

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Digital technologies for managing mild to moderate symptoms of hip or knee osteoarthritis: early value assessment

Guidance development process

NICE early value assessment (EVA) guidance provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over the next 3 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

Find out more on the NICE webpage on early value assessment.

NICE is producing this guidance on digital technologies for managing mild to moderate symptoms of hip or knee osteoarthritis in the NHS in England. The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts.

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This document has been prepared for consultation with the

stakeholders. It summarises the evidence and views that have been

considered and sets out the recommendations made by the committee. NICE

invites comments from the stakeholders for this evaluation and the public.

This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

Has all the relevant evidence been taken into account?

Are the summaries of clinical and cost effectiveness reasonable

interpretations of the evidence?

Are the recommendations sound and a suitable basis for guidance to the

NHS?

• Are there any aspects of the recommendations that need consideration to

ensure we avoid unlawful discrimination against any group of people on the

grounds of age, disability, gender reassignment, pregnancy and maternity,

race, religion or belief, sex or sexual orientation?

After consultation:

Based on the consultation comments received, the committee may meet

again.

• If committee meets again, it will consider the evidence, this evaluation

consultation document and comments from stakeholders.

The committee will then prepare the final draft guidance, which will go through

a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on digital

technologies for managing mild to moderate symptoms of hip or knee

osteoarthritis. The recommendations in section 1 may change after

consultation.

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More details are available in <u>NICE's health technology evaluations: the manual</u> and <u>NICE's early value assessment interim process and methods</u> statement.

Key dates:

Closing date for comments: 04 November 2025

Second committee meeting: 20 November 2025

1 Recommendations

Can be used with evidence generation

- 1.1 Eight technologies can be used in the NHS during the evidence generation period as options to manage mild to moderate symptoms of hip or knee osteoarthritis in adults. The technologies are:
 - getUBetter
 - Good Boost
 - Hinge Health
 - Joint Academy
 - Phio Engage
 - re.flex
 - Thrive
 - Track Active Me.

These technologies can only be used:

if the evidence outlined in the <u>evidence generation plan for</u>
 <u>digital technologies for managing mild to moderate symptoms of</u>
 <u>hip or knee osteoarthritis</u> is being generated

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- as long as they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.
- 1.2 The companies must confirm that agreements are in place to generate the evidence. NICE will contact the companies annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw the guidance if these conditions are not met.
- 1.3 At the end of the evidence generation period (3 years), the companies should submit the evidence to NICE in a format that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

More research is needed

1.4 More research is needed on Pathway Through Arthritis to manage mild to moderate symptoms of hip or knee osteoarthritis before it can be funded by the NHS.

What this means in practice

Can be used with evidence generation

The 8 digital technologies for managing mild to moderate symptoms of hip or knee osteoarthritis in recommendation 1.1 can be used as an option in the NHS during the 3-year evidence generation period and paid for using core NHS funding. During this time, more evidence will be collected to address any uncertainties. Companies are responsible for organising funding for evidence generation activities.

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After this, NICE will review this guidance and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

Potential benefits of use in the NHS during the evidence generation period

- Access and equality: Digital technologies may help to remove some barriers to accessing face-to-face care and improve engagement with non-pharmacological treatment options, such as therapeutic exercise. This could benefit people in rural communities and people who have limited mobility or other time commitments. Exercises can be tailored to people's needs without further appointments because the programmes can be adjusted remotely.
- System benefit: Healthcare professionals may be able to access user
 data to track the user's progress and follow up where needed. People
 using digital technologies to manage their condition may be less reliant
 on other healthcare resources. The technologies are not intended to
 replace face-to-face care but may help reduce the number of
 appointments someone needs.
- Clinical benefit: Using digital technologies may improve mild to moderate symptoms of hip or knee osteoarthritis and slow disease progression.

Managing the risk of use in the NHS during the evidence generation period

Training: Healthcare professionals would need training in, or a
familiarity with, any technologies they recommend. This is to ensure the
technologies are appropriate and meet the needs of people with mild to
moderate symptoms of hip or knee osteoarthritis.

