NHS R&D Forum Response, FINAL VERSION, February 1st 2018.

Supporting Research in the NHS: A consultation covering changes to simplify arrangements for research in the NHS and associated changes to the terms of the NHS Standard Contract

Members of the NHS R&D Forum working groups have written this response.

The NHS R&D Forum is a UK-wide professional network and community of practice for the research management, support and leadership workforce for health and care.

Excess Treatment Costs

We welcome this initiative to improve the management of excess treatment costs (ETC) in England. Members of the NHS R&D Forum have long called for an easy to use ETC system and have taken part in stakeholder workshops and listening events in support of change.

R&D departments in healthcare organisations, non-commercial research Sponsors and host organisations, strive to make good research happen all of the time and we are all aware that finding a UK-wide resolution for ETCS has proved difficult. We are therefore extremely pleased to be able to contribute to this consultation process and to see progress being made.

Following the listening events and stakeholder meetings we believe that, on balance, a radical National solution to ETCS is not the preferred model for change although many of our members have called for this.

Accepting a new National pooling system is unlikely to be supported and carries some risks/limitations we have responded to this consultation in the spirit of improvement. We have made many suggestions for consideration in establishing a new system for ETCS, which we hope are helpful. We note that one of the areas highlighted is the lack of data available to support future decision-making. On this basis we suggest that a well-designed data collection exercise is implemented to evaluate the usefulness of future arrangements.

Commercial study set up

We collectively support the intention to improve the set up of commercial research so that we will be better able to deliver research to improve the health and wealth of the nation. We also support the implementation of a national lead for negotiating commercial studies in England *but we do not believe* there is a need to implement a full one-cost, one contract model with out local input or feedback mechanisms additionally in place, at this time. Please see our response below for further details.

Do you agree with the six design principles we have used to develop our proposals? Y/N please comment

YES.

We agree that any modifications to the current system for payment of excess treatment costs should be based upon the six design principles as specified, however we would expand on these as follows to introduce principles of **pragmatism, flexibility (smart)** and **patient centred** and we suggest a separate set of decision-making principles are also created that will describe how ETC allocations are made at a study level.

1. Capability

We agree that it is unreasonable (and not cost effective) to expect 200 separate CCGS to manage ETC payments for individual research studies and that utilising current infrastructure to support them should improve capability *provided* that the funding itself can be contributed by those CCGs

Access to this element of research funding has proved challenging in places, not least because there is:

(1) A lack of clarity and agreement around ETCS in Tariff at Provider level, including whether this Tariff can meaningfully cover costs at all requiring additional calls on commissioner funding to be made.

(2) A lack of ability to accurately cost for research treatment savings in any one organisation or geographic area.

(3) A lack of understanding that primary, community and mental health care ETCs are not in Tariff, and

4) An ever-present tension that ETCS must compete with other immediate clinical commissioning priorities at CCG level.

We suggest it may be challenging to access ETC funding contributions from CCGs in the current financial climate and there is some concern amongst CCG colleagues that there will be double counting of funds provided if activity can't be separated out. For example if all blood samples are charged to a CCG as normal care and some of them are ETCS but not identified as such at provider level, the CCG will effectively have paid for these samples twice. There should therefore be clarity over recording and reporting on ETC spends at provider level to account for this.

ETC funding may not be easily identified in CCGs budgets therefore it would be wise to build on existing expertise and pockets of existing good practice to bring CCGs on board with these changes.

We propose that that clear communications around Tariff *and how they link to thresholds* will need to be made (see our later comments around the thresholds). We do however see benefit in separating and pooling the resources - funding will be easier to manage for treatment costs that are part of research, and we welcome the chance to provide clarity around funding capabilities. Hopefully the minimum threshold will make it clear what is considered to be within the current funding envelope/in Tariff, and when an extra contribution from the CCGS is required to support ETCS in Provider Trusts. There is some disagreement between Providers and Commissioners on this point and some CCGS believe there is not a problem to fix here. Whilst it is true that some Trusts do managing a high threshold for ETCS in their organisations this is not the case across the country and many organisations will not undertake research with ETCs as a result.

