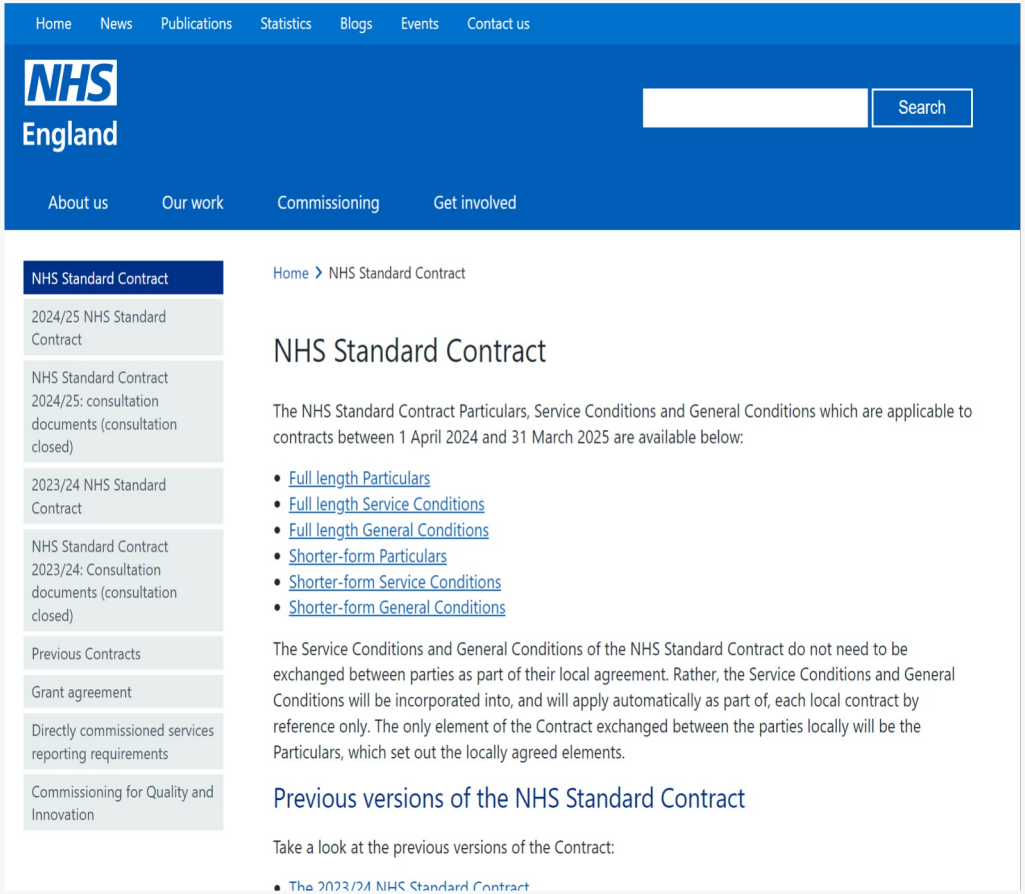
Overview

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.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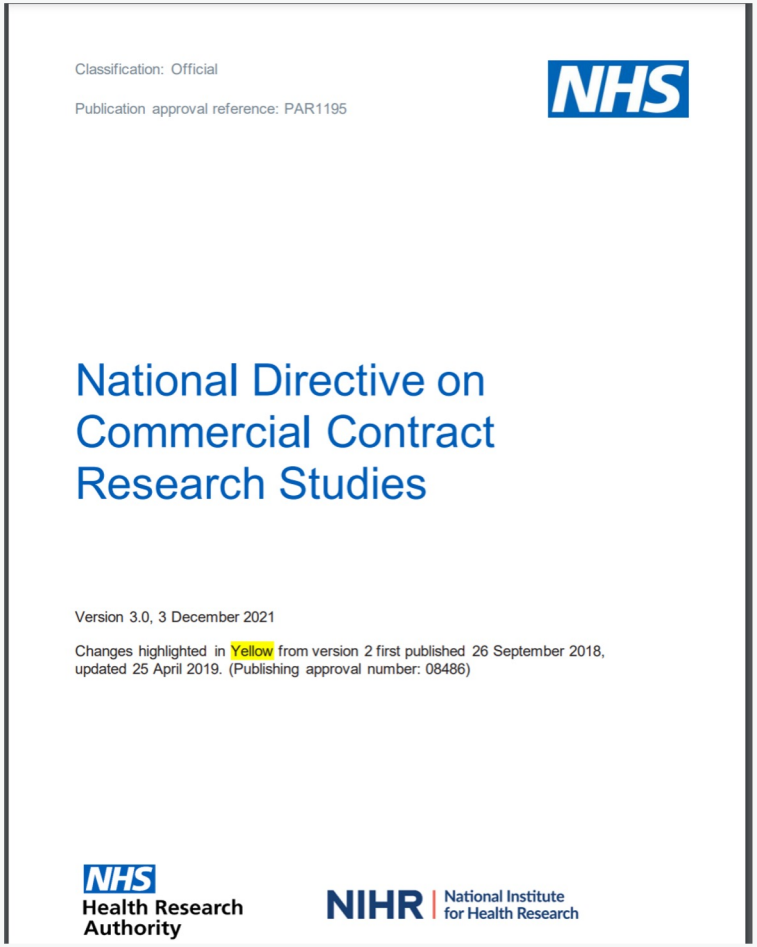
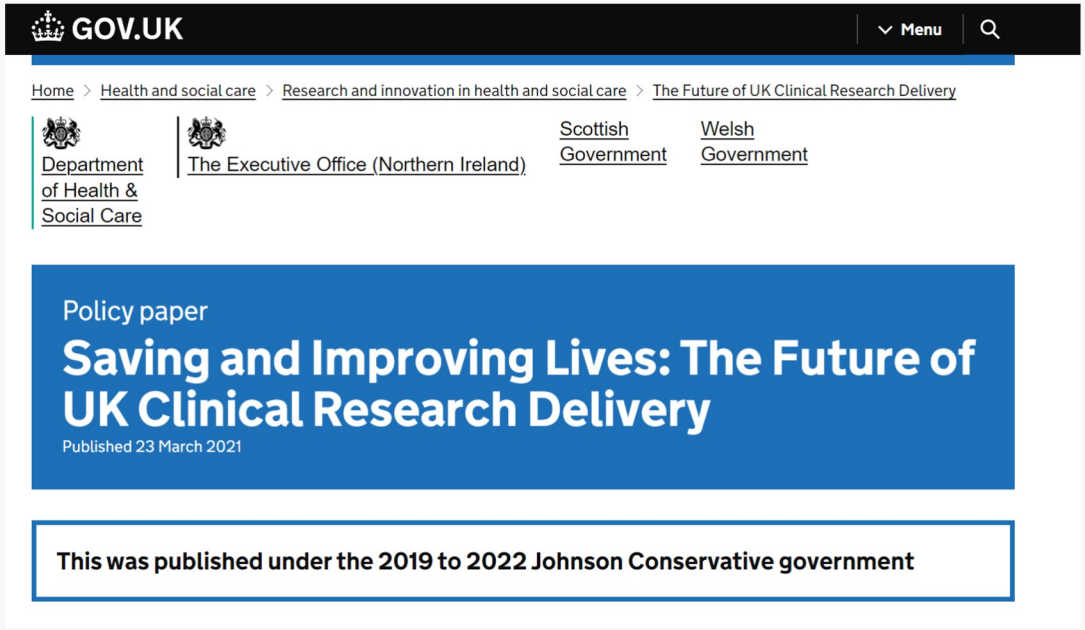
NHS Standard Contract
The NHS Standard Contract Particulars, Service Conditions and General Conditions which are applicable to contracts between 1 April 2024 and 31 March 2025 are available below:
Full length Particulars
Full length Service Conditions
