National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Larotrectinib for treating NTRK fusion-positive advanced solid tumours [ID1299]

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

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Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Response
Wording	Bayer Plc	No comment	Thank you for your response.
	The Royal College of Pathologists	Yes	Thank you for your comment.
Timing Issues	Bayer Plc	There is a relative urgency to provide guidance on larotrectinib to the NHS. There are no treatments that specifically treat advanced or metastatic TRK fusion-driven cancers and EMA has issued a positive recommendation for an accelerated assessment procedure which confirms that there is a high unmet need. Larotrectinib will be the first tumour agnostic precision medicine assessed by EMA and potentially appraised by NICE. A recent study, conducted by researchers including from the University of York & NICE and based on UK expert interviews (including experts from NICE), has described the possible future landscape of precision medicine alongside the potential implications for	Thank you for your comment. The accelerated access collaborative does not represent a separate route to market and an STA would still be required. The accelerated access collaborative has not

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		HTA agencies (Love-Koh et al. 2018). Precision medicines and progress of national programmes such as the 100,000 Genomes Project will change the way that healthcare services are organised and delivered. According to this study, precision medicines will pose challenges at each stage of the HTA pathway and will require methods and processes to adapt. We believe that larotrectinib, as the first tumour agnostic medicine approved in the UK, would be more suited to the Accelerated Access Collaborative pathway whilst NICE develops its processes and methods. Some of the hurdles in assessing precision medicines via the current NICE processes include: • The rarity of TRK gene fusion cancers have imposed constraints on the development programme, resulting in limitations to available clinical data: the clinical trial programme for larotrectinib enrolled patients across anatomically and histologically diverse solid tumours (to date 17) and is based on single arm basket studies which enrol patients who have the same molecular feature regardless of their cancer histology. As acknowledged by Tao et al. 2018, basket trials are best suited to assess the efficacy of targeting genomic alterations that occur at low frequencies across a wide variety of tumor types. For very rare mutations, a traditional disease-specific study is not feasible owing to insufficient patient enrolment. • Conducting a randomized controlled trial that would satisfy NICE evidence requirements to lower the level of uncertainty would not be feasible given the rarity of TRK gene fusion cancers, the diverse tumour localisations and the high number of comparators.	launched yet and the criteria for transformative designation are yet to be released.

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		• Cost-effectiveness is traditionally considered on a tumour-by-tumour basis. There is no precedence or guidance for assessing the cost effectiveness of tumour agnostic treatments where activity is not confined to a particular tumour type and a consistent line. Using conventional assessment, evaluating all of the relevant clinical pathways and comparators could be impractical and computationally infeasible. Combined with the rarity of patients this would increase levels of uncertainty associated with cost-effectiveness estimates presented to NICE. Given the limitations of the current NICE STA process for assessing tumour agnostic therapies, the Accelerated Access Collaborative (AAC) pathway, created to develop a streamlined pathway to enable faster patient access and support for uptake of a select number of breakthrough treatments, provides a more appropriate route for reviewing the first tumor agnostic precision medicine whilst NICE adapts methodologies for tumor agnostic products. This could also be the platform to discuss alternative funding schemes such an innovative managed access agreement. Should larotrectinib go through a NICE STA process, methods and appropriate timelines would need to be agreed.	
	The Royal College of Pathologists	Quite urgent	Thank you for your comment.
	Bayer Plc	No additional comment.	Thank you for your response.

Section	Consultee/ Commentator	Comments [sic]	Response
Additional comments on the draft remit	The Royal College of Pathologists	No	Thank you for your comment.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Bayer Plc	No comment.	Thank you for your response.
	The Royal College of Pathologists	Accurate, given space constraints	Thank you for your comment.
The technology/ intervention	Bayer Plc	No comment.	Thank you for your response.
	The Royal College of Pathologists	Yes	Thank you for your comment.
Population	Bayer Plc	Given the rarity of the patient population and the high number of tumor types represented in larotrectinib clinical studies an assessment by sub-group such as by tumour type and line of therapy may not be appropriate because the sample sizes per tumor types would be too small to derive interpretable results. In addition to that, there is limited information available on the natural history of TRK fusion cancers, patient characteristics and the clinical effectiveness of systemic treatments for TRK gene fusion cancer so it may	The difficulties of subgroup analyses were considered by attendees at the scoping workshop. It was agreed that it would be important to

