

The AHSN Network

Real-world evaluation to facilitate adoption at scale

A practical guide for innovators working
with the AHSN Network



September 2022

Contents

3	Foreword	32	Conclusion
5	Background	33	Useful resources
8	The role of the ASHN Network	33	Reference
12	Rationale for this guide	34	Appendix A: Checklist of considerations for real-world evaluations
14	Key considerations when developing a real-world evaluation	35	Appendix B: Scope of real-world evaluation and real-world validation
	<i>Planning</i>	15	
	<i>Problem</i>	15	
	<i>Innovation</i>	16	
	<i>Population</i>	17	
	<i>Clinical efficacy</i>	17	
	<i>Pathway</i>	18	
	<i>Implementation</i>	18	
	<i>Partnership</i>	19	
	<i>Others</i>	21	
	<i>Priorities</i>	23	
	<i>Investment</i>	24	
	<i>Protocol</i>	25	
	<i>Comparator</i>	26	
	<i>Outcomes</i>	26	
	<i>Outputs</i>	28	
	<i>Ongoing</i>	30	

Click on these icons throughout the document to read the case studies:

[Minuteful Kidney](#)

[Focus ADHD](#)

[Safe Steps](#)

[PIGF](#)

I Foreword

On behalf of the AHSN Network, National Institute for Health and Care Excellence (NICE), The Office for Life Sciences (OLS) and the Association of British HealthTech Industries (ABHI), we are delighted to introduce you to this Practical Guide to Real-World Evaluation.

In this guide, we seek to address one of the fundamental challenges faced by the NHS, industry and innovators in the UK – the ability for the health and social care system to adopt well-evidenced transformational HealthTech innovations at sufficient pace and scale. If we are to see improvements in health outcomes that patients rightly deserve, more efficient use of resources across the health and social care system and a thriving UK HealthTech industry that leverages investment and creates jobs, we need to drive adoption of proven high-value technologies into the NHS at scale. A key pillar of this ambition is an ability to undertake early practical real-world evaluation of innovation that generates evidence to understand and maximise its value to support adoption across the whole NHS.

We seek within this document to draw together work that the AHSN Network has been undertaking over many years with the ABHI, NICE and OLS. We have used industry case studies to construct a guide that supports future innovators to undertake real-world evaluation that produces practical evidence useful to the multitude of

stakeholders they will interact with while trying to sell their product to the NHS. Within this guide we often advise innovators to collect evidence that demonstrates not just that their innovation improves outcomes and is cost effective but that also describes how it was implemented and deployed, addressing issues such as clinical pathway reconfiguration and training of healthcare professionals. Often it is almost more important to understand ‘how did we make it work’ than to repeat efforts that confirms the ‘does it work’ challenge.

This builds on the great strides made by NICE in the development of their RWE Framework, which is an invaluable tool highlighting good practice in the development of RWE. We recognise that not all innovators will seek NICE appraisal, however the standards described in their

framework around good practice are wholeheartedly endorsed in this guide.

In this practical guide we go beyond the capture of data on efficacy and effectiveness to also focus on understanding and describing how to implement innovation when you go to your next customer. Our guiding principles have been around ensuring that RWE does not become an additional regulatory burden, it is delivered in a truly real-world setting, it supports adoption at scale and is produced collaboratively as a shared endeavour.

If you have an innovation that you believe can improve outcomes for patients in the UK, then please reach out to your local AHSN to find ways of working with the AHSN Network to help deliver improved health and social care outcomes in the UK and beyond.



Professor Gary Ford CBE, FMedSci
Chief Executive Oxford AHSN and
Chair of the AHSN Network



Dr Neville Young
Director of Enterprise & Innovation,
Yorkshire & Humber AHSN

“New medical technologies and digital health products offer NHS clinicians ever-increasing choices of innovations that could benefit the patients they look after. However, commissioners wishing to maximise benefits for their service and patients often face a dilemma when deciding which technologies to fund. Technology developers therefore have an important role to develop credible evidence that captures the benefits of their technology. There are various resources that can help in this respect. NICE recently published a framework that highlights good practice in the development of real-world evidence. Now, with this guide on real-world evaluation, the AHSN Network has provided a valuable practical resource that outlines some key questions and considerations that developers should reflect on as they outline their value proposition.”

Páll Jónsson, Programme Director – Data and RWE, NICE

“For HealthTech, real-world evidence provides a rich and important source of data to support the adoption and spread of innovations, often where traditional randomised controlled trials are not feasible. Complementing the recently developed NICE framework, this guide offers clear and practical support for innovators when considering evidence generation to optimise successful uptake by the NHS. It is a must read for innovators as early in their development journey as possible.”

**Luella Trickett, Director, Value and Access,
Association of British HealthTech Industries**

Acknowledgements

This publication has been produced with the help and support of many individuals over the past 12 months. On behalf of the AHSN Network, I would like to thank Páll Jónsson and Jeanette Kusel at NICE; Gary Ricker and Sophie Stuart at the Office for Life Sciences; Luella Trickett and Andrew Davies at ABHI; Gary Ford, Piers Ricketts and Nicole McGlennon at The AHSN Network; Jemma Lough for holding the pen; and Rob Berry who kickstarted this work.

Dr Neville Young, Yorkshire and Humber Academic Health Science Network

I Background

Generation of evidence to support the development and use of all health technologies in the UK and other markets is a complex process. Irrespective of the size of the health technology (HealthTech) company, challenges with adoption of their technology can be very real and developing the most appropriate evidence to support better adoption at scale is the challenge outlined in this work.

Traditionally, pharmaceutical companies and to a lesser extent, HealthTech businesses have used large randomised controlled trials (RCTs) as a gold-standard method to develop a strong evidence base that supports the clinical efficacy and cost-effectiveness of a new medicine or product. For the HealthTech sector, this evidence does not always guarantee adoption at scale. RCTs are expensive and time consuming, particularly for HealthTech, which is dominated by small and medium enterprises (SMEs),

whose products may be relatively cheap to develop with consequently small margins. Depending on the context, RCTs may therefore be replaced or supported by other types of evidence, including single-arm studies, cohort studies, case series/studies, post-marketing surveillance, and, increasingly, other real-world evaluations.

For medicines developed by the pharmaceutical industry, clinical and health-economic evidence enables engagement with the National Institute for Health and Care Excellence (NICE). This can generate a

recommendation through a NICE technology appraisal that means a new treatment must be funded in the NHS health and social care system by law via a funding directive. Where such a directive is applied, the NHS health and social care system has 90 days to make the treatment available. No similar route to market exists for health technologies – MedTech, digital and digital devices. When NICE appraises a technology and recommends that it should be used in the NHS health and social care system, it is only a recommendation.



