NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final appraisal document

Sacituzumab govitecan for treating unresectable triple-negative advanced breast cancer after 2 or more therapies

1 Recommendations

1.1 Sacituzumab govitecan is recommended, within its marketing authorisation, as an option for treating unresectable triple-negative locally advanced or metastatic breast cancer in adults after 2 or more systemic therapies, at least one of which was for advanced disease.

Why the committee made these recommendations

Usual treatment for triple-negative locally advanced or metastatic breast cancer is chemotherapy.

Clinical trial evidence shows that sacituzumab govitecan increases how long people have before their disease gets worse and how long they live compared with chemotherapy.

Sacituzumab govitecan meets NICE's criteria to be considered a life-extending treatment at the end of life. The cost-effectiveness estimates are within what NICE usually considers an acceptable use of NHS resources. Therefore, it is recommended.

2 Information about sacituzumab govitecan

Marketing authorisation indication

2.1 Sacituzumab govitecan (Trodelvy, Gilead Sciences) has a marketing authorisation for 'the treatment of adult patients with unresectable locally

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advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for sacituzumab govitecan.

Price

2.3 The list price of sacituzumab govitecan is £793.00 per 180 mg vial (excluding VAT; BNF online accessed May 2022).

2.4 The company has a commercial arrangement (simple discount patient access scheme). This makes sacituzumab govitecan available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Committee discussion

The appraisal committee considered evidence submitted by Gilead, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the committee papers for full details of the evidence.

Clinical need and treatment pathway

Triple-negative breast cancer has a high disease burden

3.1 Triple-negative breast cancer accounts for about 15% of breast cancers and lacks all 3 molecular markers (oestrogen, progesterone and HER2 receptors), which affects treatment options and prognosis. Chemotherapy is the mainstay of treatment because triple-negative breast cancer is not sensitive to endocrine therapy or molecular targeted therapy. The patient expert explained that being diagnosed with locally recurrent unresectable or metastatic breast cancer is extremely difficult for people, and their

family and friends. It can cause considerable anxiety and fear, and the uncertainty of the outcome can be very difficult to deal with. The aim of treatment is to stop progression of the disease, extend life, and maintain or improve quality of life for as long as possible. Treatment is continued for as long as it is controlling the disease. The committee concluded that there is a high disease burden for people with triple-negative breast cancer.

There is a high unmet need for effective treatments for triple-negative locally advanced or metastatic breast cancer

3.2 The marketing authorisation for sacituzumab govitecan specifies its use after 2 or more prior systemic therapies, one of which should have been for advanced disease. For people who have triple-negative advanced or metastatic breast cancer, first-line therapies are paclitaxel, docetaxel, nab-paclitaxel, anthracycline-based chemotherapy, gemcitabine with or without carboplatin, or atezolizumab plus nab-paclitaxel for PD-L1-positive disease (see NICE's technology appraisal guidance on atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer [TA639]). Second-line therapies are single-agent vinorelbine or capecitabine. Third-line therapies are eribulin (see NICE's technology appraisal guidance on eribulin for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens [TA423]) or single-agent vinorelbine or capecitabine (whichever was not used previously) (see NICE's clinical guideline on breast cancer: diagnosis and management). In the locally advanced or metastatic setting, the proposed positioning for sacituzumab govitecan is either second line (for people who received a systemic treatment for early disease) or third line (for people who initially presented with de novo metastatic disease). The clinical experts clarified that, in the locally advanced or metastatic setting, most people would have sacituzumab govitecan as a second-line therapy. Clinicians prefer to use the most effective treatments earlier in the treatment pathway. Therefore, people will have already had anthracyclines, taxanes and capecitabine.

The clinical experts noted that because early triple-negative breast cancer tends to relapse quickly after treatment, rechallenge with these therapies is not appropriate, leaving very few effective treatment options. The committee concluded that there is a high unmet need for effective treatments for locally advanced or metastatic triple-negative breast cancer.

