

The role of a Clinical Trials Unit

What is a CTU?

Clinical Trials Unit (CTU) is a specialist unit set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies.

What a Clinical Trials Unit does NOT do

- ✘ • Have contact with patients
- ✘ • Carry out clinical procedures
- ✘ • Give medical advice
- ✘ • Store or distribute drugs
- ✘ • Process or store tissue samples
- ✘ • No research nurses
- ✘ • Is not a SITE

What is a Clinical Trials Unit?

- A specialist unit set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies.
- Centrally manages the implementation of a clinical trial and fulfils the legal duties delegated by the sponsor (eg University or NHS Trust)
- **Coordinates the involvement of multiple partners and centres taking part in each trial (national and international)**

What is involved in running a study

- Design
- Grant application
- Protocol development
- Other trial documents
- Ethics and other regulatory stuff
- Opening sites
- Ongoing problems during recruitment
- Gathering data
- Analysis
- Report writing and publication

Partnership with the Chief Investigator to ensure:

- A robust trial design;
- Experienced trial development team;
- Accurate trial costs;
- Quality grant application;
- Inclusion of RDS, CLRN, Sponsor, PPI (as appropriate);
- Feasibility assessments;
- Appropriate vendor selection e.g. drug supply, unblinding service

Trial Set-Up:

- Development of protocol and trial documents;
- Liaison drug manufacturers/suppliers;
- Identification of central labs/services;
- Design and build database and eCRF;
- Submission to regulatory authorities; Ethics; NHS Permissions;
- Identification of trial sites and clinical teams;
- Contracts with sites and third parties;
- Site Recruitment & Set-Up;

What's Involved in Trial Management?

Outputs & Publications:

- Ongoing Progress reports to funders and regulatory authorities;
- Clinical trial summary report for regulatory authorities and funder;
- Production of abstracts, posters, articles for publication and presentation at conferences;
- Ensure publication of results

Delivery of the Trial:

- Development of recruitment strategies to facilitate patient accrual;
- Communication with funder;
- Trial Oversight – TMG/DMEC/TSC;
- Data management;
- Pharmacovigilance;
- Protocol amendments; document amendment and maintenance;
- Site & centralised monitoring;
- Grant management;
- Site closure;
- Trial closure;
- Statistical data analyses;
- Archiving;

How CTU helps with grant applications

- Have experience of applications
- Can help with trial design – know what works in practice
- Can help with costing – know what is needed
- Work with other groups – RDS, CRN, Sponsors, funders etc
- Have staff ready to set up study

When is a CTU essential?

- Funder requirement
- Sponsor requirement for IMP trials
- Provide sufficient oversight for regulatory compliance (the law)
 - Validated database
 - Expert knowledge of complex regulatory framework
 - Quality systems