In addition, the past 10–15 years has seen the emergence of digital technologies that are rapidly iterated and can have much shorter product lifecycles in the market than medicines. This means that large, expensive and time-consuming RCTs are often not feasible or affordable to generate efficacy or effectiveness evidence within an innovation's lifespan. Other methods, such as non-randomised studies and real-world evaluations are therefore increasingly being used to inform health technology guidance. However, use of these outputs by NICE is still limited, partly due to difficulties in converting data generated in this way into consistent and meaningful evidence that NICE can act on. It is vital that these types of studies generate data of the highest possible quality and with good provenance that supports reproducibility.

The UK life sciences sector (Biopharma and MedTech) employs more than 268,000 people across 6,330 businesses and generated a turnover of £88.9 billion in 2020. The MedTech part of this sector employs 40% of these people, and 85% of the businesses across both MedTech and Biopharma are SMEs.¹

The challenge, particularly for technology-driven innovators – whether small, medium or large enterprises – is driving consistent implementation of their innovation at scale and pace across the NHS. Even with a positive NICE appraisal, HealthTech innovators often struggle to achieve this, so only a few patients benefit, and businesses struggle to thrive as they should in the UK market.

The net result of these issues can be poor or patchy adoption of technologies with the potential to improve outcomes for patients and create efficiencies in the healthcare system.

As a result, this has the potential to disincentivise industry from investing and growing their businesses in the UK. Colleagues in the NHS, often pressed for time and facing capacity issues but with no regulatory or funding mandate to drive adoption, need to know how easily an innovation might be implemented and how quickly they might see benefits. Gathering high-quality evidence in 'real-world' settings to demonstrate the feasibility and practicalities of implementation is vital to enable rapid and confident adoption and scaling up of high-value health technologies that accelerate delivery of patient benefits and healthcare efficiencies.

The AHSN Network collaborates with innovators to ensure they collect evidence of efficacy and impact in real-world deployments robustly, transparently and with due reference to NICE guidance. It is also important for innovators to think about conversations they need to have with new customers about:

- how easy it is to adapt an innovation to a new system to deliver the same results
- where the pinch points might be across the system
- who needs to be in the conversation from the start to ensure organisational buy in.

NICE is working hard to support innovators who wish to engage with NICE, recently publishing guidance on this subject.

[NICE real-world evidence framework](#)



“I think most concerning for me was that the [PIGF] test was available for two years (NICE recommended it in 2016) and we were working to make clinicians aware of it, but it simply wasn’t being taken off the shelf and used. There was this unmet need, and there was something available that would fill that need, but still clinicians weren’t using it.”

Julia Eades, Roche Diagnostics

“I was keen for the AHSN Network to set up diagnostics expertise to support the diagnostics industry. Roche were one of many companies I’ve worked with to understand, from their side, particular products they were having trouble getting adopted. We were particularly interested to understand the dynamics of the NHS and why a product with NICE guidance wasn’t being adopted by clinicians.”

Julie Hart, Oxford AHSN

The role of the AHSN Network

The AHSN Network is tasked with supporting adoption into the NHS of health technologies that benefit patients and drive health system efficiencies. The Network's real-world evaluation programme aims to help innovators work with adopting organisations to secure rapid rollout of new products that deliver benefits to patients, while complementing NICE's work generating technology appraisals and adhering to regulatory requirements.

Historically, there is a perception that procurement decisions for new products and services may sometimes have involved judgements not always entirely based on rules or the available evidence. Instead, buying decisions can be influenced by positive or negative reviews from clinical or managerial peers. While it is not desirable for peer testimony to disappear completely, the availability of high-quality evidence from real-world evaluation describing implementation approaches and efficacy outputs should form a strong and consistent part of any buying decision.

The AHSN Network aims to ensure that innovators perform high-quality, relevant real-world evaluations that:

- demonstrate the value of a new product in real-world settings (outside of a controlled research environment)
- help organisations to implement new technology as easily as possible by building on learnings from previous rollouts in other organisations.

The AHSN Network (comprising 15 regional academic health science networks) offers a range of services for innovators at every stage of development.



The challenge for innovators is often not proving that their innovation works and is cost effective but understanding how to implement it in the NHS so that it delivers the promised benefits.

Our definition of real-world evaluation within the context of this work is broad and encapsulates all activities that collect evidence outside of a research governance framework requiring consent of patients or healthcare professionals. ‘Real-world use’ describes deployment of an innovation in a healthcare setting with the assumption that it will be used by the system without prejudice of any external influence, such as research inclusion and exclusion criteria. Although a real-world evaluation is not subject to the same constraints and requirements as a formal RCT, it is still critical to develop a clear protocol for the work and, where appropriate, follow the correct governance processes, as this will add value and consistency to the

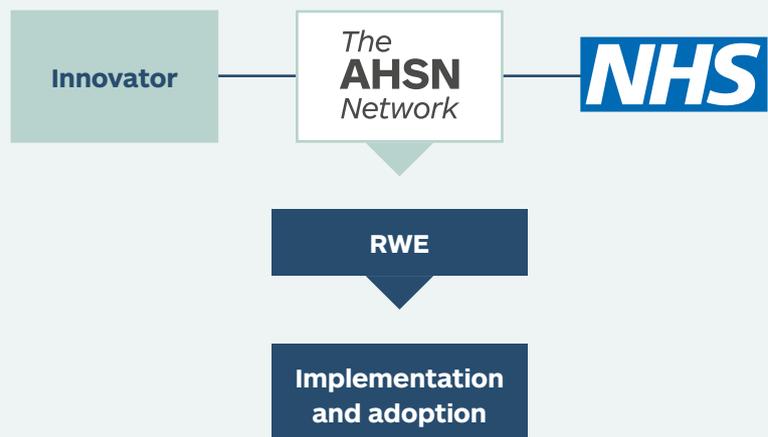
outcomes. In this way, decisions about the product and how it is used are made solely by the healthcare system, its standards and in line with accompanying product information. Assessing the impact of an innovation in this environment is vital to support spread and adoption and generating evidence of a positive impact alongside clear guidance on implementation can accelerate uptake of innovations and stimulate economic growth in the UK. The AHSN Network’s role is to ensure that data contributing to real-world evaluation is collected from real-world deployments and that co-production – the NHS health and social care system working with the business – supports an intention to implement innovative systems. We can help ensure:

- there is capacity on both sides to deliver a real-world evaluation
- there is clear purpose to the work
- that outcomes (positive and negative) are communicated transparently across the system.