Clinical evidence

Sacituzumab govitecan offers considerable benefit compared with standard care

3.3 The clinical evidence was based on ASCENT, a randomised, open-label clinical trial that enrolled people with relapsed or refractory, unresectable, triple-negative, locally advanced or metastatic breast cancer after 2 or more previous therapies. ASCENT compared sacituzumab govitecan with treatment of physician's choice, which included eribulin, capecitabine, gemcitabine and vinorelbine. The company reported trial results from a March 2020 data cut. This showed a consistent clinically meaningful and statistically significant benefit for sacituzumab govitecan compared with treatment of physician's choice for objective response rate, progression-free survival and overall survival. The objective response rate was considerably greater in the sacituzumab govitecan arm: 31.1% compared with 4.2% in the treatment of physician's choice arm. Median progression-free survival was 4.8 months in the sacituzumab govitecan arm compared with 1.7 months in the treatment of physician's choice arm (hazard ratio 0.43, 95% confidence interval 0.35 to 0.54). Median overall survival was 11.8 months with sacituzumab govitecan compared with 6.9 months in the treatment of physician's choice arm (hazard ratio 0.51, 95% confidence interval 0.41 to 0.62). The patient expert experienced tumour shrinkage while on sacituzumab govitecan, and explained that initial gastrointestinal side effects were well managed with a dose reduction and concomitant medication. The company provided a later data cut from February 2021 during technical engagement. The ERG noted that the survival data was

similar across the 2 data cuts, with no changes to the median estimates, and marginal changes to the mean estimates. The committee considered sacituzumab govitecan to be a highly effective treatment for people with triple-negative locally advanced or metastatic breast cancer who have a poor prognosis.

The results of the trial are generalisable to NHS clinical practice

3.4 In ASCENT, 32.7% of people had previously had eribulin, which is only used as a third-line treatment in the UK (after 2 or more chemotherapy regimens, in line with TA423). In the UK, eribulin would be given after sacituzumab govitecan. The ERG noted that prior eribulin in ASCENT could impact the trial efficacy results for sacituzumab govitecan. The clinical experts explained that because the trial also included people who had not had prior eribulin, the trial demonstrated that sacituzumab govitecan is effective before and after eribulin. They felt that the efficacy of sacituzumab govitecan is not affected by prior treatment with eribulin. The committee accepted that although approximately a third of the people in ASCENT had received eribulin, which does not reflect UK practice, the results were generalisable to people in the NHS.

The effect of a higher dropout rate in the comparator arm is unknown

3.5 In ASCENT, 14.5% of people randomised to the comparator arm (treatment of physician's choice including eribulin, gemcitabine, capecitabine and vinorelbine) chose not to have treatment, compared with 3.4% of people in the sacituzumab govitecan arm. The ERG noted that this differential dropout rate could introduce bias because it is unclear if common patient characteristics affected the choice to start treatment. The ERG suggested that it may have been people with a better prognosis who felt they had better options outside of participating in ASCENT. The clinical experts disagreed and explained that people who dropped out of the trial were more likely to be those with poor prognosis who chose not to have further chemotherapy as part of the comparator arm. They said that dropout was inevitable in an open-label trial, and that people may be

unwilling to remain in the comparator arm when there is already published data showing that sacituzumab govitecan is an effective treatment. The safety population included only those who started treatment, and the company used this population to conduct the quality of life analyses. The committee concluded that the survival data from ASCENT is generalisable to the NHS, and that the effect of differential dropout rates on the measured outcomes is unknown.

ASCENT trial data is appropriate for decision making

3.6 The committee noted issues with the generalisability of ASCENT including previous eribulin use (see section 3.4) and differential dropout rates between sacituzumab govitecan and treatment of physician's choice (see section 3.5), but concluded that the trial data was appropriate for decision making.

There is uncertainty in the quality of life data and therefore in the utility values used in the model

3.7 ASCENT collected data on European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 scores, which informed the utilities in the model. Scores were missing for 11.7% of the treatment arm and 30.2% of the comparator arm. The clinical experts explained that this was probably because of people in the comparator arm having earlier disease progression and their condition deteriorating more quickly; attrition for collection of data on quality of life is inevitable when people's condition progresses because they are less willing or able to complete questionnaires. The ERG highlighted that this might have biased the treatment effect estimates and noted the wide confidence intervals around the EORTC QLQ-C30 scores. It deemed the quality of life data collected in ASCENT highly uncertain. During consultation, the company did a post hoc analysis of people on treatment of physicians' choice who were not followed up for quality of life data. This group had worse overall survival than those who were followed up. The clinical experts noted that using quality of life estimates that excluded people who were not followed up

could lead to an overestimate of health-related quality of life. The committee concluded that uncertainty related to follow up had an unknown effect on the utility values used in the model.

