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## *Accelerating Patient Recruitment in Clinical Trials*



*in-depth report from the SMi 2nd Annual Conference*  
held in London, 27–28 March 2006

by Dr Richard KH Wyse



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# Accelerating Patient Recruitment in Clinical Trials:

*in-depth report from the SMI 2nd Annual Conference*

Dr Richard KH Wyse

## Executive summary

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All pharmaceutical companies want to find cost savings. The industry conducts large numbers of clinical trials each year. Regulatory requirements, as well as other scientific and marketing needs, mean that many of these studies continue to need ever-larger numbers of patients. The cost of running trials is now approaching 30% of pharmaceutical companies' entire drug development budgets. However, 75% of patient studies fail to make their timelines, often causing expensive delays in regulatory approval and market launch. Slow patient recruitment represents a major reason for this, as does poor retention of patients within ongoing clinical trials. Close scrutiny of, and adherence to, a variety of factors that promote timely patient recruitment, however, mean that pharmaceutical companies have tangible mechanisms that can substantially enhance their profitability. The 2nd Annual Conference on Accelerating Patient Recruitment in Clinical Trials, held in London 27–28 March 2006, organised by SMI, discussed a diverse range of approaches now used by some companies and their Contract Research Organisations to adhere to timelines, to shorten them, and to try to identify recently evolving best practices.

This *Conference Insights* review provides analysis of the pertinent issues raised in selected presentations made at this event, discussing proven strategies to maximise patient recruitment, tools to assist the process, investigator-site selection and public perceptions of clinical trials. It makes clear why the old method of opportunism in patient recruitment is not effective, and looks at why companies are starting to abandon expensive advertising campaigns in favour of evidence-based patient recruitment strategies.

From a business point of view, optimising patient recruitment and retention, with the aim of getting new products on the market as soon as possible, now represents an important, achievable goal for all pharmaceutical companies.

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# 2nd Annual Conference on Accelerating Patient Recruitment in Clinical Trials – Programme

Organised by SMI, London, 27–28 March 2006

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## Day one

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### Chairperson:

John Needham, *Chief Operating Officer, Patient Recruitment Strategy, LLC, USA*

### KEYNOTE ADDRESS: ACCELERATING PATIENT RECRUITMENT

#### The Eisai standpoint

Karen Foley, *Senior Director, Clinical Operations, Eisai Global Clinical Development, Eisai*

### PUBLIC PERCEPTIONS OF CLINICAL RESEARCH STUDIES: A global survey conducted in 2005

Rowena Dickerson, *Associate Director, Fast4wD Ogilvy*

### MASLOW'S HIERARCHY OF NEEDS AND CLINICAL TRIAL PARTICIPATION: Assessing, understanding and addressing the needs of potential study participants and their families

John Needham, *Chief Operating Officer, Patient Recruitment Strategy, LLC*

### ACCELERATING THE PATIENT RECRUITMENT PROCESS: The application of response technologies

Dr Simon Chapman, *Chairman, essentiapharm*

### GETTING THE MESSAGE RIGHT: STRATEGIC AND TACTICAL APPLICATION OF MARKETING PRACTICES TO THE CLINICAL TRIAL ARENA:

#### Global case studies for accessing and retaining the right patients

Janet Jones, *Director, Patient Access & Retention, Kendle*  
Kate Spencer, *Business Unit Director, Langland*

### GLOBAL PATIENT RECRUITMENT: Practical considerations and case studies

Beth Harper, *Vice President, D. Anderson & Company*

### OPERATIONAL AND LEGISLATIVE ASPECTS OF PAEDIATRIC RECRUITMENT FOR CLINICAL TRIALS: New regulations stimulating paediatric research

Dr Richard Tiner, *Medical Director, Association of the British Pharmaceutical Industry (ABPI)*

### RETENTION OF PATIENTS IN CLINICAL TRIALS: How do you avoid patient drop-out?

Jim Kremidas, *Global Enrolment Optimisation, Eli Lilly*

## Day two

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### Chairperson:

Beth Harper, *Vice President, D. Anderson & Company, USA*

### SITE SELECTION: Research site selection and evaluation

Dr Sue Tempest, *Site Implementation & Training Manager, Merck Research Laboratories*

### INVESTIGATOR SITE NETWORKS IN CONTINENTAL EUROPE: Implementing a recruitment campaign focusing on Germany

Dr Hans-Detlev Stahl, *Chief Executive Officer, Clinpharm*

### IMPLEMENTING AND DRIVING SUCCESS OF INTERNATIONAL PATIENT RECRUITMENT AND RETENTION STRATEGIES THROUGH THE CONVENTIONAL CLINICAL RESEARCH PROCESS AT THE INVESTIGATIVE SITE: The CRO perspective

Tom Ruane, *Director, Patient Recruitment, Quintiles*

### COUNTRY STUDY MANAGERS: The Cornerstone for Successful Multinational Recruitment 2006 Survey – results and analysis

Jaime Cohen, *Enrolment Manager, BBK Worldwide*

### THE ROLE OF THE REGULATOR: What did directives ever do for us?

Dr Malcolm Barratt-Johnson, *Medical Assessor, Clinical Trials Unit, Medicines & Healthcare products Regulatory Agency (MHRA)*