One size does not fit all, and advice on how to proceed with a real-world evaluation is adapted to the innovation, its setting and the needs of the innovator.

The AHSN Network has been supporting and undertaking this type of real-world evaluation with innovators for many years. The Network brings together and coordinates existing regional infrastructures to support practical and useful real-world evaluations. The ability to do this has not occurred by chance: the Network has actively sought and built these relationships over time and is now using them to help innovators build more NHS-focused business cases that support spread and adoption of high-impact innovations. Some AHSNs have an ‘in-house’ ability to deliver this work, but many work with providers in the academic and private sectors to offer this service.

The AHSN Network supports creation and growth of UK SMEs, helping them to attract significant investment and create high-quality jobs, thus contributing to UK economic growth.



A number of challenges should be considered before starting a real-world evaluation, as the needs of the NHS health and social care system and innovator must be addressed. Innovators are encouraged to engage with their local AHSN and NHS health and social care system to discuss how to take such work forward so that it is mutually beneficial. AHSNs are interested in

supporting activities that meet the needs of NHS partners and commissioners in NHS England and the Office for Life Sciences and that address key criteria: unmet need, outcomes, credibility, feasibility, and affordability. These are very broad assessment criteria and only a starting point for discussion, which will also include any existing evidence from ongoing or previous

technical and regulatory work – ideally including proof of concept in a service setting.

Appendix A suggests what may or may not be in scope for AHSN-supported RWE studies.

Unmet need	Outcomes	Credible	Feasible	Affordable
Assessed by relative priority nationally or regionally, including assessment of potential health gain	Strong enough to support the scale and spread as expected (it can be made to work)	Proposed method of implementation is easy, credible and adaptable for spread, including technical and operational elements	Resources (finance/staff) are quantified and available across sufficient proportion of market	Appropriate economic assessment (e.g. return on investment)

Fig 1. Key challenges to consider before starting a real-world evaluation project.

Benefits of working with AHSNs

- Experience in supporting real-world evaluations
- Existing connections and network
- Knowledge of unmet needs within the NHS health and social care system
- Credible
- Independent
- Support for data collection, report writing, and hosting of data and reports
- Support for scaling up projects, particularly for innovative SMEs with modest funding and resources



“From our point of view, real-world evaluation with the AHSN Network has a couple of benefits. One is clearly credibility, so having respected organisations gathering evidence makes the output much more credible, and I think that’s not to be underestimated. We’ve collected audit data and it has been helpful, but it doesn’t have the power of an AHSN-collected dataset or an independently collected dataset. The other is simply scale: some of the SMEs that will be reading this guidance are unlikely to have the resources to collect sizeable data relatively quickly.”

Tony Doyle, Qbtech

“We did think throughout the project about how we could take it wider than Oxford – how could we look at a Thames Valley approach. As the real-world evaluation was going on, we used the Maternity Network to identify a clinical leader for every trust in the Thames Valley that would be responsible for working with the AHSN, looking at implementation and the steps they would need to go through so that we had a network-wide approach to preeclampsia testing for the Thames Valley.”

Julie Hart, Oxford AHSN



I Rationale for this guide

The AHSN Network recognises that not every innovator is ready or indeed wishes to engage with NICE to seek approval for their innovations. Indeed, the outputs of a real-world evaluation might be very different to what NICE would use in a health technology appraisal. That does not mean that some of the same principles around methods, data quality and transparency in reporting should not still be applied.

This guide has been developed to bring more consistency to the process. It aims to help innovators think clearly about what they want from any real-world evaluation so that they generate outputs that fill gaps in their knowledge, help them sell products to new customers, and drive adoption at pace and scale. It is not necessarily about producing evidence to inform NICE guidance but will ensure that work conforms to the standards of and may contribute to NICE processes in time.

Within the context of this guide, real-world evaluation is a combination of activities (including quality improvement and implementation science) that increase buyer confidence that a product or solution will deliver the described benefits in their system.

The steps detailed in this guide are not intended to provide a list that must be completed, the process is not linear flow or a fixed algorithm, but an attempt to prompt innovators to think about the important elements that all contribute to a successful and useful real-world evaluation.



How this guide was developed

Development of this guide involved a series of four interviews with innovators who have achieved successful implementation of their interventions into the NHS and social care system, and their AHSN partners, to identify key steps in the process, barriers, opportunities, and recommendations.

Minuteful Kidney

- Jimmy Endicott, UK Marketing Director, Healthy.io
- Helen Hoyland, Head of Commercial, Digital Innovation and Growth, Yorkshire & Humber AHSN

Case Study

Focus ADHD

- Tony Doyle, Managing Director, Qbtech
- Dara Coppel, Head of Innovation Programme Delivery, East Midlands AHSN

Case Study

Safe Steps

- Mike Kenny, Associate Director Enterprise and Growth, Innovation Agency – AHSN for the North West Coast
- Lee Omar, Founder, Safe Steps

Case Study

PIGF

- Guy Checketts, Head of Transformation – Strategic and Industry Partnerships, Oxford AHSN
- Julia Eades, Senior Market Access Manager – Women’s Health, Roche Diagnostics UK & IRE
- Julie Hart, Director of Strategic and Industry Partnerships, Oxford AHSN

Case Study

A Steering Group also reviewed and commented on the document:

- Mike Burrows, National AHSN Network Coordination Director, the AHSN Network
- Professor Gary Ford, Chief Executive Officer, Oxford AHSN; Chair, the AHSN Network
- Páll Jónsson, Programme Director, Data and RWE, NICE
- Nicole McGlennon, Chief Executive Officer, East Midlands AHSN
- Gary Ricker, Senior Policy Advisor, Office for Life Sciences
- Piers Ricketts, Chief Executive, Eastern AHSN
- Luella Trickett, Director, Value and Access, Association of British HealthTech Industries.

Key considerations when developing a real-world evaluation

This section outlines the key considerations when developing a real-world evaluation. Some may already have been addressed prior to the decision to develop a real-world evaluation and to partner with an AHSN. However, AHSNs are increasingly encouraging innovators to engage as early as possible, even during product development, to ensure the innovations they are developing meet the needs of the NHS and provide practical and optimal solutions. [Appendix A](#) provides a useful checklist.

“The AHSN is now offering companies with early ideas stakeholder mapping, so they understand very early in their product development who their stakeholders are and what they need. We’re making sure that companies have that information during product development, or even before, to try and shorten that gap to market.”