It is plausible that quality of life is better during sacituzumab govitecan treatment than during standard chemotherapy, but not necessarily after progression

3.8 The company argued that ASCENT indicated that quality of life was better for those on sacituzumab govitecan. It assumed a quality of life benefit for those on sacituzumab govitecan compared with treatment of physician's choice in both the pre-progression and post-progression health states. The clinical experts explained that this is plausible because of the considerably greater objective response rate for sacituzumab govitecan (31.1% compared with 4.2% for treatment of physician's choice). This increased tumour shrinkage with sacituzumab govitecan would reduce symptoms associated with tumour burden and lead to improved quality of life. They considered it plausible that this would carry over upon disease progression, because people on sacituzumab govitecan enter the progressed health state with a reduced tumour burden compared with those who had treatment of physician's choice. The patient expert agreed that sacituzumab govitecan gave a good quality of life and that they were able to complete normal daily activities. Their initial gastrointestinal symptoms were managed with a dose reduction. The patient expert emphasised the psychological benefits of knowing that you were on an effective treatment compared with standard chemotherapy, and added that the hope this brings, and the potential for the treatment to act as a bridge to future effective therapies, improved their quality of life. The committee noted that to inform the post-progression utility values in the model, the company used a quality of life questionnaire completed 4 weeks after the last dose, which would be in early post-progression. The committee questioned whether this represented the true quality of life throughout the whole post-progression period. The committee concluded

that it is plausible that quality of life is better while taking sacituzumab govitecan compared with standard chemotherapy, but once the disease progresses and the people stop the therapy that is no longer effective, their quality of life would deteriorate. In addition, the committee noted that there was no evidence that the quality of life of people who had received sacituzumab govitecan would remain better right up to the time of death compared with people who had received other therapies pre-progression. However, in response to consultation comments, the committee considered scenarios in which there was a limited carry-over beneficial effect on quality of life after progression on sacituzumab govitecan.

Cost-effectiveness evidence

The company's model structure is appropriate

3.9 The company submitted a partitioned survival model to estimate the cost effectiveness of sacituzumab govitecan compared with treatment of physician's choice: eribulin, capecitabine, gemcitabine and vinorelbine. It had 3 health states: progression-free survival, post-progression survival and death. The committee considered that a partitioned survival model is a standard approach to estimate the cost effectiveness of cancer drugs and was appropriate for decision making.

Costs in the economic model

Treatment acquisition and administration costs are between the company and ERG estimates

3.10 Four assumptions contributed to the acquisition and administration costs of treatments in the model: costing by model or treatment cycle, relative dose intensity (RDI), the weight distribution applied to each treatment arm and allowance for any vial sharing.

- Costing by cycle: the company included drug costs in the model as a cost per 1-week model cycle. The ERG explained that this was not appropriate because anyone who died during a model cycle would still

have received the full treatment at the start of the treatment cycle, and this should be costed. It preferred a cost per 3-week treatment cycle which removed the risk of underestimating acquisition and administration costs. The Cancer Drugs Fund clinical lead explained that using a cost by treatment cycle was logical and the normal approach for modelling the costs of cancer drugs.

- RDI: the company included an RDI of 94.2%, which was informed by dose reduction, incomplete infusions and delays in the ASCENT trial, which the committee considered reasonable.
- Weight distribution: all treatments included in the model were dosed by weight. The company applied different weight distributions to the sacituzumab govitecan and treatment of physician's choice arms, which reflected the weight distribution of people in the ASCENT trial. It used a non-parametric distribution for the sacituzumab govitecan arm and a parametric distribution for the treatment of physician's choice arm. The ERG advised that, methodologically, the weight distribution should be identical in both arms and noted that the non-parametric distribution for sacituzumab govitecan was slightly skewed towards lower percentiles. The ERG did not prefer either distribution as long as the same distribution was applied to both arms. The company did a scenario analysis using parametric distributions for both arms. This had a minimal impact on the incremental cost-effectiveness ratio (ICER), and the change was in favour of sacituzumab govitecan.
- Vial sharing: the company assumed wastage for 50% of people having sacituzumab govitecan but that vials would be perfectly shared for the remaining 50%. The ERG felt this did not take an NHS perspective because these savings occurred at the hospital level and did not result in a reduced number of prescriptions. The committee considered the feasibility of vial sharing in practice based on the patient numbers. The Cancer Drugs Fund clinical expert agreed with the company, that 50% is a reasonable assumption for vial sharing.

The committee considered costing per treatment cycle (the ERG's approach), an RDI of 94.2%, and 50% vial sharing (the company's approach) to be most appropriate. The committee preferred using the same weight distribution in both arms but noted that varying this assumption had a small impact on the ICER and therefore did not discuss this at length.

