

Patient recruitment remains one of the most significant challenges faced by the pharmaceutical industry today and accounts for significant delays in the clinical development process. As a result, it is essential for Sponsors to devise and execute a comprehensive recruitment strategy which can both recruit and retain its subjects.



#### Benefits of Attending:

- **PATIENT RECRUITMENT FOR CLINICAL TRIALS:** Hear about the current and future management strategies and results, patient recruitment benchmarks and effective media tactics to recruit and retain clinical trial subjects
- **MEASURING SUCCESS:** Discover the critical need for measurement as part of a patient recruitment and retention programme and the importance of metrics in predicting patient and site performance
- **GLOBAL RECRUITMENT PROGRAMMES:** Is there such a thing as a global recruitment programme? Hear perspectives from both sides: Sponsors and CROs
- **PAEDIATRIC CLINICAL TRIALS:** Learn how to recruit and retain a paediatric population while being sensitive to issues of consent and ethical considerations
- **ADDRESSING MAJOR BOTTLENECKS IN THE PATIENT RECRUITMENT PROCESS:** Explore how innovative technologies can accelerate recruitment and ensure patient retention and compliance
- **NETWORK WITH KEY PERSONNEL:** Meet the leaders in the field, make valuable contacts and learn from their experience and expertise



#### Gain an insight from the key industry leaders in the field including:

- **Marianne Mancini**, Director, Global Clinical Operations, **Baxter Bioscience**
- **Jim Kremidas**, Global Enrolment Optimisation & Innovation, **Eli Lilly**
- **David Shearer**, Clinical Project Leader, CNS Division & Head, Internal Patient Recruitment Group, **Sanofi-Aventis**
- **Tom Ruane**, Director, Patient Recruitment, **Quintiles**
- **Dr Mikhail Rojavin**, Clinical Trials Leader, **Novartis**
- **Daniel McDonald**, Vice President, **Thomson CenterWatch**
- **Matthew Kibby**, Leader, Global Business Unit, **BBK Healthcare**
- **Bill Byrom**, Product Development Director, **ClinPhone**
- **Roni Thaler**, President & Chief Executive Officer, **Center for Information Study on Clinical Research Participation (CISCRP)**

SMi present their Inaugural Conference...

# Accelerating Patient Recruitment in Clinical Trials

20th & 21st April 2005, Jurys Great Russell Street Hotel, London



PLUS AN ASSOCIATED HALF-DAY PRE-CONFERENCE EXECUTIVE BRIEFING

## Evaluating Creative Concepts for Patient Recruitment Campaigns

19th April 2005, Jurys Great Russell Street Hotel, London  
In association with **BBK Healthcare**

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8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**  
**Jim Kremidas**, Global Enrolment Optimisation & Innovation, **Eli Lilly**

**KEYNOTE ADDRESS**

9.10 **How can we best accelerate the patient recruitment process for clinical trials?**

- Identifying, understanding and targeting the right patient population
- Patient recruitment benchmarks - patient demographics and recruitment costs
- Current and future recruitment management strategies and results
- Effective media strategies and tactics including database mining, media, web use and pharmacy
- Evaluating the effectiveness of recruitment strategies - Good Recruitment Practices (GRPs)
- Looking ahead - what's going to change in clinical trials?
- Subsequent impact on the future of patient recruitment?

**David Shearer**, Clinical Project Leader, CNS Division & Head, Internal Patient Recruitment Group, **Sanofi-Aventis**

**THE USE OF METRICS IN PATIENT RECRUITMENT**

**MEASURING THE SUCCESS OF PATIENT RECRUITMENT**

9.50 **The critical need for measurement as part of a patient recruitment and retention programme**

- See how metrics capture and intervention can determine predictive modelling of patient and site performance
- Measure the effectiveness of benchmarking recruitment elements to avoid study rescue
- Know how to effectively manage and measure large advertising campaigns and expenditures
- Using automated data capture information to forecast and establish ROI of the recruitment programme
- View metrics capture and reporting as a decision support model
- Learn how to 'model' future studies based on past success

