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White Paper

OPHTHALMOLOGY

Ophthalmology Site Selection

CROMSOURCE is an international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialised in clinical development and staffing solutions.

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1. Introduction

Ophthalmology studies use cutting edge technologies and highly technical endpoints. Many assessments involve an understanding of physics and the standardization of tests across study sites is crucial. Sites must be able to demonstrate that they have excellent experience in managing and conducting ophthalmic research.

This paper provides a brief overview of the site selection process and highlights points for consideration when selecting study sites for ophthalmic research.

2. Overview

Site selection involves a number of key processes that should be completed by appropriately qualified personnel. These include:

- Establishing Site Selection Criteria;
- Investigator Identification;
- Site Qualification Visit (SQV);
- SQV Reporting and Follow-up.

3. Establishing Site Selection Criteria

Appropriate study site selection criteria should be established based on therapeutic and regulatory requirements. This is a crucial step in ophthalmology studies, as they require a unique set of specialized capabilities and a thorough understanding of ophthalmic research methods. Criteria should include preferred regions and number of sites; types of site to be considered; research and therapeutic area expertise at the site; and subject profiles that fit the recruitment criteria.

Where possible, sites that have conducted many ophthalmology studies in the past should be selected. Ideally, the site should be certified for the tests included in the study protocol. Certification ensures consistency across sites and reliable data. For example, standardized approaches to visual function assessment should be considered during site selection. Recruitment expectations should be balanced with data quality.

Private practices or research sites may have many patients; but may not be experienced in conducting research. They may not reach basic expectations, such as having a dedicated clinical research space and personnel that are both qualified and experienced.

4. Investigator Identification

Investigators may be identified by a number of methods such as: known relevant expertise; prior experience of the sponsor or contract research organization (CRO); publications and presentations; or by the investigator approaching a sponsor directly. Lists of suspended investigators published by appropriate regulatory authorities should be consulted during site screening.

A questionnaire or telephone interview should be used to screen potential investigator sites. The aim is to identify potential investigators with appropriate expertise, interest, and access to resource and subjects.

Factors to consider include:

- Medical and medical device or therapeutic expertise;
- Clinical study experience;
- Understanding of ISO 14155/IDE GCP/ICH GCP/specialist regulations such as for contact lenses;
- Procedures for referring potential study subjects;
- Required equipment;
- Concurrent studies;
- Support staff including coordinators and research nurses;
- Certification for endpoints to be collected in the study;
- Budget negotiations;
- Availability and modus operandi of independent ethics committee (IEC) or institutional review board (IRB).

5. Site Qualification Visit (SQV)

Potential investigators should be short-listed and discussed with the clinical team. The SQV is intended to confirm the suitability of a site for the study by meeting key personnel and reviewing facilities and equipment. The investigator should sign a confidentiality agreement before being provided with the study protocol or any supplementary documentation.

Study and site documentation to be reviewed should include, but not be limited to: the study protocol or investigational plan; investigators brochure (IB); roles, responsibilities, experience and qualifications of staff; certifications if applicable; source data and the case report form (CRF).Regulatory aspects and intended timelines should also be discussed.

6. SQV Reporting and Follow-up

A SQV report should be issued, discussed with the clinical team, and forwarded to the trial master file (TMF). It may be possible for a study site to be initiated without a SQV, at sponsor request or if the site or relevant staff have worked with a sponsor or CRO previously. The SQV is vital to understand the current situation at the site and so should not be omitted lightly. The reason for waiving a SQV should be documented and filed in the TMF.

7. Summary

Appropriate site selection is critical to the quality and integrity of any clinical study. Specialized assessments and technologies employed in ophthalmic research emphasize the importance of the experience of site personnel in managing and conducting ophthalmic research.

Where possible, it is best to select sites that have conducted many ophthalmology studies in the past and have appropriate certification.

About CROMSOURCE

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialising in clinical development and staffing solutions. CROMSOURCE was founded in 1997, more than 25 years ago. Its successful growth has been built on stability, integrity, and high levels of customer satisfaction, all of which contribute to a high rate of repeat and referral business. We have grown steadily, but responsibly, to become an organisation of over 350 organised and well-trained experts.

A well-established full service CRO, **CROMSOURCE** is unique in offering an End-to-End Guarantee covering trial timelines, enrolment and contract price. This guarantees our clients that their trials are delivered on time and within the contract price with no CRO-initiated change orders. CROMSOURCE operates through offices across all regions of Europe and North America and delivers a comprehensive breadth of services.

CROMSOURCE supports the full spectrum of clinical development via our Pharmaceutical, Medical Device and Staffing Solutions divisions. We seamlessly move biopharmaceutical products from first-in-human, through all subsequent phases of pre- and post- approval research internationally.

We also support medical device projects through regulatory planning and execution, to pre- and post-market clinical investigations in Europe and North America.

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CROMSOURCE, with world headquarters in Verona, Italy, is a leading CRO in Europe and the US with a solid infrastructure and operational subsidiaries in Belgium, Germany, Poland, Spain, Switzerland, the UK, the Netherlands, and the US.

From our office locations across Europe and North America, CROMSOURCE employs experienced field-based teams around the globe to provide expert capabilities in regions including the Middle East, Africa, APAC, and South America.

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