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- Costs: The costs of the technologies vary widely. Commissioners should factor this into their purchasing decisions.
- Safety and suitability for patients: Digital technologies may be unsuitable for some people with mild to moderate symptoms of hip or knee osteoarthritis. Screening questionnaires should be used to check if the technology is suitable for the person before it is offered. The technologies have safety features to identify poor engagement or progress. These can alert company physiotherapists or NHS healthcare professionals (where configured) to review the information or suggest to the user to contact their healthcare professional for advice.
- **Workforce:** For the technologies that provide clinical support or offer physiotherapy as part of their service, commissioners should verify that the companies have an appropriately skilled workforce available.
- **Equality:** Some people may find it more difficult to use or engage with digital technologies and may need additional support. This includes:
 - people who are less familiar with using digital technologies or have
 limited access to equipment or the internet
 - neurodivergent people
 - people with learning disabilities
 - people with visual, hearing or cognitive impairments
 - people who have problems with manual dexterity
 - people who have difficulties reading, writing or understanding healthrelated information (including people who cannot read English).

More research is needed

There is not enough evidence to support funding Pathway Through Arthritis in the NHS.

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Access to Pathway Through Arthritis should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

What evidence generation and research is needed

More evidence generation and research is needed on the technologies, including:

- their effect on patient-reported outcomes such as pain and stiffness,
 physical function and health-related quality of life, including in the long term
- their effect on healthcare resource use and services, including additional care needed (for example, medicine use and referrals to other specialist services)
- the amount people use and engage with them, how easy they find them to use and the benefits of additional technology features
- any adverse events.

The <u>evidence generation plan</u> gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through further studies.

Why the committee made these recommendations

People with mild to moderate symptoms of knee or hip osteoarthritis may find it difficult to travel and attend healthcare appointments in person. Digital technologies for managing mild to moderate symptoms of knee or hip osteoarthritis could help remove this barrier to accessing care because people can use the digital technologies when it is convenient for them. Some technologies allow healthcare professionals to remotely monitor a user's

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progress. These technologies may also allow treatment to be started when symptoms first occur.

Clinical trial evidence for 8 of the technologies is limited. But it suggests that these technologies improve physical function and reduce pain and stiffness. They may also improve quality of life, but this is more uncertain.

Early results from economic modelling show that these digital technologies could be cost effective. But the model includes some assumptions and estimates from experts because the economic data is limited. Also, the model used an average cost for 7 technologies with non-confidential cost data, so it does not reflect the wide range of technology costs.

Because of their potential benefits and low risk of harm for users, getUBetter, Good Boost, Hinge Health, Joint Academy, Phio Engage, re.flex, Thrive and Track Active Me can be used as options in the NHS while more evidence is generated.

No evidence was found for Pathway Through Arthritis. So, it can only be used in research.

2 Information about the technologies

- 2.0 This assessment considered 11 digital technologies for managing mild to moderate symptoms of hip or knee osteoarthritis. The technologies are accessed via a web or smartphone application. They aim to give people the knowledge, skills and confidence to manage their condition when it is convenient for them. Each technology includes the following components:
 - information, education and advice on managing hip or knee osteoarthritis
 - a personalised therapeutic exercise programme
 - signposting to appropriate support services when needed.

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- 2.1 The technologies vary in terms of their delivery, access route, intended population, professional involvement, additional features, current NHS use and costs (table 1). The costs and durations of use vary. Some technologies have an annual cost, whereas others have a cost based on how long they are expected to be used. More detail is in table 1 of the external assessment group (EAG) assessment report and table 1 of the assessment report overview.
- 2.2 Physio Wizard and ESCAPE-pain digital technologies are no longer available to the NHS, so the committee could not make recommendations on them.

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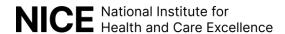
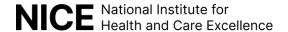


Table 1. Overview of digital technologies for managing hip or knee osteoarthritis

Technology (company)	Indication	Healthcare professional communication	Additional features	Programme adjustments	Cost
getUbetter (getUBetter)	Hip and knee	No direct communication	No	Based on user feedback	£18.86 (annual)
Good Boost (Good Boost Wellbeing)	Hip and knee	One way (professional to user)	Optional classes	Automated based on user feedback	£46.15 (annual)
Hinge Health	Hip and knee	No direct communication	Motion tracking	Automated based on user feedback	£296.25 (annual)
Joint Academy (Artho Therapeutics)	Hip and knee	Two way (messaging and video with company specialist)	No	By company physiotherapist and semi-automated based on user feedback	£112.50 (12 weeks)
Phio Engage (EQL)	Hip and knee	Two way (messaging with company or NHS specialist)	No	By physiotherapist	£45.28 (annual)
Pathway Through Arthritis (Wellmind health)	Hip and knee	One way (user to professional)	Unclear	Unclear	Unclear
re.flex (Kineto tech rehab)	Knee	No direct communication	Wearable sensor with motion tracking	Automated based on sensor feedback	£229.50 (12 weeks)
Thrive (Sword Health)	Hip and knee	Two way (messaging and video with company specialist)	Wearable sensor with motion tracking	By physiotherapist	£375 (annual)
Track Active Me (Active Health Tech)	Hip and knee	One way (user to professional)	No	Automated based on user feedback	Confidential

