

Technology aligned™

ClinPhone **RTSM**

Imaging

CTMS

EDC

ePRO

Solutions

Cytel
STATISTICAL SOFTWARE & SERVICES

A proven
partnership
for all your
adaptive trial
requirements

Your Key To **Successful** Adaptive Clinical Trials

Adaptive clinical trials are now solving key problems facing today's biopharmaceutical and medical device developers. The flexibility of adaptive designs provides clinical researchers with previously unavailable options to improve the likelihood of a successful study outcome.

By making midcourse adjustments to the study design, without compromising trial integrity or statistical validity, adaptive trials increase our ability to answer the study's key research objectives. The combination of innovative statistical techniques and trial technology advances has enabled the application of adaptive designs in today's clinical trials.

However, successfully planning and conducting these new trials presents significant challenges for sponsor companies. In considering an adaptive strategy, trial planners must carefully take into account a host of complex issues, including how to:

- Assess whether an adaptive trial is the most suitable design to achieve the study objectives
- Identify and evaluate feasible design alternatives
- Determine the optimal decision rules and characteristics of the selected trial design
- Justify and defend the design choice to regulatory reviewers and IRBs
- Accurately forecast clinical supply requirements and the optimal packaging configurations
- Implement and design an effective combination of clinical technologies to enable efficient operation of the study

Cytel and Perceptive integrated services help sponsors to confidently address each and every challenge posed by adaptive trials. Our unique partnership blends Cytel's validated adaptive trial statistical and computational expertise with Perceptive's robust suite of clinical technologies and operational knowhow. The result places at your disposal our combined knowledge and ability to successfully plan and implement adaptive and other complex study designs.

Developed in close collaboration with your study teams, each Cytel-Perceptive adaptive trial solution is tailored to match the individual requirements of the program and its objectives. Together, we deliver the essential building blocks for the entire spectrum of adaptive trial planning and operation: study design, randomization, trial simulations, supplies planning and management, clinical data collection, technology deployment, data analysis and reporting.

Our Integrated Services

Trial Design and Operations Planning

Adaptive Study Design

- Expert consulting on the statistical design of adaptive trials including:
 - Response adaptive designs
 - Early phase dose-finding and dose-ranging designs
 - "Seamless" phase I/II and II/III designs
 - Phase III studies with options to enrich study populations or re-adjust the sample size
 - Options for early stopping for futility or efficacy
 - Decision criteria using Bayesian and frequentist methods
- Trial simulation to identify optimal design properties
- Interim data analysis planning and independent Data Monitoring Committee (DMC) services
- Regulatory and Institutional Review Board (IRB) support

Trial Supply Planning

- Supply chain simulations to anticipate adaptive changes and their effect on supply requirements, optimal supply logistics and packaging configurations

Implementation Consulting

- Clinical trials technology experts provide consulting for effective study implementation including the use of IVR, EDC, ePRO and integration technologies

