FIRECREST
Study Performance Ignited

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ICON
A Symbol of Excellence

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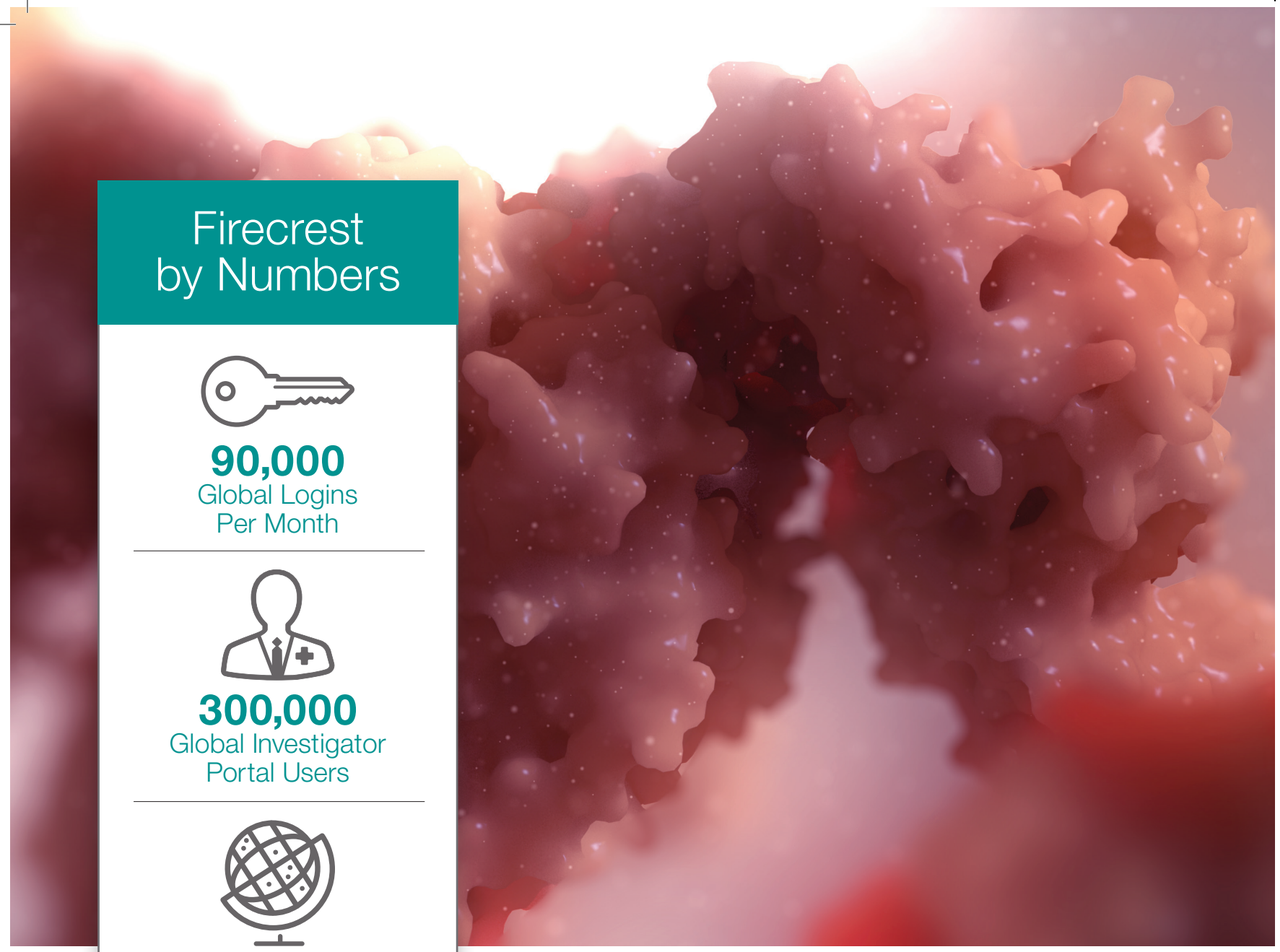
Your Virtual Study Expert:
Ensuring consistency, quality and compliance across all sites



Firecrest by Numbers

90,000
Global Logins Per Month

300,000
Global Investigator Portal Users

70+
Countries

50
Sponsors Using Enterprise Portal

1,000+
Phase I-IV Studies Using Firecrest

Study Performance Ignited

ICON Firecrest, the Virtual Study Expert, provides web-based products designed to improve communication, workflow and compliance at investigator sites and to give sponsors unprecedented study visibility and control. Firecrest's single sign-on, scalable innovations and services can be integrated with sponsor technologies and ICON services to help sites conduct research more efficiently and effectively. Firecrest's suite of products are proven to **increase screening rates by 56 percent, reduce protocol deviations by 50 percent and cut data queries by 45 percent.***

Firecrest is already a proven advantage. Every one of the top 10 pharmaceutical companies has used Firecrest technologies. For one, Firecrest increased compliance from 73 percent to 94 percent across 350 studies involving three CROs and 10,000 staff members, all in just eight months. Today the company uses Firecrest as its Enterprise Portal Solution to manage its entire clinical development portfolio.