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3 Committee discussion

The medical technologies advisory committee considered evidence from several sources. This included evidence submitted by the companies, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the <u>project</u> documents for this guidance.

The condition

3.1 Osteoarthritis is the most common form of arthritis, with around 10 million people in the UK diagnosed. It is a long-term disorder of synovial or cartilaginous joints. The knee and hip joints are most commonly affected. Joint symptoms vary from mild and intermittent to more persistent or severe. People with mild to moderate symptoms of hip or knee osteoarthritis, may experience joint pain especially when walking, and some of their daily activities may be limited. The condition often gets worse over time and usually a person's symptoms fluctuate, with some flare-ups. There is no cure, but symptoms can be managed.

Current practice

- 3.2 People with suspected osteoarthritis of the hip or knee usually present to primary or community care with joint pain. Self-referral to community musculoskeletal (MSK) physiotherapy services is also possible.
- 3.3 NICE's guideline for the diagnosis and management of osteoarthritis in over 16s describes the diagnosis pathway and treatment options. Treatment options for hip or knee osteoarthritis depend on the severity of the symptoms. Pharmacological options include analgesic medicines and corticosteroid injections. Non-pharmacological options include therapeutic exercise, weight

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management (if appropriate), information and support. Manual therapy and supportive devices (such as walking aids) may also be offered. Self-management is encouraged. A treatment package combining therapeutic exercise, education and coping strategies is usually recommended. People are encouraged to try conservative treatments for at least 3 months before onward referral is considered. People should seek follow up if planned management is not working.

Unmet need

3.4 Musculoskeletal conditions are becoming more common. There is unmet need across the NHS for access to exercise and education programmes that can start when symptoms first happen. Some NHS services struggle to meet demands and people need to wait to access services. For example, people may need to wait to see a healthcare professional to start or adjust their exercise programme. The clinical experts noted that delays in treatment can negatively affect a person's quality of life and may affect how quickly the disease progresses. Some people may struggle to attend face-to-face services for exercise therapy or to receive support and education on their condition. This may include people living in rural areas, people with reduced mobility and people with other time commitments. There is an unmet need for treatment options that can be accessed remotely when it is convenient for the user.

Innovative aspects

3.5 Both the patient and clinical experts highlighted the usefulness of the technologies collecting user data to track symptoms, adherence and exercise progress, with the option of sharing this information with healthcare professionals. This data can be used to make programme adjustments and to help ensure that exercises are appropriate for the user. Compared with paper-based exercise

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programmes, where no feedback is given, using this data can help minimise injury risk, promote user engagement and improve communication with healthcare professionals.

3.6 The technologies include a range of features that provide different potential benefits. Five technologies (Good Boost, Joint Academy, Phio Engage, Thrive, Track Active Me) use direct communication with the company or NHS healthcare professionals. This can include chat functions or video calls. Healthcare professionals can oversee progress and adjust programmes remotely. This may lower injury risk and promote user engagement. The committee noted that the company healthcare professionals who support users of the technologies should have the appropriate clinical skills. One technology (Good Boost) includes group-based interactive elements, such as virtual classes. These features may help engage users. Three technologies include motion tracking, both with wearable sensors (re.flex and Thrive) and without (Hinge Health). These can be used to track performance and check if exercises are being performed correctly. These features may help to lower injury risk and provide personalised user feedback information. The committee noted that the service users' needs vary, so a range of technologies with different features could benefit the system.

