MEDIDATA

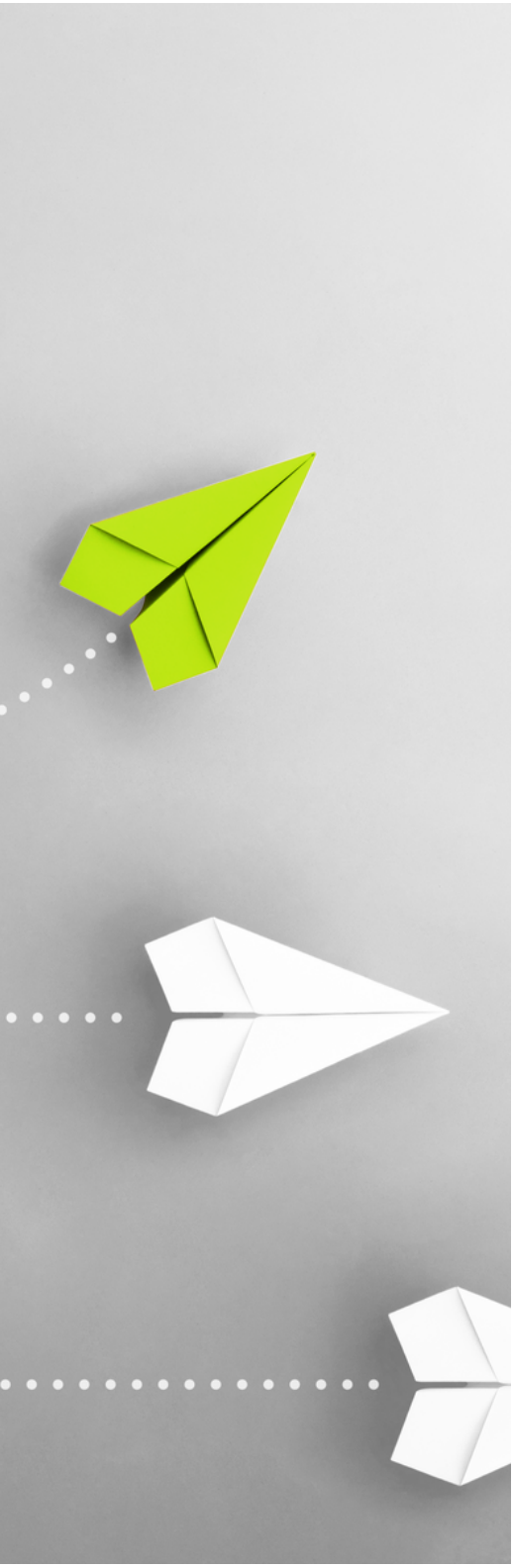
POP

Power of Partnership

ISSUE 07

POP is devoted to providing transparent and collaborative clinical trial financial management news

POP ISSUE 07 CONTENTS



POP VOICE

Interviewed by Tina Mincher

The Evolution of NIHR's Interactive Costing Template (iCT)

The future of UK clinical trial budgeting is looking very bright. With the advancements and ever-growing need for country-specific costing templates, CTFM was lucky enough to talk to two of the NIHR trailblazers

Laura Bousfield, National Head of Feasibility and Startup at NIHR, and **Phillip Good**, National Study Startup Manager at NIHR Clinical Research Network Coordinating Centre to get their story on the incredible journey with the interactive costing template (iCT). From its humble beginnings with the tool being used just for best practice to the present day with a no local negotiations approach. It has certainly come a long way.

Can you give some background on how the tool was created and how far it has come?

Bousfield: The Excel template was initially born out of the 2006 Cooksey Report, an independent review of what the Government in England and across the UK could do to support and attract life sciences research. The recommendation was having a national approach to costing, so being transparent and predictable about costs. Healthcare in England is a publicly funded infrastructure so puts us in a unique position.

Laura Bousfield, NIHR

With so much data and intelligence it allows us to be quick and benchmark ourselves across the country. In October 2023, in line with another independent review, the Lord O'Shaughnessy review, the tool moved to a revised methodology. It has taken a good 15 years to bring people on the journey, yet this is not the end of the journey, we can now develop further. There is a great quote 'beyond the mountains, there are more mountains."

