SFHCHS215
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.

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Performance criteria

You must be able to:

P1 work within your level of competence, responsibility and accountability
P2 identify the clinical problem under investigation and propose options
P3 collate and interpret current and relevant historical information to support the feasibility of the clinical trial
P4 take into consideration all the factors to determine the cost effectiveness, resource implications, time period and any other specific requirements for the clinical trial
P5 identify the boundaries, limitations, guidelines and accountability within the clinical trial
P6 draft the proposed methodology, evaluation and validation strategies and risk assessments to evaluate the feasibility of conducting the clinical trial and assess if
P6.1 pilot study is required
P7 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
P8 where applicable, confirm partnerships with clinical stakeholders for the clinical trial
P9 communicate effectively with all relevant individuals at the appropriate level, throughout the clinical trial
P10 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
P11 collate information and data from the clinical trail and perform relevant statistical analysis where appropriate
P12 critically evaluate the results and make recommendations for future action
P13 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
P14 issue the report to relevant stakeholders and where appropriate publish results
P15 maintain full, accurate and legible records of the clinical trial and store in the correct location in accordance with local policies and protocols

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Knowledge and understanding

You need to know and understand:

K1 your own level of competence, authority and specialist knowledge base related to clinical trials undertaken within your work practice

K2 the need for clinical trials and how to acquire ethical approval and financial support within your work area

K3 why it is important to ensure all relevant regulatory requirements are met within a clinical trial

K4 the importance of undertaking a literature research to identify reliable sources of information relating to best practice in the conduct of clinical trials

K5 the importance of an appropriate level of underpinning knowledge related to the chosen area under trial

K6 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

K7 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

K8 why it is important and the recommended practice to pilot a clinical trial wherever feasible, to further define the experimental design

K9 why it is important to establish the framework for intellectual property protection and exploitation prior to the clinical trial

K10 where applicable, the importance of gaining consent and maintaining anonymity within the report for participants within the clinical trial

K11 the importance of relevant qualitative and quantitative methods applicable for capture and analysis of clinical trial information

K12 why it is important to undertake statistical analysis and the relevant methods applicable to the type of clinical trial

K13 how to apply the appropriate methods for the analysis of the findings and how to construct the discussion of findings

K14 where appropriate, how to recognise biological variability and its significance and how to assess clinical outcomes when applicable to the clinical trial

K15 how to evaluate and validate findings from the clinical trial and why this is important in making reliable and validated recommendations

K16 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

K17 the importance and benefits of assessing whether the clinical trial can be applied within your work area and/or another health area

K18 the current national legislation, guidelines, local policies and protocols which affect your work practice in carrying out clinical trials

K19	the policies and guidance that clarify your scope of practice, accountabilities and the working relationship between yourself and others

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Additional Information

External Links

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

Dimension: G2 Development and innovation

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