

Enrollment Benchmarks

DecisionView Enrollment Benchmarks aggregate performance data across multiple sponsors in the industry, providing valuable insight to help identify appropriate assumptions and enable more realistic enrollment planning and forecasting. Enrollment Benchmarks are available to DecisionView StudyOptimizer™ customers who contribute their completed trial data.

Industry Performance Metrics for Enrollment

Better planning assumptions informed by data

Planning data at the point of need

Trusted data gathered from valid source systems

Clinical Trials Continue To Miss Enrollment Targets and Timelines

According to a 2007 CenterWatch survey, enrollment problems delay more than 70% of clinical trials from one to six months. The situation is somewhat better outside the U.S., although not by much - studies in other regions of the world enrolled according to schedule only 14–17% of the time.

This continuing failure of studies to meet enrollment targets and timelines forces sponsors to address the issue with costly trial adjustments, including adding rescue sites, costly media campaigns, and introducing protocol amendments. But now, with DecisionView StudyOptimizer and Enrollment Benchmarks, there's a better, more accurate way to predict enrollment performance.

STUDYOPTIMIZER – A BETTER WAY TO PLAN ENROLLMENT

DecisionView StudyOptimizer is a web-based solution that helps clinical trial organizations plan, forecast and track patient enrollment. Planners enter startup and enrollment assumptions into StudyOptimizer based on their own experience, augmented by evidence-based historical performance from studies completed by their organization, as well as external industry benchmarks. StudyOptimizer then uses these assumptions to create enrollment plans and forecasts, and tracks these plans against actual performance. Key capabilities of StudyOptimizer include:

- Planning - collaborate on and model enrollment assumptions on a global basis
- Tracking - monitor the progress of trials against plan, and visualize projected performance
- Diagnose - drill down into key performance areas to quickly identify issues
- Optimize - model course correction strategies to get trials back on track
- Analyze - evaluate historical performance trends across trials, countries, investigators
- Budget - evaluate trial enrollment and treatment costs projected across trial duration

Benchmarks – A Better Way To Inform Planning

Better predictability for clinical enrollment starts with better planning, and better plans result from better assumptions. Clinical trial organizations know this, which is why there is an ongoing demand for more and better clinical trial benchmarking data.

BUT CURRENT BENCHMARK OFFERINGS ARE INADEQUATE

Traditional sources of benchmark information include company internal study data, third party data sets, and survey-based benchmarks. But these sources are inadequate for a number of reasons:

- Lack of data granularity,
- Inconsistent data collection,
- Lack of data coverage across TAs and geographic regions,
- No integration with planning processes and tools,
- Infrequent updates,
- Significant effort to generate or cost to acquire data

Because of these challenges, DecisionView StudyOptimizer customers have agreed to share clinical enrollment data that exists in their StudyOptimizer installations to create an anonymized set of industry benchmarks for startup and enrollment.

DecisionView Enrollment Benchmarks

DecisionView Enrollment Benchmarks aggregate cross-industry performance data from clinical trials that have completed enrollment, providing valuable insight to help identify appropriate assumptions and enable more realistic planning and forecasting for similar studies. This information can be used to validate assumptions when planning for a specific study, or to benchmark enrollment performance across a portfolio of trials to determine areas for further operational improvements.



DECISIONVIEW

www.decisionview.com

At a Glance

Enrollment Benchmarks data set overview at January 2012:

Number of studies:

- 730+

Number of subjects screened:

- 375,000+

Number of sites:

- 35,000+

Number of therapeutic areas:

- 14

Number of countries:

- 85

Awards



About DecisionView

DecisionView develops innovative web-based software solutions that enable life sciences organizations around the world to improve clinical trial performance. DecisionView's flagship solution, StudyOptimizer, helps organizations optimize clinical trial enrollment by aggregating patient recruitment data from multiple sources and providing analytics, visualizations, and predictive scenario modeling that delivers unique and actionable insight. StudyOptimizer is used by 8 of the top 10 global pharmaceutical companies, and has been used on over 1,250 clinical studies with over 450,000 subjects enrolled in 17 different therapeutic areas across 91 different countries. Investors in the company include Granite Ventures and Aeris Capital. For additional information about DecisionView, go to <http://www.decisionview.com> or call 415-538-1800.

Enrollment Benchmarks are available to DecisionView StudyOptimizer™ customers who contribute their completed trial data, which is then aggregated and anonymized to ensure the confidentiality of sponsor studies. The breadth and depth of studies in the Enrollment Benchmarks data set will grow as participating sponsors complete additional studies, and as new contributors add their portfolios of completed trial data.

Key Capabilities

ANALYSIS TOOLS

The analytic tools included with Enrollment Benchmarks enable users to select and group relevant studies based on criteria such as trial phase, therapeutic area, indication and region, and then view and compare granular performance data from these study groups.

METRICS

The data in Enrollment Benchmarks includes anonymized study metadata, as well as startup and enrollment performance data broken down by phase, therapeutic area, indication and country. The metrics are the same standardized definitions used by StudyOptimizer to plan and forecast enrollment.

Key Benefits

BETTER PLANNING ASSUMPTIONS	The rich set of clinical performance data informs and calibrates both initial clinical trial planning and trial rescue/recovery planning
PLANNING DATA AT POINT OF NEED	Provides planning information at the point of need, in an easily-accessible format
TRUSTED DATA	Because the data is collected through and mapped to StudyOptimizer's data definitions, sponsors understand and trust how it is defined and gathered
NEW MARKET DATA	Provides benchmark information where sponsors have little or no prior experience, particularly for indications or countries where they have not previously run trials
ACTIONABLE DATA FOR STUDY TEAMS	Provides study teams, not just senior management, with a prospective capability to affect improved performance
STANDARDIZED DATA	All data in the knowledgebase is mapped to StudyOptimizer's standard data definitions, so that it is all comparable and normalized
AUTOMATED DATA CAPTURE	Enrollment Benchmark data is captured, validated, and aggregated automatically by StudyOptimizer, directly from our customers' source systems
CRITICAL MASS	Pharma industry leaders including GlaxoSmithKline, Merck and Roche participate in Enrollment Benchmarks. The current data set contains thousands of clinical trials covering tens of thousands of sites and hundreds of thousands of patients
PREDICTIVE INSIGHT	Provides insight into trends and influences in the industry that will drive new additional predictive analytics in our DecisionView product offerings

