CHS215 Carry out clinical trials in health

OVERVIEW

This standard relates to the range of clinical trials involving the evaluation of novel medical equipment, information technology systems, new medical devices, pharmaceutical agents or compounds, new therapeutic or diagnostic procedures, new test procedures and translational research. This standard is applicable to all clinical trials although they may vary considerably in range, size and complexity.

It can be carried out in specific clinical trial centres, research establishments or within clinical practice areas. It may involve individuals or other testing parameters.

It may be undertaken by health care individuals within a wide range of environments and may involve external clinical trial organisations.

Individuals will be assessed against this standard within the scope of their work practice.

Users of this standard will need to ensure that practice reflects up to date information and policies.

Version No 1

KNOWLEDGE AND UNDERSTANDING

You will need to know and understand:

1. your own level of competence, authority and specialist knowledge base related to clinical trials undertaken within your work practice
2. the need for clinical trials and how to acquire ethical approval and financial support within your work area
3. why it is important to ensure all relevant regulatory requirements are met within a clinical trial
4. the importance of undertaking a literature research to identify reliable sources of information relating to best practice in the conduct of clinical trials
5. the importance of an appropriate level of underpinning knowledge related to the chosen area under trial
6. the need to identify the range of factors that may have an influence within the
different stages of the clinical trial and the steps required to control them
7. where applicable, how to engage the range of relevant individuals, their
   information needs, roles, responsibilities and capabilities relevant to the health
   context of the chosen area of the clinical trial
8. why it is important and the recommended practice to pilot a clinical trial wherever
   feasible, to further define the experimental design
9. why it is important to establish the framework for intellectual property protection
   and exploitation prior to the clinical trial
10. where applicable, the importance of gaining consent and maintaining anonymity
    within the report for participants within the clinical trial
11. the importance of relevant qualitative and quantitative methods applicable for
    capture and analysis of clinical trial information
12. why it is important to undertake statistical analysis and the relevant methods
    applicable to the type of clinical trial
13. how to apply the appropriate methods for the analysis of the findings and how to
    construct the discussion of findings
14. where appropriate, how to recognise biological variability and its significance and
    how to assess clinical outcomes when applicable to the clinical trial
15. how to evaluate and validate findings from the clinical trial and why this is
    important in making reliable and validated recommendations
16. how to construct a report from the clinical trial in the appropriate format for the
    target audience and where appropriate how to write a paper suitable for a
    scientific journal
17. the importance and benefits of assessing whether the clinical trial can be applied
    within your work area and/or another health area
18. the current national legislation, guidelines, local policies and protocols which affect
    your work practice in carrying out clinical trials
19. the policies and guidance that clarify your scope of practice, accountabilities and
    the working relationship between yourself and others

PERFORMANCE CRITERIA

You must be able to do the following:

1. work within your level of competence, responsibility and accountability
2. identify the clinical problem under investigation and propose options
3. collate and interpret current and relevant historical information to support the
   feasibility of the clinical trial
4. take into consideration all the factors to determine the cost effectiveness, resource
   implications, time period and any other specific requirements for the clinical trial
5. identify the boundaries, limitations, guidelines and accountability within the clinical
   trial
6. draft the proposed methodology, evaluation and validation strategies and risk
   assessments to evaluate the feasibility of conducting the clinical trial and assess if
   a pilot study is required
7. present the clinical trial protocol to the appropriate individuals, organisations
and/or professional bodies to secure ethical and/or financial approval for the clinical trial and its associated resources

8. where applicable, confirm partnerships with clinical stakeholders for the clinical trial

9. communicate effectively with all relevant individuals at the appropriate level, throughout the clinical trial

10. undertake the clinical trial in a safe and timely manner, following approved policies, protocols and procedures and codes of conduct relevant to the work practice in line with current legislation and organisational requirements

11. collate information and data from the clinical trial and perform relevant statistical analysis where appropriate

12. critically evaluate the results and make recommendations for future action

13. document the findings, in a timely manner, in the format for the target audience, in accordance with the agreed clinical trial requirements and information governance

14. issue the report to relevant stakeholders and where appropriate publish results

15. maintain full, accurate and legible records of the clinical trial and store in the correct location in accordance with local policies and protocols

ADDITIONAL INFORMATION

This National Occupational Standard was developed by Skills for Health.

This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: G2 Development and innovation

This standard has replaced HCS_EMD19.