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		not be possible to provide a relevant comparative effectiveness analysis for larotrectinib. Whilst this creates issues for current NICE processes, as acknowledged by Tao et al 2018, conducting a basket trials are best suited to assess the efficacy of targeting genomic alterations that occur at low frequencies across a wide variety of tumor types. For very rare mutations, a traditional disease-specific study is not feasible owing to insufficient patient enrolment. A randomized controlled trial that would satisfy NICE evidence requirements to lower the level of uncertainty would not be feasible given the rarity of TRK gene fusion cancers, the diverse tumour localisations and high number of comparators	include the subgroups specified in the draft scope, because of the heterogeneity of patients included in the key trials, if evidence allows.
	The Royal College of Pathologists	Yes No	Thank you for your comment.
Comparators	Bayer Plc	There are no treatment options available in the NHS that specifically target TRK fusion-driven cancers. TRK gene fusion testing is not yet established in England and is not routinely conducted. Hence, it is assumed that patients with TRK fusion-driven cancer are currently treated per guideline recommendations according to the tumour location, with standard of care available for advanced of metastatic solid tumour cancers such as chemotherapy, hormone therapy, immunotherapy, molecularly targeted treatment or Best Supportive Care.	Thank you for your comment. The comparator in the scope has been updated to 'established management without larotrectinib'.
	The Royal College of Pathologists	Yes	Thank you for your comment.

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Outcomes	Bayer Plc	Yes.	Thank you for your comment.
	The Royal College of Pathologists	Yes	Thank you for your comment.
Economic analysis	Bayer Plc	As mentioned earlier in the “timing issue” section, there is no precedence or guidance for assessing the cost effectiveness of tumour agnostic treatments where activity is not confined to a particular tumour type and a consistent line of therapy and where the population is very small. The Love-Koh et al 2018 publication raised numerous challenges for evidence evaluation of precision medicines such as an increasing use of new trial designs (e.g basket trials) that involve smaller populations, complex clinical pathways, high numbers of comparators and the difficulty in obtaining head-to-head estimates of comparative effectiveness, all leading to the conclusion that current HTA bodies (including NICE) will need to adapt their methods and processes.	The challenges of assessing a tumour agnostic therapy for a rare mutation were discussed during the scoping workshop and it was agreed that close working between the technical team at NICE, the company and the ERG would be required.
	The Royal College of Pathologists	Yes	Thank you for your comment.
Equality and Diversity	Bayer Plc	TRK gene fusion testing is not yet established in England and is not routinely conducted. The absence of routine TRK gene fusion diagnostic testing would be an important barrier to adoption and could lead to restricting access to patients with rare tumour types with high TRK gene fusion frequency. There is an uncertainty regarding when the National Genomic service is expected to be fully operational and TRK gene fusion to be routinely tested in	Thank you for your comment. The accelerated access collaborative has not launched yet and the criteria for transformative

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		the NHS. During this interim period, larotrectinib might be mainly used for rare tumour types with high TRK gene fusion frequency. For large tumour types (e.g. NSCLC, colorectal), given the very low TRK gene fusion frequency, it is unlikely that TRK gene fusion will be tested upfront (e.g. NSCLC, colorectal) and larotrectinib might be initially limited to patients with no adequate treatment option. Establishing TRK gene fusion diagnostic testing as routine practice in England will be a critical component of equal access to larotrectinib. NHS England is working towards the creation of a national consolidated genomic service and a network of seven genomic laboratory hubs. However, it is not expected to be fully operational until substantially later after launch and the list of genomic tests they will perform is not yet known. The inclusion of TRK gene fusion diagnostic testing in the national repertoire of genomic tests would ensure a full and equal access to larotrectinib. One of the roles of the AAC is to address the whole pathways for the selected highly transformative technologies, including associated barriers to entry such as diagnosis and treatment pathways. Considering the AAC for larotrectinib could include addressing the testing barrier.	designation are yet to be released.
	The Royal College of Pathologists	n/a	Thank you for your comment.
Other considerations	Bayer Plc	Genomic medicine will play a key role in ensuring patients receive the right treatments for them at the right time with the best possible outcomes. The benefit of this approach is widely recognised, including in the Chief Medical Officer's Generation Genome report, and the NHS is rightly now looking at systematic adoption across the health service.	Thank you for your comment. The accelerated access collaborative does not represent a separate route to market and an STA would still be

