

THE CLINICAL RESEARCH
EXCELLENCE
AWARDS

THE WINNERS 2009



BEST TECHNOLOGICAL DEVELOPMENT IN CLINICAL TRIALS – COMMUNICATION SYSTEMS



L-R: Kelly Furneaux, Nigel Page, Paul Sinha

Winner: i3

Finalists: Greenphire, Phase Forward

WINNER'S RESPONSE

"i3Cube demonstrably changes the landscape and environment in which the clinical trial process is managed. Gone is the need to deal with multiple individual applications each addressing just one portion of the overall process; gone are the complicated and cumbersome interfaces which characterise other supposedly integrated solutions –for with i3Cube you have one unified interface, one core architecture, one common database and digital document repository – finally addressing the complete needs of all trial stakeholders, in real time on a global basis.

i3 is delighted to receive the Clinical Research Excellence award as further recognition of this exciting new capability. It goes to show just what is possible when you bring together clinical research specialists, technology experts and process engineers in a culture of innovation. "

Nigel Page, executive vice-president, Strategic Outsourcing & Corporate Development, i3

This category awards new communications technology that plays a role in all stages of the clinical trial process. The judging panel were looking for the product they thought best represented advances in clinical trials support management.

While the other nominees, Greenphire and Phase Forward, put forward a very strong case the judges felt i3 gave the best account of its product, i3Cube™.

This product, a web-based clinical trial and data management system, was built to address the shortfalls of other systems. The product's collaborative communications portal provides the trial's three critical players – the sponsor, investigative site and CRO – instant communication and access to real-time information using a single log-in. This system creates efficiencies at every step in a clinical trial's core processes, saving sponsors time and money.

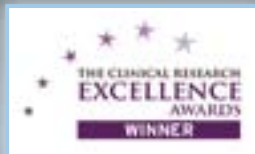
Trials should be conducted faster and more cost-efficiently with i3Cube™ because all players have instant access to the information they need and visibility to data in a real-time environment. Users of today's clinical trial software have a litany of complaints: sponsors feel out of control and have to check in constantly with their CRO to assess their project; users complain of siloed, separate systems that do not communicate with each other; combining two or more technologies that perform different functions is often tricky and expensive.

The product is the first end-to-end system with one core architecture and one centralised database to fold all clinical trial processes into a unified interface. Sponsors log-in to i3Cube™ for a real-time glimpse of all study information, communications and reporting in an easily accessed, version-controlled document library. A single log-in accesses the user's dashboard, which provides everything the user needs regardless of study stage.

The Award for Best Technological Development in Clinical Trials – Communication Systems was presented by Trial Trove.

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Best Technological Development in Clinical Trials—
Communication Systems**



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BEST TECHNOLOGICAL DEVELOPMENT IN CLINICAL TRIALS – SOFTWARE SOLUTIONS



L-R: Kelly Furneaux, Dr Stephen Cutler, Paul Sinha

Winner: Kendle International Inc

Highly Commended: Medicines Evaluation Unit

Finalists: Cisiv, Medidata, Perceptive, Phase Forward

WINNER'S RESPONSE

"We are delighted that Kendle's TrialEAS™ electronic adjudication system was named the Best Technological Development in Clinical Trials in the software solution category. With a strong focus on driving costs out of the clinical trial process we believe TrialEAS has emerged as an innovative solution that will deliver significant time and cost savings for our customers while enhancing patient safety."

Dr Stephen Cutler, chief operating officer, Kendle International

In judging the Best Technological Development in Clinical Trials Software Solutions category, the judging panel recognised the growing importance of sophisticated software in managing and maximising the value of clinical trials.

This category attracted the most amount of entrants this year and the competition was strong; hence the inclusion of a Highly Commended prize awarded to UK-based Medicines Evaluation Unit, a specialist respiratory research unit owned by the North West Lung Centre charity.

The winning entry, Trial EAS™ Electronic Adjudication System by Kendle International Inc, offers sponsors savings in time and expense by streamlining the adjudication review process.

The modular system is integrated with a web-based portal to allow seamless receipt of patient source documents and/or images from sites anywhere in the world. By allowing independent adjudicators to review all necessary documents online TrialEAS™ practically eliminates the need for face-to-face review. The efficient completion of adjudication forms speeds reports, and reduces the risk of over-enrolment.

