# ECMC: National Contract Value Review for Early Phase and Advanced Therapy Medicinal Product Trials

24th September 2024

This meeting will be recorded

ecmc Jointly funded by: CANCER RESEARCH UK, Little Princess Trust, NIHR | National Institute for Health and Care Research, Ymchwil Iechyd a Gofal Cymru Health and Care Research Wales, CHIEF SCIENTIST OFFICE, HSC Public Health Agency Research and Development

# Agenda

| | Item | Presenter |
|---|---|---|
| 1 | Welcome and Introduction | Sharan Sandhu, ECMC network Delivery Lead, ECMC Programme Office |
| 2 | NCVR and EP / ATMP trials: What changes will take effect from October 2024 | Ali Austen, Deputy Director of Research, NHS England and NHS Improvement<br><br>Laura Bousfield, National Head of Study Support Services, RDN Coordinating Centre<br><br>Clare Gillott, Industry and Research Support Operations Manager & National Service Development Lead (NCVR ATMPs/Early Phase) |
| 3 | The ECMC Pilots | Ravinder Singh Nizzer, ECMC Project Manager<br>Milly Denman, Set-up Specialist, UCLH |
| 4 | Further development | Sharan Sandhu, ECMC network Delivery Lead, ECMC Programme Office |
| 5 | Discussion & Close | |

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# Why study set up is important for the ECMC network

1: Pan-age UK network

29: Experimental Cancer Medicine Centres

240: Delivery staff funded

## Our Trials Portfolio 2023/2024

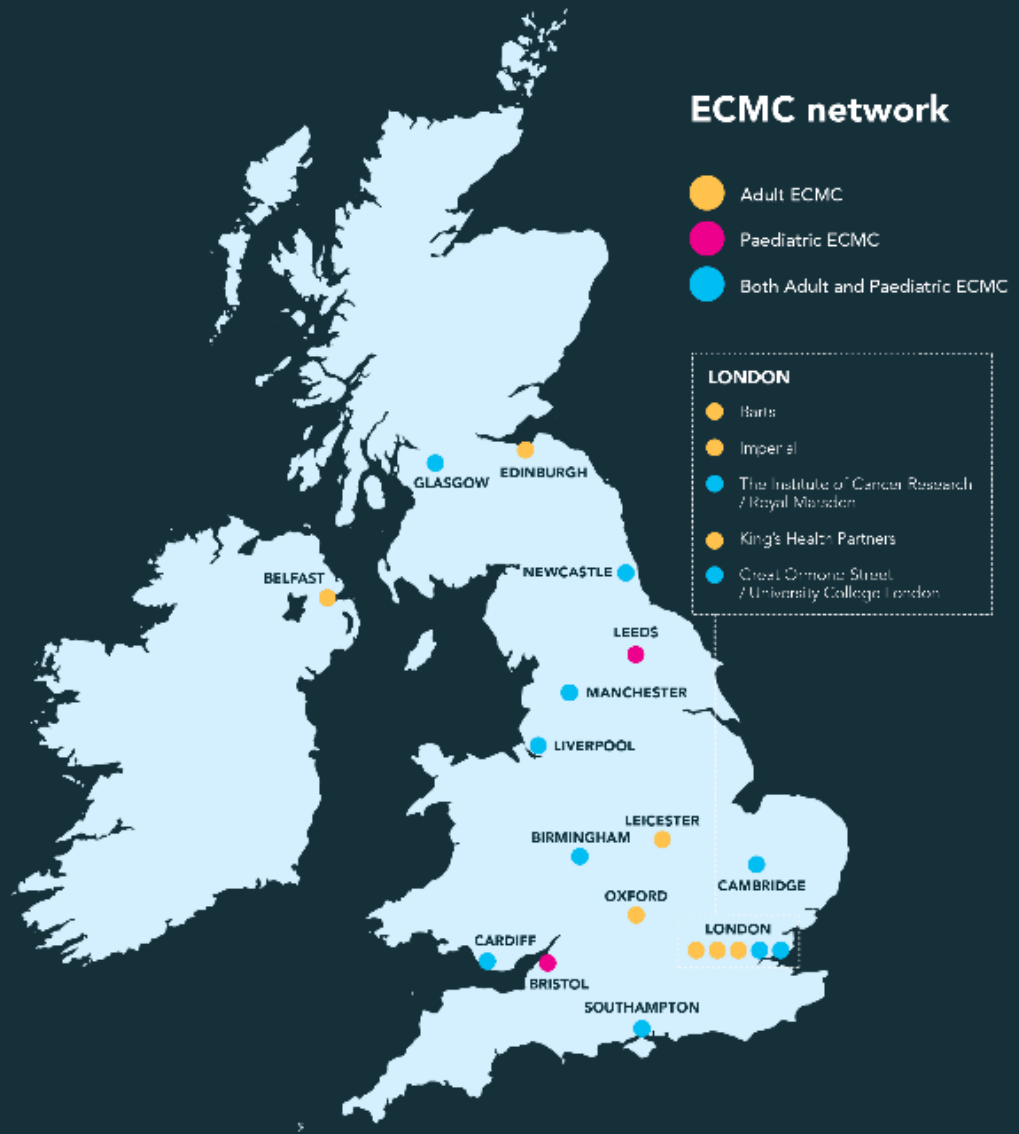
764: Trials on ECMC portfolio

299: Phase 1 & II trials open to recruitment

68%:  Commercial and 32% non-commercial

2769: Patients recruited

ECMC Network strategic objectives focus on streamlining and enhancing the study setup process across the Network.



