
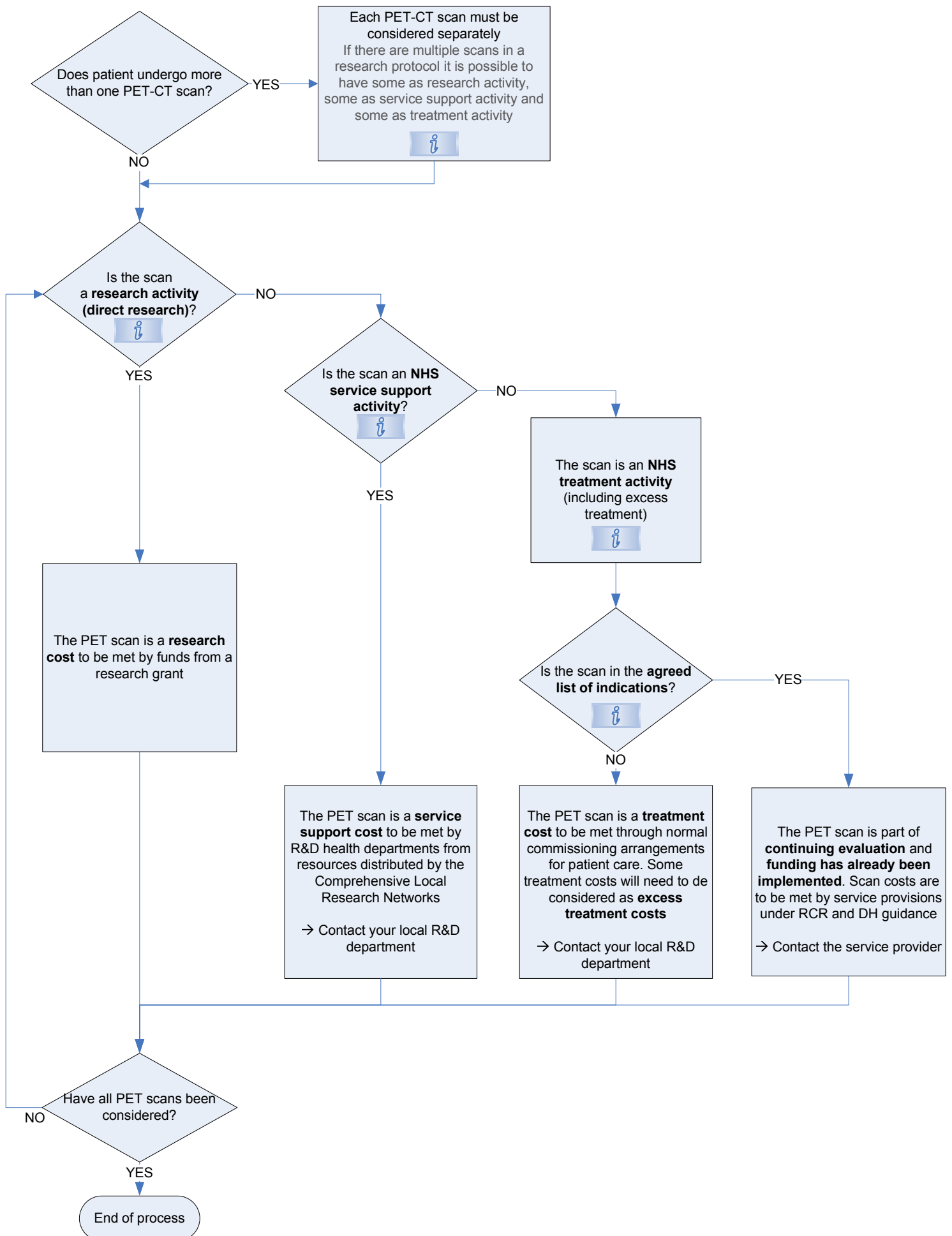


Research PET-CT scans costs attribution guidance

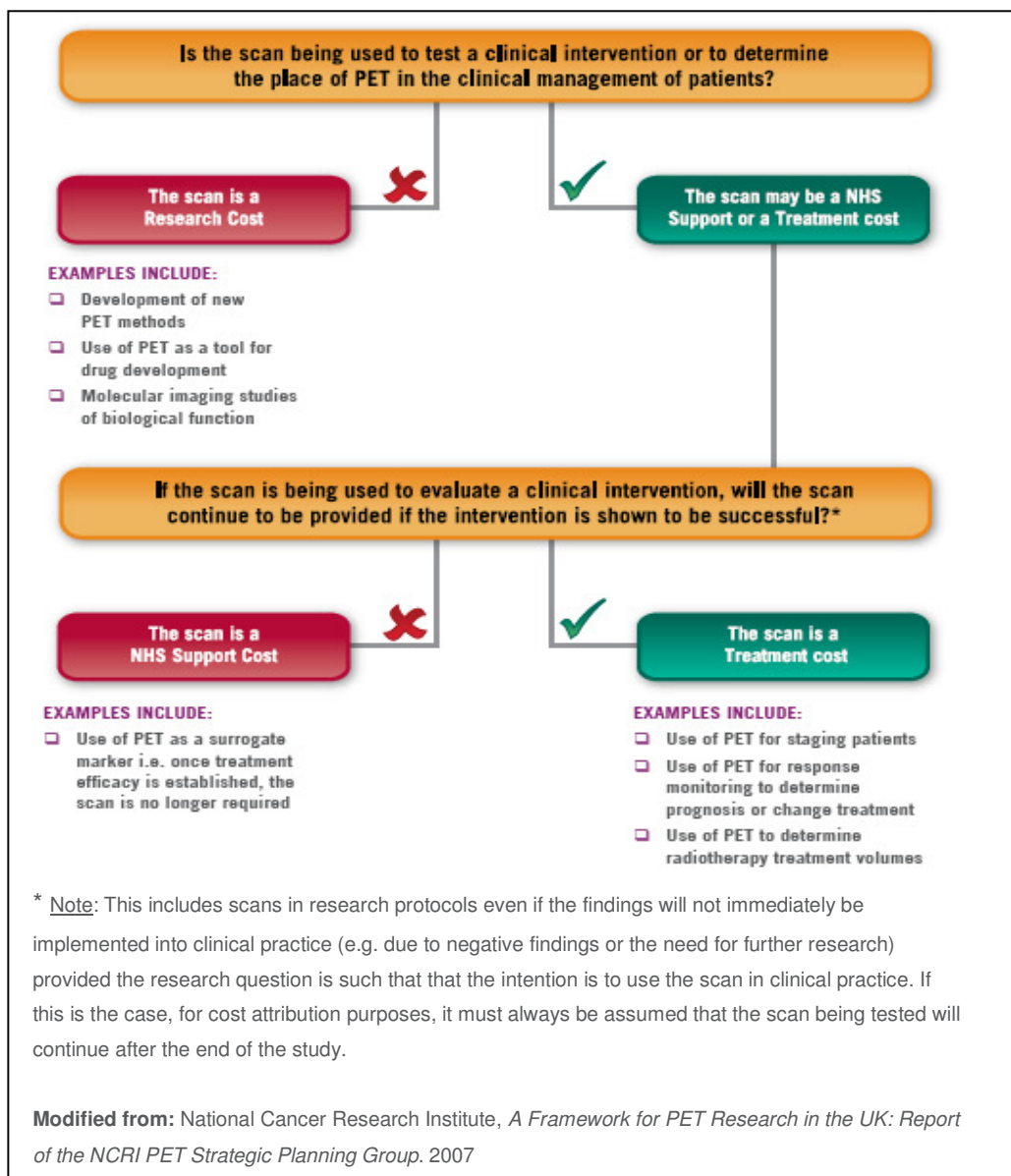
Click  for information on each of the topics below



Is the scan a research activity (direct research)?