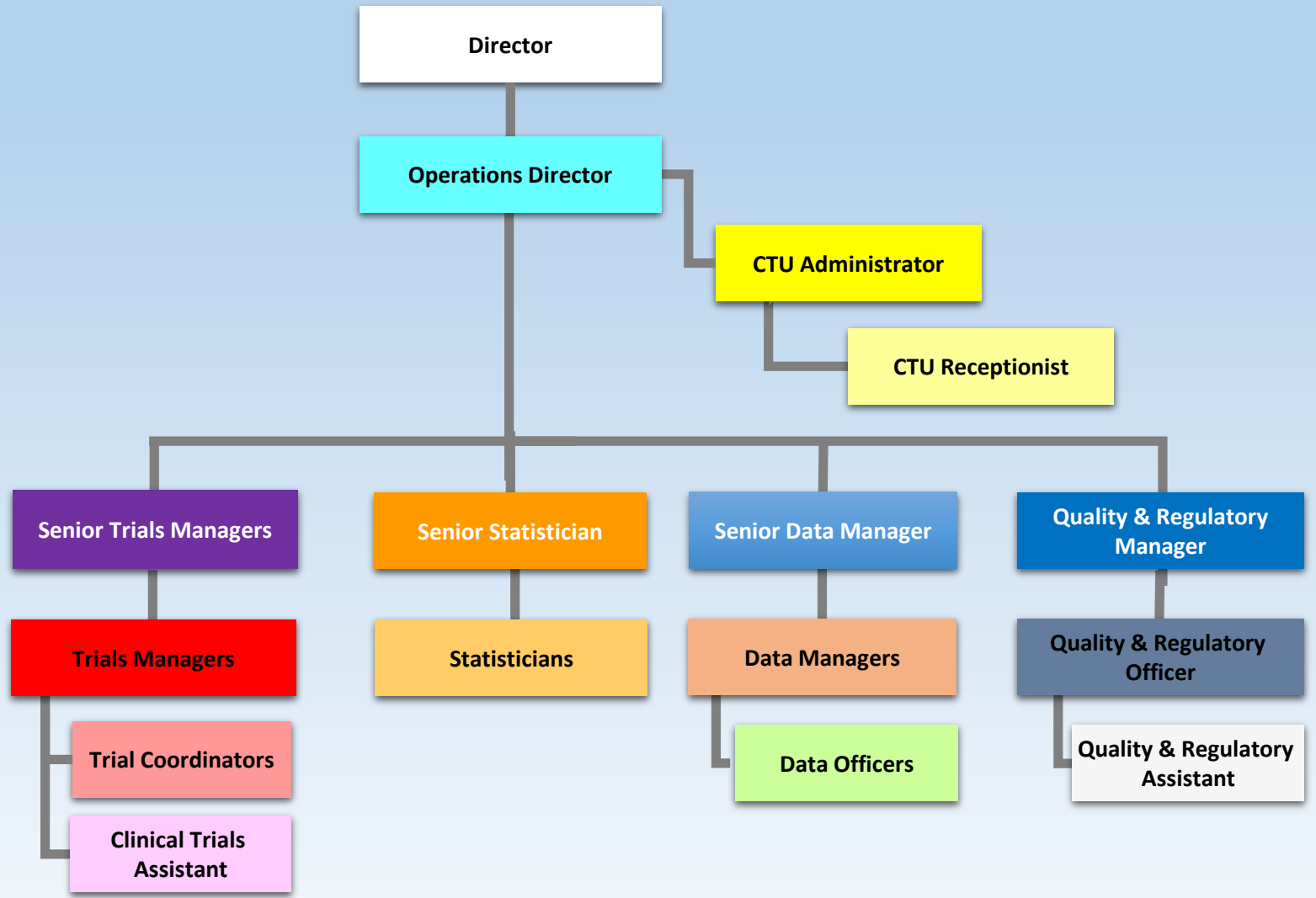
IS IT A CLINICAL TRIAL OF A MEDICINAL PRODUCT?

This algorithm and its endnotes will help you answer that question. Please start in column A and follow the instructions. Additional information is provided in the notes at the end of the table. If you have doubts about the answer to any of the questions contact the clinical trials unit of your competent authority.

| A | B | C | D | E |
|--|--|--|---|---|
| A CLINICAL TRIAL OF A MEDICINAL PRODUCT? | | | | A NON-INTERVENTIONAL CLINICAL TRIAL? |
| Is it a medicinal product (MP)?ⁱ | Is it not a medicinal product? | What effects of the medicine are you looking for? | Why are you looking for those effects? | How are you looking for those effects? |
| <p>If you answer no to <u>all</u> the questions in column A, the activity is not a clinical trial on a MP.</p> <p>If you answer yes to <u>any</u> of the questions below go to column B.</p> | <p>If you answer yes to the question below in column B the activity is not a clinical trial on a MP.</p> <p>If you answer no to this question below go to column C.</p> | <p>If you answer no to <u>all</u> the questions in column C the activity is not a clinical trial under the scope of Directive 2001/20/EC.</p> <p>If you answer yes to <u>any</u> of the questions below go to column D.</p> | <p>If you answer no to <u>all</u> the questions in column D the activity is not a clinical trial under the scope of Directive 2001/20/EC.</p> <p>If you answer yes to <u>any</u> of the questions below go to column E.</p> | <p>If you answer yes to <u>all</u> these questions the activity is a non-interventional trial which is outside the scope of Directive 2001/20/EC. If your answers in columns A,B,C & D brought you to column E and you answer no to <u>any</u> of these questions the activity is a clinical trial within the scope of the Directive.</p> |
| <p>A.1 Is it a substanceⁱⁱ or combination of substances presented as having properties for treating or preventing disease in human beings ?</p> <p>A.2 Does the substance function as a medicine? i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis or is otherwise administered for a medicinal purpose?</p> <p>A.3 Is it an active substance in a pharmaceutical form?</p> | <p>B.1 Are you <u>only</u> administering any of the following substances?</p> <ul style="list-style-type: none"> • Human whole bloodⁱⁱⁱ; • Human blood cells; • Human plasma; • Tissues except a somatic cell therapy medicinal product^{iv}; • A food product^v (including dietary supplements) not presented as a medicine; • A cosmetic product^{vi} • A medical device | <p>C.1 To discover or verify/compare its clinical effects?</p> <p>C.2 To discover or verify/compare its pharmacological effects, e.g. pharmacodynamics?</p> <p>C.3 To identify or verify/compare its adverse reactions?</p> <p>C.4 To study or verify/compare its absorption, distribution, metabolism or excretion?</p> | <p>D.1 To ascertain or verify/compare the efficacy^{vii} of the medicine?</p> <p>D.2 To ascertain or verify/compare the safety of the medicine?</p> | <p>E.1 Is this a study of one or more medicinal products, which have a marketing authorisation in the Member State concerned?</p> <p>E.2 Are the products prescribed in the usual manner in accordance with the terms of that authorisation?</p> <p>E.3 Does the assignment of any patient involved in the study to a particular therapeutic strategy fall within current practice and is not decided in advance by a clinical trial protocol^{viii}?</p> <p>E.4 Is the decision to prescribe a particular medicinal product clearly separated from the decision to include the patient in the study?</p> <p>E.5 Will no diagnostic or monitoring procedures be applied to the patients included in the study, other than those which are applied in the course of current practice?</p> <p>E.6 Will epidemiological methods be used for the analysis of the data arising from the study?</p> |

