



Contracting and Funding in a National Model

By Helen Hodgson



Introduction

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What we want to cover in this workshop

- ⌘ The evolving world of costing and contracting in study set-up in Wales
- ⌘ Going that step further to ensure rapid set-up of COVID-19 vaccine studies & piloting for the future
- ⌘ Overview of costings and contract templates that underpin the process
- ⌘ New strategy & ways of working across the UK for costs and contracts

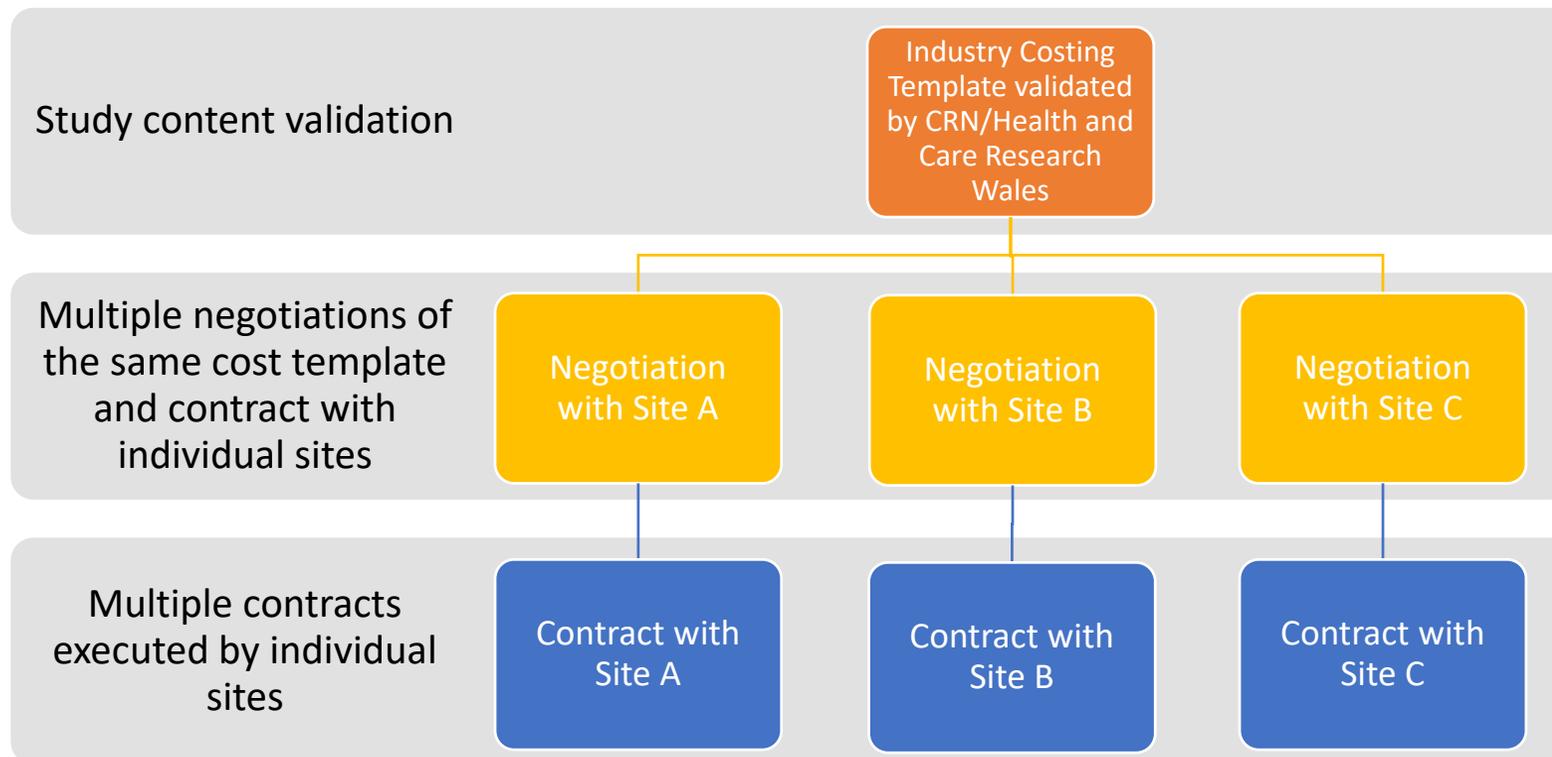
What delays have you had in study set-up?

