

Clinical trials practitioners

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Content

- * Definition of practitioners/CTP
- * Practitioners in the NHS
- * Role of the Clinical Trial Practitioner.
- * Research nurses accountability.
- * CTP accountability
- * Summary

Definition of practitioner



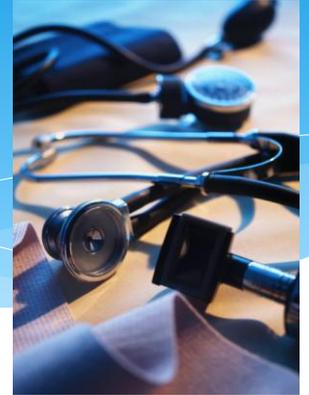
- * A person who practices a profession.
- * A person actively engaged in an art, discipline, or profession, especially medicine: *patients are treated by skilled practitioners*

Definition of CTP



- * To provide professional clinical and administrative support and to ensure the smooth running of clinical trials.
- * Work as part of the clinical trial delivery team, being mutually supportive and covering duties as necessary during colleague's absences and at times additional pressure, as directed.

Practitioners currently in the NHS



- * Not so novel, currently work across many disciplines.
- * Practitioners are at level 4 of the NHS Career Framework, they work in a broad range of areas, primarily but not exclusively, with patient contact.
- * Work in a multi-disciplinary team, assisting in the care of patients.
- * Healthcare assistants (HCAs) work in hospital or community settings under the guidance of a qualified healthcare professional. The role can be varied depending upon the healthcare setting.
- * The development of the CTP at Barts was in response to poor recruitment and retention of research nurses,

Role of the clinical trial Practitioner



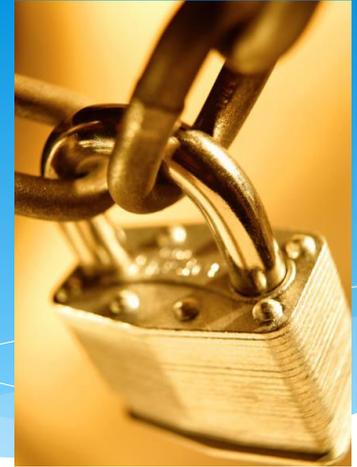
- * Maintaining CRFs, ECRFs and TMFs.
- * Assist the clinical team to ensure study protocols and procedures are adhered to in accordance with local practice and Good Clinical Practice Guidelines.
- * Organise patient assessments and visits as appropriate to relevant study protocols.
- * Support patients throughout the delivery of their care on clinical trials, seeking appropriate assistance to ensure that their concerns are addressed.

Role of the CTP con:d



- * Co-ordinate collection and preparation of biological samples as per protocol.
- * Delegate and refer to other research team members when risks and needs are beyond own competence and scope of practice.
- * Ensure effective communications between trial centres, sponsors and investigator sites nationally and internationally

Accountability



- * All Health service providers are accountable to both the criminal and civil courts to ensure that their activities conform to legal requirements.
- * In addition, employees are accountable to their employer to follow their contract of duty.
- * Registered practitioners are also accountable to regulatory bodies in terms of standards of practice and patient care (RCN et al., 2006).
- * Generally, the person in overall charge of the nursing care of the patient is usually the registered nurse. But the nurse cannot perform every task for every patient and therefore s/he will need to delegate aspects of that care to colleagues.

Research Nurses Accountability



- * The registered nurses have a duty of care and a legal liability with regard to the patients. If they have delegated a task they must ensure that the task has been appropriately delegated. This means that:
- * The task is necessary and delegation in the patient's best interest
- * The CTP understands the task and how it is to be performed
- * The CTP has the skills and abilities to perform the task competently
- * The CTP accepts the responsibility to perform the task competently.

CTP Accountability



- * HCAs, APs and students all have a duty of care and therefore a legal liability with regard to the patient. They must ensure that they perform competently. They must also inform another when they are unable to perform competently.

- * In order for anyone to be accountable they must:
 - * • have the ability to perform the task
 - * • accept the responsibility for doing the task
 - * • have the authority to perform the task within their job description,

Summary



- * Practitioners work in many disciplines across the NHS.
- * The role of the CTP and Research nurse, overlaps in many areas.
- * Accountability and delegation needs to be clearly defined.
- * We are still learning, but hopefully we can make it work for the best possible patient care and research.