

Empowering Patients to Make Informed Decisions: FIRECREST 'eConsent'

CHALLENGE

Informed consent for clinical research is an ethical and legal imperative. However, in practice many patients enrolling in clinical trials do not understand the key pieces of information contained in the traditional lengthy and technical informed consent forms (ICFs).

Frequently, in rare disease indications, protocol procedures are complex, and may require numerous clinic visits and assessments. There are often additional consenting requirements for genetic testing, collection of biospecimens, and collection of registry data, for example. Such challenges increase the burden on the patients and their families, and on the site staff.¹ Also, approximately 50% of rare diseases affect children, bringing about further challenges in the consenting process for rare disease trials.²

If a patient enrolls in a trial without adequate understanding, they may be unknowingly taking on risks or commitments which they might personally consider unacceptable. Incomplete understanding of the study procedures and requirements may lead to increased likelihood of drop-outs and protocol deviations, which can put the validity of the entire trial at risk.³

Trials in rare disease indications typically have a limited pool of suitable candidates to recruit from in the first place.¹ Thus, adequate consenting and retention of eligible participants is of particular importance for rare disease trials.

Building on fifteen years of Clinical Trial eLearning experience on more than 1,000 studies, FIRECREST have developed a patient-centric, interactive, multimedia eConsent solution, based on evidence-based research with Carnegie Mellon University.

FIRECREST eConsent facilitates patient comprehension and retention of the key pieces of trial information relevant to their decision-making.

KEY BENEFITS

BENEFITS FOR PATIENTS



ENHANCE

Knowledge retention of key information
Patient engagement in the consenting process



PROMOTE

Trust in the physician



REDUCE

Informed consent-related inspection findings and costs



SIMPLIFY

Enables a risk-based monitoring approach



SCALABLE

Fits easily as part of an integrated site solution

EVIDENCE-BASED DESIGN³

eVIEWER

FIRECREST interactive, multimedia content, hosted in our eViewer, has been informed by evidence-based research conducted by Carnegie Mellon University in collaboration with ICON.³

- Key information presented
- Streamlined content
- Tailored to the appropriate audience
- Engaging graphics and animation
- Narrated videos
- Capacity to highlight text and record questions
- Dictionary feature

WHAT THE PATIENT SEES



CONCLUSIONS

By engaging and empowering rare disease patients and their families, and by reducing the burden on clinical trial staff, FIRECREST eConsent improves the patient consenting experience and simplifies clinical trial conduct. By prioritising the key pieces of information that patients hold as most important to them, FIRECREST eConsent ensures that patients are put first during the recruitment process, leading to higher engagement in the consenting process, and better knowledge retention of this key information.

FIRECREST eConsent is transforming the conventional informed consent approach in clinical trials in a truly patient-centric manner, while enhancing the consenting process for all stakeholders involved.

References:

- [1] Institute of Medicine (US) Committee on Accelerating Rare Diseases Research and Orphan Product Development. 2010. Development of New Therapeutic Drugs and Biologics for Rare Diseases. Rare Diseases and Orphan Products. <https://www.ncbi.nlm.nih.gov/books/NBK56179/>.
- [2] <https://globalgenes.org/rare-diseases-facts-statistics/>
- [3] Krishnamurti, T; Argo, N; Creating and evaluating patient-centered consent approaches for clinical trials: Findings, commercial implications, and next steps, 2016 Medical Decision Making Vol 36, Issue 6, pp. 726 - 740