Research activities are undertaken to answer the research questions and will end when the research ends. Research activities incur **research costs**.

The diagram below provides a decision-aid to help determine which components of a PET research study are considered research costs. See from the diagram that a PET-CT scan is a research activity if it is NOT being used to test a clinical intervention or to determine the place of PET in the clinical management of patients (top X in diagram). Examples include development of new PET-CT methods (hardware, software and quantification methods), the use of PET-CT as a tool for drug development (phase I studies looking at pharmacodynamic and pharmacokinetic effects of drugs) and molecular imaging studies of biological function (mechanistic studies).



Who pays for research costs?

Research costs are met by research funding bodies, such as the MRC and the Wellcome Trust, through the award of a research grant.

Who should I notify if there are PET-CT related research costs in my study?

Your first port of call should be your local NHS R&D department. Chief investigators need to make sure that all PET-CT related research costs are fully specified in the grant application for the study or that alternative funding is secured early in the process.

Where to go for further advice?

Your local NHS R&D department should be able to give you further advice on research costs when preparing your grant application. If your local R&D department can't help then you can approach your Comprehensive Local Research Network (CLRN) for further advice. There are 25 CLRNs across the UK operating within the NIHR Clinical Research Network:

http://www.crnc.nihr.ac.uk/about_us/ccrn/ccrn_about_us

Where can I find additional information and key guidance?

Clinical Research Networks and NHS Service Support: A Guide for Researchers

http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/Guidance%20and%20process%20docs/GUIDANCE_Accessing_NHS_support3.pdf

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Department of Health ARCO guidance

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4125282.pdf

This is the current general guidance. Following consultation with research funding partners, the Department of Health has decided not to proceed with the implementation of the more recent ReSeT guidance released in March 2010.

Department of Health HSG(97)32 guidance

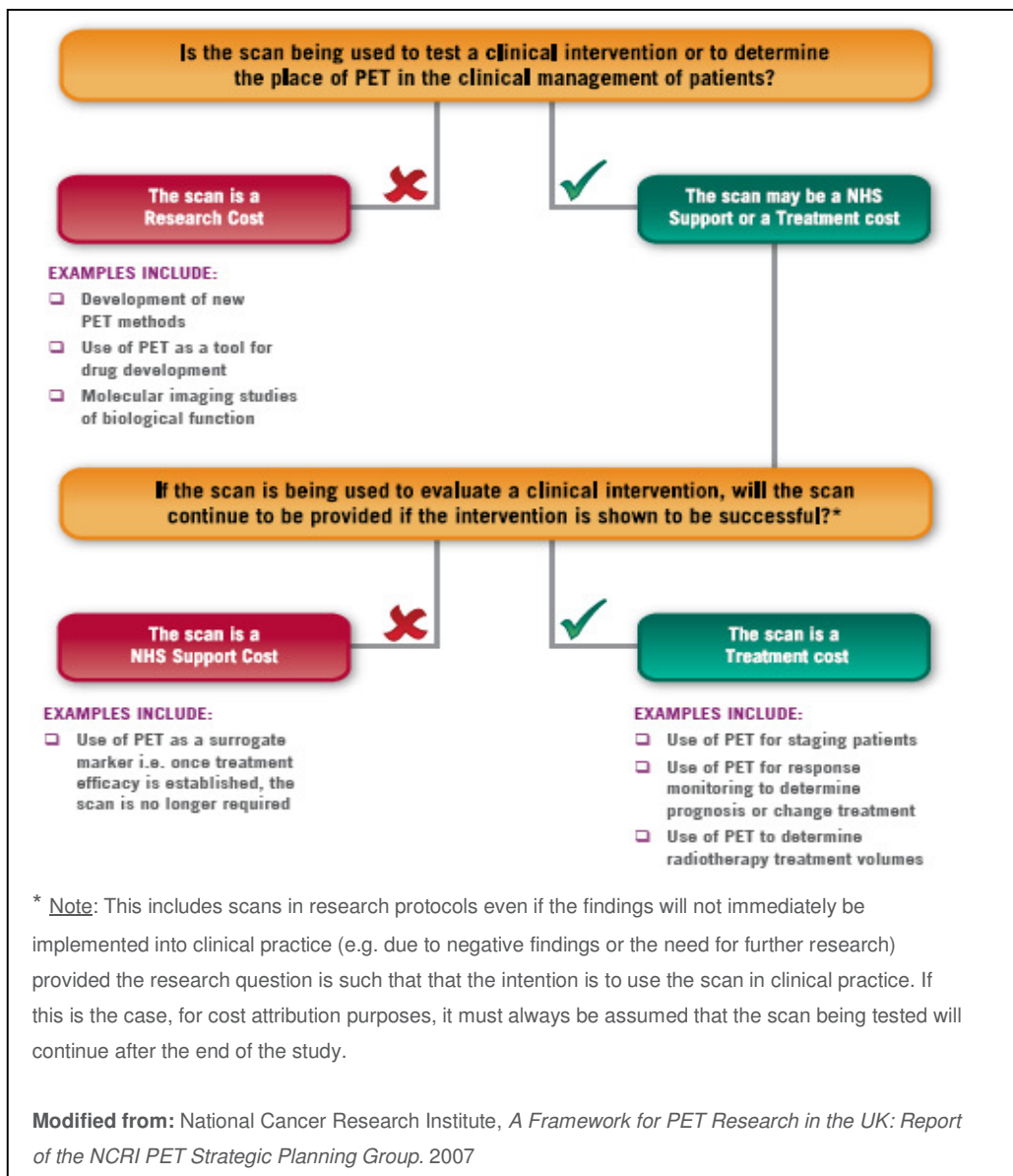
http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353?IdcService=GET_FILE&did=14533&Rendition=Web

