



KPI ENCYCLOPEDIA

A Comprehensive Collection of KPI Definitions for

PHARMACEUTICALS



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Pharmaceuticals KPI Encyclopedia

Pharmaceuticals Metric Definitions

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Clinical Trials

Pharmaceuticals*

Research & Development (R&D)

• Clinical Trials

- Drug Discovery*
- New Drug Approval*
- Post-Approval Research & Monitoring*

Pharmaceutical Manufacturing

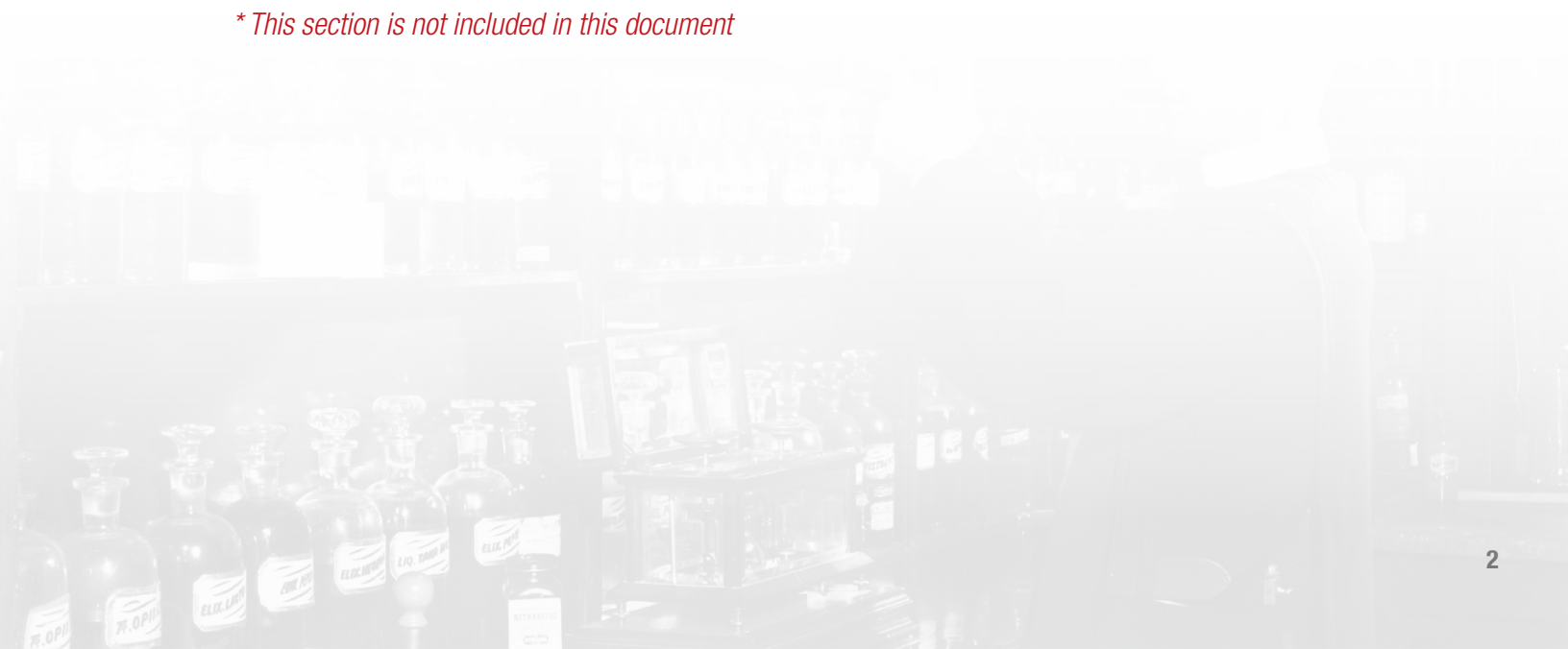
Pharmaceutical Distribution

Product Education & Compliance

Patient Assistance Programs (PAPs)

The testing phase of a new drug is a lengthy and expensive part of research and development. The Food and Drug Administration (FDA) demands that candidate pharmaceuticals pass through a three-phase process of human trials to demonstrate safety and baseline efficacy. The first two phases involve only small sample groups of test patients. The third phase involves a sample size of thousands of patients and carries huge costs. Generally, Phase III trials need to demonstrate that a drug meets the necessary efficacy requirements with a 95 percent statistical certainty.

