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

- Study content validation
  - Industry Costing Template validated by CRN/Health and Care Research Wales
- Multiple negotiations of the same cost template and contract with individual sites
  - Negotiation with Site A
  - Negotiation with Site B
  - Negotiation with Site C
- Multiple contracts executed by individual sites
  - Contract with Site A
  - Contract with Site B
  - Contract with Site C
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 of standard costing methodology present within interactive Costing Tool (iCT)
Local site adjustment

In line with the principles of 1CC

One Cost, One Contract model

Study review by allocated lead reviewer (based in one of the sites)

Removal of multiple negotiations with individual sites

Multiple contracts executed by individual sites

Study resource and contract agreed in master template

Lead reviewer Site A

Accepted by Site B

Accepted by Site C

Contract with Site A

Contract with Site B

Contract with Site C

Study resource and contract agreed in master template

Local site adjustment

In line with the principles of 1CC
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.

Provided a pilot for potential future working by having one site and one contract for Wales with multi-locations making Wales a very attractive place to do research!
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

- Working as part of the UK effort
- 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

The process may still feel a lot of effort behind the scenes.

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
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

- Interactive costing tool for commercial research
- 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