Working Together: Optimising National Systems to Accelerate Study Set Up Across the ECMC Network

ECMC Network Meeting 2023
Parallel Session

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

Welcome and Introduction

Amanda Rees

Head of Research Operations for Manchester ECMC & The Christie
Experimental Cancer Medicine Team

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Agenda:

Time	Topic	Chair
2:00pm	Introduction	Amanda Rees
2:05pm	ECMC Accelerated study set up	Sharan Sandhu / Luke Brewer
2:25pm	National Contract Value Review (NCVR) and Community of Practice	Laura Bousfield/Ali Austin
2:40pm	ECMC minimum costing standard and the current interactive Costing Tool (iCT)	Chris Barron/Helen Porteous
3:00pm	Panel discussion: How can the ECMC network operate and shape the use of national tools like iCT and the NCVR procedure to effectively cost research and accelerate study setup?	All
3:25pm	Summary	Amanda Rees
3:30pm	Close and Return to Warwick Room	All

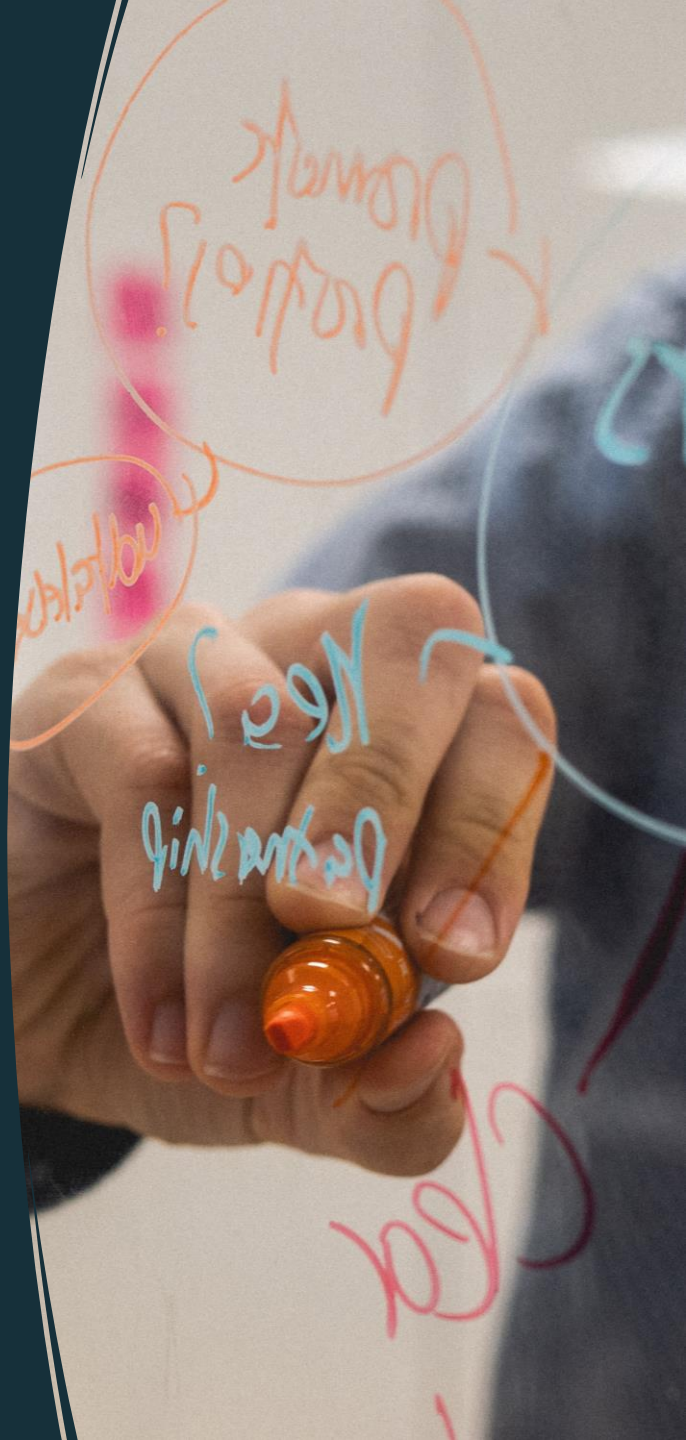
Today's session

Purpose

Optimise national costing (iCT) and review (NCVR) systems to accurately display and expedite the setup of early phase complex oncology trials across the network