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Is the scan an NHS service support activity?

Service support activities relate to patient care associated with the research that would end once the research activity in question had stopped, even if the patient care involved continued to be provided. Service support activities incur **service support costs**.

An activity is a service support activity if the patient care activity is primarily undertaken to facilitate research or is driven by the NHS duty of care to a patient, e.g. to ensure the safety of a patient participating in research. The diagram below provides a decision-aid to help determine which components of a PET research study are considered NHS service support costs. See from the diagram that a PET scan is a service support activity if (1) it is being used to evaluate a clinical intervention and (2) WILL NOT continue to be provided if the intervention is shown to be successful (bottom X in diagram).



Who pays for service support costs?

Service support costs are met by NHS R&D support funding and distributed through the Comprehensive Local Research Networks (CLRNs).

Who should I notify if my research project could incur service support costs?

Your first point of contact should be your local NHS R&D department and Cancer Network managers, who can then integrate this information in your Trust's standard operating procedures and liaise with the relevant CLRN.

When should I notify my local NHS R&D department and Cancer Network?

If you believe service support costs may be incurred for your research project, you should inform your local NHS R&D department and Cancer Network as soon as possible, ideally at the time of preparing your application for research funding. Informing them early will help ensure that any negotiation with relevant CLRNs is conducted in good time.

Where to go for further advice?

Your local R&D department should be able to give you further advice on service support costs. If your local R&D department can't help then you can approach your Comprehensive Local Research Network (CLRN). There are 25 CLRNs across the UK operating within the NIHR Clinical Research Network:

