

SHOWCASE



Safety Management

Experts Providing Experts

TalentSource Life Sciences is the dedicated flexible resourcing business unit within CROMSOURCE - a business started over 25 years ago when CROMSOURCE first entered the resourcing market.

Experts Providing Experts

TalentSource Life Sciences is the dedicated flexible resourcing business division at CROMSOURCE. Our commitment to providing the right services to support our clients has seen us at the forefront of developments in the Industry; from pioneering the provision of contract staffing solutions in Northern Europe in

the mid-90's, to being early adopters of the ISO Quality Management certification in 2000. Our successful growth has been built on stability, integrity, high levels of customer satisfaction and we have grown steadily to open offices across Europe and North America and activities on a global scale.



Our Safety Attitude

When Hannah Greener died (England 1848) after receiving chloroform anaesthetic before removal of an infected toenail, the concept of Pharmacovigilance (PV) was born. PV/Drug Safety today ensures that testing is safer and facilitates a more effective use of medicines for everyone. It encompasses all activities that relate to noticing, assessing, understanding, managing and preventing adverse effects of products for individuals and populations.

CROMSOURCE's Safety Team plays a key role within the company and our Managers provide expert oversight and leadership, to ensure high quality of deliverable to our clients. Providing expertise through our internal team or via our TalentSource consultants, embedded in our client teams.

Safety Expertise

Our team responsibilities include analysing clinical trial data, writing reports and providing accurate and real-time safety management of global trials in all phases of clinical research. Our expert Safety Team is in constant and direct communication with site staff, physicians, CRAs, regulatory authorities, and the client to ensure full control at every stage of the project. The CROMSOURCE Medical Teams are also experienced, certified users of EudraVigilance.

CROMSOURCE has staff who are experienced in addressing the disparate safety reporting requirements in different EU countries and

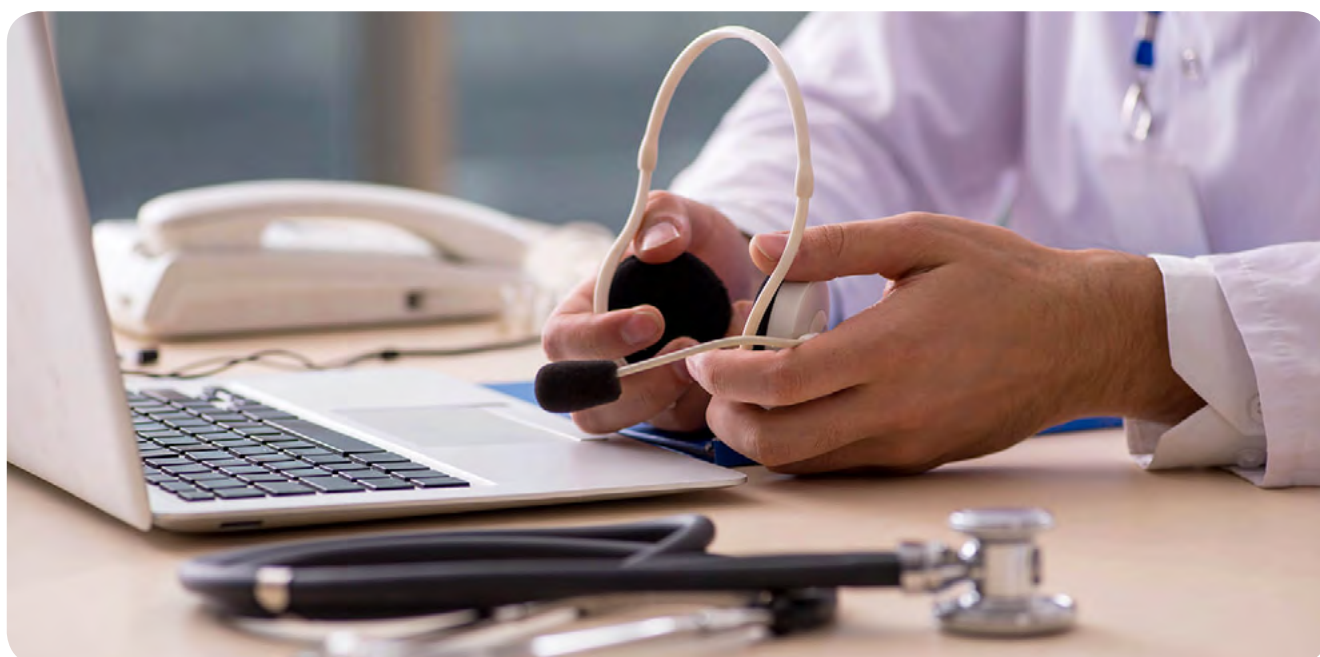
the US. We can provide staff working fully dedicated to our clients, benefitting from the back-up of our internal teams, that proactively manage reporting, keeping the sponsor and investigator teams fully invested in any safety decisions made or expedited reports submitted. Experienced CROMSOURCE medical staff also interface with regulatory authorities (including the FDA) and clients rely on us to supply staff who are able to ensure that any safety issues that arise are managed efficiently and pragmatically.

