

Strength *in* numbers



Synexus: The world's largest multi-national company dedicated to the recruitment and running of clinical trials

“Others try and sell a hub-site model, but they don't really have one. Their problem is they have no direct control over those clinicians who do not focus solely on research. Only Synexus has clinicians who are doing trials full-time. They have a concentrated effort with no distraction from other things.”

ALASTAIR MACDONALD
Study Program Director (Oncology/Infection)
Clinical Research Region, Europe AstraZeneca

ADDING SIGNIFICANT VALUE

SYNEXUS HELPS CLIENTS REACH END POINTS FASTER THUS SAVING PHARMA MILLIONS OF DOLLARS EVERY YEAR.

THE GLOBAL PHARMACEUTICAL R&D SPEND IS ESTIMATED TO EXCEED \$100 BILLION BY 2010.

Innovation has been described as 'change that creates a new dimension for performance' as well as being about 'getting new ideas adopted.'

Synexus believes that the key to innovation is not all about the idea, but putting those ideas into practice in a way that adds value. The Synexus hub model is exactly that. An example of innovation that adds significant value and is revolutionising the business of clinical trials.

Innovation in medical research has resulted in dramatic changes in the world's ability to treat disease and improve quality of life for many people. However, innovation comes at a price and rising healthcare costs and the reduced number of drugs in late-stage pipelines is putting enormous pressure on the pharmaceutical industry to reduce R&D expenditure, which continues to rise consistently.

The clinical trials industry has become one of the most complex and rapidly changing arenas of the healthcare market; the increasing complexity of studies, the rising awareness towards drug safety and an increasingly stringent regulatory environment have all contributed towards the rising costs and have been key in mandating the quest for a new approach.

Patient recruitment is the essential element when conducting a successful clinical trial. Despite this fact, the traditional recruitment methods for clinical trials have remained virtually unchanged for the past 40 years. Over 90% of later stage clinical trials are still carried out by individual primary care physicians and hospital consultants who recruit, on average, five patients each. Pharma companies spend millions of dollars on opening investigator sites that never recruit a single patient.

The traditional approach can lead to significant delays and time is not something that is in abundance. Over 80% of clinical trials currently fail to deliver on time, with more than 20% delayed for six months or more.

Synexus represents the new way of doing things; its innovative model significantly reduces recruitment times through better infrastructure, superior access to patients, universal SOPs and centralised project management.

By helping clients reach their milestones faster Synexus is saving Pharma millions of dollars every year.



INCREASINGLY SYNEXUS IS THE CORNERSTONE OF A STUDY; REGULARLY RECRUITING 1,000s OF PATIENTS.

THE MODEL IN DETAIL

OUR OWN SITES.
OUR OWN PEOPLE.
OUR WHOLE BUSINESS.

FULL-TIME PRINCIPLE INVESTIGATORS WITH, ON AVERAGE, EXPERIENCE OF 40 CLINICAL TRIALS EACH.

Synexus' unique model recruits large volumes of high quality patients for the global pharmaceutical industry, for the lowest total cost by:

- Proactively recruiting patients onto clinical trials
- Managing patients throughout the total study life
- Conducting all trial activities at its own sites through its own medics, nurses and support staff
- Operating from multiple sites in six countries

In addition to the more traditional methods Synexus employs a number of recruitment techniques including those that target the patient either directly or through patient organisations.

Advertising, PR and joint-marketing initiatives are all used to attract patients to clinical trials. The marketing initiatives are designed to educate the individual and communicate the mutual benefits of participation.

