

Illumina / GRAIL
Briefing paper on the competition case and benefits
of the Transaction to EEA patients

Executive summary: The Commission’s theory of harm in this case (vertical foreclosure) is highly speculative and unfounded by any evidence. This is not a “killer acquisition”, as Illumina and GRAIL are not competitors. GRAIL’s life-saving cancer screening test is unique: there is no other cancer screening test in development that is known to screen for anywhere near as many cancers or have other comparable characteristics. In these circumstances, Illumina has no incentive to foreclose any other cancer screening test developer, as doing so will not result in any benefit to GRAIL. Moreover, GRAIL has no presence in the European Economic Area (EEA): no research activities, no employees and no plans to enter the EEA for the foreseeable future (in fact, it is likely that it would only be under Illumina’s ownership that GRAIL’s test would become available in the EEA at scale in the foreseeable future). Any potential effects of the Transaction on competition in the EEA are therefore remote and highly speculative.

However, the societal and public health effects of blocking the Transaction are not speculative: it would mean that GRAIL’s life-saving test would not be available in the EEA for many years. The merger would accelerate the entry of GRAIL’s test to the EEA by around five years, saving tens of thousands of lives of EEA patients as a result and billions of euros in healthcare costs. It will also bring GRAIL’s test to developing countries in Africa and Asia many years earlier than GRAIL could alone. This is therefore not a case that DG Competition should prohibit.

1. Introduction

- 1.1 DG Competition will shortly issue a Statement of Objections in the Illumina / GRAIL transaction (the “**Transaction**”). The purpose of this briefing paper is to provide you with a summary of the views of Illumina and GRAIL on the issues we anticipate will be raised by DG Competition.
- 1.2 DG Competition acknowledges that the Transaction does not involve the merger of competitors, and accepts that it is not a “killer acquisition”:
- (i) Illumina is a US company that supplies next generation sequencing (“**NGS**”) systems for genetic and genomic analysis. Illumina’s core mission is to catalyse greater NGS adoption, including bringing genomic testing to under-served communities. Illumina has long pursued this strategy by driving down the cost of sequencing and improving its NGS systems and workflows.
 - (ii) GRAIL is a US start-up, founded by Illumina five years ago with the goal of developing an early screening test for multiple types of cancer. In February 2016, Illumina reduced its investment in GRAIL to allow it to procure the investments needed for the extensive, population-scale clinical trials required to create an “atlas” of cancer signals in the blood, and the state-of-the art machine learning platform required to interpret those signals, enabling early cancer screening for asymptomatic people. Since that time, GRAIL has developed a multi-cancer

early detection test, Galleri, that can simultaneously screen for more than 50 types of cancer in asymptomatic patients, with a single blood test.¹ Galleri also has the ability to predict the cancer signal of origin (i.e. the location of the cancer). Even before the Transaction, Illumina and GRAIL were never completely separate: Illumina maintained approximately a 12% equity stake in GRAIL and was entitled to a percentage of GRAIL's net revenues in perpetuity. The Transaction fully reunites Illumina and GRAIL at a critical juncture

- 1.3 GRAIL's test is run on Illumina's NGS systems. DG Competition's concern is that post-Transaction Illumina could favour GRAIL and disadvantage GRAIL's potential competitors (vertical foreclosure).
- 1.4 This case is unusual in several respects. While GRAIL has made progress in developing Galleri, it faces significant hurdles, including obtaining regulatory approval, securing payor reimbursement, and achieving production and distribution of its test at scale. Illumina is uniquely situated to help overcome these hurdles, accelerate the widespread adoption of Galleri, and reach more patients faster. The combined company will launch a new era of cancer screening, accelerating commercialisation and adoption of GRAIL's transformative multi-cancer screening test at scale. Galleri has the potential to reduce significantly the cancer burden worldwide. This Transaction will therefore lead to thousands of lives and potentially billions of euros being saved, by rolling out GRAIL's Galleri test sooner and more effectively.
- 1.5 This case is also unusual because GRAIL is a young company. It has only recently started selling its cancer screening test in the US, and its test is still years away from being approved by both the US health regulator (the FDA) and by payors for reimbursement or cost coverage (e.g. by governments or private insurers). Until the test is both FDA-approved and its costs are covered by third party payors, it may not be broadly adopted.
- 1.6 Finally, GRAIL has no presence in the EEA: no research activities, no employees and no plans to enter the EEA for the foreseeable future (the Transaction will allow GRAIL to launch at scale in the EEA years before GRAIL would be able to do so on a stand-alone basis). Any potential effects of the Transaction on competition in the EEA are therefore remote and highly speculative.
- 1.7 However, the societal and public health effects of blocking the Transaction are not speculative: it would mean that GRAIL's life-saving test would almost certainly not be available in the EEA for many years.
- 1.8 This briefing paper explains that:
 - (i) GRAIL's test is unique: there is no other cancer screening test in development that is known to screen for as many cancers or have other comparable characteristics. In these circumstances, Illumina has no incentive to foreclose