Full length General Conditions
Shorter-form Particulars
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

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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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 ATMP/EP Inclusion

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

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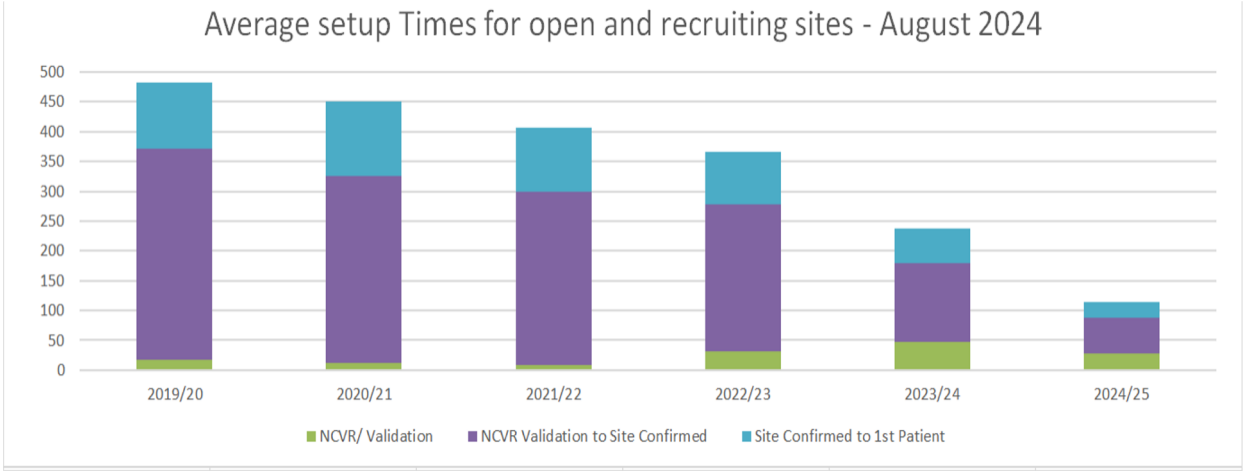
Our process data shows it works - experiences remain subjective