Training

Generally, our clients are responsible for staff training on their SOPs, IT systems and therapeutic areas assigned. Our experts are trained in Safety and our client-based teams have access to our internal training specific to this specialist area, being part of a CRO. In addition, our professionals can benefit from access to our Medical/Safety Team and our various leaders in therapeutic areas, to capitalise on their





knowledge and experience. All our resources are trained in ICH/GCP and local regulations.

We also work closely with our clients to identify development needs during our staff's assignments and offer support and training to ensure enhanced performance in the role, as well as development opportunities.



Case Study

Case Study – Partnership in Drug Safety

Program Description	Staff Requirements	Results	Key Learning
 <p>A large biopharmaceutical company approached us for the resourcing of pharmacovigilance employees as Drug Safety Associate in Belgium.</p> <p>Under the staff augmentation model, with CROM-SOURCE supplying employees to provide services to the client.</p>	 <p>Initially, 4 staff working in Pharmacovigilance as Drug Safety Associate.</p>	 <p>Due to our recruitments strengths we were able to present several suitable candidates within a week.</p> <p>Average time of placement 40 days.</p> <p>Retention (completion of initial assignment) min 95%.</p>	 <p>Partnership approach to relationship, transparency, integrity and shared goals. Clear communication plans set-up immediately.</p> <p>Regular reviews to check on progress.</p> <p>The assignments were successfully concluded, enhancing our partnership with the sponsor.</p> <p>One of our employees eventually also moved under permanent headcount with the client.</p>

Functions Covered in this area:

- Drug Safety – Assistants through to Project Manager and Director levels Clinical Safety Officers
- Pharmacovigilance Licensing
- Pharmacovigilance Officers
- Safety Reporting Specialists
- Materiovigilance and Pharmacovigilance Associates
- Medical Device Vigilance Specialist
- Safety Data and Database Specialists
- Safety Risk Leads
- Medical Reviewers

Choose the right Flexible Resourcing model that suits you or let us advise you on the best fit for your business:

Insourcing/Staff Augmentation

Providing our resources, contracted to work directly under your direction and control. Enabling temporary increase in capacity, while maintaining complete oversight.

Functional Resourcing (FSP)

For clients who want to outsource complete functions across multiple projects. Full leverage of CROMSOURCE's global capabilities, infrastructure, and functional expertise. This approach gives speed, flexibility, efficiency, innovation and a potential for reduced cycle times.

Hybrid Delivery Model

Creating a more flexible model is key to success for many clients, with our Hybrid Model, we are able to provide clients with full, multi-disciplined teams, utilising the project management and core strengths of CROMSOURCE. Ideal for clients who need to start projects quickly where they do not have their own structure in place.

Services can be bundled together for increased flexibility in allocation of internal and/or external resources to quickly ramp-up or down.

Combined Services

For a combination of development services, we will work with you to design a model that suits your specific needs for quality, geographic coverage and speed of delivery. By offering an option to our clients to have control but also be able to ramp-up a large team of staff to support a single study or studies, the combined service model is ideal.

Permanent Placements

For finding qualified & competent candidates for permanent employment. Using our extensive database for filling clients internal roles.

Staff Recruitment Expertise

TalentSource's dedicated staff recruitment team allows our clients to capitalise on the state of the art technology and database within CROMSOURCE. Recruitment and acquisition of talent is a corporate core competency at CROMSOURCE and one of the reasons why we are able to support our clients with a fast ramp-up of resources for their studies. Our recruiting process is established to attract and hire qualified candidates and utilises a variety of methods to recruit new hires including: direct sourcing, outsourcing and retained searches.

We place major emphasis on direct and clear communication lines between CROMSOURCE and Clients at the start-up phase of any relationship and Clients can be closely involved with the selection of resources assigned, if required.



Why work with CROMSOURCE?

- **Commitment to Clients:** Critical to program success, we have a dedicated Account and Line Management Team. Formal communication/Governance for fast issue resolution. High level of client control and regular interaction at all levels.
- **Resource Availability:** TalentSource has the ability to quickly ramp-up resources, either via our existing employees or finding the best matched people externally. We have a database of pre-identified resources, who can quickly start on your projects.
- **Training:** Our own internal training structure, with dedicated trainers and electronic training system, covering both Medical Device and Pharmaceutical regulations.
- **Client and Employee Support Infrastructure:** We have robust management oversight, IT, HR, Finance, Legal, Quality, etc.
- **Employee Retention:** Robust management structure for performance and problem resolution, career development to give us a stable workforce. Offering reward and recognition programs and long-term retention techniques. We are proud that our employee turnover rate is less than 15% per year.
- **Management Structure:** Formal communication/Governance with high level interaction and fast resolution



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