¹ GRAIL is also developing two additional multi-cancer detection tests: a diagnostic aid for cancer ("DAC") test and a minimal residual disease ("MRD") test, each based on the same underlying platform as Galleri. There are no firm plans to offer any of these tests in the EEA through clinical trials or commercial launch in the foreseeable future.

any other cancer screening test developer, as doing so will not result in any benefit to GRAIL or Illumina. This case is unusual because a hearing before an FTC judge in the US was recently completed, involving testimony and cross examinations under oath of other cancer screening test developers. As Illumina's lead US counsel stated in the FTC hearing, having reviewed all of the evidence, including that submitted by those developers: "*The Galleri test is the only one on the market. Other developers are at very early stages. It's not clear whether they will succeed. It's not clear when they will succeed. It's not clear, if they succeed, what features and functions their tests will have. And the evidence is going to show in any event, given what is being developed, given the nature of this marketplace, other tests are likely to be complements for one another, not substitutes*".

- (ii) Illumina would not have the ability to foreclose any future NGS test developer that does develop a test that competes with GRAIL, because there are already NGS systems that are comparable in performance and cost to Illumina's, and there are many more in development attracting substantial investment, some of which are run by former Illumina executives with deep experience in NGS. As certain Illumina patents expire in the next few years, it is generally accepted by market analysts that Illumina will lose upstream share to such new entrants, a number of whom are poised to enter the market. There is ample evidence that NGS test developers could switch to these alternative platforms were Illumina to pursue a foreclosure strategy in the future (which it would not have the ability to do in any event). On this basis alone, a foreclosure strategy by Illumina is implausible. When taking into account the fact that Galleri is unique in its performance attributes, and will be for some time, such that significant diversion to rivals is unlikely, a foreclosure strategy becomes even more speculative.
- (iii) The Transaction will result in merger-specific and verifiable efficiencies: in particular, it will accelerate the entry of GRAIL's test to the EEA by around five years, potentially saving tens of thousands of lives of EEA patients as a result. It will also bring GRAIL's test to developing countries in Africa and Asia many years earlier than GRAIL could absent the Transaction. This is therefore not a case that DG Competition should prohibit.

2. DG Competition's concerns

- 2.1 We understand that DG Competition's concerns that will be set out in the forthcoming Statement of Objections are largely unchanged from its Article 6(1)(c) decision at the end of Phase I.
- 2.2 In summary, in the Article 6(1)(c) decision the Commission considered that post-Transaction "*the combined entity could engage in different input foreclosure strategies against GRAIL's downstream rivals active in NGS-based cancer detection tests*", and that "*such foreclosure strategies would significantly impede effective competition in the development and supply of NGS-based cancer detection tests*".² The Commission also

² EU Commission Article 6(1)(c) Decision of 22 July 2021, paragraph 74. The Commission considers that possible foreclosure strategies could include refusing to supply Illumina's NGS systems; raising prices; degrading the quality of Illumina's NGS systems; degrading or denying collaboration with GRAIL's downstream "rivals"; hampering the

stated in that decision that “*based on the evidence available in the file at this stage, the Commission preliminarily considers that it is far from obvious that the Transaction would result in verifiable and merger-specific efficiencies, which would benefit to consumers*”.³

3. The downstream market: cancer screening testing

3.1 DG Competition has concerns that Illumina would have the **incentive to foreclose** GRAIL’s so-called “competitors”. For Illumina to have the incentive to do so, those companies would need to have the prospect of launching a competitive cancer screening test that is comparable to GRAIL’s test in the reasonably foreseeable future.