# NCVR and EP / ATMP trials: What changes will take effect from October 2024

Ali Austen, Deputy Director of Research, NHS England and NHS Improvement

Laura Bousfield, National Head of Study Support Services, RDN Coordinating Centre

Clare Gillott, Industry and Research Support Operations Manager & National Service Development Lead (NCVR ATMPs/Early Phase)

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# Overview

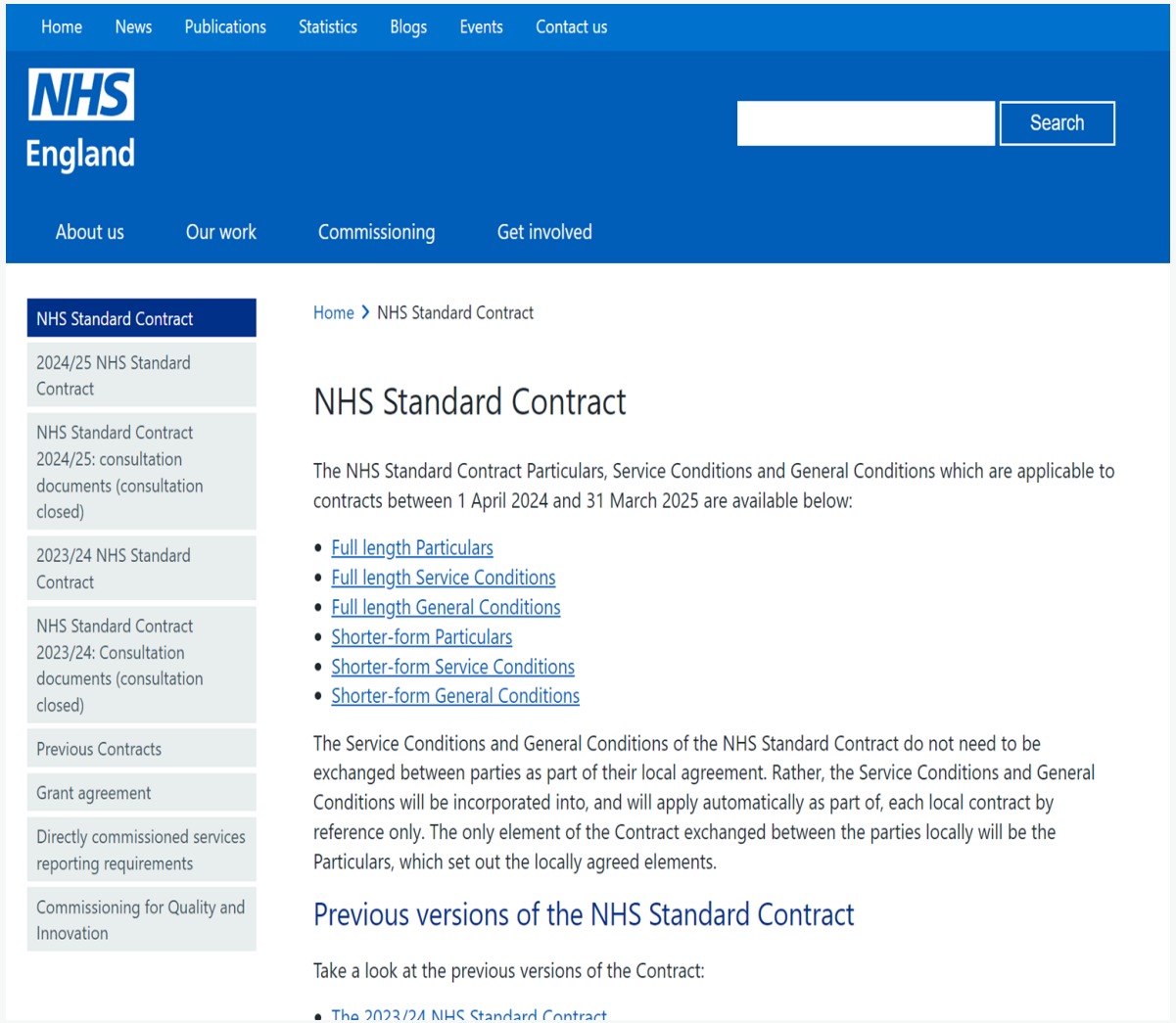
**The national contract value review (NCVR) is a standardised, national approach to costing for commercial contract research.**

**NCVR is underpinned by the National standard contract and the National directive on commercial research studies.**

**NCVR focuses on agreeing the resources and price needed to set up commercial research studies within NHS providers. This work forms part of a broader common goal to ensure clinical research continues to thrive in the UK, for the benefit of patients and the public.**

# Embedding a new way of working for us all

A nation-wide review
to define study-wide resource requirements
and apply standardised and transparent pricing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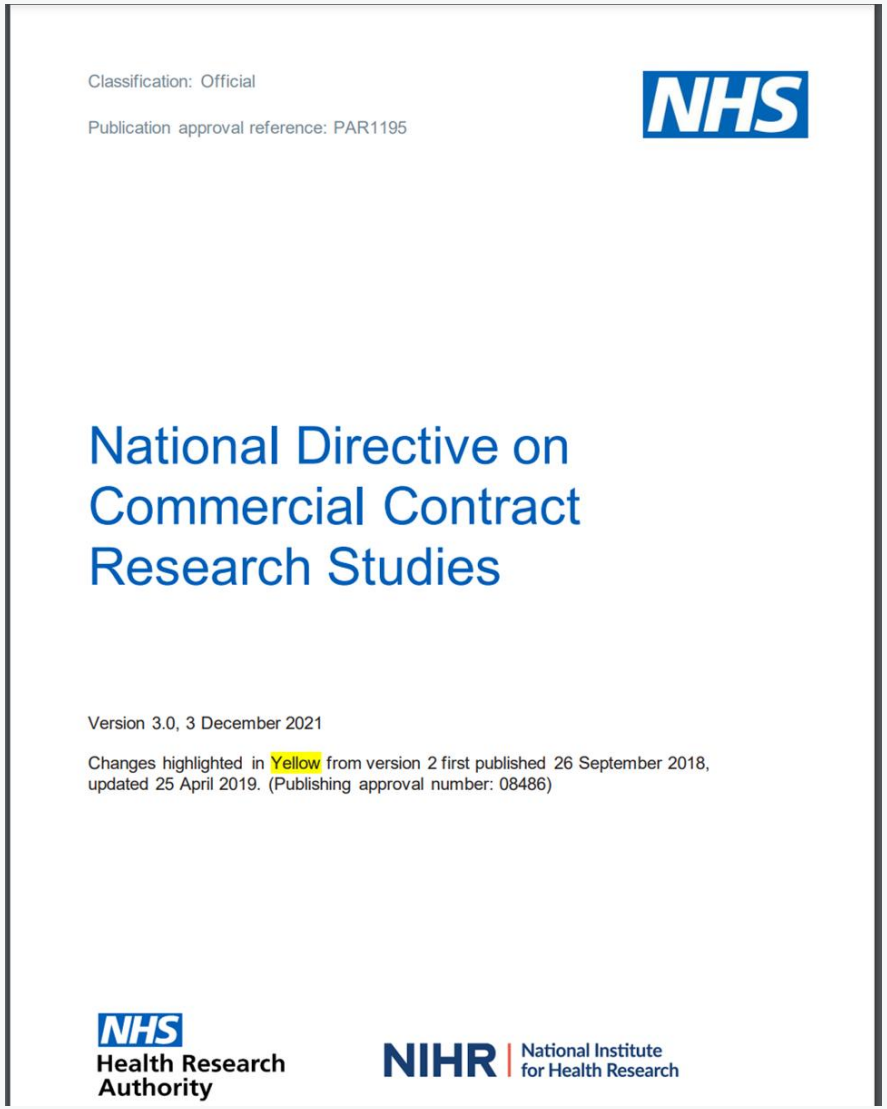
NHS Standard Contract
2024/25 NHS Standard Contract
NHS Standard Contract 2024/25: consultation documents (consultation closed)
2023/24 NHS Standard Contract
NHS Standard Contract 2023/24: Consultation documents (consultation closed)
Previous Contracts
Grant agreement
Directly commissioned services reporting requirements
Commissioning for Quality and Innovation
Home › NHS Standard Contract
NHS Standard Contract
The NHS Standard Contract Particulars, Service Conditions and General Conditions which are applicable to contracts between 1 April 2024 and 31 March 2025 are available below:
Full length Particulars
Full length Service Conditions
Full length General Conditions
Shorter-form Particulars
Shorter-form Service Conditions
Shorter-form General Conditions
The Service Conditions and General Conditions of the NHS Standard Contract do not need to be exchanged between parties as part of their local agreement. Rather, the Service Conditions and General Conditions will be incorporated into, and will apply automatically as part of, each local contract by reference only. The only element of the Contract exchanged between the parties locally will be the Particulars, which set out the locally agreed elements.
Previous versions of the NHS Standard Contract
Take a look at the previous versions of the Contract:
The 2023/24 NHS Standard Contract