Julie Hart, Oxford AHSN

“Start the conversation with the AHSN Network early rather than later, because it has different schemes for innovations that are at different stages in their lifecycle.”

Jimmy Endicott, Healthy.io

“All AHSNs have their own cohort of innovations and innovators that we’re supporting at any given time. At a very high level that falls into three spaces: ‘Discover’ for very early-stage innovations, ‘Develop’, which is more evolved, and ‘Deployed’, which is where things are tested. If you feel you would benefit from a real-world evaluation or you’re struggling to get your foot in the door or have a conversation about what to measure and what the NHS health and social care system wants from you, that would be the right place to start.”

Helen Hoyland, Yorkshire & Humber AHSN

Planning

- **What steps are involved in an RWE project to deliver the most appropriate evidence and outputs?**

Before you start planning, determine whether your innovation is suitable for a real-world evaluation in collaboration with the AHSN Network by assessing whether it is addressing a clinical or NHS system problem that exists at scale. If the problem you are solving is only relevant to a localised area, a real-world evaluation involving the AHSN Network is not necessarily going to be a valuable investment of time or money. If your innovation will resolve a problem that requires implementation at scale, planning should start as early as possible and should be a thread that runs throughout your real-world evaluation.

Planning is a key part of any project and is vital for a successful real-world evaluation.

“You need to be very clear on what your product does, where it fits, who it helps, the space that it fills, the problem it addresses, and who you are going to tell about it. The NHS is such a complex organisation, almost a series of franchises organised into a hierarchy with different mechanisms and processes at each level. If you’re not clear on where to inject your solution into the system, you’re just not going to even get started.”

Jimmy Endicott, Healthy.io

Problem

- **What is the problem you are trying to solve?**
- **What need are you servicing?**

You will need to show that there is a space for your innovation by providing evidence of the problem that you are trying to solve and some suggestion of the size or scale of the problem. Look for existing evidence in the form of audits and reports, work with clinicians, NHS finance contacts and AHSN colleagues to really understand the issue. If a national dataset is not available, use accessible data to evidence the problem. Identify factors causing the problem where your intervention is likely to improve outcomes. Show the problem you are trying to solve exists at scale, such that a real-world evaluation in collaboration with the AHSN Network is worthwhile.

AHSNs may already be aware of problems that need solving and trying to identify solutions.

“If I were to advise other innovators, I would suggest that they really need to figure out what they need to prove and how they can show value before undertaking a real-world evaluation. We started with a small audit and the finding from that audit and then subsequent audits really gave us the confidence and informed what we might be looking for in terms of real-world evaluation.”

Tony Doyle, Qbtech

“From an AHSN perspective, we were very well aware of the needs right there in the system. We knew that the ADHD diagnosis pathway for children was chaotic, was broken, with huge variations across the country, with high numbers of children to be seen, workforce issues etc. We knew there were big problems, so were going to try and find something that already had an evidence base to show that there was a solution to help with this chaotic mess and this inefficiency in the pathway.”

**Dara Coppell,
East Midlands AHSN**

Innovation

- What exactly are you doing to the population you have identified?
- Are you replacing or adding something completely new?

For your innovation to be used within the NHS, all the necessary regulatory and governance approvals should ideally be in place before a real-world evaluation begins.

Make sure you can describe your innovation and its intended impact in a way that your target audience will understand, with sufficient detail for those new to the concept to see how it works and will solve the problem you have identified. It is rare for any innovation to be cash releasing at scale, so it is best to avoid extravagant claims of impact unless you can fully back them up.

The evidence you collect needs to tell the story of the benefits of the innovation.



Population

- **What is the patient population you are treating? Can you describe it accurately?**
- **Will different populations and systems be differentially impacted by your innovation?**
- **Are health inequalities within your population being addressed?**

Describe the population and system that the problem is affecting and how they could be impacted by your innovation. What will be different afterwards? Your innovation may have different effects and impacts in different populations and settings – for example, different geographies (e.g. rural versus urban), different ethnic breakdowns, different levels of deprivation, and different NHS organisations. Consider all of the varied settings in which you will need to investigate your innovation to provide evidence of its value to different stakeholders and organisations. Health inequalities are a significant driver in the decision-making process around adoption of products and services, so be aware of any impact your innovation will have on population health. Innovations that impact positively on this agenda will have an advantage.

Real-world evaluations should be developed in multiple geographies and settings to provide enough evidence to make repeat pilots unnecessary.



Clinical efficacy

- **Have you proven the clinical efficacy of your innovation?**

Before starting a real-world evaluation, it is important to prove first that the innovation works and will offer value to the NHS. Collate your evidence to date to show effectiveness and confirm that there are no unintended disbenefits from the innovation. Real-world evaluation in this context is not so much about proving it works but how to make it work at scale.

Research evidence that proves the clinical efficacy and predicted value of the innovation in a controlled setting is an important foundation before verifying the innovation through real-world evaluation

“Step one is to show the clinical value... and that was shown through multiple studies before we started the real-world evaluation, which was, in this case, more focused on patient benefit through shortening waiting times and efficiencies. Because otherwise, you could end up with some great efficiency data, but we’ve just made the system faster at doing the wrong thing. That’s why you need a certain level of evidence beforehand.”

Tony Doyle, Qbtech

Pathway

- **What is the wider pathway for this patient population?**
- **Where does your innovation fit within the current pathway or care setting?**

You will need to identify where your innovation fits within the patient pathway and how it will impact on the existing pathway.

- Will your innovation replace an existing step in the current pathway or require an additional step?
- Which organisations and staff will it impact?
- Will additional staff and other resources such as clinics, beds, laboratory time or information technology (IT) support be needed?
- Will staff need training?
- Will new equipment be needed?
- Will the location of patient access be affected?
- Will it impact outside of the immediate clinical setting – for instance, implemented in primary care but impacting on acute services?

Implementation

- **How would your innovation be implemented within the NHS?**
- **What staff and resources would be needed?**
- **What happens to the patients, clinicians and system?**
- **What are the consequences to the customer upon implementing this innovation?**
- **What impacts are there across the wider health and social care system?**
- **What are the costs in resources and time to implement alongside the price?**

Once you have identified your innovation's place in the pathway, you will need to develop a strategy to implement the technology. At this point, implementation can be as much an art form as a science, as the aim is to ensure roll out of an innovation in a way that embeds its use into the system.