3.2 It is common ground that no such competitive test exists today. The only competitors, if any, are potential competitors.

3.3 The Court of Justice of the European Union ruled in the Paroxetine case in January 2020 that a company is only to be considered a potential competitor if “*there are real and concrete possibilities of [that company] joining that market and competing [...] there can be no finding of a potential competitive relationship as an inference merely from the purely hypothetical possibility of such entry or even from the mere wish or desire of the manufacturer of [the product] to enter the market*” (emphasis added).⁴ DG Competition must therefore establish that any potential competitors are likely to enter the market with a competing product to GRAIL’s in the foreseeable future: mere ambition to do so is not enough.⁵

3.4 GRAIL’s cancer screening test, Galleri, is unique in that it has a proven capability to detect signals from more than 50 types of cancer and predict the cancer signal of origin with high accuracy. Experts agree that being able to predict the cancer signal of origin is critical for an early detection multi-cancer screening test to gain adoption in the market.

3.5 There are only two other companies globally that have tests in development that have demonstrated in clinical trials the ability to screen for more than one cancer type – see Table 1 below, which shows that these other companies reported detection of far fewer than 50 cancer types and cannot predict the cancer signal of origin. Other so-called “competitors” that have been identified by the FTC and DG Competition are known to be developing a single cancer screening test. Single cancer screening tests are likely to be complements, not substitutes, for GRAIL’s Galleri test, which can screen for over 50

distribution of kitted versions of the tests developed by GRAIL’s downstream “rivals”; and accessing and making use of commercially sensitive information of GRAIL’s downstream “rivals” (paragraph 75).

³ *Ibid*, paragraph 74.

⁴ See paragraph 38 of the Paroxetine Case.

⁵ This is not a sector where R&D takes place in secrecy. It is a feature of cancer screening test development that test developers routinely make announcements of their progress, to attract investment and for their discoveries to be peer-reviewed. Any clinical trials that are carried out are typically recorded and published online (e.g. on ClinicalTrials.gov, which is a database of privately and publicly funded clinical studies conducted around the world). Publication is also essential to obtain the support of Key Opinion Leaders, whose views can be highly influential for obtaining both regulatory approval by the relevant government agencies and reimbursement. Without reimbursement approvals, no test would be likely to reach profitability. This means that developments of importance in the cancer screening space around the world would be published and well known in the scientific community – and well understood by the Parties.

cancer types and predict the cancer signal of origin, and is designed to be used as part of an interval health check for asymptomatic patients.

Table 1
Major NGS-based cancer screening tests
that are known to be in development

Test developer (and location)	Test	No. of cancer types detected	Ability to predict cancer signal of origin
GRAIL (US)	Galleri	>50	Yes
Exact Sciences / Thrive (US)	CancerSEEK	8-10	No
Singlera (China)	PanSEER	5	No
Guardant (US)	LUNAR-2	1	Not applicable (single cancer detected)
Freenome (US)	Multianalyte	1	Not applicable (single cancer detected)

- 3.6 The two companies that have demonstrated in clinical trials the ability to screen for more than one type of cancer simultaneously are many years behind GRAIL. Exact Sciences / Thrive is the closest so-called “competitor” in terms of the number of cancers detected, although its CancerSEEK test has not reported detection of more than c. 8 to 10 cancers and does not identify the cancer signal of origin. Moreover, its test has only reported detection of 49% of the world’s most common cancer types by incidence. GRAIL’s test, in contrast, is able to detect 96% of the most common cancer types. Unless multi-cancer screening tests can detect the cancer types that cause the majority of cancer mortality, they would not be substitutable for GRAIL as a tool for cancer screening programmes.
- 3.7 As Exact Sciences’ / Thrive’s test does not identify the cancer signal of origin, a patient that receives a positive test result is informed that they are likely to have cancer, but does not know where it is located. Its test therefore relies entirely on a follow-up full body PET/CT scan for patients with a positive result, which is very expensive (average \$5,000) and can also expose patients to potentially harmful radiation. The procedure is therefore likely to be far more expensive than Galleri, which currently costs around \$949. Given the performance and cost of the CancerSEEK test, it is not an adequate substitute for the Galleri test today and is unlikely to be a close substitute for Galleri at any point in the foreseeable future
- 3.8 Singlera’s PanSeer test in development is also unlikely to be a substitute for Galleri. It reported detection of just five cancer types, which are only 26% of the world’s most common cancer types, compared to Galleri’s 96%. It does not have the ability to predict cancer signal of origin. Moreover, its only published results come from a study of just 418 participants with samples from 113 post-diagnosis cancer patients. Nothing in Singlera’s published studies, announcements or website, nor any analytical or clinical data that