Classification: Official
Publication approval reference: PAR1195
NHS
National Directive on Commercial Contract Research Studies
Version 3.0, 3 December 2021
Changes highlighted in Yellow from version 2 first published 26 September 2018, updated 25 April 2019. (Publishing approval number: 08486)
NHS Health Research Authority
NIHR | National Institute for Health Research



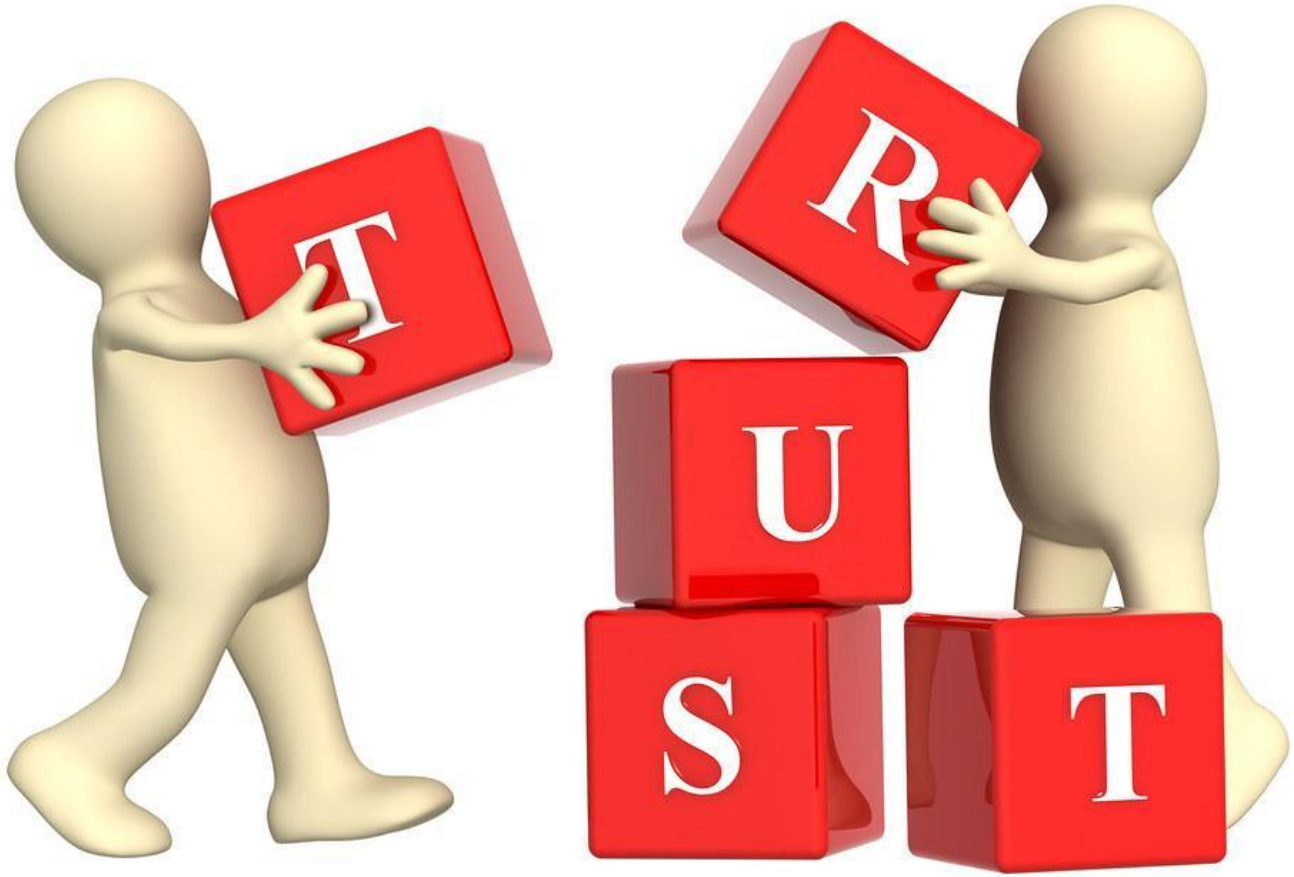
***From October 2024 – NCVR will encompass all commercial contract research within the NHS***