Objective

To reach a consensus on a network approach to streamline NCVR application and the iCT to efficiently setup early phase oncology commercial studies



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Panel Discussion

How can the ECMC network operate and shape the use of national tools like iCT and the NCVR procedure to effectively cost research and accelerate study setup?

Amanda Rees	Head of Research Operations, Manchester ECMC
Laura Bousfield	Head of Feasibility and Start-Up, NIHR Clinical Research Network
Ali Austin	Deputy Director of Research in the Innovation, Research and Life Sciences Group, NHS England & NHS Improvement
Bindu Rao Baikady	Head Of Operations I Drug Development Unit & Clinical Studies, ICR
Chris Barron	Cancer Trials Unit Manager, Newcastle ECMC
Helen Porteous	Early Phase Oncology Clinical Trial Coordinator, Newcastle ECMC
Kate Greenwood	Senior Improvement Delivery Manager, Health Research Authority

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Discussion Points

1. What needs to change to get the best from these national systems?

2. What challenges around costing and contracting would remain and how could we address them?

3. How can we standardise practices between Sponsors/CROs, Centres and the NIHR and work smarter?

ECMC Accelerated Study Set-Up

Sharan Sandhu, ECMC Network Delivery Lead
Luke Brewer, Wendy Fisher Consulting

Improving the efficiency and set-up of early phase trials

Working in partnership with the Health Research Authority and the Clinical Research Recovery, Resilience & Growth Board

Working with key clinical trial stakeholders to create transformative change

Creating routes that enable the UK to compete internationally on set-up times

Developing sustainable improvements that are transferable beyond early phase cancer

Globally Competitive Research Delivery

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Our Progress

Intelligence Gathering:

- Site level team engagement
- Industry & Regulator engagement
- Emerging Areas for Improvement
- International study set-up review

Improve (solution co-creation):

- Co-create a simplified set up pathway
- Proceeding with several workstreams to address the highest priority themes
- Conduct series of iterative pilots, 2-way feed into national initiatives

Our neighbours:

Regulatory Review

- 60 days for ethics and regulatory approvals – EU Clinical Trial Regulations (mirrors UK)
- System of parallel ethics, regulatory, and costing/contracting reviews is in place
- France have a fast-track process for Phase 1 studies
- Unparalleled R&D Department to UK

Contracting

- Model single and master agreements - Non-negotiable
- Built into regulation – Mandatory to use

Costing

- Costs agreed at a national level or by a single coordinating site
- Costs negotiated with individual departments directly, for e.g., pharmacy and imaging (Germany)

Support Services Review

- No operational manuals or final protocols receive same information as UK
- No requirement for an equivalent of the UK imaging review process (IRMER) or ARSAC
- PI is responsible for ensuring imaging is clinically safe for their participant's

Competition

- Dedicated Early phase resources
- There is a level of competition between sites which drives sites to try to deliver as quickly as possible
- Sponsors report being able to withdraw a study from sites during set-up if negotiations or timelines are too drawn out

Key themes from optimal process workshop

Standard of Care Imaging

To gain consensus on standard of care imaging arrangements for early-phase cancer trials and implement an improved process.

Information support departments and delivery teams

To define the minimum information set required for imaging and pharmacy stakeholders to complete the study set-up process, including costing arrangements, and implement an early-phase solution.

Costings

To determine and pilot a solution within the national costing and review systems to accurately display and expedite the setup of early phase oncology trials and ATIMPS.