Understanding AcoRD and the nuance of current health research funding policy is not something that one can reasonably expect 200 CCGS to take on individually with consistency and confidence, unless they come together as a group to provide this. We know good research support for CCGs does exist in places across the country for the provision of ETC funding in community and primary care research (see Avon Primary Care Collaborative for an example of this in practice) but that this is patchy and inconsistent across the country.

Examples of successful CCG pooling for ETCs have already been cited in the consultation document and members who have responded here shared some experience of these. We are therefore optimistic that this can be achieved, please see our additional comments on risk pooling for further consideration.

We are aware that some Forum members would go further and call for a centralised National solution to ETC management however we understand that this may not be something that can be afforded and would require a new layer of infrastructure to be created. As a step towards improvement therefore we agree that good utilisation of existing systems and current capability seems to be a sensible solution to a currently complex system. It would also have the additional benefit of enabling local insight through close partnership working with providers and commissioners.

Please see our comments below on LCRNs as a mechanism for improving capability for ETC funding allocation.

2. Consistency

We acknowledge and agree with the imperative to improve consistency in study set up and delivery across the UK. Consistent, streamlined approaches to research management should make it easier to run and deliver research, which is good for patients and for science and improvement.

We agree for the management of *ETC funding* that the whole country should follow the same system **because we believe the cost of the current variability and complexity is too high**, particularly in terms of research waste and patient opportunities.

We stress however that consistency should not necessarily mean 'one size fits all' or be at the expense of simple, common sense solutions, and that decisions can be based upon principles that are consistently applied. Consistency is indeed required right now and this should be in addition to an improved ability to make good decisions where it is sensible and pragmatic to do so. We should be mindful to create improvements that are also both **pragmatic** and **smart** and we suggest incorporating these into both design and decision-making principles.

ETC management is currently particularly complex. Discussions around funding are often too far into the research project pathway such that challenges disrupt and cause waste. Whilst consistency across the UK is absolutely fundamental to supporting research and in particular multi-centre projects, we would like to see a mechanism that also enables some flexibility for payment of ETCs at project level that is inline with principles of good practice and not to do so may risk these studies being 'parked' or rejected by sites. This could be achieved through a local decision-making mechanism or a national escalation process but either way the aim should be to ensure particularly difficult or complex cases (not necessarily the most expensive studies) are enabled and unblocked readily where appropriate. Ideally ETC arrangements for multi-site studies should be agreed with the Sponsor in advance of site roll-out.

Cost neutrality

The creation of any new system should not cost any more for the NHS if there is (a) not the money to pay for it and (b) that new system is not worth it.

In this instance we are hopeful that in unlocking some of the current complexities for managing ETCs we will make relatively large gains for limited extra infrastructure cost, whilst at the same time making savings in waste and administration. As things stand it is particularly challenging to argue for the release of funds to support research treatment that is a cost pressure, when those cost pressures are competing with other clinical commissioning priorities on the front line. We are therefore supportive of ring fencing funds to help reduce this tension but this should not mean, and it is not the same as saying, high value research must not increase the cost pressure to the NHS.

We do not believe that reducing the total cost of ETCs is the absolute aim of the proposals here for we don't know what research is going to come through the system in the future. Some research may be high cost but of particularly high value to patients and public health and we therefore argue that:

(1) We should strive to ensure the cost neutrality of the *infrastructure*
(2) That any new system should not create more research waste or create additional bureaucracy
(3)That it should not make it any more difficult for research to happen
(4) That it should not destabilise clinical care.

In the current climate there are concerns that creating ring-fenced budgets assumes there is the funding currently identifiable and 'extractable' in the system to pay for ETCs. Whilst theoretically this is true there is not a defined budget currently or meaningfully in place for ETCS that cost more than the Tariff or for ETCs outside of Tariff. We should therefore perhaps be transparent about this and be clear that by meeting ETCS, other clinical commissioning priorities may not be supported in the absence of additional funding. There will be a cost pressure somewhere in the system and becoming wedded to the principle of cost neutrality may prevent the case for further funding in the future

We agree that the new system of managing ETCS should be cost effective and we are hopeful that a new clear and transparent system of communication between funding partners will support this.

More studies might also go through the system in the first instance and create a cost pressure where they might otherwise have been 'stuck' but this does not mean they ought not to have been previously funded. We are unclear if this would be considered cost neutral but plans should be in place to fund an escalation in studies applying for ETCS in the first instance.