Please enter comments in the chat

Study set-up & delays

Main factors that delay study set-up is contract and costings

Previous costings & contract review process



Improving costings and contract reviews

Health and Care Research Wales infrastructure worked together to develop a One Wales costings and contract (1CC) approach to:

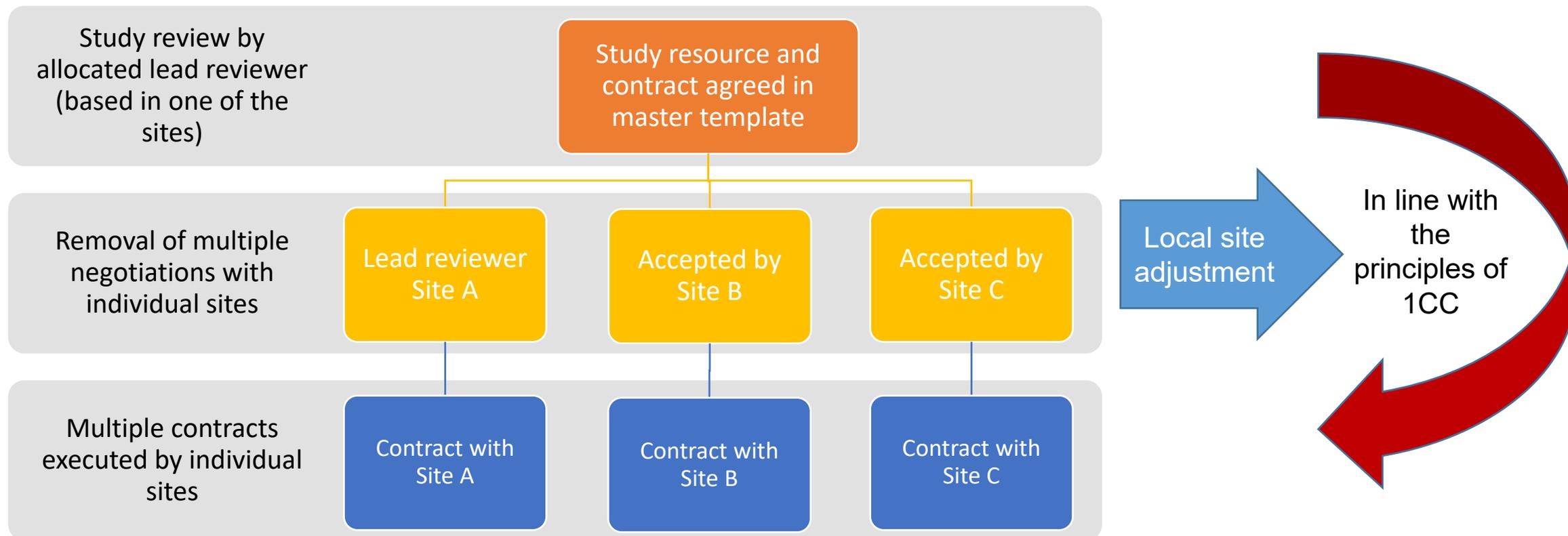
- ⌘ Increase the number of multi-site studies in Wales
- ⌘ Allow research studies to be set up across Wales as swiftly and as streamlined as possible

One Cost, One Contract

This model brought together three key elements:

1. Lead reviewer who undertakes a collaborative review on behalf of all sites
2. Mandated the use of a **commercial site agreement**
3. Implemented the use **standard costing methodology** present within **interactive Costing Tool (iCT)**