NIHR | National Institute for Health and Care Research

# Expansion of National Contract Value Review

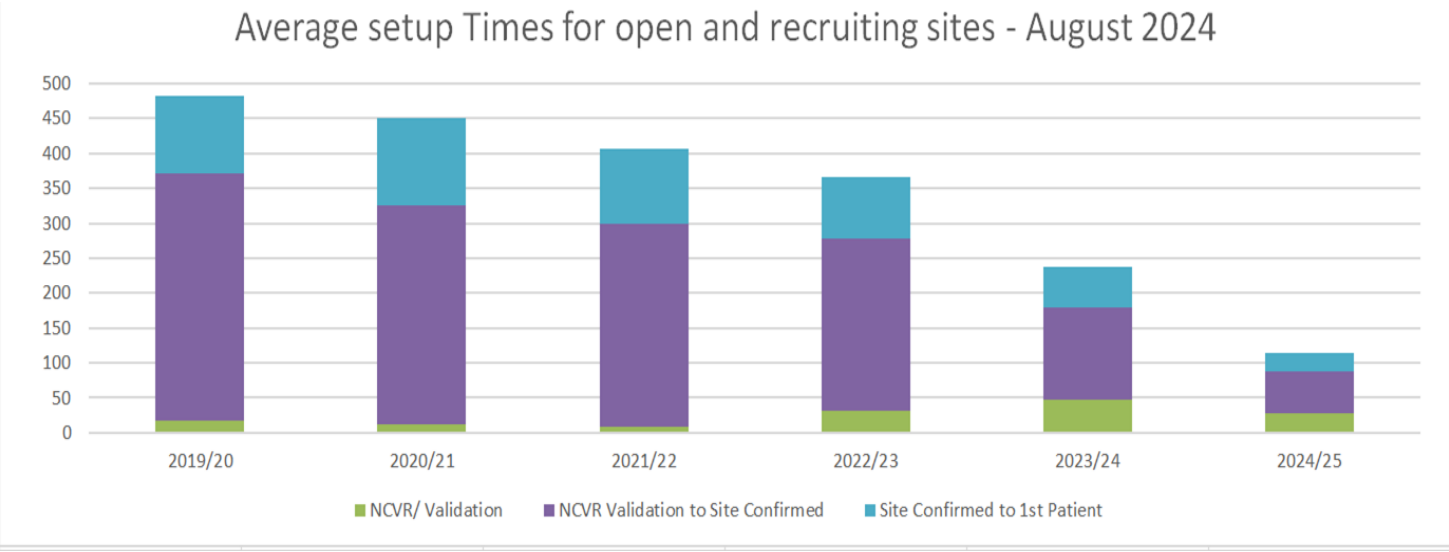
## What we have learnt so far

# It’s all about building trust



# Our process data shows it works - experiences remain subjective

**Commercial study set up times reduced by a third, according to new data**



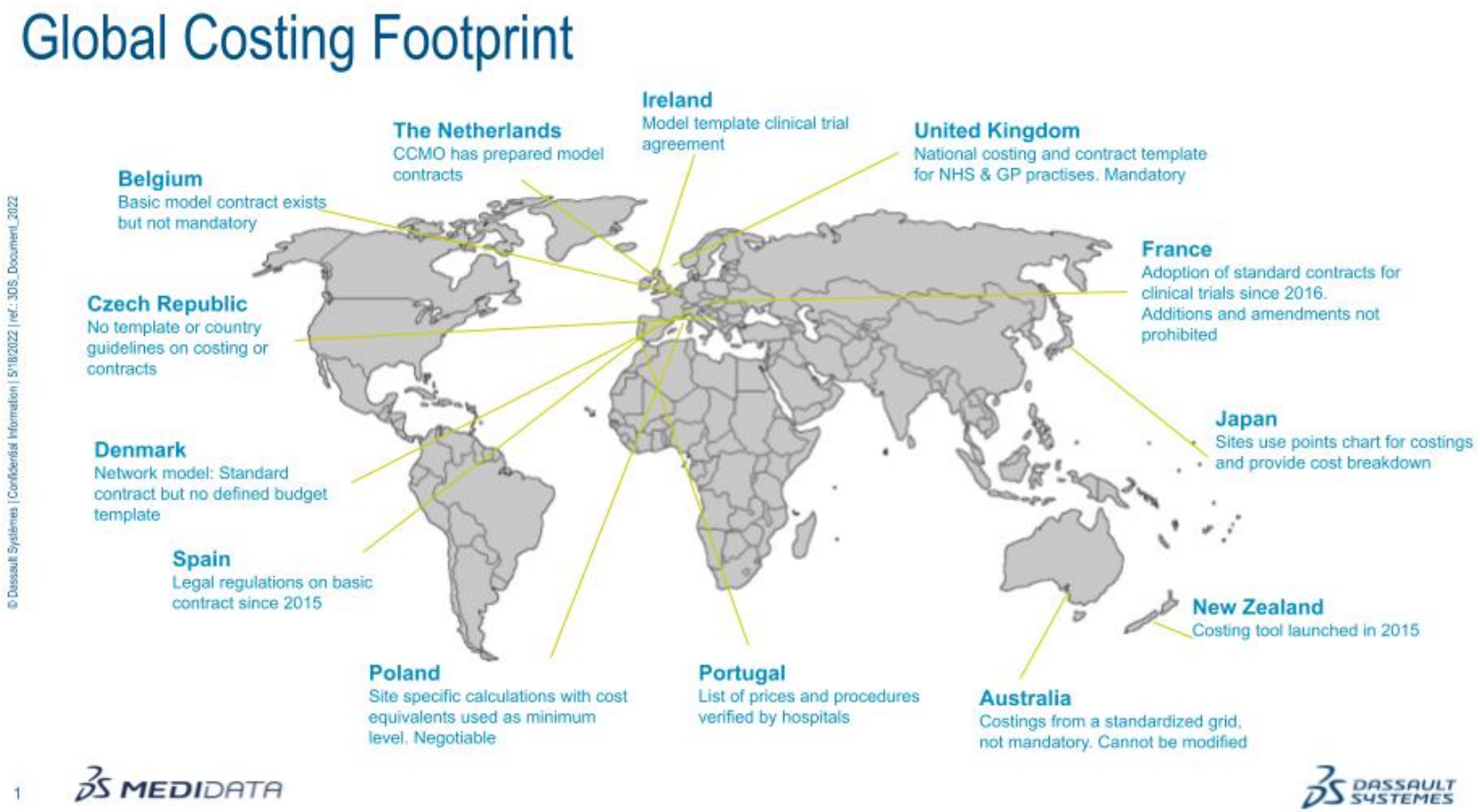

**Over 1400 study reviews completed**

**Median timelines is 34 days**

**80% have had no escalations from sites**

**Majority of studies with escalations are 1 or 2 sites**

# The UK is leading the way: growing global interest in country wide cost/contracts




- + **Taiwan** use previous UK excel costing tool
- + **French** government interest in tool
- + **Singapore** Clinical Research Institute exploring harmonisation
- + **UAE** network exploration

SOURCE: https://www.medidata.com/en/life-science-resources/medidata-blog/nihr-and-medidata-clinical-trial-budgeting-approach/

# Implementation timeline


### CRN Validation

All participating sites negotiate individually with sponsor/CRO on their local prices.

