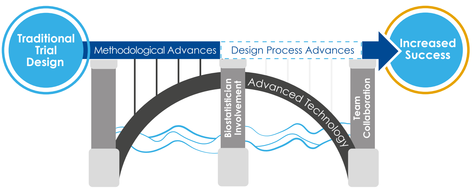
REIMAGINING CLINICAL TRIAL DESIGN

Solara™

Challenge

Innovations in clinical trial design alone cannot improve drug development success



The mere availability of complex innovative trial design methodologies cannot translate into higher success rates in regulatory submission or approval if the process that drug development teams use for statistical design remains unchanged. **Advanced technology now enables leaders to actively facilitate process improvements.**

Opportunity

Design process improvements supported by advanced technology can increase R&D productivity by **10-20%**

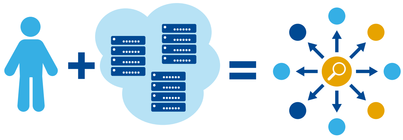
Development teams must overcome historical risk aversion and embrace new ways of interacting to realize the benefits of advances in trial design methodologies.

Keys to increased success:
1) Improve cross-functional collaboration.
2) Strategically involve a biostatistician earlier in the process.
3) Invest in advanced technology.

What are the benefits?

1 Thoroughly explore

Better informed statisticians supported by cloud computing enable development teams to search the expansive design space for more options than the traditional approach to trial design.



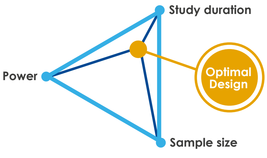
For example, the massive computing power in Cytel's patent-pending Solara™ enables biostatisticians to map the entire relevant design space in minutes, helping development teams optimize for speed, savings, and success.

2 Decide together

Accounting for multi-disciplinary perspectives, such as the commercial implications, in the modeling reveals a global optimum that supports business goals rather than a local optimum to a much narrower problem.

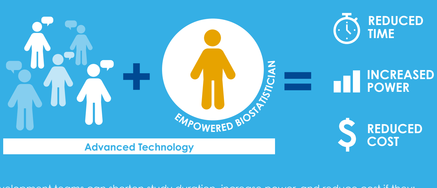
3 Communicate trade-offs

Visually communicating the nature of the trade-offs between study duration, sample size, and power can help teams reach data-driven consensus on the optimal design.



Conclusion

Collaboration, strategic application of statistics, and technology can increase development productivity



Development teams can shorten study duration, increase power, and reduce cost if they:
1) Improve collaboration across the various disciplines in the development team.
2) Involve the biostatistician early in the strategic study planning process.
3) Activate the full potential of the biostatistician with advanced technology.

With the latest cloud-powered decision-support technology like Cytel's Solara, biostatisticians can help development teams thoroughly explore the innovative design space, collaboratively decide on promising options, and clearly communicate trade-offs that can **increase clinical development productivity by 10-20%.**

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About Cytel

Cytel is the largest provider of statistical software and advanced analytics for clinical trial design and execution. Cytel's Solara™ is a patent-pending software platform that unifies statistics and strategy to optimize clinical trial design.

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