FIRECREST

ICON
A Symbol of Excellence

Firecrest Investigator Portal

Ensuring consistency, quality, transparency and compliance across all investigative sites and study personnel

ICONplc.com/firecrest

Proven Results

The Ultimate Investigator Training & Support System

As clinical trials become more complex, an increasing burden is being placed on investigators who have to deal with frequent protocol amendments, more complex procedures and an ever expanding case report form. Ineffective training, inadequate communications and poor data capture methods contribute to poor trial performances which inevitably result in delayed recruitment, frequent non-compliances with protocols and ultimately, delayed study close-out and market approval.

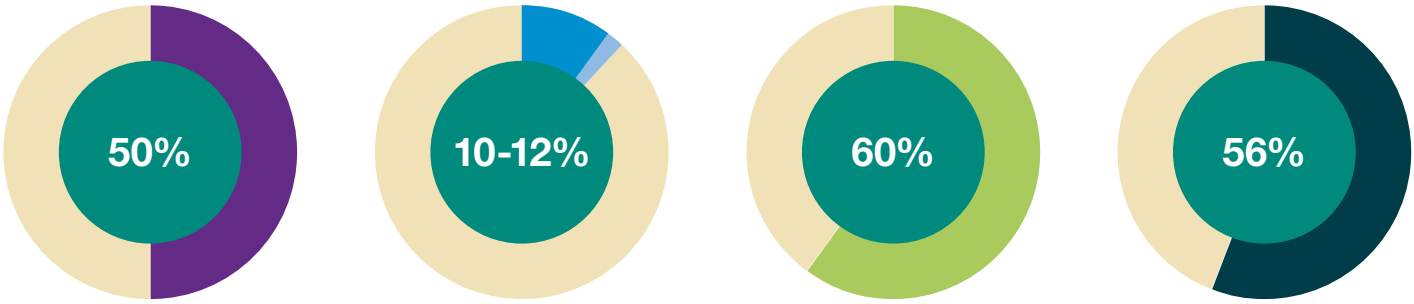
ICON's Firecrest delivers an innovative suite of training, performance support and study management tools which can significantly improve the compliance, consistency, and execution of all study-related activities at all sites and by all study personnel.

Firecrest eliminates inefficient and labour intensive study processes, reducing costs and providing full transparency of investigator competency, compliance and execution to site monitors and sponsors.

Step-by-Step Training, Support & Communication

- Enhance global standards of investigator knowledge and compliance
- Quickly identify protocol deviation and lapses in investigator diligence
- Eliminate error susceptibility in data entry
- Reduce incidence of inadequate or missing informed consents
- Improve retention and patient safety
- Deliver real-time site performance data to sponsors and study teams

"Simplifies study procedures so I can focus on the patient"



Reduce protocol deviations | **Increase patient recruitment** | **Reduce mean training costs** | **Increase screening rates**

Training

Interactive web-based training available when it is most relevant and most beneficial

Specific customisation for role and protocol requirements

Training certification to measure progress and enforce competency levels

Standardised instruction on a global level, even without online connectivity

Support

24/7 study support with a centrally located 'Visit-by-Visit' Guide

Web and mobile based data entry to reduce clinical and data collection errors

Procedure updates rolled out quickly and simultaneously across all sites

Localised information in multiple languages for global support

Communication

'Meeting Centre Manager' for flexible, low-cost communications

Meeting facilitator to record minutes, and Q&As so focus can be kept on important tasks

Enforced accountability with training certification and attendance logs

Archive of previous meetings/ events available for access

Key Visit Requirements

Visit-by-Visit Guide

Combining information from a number of sources, including the protocol, CRF, and laboratory manuals, the online Visit-by-Visit Guide is an integral part of the Firecrest solution and provides on-the-spot essential training and performance support for investigators, site coordinators, study monitors, and other study personnel. In addition, the guide includes an electronic Case Report Form (eCRF) completion facility enabling immediate capture of patient data at point-of-care.

The Firecrest Visit-by-Visit Guide is simple and intuitive focusing on the operational detail and day-to-day conduct of a clinical trial. It provides sites with access to detailed protocol-compliant instruction and data entry forms to ensure quality execution of procedures and study visits.

The Visit-by-Visit Guide is of vital importance to the quality of data which is critical in ensuring that each and every trial achieves its study outcomes. It provides key information and decision support tools that are necessary to ensure that the conduct of the trial and its procedures are consistent with the protocol across all study sites. This consistency is crucial, as variance kills power calculations in studies. The Visit-by-Visit Guide gives each site a tool that allows just-in-time access to critical protocol information so that they can use this information to positively impact the conduct of the study at each site.

