

### **Quality Assurance**

Our working practices are governed by a full set of SOPs to ensure compliance with ICH Good Clinical Practice and all required local and international regulatory requirements. We ensure documentary evidence of quality at every point in a project. Our Quality System is supported by an external QA consultant. Our experience and selection procedures ensure that we provide the highest quality in personnel while our monitoring and client liaison procedures ensure the smooth flow of information at all times.

# Leveraging an international partner network

Java offers international coverage through our formalised alliances with networks of European CROs comprising of companies similar in size to Java. These alliances have proven very successful for Java's clients who wish to run pan-European projects and enable us to provide a unified national expertise under the umbrella of common SOPs and a central Project Management.

Through such networks Java are truly a gateway to Europe, providing maximum flexibility and optimal, cost-effective, trial management at local level.

### Contact us:

#### Java Clinical Research Ltd

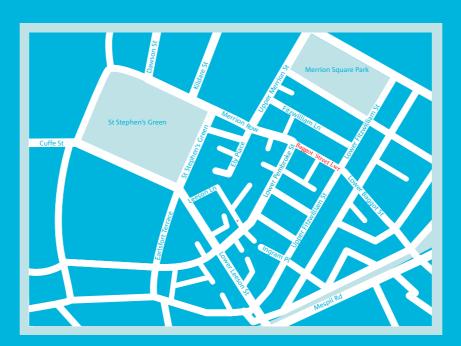
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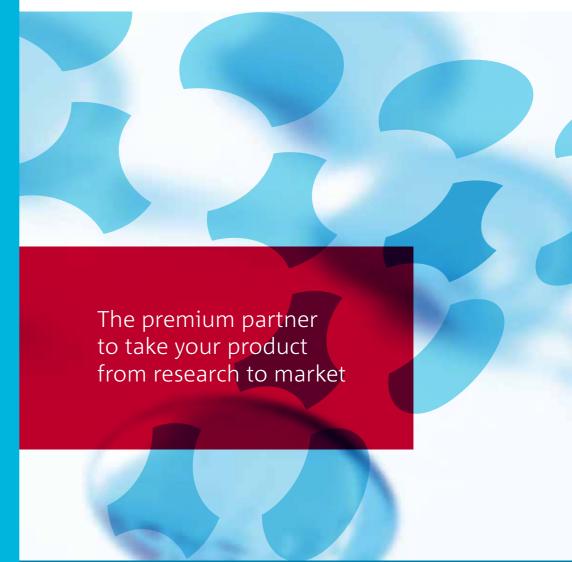
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JAVACLINICAL

designed by catalysto

# The expert Irish source for investigators, patients and complete trial management

A Contract Research Organisation based in Dublin, Ireland, Java Clinical Research provides a complete range of clinical trial services to the pharmaceutical, medical device and biotechnology industries. Working with our clients as a development partner on phases i-iv, we help take new products all the way from research through to market.

Java offers a top-quality team of research professionals and support staff, fully committed to delivering every client's project on time and to the highest quality standards.

Java's experienced management team has in-depth skills and expertise in both early and late phase studies. Tried and tested support structures ensure the smooth, efficient progress of projects across a wide range of endeavors. Our strong commitment to effective monitoring and client liaison means our clients are kept full briefed on progress every step of the way.



## Comprehensive clinical trial services

Established in 1999, we have a long collaboration with Investigators throughout Europe. These Investigators are experienced research professionals with highly trained staff and excellent facilities. This enables us to carry out quick feasibility assessments and advise sponsor companies on realistic timelines and the milestones achievable for their project.

Through Java's affiliation with two of Ireland's largest medical schools, University College Dublin and the Royal College of Surgeons in Ireland, we have direct access to world renowned Specialist Investigators and Researchers. The range of therapeutic expertise includes, among others, cardiology, respiratory medicine, immunology, gastroenterology, urology, metabolic diseases and neurology.

Our clients can be assured of the service and expertise they need to achieve overall project goals.

### Java services include

- Project Management
- Clinical Monitoring
- Investigator Selection
- Competent Authority Submissions
- Ethics Committee Applications
- Protocol Writing
- SOP writing

- Management of Investigator-Led Trials
- Consulting Services
- ICH-GCP Training
- ICH-GCP Audits
- Translational Medicine Consultancy

## The CRO with innovative biomarker expertise

Java's specialist expertise - under the guidance of founder Director, Professor Desmond Fitzgerald - is in the area of Molecular Medicine and especially in the design of clinical trials that provide early evidence of clinical benefit. We work in close collaboration with Investigators, scientists and researchers in hospitals and universities who are engaged in novel translational and biomedical engineering programmes. Working with physicians, scientists, engineers and the biosciences industry, we keep abreast of the latest and best research technologies.

Java's skilled research team have significant experience customising complex laboratory procedures for implementation in a clinical trial setting. Our specialist expertise includes:

- Biomarker discovery
- Platelet function testing
- Flow cytometry
- Proteomics

- Genomics
- Monocyte isolation and analysis
- Stem cell culture and differentiation
- Microparticle analysis

Expert project support ensuring a thorough understanding and appreciation of the factors critical to the success of each clinical trial.