Some research produces treatment costs savings (ETS) and it is not clear how these should be best taken into account here. The new ACAT schedule of events will ensure ETS are identified early on but there may still be a locally specific cost pressure. It is also not clear how we should best manage, record and demonstrate ETS within organisations and further information on each of these points would be welcome.

Simplicity

We agree that simplicity is an important principle to achieve wherever possible. The current system for the management of ETCs is far too complex and extremely difficult to navigate. Research is also complicated to design, manage and deliver and so anything to reduce unnecessary complexity is welcomed.

Single (visible) point of access

Reducing complexity, improving simplicity and creating consistency should improve the system and ensure there is clarity for researchers, research participants and Sponsors of research. Above all researchers (and research managers and support teams) often do not know where to go or who to talk to for ETC funding when they get to it. As with the consistency principle this does not necessarily need to translate into one single point of access but should certainly ensure a clearly defined route or pathway for entry into the system. We do not take any issue with this principle however a **visible** point of access is also as important.

Transparency

All decisions made should be transparent in line with agreed principles of good practice. This should improve consistency across the country and ensure patient focus. We agree that a lack of transparency in decision-making, prioritisation of funding and budget allocations currently frustrates the process. Transparency is a principle that all health and care systems should embrace.

Patient and Public Interest

We are reminded that any health and care system should have **patient and public** wellbeing at it's core and that it would be valuable to include these in the design and decision-making principles. Any new system and the principles upon which it is based should ultimately work well for patients and add value rather than duplicate with additional layers of bureaucracy.

Example:

One member described a scenario from some years ago where a study had been stuck on their desk for some months due to ETC funding issues. The ETCs were of relatively very little financial value in comparison to the patients total cost of care but they could not get agreement to fund it because of the 'rules' around which pot it should come from. Thankfully NHS R&D has become more enabled and integrated with clinical care over recent years such that a good R&D manager is now better able to try and make things work, however in this case the patient was sent for their treatment (in an AML trial) to another local hospital that was very much further away from their home. This was clearly not in the patient's interest and our member was keen to emphasis this as an example of how a patient-centred principle might be applied.

Design principles vs. decision-making principles

It might be worth separating out a second set of decision-making principles for ETCs that embrace the design principles but which have a different focus. For example cost neutrality should not perhaps be the principle used for ETC funding decisions although it is a clear consideration in the design of the system itself. It should also be clear who could make these decisions and if it is to be LCRNS there should be clear procedures for oversight and accountability with involvement from CCG representatives (see further details below)

We received a number of comments also around threshold 'gaming', and so a flexible, sensible set of decision-making principles around which decisions can be made consistently might go some way to help to address this challenge.

Partnering with 15 NIHR Local Clinical Research Networks (LCRNs) to help manage the ETC process on behalf of their local CCGs

• Do you agree that ETCs will be better coordinated by LCRNs at sub regional level with a single point of contact rather than managed by CCGs individually?
(Y/N/ Please comment)

YES

On balance those members who contributed felt that **managing the funds/budget** via the current 15 NIHR LCRNS would improve consistency, simplicity and bring clarity for all, whilst utilising existing infrastructure and research capability across England. As outlined above, some would prefer a centralised national solution but in the absence of funding for this we agree that utilising current regional research-based systems for the administration of funding has many advantages and may help to map onto STPs in the future.

We are mindful that managing resource identification also requires local knowledge, that is part of capability and capacity assessment by both Sponsor and local host organisation therefore this part of the process should be *enabled* by the network team but not *necessarily* undertaken by them where it is more appropriate to do it at a Provider level.

As network support and ETC funding is for non-commercial portfolio studies it makes sense that support is provided by LCRNs however R&D departments must manage all types of research and a clear route map for researchers would be helpful to avoid confusion; studies run in different ways and often across numbers of organisational boundaries and we should therefore be careful to ensure flexibility is built into the system and not create a point of entry that force-fits all scenarios.

Members were clear that transparency in decision-making is essential for this system to work well, and that a mechanism for oversight and escalation must be in place to ensure funding decisions at LCRN level can be reviewed and challenged if necessary. Involving CCGs in any such LCRN managed system and clarifying accountability arrangements for the use of local commissioning money is important.
If oversight for this is indeed to be by CRN Partnership Boards, then these should ensure they have good CCG representation in order to do so.