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



Over 1400 study reviews completed

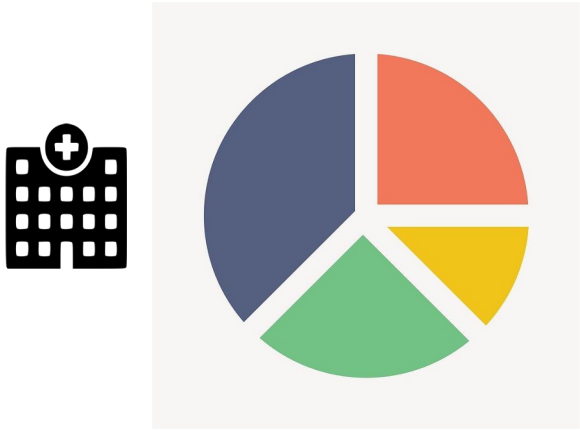
Median timelines is 34 days

80% have had no escalations from sites

Majority of studies with escalations are 1 or 2 sites

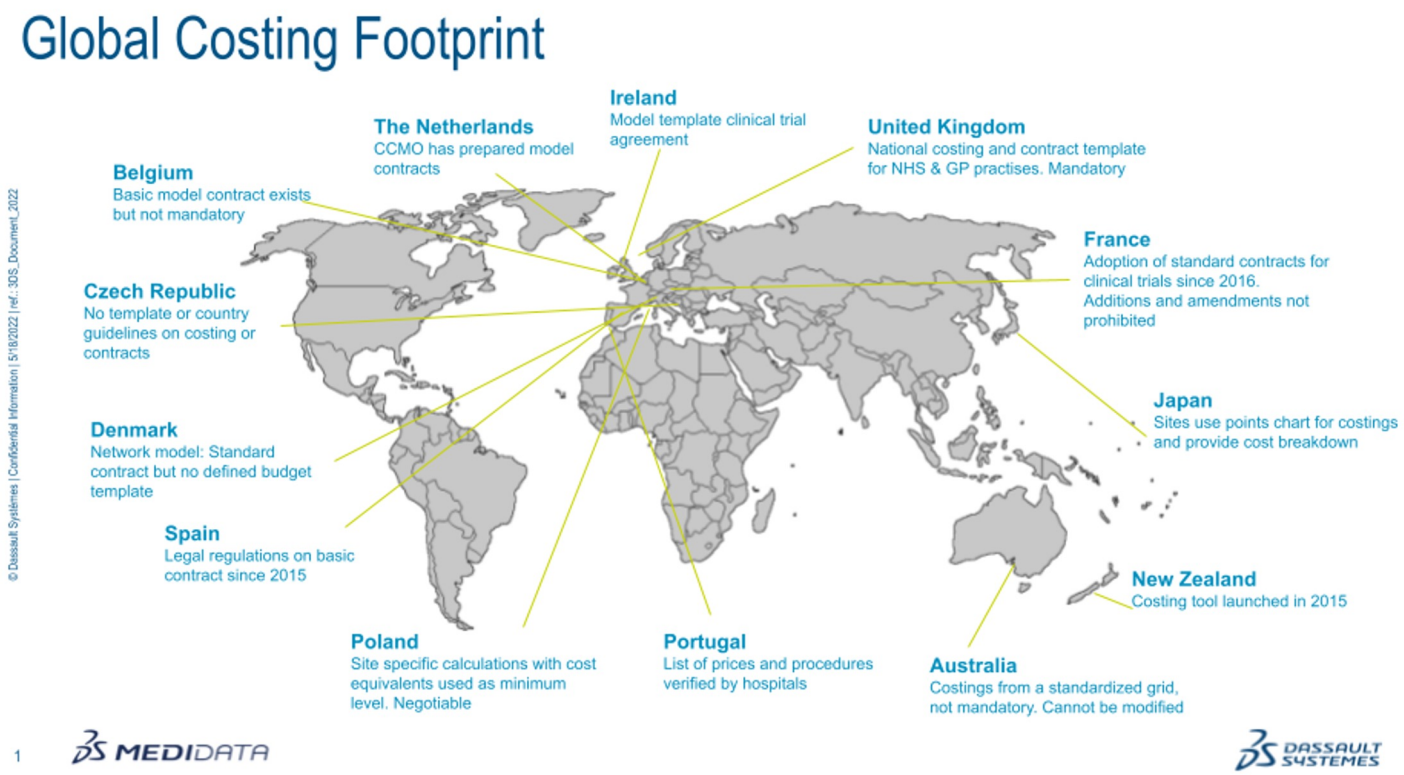
Financial management and internal distribution

Study wide resource
creating a site specific price



Internal distribution models now being
changed to reflect upfront standardization