Contracting

To develop solutions for network partnerships with industry by utilising national model agreement templates

Sites best practice and standardisation

To develop guidance on an ideal path for early phase trials.

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ECMC Programme Plan

May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan

1. Support departments

Imaging
SOC + Define minimum information set & costing requirements

Pharmacy
Define minimum information set & costing requirements

Agreement on SOC arrangements from multiple stakeholders

A 'minimum information set' required to be able to undertake local set-up and costing (in combination with the study protocol)

Engage Tech Assurance (HRA)
Engage Delivery Teams
Engage ARSAC (Imaging only)

Design revised process and pilot leading to implementation

2. Costing commercial research

iCT updated with early phase activity tariff

Consultation on ECMC Network-NCVR process for early-phase & ATIMP trials

Create a network minimum costing standard and early phase costing guidance

Design and pilot ATIMP NCVR process and guidance

Broader NCVR and implementation

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ECMC Programme Plan

May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan

3. Contracts for commercial research

- Engagement and consultation with sponsors/network on contracting solutions and ECMC Network options (incl. model agreement financial schedule from iCT)
- Develop network contracting solutions
- Implement

4. Sites – Ideal Path for Early-Phase Trials

- Create a framework of an ideal path for study set-up, incorporating network solutions
- Streamlined Expression of Interest (EOI) process and study feasibility
  Define and match roles and responsibilities to skillset at each stage of SSU
- Guidance to support development of ideal paths across network

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Workstreams in flight

1. Support departments

- Identified lead pharmacy and imaging contact from within each site to support the development of this workstream's outputs
- Questionnaire to support departments to identify minimum information dataset
- Collation and analysis of information currently collected by HRA Tech Assurance process
- Pharmacy and Radiology workshops on 8th June

2. Costing commercial research

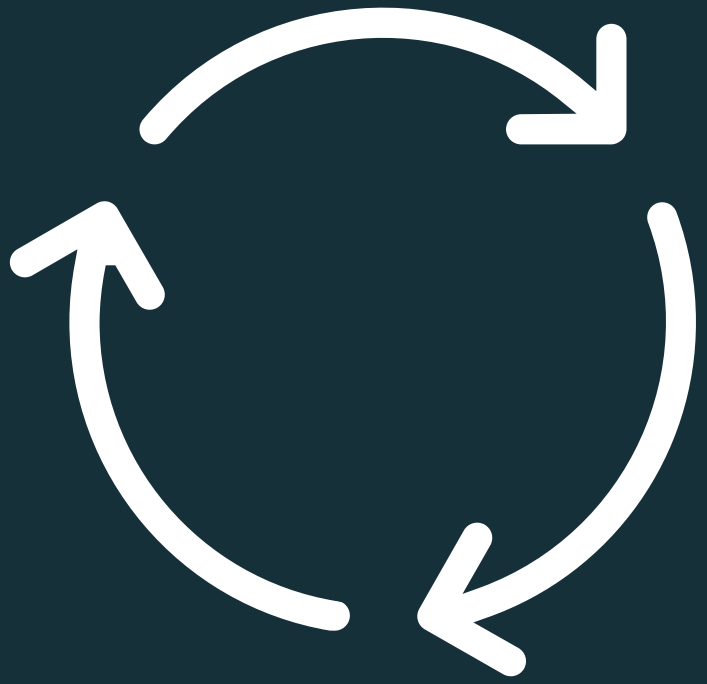
- Data comparison of the iCT against Newcastle ECMC minimum costing standard and ECMC 2021 iCT review, identifying potential additions for iCT and variances
- Today's session; reach a consensus on how the network can benefit utilising the iCT NCVR
- Identified potential sites for the ATIMP costing pilot

3. Contracts for commercial research

- NCVR commitment is to have a revised finance schedule available from October 2023. This schedule forms part of the UK template agreements into which the NCVR derived budget is pasted
- Consultation launch on the financial schedule template , ECMC response
- Agreement for the ECMC to lead on the utilisation of an early draft of the finance schedule