The Award for Best Technological Development in Clinical Trials - Software Solutions was presented by Trial Trove.

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MOST INNOVATIVE PATIENT RECRUITMENT STRATEGY

This award recognises those companies, trial sites or individuals that are using innovative solutions to tackle the ongoing problem that is patient recruitment.

Of the three shortlisted companies the judging panel decided Novartis AG submitted the most novel strategy.

The Novartis clinical team accelerated patient recruitment for a study evaluating the combination of aliskiren and amlodipine in hypertensive patients. The team was tasked with screening 2700 patients and recruiting more than 1600 randomised patients in 18 countries for this eight-week multicentre, placebo-controlled study.

Through strategic planning the team accelerated timelines by four months and one country finished recruitment in 17 days. As a result, Novartis accelerated its submission timelines for the study in the US and the EU by two months.

To do this the Novartis team looked at similar past trials to determine how many patients would have to be screened in order to meet sample size. They set solid screening targets to ensure they did not enrol more than 5% of their target. Plans were also in place to close enrolment in the countries with the highest costs to help offset financial impact.

The team originally predicted the screen failure to be 40% and in reality it turned out to be 47%, so more patients had to be screened. There was a four-week pause between screening and randomisation, and with a third of all patients screened during the last three weeks of enrolment it was impossible to predict the failure rates of countries completing the screening in less time than the run-in period.

The team overcame this by keeping in close contact with each country and constantly monitoring figures with numerous spreadsheets to predict and calculate failures as the numbers were updated.

The Award for Most Innovative Patient Recruitment Strategy was presented by Scrip.



L-R: Philip Jarvis, Dr Shelley Moores, Paul Sinha

Winner: Novartis AG

Finalists: D Anderson & Company, Exco InTouch

WINNER'S RESPONSE

"I was thrilled to learn that all of the hard work, dedication and meticulous attention to detail from our teams was externally recognised. It is gratifying to know that our efforts have, not only made us a leader in our industry, but, more importantly, have helped the appropriate patients gain access to new and innovative therapies during the clinical trial process."

Dr Shelley Moores, clinical trial head, Novartis Pharma AG

sponsored by:

SCRIP

MOST SUCCESSFUL EARLY PHASE TRIAL



L-R: Todd Johnson, Dr Josi Holz, Paul Sinha

Winner: Ablynx

Finalists: Daiicho-Sankyo Pharma Development,
Glenmark Pharmaceuticals Inc / Kendle,
NovImmune SA / Kendle, PAREXEL International

WINNER'S RESPONSE

"It is a great honour to receive this particular award in the category of Most Successful Early Phase Trial.

We believe some of the key reasons which have resulted in Ablynx winning this award have been: a safe and efficacious product candidate, ALX-0081, an innovative clinical trial design guided by an excellent pre-clinical data package, an accelerated phase I program that utilized biomarkers and PK/PD modelling to establish biological effective dosing in patients and a focused and dedicated clinical team.

This is possible in just one year if you have the right team, the Ablynx team."

Dr Josi Holz, chief medical officer, Ablynx

This new category honours the most successful early phase trial at preclinical or Phase I stage. The judging panel were looking for excellence in specific brackets including site start-up, enrolment targets and time to database lock.

Of the five shortlisted entrants the judges thought Ablynx's Phase Ib study of anti-von Willebrand Nanobody® ALX-0081 multiple dosing in stable angina patients was most successful in advancing the drug to its next development phase.

The main challenge in the design of this trial was the well-founded and sensible choice of different dose levels in order to reach the efficacy endpoints as soon as possible.

This study was only the second clinical trial ever with Nanobodies®, nevertheless it was conducted immediately in the target patient population. Accurate assessment of safety parameters in determining the different Phase Ib dose levels allowed the safety profile established in the first-in-man study. No additional safety concerns arose as a result of the outcome of this Phase Ib trial in angina patients.

Whereas it is common practice to include efficacy dose ranging in Phase II trials, this Phase Ib trial already delivered the biologically effective dose to maintain RIPA/RICO inhibition during 24 hours, as requested by clinical experts, which will be administered to all ALX-0081 treated patients in the planned Phase II trial.