### METHODS AND METRICS FOR PATIENT RECRUITMENT AGAINST PROTOCOL DESIGN: Recruitment success by design

Dr Alan Wade, *Director, Community Pharmaceutical Services (CPS) Research*

### CANDIDATE QUALIFICATION AND MEASUREMENT OF CAMPAIGN PERFORMANCE METRICS: A technological approach

Dr Bill Byrom, *Product Strategy Director, ClinPhone Group Ltd*

### RECRUITING ADULTS WITH NORMAL LIPID BUT ELEVATED CRP LEVELS: Budgetary implications on recruiting adults without disease and unknown CRP levels

Dr Ian Smith, *Medical Director, Synexus*

### PATIENT RECRUITMENT BEST PRACTICES AMONG TOP PHARMACOS: The Wise Investments initiative

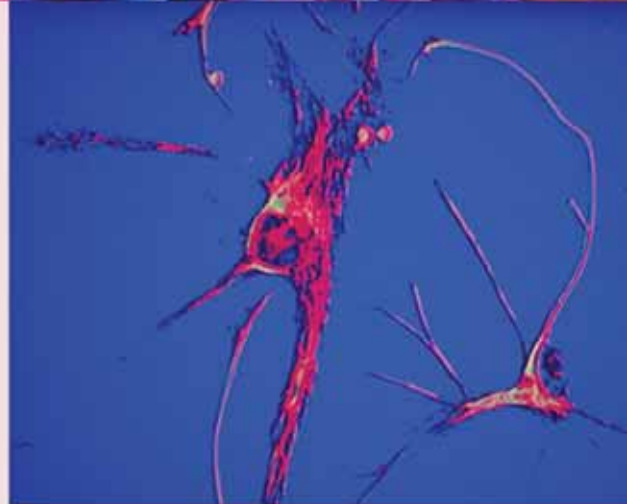
Donald Greene, *Vice President, Veritas Medicine*

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## Introduction

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The 2nd Annual Conference on Accelerating Patient Recruitment in Clinical Trials, held in London 27–28 March 2006 and organised by SMi, brought together speakers and delegates from a wide range of pharmaceutical and medical device companies and Contract Research Organisations (CROs). Many of the speakers enjoy direct responsibilities for ensuring patient studies are optimised within their companies, and that they run to budget and to agreed timelines. Over the course of the conference it emerged that, although speakers often shared similar patient recruitment problems, the approaches they take to address these issues now vary considerably between companies, as do their relative success rates. Some companies have replaced inefficient large advertising campaigns (that seldom produced sufficient patients anyway) with streamlined evidence-based patient recruitment methodologies that are adaptively agile to the particular requirements of each individual trial. Further, it became clear that, to assist both patient recruitment and investigator support and morale, 'best-practice' companies have been able to identify optimum managerial structures for handling their multinational clinical trials across large numbers of investigator sites across many countries. They have also been able to identify the factors that predispose to higher levels of patient recruitment and retention in different countries, and the most cost-effective solutions. Several companies shared how they benefit by the use of a range of support tools (patient databases, metrics and benchmarking, and cost-effectiveness analyses) to make better choices about their patient recruitment strategies (and their selection of investigator site where this impinges on rates of recruitment). Subsequently, some have now found out what works well and what doesn't. The audience seemed fascinated to learn by these experiences.

The issue of public and patient perceptions of clinical trials was at the forefront of many of the presentations, since a very high-profile incident during a drug trial, news of which immediately reached television and newspaper audiences globally, had occurred only days before in a nearby hospital. Everyone was aware that this crucially important new public image onslaught poignantly affects the livelihoods of almost all the speakers and delegates in the auditorium. This is because, as industry patient recruitment specialists, and as individuals, their future success depends on their own abilities to try to regain supportive perceptions of clinical trials within the general public. They are also aware that they now need to come up with the most effective reasoning for their patients to ensure they remain enrolled in existing trials, and to find the best ways to persuade patients to enrol in adequate numbers in all of their new prospective studies.

**Dr Richard Wyse**  
July 2006

### About the author

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Formerly senior lecturer in paediatric cardiology at Great Ormond Street Hospital in London, Dr Richard Wyse now has joint commercial and academic careers. He is the author of over 100 medical and scientific papers, and pharmaceutical industry articles in journals. He has also written four industry books, and several independent evidence-based medicine reports in various therapeutic areas. Commercially, he has worked for a CRO as Director of European Health Economics, and as Medical Director for a US pharmaceutical IT company, and a medical device company. He has been involved in a wide variety of industry clinical trials and several other areas of drug development for many years. Academically, he is currently a visiting professor in Saudi Arabia and President-Elect of the Division of Genetics at the Royal Society of Medicine. He is on the editorial board of several journals.

Richard has spoken at many academic and international pharmaceutical and medical device conferences, and has chaired 25 of them. Notably, he was global chairman of a major cardiac patient database initiative that involved 2700 hospitals worldwide, speaking at national conferences in a large number of first- and third-world countries. In this capacity he reported a landmark paper on risk prediction and outcomes in more than 600,000 US patients.

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