http://www.crncc.nihr.ac.uk/about_us/ccrn/ccrn_about_us

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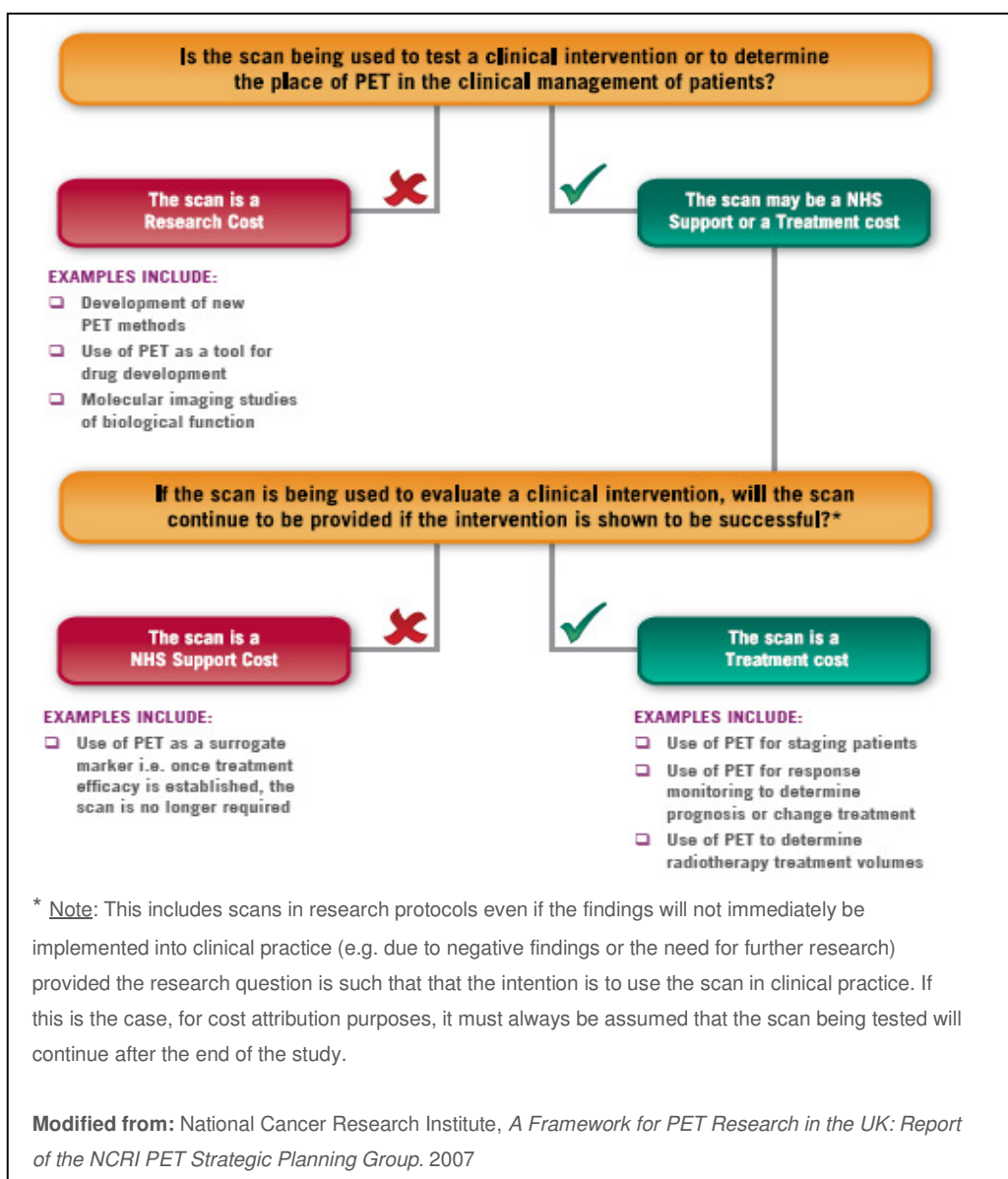
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Is the scan an NHS treatment activity?

NHS treatment activities are patient care activities that would continue if the service continued to be provided after the R&D study had stopped. Treatment activities incur **treatment costs** and cover all types of patient care services including diagnostic services. NHS Treatment activities are integral to the provision of a treatment or diagnostic regime, whether this is standard or experimental. For the purposes of the attribution process it **must** be assumed that an experimental intervention/service being tested will continue after the end of the study. As a rule of thumb most interventions that are being tested or compared as part of a study will be NHS Treatment Costs even if they are experimental, unlicensed for the condition, not NICE approved, or there are no plans to continue with the intervention after the study has ended because the PCTs won't fund.