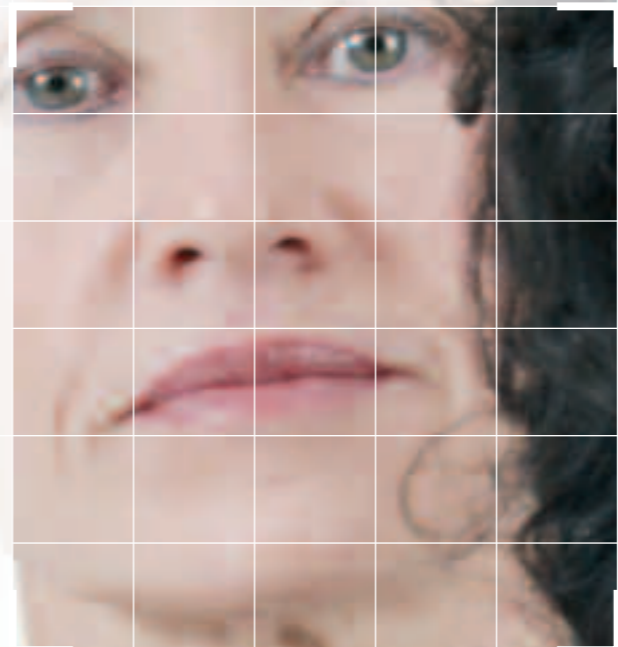
Synexus also maintains a positive relationship with a number of healthcare professionals throughout the world recognising the important role they play in the recruitment of patients onto clinical trials. In the UK, for example, Synexus has relationships with in excess of 1,500 GP practices, each of whom can be mobilised to send mail shots out to potential patients.

All of these recruitment methods have enabled Synexus to engage with many thousands of individuals who have expressed an interest in participating in a clinical trial. Each response is added to the Synexus database that has grown to become a unique and valuable tool housing in excess of a quarter of a million individuals; many of whom have already consented to be on a trial.

These pro-active recruitment methods enable Synexus to significantly shorten the recruitment process. A uniform process, centralised project management, and attention focussed solely on the task at hand can save even more time, which is crucial to the success of a trial. For Synexus, clinical trials are its core business; it means more to Synexus to succeed.

Synexus' extensive experience has helped it become an expert in assessing patient acceptability – what is likely to make a patient say yes to a clinical trial – taking into account factors such as lifestyle and cultural differences.

Project management and full-time, highly experienced principle investigators are vital to the process and are a unique feature of the Synexus model. Success is planned for from the outset.



THE SYNEXUS MODEL CAN BE A MORE COST EFFECTIVE OPTION BY UP TO A FACTOR OF 10.

MEASURING UP GLOBALLY

THERE ARE MORE THAN 10,000 PATIENTS CURRENTLY ON TRIALS WITH SYNEXUS.

GLOBAL COVERAGE ENABLES SYNEXUS TO ACCESS MILLIONS OF DIVERSE PATIENTS.

Synexus' operating model varies by region. The hub-site model is predominantly used. However, in order to maximise recruitment, some countries favour the more traditional SMO model. Local knowledge and experience enables the model to be tailored to each individual country's needs. In South Africa, for example, investigators visit township clinics to discuss clinical trials with walk-in patients.

Synexus recognises the validity of the 'think local; act global' adage and is well aware of sociocultural differences across the world.

It has developed specific strategies designed to address and overcome issues which can be created by different beliefs about a disease, the economic barriers which make the cost of transportation, participation and lack of insurance significant in some areas and individual barriers such as lack of time.

Synexus currently has hub-sites in Eastern Europe, South Africa, the UK and India. Its dynamic growth strategy, driven by the demands of clients, will see further expansion into the USA, South-America, Central and Eastern Europe and China.

IN A PROSTATE CANCER TRIAL SYNEXUS UNDERTOOK MORE THAN 44,000 PSA TESTS AND 2,000 PROSTATE BIOPSIES.



DYNAMIC EXPERIENCE

LEADERSHIP. FOCUS. EXCELLENCE

Synexus' Management Team comprises a number of dynamic individuals who, by focussing on their complex and demanding roles, together achieve excellence.



PROFESSOR TREVOR JONES CBE PhD FRCP(Hon) FRSM Chairman

Professor Jones has led a distinguished career in the pharmaceutical and biotech industry and, among many other senior positions was head of the British pharmaceutical industry for 10 years as Director General of the ABPI (The Association of the British Pharmaceutical Industry). He still holds various Board and senior positions among other leading organisations and associations.



MICHAEL FORT Chief Executive

Michael Fort joined Synexus in 2001 as Commercial Director following the investment by Aberdeen Murray Johnstone Private Equity. Before Synexus he was a director of Trinity Pharmaceuticals Ltd. He was also a former executive chairman and non-executive director of Zi Medical PLC. Currently, he is a non-executive director of Compass Finance Group PLC. Michael is also a Fellow of the Chartered Institute of Management Accountants.



