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Vlad Dragalin
Assistant VP of Statistical Research & Application
Wyeth

Wyeth accelerate adoption of Adaptive Clinical Trials with Tessella expertise

When Wyeth decided to adopt an Adaptive Clinical Trials methodology, it turned to Tessella to help build an extensible software environment that would enable its statistician and clinical teams to more easily develop, compare and evaluate different trial designs. The resulting Adaptive Design Explorer system has helped accelerate the adoption of adaptive trials at Wyeth, leading to reduced drug development costs and time to market.

Background

Wyeth, now part of Pfizer, has a long history of innovation, from the first “compressed pill” (tablet) to well known consumer brands such as Anadin, Ibuprofen and Centrum. In 2008, the company employed nearly 50,000 people worldwide and invested £1Billion a year in new drug discovery and development, equivalent to £3M every day.

The Adaptive Clinical Trials (ACT) methodology has long been accepted by the pharmaceutical industry as a way to accelerate drug development, reduce costs and improve time to market. However, there have been very few, if any, large-scale, real-world implementations of ACT, due in part to the commitment needed to rework legacy systems and processes, and also the lack of appropriate software and simulation tools.

Vlad Dragalin, Assistant VP of Statistical Research & Application at Wyeth, explains further, “Wyeth has always been an innovator, and we wanted to be one of the first to realise the benefits of ACT on a broad scale across the business. We started by establishing a team to lead the adoption of adaptive trial processes and information flows across the different departments such as bio-statistics, clinical and drug supply.”

However, the team also recognised that such a major change would not happen overnight, so initial efforts were focussed on equipping the statisticians within Wyeth with the right software and simulation tools. Being able to simulate, fine tune and compare a large number of different scenarios and trial designs is fundamental to the success of ACT.

Vlad continues, “Through our involvement with the PhRMA Adaptive Design working group we knew there wasn’t an off-the-shelf software environment



In 2009, Wyeth Research were awarded the “BIO-IT World Best Practices Award” for the “Best Clinical Trial Design” with special reference to the most innovative adaptive designs and Wyeth’s industry leading Adaptive Design Explorer simulation software.

that would provide what we were looking for, so we decided to engage with a software development partner to help us build to our specification. This approach would also give us full control over the parameters used in our models and simulations. Tessella were a natural choice, not just because of their software development expertise, but also their experience in simulation and knowledge of the pharmaceutical industry.”

Solution and Benefits

The Wyeth team drew up outline requirements for the trial design simulation system. The specification included an easy to use GUI that would guide users through the ACT process, aligned to an extensible and modular framework of trial design engines that would enable a large number of different design simulations to be easily developed, evaluated and compared.

It was also important that the system self-validated different designs in order to ensure compliance with drug trial regulations and facilitate design engine deployment in a production environment.

Tessella fully project managed the detailed specification and development of what became known as the Adaptive Design Explorer (ADE) using an iterative process to ensure the system evolved in line with requirements. Berry Consultants, leaders in adaptive trial design and Bayesian simulation, were later engaged to build out an extensive library of different design engines.

The ADE enables Wyeth statisticians and clinical teams to configure and evaluate different designs with a wide range of options including target of the trial, different adaptive elements of the design, such as sampling rule, allocation rule, stopping rule, model to fit response data, model to fit longitudinal data, and criteria for evaluating the success of the compound at the end of the trial.

Vlad was delighted with the results, “One of our original aims was to use ADE as a real-world environment for training and educating our statisticians in the design of adaptive trials.

This has been very successful. However, the real value has come from using ADE to demonstrate the benefits of adaptive trials to our clinical and drug supply teams using tables, figures and charts – rather than just words and theories. This means they are now actively engaged in helping to roll-out the ACT process across the business.”

Vlad continues, “Tessella’s expertise in software development has made a big difference to the success of the project. They were very responsive to our often changing requirements, and expertly handled all the software housekeeping tasks such as code repositories, release cycles, backups, testing and documentation. In addition, their knowledge of the pharmaceutical industry and simulation has been vital.”

Future

With ADE now in use, the next challenge is to rework processes and information flows across different departments.

Vlad explains, “Using ADE to clearly demonstrate the benefits of adaptive trials has helped us overcome much of the cultural resistance. We are now in the process of integrating data and information from legacy systems and upgrading process across the business. This will enable us to realise the full benefits of ACT of reducing drug development times and costs. For example, proper drug supply is a key part of any trial. In order to ensure we only supply according to specification of the adaptive trial we have stopped bulk shipping drugs and are now able to supply in smaller batches as needed.”

Vlad concludes, “The ADE and Tessella have enabled us to take a major step down the road to a business wide adoption of ACT, and I look forward to working with them further in order to build on our success.”

Tessella plc 26 The Quadrant, Abingdon Science Park, Abingdon, Oxfordshire OX14 3YS, UK
T: +44 (0)1235 555511 | F: +44 (0)1235 553301 | E: info@tessella.com

Tessella Inc 233 Needham Street, Suite 300, Newton, MA 02464, USA
T: 1 617 454 1220 | E: info@tessella.com

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