Study Delivery and Reporting

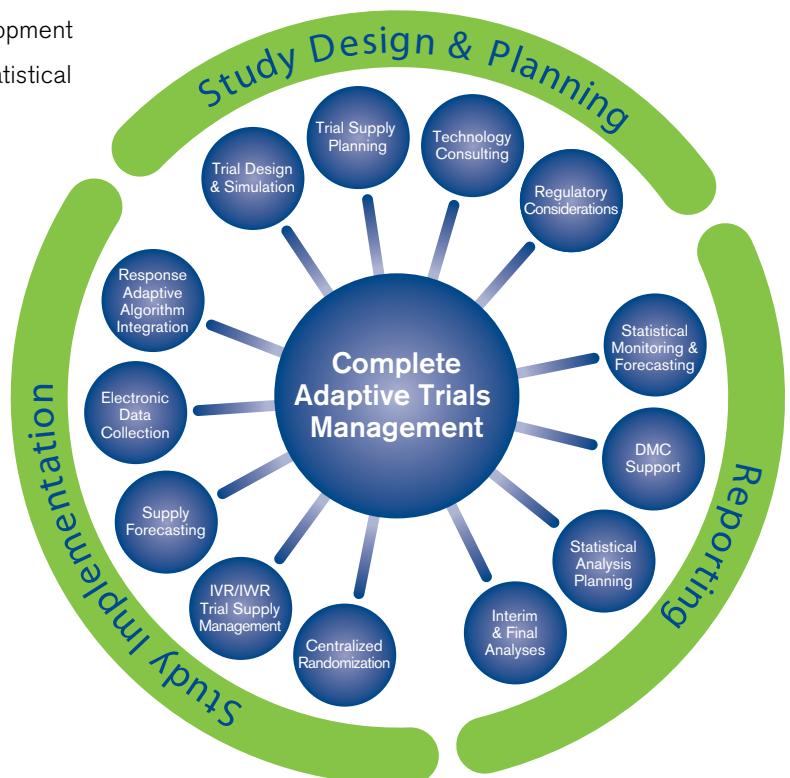
- Flexible validated central randomization capabilities powered by IVR/IWR including full integration with response adaptive statistical algorithms
- IVR/IWR trial supply management including site supply strategy adjustment in response to design adaptations
- Mid-study trial supplies forecasting to assess future supply production and packaging requirements
- Rapid collection and maintenance of clinical efficacy and safety response data using EDC (DataLabs®), ePRO and IVR/IWR solutions
- Study design monitoring by statistical experts to ensure appropriate performance of trial methodology and assumptions
- Full integration of technology components including IVR, EDC, ePRO and adaptive statistical algorithms eliminating data and end-user activity duplication
- Analysis and reporting
 - Statistical Analysis Plan development
 - Integrated clinical data and statistical analysis reports for the DMC
 - Interim analyses that include forecasts of future study performance
 - Final analyses and clinical study report preparation

Bringing You the Advantages Of Adaptive Clinical Trials

The Cytel and Perceptive integrated services partnership provides a comprehensive solution for the sponsor organization wishing to benefit from the power of adaptive trials.

Bringing together validated expertise, tools and systems, our unique approach offers companies the following advantages:

- Reliable and statistically defensible trial designs to fully address the study objectives employing adaptive, Bayesian or classical methodologies
- Secure and tailored technology solutions to ensure seamless implementation of your study
- Improved decision making in early-phase dose-finding studies, increasing the likelihood of successful confirmatory studies
- Ensuring your study remains on track with ongoing statistical and clinical supply monitoring
- Immediate access to key response and decision data
- Rapid delivery of data and statistical reports for decision making
- Confidence that study personnel will remain unaware of the timing and nature of trial adaptations
- Reduced burden on study teams by working with a well-integrated, proven collaboration to satisfy the demands of adaptive trials



About Perceptive Informatics

Perceptive is the leading technology provider in adaptive trials, having delivered more than 100 applications to support protocols with design adaptations.

Perceptive's solutions provide all the building blocks required to implement an adaptive trial design including central randomization, trial supply management, EDC, ePRO and real-time integration with sophisticated statistical software required by some adaptive trials. Perceptive's adaptive trial solutions are tailored combinations of these technologies delivered fully integrated through the company's unique integration platform.

As a leading eClinical Solutions provider Perceptive has experience in over 3000 clinical trials spanning 88 countries and 71 languages. Perceptive is a trusted provider with a proven track record of delivering flexible technology applications for highly complex clinical trials. Our in-house statistical and trial supply experts provide pre-study consulting on the effective implementation and utilization of technology to support adaptive designs.

About Cytel

Cytel pioneered the statistical science and computational technology of adaptive clinical trials. Benefiting both sponsors and patients, Cytel has designed more validated adaptive trials than anyone else.

Biopharmaceutical and device companies of all sizes turn to the clinical study planning, simulation and implementation experience of Cytel. Cytel experts have trained thousands of health sciences industry biostatisticians, clinicians and regulatory staff in the latest trial design techniques.

Cytel's Clinical Research Services place this clinical study innovation experience at the disposal of your research and development programs. From trial simulation and process development to independent data assessment and regulatory review, Cytel stands with you every step of the way.

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