The diagram below provides a decision-aid to help determine which components of a PET research study are considered treatment costs. See from the diagram that a PET scan is a treatment activity if (1) it is being used to evaluate a clinical intervention and (2) WILL continue to be provided if the intervention is shown to be successful (bottom tick in diagram).



Who pays for Treatment Costs?

Treatment costs form part of the normal commissioning processes between NHS Trusts and the Primary Care Trusts (PCTs) commissioning NHS services on behalf of patients. Very exceptionally DH may make a contribution. Treatment costs are not covered by the research funding body nor the CLRNs.

Important note for researchers on PET as treatment costs:

Although the inclusion of PET in research often increases treatment costs, it is possible that the inclusion of PET could reduce costs in some circumstances. For example a trial evaluating the clinical utility of PET in pre-surgical staging, could reduce treatment costs by identifying unsuspected metastatic disease and so reducing the number of patients undergoing surgery. Researchers are strongly encouraged to use examples such as this to present their studies to show their organisations the relevance of using PET in their research both in terms of patient outcomes and potential overall costs gains.

What are Excess Treatment Costs?

Excess Treatment Costs (ETCs) are the difference between the treatment costs incurred in the research and those that would have been incurred had the patients involved received standard clinical care. Where patient care is provided that is either an experimental treatment or a service in a different location from where it would normally be given and it differs from the normal, standard treatment from that condition, the difference between the total Treatment Cost and the cost of the standard treatment (if any) is the ETC.

There is considerable concern among researchers, medical research charities and research councils that problems with funding ETCs remain a barrier to conducting research in the NHS. There is still local ambiguity on the funding of ETCs in many UK regions and this is a problem that extends beyond PET-CT scans. Some CLRNs have recently proposed local procedures to administer ETCs in an attempt to address this issue. An example can be found following the link below:

http://www.crnc.nihr.ac.uk/about_us/ccrn/thames_valley/funding

Who should I notify if my research project could incur Excess Treatment Costs?

Your first point of contact should be your local NHS R&D department and Cancer Network, who can then integrate this information in your Trust's standard operating procedures. The Trust can then ensure that these costs are included in the regular negotiations with the relevant PCTs and commissioners.

When should I notify my local NHS R&D department if I believe my project might incur Excess Treatment Costs (ETCs)?

If you believe ETCs might be incurred for your research project, you should inform your local NHS R&D department as soon as possible, ideally at the time of preparing your application for research funding. Informing your NHS R&D department early will help ensure that the ETCs for your project are included in the next round of negotiations with PCTs. Many researchers notify their R&D department about the possibility of incurring ETCs funding too late and this may result in difficulties in obtaining the funds.

Should I approach my Primary Care Trust or Commissioners?

If you believe your project might incur ETCs, your point of contact should be your NHS R&D department and Cancer Network. It is advisable that any approach to PCTs or Commissioners is made in conjunction with your NHS R&D department. Careful consideration should be made before raising individual research projects with PCTs or Commissioners as to do so may not necessarily help secure ETC funding.

Where to go for further advice?

Your local R&D department should be able to give you further advice on ETCs. If your local R&D department can't help then you can approach your Comprehensive Local Research Network (CLRN). There are 25 CLRNs across the UK operating within the NIHR Clinical Research Network:

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Department of Health Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for a subvention

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_097627.pdf

This is based on the current ARCO and the HSG(97)32 guidance listed below

Department of Health ARCO guidance

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4125282.pdf

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Department of Health HSG(97)32 guidance

http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353?IdcService=GET_FILE&dID=14533&Rendition=Web

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Is the scan in the agreed list of clinical indications?