**Set up times are at 305 days.**

### NCVR Stage 1 Roll Out

75% of NHS Trusts voluntarily agree to accept the result of the national review with no negotiation.

**Set up times reduced to 194 days.**

### NCVR Stage 2 Roll Out

All NHS Trusts **must accept** the result of the national review with no negotiation.

**GP Practices can sign up to NCVR on a voluntary basis.**

### ATMP/Early Phase Pilot

Work to include ATMP and early phase trials.

### NCVR Stage 3 Roll-out

All phases of studies included in NCVR to establish as business as usual approach.

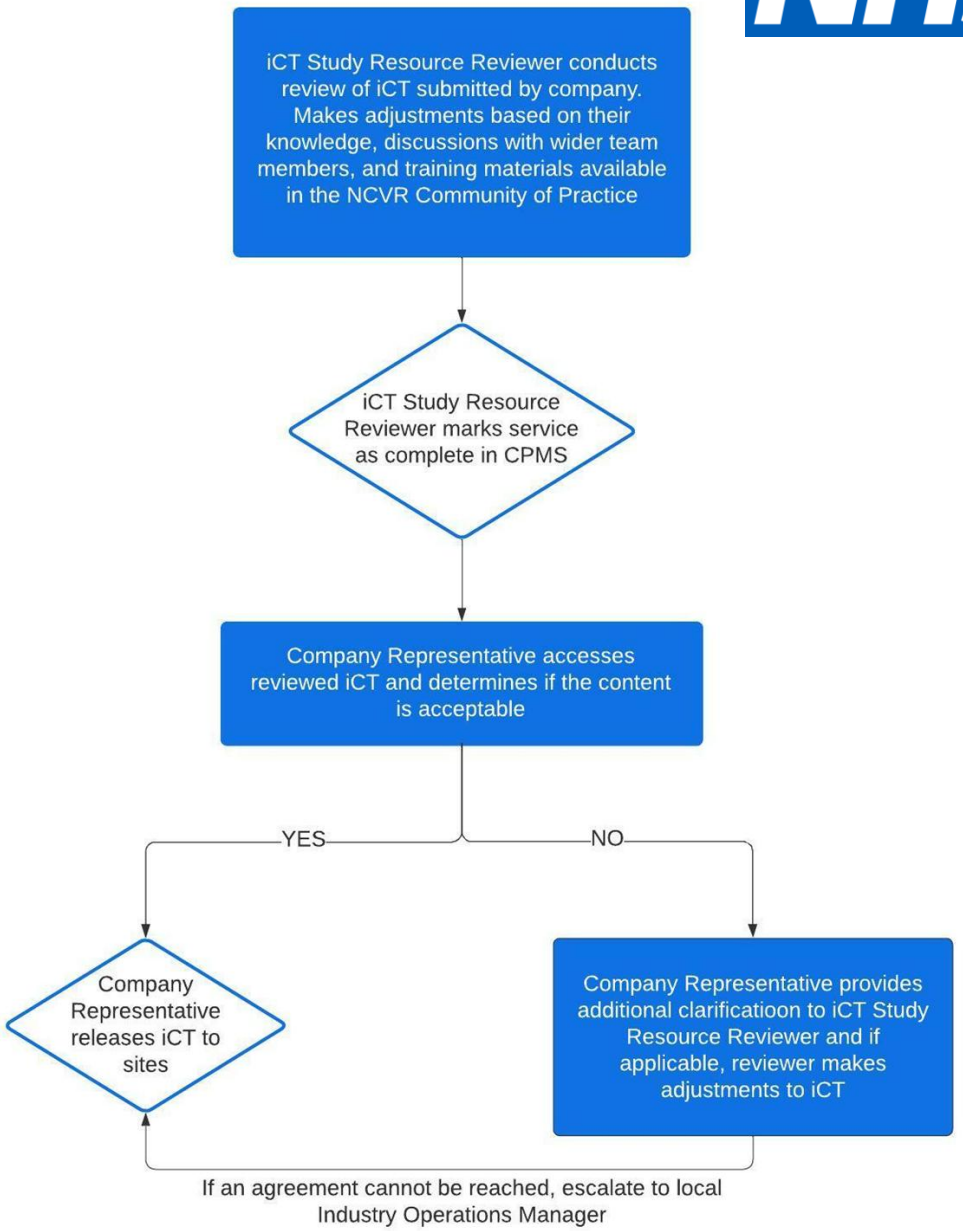
# Consistent approach to cost recovery and distribution