**Kathleen Drennan**, Vice President & Managing Director, **Iris Global Clinical Trial Solutions**

10.30 Morning Coffee

**CONDUCTING FEASIBILITY TESTING**

11.00 **Practical considerations**

- Ensuring proper feasibility testing has been conducted
- Uncovering potential recruitment challenges and assisting in the establishment of appropriate budgets and timelines
- How many subjects are required?
- Trial placement strategies
- Site viability
- Problems related to poor feasibility testing - the onset of rescue studies
- Case histories

**Matthew Kibby**, Leader, Global Business Unit, **BBK Healthcare**

**OPERATING A GLOBAL RECRUITMENT PROGRAMME**

**GLOBAL RECRUITMENT PROGRAMMES**

11.40 **Designing and implementing a global recruitment campaign**

- Country specific strategies - with a focus on the US, Europe, Latin America and Asia
- Reaching the patient
- Obstacles and recruitment solutions/strategies
- Is there such a thing as a global recruitment campaign?
- How to operate a global trial that works
- Experts in the US/EU - how can they work together/who can they work with?
- Current success stories

**Jim Kremidas**, Global Enrolment Optimisation & Innovation, **Eli Lilly**

12.20 Networking Lunch

**GLOBAL PATIENT RECRUITMENT - THE CRO PERSPECTIVE**

1.50 **The evolution of patient recruitment and retention as a core CRO service from a peripheral service**

- The mind-set change around patient recruitment for the key stakeholders
- Is patient recruitment compatible with core CRO services?
- Is it expensive and where does the money go? Where is the ROI?
- What do the patients and site staff think?
- Examples of success stories (and maybe some not so successful!)

**Tom Ruane**, Director, Patient Recruitment, **Quintiles**

2.30 **DIFFERENT STRATEGIES TO ACCELERATE PATIENT RECRUITMENT IN WESTERN AND CENTRAL-EASTERN EUROPE**

- Large centralised treatment units in CEE established by state healthcare system vs decentralised small study centres in Western Europe
- Different motivations of patients and doctors in Western Europe and CEE
  - in CEE patient desire for modern treatment
  - in Western Europe patient desire for more controlled and sufficient treatment

**Professor Ralf Kohnen**, Chief Executive Officer, **IMEREM** & Director, **European Clinical Trials Associates (ECTA)**

3.10 Afternoon Tea

**NEGOTIATING AND MANAGING PATIENT RECRUITMENT BUDGETS**

3.40 **The economics of accelerating recruitment to achieve the best end results**

- Calculating, realistically, the impact of subject recruitment expenditures on trial cost
- Determining the value that spending on patient recruitment provides
- Justifying the cost
- Learning how to design and implement an effective patient recruitment budget
- Accounting for difficulties along the way
- Negotiating a patient recruitment contract
- Defining the roles and responsibilities of the sponsor, CRO and recruitment provider

**Bruce Gould**, Director, **Acurian\***

**SITE IDENTIFICATION**

**SITE IDENTIFICATION**

4.20 **Working with sites to enhance patient recruitment in clinical trials**

- Improving site selection - reaching patient groups
- Evaluating your site requirements and expectations - including the ability to sustain enrolment
- Co-ordinating the needs of the sponsor with the capabilities of the sites
- Moving through the contract process
- Reducing the amount of time to get sites started
- Trial recruitment from the site operator's perspective
- Communication between sponsors and sites - clear objectives and expectations, collecting and reporting metrics and reducing cycle times to initiate trials
- Assessing the impact of your trial success

**Marianne Mancini**, Director, Global Clinical Operations, **Baxter Bioscience**

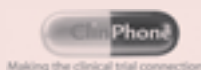
5.00 **Chairman's Closing Remarks and Close of Day One**

5.10 **Networking Drinks Reception sponsored by**



\*Interactive presentation via e-Conference

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- 8.30 Re-registration & Coffee
- 9.00 **Chairman's Opening Remarks**  
**Tom Ruane**, Director, Patient Recruitment, **Quintiles**
- 9.10 **A SITE CENTRIC APPROACH TO EFFECTIVE RISK MANAGEMENT**
- Current approach
  - Understanding variability
  - Targeting mitigation
  - Barriers to success
- Lorna Leonard**, Senior Manager, Project Risk Assessment & Prevention Support, **Covance**