What a CTU does

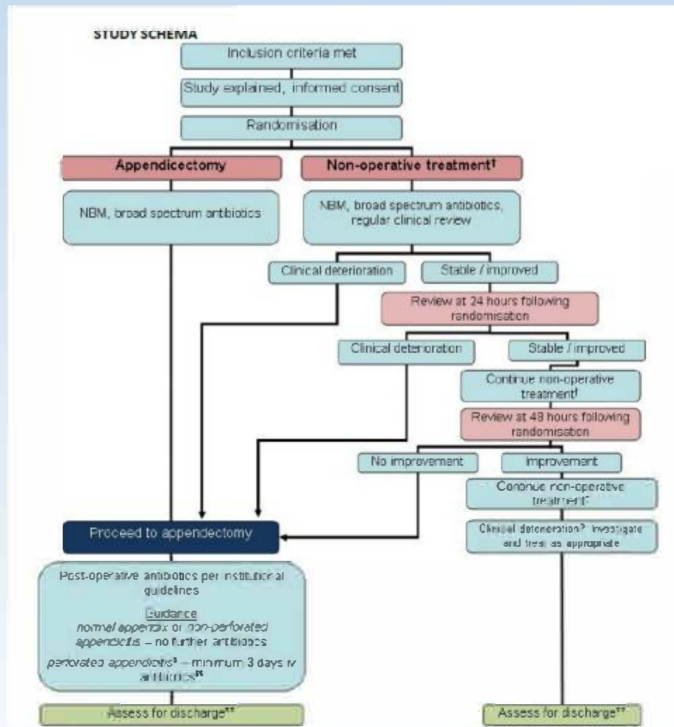
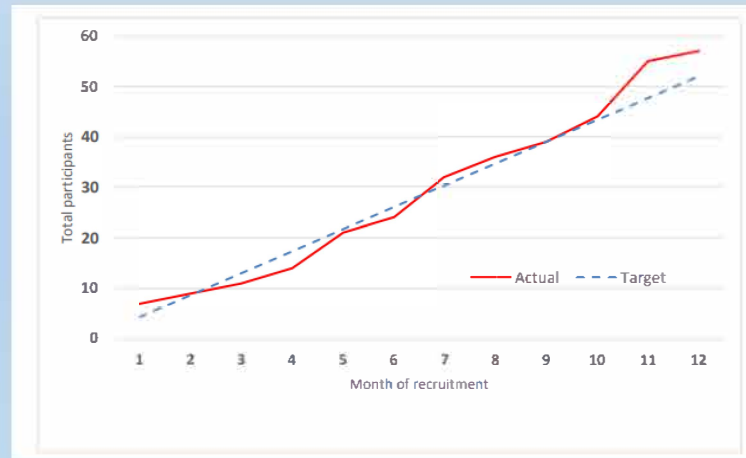
- Trial design
- Costing trials
- Grant application
- Trial set up
- Obtaining ethics, R&D and regulatory approval
- Liaising with sponsor and funder
- Budget management
- Design of CRFs and design and build of validated database
- Data management
- IMP management
- Setting up and ongoing liaison with participating sites
- Maintenance of TMF
- Monitoring
- Preparation of reports for funders, REC, oversight committees
- Publication and dissemination of results (manuscripts, posters, presentations)
- Readiness for MHRA Inspection