*Results tabulated in a controlled environment across 50 studies.

Firecrest: Your Virtual Study Expert

Firecrest was designed by investigators and study coordinators, which means it's built to work the way trial personnel work. Firecrest is web-based, scalable, flexible and modular, so studies are outfitted with the tools your trial personnel need and nothing more.

The ICON Investigator Portal

The ICON Investigator Portal is your gateway to all Firecrest products and information. This customised, single sign-on portal connects your sponsors, investigators, site coordinators, study monitors and all other study personnel worldwide. Built to work the way investigators do, the ICON Investigator Portal enhances communication and clinical conduct and will scale to manage a few studies to your entire portfolio of clinical studies worldwide.

Single Sign-On: The single point of entry for all ICON services and Firecrest products that can integrate your systems and technologies

- *Backed by 24/7 Firecrest support*
- *No more multiple logins and passwords to maintain to log into sites/IT applications*
- *Electronic data transfer in real time of data compliant with HIPAA and 21 CFR Part 11*
- *Eliminates inefficient and labour-intensive study processes, reducing costs and providing full transparency of investigator competency, compliance and execution to you and your site monitors*
- *Interoperable with existing data collection and management tools (e.g., automatic investigator account creation and management based on CTMS data, data integration with enterprise systems)*

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Scalable: Versatile products are built to accommodate single studies to an enterprise-wide portfolio of studies

Secure: Integrates with your existing technologies to create a secure, compliant environment

Dashboard Advisor: Customisable dashboards display real-time study performance metrics
- *Business intelligence drives strategic decisions, establishing a competitive advantage*

Localisation: All training and study communications are available in the local language of the investigator sites
- *Global studies can be conducted simultaneously in multiple languages*

HyperTrial

HyperTrial puts an entire trial in a mobile device. Investigators get the tools and resources they need on the go, enabling real-time data entry from the bedside. Going well beyond routine information, HyperTrial offers a full range of issue and event decision management tools to minimise human error and maximise protocol adherence.

Mobile Gateway to Firecrest Resources: Access Firecrest clinical products that are especially valuable on the go via an iPad
- *The eConsent signature viewer guides patients through the consent process in advance of meeting with investigators to accelerate education*
- *Electronic data transfer in real time of data compliant with HIPAA and 21 CFR Part 11*

Direct Data Entry: Online and offline, real-time data collection (including site administered ePROs) that streams to and synchronises with EDC systems (e.g., RAVE, InForm)
- *Eliminates the need for double data entry or data reconciliation*
- *Facilitates rapid response from study teams when necessary*

Site Administered ePRO (EDC system integrated): Designed for collection of PROs or COAs performed in the clinic, all with automatic transfer to the EDC system

Dynamic Decision Support Tool: Interactive patient management system provides real-time guidance on key protocol events (e.g., toxicity events, endpoints, adverse events of special interest)

Data Capture, Management & Review

TrialDrive

Trial management presents a myriad of logistical challenges, one of the most arduous being the job of organising, managing, updating and deploying documentation. This problem is compounded when trials span multiple countries, and when time zones, language barriers and the need to deploy targeted information come into play. TrialDrive simplifies version-controlled document management and distribution to particular countries, individual sites, specific job roles or the entire study.

Security Meets Simplicity: Controlled-access to official documents (negates need for circulating copies of documents and managing out-of-date versions) and secure, 21 CFR Part 11 compliant version-controlled document storage, deployment, publishing, approval and monitoring tools

Always Available: Staff can access clinical trial documentation anytime, anywhere

Replaces Paper With Productivity: Eliminates manual paper-based processes and administrative burden on your staff

Stays Current, Stays Compliant: Keeps complete audit trails to support regulatory compliance and inspection readiness, reducing labour-intensive processes with one central repository

Version Control: Site staff always see the latest version of documents
- *Real-time monitoring of document status*
- *Centralises communications to all research personnel, reinforcing protocol adherence and mitigating human error*

Makes Your Workflow Work Better: Integration with other electronic systems; CTMS connectivity (e.g., for monitoring visits and distribution of associated follow-up letters) available now, with other system compatibility coming soon

Read and Acknowledge: TrialDrive will enable tracking and confirmation of documents across sites by confirming electronic signatures and monitoring via built-in dashboards

Suit Your Study: Options for configuration, with new add-on products becoming available for implementation

Visibility & Metrics

Dashboard Advisor

Firecrest's Dashboard Advisor provides real-time visibility into performance metrics of studies of any scope. From single studies to enterprise-wide portfolios of studies, the Dashboard Advisor is a scalable solution for companies of all sizes and provides business intelligence to drive strategic decisions.