Clinical effectiveness

Available evidence

3.7 Evidence was found for 9 of the 11 technologies. No evidence was found for Pathway Through Arthritis or Physio Wizard. The EAG prioritised 10 studies as key evidence. This included 3 randomised controlled trials (RCTs), 5 single-arm studies, 1 audit and 1 company data submission. The evidence came from a range of countries, with 6 sources from the UK, 2 from the US, 1 from

Germany and 1 in which the location was not disclosed. The EAG Draft Guidance – HTE10057 Digital technologies for managing mild to moderate symptoms of hip or knee osteoarthritis: early value assessment

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noted that only 2 studies were directly applicable to the population in scope. The other evidence included people with different severities of osteoarthritis symptoms, did not report the severity, included only single joints or did not account for different types of musculoskeletal condition at baseline. Although the committee noted that reporting of severity was a limitation in the evidence, it acknowledged that there is no consensus on classifying severity because imaging is not normally used to diagnose osteoarthritis. But because 6 of the studies were done in the UK, the committee concluded that this evidence was most likely to reflect the UK population that is self-managing mild to moderate symptoms of hip or knee osteoarthritis. The committee also noted that the maximum follow-up time among the prioritised studies is 12 weeks (included in 6 studies). Section 6.7 of the EAG's report describes the limitations of the evidence base.

3.8 The primary outcomes were pain and stiffness, physical function and health-related quality of life (HRQoL). Pain and stiffness was reported in all 10 studies. Physical function was reported in 9 studies. The results suggested that these technologies could improve pain and stiffness and physical function. HRQoL results were available for 5 technologies from 2 RCTs and 3 single-arm studies. The committee noted the modest benefit of the digital technologies, but it understood that this was to be expected in people with a progressive condition. The clinical experts noted that the potential benefits of the digital technologies may be better captured if changes in rates of disease progression were also measured. The committee also discussed the use of conditionspecific measures, such as the Knee injury and Osteoarthritis Outcome Score quality-of-life subscale. The EAG highlighted that condition-specific measures need to be mapped to the EQ-5D. The committee concluded that future evidence should ensure that

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- measured HRQoL outcomes are relevant and usable in a cost—utility model.
- 3.9 Limited evidence was found for other outcomes included in the scope, including psychological outcomes, self-efficacy, activity impairment, referral for corticosteroid injections, medication use and number of appointments. The committee was aware of the limited evidence, the range of outcome measures used and that some of the technologies were included in only single-arm studies. It concluded that, overall, the evidence suggests that these technologies could improve symptoms of osteoarthritis.

Adverse events and patient safety

3.10 Limited evidence was found for adverse events. Only 3 key studies included this outcome and only 1 of these reported any adverse events. Details on the nature of the adverse events were not available, but the clinical experts advised that increased pain is the most common. The committee concluded that the risk of adverse events is low for people with mild to moderate symptoms of hip or knee osteoarthritis. But, more data on adverse events and their nature should be captured in future evidence generation.

Patient considerations

3.11 Digital technologies have the potential to increase treatment options for people with mild to moderate symptoms of hip or knee osteoarthritis, and in many cases will provide quicker access to treatment. The patient experts explained that following a personalised exercise plan and learning about self-management tools helps empower people to manage their condition. This could help reduce pain and increase muscle strength and mobility. One patient expert highlighted that the user feedback data is useful for

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tracking progress, increasing motivation and communicating with healthcare professionals.

- 3.12 The committee understood that patient choice is important and agreed that this should be taken into account when deciding who the digital technologies are most suitable for. It also concluded that the size of the user population should be explored in evidence generation. The patient experts commented that some users struggled with motivation and consistency, and that using these tools sometimes feel disconnected from NHS care pathways. A clinical expert advised that they expect the digital technologies to be suitable for around only 25% of people with mild to moderate symptoms of hip or knee osteoarthritis. The committee agreed that these technologies are not appropriate for everyone. It was understood that digital technologies are not intended to fully replace face-to-face services and instead would complement standard care. A clinical expert advised that they expect the digital technologies to be suitable for around only 25% of people with mild to moderate symptoms of hip or knee osteoarthritis.
- 3.13 The committee discussed integration of the digital technologies with NHS systems. It concluded that there needs to be appropriate means of ensuring progress and suitability for patients. Company information confirmed that screening questionnaires or clinician referral should be done to check suitability before a technology is offered. The clinical experts noted the importance of having a mechanism to raise issues like lack of progress, negative symptom changes or lack of engagement. This allows users to be given the support they need or be signposted to alternative services if needed. The committee understood that the technologies have safety features to identify poor engagement or progress. These can alert company physiotherapists or NHS healthcare professionals

(where configured) to review the information or suggest the user Draft Guidance – HTE10057 Digital technologies for managing mild to moderate symptoms of hip or knee osteoarthritis: early value assessment

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contact their healthcare professional for advice. Companies confirmed that none of the technologies are directly linked to NHS systems, but most companies confirmed that it would be possible to integrate the technologies with NHS systems if needed.

