **Active Not Recruiting and Completed**. However, a significant operational challenge is evident in trial abandonment, as the number of **Terminated** trials (around <u>83</u>) is high.

Regarding duration, the most frequent trial length falls between 1,500 and 2,000 days (4 to 5.5 years), with the overall distribution being positively skewed toward longer, though rare, durations. On a macro level, the dataset shows a dramatic shift toward recent activity, with both trial **Initiations and Completions** demonstrating an accelerated, near-vertical increase starting around the year 2000.

Sponsor performance is highly variable: while institutions like the **University of Washington** face high dropout rates (around 70%), specialized **cancer research centers** (e.g., M.D. Anderson) generally exhibit **effective participant engagement** and high completion rates.

### **Recommendations**

- 1. Implement an early risk assessment and monitoring framework focused on the most common drivers of termination. Sponsors should leverage mid-trial data reviews and adaptive design elements to course-correct, salvaging trials before formal termination.
- 2. Prioritize trial protocols that are explicitly designed to be completed within a 4 to 5.5 year window to align with industry norms and participant tolerance. For necessary long-duration trials (over 3,500 days), implement staged milestones and interim analysis points to justify the extended commitment and maintain participant engagement.
- 3. Conduct targeted site-level audits and best practice sharing focusing on institutions with the highest dropout rates. Implement mandatory training programs on effective patient-centric recruitment and retention strategies, leveraging the expertise of high-performing centers like the Mayo Clinic and specialized cancer centers.
- 4. Proactively scale infrastructure (staffing, regulatory review capacity, IT systems) to match the accelerated initiation rate. Regulatory bodies should streamline the review process to prevent bottlenecks, while sponsors should increase investment in new pipeline candidates to capitalize on the sustained growth in clinical research volume.
- 5. Focus resource allocation and research partnerships on Phase 2 development to maximize the chance of advancing candidates to later stages. For localized research hubs like Missouri, establish regional excellence centers to foster collaboration, shared resources, and a centralized talent pool, thereby consolidating expertise and efficiency.

## **Limitations**

The analysis is constrained by three primary data quality and bias issues:

- 1. **Data Incompleteness and Missing Values:** The true rate of trial failure may be underestimated, as the number of trials with a lapsed or missing status is likely higher than the small "Unknown" category. Furthermore, dropout and completion rates are affected by participants lost to follow-up, potentially biasing the sponsor performance metrics.
- 2. **Inconsistent Reporting and Definitions:** Historical data (pre <u>2000</u>) is unreliable due to sporadic data entry, and recent completion figures may suffer from reporting lag. Critical metrics like "Dropout" and "Completion" are subject to inconsistent definitions across various sponsors, complicating direct comparison.
- 3. Regional and Scope Bias: The finding that Missouri hosts the highest number of trials suggests a strong geographic sampling bias in the dataset's source. Additionally, the focus on the Top 15 Sponsors means the highly variable dropout/completion rates may not be generalizable to smaller or less specialized research organizations.