Project Legacy

'An optimal simplified process that can consistently & sustainably be delivered to achieve efficient approval and set-up of early phase oncology commercial trials'



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NIHR | National Institute for Health and Care Research

Standardising the costing element of contracting for early phase trials

Ali Austin, NHS England and Laura Bousfield, NIHR

Start with why

A national approach to resource requirements and price calculation

across all ECMCs

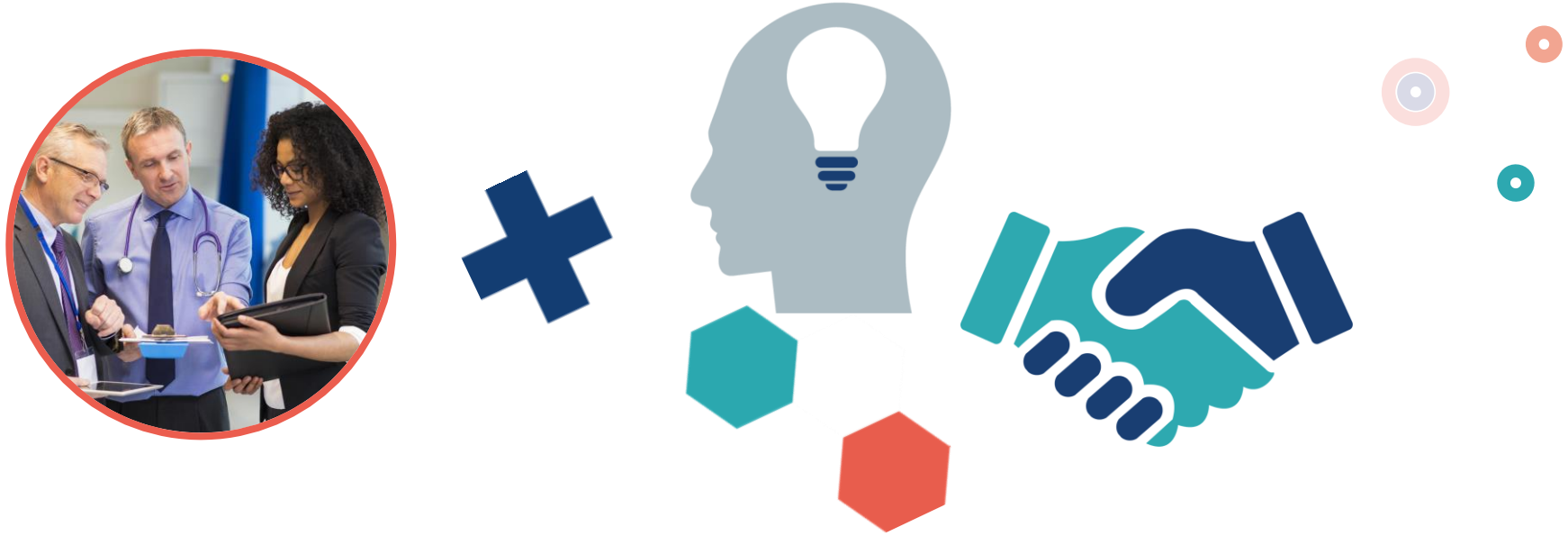
speeds up patient access to research

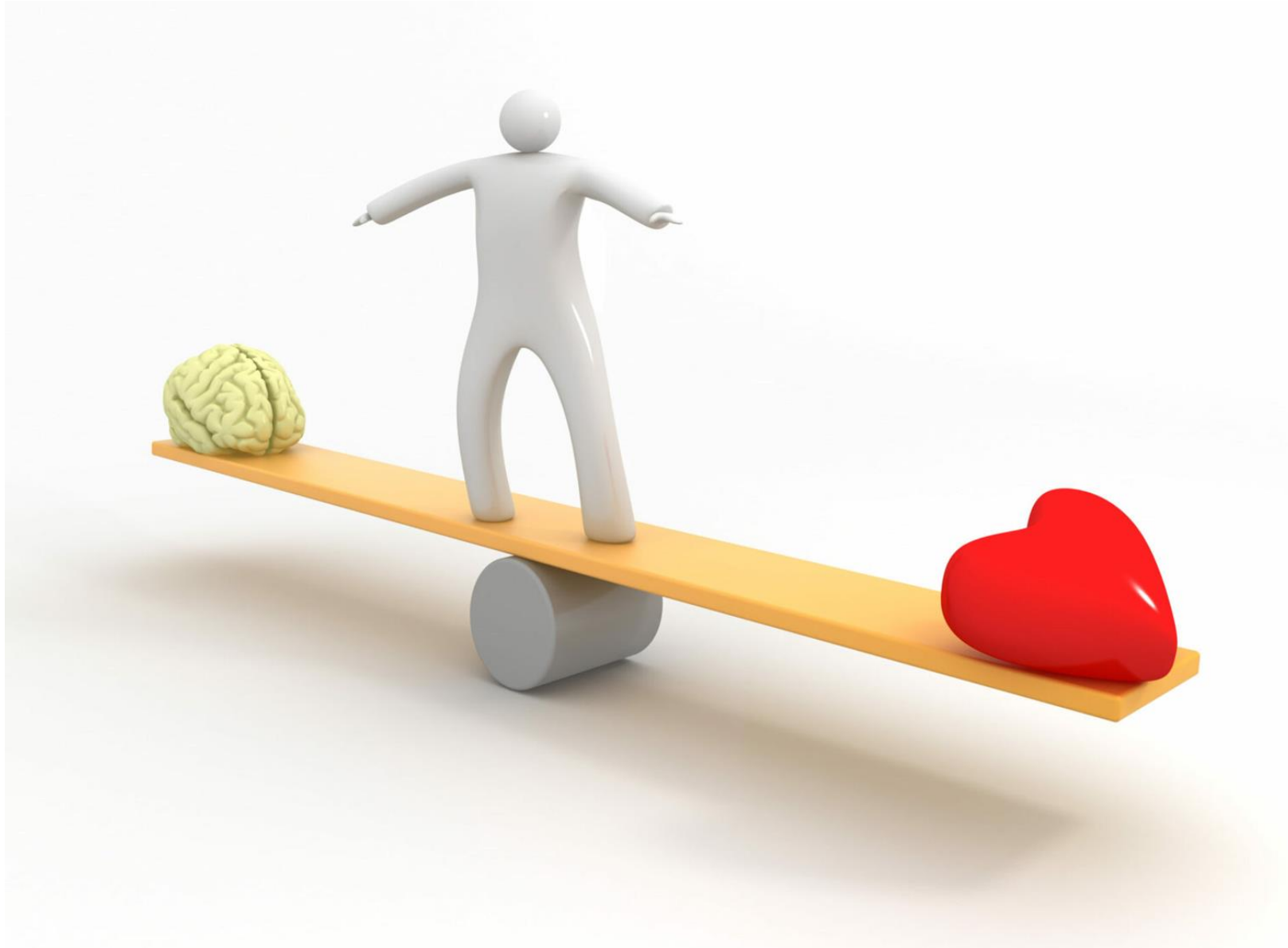
Move into how

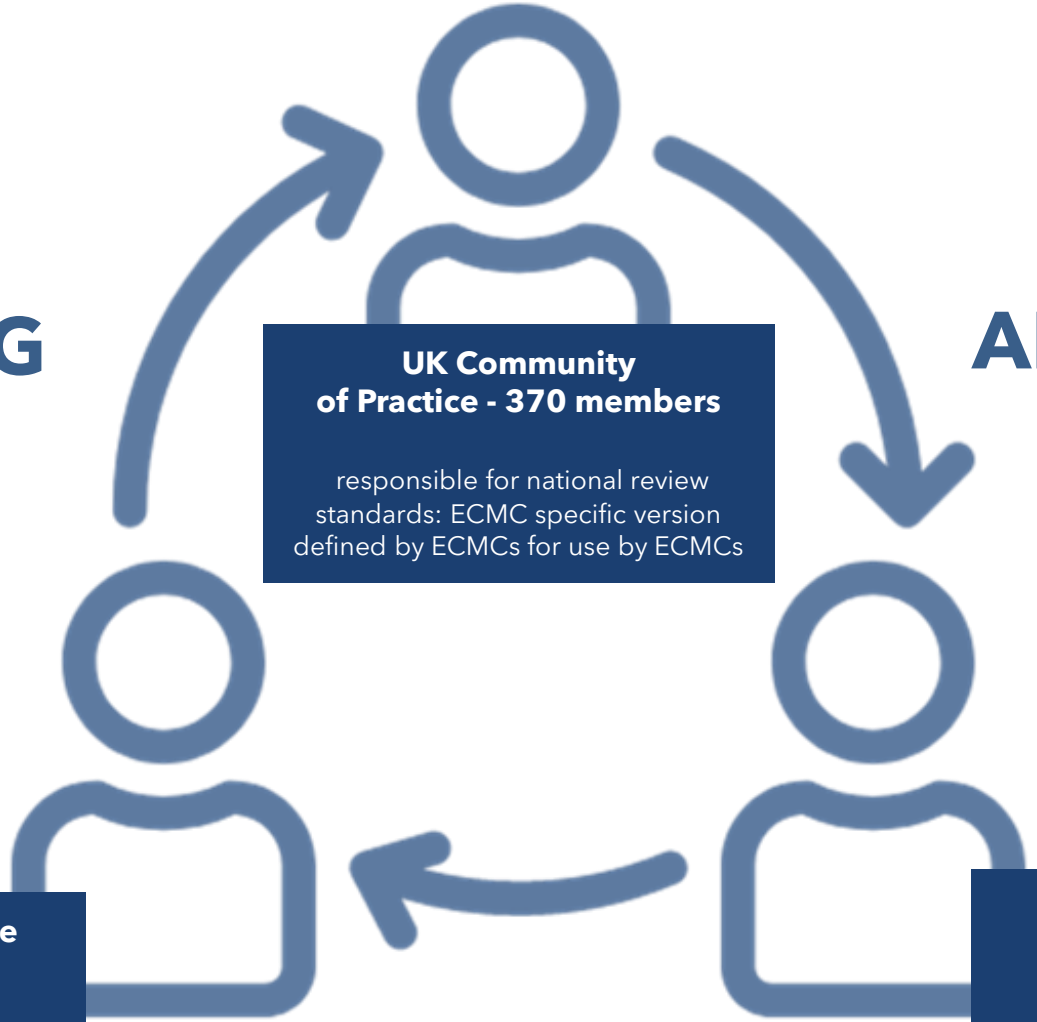
Facilitate partnership working between companies and ECMCs