NIHR | National Institute for Health and Care Research

# Expansion of National Contract Value Review (2)

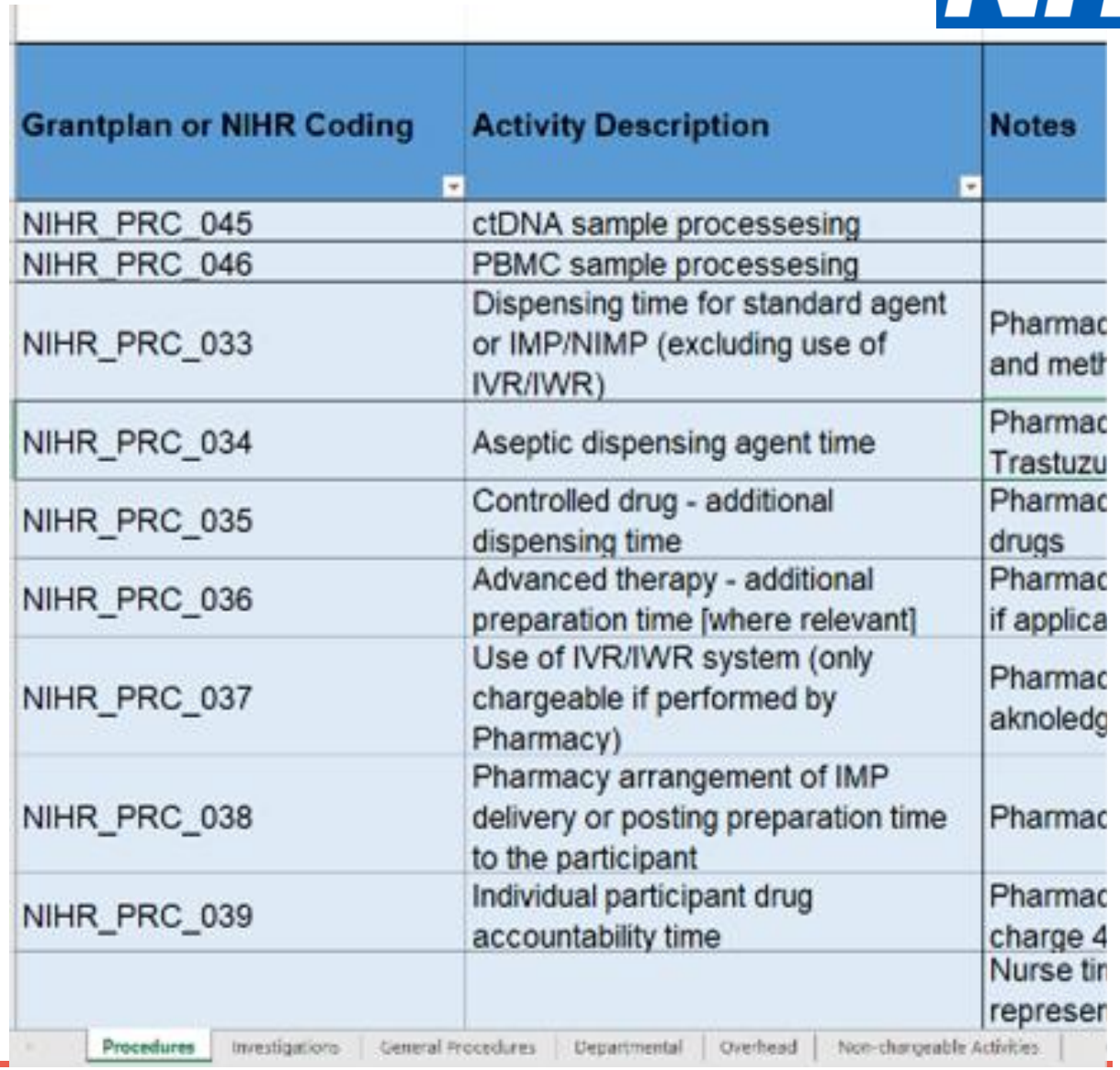
## What we have learnt so far

- NO changes to the current process for ATMP/Early phase studies
- Pilot all sites budget meeting to be recommended for complex studies, but not mandated
- All materials to be made available online for both Trusts and Companies to access



# UK Tariff updates

- 700 line items reviewed
  - Collected as part of pilot
  - Feedback from existing workstreams
- Many duplicates and/or items already in the tariff
- Approx. 30 ATMP/Early phase specific line items to be added in October



| Grantplan or NIHR Coding | Activity Description | Notes |
|---|---|---|
| NIHR_PRC_045 | ctDNA sample processesing | |
| NIHR_PRC_046 | PBMC sample processesing | |
| NIHR_PRC_033 | Dispensing time for standard agent or IMP/NIMP (excluding use of IVR/IWR) | Pharmac and meth |
| NIHR_PRC_034 | Aseptic dispensing agent time | Pharmac Trastuzu |
| NIHR_PRC_035 | Controlled drug - additional dispensing time | Pharmac drugs |
| NIHR_PRC_036 | Advanced therapy - additional preparation time [where relevant] | Pharmac if applica |
| NIHR_PRC_037 | Use of IVR/IWR system (only chargeable if performed by Pharmacy) | Pharmac aknoledg |
| NIHR_PRC_038 | Pharmacy arrangement of IMP delivery or posting preparation time to the participant | Pharmac |
| NIHR_PRC_039 | Individual participant drug accountability time | Pharmac charge 4 |
| | | Nurse tir represer |

Procedures | Investigations | General Procedures | Departmental | Overhead | Non-chargeable Activities

# Early Phase and ATMP Guidance

- Developed with input from:
  - Pharmacists
  - ATMP Specialist centres
  - Early phase specialist centres
  - Pharmaceutical company
  - Devolved Nations
- Guidance built around existing UK Tariff items
- Will be kept as a ‘live’ document with quarterly updates

# Life Sciences Learning Centre


https://learn.nihr.ac.uk/course/view.php?id=1114

# The ECMC Pilots

Ravinder Singh Nizzer, Project Manager
ECMC Programme Office

# Our approach to finding a solution

**ECMC ATMP Costing Steering Committee and multi-disciplinary working group** established to co-create a proposed solution to cost early-phase and ATMP clinical trials.

**Conducted a comprehensive review** of various guidelines and websites to map the NCVR process for late-phase trials from start to finish, enabling a thorough understanding of the costing procedures involved.

**ECMC expertise on multiple working groups** set up specifically for developing NCVR for EP/ATMP trials. Operational Centre Business Lead representation on the NIHR National Commercial Costing Reference Group.

**An ECMC network review and update** of key guidance documents and iCT tariff line items was undertaken as part of the work conducted by the NHSE NCVR ATMP Working Groups.

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# The ECMC Adapted Costing Process

- A **single, lead-site** costing approach
- Implementation of a **mandatory call with sponsor** ahead of the budget build in iCT
- Enable access to essential **documents/information** at an **earlier stage** in the process
- Inclusion of the **"Network Sites Review"** for multicentre trials
- **Staged budget review process**, including a second mandatory call between company and lead site to resolve queries.
- Through **learning and collaboration standardise** how complex trials are costed across the network

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# Pilot Study Criteria

- A **commercial** study (FIC or FIH up to phase IIa) for **adults** or **paediatrics**.
- An **ATIMP** or **early phase** oncology trial.
- **Multi-centre** study, with an **ECMC** assigned as **chief investigator** site.
- Additional **participating sites** should preferably be an **ECMC** site or a **UKCRF** site.
- No study budget costing or contracting between sites and sponsor should have taken place.
- The study must have regulatory permission from the MHRA/HRA or be in the process of getting it.
- The **Sponsor must agree** to their study being selected for use in the pilot. The ECMC Programme Office can meet with the study team and sponsor to give more information before deciding.
- **All sites** must **consent** to work together and participate in the pilot.