A portable interactive version of the Visit by Visit Guide is also available for the Apple iPad® enabling busy site staff and investigators on the go to take all their Firecrest materials with them on their daily routines and patient visits.

The Visit-by-Visit Guide includes the following:

- Scheduling Tool
- Integration with Email
- Detailed Instruction and Information for Every Procedure
- Interactive Lab Manual
- Decision Support Tools and Calculators
- Source Documentation
- eCRF Completion Facility
- Toxicities Plan Management
- Dose Management Plans
- Safety Reporting
- Follow-up Procedures
- Withdrawal/Discontinuation Procedures

Meeting Centre Manager

Compliance, consistency, and quality of execution throughout the life of the study are greatly enhanced by improving communications at the site level.

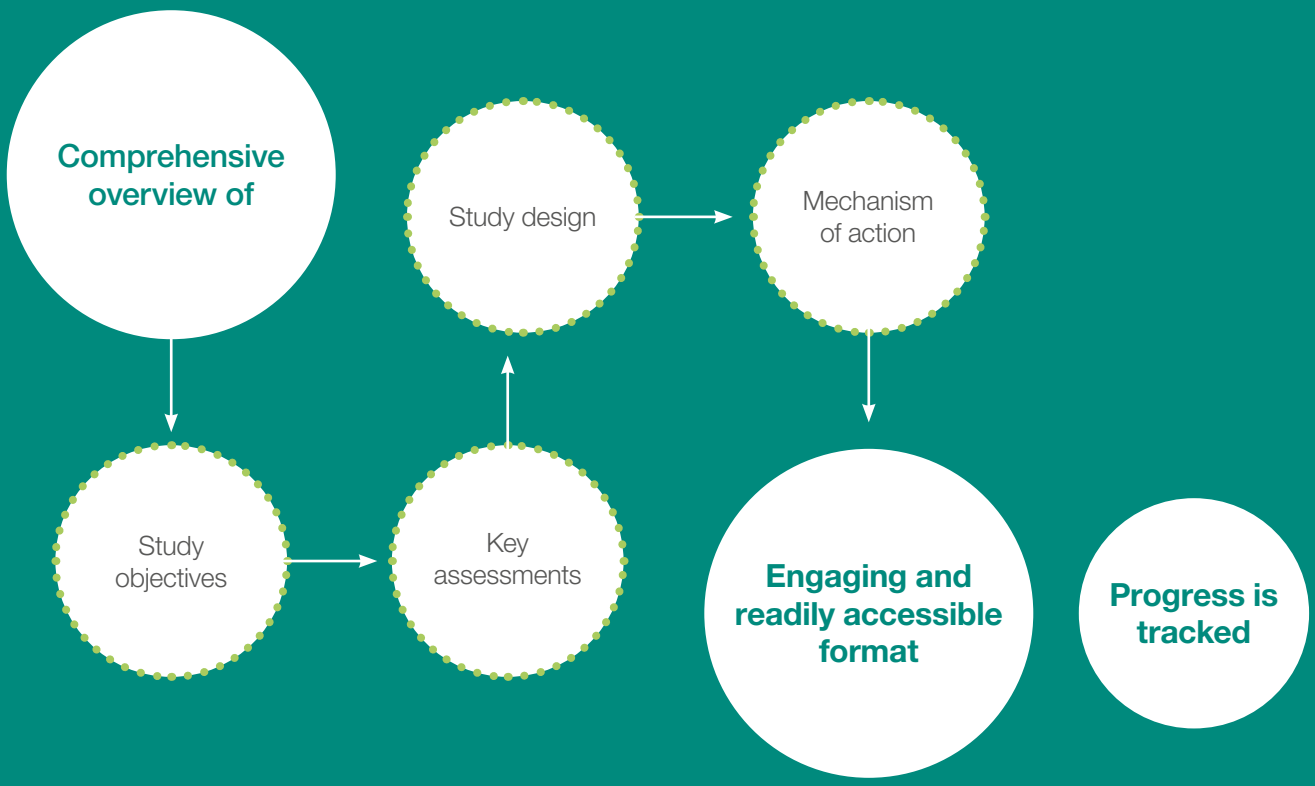
The Firecrest Meeting Centre Manager is a convenient, user-friendly solution that facilitates online meetings between study teams, monitors, and site staff in addition to being used for training purposes. The Meeting Centre Manager uses video and audio interaction to allow meetings to be held without travel and at times convenient to participants, enabling up-to-the-minute study information to be shared quickly and easily. Attendance can be logged and certified where appropriate.

