

# Clinical trials practitioners

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# 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*

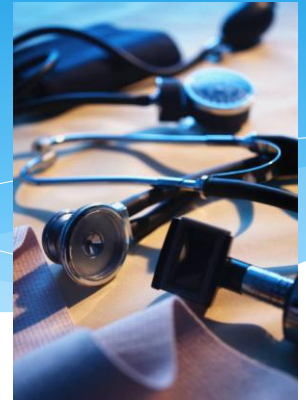


# Definition of CTP



- \* 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.