Clinical Trials Operations Management for Emergency Care

Clinical trials represent the most expensive, recourse- and time-absorbing component of the whole drug development procedure. Operations within the biopharmaceutical field involve a wide variety of separate operations that include **researching, collecting, estimating, systematizing and rationalizing data from a huge volume of sources**. In order to ensure efficient Good Clinical Practices (GCPs), regulators urge sponsor organizations to provide a whole-system approach. Such approach will guarantee the well-being of patients and will also serve to orchestrate administrative and operational processes in a more accurate and quality manner especially when it comes to emergency care in clinical studies.

Regarding this and in response to emergency service inquiries, the Royal College of Physicians (London) points out that;

"There is an **urgent clinical need to redesign acute services primarily to drive up quality, as well as to deliver effective and efficient services.** Problems with emergency services and care are the most visible manifestation of a whole system failure. Solutions to the issue require integration of working (between primary, secondary and community care), but **also a more collaborative working approach within the hospital itself."**

To present this differently, the adequate management of operations related to emergency care requires the adaption of a redesigned clinical operating framework. **Properly functioning framework of this type is expected to be built on stable clinical principles** and to mark out all rules of operation and/or behaviors which are expected to be maintained by clinical teams working within the emergency care system. Using such approach will produce highly operative core urgent system that is simultaneously responsive to various changes that occur in urgent care demands and to the clinical

needs of patients. Yet, **to promise 100% efficacy of the clinical operating framework and system, the key principles need to be realised by professionals who act together**. In this sense, there is a growing expectation that clinical leaders will collaborate with their clinical teams to make sure that the standard responsibilities of the framework are kept.

In relation to this, here we are listing **several of the standard responsibilities** of the framework:

1. There is a need of a response from the team of specialists as a whole to a seriously sick or deteriorating patients within the ED department.
2. For the most injured or sick individuals there should be an expectation following a formal consultant assessment.
3. The clinical team is supposed to promptly respond to requests for attendance and visits within timescales outlined in the policy of patients.
4. Implementing a Standard Procedure for handover between specialties in order to provide with responsiveness and safety of the whole system.
5. Achieving a minimum of 12 hours emergency presence with on-site consultant access for emergency care.

Dealing with practical complexities and overcoming practical barriers is a common challenge in the Pharmaceutical field**. As part of the solution-finding methods, regulators insist on the use of game-changing and, most importantly, effective systems that will facilitate the work of experts when it comes to clinical trials and emergency care**. Creating a clinical operating framework on core standards and behaviors will allow the development of **a whole system that will reinforce the work of clinicians who operate closely with managers across the health board**.

Originally posted here: https://crotraining.co.uk/clinical-trials-operations-management-for-emergency-care/