The work may be described as a 'contact sport', in which relationships are often key, so being able to identify and replicate who you need to build relationships with to drive success e.g., IT, finance, nursing staff, porters, allied healthcare professionals, etc – is vital. Layered on top of this is the need to develop an understanding of why these relationships are important. Documenting that is then really useful, because if your next customer does not have a particular job role, they will probably still have the function under another guise.

Overall, implementation is about understanding how to drive adoption into a new system and is a combination of information on the practicalities of adoption (e.g., regulation and cost benefit) as well as more holistic skills to identify the people needed to influence and drive procurement, integration, and use. A real-world evaluation that generates this sort of evidence will support adoption and spread of innovation in the system.

“If we think about the pathway for the patient, we have to think about all the healthcare providers that touch the patient in that pathway. Not just the obstetricians and gynaecologists but midwives in our case. Who else within that pathway do we need to educate and convince of the benefit of the test, because each pregnant woman spends far more time with their midwife than they do their consultant or registrar, and for them to understand the test as well becomes quite a large training and updating exercise.”

Julia Eades, Roche Diagnostics

Partnership

- **Which partners would be appropriate to support your RWE?**

Every innovator will need a team around them to offer advice and guidance, provide connections and introductions, identify suitable funding, and translate the findings into useful outputs. Relevant stakeholders who contribute to the planning of your real-world evaluation will have increased engagement and a sense of ownership.

Identify suitable partners to support your real-world evaluation early to ensure you are collecting the right data and information to provide appropriate evidence and develop outputs useful to the relevant decision-makers.

Potential partners

- **Your local AHSN**
- **The AHSN Network**
- **Clinical network**
- **NHS England**
- **GIRFT (Getting It Right First Time)**
- **Office for Life Sciences**
- **Community of Interest groups**
- **Academic units**
- **Service director**
- **Health economist**
- **Real-world evaluation project manager**
- **Independent validation**
- **Report writer**

“You have to identify the stakeholders who are involved – the patients, the practitioners, the commissioners, all the third-party regulators and the third sector, etc – and spend time with them. It’s easy for us as innovators to fall into telling people how we think our solution can help. It’s important to show people your ideas, listen to them, and understand how they think our solution can help – then make the solution fit their needs.”

Jimmy Endicott, Healthy.io

Working with stakeholders experienced in the relevant disease area will provide valuable insight. Clinical champions can suggest improvements and adaptations that will help your innovation work in the NHS system, provide guidance on positioning your innovation correctly in the pathway, and advise on how the innovation will need to be implemented within the existing NHS framework. They will be able to pinpoint which clinicians, healthcare professionals, allied healthcare professionals and other stakeholders, e.g., laboratories, pharmacies, and IT support, will be affected by the innovation. Clinical champions are also best placed to advocate for your innovation to other clinicians, providing testimony for their peers about the value of your product or service from their own experience.

Clinical champions are vital to support your innovation.

“I think some of the clinicians found it quite challenging that we may be suggesting that their use of the test perhaps wasn’t as good as it could be. So we had to be careful and clear that we weren’t challenging their experience and knowledge. That’s perhaps where the key opinion leaders came in, the champions, because they could challenge their counterparts, more so than a company or even an AHSN.”

Julia Eades, Roche Diagnostics

Encourage early adopters to engage with prospective adopters from a similar setting to explain how the innovation works in practice and provide reassurance.

Public and patient involvement is critical to ensuring that the innovation is acceptable to the people who will be most affected – the patients and their carers. Involving patient charities and third-sector organisations is therefore essential to refine your innovation and plan its implementation into the NHS. This work will also help you address any impact you might have on the health inequalities challenge currently confronting healthcare in the UK.

Co-production with clinicians, users, patients and carers is key to developing an innovation that will be successful in the NHS.

An innovator’s journey of bringing a product to market should include strong patient and public involvement; where this can be brought to bear on planning of a proposed real-world evaluation, it will add value.

“We started in the Wirral in Merseyside in a partnership brokered through the Innovation Agency North West Coast. We started solving a real problem from day 1, and we co-designed the app with clinicians – the experts – and the carers and the family. It was based on the NICE guidelines and best practice, a kind of standardised falls prevention in care homes in the world. The first project was a pilot that went into about 20 homes, and it had a big reduction within the first year. The data showed about a 25% reduction in falls, so we knew it was working, but we didn’t have any independent rigorous evaluation to prove our claims.”

Lee Omar, Safe Steps

Others

- With which other stakeholders do you need to engage?
- Who else will use these data? (AHSN, NICE, primary care networks, National Institute for Health and Care Research, Medicines and Healthcare products Regulatory Agency, integrated care boards etc.)

Your innovation will have different implications for different stakeholders – be that commissioners, finance, providers, clinicians, users, patients, thirty-party regulators, third-sector organisations or charities. A strong multisector steering group involving all stakeholders with an interest is important to drive real-world evaluations and will ensure you are asking the right questions for your different audiences and, at a later stage, communicating your results in the right ways. If you can't pull this steering group together, work with your AHSN to canvas the views of as many key stakeholders as you can – it is time consuming but will help build a better product that will be more readily adopted at scale.

AHSNs can help you make connections with NHS stakeholders who will be able to provide guidance on outcomes that matter to the NHS.

“It’s really important to have a strong multisector steering group to drive forward a real-world evaluation, because you can easily ask the wrong questions. You’ve got to be able to predict the questions that people are going to ask when they hear about it and answer a commissioner who says ‘yes, but what if, or what happens when...?’ Getting the people who are going to benefit – in the system but also the users – in the room is really important to guide that evaluation.”

Dara Coppel,
East Midlands AHSN



“It’s important to have upfront dialogue and buy in early on, so they are aware of what is happening and can influence it, rather than presenting them with the findings two years down the line. My unfamiliarity with NHS processes meant that we probably didn’t bring procurement or commercial into the discussions as early as we should have.”

Julia Eades, Roche Diagnostics

“I think it would have been super difficult if we hadn’t worked in partnership with the AHSNs, royal colleges, NHS England, public health and the patient charity. We wouldn’t have thoroughly understood what all the barriers could be and identified whoever was in the best position to address that barrier, be that clinical champion, a finance person or a health economist to drill down to the true financial implications of using or not using the test.”

Julia Eades, Roche Diagnostics

“There is something about the different types of NHS stakeholders: from very senior director level, who have the gift to make it happen, your clinical audiences, commissioners, procurement people. All of the evidence that you need to summarise in real-world evaluation needs to speak to all of those and talk about the benefits realisation for that variety of audiences. It’s really important upfront to understand from a commissioner’s perspective, from a clinician’s perspective, what they are expecting to see, what measures will give them the reassurance that the innovation is doing well and doing its job, so you have to think about all of this very holistically.”