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# ECMC Pilot Studies:

**ECMC Study 1**

A single site CAR-T study

B-cell Non-Hodgkin Lymphoma

**ECMC Study 2**

A multi-site CAR-T study

B-cell Non-Hodgkin Lymphoma

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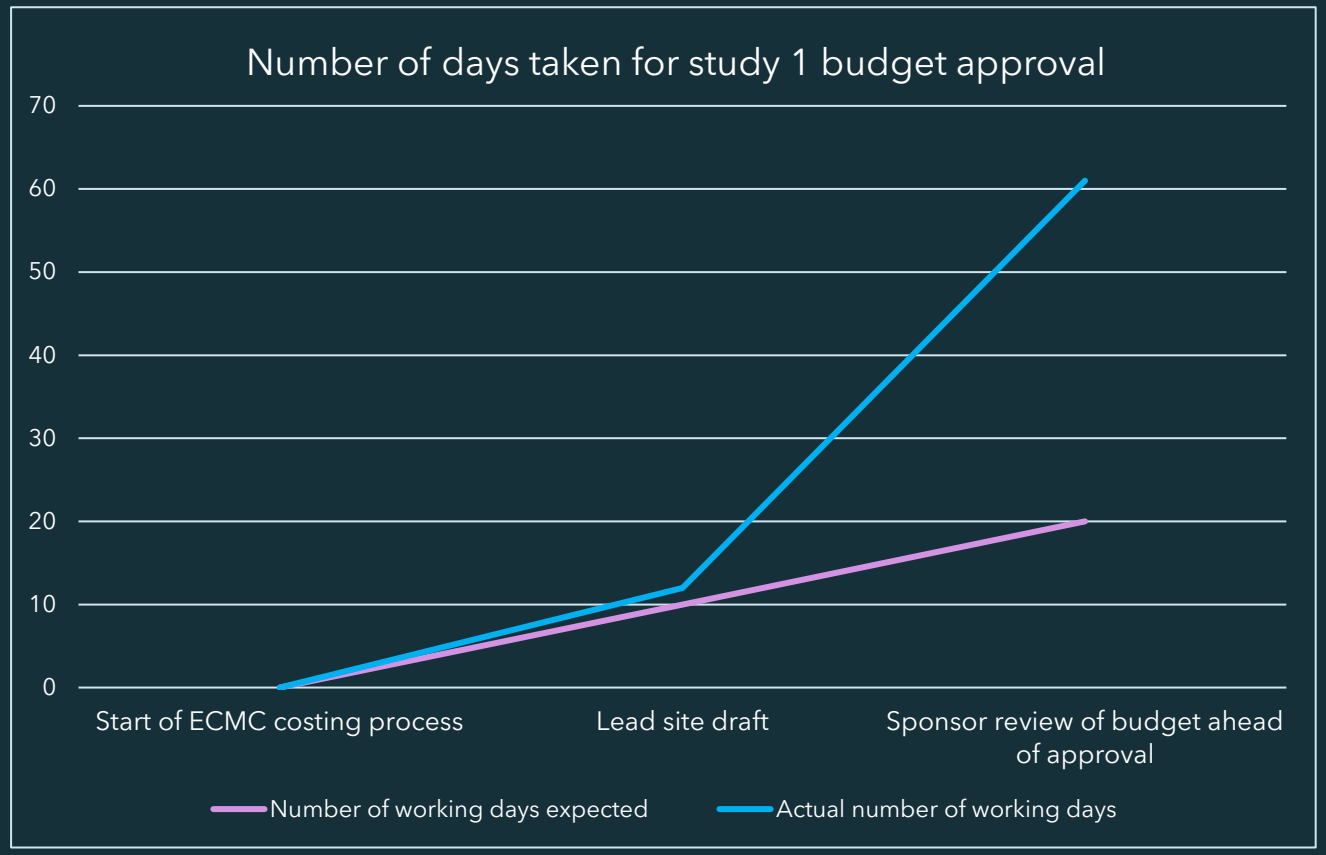
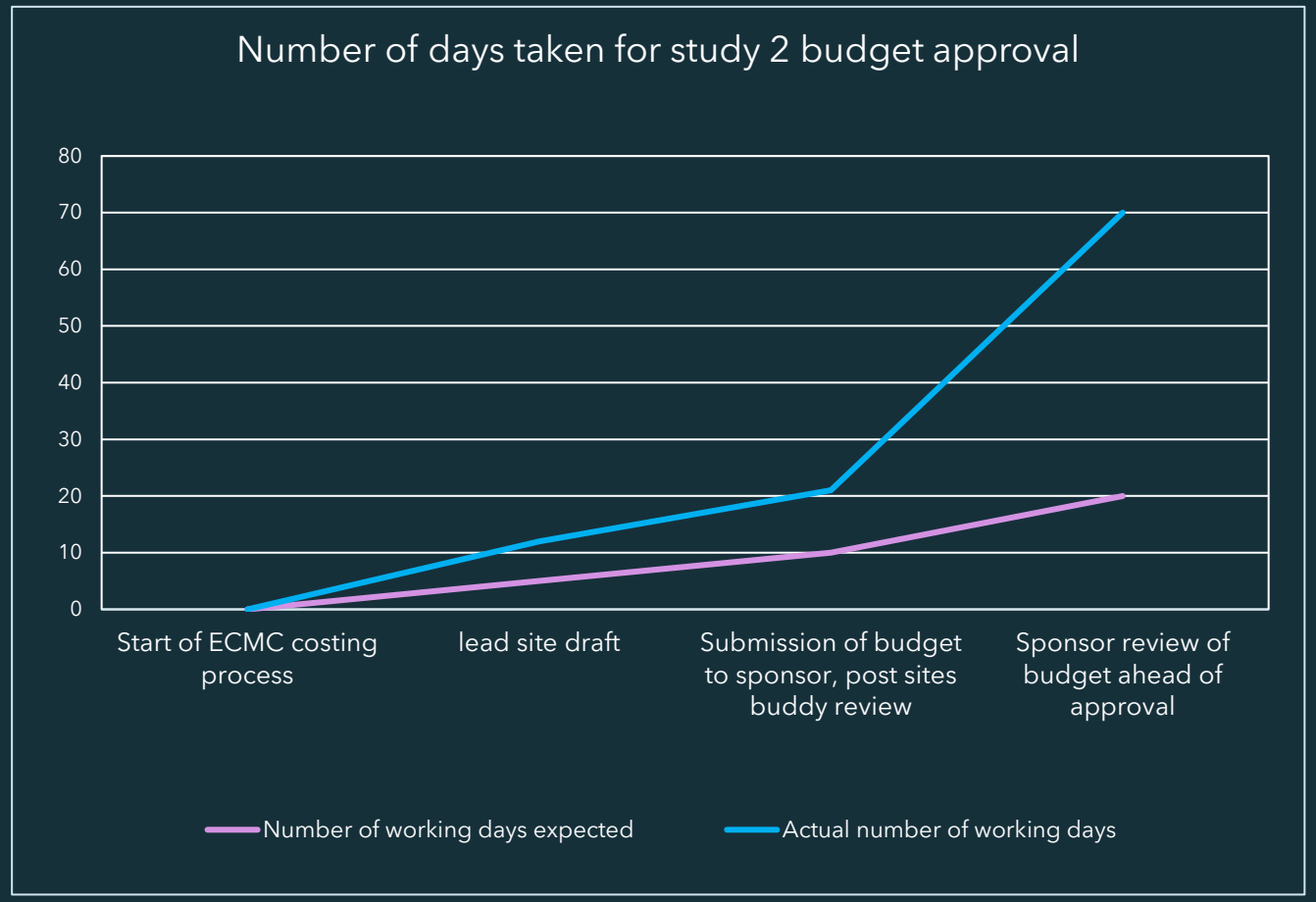
# Study 1, Single Site