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



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

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

The Royal Marsden NHS Foundation Trust NCVR Experience

Lee Conneely: Senior Research Operations Manager

24th September 2024

RMH Model

- 14 delivery units by disease
- 40 study resource reviewers
- Disease specific

Our Portfolio

- 980 studies
- 473 commercial studies
- 506 academic studies
- 234 studies sponsored by RM/ICR

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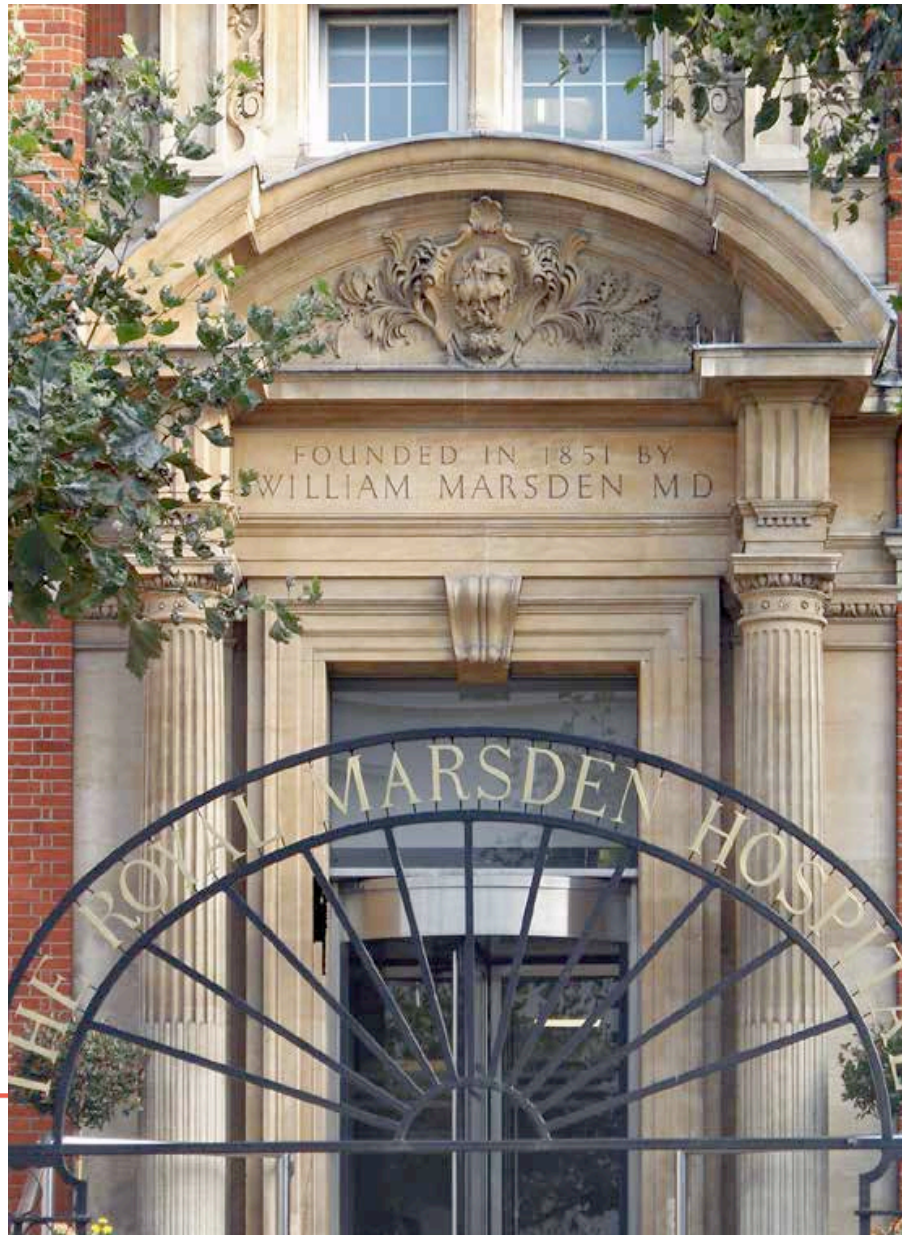

NCVR
Stage 2 Implementation

The Fear is Real

- Loss of control
- Additional responsibility
- Cost recovery
- Workload
- Exam??!!

Feel the Fear and do it anyway

- Trust our collaborators
- Rapid opening
- Abolish negotiation fatigue

How did it go?

- Role out delay
- Silo working
- Study documents
- Tariff
- Escalations
- Volume
- Deadlines
- Laborious

What did we do?