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		In addition, the UK government has given strategic priority to the life sciences sector in the UK and agreed the Life Science Sector Deal which includes an extension of the cancer branch of the 100,000 Genomes Project and the creation of the Accelerated Access Collaborative (AAC) to develop a streamlined pathway to enable faster patient access and support for uptake of a select number of breakthrough treatments. Critical to realising the full benefits of creating a genomic medicine service to deliver personalised treatments and cementing the UK's status as a go-to destination for life sciences, is ensuring timely patient access to innovative treatments. Given the limitations of the current NICE STA process for assessing tumour agnostic therapies previously identified, the AAC provides an effective route for reviewing larotrectinib - a highly innovative treatment which are likely to satisfy the key transformative criteria the AAC considers. It would provide a clear and strong demonstration of a collaborative approach between the public sector and industry, and underline the UK government's commitment to enhancing the international competitiveness of UK life sciences sector.	required. The accelerated access collaborative has not launched yet and the criteria for transformative designation are yet to be released.
	The Royal College of Pathologists	n/a	Thank you for your comment.
Innovation	Bayer Plc	Larotrectinib is an innovative and highly transformative medicine with the potential to make a significant and substantial impact on health-related benefits for the following reasons : [redacted]	Thank you for your comment. The company will have the opportunity to submit evidence about innovative aspects of the technology that are not

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		2. First tumour agnostic precision medicine: larotrectinib specifically targets the protein product of the neurotrophic tyrosine kinase receptor (NTRK) fusion genes, irrespective of the location or histology of the tumour. The complication of NTRK gene fusion rarity has been approached with a tissue-independent development program. 3. Step changing disease management: the development of precision medicines could lead to a paradigm shift in cancer care from a clinical management based on histologic subtype or tumour location to a management based on molecular profiling. Significant and substantial health benefits: there is a high unmet need in patients who have a TRK-fusion driven cancer as there are no targeted therapies available. Larotrectinib is the first targeted treatment option for these patients and has demonstrated rapid (median time to response=1.8 months) and high response rates (~75%) across anatomically and histologically diverse solid tumours compared to what is usually observed in the advanced and metastatic population.	captured in the QALY during the appraisal.
	The Royal College of Pathologists	Yes, potentially. There is a precedent for therapy that targets changes found in only small sub-populations of particular cancer types (eg ALK/ROS1 inhibitors in NSCLC). Incremental increases in the number of targetable subpopulations will have a significant impact on cancer outcomes overall. I would expect everything to be captured by the QALY calculation. Published/peer-reviewed trial data.	Thank you for your comment.
Questions for consultation	Bayer Plc	**What is the population size for TRK gene fusion-positive advanced solid tumours?** The eligible patient population is the proportion of patients with an advanced or metastatic solid tumour with an NTRK gene fusion after prior standard therapy (2L and beyond) or as initial therapy (1L) when there is no adequate treatment option :	Thank you for your comment. Likely population size has been considered during