"Beyond the mountains, there are more mountains."

-Laura Bousfield

The National Contract Value Review (NCVR) with NHS England and Improvement has been working tirelessly to improve and build trust when using the costs within iCT. When asked about the accuracy of the data, 75% of sites agreed the costs were acceptable and the other 25% there were some minor tweaks on a line-item level. This must make you proud that there is such a transformation with the iCT.

Good: Absolutely, we put a lot of effort into engaging the stakeholders, getting feedback through the right channels, and then having others verify. The iCT is not the sum of one person.

Phillip Good, NIHR

It is not Laura or just me, it is a sector-wide tool with a multi-stakeholder governance group. Each stakeholder representative can bring an idea and then the others will rubber stamp it and say yes or no, that is how we improve the tool collectively. Everyone is equal and it has to be for it to be a success. There are many different points of view and we do have debates; people do not just roll over and accept what is suggested if they feel it will not bring value. We love contributions.

It is important to get the voice of the user into the systems. Is there a way iCT users can send feedback to NIHR?

Good: It's so easy to send us feedback via our online form and we look at everything that is sent so please send us your ideas as this improves the tool.

Bousfield: We are always open to feedback, the iCT feedback gets reviewed twice a year and looks at what is required. Even when we do get suggestions that might have already been covered or misunderstandings of how the tool operates, these still give us a better understanding of what and how we can better communicate. Every piece of information is used. My one request is please give feedback, we want this to remain a tool that is developed in partnership with all the users interfacing with it. We are working very hard with the NHS organizations to drive a sense of ownership with the tool. There is also the user interface with life science companies. This tool is globally unique in terms of having it built in the same system with all our other national services, for example, site identification and so feedback around how we can make this transition smoother or how we help global studies to accommodate a countrywide tool with a countrywide contract is valuable.

With the number of countries delivering research well across the world, we are trying to understand how we can improve. If we don't hear about it, we assume no news is good news. UK interactive Costing Tool Feedback

What do you see for the future of iCT?

Good: What isn't the future of iCT? It's always progressing, we are always looking to see what we can do next. When we built iCT we built it as a continuation of the Excel so it was built as a set of guidance values with a set of tables, to help you negotiate. I didn't foresee when we built it that we would be at this point now moving from being guidance values to now being mandated values that NHS organizations must accept.

One thing we would like to facilitate more is the engagement with industry, requesting services that we can facilitate. For example, the iCT collects a lot of data and we could use that data in order to find out where the sites that did a study are similar or a certain clinical area of a particular therapy. Why can't we make it into other things? What I would love to do, and this is where my heart is, is to use it as an educational tool. So rather than saying to someone here is a blank sheet, fill in this, and here is a training video what you actually say is what would you like to see? How big is your study? How complex is your study? Are you using a drug or a medical device? Are you doing a central lab? How long will the study run for? If you answer all those questions, it could prepopulate the pricing data. The better the data gets the more these types of enhancements become possible, and the user is using a system they have confidence in. The next stage is making it more service-orientated.

There is so much data available within the tool would there be the possibility of creating an iCT Dashboard?

Good: I created a dashboard earlier in 2023 where all the data was exported into a big spreadsheet, and I looked at how much was useful and what was junk. It was really insightful.

Bousfield: Making the content visible and digestible, building on what Phil described as an education piece, is one enhancement. Given we have a costing tool with information about their study, we could use it as a springboard to suggest other services or to promote innovative approaches for research delivery. For example, one of the new things we have in England and the rest of the UK is around digital recruitment, where patient datasets across the country are available through various other national bodies, sister organizations to the NIHR. The iCT gives us the springboard to highlight what is available and promote it. A big initiative is to highlight other areas and support users to think differently. The dashboard is testing out how we make information more visible; for example, how we can make it easier to see what organization access to an MRI scan has because it's based on who was able to cost it. Currently, we are using the dashboard to support the no local negotiation of prices, trying to minimize the back-and-forth queries about how the costing methodology works and try to handle that through tools like the dashboard.