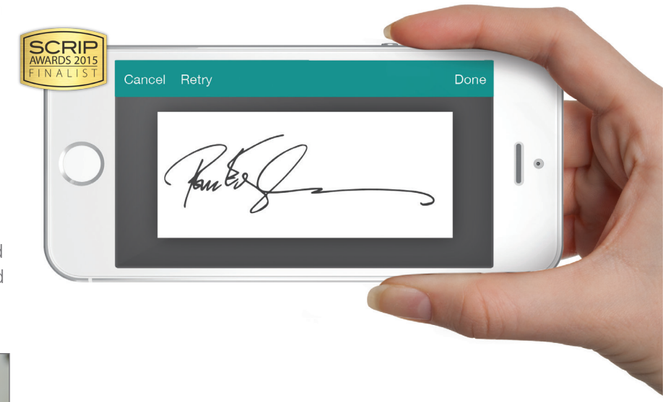
Patient Recruitment, Interaction & Education

eConsent

Firecrest's eConsent substantially improves efficiency, oversight, data quality and compliance within clinical trials. Despite intensive and costly monitoring, 5 percent of all FDA findings are due to errors in the consenting process.

Firecrest's eConsent virtually eliminates these errors while providing a real-time view of your trial compliance.

Based on groundbreaking research sponsored by ICON Firecrest and conducted by **Carnegie Mellon University,** the style and delivery of content within eConsent are tailored to enhance patient knowledge and comprehension. Leveraging dynamic, interactive and evidence-based multimedia, Firecrest's eConsent empowers patients to make truly informed consent decisions. For study staff, eConsent enables real-time remote monitoring. Moreover, patients get the power to review new information at home, simplifying the re-consenting process and reducing the likelihood of uninformed patient consent.



Real Patient-Centricity: Multimedia designed with evidence-based research from Carnegie Mellon University

Automated Consent Validation: Ensures participants sign the correct version and that the forms are complete, correctly dated and accessible for remote viewing by study monitors

Simplified Consent Process Management: One centralised, secure environment to store all consent records, with tools for version-controlled document storage, deployment, publishing, approval and monitoring

Electronic Signatures: Captures biometric signatures (written signatures) using USB signature pads or smartphone screens
- *All signatures are encrypted and electronically applied to consent forms; the system captures a full biometric profile and uniquely identifies signatories (same system used by many major European banks and U.K. social services)*

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Paperless, Web-Based System: End-to-end, cloud-based consenting process, which can be securely accessed via any computer

- *Can interface with other clinical trial platforms, ensuring no study participants proceed without first providing consent*

Remote Monitoring: Automated emailing to authorised monitors, notifying them of the signed consent form in real time, enabling validation of signed consent forms without site visits

Easy Setup: Deployment within your **ICON Investigator Portal** (and within existing site technologies) makes setup easy and cost-effective to scale

Patient Portal

Patient Portal is the comprehensive solution for recruiting and retaining patients worldwide. By connecting trial and patient information, Patient Portal gives patients the resources they need to stay engaged with a clinical trial from pre-enrolment all the way through the trial, which supports investigators' ability to recruit and retain patients. **Firecrest worked directly with patients to build Patient Portal,** tailoring the interface, information and tools to maximise patient usability and comprehension. With Patient Portal, connectedness means convenience.

Training & Reference

Essential Training Library

Firecrest makes real-time training interactive, user-friendly and blazing fast. Training programs are individualised for users, translated into all necessary languages and come with complete monitoring and certification options. Also, training and reference materials are version controlled, so staff are certified to the latest standards, while versatile certification options and real-time training/certification simplify monitoring. Training program development teams are led by clinical and medical experts ensuring absolute medical, technical and scientific accuracy. Fifty thousand GCP courses have been completed by investigators and site staff, all through Firecrest.

GCP Personal Training (TransCelerate attested), RECIST, IMWG, Expanded Disability Status Scale, Conducting the 6-Minute Walk Test, IATA Dangerous Goods Regulations, Subject Retention and Patient Information available now and more courses coming soon.

Virtual Training Curriculum

When preparing to launch a research program, Firecrest's clinical experts take protocols and develop role-specific training programs for all study personnel. Using dynamic multimedia — from presentation decks to hyper-real 3D video — Firecrest makes study-specific training interactive, engaging and user-friendly.

PowerPoint Lesson: Narrated PowerPoint presentations provide detailed, always-available training sessions, for example, Protocol Overviews (POs), our simplest solution

2D Workshop: Customised graphics and narration for your PO to improve engagement and knowledge retention and accelerate the training process

3D Masterclass: Our award-winning, 3D training videos and visualisations, which have been proven to reduce deviations and queries, showcase your compound and describe the disease pathology and Mechanism(s) of Action using hyper-real graphics for the deepest understanding

Visit-By-Visit Guide

The Visit-By-Visit Guide consolidates up-to-date information from the protocol, lab manuals and other study documents to deliver information when it is most relevant and beneficial. The guide reinforces consistency and efficiency to uphold protocol-compliant conduct, preventing error in everything from data collection to sample packaging and shipping.

Save money and accelerate timelines

Insight Innovation Performance

Ready to Ignite Your Study Performance?

Altogether, Firecrest's products create your Virtual Study Expert — the best study performance solution available, and it's only getting better. Sponsors can monitor study performance from their desks, and new products will provide unprecedented visibility into their trials.

To ignite study performance, you have your match: Firecrest.

Schedule a Demo

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