It is unclear what will happen for studies when the “pot” has run dry and whilst acknowledging that having a pot at all is an improvement, additional calls on the funding might be made (particularly at first) as studies which might otherwise have been ‘stuck’ come through the system.

Part of the problem currently is that CCGs are approached for funding too late in the process causing waste and more certainty should be built into the system to ensure funding decisions can be confidently made. Costing and cost attribution should now be better enabled earlier using the planned schedule of events for cost attribution, joining up with funding applications and review. Care must be taken to ensure this new process will enhance rather than add burden to making grant applications and submissions.

Visibility is critical for researchers to access support services meaningfully and we are already at risk of confusing layers. Many researchers do not fully understand the role of the lead network verse the role of the lead R&D department and in addition to these proposals we should work closely together to make sure this is made clearer for all.

We believe that the complexity of ETC management is such that all partners have a role to play in ensuring a smooth system of access to treatment funding for research. A visible clear point of entry is important to researchers but streamlined joined up systems are even more essential for the smooth running of research.

The NHS landscape is hugely complex and with the development of new organisations, new commissioners of NHS services, and system level organisations researchers should be facilitated through a process where all parts of the system understand their role.

We would like to see some clarity around how non-traditional providers of NHS services are to be included in the system for example, social enterprises, charities and private providers. This is also the case for research involving Local Authority commissioned NHS services e.g smoking cessation services and health related research taking place in care homes and schools etc.

<u>Commissioning review of funding for ETCS.</u>

We understand that NHSE are considering the introduction of a process whereby high value low cost studies are funded through ETCs and that a committee will judge this prior to grant award. Where the committee reject the study the funder will need to take a decision whether to meet the ETCs themselves.

We believe it is right that a national review process should be introduced to support commissioners when creating a budget to be managed on behalf of CCGs, and that this review process should support decision making so that funding is used for research of relevance to commissioners and the NHS. We are pleased to see NHS priorities and needs brought into early discussions around funding allocation however we do feel this should be in *partnership* with funding bodies and not a linear process of one review/committee decision before another. This is because many funders eligible for the Portfolio will already have systems in place to ensure value for NHS patients and although this is not currently a fail safe, it does not seem right to bring one funders decision ahead of another's, prioritising application over science or other means of grant assessment. The practicalities of this system will need to be worked through however our thoughts are currently that it is much better to

encourage dialogue and remove delays in the process, rather than have a stepwise system that prevents learning and quick decision-making.

In short:

- We are supportive of LCRNS managing pooled CCG funds, which we understand is a successful model currently running in Wessex and else where. However we believe more than this is required and efforts should be made to ensure a comprehensive, clear, system-wide pathway is in place in the absence of a nationally administered pot.

- A pooled budget for primary care ETCs would be required as they are not in receipt of Tariff and this is already running successfully in places across the country.

- **Systems for transparency, partnerships between commissioner review panels and grant funding bodies, principles for shared decision making, and monitoring and escalation processes are suggested ways to make the above happen.**

- **Plans for new models of care should be taken into consideration at this stage to ensure the system can evolve and deliver in the future.**

• Do you agree that pooling risk across the 15 LCRNs to manage annual variation in ETCs would be an appropriate approach?
(Y/N/ Please comment)

YES from a research perspective however there was not agreement on this when assessing from a Clinical Commissioning perspective.

Many members felt that risk pooling was in principle a fair way to enable equitable access to research for all and that it ensures some CCGS are not penalised for having more or less research in their patch. Some CCGs however have limited access to research in their population due to geographic location or access to large hospitals or academic centres and there was therefore some concern that risk pooling would significantly disadvantage these CCGs.