CONTRACT



CONservative TRreatment of Appendicitis in Children – a randomised controlled Trial – CONTRACT (Feasibility study)



| | | | |
|--------------------------|------------|------------|------------|
| Total: £12,378.00 | | | |
| CTU CTC | £17,480.00 | £17,903.00 | £2,999.00 |
| HEI | 40.00% FTE | 40.00% FTE | 40.00% FTE |
| Total: £38,362.00 | 12 Months | 12 Months | 2 Months |
| CTU CTM | £11,475.00 | £11,772.00 | £1,972.00 |
| HEI | 20.00% FTE | 20.00% FTE | 20.00% FTE |
| Total: £25,219.00 | 12 Months | 12 Months | 2 Months |
| CTU DM | £7,630.00 | £4,476.00 | £750.00 |
| HEI | 20.00% FTE | 10.00% FTE | 10.00% FTE |
| Total: £12,865.00 | 12 Months | 12 Months | 2 Months |
| CTU DO | £5,609.00 | £5,758.00 | £965.00 |
| HEI | 40.00% FTE | 40.00% FTE | 40.00% FTE |
| Total: £12,332.00 | 12 Months | 12 Months | 2 Months |
| CTU QRO | £3,485.00 | £3,554.00 | £565.00 |
| HEI | 10.00% FTE | 10.00% FTE | 10.00% FTE |
| Total: £7,614.00 | 12 Months | 12 Months | 2 Months |
| CTU SDM | £8,684.00 | £8,856.00 | £1,148.00 |
| HEI | 5.00% FTE | 5.00% FTE | 5.00% FTE |
| Total: £14,688.00 | 12 Months | 12 Months | 2 Months |
| CTU Statistician | £4,385.00 | £4,476.00 | £750.00 |
| HEI | 10.00% FTE | 10.00% FTE | 10.00% FTE |
| Total: £9,591.00 | 12 Months | 12 Months | 2 Months |

RESEARCH

Open Access



Comparative costs and activity from a sample of UK clinical trials units

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Abstract

Background: The costs of medical research are a concern. Clinical Trials Units (CTUs) need to better understand variations in the costs of their activities.

Methods: Representatives of ten CTUs and two grant-awarding bodies pooled their experiences in discussions over 1.5 years. Five of the CTUs provided estimates of, and written justification for, costs associated with CTU activities required to implement an identical protocol. The protocol described a 5.5-year, nonpharmacological randomized controlled trial (RCT) conducted at 20 centres. Direct and indirect costs, the number of full time equivalents (FTEs) and the FTEs attracting overheads were compared and qualitative methods (unstructured interviews and thematic analysis) were used to interpret the results. Four members of the group (funding-body representatives or award panel members) reviewed the justification statements for transparency and information content. Separately, 163 activities common to trials were assigned to roles used by nine CTUs; the consistency of role delineation was assessed by Cohen's κ .

Results: Median full economic cost of CTU activities was £769,637 (range: £661,112 to £1,383,323). Indirect costs varied considerably, accounting for between 15% and 59% (median 35%) of the full economic cost of the grant. Excluding one CTU, which used external statisticians, the total number of FTEs ranged from 2.0 to 3.0; total FTEs attracting overheads ranged from 0.3 to 2.0. Variation in directly incurred staff costs depended on whether CTUs: supported particular roles from core funding rather than grants: opted not to cost certain activities into the grant: assigned clerical or data

UKCRC Registration

CTUs which have been awarded UKCRC Registration were required to provide evidence to an international panel of experts of their capability to **centrally coordinate multi-centre clinical trials** (i.e. having overall responsibility for the design, development, recruitment, data management, publicity and analysis of a portfolio of trials), and that they had established robust systems to ensure conduct and delivery of clinical trials to the highest quality standards.



UKCRC Registered Clinical Trials Units Network

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Resource Finder

Please use any of the fields below to search for a registered CTU.

CTU Registration Status: Current registration status of the Trials Unit

Region: Please select your region of interest.

Company/Employer:

Director:

Available Randomisation Services: Randomisation services the CTU is currently able to provide to potential collaborators.

Geographical Extent: The geographical extent to which a CTU recruits clinical sites and patients into studies.

Sponsorship of International Studies: Whether a CTU is able to take on sponsorship of international studies.

Experience of Applying to Funding Bodies: The non-commercial bodies to which a unit has experience submitting grant applications.

Previous Experience of collaborative industry:

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UK CLINICAL RESEARCH COLLABORATION igniting our potential

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PATIENTS & PUBLIC
INDUSTRY
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RESOURCE FINDER
NEWS
PUBLICATIONS
RESOURCES

<https://www.ukcrc-ctu.org.uk/>

- Consider whether you need a CTU
 - Complexity of trial
 - Funding restrictions
- May just need certain services eg randomisation service
- CTUs vary
- Engage with CTU early!