- Training
- NCVR Community of Practice
- TEAMS Channel
- Site Checklist
- Study documents
- Internal timelines
- Head of Research Delivery
- CI Agreement
- Tariff Log

Future Actions

- A central log
- Streamline back fill
- ATMP/EP checklist
- Bespoke reviewer training
- PPI Agreement
- Industry pack

Thank you

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ATMP and Early Phase studies

ATMP/EP Workstreams - Task and finish groups

- iCT
  - Encouraged group members to submit iCT activites
  - Suggest amendments to current iCT lines
  - Possible future iCT interactivity

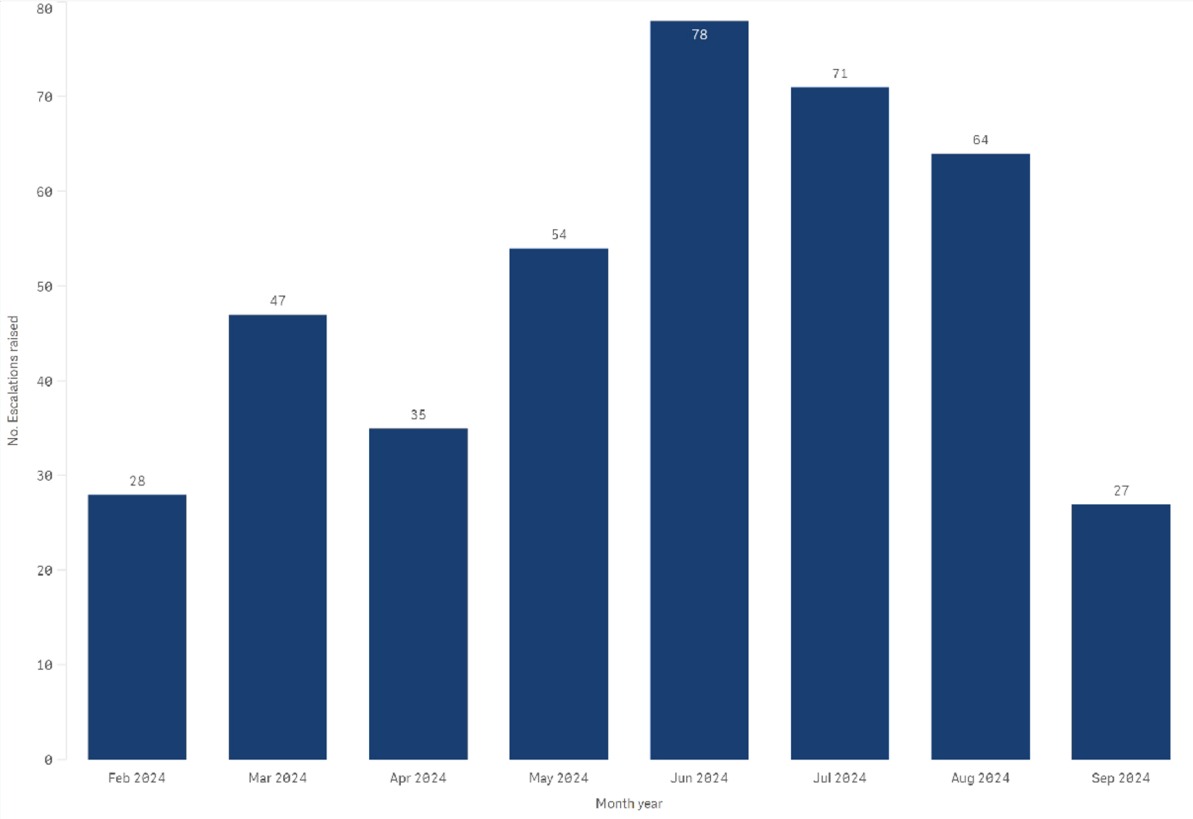
  - +/- 700 submissions
    - Add Update Inadmissible
  - UK Costing group (sept) for addition
  - Ongoing items (OOO) for further discussion

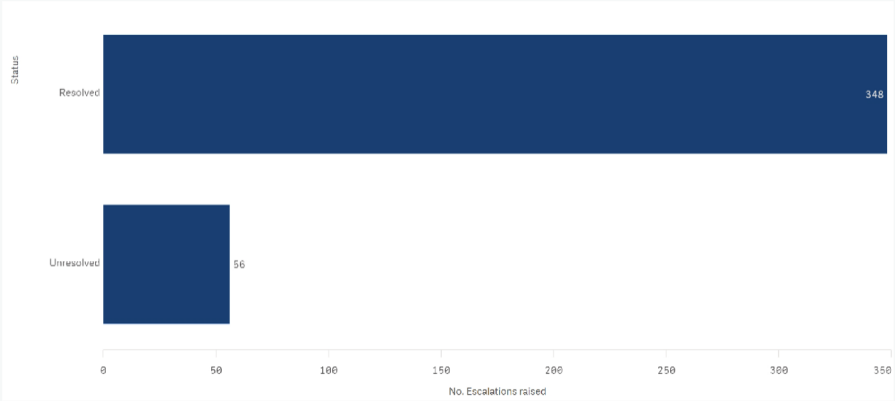
ATMP/EP Workstreams - Task and finish groups

- Guidance and SOP update
  - Review the current guidance, insert new section covering ATMP/EP
  - Suggestions on increasing accessibility and usablitity

- Communications
  - Development of a communications strategy
  - Membership
    - NHSE – DHSC – HRA – NIHR and DA representation