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		NTRK gene fusions are very rare and appear to be widely distributed across anatomically and histologically diverse solid tumour types. The frequency of the NTRK gene fusions varies and ranges from 0.5% – 1% for many common cancers to greater than 90% for certain rare cancers. Overall, the eligible population in England and Wales is estimated to be less than 1000. **Which solid tumour sites are most commonly associated with TRK gene fusion mutation?** Infantile fibrosarcoma, mammary analogue secretory carcinoma (MASC) of the salivary gland and secretory breast carcinoma are the tumour types most commonly associated with TRK gene fusion alterations. However, it is important to note that NTRK gene fusions have been reported with varying frequencies across anatomically and histologically diverse solid tumours in paediatric and adults and larotrectinib has demonstrated high response rates across these tumour types. **How will larotrectinib be used in clinical practice?** • **Would larotrectinib be used differently based on tumour site?** Larotrectinib is a precision medicine, which specifically targets the protein product of the neurotrophic tyrosine kinase receptor (NTRK) fusion genes, irrespective of the location or histology of the tumour which would imply as well different therapeutic objectives (e.g. reduce the tumor size to avoid disfiguring surgery as opposed to delay progression) When the consolidated National Genomic service is in place and molecular profiling at diagnosis is used routinely in practice, it is expected that larotrectinib	the topic selection and scoping process. Thank you for your comment. Thank you for your comment. The treatment pathway was considered at the scoping workshop and will be considered during the appraisal.

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		and other precision medicines would inform new care pathways where treatment decisions are irrespective of tumour site. However, current management of cancer patients remains mainly based on tumour site and molecular profiling is not yet routinely established across all tumour types. Hence, would potentially be used differently based on tumour site. There is an uncertainty on when the National Genomic service is expected to be fully operational and TRK gene fusion to be routinely tested in the NHS. During this interim period, larotrectinib might be mainly used for rare tumour types with high TRK gene fusion frequency. For large tumour types (e.g. NSCLC, colorectal), given the very low TRK gene fusion frequency, it is unlikely that TRK gene fusion will be tested upfront (e.g. NSCLC, colorectal) and larotrectinib might be initially limited to patients who have exhausted all previous alternatives. More feedback from clinical experts on how larotrectinib would fit in the current cancer care pathway is required. One of the roles of the AAC is to address the whole pathways for the selected highly transformative technologies, including associated barriers to entry such as diagnosis and treatment pathways. **Have all relevant comparators for larotrectinib been included in the scope?** As described in the "comparator" section: There are no treatment options available in the NHS that specifically target TRK fusion-driven cancers. **Which treatments are considered to be established clinical practice in the NHS for TRK gene fusion-positive advanced solid tumours who**	Thank you for your comment. Following the scoping workshop, the comparator in the scope has been updated to 'established

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		• **Have either progressed on or not responded to prior therapies or** • **Are unfit for chemotherapy or for whom no curative therapy exists?** TRK gene fusion testing is not yet established in England and is not routinely conducted. Hence, it is assumed that patients with TRK fusion-driven cancer are currently treated per guideline recommendations according to the tumour location, with standard of care available for advanced of metastatic solid tumour cancers such as chemotherapy, hormone therapy, immunotherapy, molecularly targeted treatment or Best Supportive Care. **How should standard of care be defined?** In the absence of options that treat TRK fusion-driven cancers, standard of care could be defined as treatments available for advanced of metastatic solid tumour cancers such as chemotherapy, hormone therapy, immunotherapy, molecularly targeted treatment or Best Supportive Care. Given the limited information available on the natural history of TRK fusion cancers, patient characteristics and clinical effectiveness of systemic treatments for TRK gene fusion cancer so it may not be possible to provide a relevant comparative effectiveness. **Is testing for TRK gene fusion expression routine in the NHS for advanced solid tumours?** TRK gene fusion testing is not yet established in England and is not routinely conducted. Only few centres have the capacity to test for TRK gene fusion and more feedback from the clinical experts in those centres is needed to understand current clinical practice and assay methods used to detect TRK gene fusion. Progress of genomic medicine will play a key role in ensuring	management without larotrectinib'. Thank you for your comment. Following the scoping workshop, the comparator in the scope has been updated to 'established management without larotrectinib'. Thank you for your comment. Availability and costs of diagnostic testing will be considered during the appraisal.