to define study-wide resource requirements

and apply standardised and transparent pricing







LEARNING

ADHERENCE

CONTENT

UK Community of Practice - 370 members

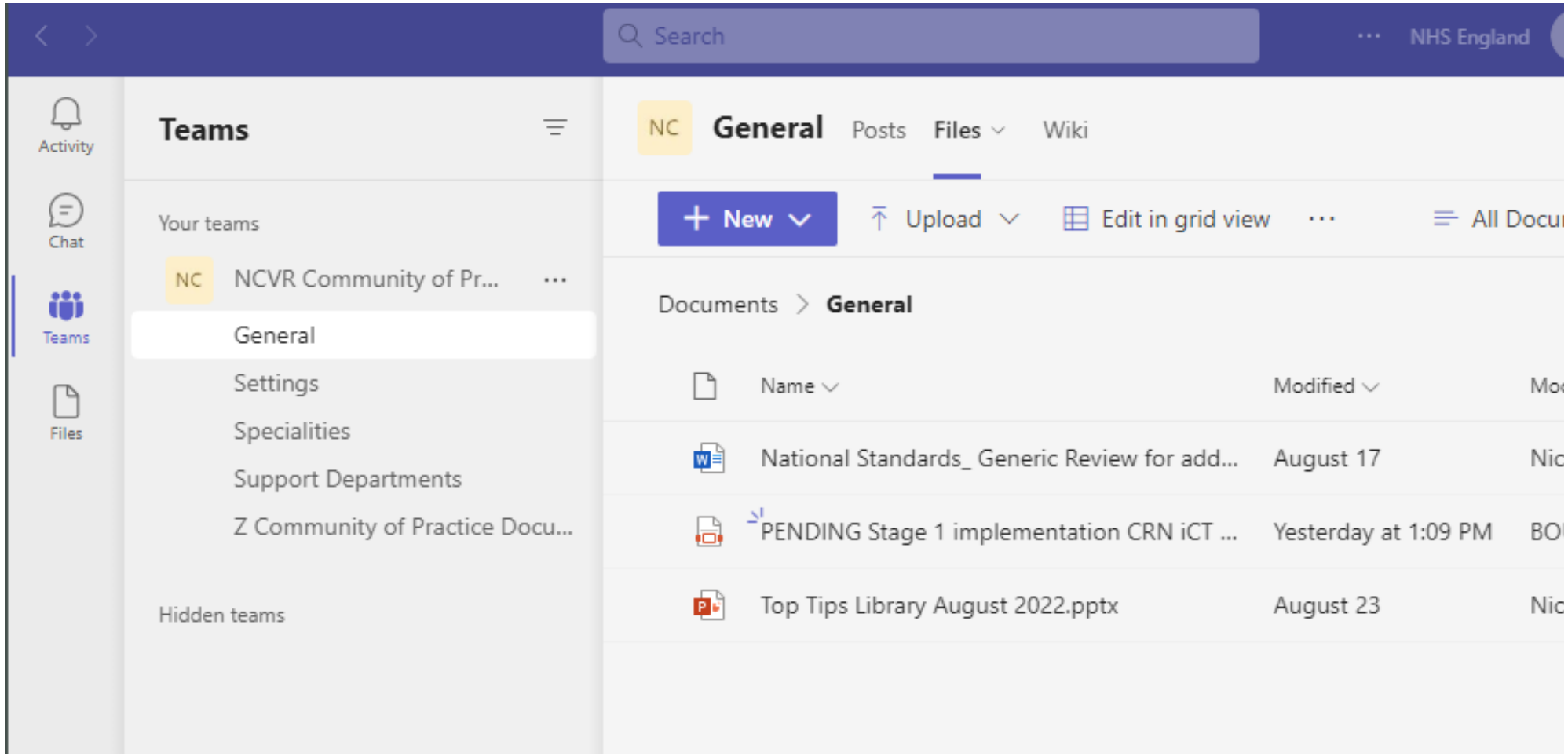
responsible for national review standards: ECMC specific version defined by ECMCs for use by ECMCs

UK Commercial Costing Reference Group - ECMC membership

responsible for the UK iCT functionality and content

NHS England/ DA Office

responsible for standard contract adherence or DA equivalent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National Standards_ Generic Review for add...
August 17
PENDING Stage 1 implementation CRN iCT ...
Yesterday at 1:09 PM
Top Tips Library August 2022.pptx
August 23

This community of practice is a:

- group of people who share a passion for costing commercial research and know how to do it.
- virtual communication forum enabling regular interaction to learn how to do it to a collective and high standard across the NHS.