Escalation


80
70
60
50
40
30
20
10
0
No. Escalations raised
28
47
35
54
78
71
64
27
Feb 2024
Mar 2024
Apr 2024
May 2024
Jun 2024
Jul 2024
Aug 2024
Sep 2024
Month year


Status
Resolved
348
Unresolved
56
0
50
100
150
200
250
300
350
No. Escalations raised

Escalation Group

- Escalation
  - Formed a group of NIHR Champions, Resource reviewers, Costing experts and R&D colleagues
  - UK wide membership

  - Experiences of study and resource reviews
  - Solution/suggestions to take through established BAU sign off processes (where applicable)

  - Review and update of the Guidance and SOP (Oct)
  - Review of the escalation timeframe (keep and monitor)
  - Review of the SoE 5% change (needs further discussion and data collection)
  - Increase feedback via the Community of Practice (development of the CoP framework – post Oct)

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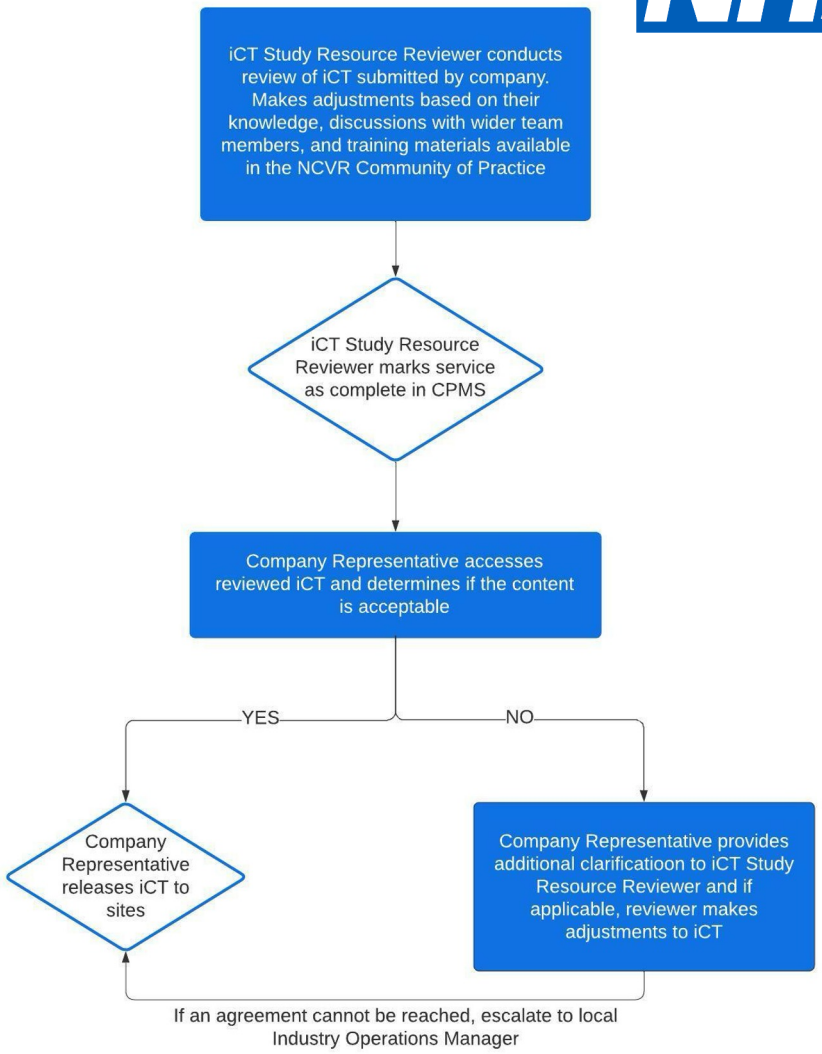
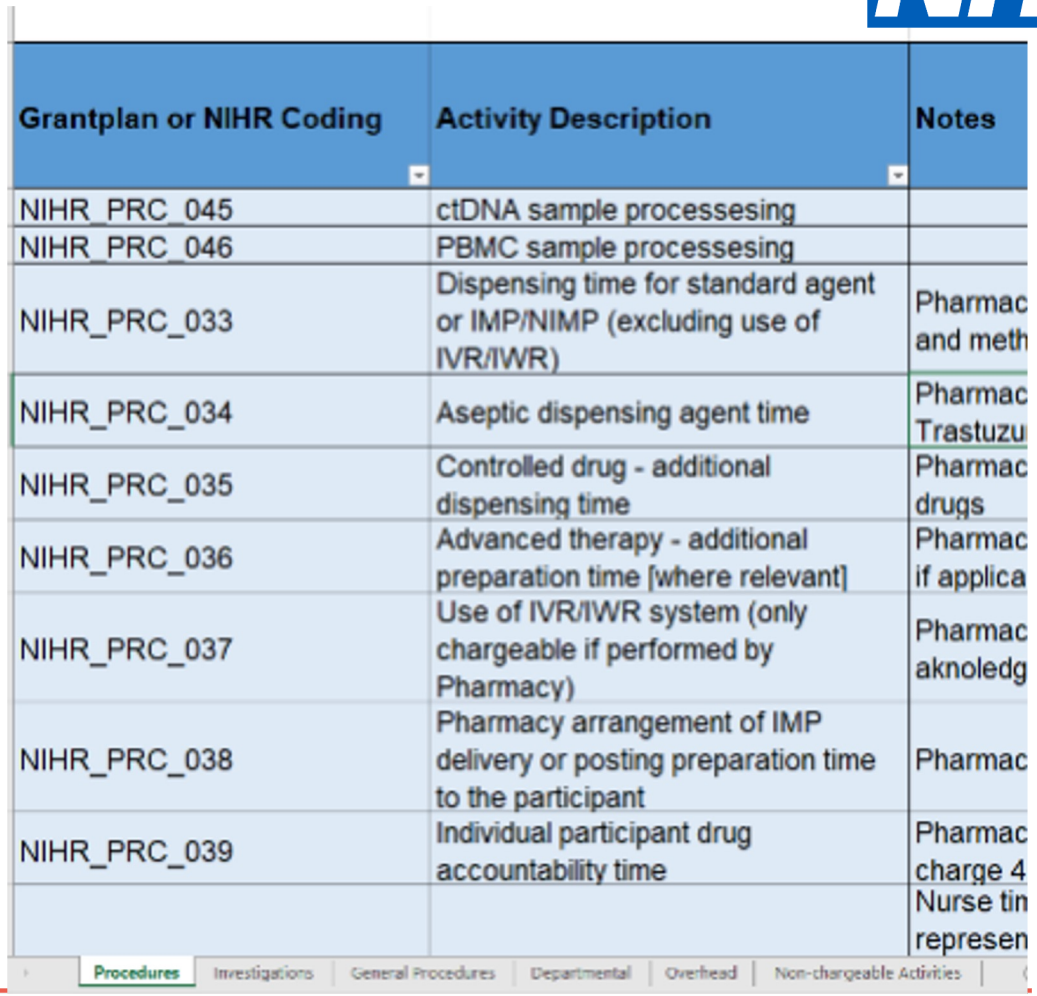
ATMP and Early Phase process