#### ENGAGING PATIENT PARTICIPATION

- 9.50 **HOW TO FIND PATIENTS THAT DO NOT EXIST**  
**Symptomology-based recruitment**
- How to find patients which might be required for a study (as defined by inclusion/exclusion criteria) that do not know they have the condition
  - Targeting specific disorders such as diabetes, Alzheimer's and hypertension
  - Designing and executing a recruitment campaign based on symptomology
  - Possible marketing methods to be employed
  - Looking ahead – new and innovative recruitment strategies and technologies
- Richard Anderson**, Chief Executive Officer, **De Facto Communications**
- 10.30 Morning Coffee
- ENGAGING AND EDUCATING THE PUBLIC ABOUT CLINICAL RESEARCH PARTICIPATION**
- 11.00 **The importance of increasing awareness and information about clinical research participation**
- Participants will be presented information and data regarding the influence that the various stakeholders play in patient volunteerism
  - Presentation of most recent data regarding clinical research participation
  - Discussion of recent trends in 'public trust' of the clinical research enterprise and actions taken by the clinical research enterprise to address this issue
  - Review of the particular challenges in the recruitment of minority and non-English speaking populations
  - Strategies for increasing general education and awareness about clinical research participation including examples of both print, TV and radio public service announcements
- Roni Thaler**, President & Chief Executive Officer, **Center for Information and Study on Clinical Research Participation (CISCRP)**

#### RECRUITING FOR PAEDIATRIC TRIALS

- 11.40 **RECRUITING AND RETAINING A PAEDIATRIC POPULATION**
- Paediatric clinical trials today
  - Confident consent – the legal perspective
  - Managing your clinical trial
    - How to successfully recruit a paediatric population
    - Retaining your patients
  - Ethical considerations
- Michelle Argument**, Client Services Director, **Fast4wD Ogilvy**  
**Gaynor Anders**, Communications Director, **Fast4wD Ogilvy**
- 12.20 Networking Lunch

#### CHALLENGES FOR PATIENT PARTICIPATION

##### FACTORS MOTIVATING PATIENTS' PARTICIPATION IN CLINICAL RESEARCH

- 1.50 **First results of PEAK Programme**
- Main features of PEAK programme
  - What attracts patients to a clinical study?
  - What concerns patients during the study?
  - Their experiences at the last office visit
- Dr Mikhail Rojavin**, Clinical Trials Leader, **Novartis\***

#### ADVANCES IN PATIENT RECRUITMENT STRATEGIES AND TECHNOLOGIES

##### SETTING RECRUITMENT UP RIGHT FROM THE START

- 2.30 **When time and money is of the essence, steps to take to ensure success and minimise financial loss**
- Recruitment success is predicated on good planning
  - Data driven decisions eliminate recruitment investment loss and keep recruitment on track
  - Taking the recruitment-retention leaks out of the Leaky Pipe™
  - Performance management against recruitment milestones
- Elizabeth Moench**, President & Chief Executive Officer, **MediciGroup**

- 3.10 Afternoon Tea

##### ASSESSING THE IMPLEMENTATION OF PATIENT RECRUITMENT TECHNOLOGIES

- 3.40 **Addressing major bottlenecks in the patient recruitment process**
- Allowing sponsors early access to potential patient populations
  - How innovative technologies can accelerate patient recruitment and ensure patient retention and compliance
  - How to enhance patient communication, access and follow up
  - Current technologies available
  - Useful statistics
  - Future technological advances
- Dr Bill Byrom**, Product Development Director, **ClinPhone**

- 4.20 **THE EVOLVING FACE OF ONLINE PATIENT RECRUITMENT**

- How the internet can be used to improve/aid patient recruitment
- The patient and internet community – internet statistics
- How do patients and sponsors use this resource?
- Evaluating current and future recruitment models and practices
- Choosing an online patient recruitment service
- Creating an internet patient recruitment campaign
- The impact of web-based recruitment in the US – possibilities and usage in Europe

**Daniel McDonald**, Vice President, **Thomson CenterWatch**

- 5.00 **Chairman's Closing Remarks and Close of Conference**

\*Interactive presentation via e-Conference

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# Pharmaceutical Forward Planner

## January 2005

- 24/25 High Throughput Screening
- 26/27 Nutraceuticals & Functional Foods
- 31/1 Feb Computer Systems Validation