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		patients receive the right treatments for them at the right time with the best possible outcomes. **Where do you consider larotrectinib will fit into the existing NICE pathway?** Larotrectinib is a precision medicine, which specifically targets the protein product of the neurotrophic tyrosine kinase receptor (NTRK) fusion genes, irrespective of the location or histology of the tumour. When the consolidated National Genomics service is in place and molecular profiling at diagnosis is used routinely in practice, it is expected that larotrectinib and other precision medicines would inform new care pathways where treatment decisions are irrespective of tumour site. Because current management of cancer patients remains mainly based on tumour site and molecular profiling is not yet routinely established across all tumour types, current NICE guidelines are established per tumour location. Larotrectinib will not fit into any existing NICE pathway and will require guidelines to adapt to this cancer care new paradigm. **Do you consider that the use of larotrectinib can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?** Diagnostic tests are used to identify patients who have NTRK gene fusions and are suitable for treatment with larotrectinib. This diagnostic screening may also identify alternative targets, guiding treatment decisions for alternative therapies. In this respect there is a wider benefit in testing and screening patients that is not included in the QALY calculation.	Thank you for your comment. The treatment pathway was considered at the scoping workshop and will be considered during the appraisal. Thank you for your comment. The company will have the opportunity to submit evidence about innovative aspects of the technology that are not captured in the QALY during the appraisal.

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		Please identify the nature of the data, which you understand to be available to enable the Appraisal Committee to take account of these benefits. There are three ongoing clinical studies with larotrectinib : • Study LOXO-TRK-14001 : Phase 1, Multicentre, Open-label study in the US • LOXO-TRK-15002, "NAVIGATE" study : a Phase 2, Multicentre, Open-label Study in the US, Europe and Asia • Study LOXO-TRK-15003, "SCOUT" Study : Paediatric, Phase 1 and Phase 2, Multicentre, Open-label Study in the US and Europe As of 19 Feb 2018, a total of 176 patients have been treated with larotrectinib across Studies 14001, 15002 and 15003 (overall safety population) including 105 with a TRK fusion-driven cancers. The efficacy data from the first 73 TRK fusion-positive patients, across 17 tumour types, are available. Basket trials are best suited to assess the efficacy of targeting genomic alterations that occur at low frequencies across a wide variety of tumor types and for very rare mutations, a traditional disease-specific study is not feasible owing to insufficient patient enrolment (Tao et al 2018). However, there is no precedence or guidance for assessing the cost effectiveness of tumour agnostic treatments where activity is not confined to a particular tumour type and a consistent line (Love-Koh et al 2018). **To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.** TRK gene fusion testing is not yet established in England and is not routinely conducted. The absence of routine TRK gene fusion diagnostic testing would	Thank you for your comment. Thank you for your comment. Availability and costs of diagnostic testing will be considered during the appraisal.

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		be an important barrier to adoption and could lead to restrict access to patients with rare tumour types with high TRK gene fusion frequency. Establish TRK gene fusion diagnostic testing as routine practice in England will be a critical component of an equal access to larotrectinib. NHS England is working towards the creation of a national consolidated genomic service and a network of seven genomic laboratory hubs. However, it is not expected to be fully operational until substantially later after launch and the list of genomic tests they will perform is not yet known. The inclusion of TRK gene fusion diagnostic testing in the national repertoire of genomic tests would ensure a full and equal access to larotrectinib. The launch of a consolidated genomic medicine service will play a key role in ensuring patients receive the right treatments for them at the right time with the best possible outcomes. The benefit of this approach is widely recognised, including in the Chief Medical Officer's Generation Genome report, and the NHS is rightly now looking at systematic adoption across the health service. Given the limitations of the current NICE STA process for assessing tumour agnostic therapies previously identified, the AAC will provide an effective route for reviewing larotrectinib - a highly innovative treatment which is likely to satisfy the key transformative criteria the AAC considers. It would provide a clear and strong demonstration of a collaborative approach between the public sector and industry, and underline the UK government's commitment to enhancing the international competitiveness of UK life sciences sector. **NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process.**	Thank you for your comment. The accelerated access