- 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

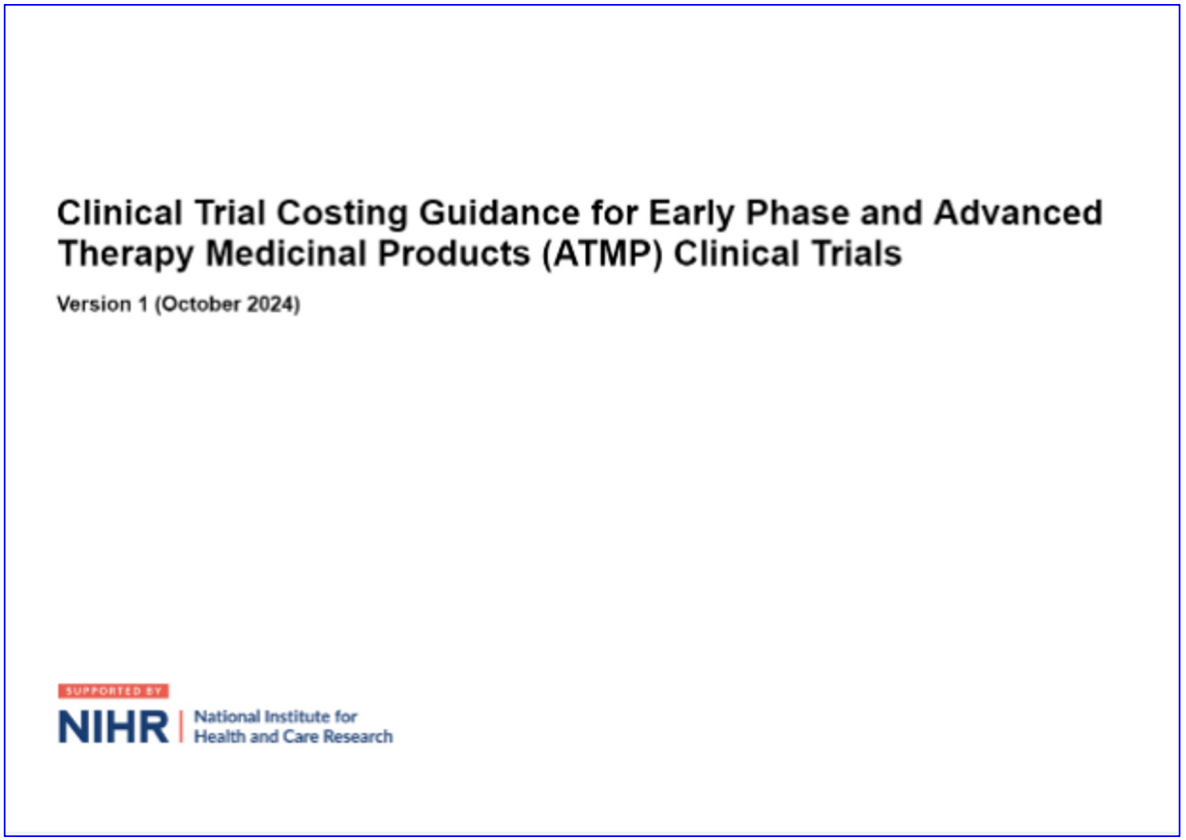


Grantplan or NIHR Coding	Activity Description	Notes
NIHR_PRC_045	ctDNA sample processesing	
NIHR_PRC_046	PBMC sample processesing	
NIHR_PRC_033	Dispensing time for standard agent or IMP/NIMP (excluding use of IVR/IWR)	Pharmac and meth
NIHR_PRC_034	Aseptic dispensing agent time	Pharmac Trastuzu