NHS Costing Experts working study wide

Looks like:

- Self defined
- Self managed
- Self selected sub-group leaders

Structured community in familiar communication technology

Looks like:

- MS Teams collaborate space providing: chat function, document sharing and live discussion space
- Moderated NHS email account based access
- Bespoke notifications to keep to up date with relevant content for each memb

Shared body of knowledge

Looks like:

- Reflective review feedback creating hints and tips
- Collated negotiation examples, sharing challenges, pitfalls and approaches
- Learning by doing

Integrated into day-to-day activities

Looks like:

- The single communication channel across UK alongside the interactive Costing Tool
- Day-to-day activities of community shape and evolve the national review standards NHS wide
- Supported UK research system wide

The collective trust built up through partnership working across this community of practice streamlines commercial research costing and therefore minimises set-up time to maximise patient access to research

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ECMC Network Meeting

A minimum costing standard and the current interactive Costing Tool (iCT)

Chris Barron and Helen Porteous

Newcastle ECMC

Sir Bobby Robson Cancer Trials Research Centre

Major Findings

iCT Pros

- Very useful tool
- Gives clarity of equipoise
- Audit trail
- Support departments have confidence

iCT Cons

- Lack of understanding from sponsors/CROs
- Training within organisations
- Confusion with NCVR

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Major Factors

NCVR

- Lack of understanding of process within CROs/Sponsors
  - Want everything costed at a minimum
  - Lack of understanding of site processes
  - Not all documentation available e.g. Lab Manual
- Lack of understanding within clinical team
  - What are we supposed to enter as a CI site?
  - What can we do to ensure consistency

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Major Factors

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Newcastle Approach

Standardised costing template

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Set-up and Close Down – Standard Costing Template Snapshot

Category A or B amendment fee - Major changes (chargeable per amendment) R&D Fee	£175.00		
Category A or B amendment fee - Major changes (chargeable per amendment) SBRU Fee	£550.00		Time spent preparing a major cat A or B amendment for submission to R&D (incl. negotiating updated costs, seeking continued support from support departments, localising documents, superseding previous versions, preparing submission pack for R&D and implementation email to SBRU team)
Amendment Training Fee	£81.00	Per delegated member of staff/per amendment	Training fee for every delegated team member who joins the study after SIV session to familiarise themselves with protocol/IB requirements; to be invoiced also after every amendment when training required
New staff member training fee	£81.00	Per delegated member of staff	
Safety call attendence	£100.00		preparation and time of attendence
Review of SAE/SUSAR reports and distribution to team	£5.00	per report	
Worksheet Creation	£150.00		Creating worksheet based on the current protocol to aid nursing and clinical team with completeness of data collection for all assessments required per specific visit (source data for eCRF)
Worksheet Amendments	£75.00	per amendment (if changes made due to Sponsor/CRO)	Amending worksheet to reflect changes to schedule of assessments (if applicable)
Refreshments for Patients (applicable for visits lasting over 3 hours)	£15.00	per visit	
Refreshments for Carers (applicable for visits lasting over 3 hours)	£15.00	per visit	
Maximum patient travel costs per visit	£0.00	We should push back on any cap and quote the IRAS form which will say thet they will pay all reasonable travel expensses. If they insist on a cap they say it can be no lower than £250. Contingency for higher costs should also be included if a cap is in place.	IRAS form and PIS says it will pay wih no cap. Minimum of £250 per journey required as we cover a large geographical area.
Hotel stay	£250.00		

Newcastle Approach

Standardised costing template

Conversations with other sites

Cost as if it were a site cost – Where possible

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ECMC Approach?

- Standardised costing template?
  - Minimum requirements for all centres
    - Sharing of local data to compile national template
- Guidance for sponsors as to what EP
- Oncology trials require
  - Info pack – not changes to iCT
- Guidance for sites for NCVR process
    - Use CTC forum?
- Conversations with other sites
  - To reduce site level changes
  - Sharing of information and good practice
- Cost as if it were a site cost
  - Truer representation of costs for CRO/Sponsor
  - Reduce time requirement of site level costing

ECMC Solution?

It's our chance to dictate the process...

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Thank You

Chris Barron and Helen Porteous

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