The Award for Most Successful Early Phase Trial was presented by MDS Pharma Services.

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BEST INTERNATIONAL TRIAL



L-R: Kevin Logan, Dr Marius Moscovici, Tom Giannaris, Dr Jacques Ninane, Paul Sinha

Winner: SHARP (Sorafenib HCC Assessment Randomized Protocol), Bayer Schering Pharma AG

Finalist: JUPITER (Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin), AstraZeneca

WINNER'S RESPONSE

"This is a clear demonstration of our organization's excellence, and we are all proud of this outstanding achievement.

To patients and clinicians, SHARP brought an important treatment option in an area of high unmet need. It represented a breakthrough in the management of HCC leading to worldwide approval of the first systemic treatment for HCC, and established sorafenib as the standard of care in advanced HCC. It is the first large, randomized, double-blind, placebo-controlled study in HCC demonstrating an improvement in overall survival. SHARP is therefore giving hope to patients who had few, if any, other treatment options open to them. Following the results of SHARP, there is now for the first time a pharmacological treatment option with a clinically meaningful survival prolongation available for patients who are affected by this devastating disease.

From a business perspective, SHARP met all the initial business objectives. Sorafenib has been approved for the HCC indication in over 70 countries worldwide, and the trial has opened the door to additional trials on HCC to expand the fight against this disease.

The SHARP trial was a career highlight for the entire study team, which gives its best on a daily basis. SHARP's exceptional quality, together with its timely completion, is a testimony to the team's hard work and focus."

Tom Giannaris, manager of Study Management, Bayer HealthCare Pharmaceuticals

Drug development costs are increasing all the time. To ensure the timely and successful management of clinical trials sponsors are increasingly basing their trials in different locations around the globe. Such moves not only address the shortfalls in patient recruitment and high running costs in the US and Western Europe, they help to ensure clinical programmes meet the regulatory requirements of all the major markets.

The 2009 winner was the Sorafenib HCC Assessment Randomized Protocol (SHARP) trials carried out by sponsor Bayer Schering Pharma AG.

The objective was the approval and launch of the hepatocellular carcinoma (HCC) for single-agent Nexavar® (sorafenib) by the second half of 2007. This was achieved through a high quality trial which produced a major breakthrough in the field of liver cancer treatment to support this need.

The trial argued successfully the ethics and scientific value of having a placebo controlled arm instead of an unproven and potential toxic systemic chemotherapy arm. The informed consent detailed this point and allowed for a positive and definitive effect to be seen by sorafenib.

For patients, SHARP has established sorafenib as the standard care for patients with advanced HCC. It is the first study in HCC with a statistically significant improvement in overall survival.

For the sponsor, the timely completion of SHARP met all business goals; the HCC indication for sorafenib has led to approval in over 70 countries worldwide and allowed for the initiation of additional trials in HCC.

The Award for Best International Trial was presented by INC Research.

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PROJECT MANAGER OF THE YEAR



L-R: Katie Huffine, Paul Sinha

Winner: Katie Huffine, Chiltern

Finalists: Joeleen McKenna, Medicines Evaluation Unit,
Shana Ostermueller, Premier Research Group

WINNER'S RESPONSE

"I was very humbled to have my name and application submitted for consideration for the Project Manager of the Year award. I was further humbled when it was announced that I had been included in the list of finalists. I was very surprised to be named the winner and consider it to be the highest honor to have been selected for this award. It was so exciting to be in the company of the other award winners."

Katie Huffine, project manager, Chiltern International

The Project Manager of the Year Award is designed to recognise the importance of careful and systemic planning and management in clinical trials.

Three candidates made it through the judges' criteria and the worthy winner was Katie Huffine of Chiltern. Although Katie is a veteran in the healthcare industry, it is of particular note that this is the first study Katie has project managed.

Katie managed an adult vaccine study sponsored by a top twenty pharmaceutical company, conducted in an elderly population and expected to enrol 1332 subjects at 25 investigative sites in six months. Through Katie's leadership the study was fully enrolled in 28 days utilising 24 investigative sites, greatly exceeding sponsor expectations.

The winner in this category developed protocol-specific site questionnaires resulting in a rigorous site selection process. The completion of those documents yielded a greater understanding of those site experiences and capabilities thus providing information with which to narrow site selection.