Risk pooling from a national pot was also considered acceptable. Some however felt that once funds reach the CCGS and are intended for local patient populations (taking into account demographic profiles etc) it would be unfair and disadvantageous to patients from those CCGS that are paying from their local provision but running fewer studies. This is not an easy question to answer however from a **research** perspective it would be preferable to run the pooling system, supporting more sites to get involved and sharing the burden across organisations. As funding is likely to be limited in the current climate this seems a sensible solution *if* it can be achieved pragmatically (i.e. that the cost of moving and accounting for the funds across the network doesn't outweigh the benefit)

Should risk pooling be introduced then those members from CCGS were clear they wanted some involvement or oversight from the CCGs at the LCRN, perhaps as a member on the decision making panel or board and very clear understanding of terms with regards to when underspent funds might be passed back to those who had contributed.

NB: The language around risk here may or may not be helpful in persuading CCGS of its merit. Pooled funding might be more acceptable as part of their contribution towards research treatments of the future. The actual amounts required to be paid by CCGS who are not currently very research active might be unsustainable in the first instance as these would be very new costs to them and cause undue pressure on other commissioned services.

• Will the proposals outlined work for both single site and multi-site studies? (Y/N/Please comment)

YES

The real gains here are for multicentre studies the funding for which is currently being negotiated with individual CCGS across the country. A Lead LCRN could support access to funding across the network, which is precisely the value a national network should bring.

National agreement on the costing via the new ACAT schedule of events should ensure smoother co-ordination across the country however we believe this is unlikely to work if providers and commissioners do not take a pragmatic 'swings and roundabouts' approach to the real costs, for which some good communications and support would be required. Again systems should be in place to ensure payment for these ETCS are separated out and not charge directly to the CCG as normal practice, creating a double charge.

For such a new system to work the principle of pragmatism really needs to come into play as it will be rarely possible to calculate exact ETCS at every locality. A national costing can only ever be a '*best assessment'* based on estimates of standard care numbers of patients randomised to each arm, where the cost is likely to be incurred, and local intelligence from early adopting sites. True *actual* costs to individual organisations may not be known until years later, as many allocations will also be blind.

Therefore much like the ABF funding it should be made clear from the outset that payment for ETCS cannot always be for exact costs of treatment and that funding will not be a direct '*pass through'* model, as it isn't for service support cost funding via ABF allocations.

However whilst this message is a pragmatic one it will be undoubtedly easier for those Trusts with larger 'buffers' and it will be a much harder message for smaller organisations in the current financial climate. Some costs are incurred at a local level where there is actually a study-wide cost saving (so a local ETC but a study-wide ETS) which makes undertaking the study very difficult if the there is not the money at the site to meet that cost. This needs to be enabled and managed carefully to ensure sites are able to take part.

Clarity in language around whether a local cost pressure is the same as a study-wide ETC is important and a whether ETC funding will be available through the new funding mechanism to pay for them where costs are incurred by different organisations involved (not just the one running the study)

In summary a national costing from a pragmatic 'general' perspective will possibly enable more research to be funded for ETCs but we should be honest that it will not fund exact costs and there are often very clear differences in clinical pathways.

For ETCs we feel the current complexity probably warrants a pragmatic, '*swings and roundabouts*' approach to funds with the following caveats:

(1) That there is support for R&D management teams who must report back to their organisations on the costs of their research, including advice on local level costing and when a local cost pressure is an ETC.

(2) That there is a clear incentive for Trusts to take on studies that might be causing a cost pressure to them (particularly if they can choose to do studies where there are no ETCs and high recruitment numbers)

(3) That there is a mechanism in place to feed local intelligence from host provider sites (including primary care, community and mental health providers) through to the Lead LCRN to ensure any local issues with the national costing can be adjusted,

(4) That there is the means by which local cost pressures or difficult costs can be unblocked if appropriate, according to a clear set of decision-making principles and/or an escalation process.

Establishing a more rapid, standardised process for ETCs associated with specialised commissioning

• Do you agree with the proposal to strengthen the process for specialised services? (Y/N/Please comment)

YES

Specialised commissioning is particularly unclear and complicated to research teams and research departments. It is extremely difficult to navigate or understand and should not be treated any differently to the CCGS. Providing clarity, transparency, a route of entry and hopefully a pooled budget (that for all intents and purposes could also even be managed by the LCRN)

• Do you agree that applications that fall below the proposed minimum threshold would not be considered by NHS England?
(Y/N/Please comment)

YES

There are absolutely times when the administrative burden of processing an ETC is more than the actual cost of the ETC itself. A minimum threshold is a good idea and if it would be at all possible to link in some way to the tariff figure then it would make good sense to do so.