The Firecrest team provides full management and support services for all online meeting events, from sending out invitations and checking compatibility, to facilitating the meeting and storing an archive of the event. When used for training purposes, online meetings can also be integrated with training certification, ensuring the training status of all logged attendees is automatically updated.

The Firecrest Meeting Centre Manager facilitates:

- Study launch meetings
- Study team meetings
- Corporate “round table” meetings
- Investigator meetings
- Video presentations
- Training tutorials

Animated and Interactive Protocol



Role-based, Protocol Specific Training

Firecrest's customised web-based training modules are available for each participant at every phase of every trial, replacing the cumbersome, expensive, and often ineffective group training meetings for investigators.

After receiving your protocol, our investigator-led development teams generate dynamic and engaging protocol-specific training solutions in six weeks or less. These solutions utilise a range of graphics, audio, animations, and other interactive instructional aids to help users to quickly process, retain, and apply study-specific information in the day-to-day conduct of a clinical trial. Each training program is adapted to allow users to progress at their own pace with information that is appropriate and relevant to their role, facilitating the different levels of knowledge and experience of investigators, site coordinators, and study monitors.

A typical Protocol Overview Lesson provides thorough training to study personnel on topics including patient selection, drug handling, dosing, and accountability, key efficacy assessment and protocol-specific safety considerations. The Firecrest team can also create custom content from existing paper-based training materials or slide presentations.

Each training participant can be tracked to ensure training has been performed and understood, timelines are met, and study parameters are maintained. This also allows the study manager to analyse performance on a site-by-site basis, to determine the percentage of sites that have reached a particular milestone, and to guarantee compliance to the requirements set by regulatory bodies. Global training reports are provided to study teams and can be filtered by site, role, and country/region as required. Our integrated Learning Management System (LMS) enables you to assign training modules, host online meetings and webinars, track participation and completion rates, assess competency, and provide documented training records for all users.

Assessments & Certification

All Firecrest training courses are linked to an online certification engine, which ensures tracking and monitoring of course completion.

Study Pack

The Study Pack module provides information in the form of downloadable slide presentations to facilitate training for trial sites in countries which have limited internet availability and where online training is not possible. These presentations mirror the e-learning modules and can also be used to enhance face-to-face meetings with individuals or small groups, ensuring consistent training is provided to all sites.

Technology Delivering Improved Safety & Compliance

The Firecrest solution is delivered via an Investigator Portal which provides a user friendly, web based gateway to all investigator resources including EDC, IWRS/IVRS, training modules, operations manuals and support tools such as the Visit by Visit Guide and Meeting Centre Manager. The Firecrest Investigator Portal facilitates global communication and site management providing a full clinical trial system for all sites worldwide throughout the entire duration of a study.

Deployed as a 'Software as a Service' (SaaS) model, each portal is customised and immediately available for study teams without the major financial and IT resource investment that is normally required with building and maintaining on-site integrated IT systems.

Access to each portal is strictly controlled via user accounts with password protection and is fully 21 CFR Part 11 compliant.

The Investigator Portal can be fully localised in multiple languages for global studies and additional languages can be incorporated as required. Each portal is accessed via a single URL which can support multiple studies and other vendor websites and eClinical applications. It uses the most advanced IT systems with full backup and redundancy facilities and full disaster recovery support. A secure, high speed data communication infrastructure ensures, reliable, uninterrupted, access to all applications.

The Firecrest Investigator Portal is supported by an Investigator-led development team who manage all portal maintenance tasks, generate training modules and facilitate all study team communications, ensuring a streamlined, problem-free study.

Excellence in Innovation

Building on its reputation as one of the most successful and trusted CROs in the global pharmaceutical industry, ICON is revolutionising clinical trial processes using integrated technologies, enabling us to significantly enhance the efficiency and productivity of our clients' drug development programs.

Our range of innovative solutions include:

- Complete solutions for the management and analysis of medical image data
- Powerful integrated information platform to analyse a blend of operational, quality, efficacy and clinical safety data across multiple studies and different therapeutic areas
- Dedicated investigator training and performance support portal

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