There is definitely a way to use this information for site selection and what is close to my heart spreading research across the UK. Phil is based in London, and I am in the north of the country. There are vast differences, where many health and inequalities take place. We want to think about more than just the price and think about informed decision-making to deliver culture changes that we want to see to deliver research to everybody who needs it.

Will the tool be linked to Grants Manager; it is obviously preferable to use one tool?

Bousfield: Yes, we are thrilled to be able to have this conversation and it's been a long time coming. But we are finally climbing the mountain together. NIHR and Medidata have been working together for many years and both parties understand the importance of connecting the iCT and Grants Manager systems, finally, we are at a stage where this is a possibility. Adding the iCT costs into Grants Manager is a groundbreaking achievement, enabled by this move to a single-price approach across the UK. It is a slow process but one we are passionate about.

How can the users of iCT know when there are updates in the system?

Good: These are updated annually at the start of each new financial year in the NHS (April), and the updates are published on our web page. It would be great to also house this in Medidata's product Grants Manager to bring visibility to all users, so they are aware of new updates and changes. Guidance: Using the interactive Costing Tool (iCT) | NIHR.

As the UK has been such a trailblazer, have other countries asked for feedback and intelligence due to the success of the iCT?

Bousfield: We help bring investment into the UK with initiatives like the costing tool. New Zealand came to speak to us recently. There are colleagues from Germany trying to establish a model agreement, and there is a model agreement in Spain because they have a national healthcare system. We have been involved with many countries-wide discussions; the Nordic countries have taken what we did and supercharged it. So many countries are exploring ways to create their own versions and we love supporting this. It's a win-win for us as it helps normalize the country-wide approach and attract more investment to the UK.

Good: Australia, too; a previous colleague went to work in NSW, and they were asked how they could build their own costing tool and provide the tariff data and how they can do it. It was exceptionally satisfying to see what they created. We are always happy to have these conversations with other countries.

In conclusion, it shows that trust and transparency are the keys to any budgeting system's success. Along with teams willing to collaborate and evolve for the common goal of bringing treatments faster to the patients.

The network is always evolving, so find out what is next for NIHR. To learn more about how the NIHR can support your study's planning, placement, and performance, please contact supportmystudy@nihr.ac.uk or via our webpage. For more about the interactive Costing Tool, on the NIHR website.

To learn more about the work being done with Medidata's Clinical Trial Financial Management and NIHR collaboration, contact tina.mincher@3ds.com.

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INDIVIDUALLY WE ARE ONE DROP, BUT TOGETHER WE ARE AN OCEAN.

RYUNOSUKE SATORO

POP PERSONALITY

Global Costing Task Force

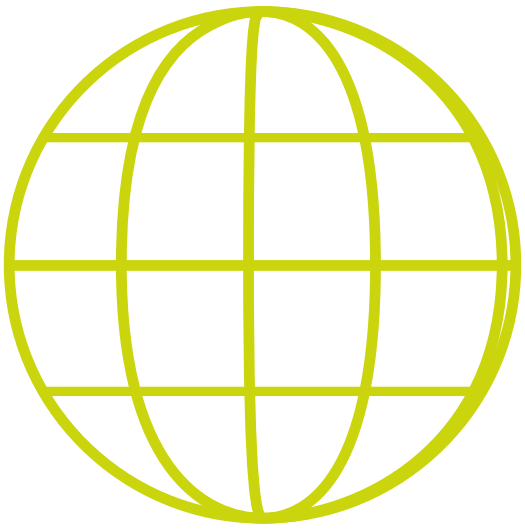
Elevating the global conversation

We are excited to announce that Medidata's CTFM and the UK NIHR have established a Global Costing Task Force.

With many countries striving to bring consistency while understanding local laws and regulation differences, the task force's objective is to bring together industry experts across the globe with the goal of better understanding each other's strengths and challenges.

Through the Power of Partnership, together, we can globally improve clinical trial financial management.