As already stated above, there is some concern amongst CCG colleagues that there will be some double counting of funds provided '*we don't want to pay for something twice because organisations can't identify what has already been paid to them'*, and a minimum threshold says where the provider responsibility starts and ends.

Hopefully the minimum threshold will make it clear what is considered within the current funding envelope/in Tariff, and when an extra contribution from the CCGS is required to support ETCS in Provider Trusts. There is some disagreement between Providers and Commissioners on this point and some CCGS believe there is not a problem to fix here. Whilst it is true that some Trusts do manage a high threshold for ETCS in their organisations this is not the case across the country and many organisations will not undertake research with ETCs as a result.

• Are there any additional comments to add to the specialised services proposals?

We believe Specialised commissioning should be subject to the same principles as all other commissioners however transparency and clarity is perhaps of even higher priority, as many do not understand it.

A single pooled budget combining all funds for commissioning and managed by the LCRNS might support even further streamlining and reduction in bureaucracy

Setting a minimum threshold under which ETCs will need to be absorbed by providers participating in studies.

• Please rank the options outlined in Table 2 in order of preference with your preferred option first and your least preferred last.

Our order of preference is as follows with our most preferred option first and least preferred option last:

- 4
- 2
- 1
- 3

• Why do you think your preferred option is the best one?

We believe that 4 is the option currently running successfully in Wessex and therefore there is some evidence that this is manageable and achievable. It also would allow study-level data to be collected however individual funding applications may create an administrative burden and this should be worked on to ensure a manageable process is in place.

There is a risk that some smaller organisations may find this cost pressure too high however if our principle of pragmatic flexibility, good consistent decision-making principles and an escalation or feedback mechanism are adopted, then these cases could be looked at individually and unblocked if appropriate. Managing numbers of studies to an annual banded threshold is more akin to the ABF funding principle however it seems sensible to start with study-level clarity so that and researchers, funders, providers and commissioners all understand where the funding is coming from for any one project.

• Are there any other ways to set thresholds that would work better than those presented?
(Y/N/ Please comment)

As above we suggest supporting the thresholds with a flexible system based around good decision-making principles and a feedback/escalation process to support projects that become blocked and to prevent threshold 'gaming'

• Do you think there should be a nominal payment cap for primary care to discourage applications for ETCs where the cost of processing will significantly out-weigh the cost of the ETCs? (Y/N/Please comment)

There is no tariff for primary care research so all costs are new to them and we know that some GPs still require persuading to become engaged in research. Some Primary care practices do however attract both non-commercial and commercially sponsored studies, which create a treatment cost saving to them and these should be taken into consideration if Provider Trusts are expected to do so. Further clarity on how to manage and account for system-wide ETS would be welcome.

COMMERCIAL STUDY SET UP

Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK:

• Which do you think is the best option for costing NHS provider participation in commercial research? [Option 1,2,3?]

Our preferred option for costing NHS Provider participation in commercial research would be **'Other' #Option 3**

• If you have selected Option 3, what is your proposal and how does it meet the design criteria outlined, i.e. capability, consistency, transparency, speed and simplicity, single point of access and continuous improvement?

We are supportive of the design criteria outlined here, with the caveat that communication and improvement should be inherent in our model instead of a '*one-size-fits-all', 'take-it-or-leave it*', approach.

Our alternative option is effectively a **revision to Option 1**, introducing a well-trained national coordination and costing function using all the tools and model templates specified in the proposal; where sites are expected to accept the contract costs but are not *mandated* to do so and have the option to feedback amendments within an agreed period of time, according to some agreed principles. This would ensure the lead negotiator is supported in their role also.

First site leads have been tried in the past and we do not believe successfully. This is often because sites naturally think about their own organisations and are not trained (or often funded) to consider all types of sites or scenarios. From this perspective we do not support Option 2.

We fully acknowledge the value in creating consistency across the UK and a national point of entry for commercial sponsors is a good idea already in place in the Devolved Administrations; there is much to be gained in providing a professional one-stop -shop for all sites in England. However we are not clear there is good evidence that a "*one cost, one contract*", "*take-it-or leave it*" method is necessary or that it serves the NHS well. It risks sites turning studies down where there is a perceived cost pressure, and it risks under-costing commercial studies at sites during a very financially challenging period.