The appropriate proportion of people having subsequent eribulin in the treatment of physician's choice arm of the model is 47%

3.11 The model included eribulin, paclitaxel, carboplatin, capecitabine, epirubicin and vinorelbine as subsequent treatments. Eribulin is the most expensive, and so the cost-effectiveness estimates were sensitive to the proportion of people assumed to have eribulin as a subsequent treatment. The committee appreciated that it was difficult to appropriately incorporate subsequent eribulin costs in the model given that a third of people in the trial had prior eribulin, which does not reflect UK clinical practice (see section 3.4) or the expected treatment pathway (see section 3.2). The committee recalled the clinical experts' view that prior eribulin use would not affect future outcomes and would predominately affect costs. The company sought UK clinical expert opinion about the expected proportions of people having subsequent eribulin in UK practice. The estimated proportion of people having eribulin after sacituzumab govitecan is commercial in confidence and cannot be reported here, but the ERG agreed with the company's estimate. The proportion of people having subsequent eribulin in the comparator arm of the model was 47%; this was based on those who did not get eribulin in the treatment of physician's choice arm in ASCENT, and would therefore get it subsequently. The ERG was concerned that a large proportion of people in the treatment of physician's choice arm of the model had eribulin twice because of the proportion of people who had it before entering the trial. This would overestimate eribulin costs in the comparator arm only and would underestimate the ICER for sacituzumab govitecan. The ERG's preferred approach was to only model subsequent eribulin for the 14% of

people in the treatment of physician's choice arm of ASCENT who had not previously had eribulin. The committee acknowledged the complexity of the issue but concluded that it was appropriate to assume subsequent eribulin for all who had not had it as part of the treatment of physician's choice (47%) arm, because this reflects what would happen in clinical practice in the NHS.

Utility values in the economic model

Higher pre-progression utilities for sacituzumab govitecan than for treatment of physician's choice are acceptable

3.12 The company used utility values in the pre-progression state that were 0.084 higher for people on sacituzumab govitecan than for those on treatment of physician's choice. These values came from the company's safety population analysis of the EORTC QLQ-C30 data collected in ASCENT. The ERG considered that this health-related quality of life analysis was invalid because of the attrition in quality of life data (see section 3.7) and the higher dropout rate of people assigned to treatment of physician's choice (see section 3.5), noting that this broke the randomisation. The clinical and patient experts provided a rationale to support the company case for higher utilities for people on sacituzumab govitecan compared with treatment of physician's choice (see section 3.8). The committee accepted the biological plausibility and magnitude of quality of life benefit and agreed that utility values would be higher in the pre-progression state for those on sacituzumab govitecan.

A higher utility value for the whole of the post-progression state for sacituzumab govitecan is not plausible

3.13 The company used the same analysis to inform the utility values in the post-progression and pre-progression states, meaning the post-progression utility was higher for people who had sacituzumab govitecan. The clinical experts stated that it was clinically plausible for sacituzumab govitecan to confer better quality of life in the post-progression state,

because people who had it before progression had reduced tumour burden and therefore symptoms, and this quality of life would carry through to the post-progression state. The committee questioned the numerical connection between tumour burden and quality of life improvement. The clinical experts noted that improvement in tumour burden is closely related to symptoms and therefore quality of life, but agreed it does not necessarily have a simple linear numerical relationship to utility because quality of life could also be related to, for example, the site of disease. The Cancer Drugs Fund clinical lead noted that tumour burden is a contributor to quality of life, but also that side effects of chemotherapy and factors such as further lines of chemotherapy, which was more likely in people having sacituzumab govitecan, also influenced quality of life. In the company's original submission, the pre-progression utility benefit (0.084) associated with sacituzumab govitecan compared with treatment of physician's choice was carried over into post-progression until death. The ERG was concerned that the data informing post-progression quality of life had been collected in ASCENT only 4 weeks after the last dose, which it considered did not reliably reflect post-progression utility over the longer term. The Cancer Drugs Fund clinical lead noted that utility would continue to decline in the progressed state as people neared death and would not be maintained at the 4-week level. The ERG preferred to use a post-progression utility (0.653) accepted in a previous appraisal in locally advanced or metastatic triple-negative breast cancer (TA639). The committee agreed that a higher utility for the whole of the post-progression state for people who had sacituzumab govitecan compared with those who had treatment of physician's choice is not plausible.