- Lead site completed the initial draft of the budget within 12 working days.
- Sponsor review of network sites agreed budget completed in 49 working days.
- Total time taken: 61 working days

# Study 2 Multi-Site




- Lead site completed the initial draft of the budget within 12 working days.
- Network sites review completed in 9 working days.
- Sponsor review of network sites agreed budget completed in 49 working days.
- Total time taken: 70 working days

*'A single, lead site costing approach is a better implementation for EP/ATMP trials due to their complexity'*

Sponsor feedback

# Achieving A Globally Competitive Study Costing

| Stages of Process | % change of total cost |
|---|---|
| **Initial sponsor** budget to **final approved** | 88% |
| **Lead site** costing and **network sites review** submitted to sponsor for review | 19% |
| **Lead site** costing and **Final approved** | 12% |

*'The UK per patient budget was within the overall global budget and comparable to other countries'*

Sponsor feedback

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# Key Findings

## System Functionality

- To accommodate the ECMC single, lead site costing approach, the LCRN were manually required to assign the initial iCT to the lead site rather than sponsor.

## Budget Creation

- The importance of aligning the iCT build with sponsor global study milestones for efficient budget approval and invoicing purposes.
- Lead CI site costing approach allowed for site expertise to be utilised sooner in the costing approach, allowing for a more accurate initial budget build.

# Key Findings Continued

## Complexities of Costing

- Difficulty in matching the NIHR tariff items to the specific activities of complex studies, especially ATMP trials
- Problems can arise from the detailed and at times duplicative nature of the tariff data
- The tariff needs to be simplified and updated with new line items to facilitate a more efficient/accurate costing

## Collaboration and Communication

- A mandatory call between lead site and the company is important in aligning expectations and sharing crucial costing specific information, even in draft format
- The network sites review stage in the process allows for cross-functional collaboration and costing alignment amongst participating sites
- Reduced burden on company and participating sites due to the lead site being responsible for budget negotiations

All key findings and specifics around the iCT tariff; line items descriptors and guidance's has been shared with the ECMC & NHSE working groups.

The ECMC Pilot

Lead Site Experience

Milly Denman: UCLH Site Set up Specialist

# Benefits to the ECMC Model

**Efficiency**: as the Lead reviewer drafts the iCT (budget), this will save time (sponsor rep drafting and site reviewing)

**Quality:** costing experts at participating sites draft initial budget, so the quality is higher, reflecting full cost recovery

**Delivery:** considerations are made with how the study is being run across different sites removing the need for escalations relating to interpretation/clarification

**Transparency:** initial discussions between sites only (no sponsor rep) resulted in proactive conversations regarding true costs

Lead reviewer maintains responsible for final decisions, negating ongoing, unnecessary discussions

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# Lessons learnt during ECMC Pilot CPMS

CPMS functionality doesn't currently allow allocation of the initial budget to site-level lead reviewer to draft

Resolution: understand there is a CPMS update pending, could a resolution be included in this update?

# Lessons learnt during ECMC Pilot

## NIHR Tariff Items:

- Multiple levels of escalations within industry for tariff items extends timelines
- Ambiguity in what activities are covered in each itemised activity (i.e. Pharmacy D cost)

**Resolution**: when NIHR Tariff is updated and mandated for early-phase/ATIMP studies, this should mitigate these issues – comprehensive, improved descriptions required

# Lessons learnt during ECMC Pilot

## Cross-site Discussions:

- Potential difficulty in organising initial network sites discussions if there are many participating sites
- Lead reviewer responsible for final decision-making during negotiations in accordance to guidance

**Resolution**: Experience required - with enough sites contributing

# Key Takeaway Points:

- **Higher quality** budgets approved in a **timely** manner
- **Transparency** across sites and transparency with Industry
- **Fewer escalations** required due to upfront discussions
- **Smarter working and increasing capacity** to manage workload around other set up activities

# Looking Ahead: ECMC and NCVR Development Plans

## October 2024: Optional Use of ECMC-Adapted NCVR:

- NHSE and NIHR will not mandate the ECMC adapted process for all studies initially.
- Available for sites and sponsors preferring the ECMC-adapted process, particularly for EP/ATMP oncology trials.

## Ongoing improvements:

- ECMC combination of CAR-T & Vaccine trial pilot, CRO and Multiple sites.
- Continuous improvements to the process, systems and tools.
- ECMC will continue to be part of the NHSE NCVR working group(s).
- Publish a report on the work ECMC has done to help shape NCVR for EP/ATM trials in cancer and beyond

# Discussion

# Thank you for attending

Slides and recording will be available via the ECMC Website
www.ecmcnetwork.org.uk

For more information, please contact
Sharan.Sandhu@cancer.org.uk
Ravi.Nizzer@cancer.org.uk

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