The Royal College of Radiology (RCR), supported by the National Cancer Action Team, has issued guidance for PET-CT indications ^[1], based on benchmark figures for the likely demand for PETCT scans by indication published by the Department of Health based on a review of the evidence ^[2]. If a PET-CT scan in a study is in the agreed list of clinical indications, then it would be considered as part of continuing clinical evaluation for good clinical practice under the Framework for the Development of Positron Emission Tomography (PET) Services. ^[3]

Please follow this link for the RCR guidance for PET-CT indications:

http://www.rcr.ac.uk/docs/radiology/pdf/BFCR%2810%2916_PETCT.pdf

Who pays for scans that are in the agreed list of indications?

The cost of PET-CT scans that are in the agreed list of indications should be met by the service providers under the aforementioned guidance ^[1,2,3]. It is important to highlight that PET scans as treatment costs for the agreed indications are already included in the funding that has been implemented and these should be locally funded by PCTs. Arrangements are already specifically in place for PCTs to meet their obligations in funding the treatment costs of PET-CT scans in the agreed list of indications.

However, there are slight variations in the local interpretation of this guidance and certain places may not have agreed to include a particular scan within their locally agreed indications, even if the majority of other sites agree otherwise. In these cases, the PET scans will need to be considered as Excess Treatment Costs.

Who should I notify if PET-CT scans in my study are in the agreed list of local indications?

Your first point of contact should be your local NHS R&D department and Cancer Network managers, who can then integrate this information in your Trust's standard operating procedures and inform the local service providers of the intention to fund these PET-CT scans within the list of clinical indications.

When should I notify my local NHS R&D department and Cancer Network?

If you believe PET-CT scans in your study are in the agreed list of indications you should inform your local NHS R&D department and Cancer Network as soon as possible, ideally at the time of preparing your application for research funding. Informing them early will help ensure that any negotiation with service providers is conducted in good time.

For multicentre studies it is recommended that the Chief Investigator or managing Clinical Trials Unit checks the position of local providers of potential participating centres, as part of their screening procedure for enrolling these centres.

Where to go for further advice?

Your local R&D department should be able to give you further advice on service support costs. If your local R&D department can't help then you can approach your Comprehensive Local Research Network (CLRN). There are 25 CLRNs across the UK operating within the NIHR Clinical Research Network:

http://www.crnc.nihr.ac.uk/about_us/ccrn/ccrn_about_us

Where can I find additional information and key guidance?

Specific guidance on PET-CT indications can be found in the references section below.

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References

1. The Royal College of Radiologists. *Indications for PET-CT: guidance from The Royal College of Radiologists*. London: Royal College of Radiologists, 2010. Available from: http://www.rcr.ac.uk/docs/radiology/pdf/BFCR%2810%2916_PETCT.pdf
2. Department of Health, *Benchmark figures for the likely demand for PETCT scans by indication*. London: DH, 2010. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_110860
3. Department of Health, *A framework for the development of Positron Emission Tomography (PET) services in England*. London: DH, 2005. Available from: http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4121029

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Multiple PET-CT scans

If the patient is undergoing more than one PET-CT scan, then each PET-CT scan must be considered separately because it is possible to have some scans as research activity, some as service support activity and some as treatment activity. Two examples are presented next to illustrate specific cases involving multiple scans that may cause confusion amongst researchers. These examples might be better understood after going through the rest of the flowchart and getting familiar with the different costs that might be involved.

Example 1

A clinical trial involves several scans performed to determine the optimal time for a scan. In this case, only one scan would continue in practice (i.e. Treatment Cost) with the additional research scans being defined as NHS Support Costs.

Example 2

A clinical trial compares two imaging methods conducted in the same patient for an outcome. Under current guidance they will both be treatment costs for the duration of the study because both could potentially continue after the study. It is important then to highlight that there is the possibility of having an imaging test and its comparator both as treatment costs.

Note of caution: this applies to England only as the devolved nations have a different opinion.

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