Join the GCTF LinkedIn community



For more information about CTFM's GCTF, contact
Tina Mincher, Director, CTFM Client Strategy at Tina.Mincher@3ds.com

IMPACT REPORT

NIHR Published: 26 October 2023

Commercial study set up times reduced by a third

New NIHR data shows that the National Contract Value Review has significantly reduced the time it takes to set up commercial studies in the NHS.

Commercial studies are achieving study set-up milestones over 100 days quicker.

This increased speed and efficiency of research set-up together with improved consistency in multi-site study costing, bolsters the UK's position as an attractive place for health and care research.

The NCVR process, is the UK's standardised, national approach to costing and contracting for commercial contract research. It is a UK wide programme led by NHS England in partnership with DHSC, NIHR Clinical Research Network, the Health Research Authority and the devolved administrations, for the benefit of patients and the public.

Positive results from phase one of NCVR are encouraging news as stage 2 of implementation commences this month.

Quicker set-up times

Within the last 12 months, over 600 studies have had a national review completed and over 60 have gone all the way through the set-up process. This means they have had a national review conducted, opened to recruitment at participating sites, and participants have been enrolled in the study.

An analysis of these 60+ studies confirms that:

- Set-up times are over 100 days quicker and as much as 185 days quicker when compared to the pre-pandemic data for 2019/20.
- When compared to the 12 months prior, the average time from initial costing submission to the date of the first participant consenting to take part in the study, has reduced from 305 days to 194 days; a reduction of 110 days or 36%.

Analysis of the data will continue as more studies complete the NCVR process.

Laura Bousfield, National Head of Feasibility and Start-up, NIHR Clinical Research Network said:

“This analysis demonstrates the efficiencies that can be achieved with a system-wide costing tool and model agreements; reducing not only time but resource and duplication of effort. With the next stage of roll-out removing modifications, we can continue to demonstrate that this approach removes costing and contracting delays for patient access to research.”

Professor Lucy Chappell, Chief Scientific Adviser to the Department of Health and Social Care and CEO of the NIHR said:

“The impact being made by NCVR is a real positive step for the life sciences industry, for health and care research and most importantly for patients and the public. By working closely with our partners, we have made excellent progress in improving the costing and contracting aspect of study set-up times for commercial studies and we will now explore other ways in which we can further speed up patient access to research. The UK is already one of the best places in the world to do research and this latest positive news provides yet more impetus for all key stakeholders, including the life scenes industry, to continue to work with us to drive further improvements.”

Alastair Nicholson, Head of Co-ordination and Standardisation at the Health Research Authority, said:

“We understand how important it is for site set-up to be predictable, consistent and fast. Removing local contract and contract value negotiation and replacing them with standard templates and transparent, up-front prices, is a huge step towards this. NCVR demonstrates what we can achieve when working in partnership with industry, the NIHR, the NHS and the devolved administrations. We hugely appreciate the support of all our partners in bringing about this change quickly, and we are excited to continue working together to make the UK the easiest place in the world to do research that people can trust.”

NCVR stage 2 roll out

Stage 2 of the NCVR which commences from October 2023, brings an end to local negotiation with NHS organisations. This is expected to further improve commercial set up timelines across the UK.

Bringing the benefits of NCVR to ATMPs and early phase studies

The NCVR national partners are committed to bringing the benefits of the current NCVR model to the set up of Early Phase (phase I and IIa) and Advanced Therapeutic Medicinal Products (ATMPs) studies. NCVR is being introduced in a small number of ATMP studies to test and refine the process.

Dr Jennifer Harris, ABPI Director of Research and Development policy at the Association of the British Pharmaceutical Industry (ABPI) said:

“We welcome the significant improvements to commercial clinical trial set-up timelines through the implementation of the National Contract Value Review. Standardising costing and contracting is an approach that has been successful in other countries, so we’re keen to see this roll out nationwide. The progress being made here demonstrates that steps forward are being taken in the UK clinical trial ecosystem, helping to rebuild our reputation as a destination of choice. The next phase of NCVR is set to bring even further improvements to study set-up and we look forward to working with NHS England, HRA, NIHR and the devolved administrations on that.”