3.14 A range of technologies are included in the assessment, with varying levels of healthcare professional support and guidance. Some people may prefer a fully automated system for adjusting the programme, whereas others could benefit from an intervention that involves more healthcare professional support or supervision. The committee understood that some of the technologies included wearable sensors with motion trackers or AI-based personalised exercise programmes. The committee acknowledged that evidence generation will give companies the opportunity to collect more evidence on potential benefits to both people with mild to moderate symptoms of hip or knee osteoarthritis, and the healthcare system.

Cost effectiveness

3.15 Early economic modelling using a simple cost—utility model suggested that digital technologies for managing mild to moderate symptoms of hip or knee osteoarthritis may be cost effective. But the model parameters included estimates and assumptions because of the lack of data (see section 7.1 of the EAG report). The services provided by the technologies vary (for example, some include wearable sensors and access to company physiotherapists whereas others do not). There is also no evidence on the effectiveness and resource use for individual technologies. So, it was not possible to compare each technology alone with standard care. Instead, the model used evidence from various technologies, where available, and was informed by clinical opinion. The committee understood the results from the early economic modelling were exploratory and that the likely cost effectiveness for

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each technology is uncertain. It noted that more evidence is needed to provide more accurate results for each technology to inform future economic modelling.

3.16 The committee queried if a 1-year time horizon was appropriate for this population. The EAG explained that the model was limited by the data available. For example, there was no data on referrals for corticosteroid injections or surgery. The committee understood that further evidence generation needs to capture longer-term effects.

Technology costs

3.17 The committee understood that a significant limitation of the early modelling was that an average technology cost was used instead of individual technology costs. This is because of the variation in the costing models used. For example, some technologies included costs for staff training, company physiotherapists or sensors. An average cost of £160.51 per person per year was calculated across 7 technologies, using non-confidential cost data. One technology was excluded from the average because its cost data was confidential. The committee noted the costs ranged between £19 and £375 per person, with 4 technologies with non-confidential costs priced below the average cost used in the model. The EAG also noted that some costs represented an annual cost, whereas others were based on their expected use duration. There was uncertainty in the additional technology costs because of the potential need for licence extensions if the programme continued beyond its expected duration. Future economic modelling needs to be based on an individual technology's costs to provide more accurate estimates of cost effectiveness.

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Resource use

3.18 There was limited evidence on resource use. Expert elicitation was used to inform assumptions on resource use in the model's base case. This included estimates of medication use, primary care and physiotherapy service appointments, and changes to resource use resulting from the intervention. The EAG highlighted that expert assumptions were necessary because of the very limited data available. The committee discussed the standard care appointments assumptions and heard from a clinical expert that these may be underestimated. The committee also acknowledged that the associated resource use would vary because of the different business models used for individual technologies. For example, some technologies rely on regular NHS healthcare professional support, whereas others are automated. The lack of data on resource use was noted as a key area of uncertainty. The committee concluded that accurate data on resource use for individual technologies would be needed to accurately estimate cost effectiveness in the future.

Equality considerations

Digital inclusion and accessibility

3.19 The committee agreed that digital inclusion and wider accessibility issues need to be adequately addressed and included within future evidence generation. It noted that digital technologies require an internet connection, a suitable device, and digital and literacy skills to correctly navigate the applications. Although this is a prominent issue associated with digital technologies, no evidence relating to digital inclusion was found for any of the technologies. One clinical expert highlighted digital inclusion as the biggest gap in the evidence base. Another clinical expert advised that local and national charitable organisations can help bridge the gap in

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accessing the required devices and internet. The need to investigate wider accessibility issues, such as technologies being available in additional languages or easy-read format, was also highlighted.

3.20 Specialist committee members noted a large digital literacy gap, particularly for people living in rural areas. Digital literacy among users, their families and carers was a key consideration. Training for users, their families and carers was discussed as a possible solution to help reduce digital exclusion, with short video instructions suggested as a minimum.

4 Committee members and NICE project team

This topic was considered by <u>specialist committee members appointed for this</u> <u>topic</u> and <u>NICE's medical technologies advisory committee</u>, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The <u>minutes of each committee meeting</u>, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Teik Goh

Chair, medical technologies advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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