DR IAN SMITH MB ChB BMedSc(Hons) Medical Director and Founder

Dr Ian Smith spent the early part of his medical career in NHS general practice. It was during his time as a GP that his interest in clinical research developed and inspired him to become a part-time investigator. In 1992, he established the first dedicated patient recruitment centre in the UK, which is the business model that Synexus grew from.

Over the past 15 years, Dr Smith has developed Synexus from just an idea about how the clinical trials industry could be improved and, by doing so, has attracted the interest of many of the world's largest pharma companies.

JANE RESTORICK MIBiol

Executive Vice President International Client Services
Jane Restorick joined Synexus in 2001 as the Director of Quality Systems. From 2002 to 2006, Jane led Synexus' International Operations and since 2006 she has been Executive Vice President International Client Services. Jane has a strong background in clinical operations having held senior positions at Pfizer, Fujisawa Limited and Vernalis Ltd (formerly Vanguard Medica Limited). Jane began her career as a Medical School Research Assistant in Urological Research at Guy's Hospital.



DR ANITA SEXTON MBA

Executive Vice President International Operations
Dr Anita Sexton has responsibility for the management and operation of all Synexus research centres in the UK, Eastern Europe, India and South Africa. Anita has over twelve years' experience in pharmaceutical contract research and R&D. She was previously Director of Business Strategy at Quest Diagnostics Clinical Trials, and had responsibility for developing and implementing long-term strategy and for assessing international market growth opportunities.



CHRIS HANNIGAN BSc(Hons)

Executive Vice President Business Development
Chris Hannigan is the Executive Vice President of Business Development having joined Synexus in 2007. Chris has extensive experience of outsourcing clinical trials across the globe having worked in the industry for 23 years. At Kendle International, one of the world's leading global clinical research organisations, Chris was the UK Managing Director. He has also held senior outsourcing positions at Roche.



PAUL McCLUSKEY Ba FCA

Chief Financial Officer
Paul McCluskey joined Synexus in September 2006. Prior to this he managed a European FMCG business for a group of US private investors. Paul began his financial career with KMPG before embarking on a series of financial roles with RHM, BAE Systems and GlaxoSmithKline. He is a Fellow of the Institute of Chartered Accountants in England and Wales.



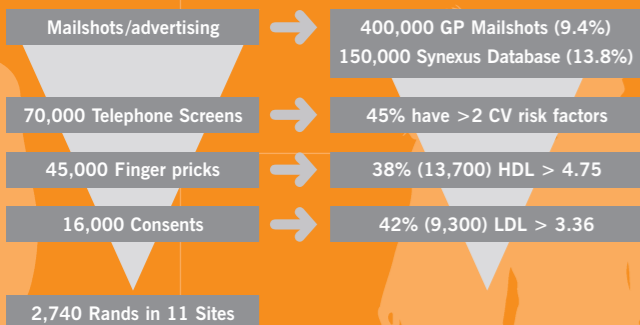
← CASE STUDY

Elevated CRP is illustrated underneath this flap.

FINANCIAL STRUCTURE

Prior to 2007 Synexus was listed on the London Stock Exchange's AIM. Following acceptance of a cash offer Synexus delisted. Synexus is now financed through a combination of private equity and management ownership. The new financial structure and continuing investment best supports the growth momentum of the business.

CASE STUDY Elevated CRP



	Non-Synexus Sites	Synexus Sites
Sites : Patients	250 : 2,740	11 : 2,740
Sites Set-up Costs (@\$35K per site)	\$8.7m	\$0.4m
Monitoring Days (4-weekly)	10,000	4,000
Monitoring Costs (@\$1K per day)	\$10m	\$4m
Query Resolution (35 pp @\$11)	\$1m	\$0.6m
Audit Costs (10% of sites @\$40K)	\$1m	\$0.08m
Internal Costs	\$20.7m	\$5.8m
Investigator Fees	\$17m	\$17m
Recruitment Costs	Unknown	\$4m
Total Delivered Cost	\$37.7m	\$26.8m
Saving to Sponsor		\$10.9m



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“The 20th Century will be remembered chiefly, not as an age of political conflicts and technical inventions, but as an age in which human society dared to think of the health of the whole human race as a practical objective.”

ARNOLD TOYNBEE 1889-1975