**Helen Hoyland,
Yorkshire & Humber AHSN**



Priorities

- **Does your innovation address any NHS priorities?**

Although every aspect of healthcare is important, finite resources mean that the NHS has to identify priorities to focus on depending on the prevailing environment. For example, during the peak of the coronavirus (COVID-19) pandemic, reducing the need to attend primary care and hospital locations in person became important to limit exposure to the virus, therefore care closer to home and digital solutions became priorities. Innovations that had initially focused on finding high-risk patients pivoted rapidly to finding low-risk patients who did not need to be attending hospital. This agility and ability to respond to system needs are great assets for any innovator.

The pandemic has also shed an uncomfortable light on the fact that unfair and avoidable health inequalities exist across the healthcare system, with different groups within our society receiving poorer care than others. Innovators should note this and acknowledge how their innovation impacts on these disparities in the real-world setting. The [Core20PLUS5 framework](#) outlines how this can be approached.

Identifying NHS priorities and policy drivers that your innovation is addressing will allow you to frame your evaluation in a way that will resonate with NHS leaders and organisations. An innovation that addresses a national priority or policy issue will be more amenable to adopting at scale and thus suitable for a real-world evaluation developed in partnership with the AHSN Network.

Review priorities throughout your project, as health and political drivers may change and new ones may emerge, so you will need to adapt your strategy accordingly. When looking at the Life Sciences Vision and missions, its priorities around early diagnostics for cancer, cardiovascular and respiratory disease, ageing and mental health are all related to challenges in the NHS around capacity and demand in urgent and emergency care settings, elective waiting lists and diagnostic backlogs. Aligning your innovation and its impacts to current pressure points is really important.

Potential priorities

- [NHS Long Term Plan](#)
- [2022/23 Priorities and Operational Planning Guidance](#)
- [The Life Sciences Vision](#)
- [NHS Backlog Recovery Plan](#)
- [Integration and Innovation](#)
- [Care closer to home](#)
- [Point of care testing](#)
- [Relevant NICE guidance](#)
- [Sustainable development management plan](#)
- [Delivering a net zero NHS](#)
- [Core20plus5 – An approach to Reducing Health Inequalities](#)

“Think about the big headlines out there at the moment: what are the strategy and policy drivers? Elective recovery is a priority at the moment, keeping people well at home, point-of-care testing. Looking after people at home and digital access to primary care were huge government ethos in the midst of the pandemic and catalysts for a lot of innovation. It’s always contextual in terms of the current landscape, current pressures, and how you frame the conversation. And those priorities often come with funding opportunities.”

**Helen Hoyland,
Yorkshire & Humber AHSN**

Investment

- **Which financial partners would be appropriate to support your RWE?**

Real-world evaluations will incur costs. Priorities and policy drivers are often associated with transformational funding, which can help finance your evaluation. [The AHSN Quarterly Bulletin](#) is useful to identify potential sources of funding and direct you to innovation managers, who will be able to advise on how to optimise any funding that you receive. Contact your local AHSN for information on national and local opportunities.

Potential funding streams

- [Accelerated Access Collaborative](#)
- [NHS Innovation Accelerator](#)
- [Small Business Research Initiative \(SBRI\) Healthcare](#)
- [AHSN Network AI \(Artificial Intelligence\) Initiative](#)
- [The MedTech funding mandate](#)



“Becoming an Accelerated Access Collaborative rapid uptake product made the difference, because then it became a formal partnership, rather than under the NICE Implementation Collaborative, where it was a loose partnership, just a committee really. The AAC became a partnership, whereby where there were problems that we couldn’t solve, there were people who were tasked to go away and try and solve those problems. It was probably easier for the charity to become involved, for NHS England to be having a direct dialogue with the charity and for that patient and public involvement group to be set up.”

Julie Hart, Oxford AHSN

“The Accelerated Access Collaborative service was completely pivotal in raising awareness within the NHS and Public Health England that there were these amazing technologies that were not being utilised – and that they could bring a wider benefit not just to the patient but to the whole health system.”

Julia Eades, Roche Diagnostics

Protocol

- **What steps do you need for your evaluation?**
- **Can you describe them so the process can be replicated?**

Although a real-world evaluation is not subject to the same constraints and requirements as a formal RCT, it is still critical to develop a clear protocol that follows all appropriate governance processes and with clearly described core standards providing good foundations for this work in all future deployments.

Core standards

- **Methods** – such that the work could be reproduced independently
- **Data** – so that data fidelity, provenance and quality can be acknowledged
- **Population** – who was included in the evaluation
- **Care setting** – reflecting routine care in the NHS
- **Pathway** – where an innovation impacts in a care pathway
- **Outcomes** – clearly described
- **Implementation** – how the work was undertaken, including challenges to be addressed on future roll-out



Comparator

- **With what are you comparing the impact of your innovation – NICE guidance or a bespoke process?**
- **Does it replace an existing product or system or is it entirely new?**

The impact of implementing an innovation within the NHS will differ greatly depending on whether it is replacing an existing service or pathway or results in a new pathway or service. To provide evidence of the benefit of your innovation, your real-world evaluation will require an appropriate comparator. Where possible, choose a comparator for which you can obtain baseline values to show that your innovation represents an improvement rather than just an additional cost to the system.

Outcomes

- **Can you describe the outcomes of the intervention in a way that your customer values?**

Outcomes are the heart of your real-world evaluation and it is critical to get these right from the very start.

The outcomes that you perceive as important may not always resonate with your potential NHS customers, and different outcomes will be of interest to different stakeholders within the same organisation. Demonstrating patient benefits is essential, but outcomes of interest for the NHS will also reflect the impact of the innovation on clinicians and the systems, often including the local IT teams. It is therefore important to consider the consequences for all of the customer's moving parts upon implementing your innovation, such as how staff are involved in the innovation (including whether they will need training), and the impact on the wider pathway, including clinic capacity, clinic location, laboratory involvement, IT support, staffing levels and new equipment.

“The patient experience cannot be ignored. There are clinics and trusts where patient benefits and patient stories are what made them want to adopt the innovation. It would be a big mistake not to include that.”