One Cost, One Contract model



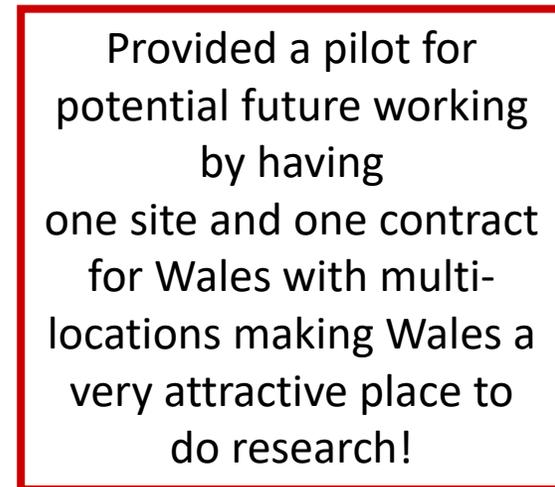
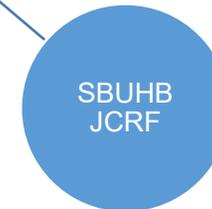
Regional approach - Hub and Spoke during COVID- 19 vaccine trials

- ⌘ 1CC approach and one site for Wales (Public Health Wales)
- ⌘ Development of the vaccine hub
- ⌘ Site Agreement, one PI
- ⌘ Locations delivered studies through a pass-through via a Service Level Agreement (SLA) - UK wide initiative
- ⌘ UK-wide SLA template developed by Wales

Wales 'regional' vaccine research delivery model

Costings and contracts:

- One site Public Health Wales
- One point of contact for costs & for contracts
- One costs agreed via UK validation with local adjustments where agreed
- Two contracts: Site agreement Public Health Wales and Sponsor (and CRO), a pass through Service Level Agreement to the service provider
- One PI with local PIs and Sub Investigators for each trial
- Contracts and costings teams in Health and Care Research Wales working closely together with Public Health Wales.



Regional approach – Hub and Spoke massive achievements

- ⌘ Rapid set up of the Vaccine Hub
- ⌘ Engagement with Sponsor and CRO - acted as one point of contact for costs and contracts
- ⌘ Accepted with confidence by Sponsors

Regional Approach – Hub and Spoke massive achievements

- 8 Working as part of the UK effort
- 8 Agreed the costs and contracts and set up for the first vaccine trial in **less than one week!**

One Wales approach Benefits to Sponsor/CI

- 8 The process may still feel a lot of effort behind the scenes
- 8 Focusing on the sponsor experiences/perspective, the one Wales model is highly beneficial:
 - 'One' slick front door
 - Set-up quicker
 - Amendments agreed quicker
 - Making Wales an attractive place to do research

Tools that underpin the one Wales & UK-wide way of working now and in the future

Contracts Current Model Agreements Overview

Current suite of Model Agreements:

- ⌘ mCTA/ CRO mCTA (January 2021)
- ⌘ mNCA (January 2021)
- ⌘ Primary Care mCTA (January 2021) Bipartite & Tripartite Agreements
- ⌘ OID
- ⌘ PIC Agreements (Commercial and Non-Commercial)
- ⌘ mCIA /CRO mCIA
- ⌘ MICRA

Contracts new templates in development

New templates being developed within the Four Nations
Contracts Group for 2021 release:

1. CDA (site specific)
2. Stand alone DPA (Commercial and Non Commercial)
3. ATMP mCTA
4. Non-Interventional Commercial Agreement (mNICA)
5. MTA
6. Third Party Provider Agreement
7. Central Technical Review Agreement

Costings tools overview

- 8 Interactive costing tool for commercial research
- 8 SoECAT for the validation of attribution for non-commercial research

Single contract value review

- ⌘ A UK approach to costing and contracting for commercial contract
- ⌘ Further Improving consistency and standardisation of costs
- ⌘ Increasing the speed and efficiency of research set-up
- ⌘ Feeds into a nationally coordinated Study Support Service
- ⌘ Required to deliver several of the UK-wide actions as part of the Recovery, Resilience and Growth (RRG) Programme

Thank you!

Any questions – please put in the chat