## February 2005

- 14/15 Controlled Release
- 21/22 Obesity & Related Disorders
- 23/24 Market Opportunities & Technology  
Trends in Point of Care Diagnostics
- 28/01 Drug Design

## March 2005

- 07/08 Superbugs & Superdrugs
- 14/15 Pharmaceutical Pricing &  
Reimbursement in North America
- 16/17 Preclinical Models & Biomarkers

## April 2005

- 06/07 Generics, Supergenerics & Patent  
Strategies
- 18/19 Reporting Adverse Events
- 20/21 Accelerating Patient Recruitment in  
Clinical Trials
- 27/28 Asthma & COPD

# Evaluating Creative Concepts for Patient Recruitment Campaigns

19th April 2005, Jurys Great Russell Street Hotel, London

In association with:



## About the Briefing:

What exactly are 'creative concepts' and how can they be effectively developed for a clinical study enrolment campaign? This session will outline the criteria for developing creative concepts for engaging and motivating potential subjects, referring physicians, and investigative sites. Participants will learn about the importance of researching the patient population and crafting a strategy, positioning and messages. They will also learn to evaluate the development of language, images and design within creative and regulatory contexts, as well as understand and assess the impact each of these elements can have on target audiences.

- 1.45 **Registration and Coffee**
- 2.00 **Introduction**
  - What is a creative concept?
- 2.15 **Developing a creative strategy**
  - Understanding the target audience (demographics, psychographics etc.)
  - Development of strategy, positioning and messages
- 2.35 **Evaluating concepts objectively**
- 2.45 **Regulatory guidelines**
  - IRB and ethics committees
  - Impact on copy and graphic development
- 3.00 **Multinational studies**
  - The impact of the EU Directive
  - Language and cultural barriers
- 3.30 **Afternoon Tea**
- 3.50 **Case study**
- 4.15 **Attendee hands-on analysis of several creative concepts**
- 4.45 **Discussion and questions**
- 5.00 **Close of Briefing**

## About your Briefing Leader:

**Matthew Kibby** leads BBK Healthcare's Global Operations, directing worldwide patient recruitment, enrolment, and retention campaigns. Matt developed and supervises BBK's global enrolment feasibility model by which recruitment campaigns for any country or region are created. In prior positions at BBK, Matt contributed to the evolution of BBK's sophisticated metrics and evaluation services for monitoring and evaluating real-time enrolment data that support client decisions about campaign resource allocation.



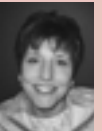
**Rob Laurens** supervises the management of EP Studio, BBK's in-house design and production vendor resource, which specialises in providing cost-effective creative services. As BBK's principal copywriter, he brings strategic and creative talents and expertise to the execution of BBK client and creative projects.

He has produced print ads, radio and television spots, direct mail, brochures, and the like, for the complete range of BBK clients – from providers and pharmaceuticals to medical device companies and public health institutions.



**Joan Bachenheimer** co-founded BBK in the 1980s and drove the company to a leadership position in the emerging arena of direct-to-patient communications for healthcare services and products. Over the last decade, her innovations have helped shape the young field of patient recruitment for clinical studies and kept BBK at the forefront of emerging trends. Most recently she has begun redefining the field with the new discipline of study relations by which, clinical study enrolment is accomplished through a communications and management infrastructure.

In 2002 she conceived and developed Good Recruitment Practice<sup>SM</sup>, a set of industry standards for optimising patient and physician participation in clinical studies. In 2000, Joan spearheaded the development and launch of TrialCentralNet<sup>SM</sup>, BBK's e-process project management application for clinical study enrolment.



## About the Company:

**BBK Healthcare**, is a marketing consulting firm for the global clinical R&D segment of the pharmaceutical, biotechnology, and medical device industries, helping to accelerate time to market for new medicines and treatments. A global leader in patient recruitment, BBK is committed to continual innovation, contributing ideas that accelerate and optimise the clinical development cycle.



# ACCELERATING PATIENT RECRUITMENT IN CLINICAL TRIALS

20th & 21st April 2005, Jurys Great Russell Street Hotel, London Executive Briefing: 19th April 2005

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