Bringing the benefits of NCVR to primary care

Whilst the data for stage 1 encompasses secondary care settings, work is also underway to bring the benefits of NCVR to primary care. A national voluntary sign-up scheme for primary care has been developed whereby general practices agree to accept the prices generated by the iCT to develop the evidence and support the wider roll out of NCVR in primary care.

Dr Sam Davies is a GP Partner at West Walk Surgery in Bristol. He has been a Principal Investigator for 30+ studies for South Gloucestershire Medical Research Unit. He has extensive experience of contract and budget negotiation with over 20 different Sponsors. He says:

“The contracts and costings process during the setup of research studies in general practice is often challenging, time-consuming, and has the potential to create conflict at an early stage of a new collaboration between site and sponsor. The NCVR represents a fantastic opportunity for primary care to take advantage of nationally negotiated terms. It should free up site time and expedite study setup, contributing to efficient recruitment and improved relationships, whilst ensuring our work is appropriately remunerated.”

UK wide collaboration

The NCVR focuses on agreeing the resources needed to deliver the study within an NHS provider and uses the UK iCT to generate each NHS provider specific price. 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.

The NCVR is part of the UK programme Saving and Improving Lives: The Future of UK Clinical Research Delivery. Further information on the National Contract Value Review is available on the NIHR website.

HAVE YOU HEARD

RAVE GRANTS MANAGER

Other Direct Costs Enhancement

Additional character expansions allow Medidata to expand the Grants Manager ODC library descriptions to provide accurate and detailed content.

Reference Cost and CPT Update

CTFM annual maintenance to align with AMA CPT and update Medidata internal third-party reference cost sources

Financial Scenario Planning

Grants Manager Financial Scenario Planning is a proactive approach to study budget and forecasting that allows the industry to anticipate and prepare for future clinical study financials. By developing and analyzing multiple scenarios, clients gain valuable insights into the possible outcomes and financial implications.

Rave Grants Manager Knowledge Hub

Rave Site Payments Knowledge Hub

RAVE SITE PAYMENTS

Auto Email Communication

Notifications to Site Payees and Sponsors when Invoices awaiting action

Notifications for Site Payee contracts (SPC) when in Awaiting Approval status and using Site Payee Contract Approval workflow

Email Notifications to Site in Local Language

Localized email notifications (multilingual email - Supported Spanish and Turkish)

Usability Improvements

Improving the usability of the core payments application

Enhancements to Export

Enhancements to Study Costs and Payments export to include additional columns for more relevant information to provide an overview of cost costs and payments

Convera Disbursement Support

Send Withholding Tax(WHT) details to the Payment Disbursement Gateway(PDG) service as a part of the payment extract.

NIHR NEWS

Department for Health and Social Care announces new NIHR Research Delivery Network
The Department of Health and Social Care (DHSC) announced a new NIHR Research Delivery Network (RDN) will commence in 2024 to support the successful delivery of health and social care research in England.

New UK-US collaboration launched to develop early to mid-career cancer researchers
Funding will help place researchers focusing on cancer with leading US cancer research institutions.

NIHR Patient Recruitment Centres exceed targets for set-up and recruitment to studies
Data from the financial year 2022-23 shows that the national Patient Recruitment Centres (PRCs) exceed their study set-up and recruitment ambitions and continue to achieve positive participant experience.

GROW WITH US

CTFM Resources

Clinical Trial Financial Management Resource Page

Join Medidata's Clinical Trial Financial Management team in exploring timely and compelling clinical trial financial news and information.

White Papers

Better Data, Better Decisions

The industry's demand has crystallized: a need for precise, defensible, and agile cost management that seamlessly translates study financial plans into site budgets.

Unveiling Clinical Trial Financial Management Patterns

Managing clinical trial finances has always been complex, but the global changes and challenges experienced since 2020 have compounded existing issues for all stakeholders.

CTFM Innovation Labs

Provide market-leading clinical trial experience and global community through differentiated end-to-end clinical trial financial management. Contact Tina Mincher at tina.mincher@3ds.com to learn more.

For CTFM POP questions, comments, and collaborations, contact Tina Mincher at Tina.Mincher@3DS.com.

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