The company's revised base case with a restricted post-progression utility benefit for sacituzumab govitecan is the least flawed approach

3.14 After consultation, the company maintained its position that the post-progression utility benefit of sacituzumab govitecan compared with treatment of physician's choice would continue for the duration of the

person's life. But it also provided an alternative approach, in which people who had previously had sacituzumab govitecan had a higher utility than those on treatment of physician's choice for 6 months, after which the utilities converged. The converged utility after 6 months was slightly higher than post-progression utility for the first 6 months for people having treatment of physician's choice, constituting a rebound in post-progression utility for this group. The clinical experts did not consider this rebound to be clinically plausible. The committee acknowledged that if it accepted the company's pre-progression utility difference, and the ERG's preferred post-progression utility, this also resulted in an increase in the quality of life estimates in the treatment of physician's choice arm on progression. The ERG raised concerns about the lack of detail in the methodology in the company's revised approach. It preferred its initial base case of equal post-progression utilities for both arms, as with a previous appraisal (TA639). The ERG noted that the convergence of post-progression utility substantially affected the cost-effectiveness results, and did scenario analyses to further explore the company's approach of higher post-progression utility for people on sacituzumab govitecan for a limited time. The ERG's analysis was informed by ASCENT trial data and limited the higher utility to: (i) a period of continued response in the post-progression state and (ii) the proportion of people who had a clinical response to sacituzumab govitecan in the clinical trial. This increased the ICER compared with the company's adjustment. The committee noted that the ERG's analysis explored the effect of different response rates, but also noted that because the average utility used for the analysis included people whose disease responded and those whose disease did not respond, this approach was not entirely satisfactory. In total, the committee considered 4 different approaches to modelling post-progression utilities. It noted the uncertainties associated with each of the approaches and considered that none was entirely satisfactory. The committee acknowledged the challenges surrounding the post-progression utilities explored, noting the substantial effect on the cost-

effectiveness estimates despite the inherent uncertainty. But it concluded that the company's revised base case with a carry-over utility benefit for 6 months was the least flawed approach.

Long-term survival estimates

The long-term overall survival benefit for sacituzumab govitecan is uncertain

3.15 The company chose a jointly fitted log-logistic model to extrapolate overall survival. It chose this approach based on goodness of fit statistics and visual fit to the trial data. The company noted that the more mature data from the February 2021 data cut validated the joint log-logistic model. The ERG did not have a strong preference but recommended that the company explored both jointly and independently fitted curves. It noted that the jointly fitted generalised gamma curve had a similar statistical fit and a better visual fit than the joint log-logistic curve, but gave lower longer-term survival estimates. The committee noted that the trial data was mature and therefore the extrapolated overall survival was a true area of uncertainty rather than uncertainty because of data immaturity. It agreed that the true survival extrapolation could be anywhere between the log-logistic and the more pessimistic generalised gamma models. The committee concluded that the joint log-logistic model of extrapolating overall survival as suggested by the company was uncertain, but acceptable.

End of life

End of life criteria are met

3.16 The committee considered the advice about life-extending treatments for people with a short life expectancy in NICE's guide to the methods of technology appraisal. It considered that all scenario analyses presented by the company and the ERG indicated that sacituzumab govitecan offers more than 3 months' extension to life in a population that has a life

expectancy of less than 24 months. Therefore, it concluded that sacituzumab govitecan fulfils the end of life criteria.

Cost-effectiveness results

The cost-effectiveness estimates are within what NICE considers a cost-effective use of NHS resources

3.17 The company's revised base case ICER, using the confidential patient access scheme discount for sacituzumab govitecan and the undiscounted list prices for the comparators and subsequent treatments, was £47,170 per quality-adjusted life year (QALY) gained. The company used some of the committee's preferred assumptions in its response to consultation. When the confidential discounts for the comparators and subsequent treatments were applied, the ICER was within the range NICE considers a cost-effective use of NHS resources, for an end of life treatment. The ICER was subject to several uncertainties, including the extent of eribulin use, the extrapolation of long-term survival and the post-progression utility values. However, the committee concluded that the ICER was acceptable because of the high unmet need, and the substantial improvement in response rates compared with standard care. Overall, the committee concluded that sacituzumab govitecan is cost effective.

Conclusion

Sacituzumab govitecan is recommended for use in the NHS

3.18 The committee concluded that the cost-effectiveness estimates for sacituzumab govitecan were within the range NICE considers an acceptable use of NHS resources, in the context of the end of life criteria being met. Therefore, the committee recommended sacituzumab govitecan for use in the NHS.

4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

4.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016 (including the new Cancer Drugs Fund) – A new deal for patients, taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or fast track appraisal), at which point funding will switch to routine commissioning budgets. The NHS England and NHS Improvement Cancer Drugs Fund list provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

4.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.

4.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has unresectable triple-negative advanced breast

cancer after 2 or more therapies and the doctor responsible for their care thinks that sacituzumab govitecan is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Review of guidance

5.1 The guidance on this technology will be considered for review 3 years after publication. NICE will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Jane Adam
Chair, appraisal committee
July 2022

6 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee A.

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

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

NICE project team

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

Claire Hawksworth and Raphael Egbu

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