Tony, Qbtech

Understanding costs of inputs and outputs is particularly important, as, broadly speaking, very little innovation is directly cash releasing. Claiming to save the NHS millions of pounds per year can be risky. For example, an inpatient procedure may generate a payment (a tariff) from the commissioner to the provider organisation of £2,000 to cover the whole procedure, including consumables and predicted length of stay, etc. It is important to know whether this tariff enables the organisation to undertake the procedure at a profit or a loss, as the whole costs may be more or less than the £2000 payment from the commissioner.

Armed with this knowledge, an innovation that reduces length of stay from three days to one day does not automatically reduce the cost by a third but may generate income that may be invested elsewhere. The true savings are then dependent on the costs of those bed days for that procedure, and it is vital to understand that bed-day costs are different in different places (e.g., general ward versus high dependency unit) and that they also include associated fixed costs for items such as heating, laundry, etc. It is important to be accurate about your claims and resist hyperbole. Note also that removing a procedure altogether can have the effect of reducing an organisation's income, which is good for the system but not necessarily the provider, and this should influence how you engage with new customers.

“Understanding upfront what the test will actually give you, I think has been important. Being able to have that conversation with the finance teams, explaining that they’re not going to get £50,000 in their back pocket and we’re not going to save you enough money to close an entire ward down, but it will free up capacity, and the patient safety benefit is not insubstantial.”

Guy Checketts, Oxford AHSN

All data and outcomes that will ultimately be relevant to buyers should be identified from the start of the project, as it will be difficult to address any oversights retrospectively. However, it is also important to reassess the relevance of your chosen outcomes and the emergence of new outcomes throughout the evaluation and beyond, as these may change as NHS priorities change. For example, who benefits from the cost perspective is likely to change with ongoing transformation and reorganisation within the NHS.

Potential outcomes

- Clinical outcomes
- Time to and accuracy of diagnosis
- Outpatient appointments, including follow-up appointments
- Inpatient admissions, including bed-days, length of stay, and readmissions
- Ambulance calls
- Primary care appointments
- Medicines use
- Workforce capacity
- Releasing beds
- Quality of life
- Patient experience
- Efficiencies
- Acceptability to patient and clinicians
- Costs, including procurement cost, associated costs, downstream costs, cost-saving, cost-releasing
- Sustainability and environmental impact

Outcomes of interest may vary for different stakeholders, so identify levers and language that will resonate with your audience.



“It’s important to agree meaningful metrics with the stakeholders. It sounds terribly obvious but knowing where the benefits will land in the system is important. With changes with integrated care systems coming in, now you have so many stakeholders and no-one can agree on metrics or how to divide the spoils.”

Tony, Qbtech

Outputs

- **What are the most appropriate outputs for your RWE project?**

Real-world evaluation can be used to produce a variety of outputs, so think carefully about what you need and how you can maximise these. Outputs should be tailored to the needs of the different stakeholders for your innovation, and it is likely that you will need to produce more than one output. For example, a budget impact tool or cost-benefit analysis in which providers and commissioners can enter their own data and see potential impacts, savings and return on investment in their own setting may be useful. Your real-world evaluation may also be combined with other empirical evidence that you have developed through technical or regulatory development – e.g. sensitivity and specificity and Digital Technology Assessment Criteria (DTAC) – to provide a more complete package of support to drive scaled-up adoption at pace across the system. Consider developing an audit template for collection of data using the innovation, thus allowing new users to build data collection into embedding of the innovation in their area.

“If you can write up an evaluation that offers the tools that were used within it for people to adapt to their own circumstances, it would be really helpful from an innovator’s perspective.

One of the tools that was particularly helpful for us was the budget impact model we commissioned. When you’re talking to people and you can say, ‘look, this makes brilliant sense from a patient and family perspective and, by the way, this is going to really help you with your workforce and your cost avoidance. Plug in your data here, and we can show you what it’s going to do for your own system.’ It was massively helpful to have tools so they can see it for themselves and not just read what’s on a piece of paper.”

**Dara Coppel,
East Midlands AHSN**

Typical outputs

- Case studies confirming the benefits realised
- Financial information (budget impact model, cost–benefit analysis, return on investment, etc)
- Key materials for the business case to present to the NHS health and social care system
- Defined procurement approach
- Defined commissioning approach
- Implementation guide
- Marketing and communication tools – websites, detail aids, brochures
- Company scaling plan (staff, money, supply, etc)
- Adoption and spread plan
- Budget impact model
- Environmental impact report
- Frequently asked questions

Agree the key outputs in discussion with the AHSN and evaluation team (who know what can be extracted from the system and what can't) at the outset of the project, so the correct evidence exists and can be gathered in the best possible format. Provide context for the evidence you are reporting rather than reporting data in isolation – for example, a reduction in falls is great, but it will also translate into a reduction in ambulance calls for that service and hospital admissions in the urgent and emergency care settings.

You may need to identify other datasets that provide evidence of downstream consequences of interest to your customers.

Outputs can take several forms, which should be agreed between innovator and AHSN at the outset.

“We were really clear from the beginning about the messaging that we needed to give to commissioners, the messaging for the providers, and the messaging for the finance people.”

**Dara Coppel,
East Midlands AHSN**

Ensure the tone of voice used in each output is appropriate to its specific audience – for example, the language in a business case will differ from that on a commercial website or in a leaflet for patients or carers. Include core standards in reports, or make them publicly available, to assure stakeholders that appropriate and proportionate rigour was applied to the real-world evaluation.

Identify partners to develop outputs who understand the context and can highlight benefits of the identified outcomes in appropriate language and formats.

“The key is to construct the business case in a way that resonates with the trust. The average finance director doesn't want to see a giant Markov model, because it means nothing to them. The whole purpose of a real-world evaluation is for them to see what it does for their trust, their patients, their hospital.”

Julie Hart, Oxford AHSN

“There’s an issue around language, the way in which things are described that is important for real-world evaluation. It’s not a randomised clinical trial or a paper that will be published in the same way that a research paper will be. Its job is to help the Safe Steps team explain the value proposition of Safe Steps, so you know the potential impact and a reason to invest in it.”

Mike Kenny, Innovation Agency

Ongoing

- **How will you continue to build on the RWE to develop further evidence?**

A real-world evaluation is not a one-off project with a completion date or endpoint, but the start of a continuing process of developing evidence as your innovation is more widely adopted. Indeed, every implementation in another setting provides a new opportunity to build up evidence to prove the case for your innovation and improve and streamline the implementation process. Plan from the start how you will incorporate ongoing activities and evidence collection so that your real-world evaluation grows and evolves with every new roll out.

Real-world evaluation is not a one-off project but the start of a continuing process that should be built on to support and encourage spread.