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		Larotrectinib does not fit to the current single technology appraisal process: it is a precision medicine, which specifically targets the protein product of the neurotrophic tyrosine kinase receptor (NTRK) fusion genes, irrespective of the location or histology of the tumour and will potentially be the first tumour agnostic drug assessed by EMA and appraised by NICE. Because TRK gene fusion cancers are rare and can present in various locations, the clinical trial programme is based on single arm basket studies. Basket trials are best suited to assess the efficacy of targeting genomic alterations that occur at low frequencies across a wide variety of tumor types. For very rare mutations, a traditional disease-specific study is not feasible owing to insufficient patient enrolment (Tao et al 2018). A recent publication has identified that precision medicine will require HTA and clinical guidelines to adapt methods and processes (Love-Koh et al 2018) : The NICE submission would be based on 73 NTRK gene fusion patients across 17 tumour types. Through follow-up of this study and a subsequent international Non Interventional Study (NIS) the number of participants will increase, however not to the degree where a conventional tumour by tumour assessment is feasible. Evaluating all of the relevant pathways, populations and comparators could be practically and computationally unfeasible. Multiplicity of tumour types and clinical pathways would most likely lead to a complexity and uncertainty which couldn't be addressed within the current NICE STA methodological framework. Such complexity and uncertainty of treatment pathways are at the centre of Love-Koh et al 2018 rationale for the need to adapt HTA processes. Given the limitations of the current NICE STA process for assessing tumour agnostic therapies, the Accelerated Access Collaborative (AAC) pathway,	collaborative does not represent a separate route to market and an STA would still be required. The accelerated access collaborative has not launched yet and the criteria for transformative designation are yet to be released. It was agreed by scoping workshop attendees that an STA would be appropriate for larotrectinib and that close working between the NICE technical team, ERG and the company could help to resolve any issues.

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		which focuses on speeding up highly transformative innovations to NHS patients including associated barriers to entry such as diagnosis and treatment pathways, will provide a more appropriate route for reviewing larotrectinib, first tumor agnostic precision medicine to be assessed by EMA, whilst NICE adapts methodologies for tumor agnostic products. This process considers technologies that would potentially offer significant improvements to patient outcomes, increase the system efficiency and which present barriers to uptake: • larotrectinib is a precision medicine that has demonstrated rapid (median time to response= 1.8mo) high response rates= ~75%) across anatomically and histologically diverse solid tumours compared to what is usually observed in the advanced or metastatic population. • Utilising precision medicine such larotrectinib has the potential to significantly improve patient outcomes which could generates savings by reducing the use of drugs that are unlikely to benefit the patient. • The National consolidated genomic service is not yet in place and NTRK gene fusion testing is not routinely used in the NHS which will limit the ability to detect patients who could benefit from larotrectinib. Access to larotrectinib and TRK gene fusion testing will ensure that patients receive the right treatment for them at the right time with the best possible outcomes and will then contribute more widely to realising the full benefits of creating a genomic medicine service to deliver personalised treatments. It would provide a clear and strong demonstration of a collaborative approach between the public sector and industry, and underline the UK government's commitment to enhancing the international competitiveness of UK life sciences sector.	

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	The Royal College of Pathologists	Regarding testing for somatic TRK gene rearrangements, it would be important to ensure that NHSE's Genomics Implementation Unit are involved in this consultation since they are responsible for curating the national genomic test directory and thus for any decision on approved testing platform (which will be informed by, but not entirely dependent on, the outcome of this consultation). This will also ensure that the GUI is aware of the possible need to add TRK testing to the directory within a potentially short timeframe post-consultation.	Thank you for your comment. NHSE's genomic implementation unit are aware of the ongoing appraisal for larotrectinib.
Additional comments on the draft scope	Bayer Plc	No additional comments.	Thank you for your response.
	The Royal College of Pathologists	none	Thank you for your response.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Breast Cancer Now
The Department of Health and Social Care