



## **FIRECREST**

Site Performance Ignited

### **Digital solutions that increase efficiency in clinical trials by driving site performance**

Clinical trials continue to grow in complexity, creating new challenges in maintaining quality, reducing the cost of development and the time it takes to bring a drug to market. According to industry statistics, it can cost 25-50K on average to set up a single site ready to screen, and yet 11% of sites fail to enroll a single patient and 37% under enroll.

Our solutions improve the clinical trial experience for sites, patients and study staff resulting in reduced time, cost and better quality data.

#### **Site Portal**

The FIRECREST Site Portal is a single sign-on portal that enables centralised role based user management across studies, connecting site and study staff. Built to work the way investigators do, it improves site performance and will scale to manage a few studies or your entire portfolio.

#### **Customisation**

- Increase your brand profile with sites by customising your portal with your logo and your company messaging and mission

#### **Easy to access and use**

- Provide site staff with access to your studies with a single user name and password.

#### **Role-Based Management**

- You control access to applications and portal functionality according to the users role.

#### **Learning Management**

##### **Bringing your protocol to life**

FIRECREST's multi-award winning range of interactive, user-friendly training options bring your protocol to life and support better understanding of your study by site and study staff. Our clinical and learning management experts can take your protocol and work with you to develop role-specific training programs designed specially for your study.

##### **3D Medical Animation**

- High definition videos designed to illustrate and demonstrate diseases, pathophysiology and drug mechanism of action (DOA)

##### **Protocol Overviews**

- Study specific protocol training to improve understanding of the protocol and leading to improved compliance

##### **Off-the-shelf training modules**

- GCP (R2), RECIST 1.1, 6 minute Walk Test – IATA, Dangerous Goods Regulations (DGR), Expanded Disability Status Scale (EDSS), Subject Retention – Informed Consent – Short Physical Performance Battery (SPPB).

## Visit by Visit Guide

**Study information available on demand during and after the patient visit**

FIRECREST Visit by Visit Guide provides step by step instructions on essential instructions. In-time guidance reduces the time burden on staff to page through manuals and leads to increased compliance and reduced protocol deviations.

## Pre-Screen

**Improving the speed and accuracy of identifying patients for screening**

Patient access continues to be one of the biggest industry challenges impacting on time and cost in clinical trials. Accurate and rapid pre-screening for a clinical trial offers the potential to increase enrolment rates while also preventing ineligible patients being enrolled in your study.

FIRECREST Pre-Screen is an innovative digital solution to improve the speed and accuracy of the pre-screening process compared to other current paper-based and eScreen methods. Pre-Screen aggregates the data that flows from the process to form actionable insights into the key drivers of pre-screen success and failure.

## eConsent

**Making it easier for the patient and the site**

eConsent has the potential to transform the conventional consent approach by making the process easier for the site and the patient. Enhanced informed consent is truly patient centric and improves the patient's experience right from the start leading to the better engagement. With the entire patient consent process conducted on line you get increased transparency into what is happening at site level.

FIRECREST eConsent solutions addresses both elements of ICH GCP, patient understanding and documentation of written consent and has already been implemented successfully at sponsor sites.

# FIRECREST

**Empowering sites to accelerate trials**



## Trial Drive

**Secure, compliant document management and tracking**

Trial management presents a range of logistical challenges with one of the most arduous being document management and tracking. This problem is compounded when trials span multiple countries, time zones, language barriers and the need to deploy targeted communications. FIRECREST Trial Drive is a secure e-document distribution and tracking solution featuring role based and read and acknowledgement tracking.

Sample applications include

- Safety Letters
- Protocol Amendments
- Clinical Study Reports
- Follow-Up Letter

## Financial Disclosure

Financial Disclosure is mandated by FDA 21CFR Part 54 (Financial Disclosure by Clinical Investigators). ICON provides a robust solution for you to distribute, track and manage the completion of forms. It also enables secure, centralised, electronic distribution and response capture of this information. FIRECREST Financial Disclosure supports you by reducing the risk of regulatory findings and reduces administrative costs associated with traditional distribution and tracking of form completion.

## Improving the clinical trial experience for sites, patients and study staff

### Increases Compliance

- Education and training on demand
- eDocument distribution and tracking
- Inspection ready documents and training records

### Increases Quality

- Better trained site and study staff leads to higher quality data
- Unique requirements of each study transformed into tailored interactive medical animation
- Dynamic, easy to understand, accessible digital content

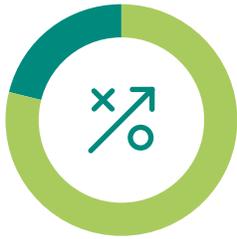
### Reduces Cost

- Reduction in training, logistics, paper and site administration costs

### Increases Patient Engagement

- Study specific education in the consent process

## Recent examples of results from FIRECREST enterprise solution



**21%**

Increased  
Compliance Training



**35%**

Reduction Protocol  
Deviations



**47%**

Cost Reduction  
Training



**50%**

Cost Reduction  
Document Distribution

## Tried and Trusted Performance

### Track Record since 2001



Deployed by Top 20 Pharma  
100+ Clients

### Extensive Therapeutic Experience



13+ Therapeutic Areas  
140+ Indications

### Robust, Scalable Solutions



540,000+ Users  
1600+ Studies