Due to a quick enrolment, management structure and a quality CRA team, the study ended 18% under budget and five months ahead of the study timeline.

CLINICAL RESEARCH PROFESSIONAL OF THE YEAR

This category was understandably very popular and the standard of entries and those nominated was very high. The award recognises the drive of one particular person in a clinical trial team.

Standing out from the nominees to win the 2009 Clinical Research Professional of the Year was Dr Silvia Zieher, senior director, Head of Clinical Operations in Latin America.

Dr Zieher was involved in numerous achievements within the qualifying period, of particular note were: the launch and initiation of clinical trials in a new office in Sao Paulo, Brazil, leading a clinical operations team to recruit 216 patients with moderate to severe asthma in Argentina, Chile, Peru and Mexico in just a month and a half, and leading a clinical operations team for a study that enrolled 266 paediatric patients in two months.

The success of the Phase III study into asthma, led by Dr Zieher, was instrumental in helping the sponsor in its NDA process and the Phase III study into vaccine will contribute to the registration dossier of a paediatric vaccine.

Dr Zieher's regulatory involvement is also worthy of note. She served as chairman of the Scientific Program committee of the 5th Latin American Congress of Clinical Research, Drug Information Association and SAMEFA (member of Argentine Society of Pharmaceutical Medicine). She was invited to serve as chapter chair of the DIA PEACH book initiative for "Computerized Systems in Clinical Research." The first draft was completed in September 2008 and the book will be used as an international reference for GCP. She also found time to co-author a chapter in Good Clinical Practice: A Question & Answer Reference Guide.

The Award for Clinical Research Professional of the Year was presented by Partnerships in Clinical Trials.



L-R: Alex Shimmings, Dr Silvia Zieher, Paul Sinha

Winner: Dr Silvia Zieher, INC Research

Finalists: Janet Holden, Medicines Evaluation Unit, Rachael King, CRF Health, Barbara Schnurr, Harrison Clinical Research Group, David M Shearer, Integrated Trial Services

WINNER'S RESPONSE

"I feel extremely honored with this wonderful award. I am very passionate about contributing to the growth of clinical research in Latin America. Luckily, we can witness nowadays a significant growth both in quantity and quality of clinical trials in my region. I would like to express my sincere gratitude to Good Clinical Practice journal, the judging panel for this great recognition of my efforts in the region and to INC Research for supporting me on my career and activities in Latin America every day."

Dr Silvia Zieher, senior director, head of Clinical, Operations in Latin America, INC Research

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CLINICAL RESEARCH TEAM OF THE YEAR



L-R: Dr Anita Cooper, Deil Baldwin, Paul Sinha

Winner: Medicines Evaluation Unit

Highly Commended: INC Research

Finalists: Boehringer Ingelheim GmbH, ClinTec International, HRA Pharma, Premier Research Group

WINNER'S RESPONSE

"It was a fantastic achievement to win this prestigious award in such a strong category. Being a team award was particularly satisfying as the success of the Medicines Evaluation Unit is based on the ethos of teamwork. Several members of staff attended the event and had a fantastic evening, and were thrilled to have won."

Deil Baldwin, clinical nurse manager, Medicines Evaluation Unit

This award honours the achievements of a team that has made the most difference to a sponsor company's research programme.

There was strong competition in this category this year, resulting in a winning and highly commended place. The award went to MEU Study Team 1, from the Medicines Evaluation Unit.

The winning team took part in a multi-centre study starting in March requiring 40 randomised subjects to take part in a five way cross over study with 14 hour treatment days.

The team's greatest achievement was randomising all 40 subjects within a 17 day period. The First patient was randomised was mid-April and the 40th patient was randomised by 27 April, resulting in the study being completed six weeks ahead of the sponsor target timelines, and the most effective study conducted in the 14 year history of the MEU.

The consequence of this has resulted in: reducing overheads thus increasing the profitability of the study budget, freeing up space within the clinical unit sooner to facilitate start up of subsequent studies, enable sponsor to database lock earlier therefore progressing their trial programme sooner, created confidence within the team that the study could be conducted in larger group sizes without compromising quality of data, the safety of subjects or the overall integrity of the study.

The Award for Clinical Research Team of the Year was presented by PAREXEL International.

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