NHS Research and Development Forum

# Managing Excess Treatment Costs in Non-Commercial Research Outcome of the National Consultation.

## Briefing note and main messages for NHS R&D management staff

### 1. Purpose

- The purpose of this document is to brief the NHS R&D management community about the developing plans for implementing a new national Excess Treatment Cost (ETC) process in England and its progress to date. The public consultation and response document can be found here.
- This document aims to help staff to understand the new process that will begin as a trial period from 1 October 2018 and that will be rolled out in full by April 2019. HRA and NIHR CRNCC leads have reviewed and contributed to this document.
- **Please be aware that some final elements of the system are still in development.** You can keep updated via the NHS R&D Forum news and Twitter feed, HRA Latest and NIHR CRN communications including the dedicated webpage for the latest information at: https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm

### 2. What is new or changing?

- There will be a mechanism in place for identifying a single, national per-patient ETC for every portfolio study, which will be supported by a new **Schedule of Events Cost Attribution Tool** (SoECAT). This per-patient ETC will apply to all patients recruited to that study by all participating sites for ETCs associated with CCG commissioned services. A complementary costing methodology will be introduced for studies with ETCs relating to specialised commissioned services.
- Non-Primary Care providers will be expected to absorb ETCs within a defined provider threshold. After this threshold has been reached, ETCs will be reimbursed through the new system administered by LCRNs.

- The threshold for Providers will be calculated at 0.01% of operating income with a lower threshold limit of £10,000. The threshold levels will be monitored, as data is collected over time.
- For Primary Care providers, ETCs will be fully reimbursed but there will be a minimum level of payment, which will act as an administrative cut-off to avoid unnecessary bureaucracy for small amounts of money and to increase efficiency.
- The budget to reimburse ETC spend in excess of the (non-primary care) provider threshold (and all primary care ETC spend) will be managed by the CRN with payments made through the 15 LCRNS on behalf of CCGs in England.
- There will be a single national process for reimbursement of ETCs relating to services commissioned by Specialised Commissioning.
- There will be a single point of access to support attribution and ETC payment at the Lead LCRN for each study, whether they involve CCG and/or specialised commissioned services

## 3. What are NHS Providers and Primary Care sites expected to do when the new system is in place?

### As a general process, sites will need to:

- Familiarise themselves with the SoECAT and supporting guidance which can be found here
- Accept the costing per patient that has been calculated for the study at each participating site. In support of a pragmatic approach and to avoid delays during set-up, organisations are expected to accept this as the cost even if it doesn't reflect their actual specific costs for ETCs associated with CCG commissioned services
- R&D departments will be required to manage ETCs at a portfolio level and not per study. They will need to take a 'swings-and-roundabouts' approach to any specific losses and gains and communicate this to their organisation. Organisations are asked to do this to enable treatment opportunities for patients in research.
- Non-Primary Care providers will absorb the accumulating per-patient ETCs until their organisational threshold has been reached. Providers need to manage this internally as some departments may be asked to absorb more costs than others.

- Continue to add participant recruitment to the central portfolio management system (CPMS) in near time so that per-patient level ETCs payments due will be calculated. Work is underway to ensure the participant recruitment activity in Local Portfolio Management Systems will feed through to CPMS automatically, but will not be in place in time for the start of these new arrangements.
- Patient recruitment in CPMS will be used to calculate when the threshold is reached. Once the threshold for their organisation has been reached, ETCs will be reimbursed directly via the LCRNs. Payment schedules will be published and will be linked to the existing quarterly data cuts for reporting recruitment activity to the CRN.
- Continue to manage local capacity and capability for their research studies, including logistical issues.
- Most studies will be managed through this process, however studies, which have very high ETCs, above a threshold that is to be confirmed, will be scrutinised through a national process which will be accessed through the same single point of access in the Lead LCRN. Further information on this process will follow.

## 4. What happens for studies that are ongoing after October 2018?

- ETCs related to patients recruited after 1 October 2018 will be managed via the new system. Any ETCs related to patients recruited before 1 October 2018 will not be included and should be funded through existing mechanisms.
- Studies with ETCs that relate to CCG commissioned services will be transitioned into the new model. CCGs have been asked to submit data on their commitments for studies recruiting after 1 October and sponsors have been asked to support this data collection
- Existing Studies that will continue to recruit after 1 October with ETCs relating to specialised commissioned services should continue with existing arrangements.

## 5. What else do I need to be aware of?

- Further information will be provided around the costing process for ETCs that are funded via specialised commissioning routes and how these will be identified.

- Sometimes the logistics of running a study locally will mean funds and resources need to be managed internally to provide additional staff, staff time or equipment across departments and even organisations. There will be mechanisms in place to monitor the new ETC model via the CRN, NHSE, HRA and DHSC partnership group and to support logistical issues wherever possible. These processes are to be confirmed.

## 6. What should researchers and Sponsors do?

- Researchers and Sponsors should familiarise themselves with the SoECAT and guidance which can be found here
- Be aware of the Local CRN AcoRD Specialist to support with attribution in line with the Department of Health and Social Care policy, as they will need to have confirmed the attribution to access ETC payments. More information can be found here: https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/acord/
- Encourage researchers to liaise with their Lead NHS R&D Office (if not the Sponsor) and LCRN AcoRD Specialist early in the grant application process to enable early accurate costing and attribution of the anticipated study activities.
- Work with Lead R&D Offices and LCRN team as applicable to ensure that the clinical pathway for patients is well defined to enable robust costing to take place.

## 7. What do we need to do right now?

- Carry on as usual for now and familiarise yourself with the changing arrangements
- Communicate main messages to your organisation, partners, non-commercial sponsors and lead researchers
- Send any ongoing questions to info@rdforum.org.uk
- Continue to monitor communications, the NIHR dedicated webpage and news for updates.

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