We believe we can improve national services without doing this and that maintaining capacity and capability within NHS organisations is also important to the national research interest.

We are making excellent progress embedding research into an NHS setting, with many Boards embracing research as their core business. If the ETC model is passed and we take a pragmatic step towards accepting national costings in the national interest, it would be prudent to ensure all commercial costs are fully recovered as best we can. In reality we believe most Sponsors are accepting of change requests if they are reasonable and communicated to them efficiently and once the system is set up we suggest unlikely lots of amendments will be requested.

We therefore propose that the national function brings improved capability, consistency, transparency, speed and simplicity but that clear communication channels and decision making principles exist such that negotiators are working *for and on behalf of* all sites, and that sites can feed in locally required amendments (for example where services are subcontracted or outsourced, or run via regional centres). Local care pathways that significantly deviate from the costs presented in the contract would be fedback to the lead within a set time period and the lead would be able to negotiate this *on behalf of* the site provided they were reasonable amendments. We are not sure that contracts and costing present such a big barrier to site set-up that lead negotiators cannot work *on behalf of* organisations in this way.

If this is not done well the risks are that sites will stop accepting studies they believe are a cost burden when they can take on other studies, and that the lead negotiator becomes removed from the local set up such at they are unable to support sites well.

Currently contract costings can be poor and do not even pick up protocol driven activities therefore any improvements in this regard would be welcome.

• Why do you think the option you have selected is the best one?

As above.

We believe it is a real and practical step to improvement whilst embracing the right values and principles of working for all within agreed, pragmatic decision making principles. It also sends the message that Trusts are being supported nationally to negotiate commercially sponsored research contracts effectively and pragmatically, enabling Trusts to work together with the national function instead of being given a fixed, non-negotiable price. We believe it is always worth trying to improve communication channels before mandating a set approach and without this caveat a single person could affect site set up selection across the UK.

Please refer to the preceding section and Annex B. Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK:

• Do you agree that we should reaffirm, through the NHS Standard Contract, the requirement for NHS providers to report and publish a standard dataset for performance in clinical research initiation and delivery? [Y/N/Not sure]

Not sure

We are supportive of visible performance measures but our members were clear that they any metrics must meaningful and cost effective, indeed they should meet the design principles stated in this consultation themselves and we are not convinced that the published metrics on Trust websites are meaningful to patients or justify the time spent collecting and analysing them. Accepting the value in good metrics and the broader national interest we would support the requirement should meaningful metrics be agreed, taking into account changes that are new to the system. It would be helpful if the information required to collect metric data were not so manual and that these were more streamlined across partners.

• If you have answered "N" to the above, what are the concerns/objections we should consider? [free text]

Thinking about commercial research generally, and noting that responsibility for delays sometimes lies with research sponsors:

• Are there any additional steps that you think would be helpful on the part of commercial research sponsors and/or their representatives?

Members have fed back that it would be helpful for commercial sponsors, partners and representatives to better understand the challenges around ensuring capacity and capability within an NHS setting, particularly in the current climate, separate to R&D processes. We are not sure that contracting is necessarily the biggest barrier to study set up however robust costing and pricing will improve our capacity to do research and this should be supported. R&D processes can be efficient within an organisation that has extremely challenging capacity issues affecting the metrics and our performance. It would therefore be helpful for us to agree together what really needs to be measured (what is important to commercial research sponsors as well as to the NHS) and to ensure that where capacity is stretched we have the means of trying to improve it for the sake of the national interest. Support for real cost pressures at an NHS organisational level, improved information packs, provision of study manuals and set up information plus a pragmatic approach to mandated training/site set up would be welcome

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Do you agree with our proposed wording for a future National Variation to the NHS Standard Contract?
(Y/N/Please comment)

No.

Please see our comments on accepting the national NHS price. We would request this is amended to reflect considerations for local consideration within agreed principles and time frames.

The wording is a little confusing and leaves room for error, as we don't believe Trusts 'must comply with guidance'. Guidance is not usually something that is mandated and therefore we suggest you either mandate the guidance as a policy or state Trusts 'may'/'are requested to' comply with the guidance.