NIHR_PRC_035	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 tin represen

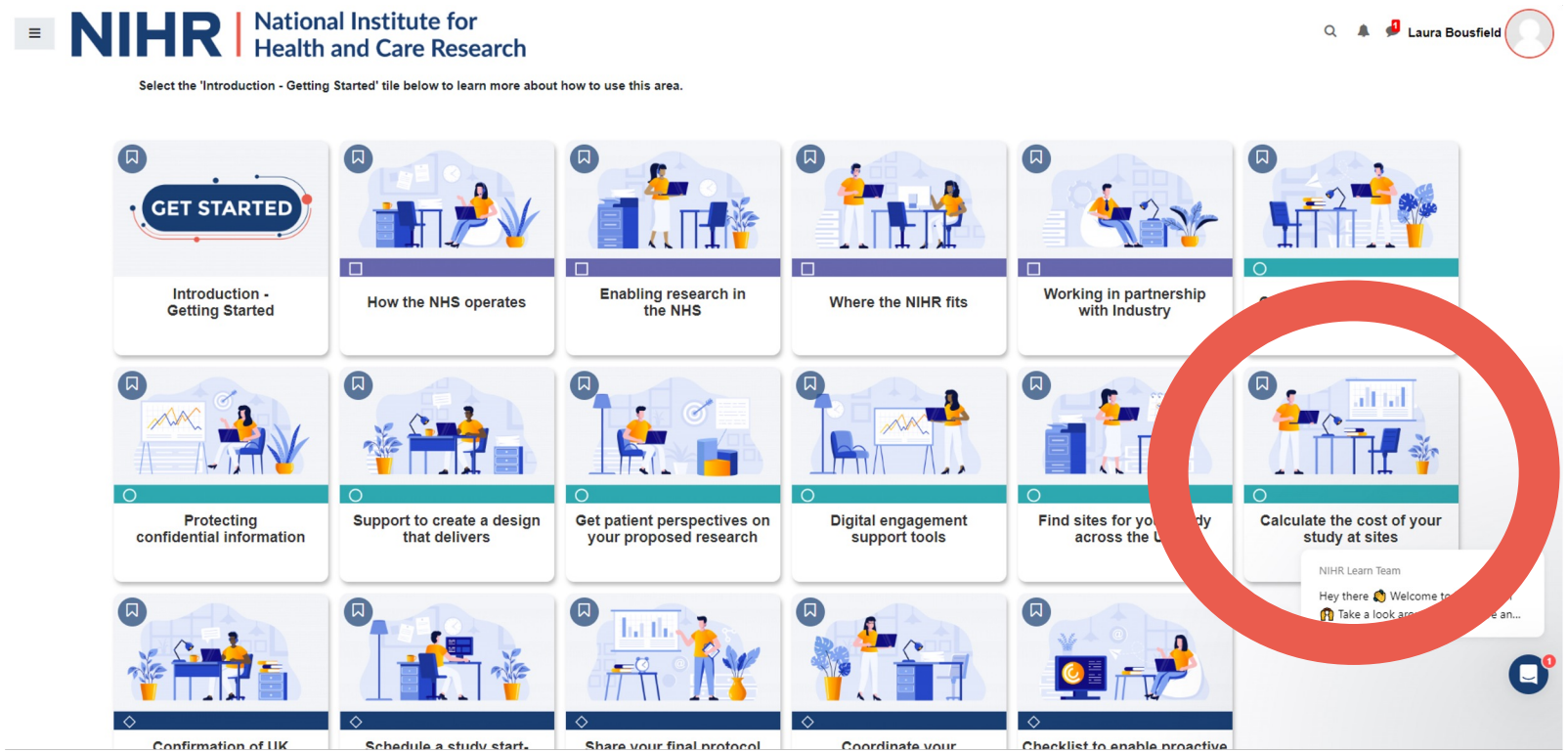
Procedures | Investigations | General Procedures | Departmental | Overhead | Non-chargeable Activities

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

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Questions