“You never stop learning. These days we’re testing hundreds of thousands of people at home as part of the work that we’ve been doing nationally and through the AHSN Network – but we’re still learning every day how we can work better with healthcare providers and how we can support patients better.”

Jimmy Endicott, Healthy.io



“I feel very strongly that we don’t just stop with a real-world evaluation. To start the spread process, you need to keep going with it and keep building on that. We have commissioned an evaluation of the whole national spread programme with independent partners and using our steering group and the wider sectors to make sure that it’s hitting the blueprint of what NHS England want, what the charities see and feel is happening on the ground, etc. I think that’s all really important.”

**Dara Coppel,
East Midlands AHSN**

“It’s also important to think about the capacity of your team to support adoption and spread. As an SME, you need to think very carefully about whether you want to and can support national spread. Some small companies have been awarded national funding, but could not support the entire UK, because the funding is aimed at the product and not expanding the resources of the company to discuss the product and to support and provide training.”

Julia Eades, Roche Diagnostics

“Businesses think at the start that you get the evaluation, box ticked and you can go to anyone. We now realise that this is something we will always do, it’s going to be something every year, when you do a new evaluation with another region or another research institute or another clinician, and it’s going to be baked into our way of working.”

Lee Omar, Safe Steps



I Conclusion

Real-world evaluation in this context is an art form as much as a science. The AHSN Network wants to see high-value innovations adopted at scale across the NHS, improving lives of patients and helping build high-growth potential businesses that create jobs and leverage investment into the UK. Appropriate, well-designed,

real-world evaluations, which respect the work that NICE have completed in their framework but are much more 'practical' in their approach, will help decision-makers in the NHS health and social care system make good and consistent decisions on what innovations to adopt and, importantly, how to implement them to ensure

they return the high-impact health benefits promised.

The AHSN Network hopes that you will learn from this publication and engage and work with your local AHSN to develop your innovation and plan real-world evaluations that will support its spread and adoption across the NHS health and social care system.



I Useful resources

- [The AHSN Network. Bridging the gap](#)
- [The AHSN Network. Directory for innovators](#)
- [NHS long term plan](#)
- [2022/23 priorities and operational planning guidance](#)
- [NHS backlog recovery plan](#)
- [Integration and innovation working together to improve health and social care for all](#)
- [Accelerated Access Collaborative](#)
- [NHS Innovation Accelerator](#)
- [Core20PLUS5 framework](#)

I Reference

1. Department for Business, Energy & Industrial Strategy, Department of Health and Social Care, Office for Life Sciences. Bioscience and health technology sector statistics 2020. Available at: www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2020/bioscience-and-health-technology-sector-statistics-2020 (Accessed 20 June 2022).

Appendix A:

Checklist of considerations for real-world evaluations

Planning

- What steps are involved in an RWE project to deliver the most appropriate evidence and outputs?

Problem

- What is the problem you are trying to solve?
- What need are you servicing?

Innovation

- What exactly are you doing to the population you have identified?
- Are you replacing or adding something completely new?

Population

- What is the patient population you are treating? Can you describe it accurately?
- Will different populations and systems be differentially impacted by your innovation?
- Are health inequalities within your population being addressed?

Clinical efficacy

- Have you proven the clinical efficacy of your innovation?

Pathway

- What is the wider pathway for this patient population?
- Where does your innovation fit within the current pathway/care setting?

Implementation

- How would your innovation be implemented within the NHS?
- What staff and resources would be needed?
- What happens to the patients, clinicians and system?
- What are the consequences to the customer upon implementing this innovation?
- What impacts are there across the wider health and social care system?
- What are the costs in resources and time to implement alongside the price?

Partnership

- Which partners would be appropriate to support your RWE?

Others

- With which stakeholders do you need to engage?
- Who else will use these data (AHSN, PCNs, NIHR, MHRA, NICE, ICS, etc)?

Priorities

- Does your innovation address any NHS priorities?

Investment

- Which financial partners would be appropriate to support your RWE?

Protocol

- What steps do you need for your evaluation?
- Can you describe them so the process can be replicated?

Comparator

- With what are you comparing the impact of your innovation – NICE guidance or a bespoke process?
- Does it replace an existing product or system or is it entirely new?

Outcomes

- Can you describe the outcomes of the intervention in a way that your customer values?

Outputs

- What are the most appropriate outputs for your RWE project?

Ongoing

- How will you continue to build on the RWE to develop further evidence?

Appendix B:

Scope of real-world evaluation

In scope

- Evaluation of a product developed by a private company that has regulatory approval and is market ready (or on the cusp) but does not have any evidence of impact in a real-world NHS setting
- Evaluation of the impact of an AHSN local or national programme to support continued adoption and uptake following an initial trial/funding period and to support wider spread and adoption and evidence of impact. In the case of national programmes, care should be taken to ensure work being conducted nationally or in other parts of the country is not being duplicated
- Evaluations that are generally described as ‘service evaluations’ by an integrated care board (ICB), integrated care partnership (ICP) or Trusts. For example, changes to pathways or service improvement, which sit outside of the formal research and development (R&D) governance process and generally do not need ethical approval.

Out of scope

- Evaluating clinical efficacy of an early stage or research product that is not UK Conformity Assessed (UKCA) marked and not market ready and/or evaluations designed to generate evidence for regulatory approval
- Evaluation of a new service or a service redesign project, where the background and implementation have been conducted solely by the health system and the AHSN Network has had little or no involvement
- Funding an evaluation that seeks to evidence impact of a nationally or regionally mandated or funded programme. Such requests should be directed back to the national or regional commissioner (NHS England/NHS Digital) in the first instance to avoid duplicating activity
- Conducting evaluation projects without following generally accepted tools and techniques and relevant standards. For example, evaluating a digital product without referring to the [NICE Digital Evidence Standards Framework](#)

- Lengthy, costly and overly rigorous evaluations akin to a clinical trial, where a real-world evaluation would be more appropriate. Real-world evaluations by their nature should be completed at pace if they are to accelerate spread
- Evaluations that solely consider qualitative impact of an intervention, likely assessed through questionnaires or interviews etc, although consideration may be given to ethnographic approaches when evaluating non-technical projects – for example, patient and public involvement or systems leadership.



Contact us

For more information about past and future work, visit [ahsnnetwork.com](https://www.ahsnnetwork.com)

You can also follow us on social media:

 @AHSNNetwork

 the-ahsn-network

 AHSN Network

To find contact details for your local AHSN, visit: www.ahsnnetwork.com/contact