** This section is not included in this document*



Clinical Trials

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Cost

- **R&D Cost Allocation: Phase I** – Total R&D-related expenses that are accumulated during Phase I clinical trials for drugs in the R&D pipeline divided by the total R&D Expense over the same period of time.
- **R&D Cost Allocation: Phase II** – Total R&D-related expenses that are accumulated during Phase II clinical trials for drugs in the R&D pipeline divided by the total R&D Expense over the same period of time.
- **R&D Cost Allocation: Phase III** – Total R&D-related expenses that are accumulated during Phase III clinical trials for drugs in the R&D pipeline divided by the total R&D Expense over the same period of time.
- **R&D Cost Allocation: Phase IV** – Total R&D-related expenses that are accumulated during Phase IV clinical trials for drugs in the R&D pipeline divided by the total R&D Expense over the same period of time.
- **R&D Cost Allocation: Prehuman/Preclinical** – Total R&D-related expenses that are accumulated during prehuman/preclinical trial phase for drugs in the R&D pipeline divided by the total R&D Expense over the same period of time.
- **Average Cost of Failure** – The average expense incurred through the research and development of a drug or compound that fails (i.e., does not pass clinical trials or regulatory approval) at some point during the discovery or clinical trial process over a certain period of time.
- **Clinical Trial Cost per Patient** – The cost of running a clinical trial round (labor, overhead, marketing costs, etc.) divided by the total number of patients participating in the trial over the same period of time.
- **R&D Cost Allocation: Approval Stage** – Total R&D-related expenses that are accumulated during the approval stage for drugs in the R&D pipeline divided by the total R&D Expense over the same period of time.

Organizational

- **Percentage of Clinical Trial Work Outsourced** – The amount of clinical trial work (protocol development, patient recruitment, testing, data collection, etc.) outsourced to contract research organizations (CRO) divided by the total amount of clinical trial work performed at the same point in time, as a percentage.

Productivity

- **Cycle Time: Clinical Trial Enrollment Quota** – The number of business days required to recruit and onboard test subjects for a round of clinical trials, from the time the recruitment process begins until when the subject onboarding process ends.
- **Cycle Time: Clinical Trials (I-IV)** – The number of months required to complete clinical trials (Phases I - IV), from the time Phase I begins until when Phase IV ends. Drugs should clear Phase II clinical trials before being compared or assessed using this metric.
- **Cycle Time: Clinical Trial Phase I** – The number of months required to complete Phase I clinical trials (typically less than 100 participants), from the time Phase I begins until enough data has been collected to make a decision regarding moving into Phase II trials.
- **Cycle Time: Clinical Trial Phase II** – The number of months required to complete Phase II clinical trials (typically from 100-300 participants), from the time Phase II begins until enough data has been collected to make a decision regarding moving into Phase III trials.
- **Cycle Time: Clinical Trial Phase III** – The number of months required to complete Phase III clinical trials (typically from 1,000-3,000 participants), from the time Phase III begins until enough data has been collected to make a decision regarding moving into Phase III trials.
- **Cycle Time: Clinical Trial Phase IV** – The number of months required to complete Phase IV clinical trials (typically from 3,000+ participants), from the time Phase IV begins until enough data has been collected to make a decision regarding large-scale drug production and distribution.
- **Product Complaints & Queries Handled per Medical Information Employee** – The total number of product complaints or technical queries received over a certain period of time divided by the total number of medical information employees responsible for replying to these requests.

Quality

- **Phase I Survival Rate: New Molecular Entities** – The number of drugs that make it past Phase I clinical trials divided by the total number of drugs researched during Phase I trials over the same period of time, as a percentage.



Clinical Trials (Cont.)

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Quality (Cont.)

- **Phase II Survival Rate: New Molecular Entities** – The number of drugs that make it past Phase II clinical trials divided by the total number of drugs researched during Phase II trials over the same period of time, as a percentage.
- **Phase III Survival Rate: New Molecular Entities** – The number of drugs that make it past Phase III clinical trials divided by the total number of drugs researched during Phase III trials over the same period of time, as a percentage.
- **Clinical Trial Protocol Submission Approval Rate** – The number of clinical trial protocols submitted to the FDA (or another international regulatory agency) that are approved and available to begin full-scale clinical testing divided by the total number of protocols submitted over the same period of time, as a percentage.
- **Number of Medication Labeling-Related Complaints** – The number of complaints from consumers and/or regulatory agencies related to product labeling accuracy and quality (segmented by product) received over a certain period of time.
- **Percentage of Medication Labels Audited and Scored as Inaccurate** – The total number of medication

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