Singlera has reported, suggest that its test could detect more than five cancer types. Singlera has testified in the US that it would take decades for it to come anywhere close to GRAIL's test: *"So for five different kinds [of cancer] that we can estimate, you know, it may take seven to eight years prospective trial to have FDA approval. For 50 or 100 kinds of cancer, it would take maybe 50 years. You know, that's just the reality of it"*.

4. The upstream market: next-generation sequencing

4.1 Illumina makes and sells sequencing instruments and consumables for NGS systems. Illumina's NGS platforms may be used for a variety of applications, including basic and translational research for genetic and genomic analyses, reproductive health, genetic health and oncology.

4.2 NGS is a relatively new technology platform. In 2003, when Illumina was a fledgling company, it cost more than \$100 million to sequence the complete human genome. In the years since, Illumina has invested billions in R&D and driven innovation in NGS, bringing the cost of sequencing a complete genome down to less than \$1,000. It is part of Illumina's DNA, so to speak, to continuously improve its systems and to continuously drive down the cost of sequencing. In fact, Illumina drove down the cost of sequencing so substantially that this cost reduction was referred to as "Flatley's Law", after Illumina's then CEO.

4.3 Illumina has built and cultivated a reputation as a trusted supplier of NGS technology through decades of investment and partnership with laboratories, research institutions, hospitals and government entities, and by supplying cutting-edge NGS technology to anyone willing to invest in the research, development or commercialisation of NGS applications to improve human health. Illumina firmly believes that it benefits when multiple innovators develop NGS-based tests for emerging applications, such as cancer screening, for which NGS is not yet an accepted modality.

4.4 More recently, Illumina has made numerous well-publicised commitments - and its senior leadership has reiterated those commitments under oath at trial - that the Transaction will not change Illumina's core mission nor its treatment of its clinical oncology (or any other) customers. Turning its back on these commitments would risk swift backlash and lasting damage to its brand and NGS business. If Illumina were to attempt to foreclose potential competitors to GRAIL, many innovators would choose not to invest in developing their emerging and future applications using Illumina's platforms (not limited to cancer screening), turning instead to rival NGS platforms.

4.5 DG Competition's concerns about vertical foreclosure are based on the assumption that the so-called "competitors" of GRAIL are dependent on Illumina's NGS systems, and therefore that Illumina will have the **ability to foreclose them**. To substantiate its concerns, the Commission relies on Illumina's historic NGS systems market share. Its concern does not take into account the following facts.

4.6 First, there are already competing NGS systems on the market that are comparable to Illumina's in terms of performance.

- 4.7 For example, BGI Genomics is a Chinese genome sequencing company with sequencing products that are substitutes for Illumina’s technology. Illumina’s internal documents (dated well before the Transaction) recognise that “*BGI is impacting ILMN business globally*” and that its NGS instrument portfolio “*is increasingly competitive with Illumina’s*”. BGI claims that its highest throughput instrument has a higher throughput than the highest performance instrument currently offered by Illumina. BGI’s NGS systems are clear substitutes for Illumina systems and have comparable performance, and BGI competes aggressively by significantly discounting the price of sequencing on its platform below Illumina. BGI is present in a number of EEA countries, and its NGS systems are of the required performance to support multi-cancer screening test developers.
- 4.8 Oxford Nanopore Technology (“**ONT**”) is a spin-out from the University of Oxford that currently makes four NGS sequencers, with one more in development. ONT has recently published research showing its capability to perform short-read sequencing (the same type as Illumina). ONT claims that its highest performance instrument has a higher throughput than the highest performance instrument currently offered by Illumina, and that the cost of sequencing on ONT platforms is less than on Illumina’s platforms.
- 4.9 Second, there are a number of new entrants that are developing NGS systems similar to Illumina’s, which have raised substantial investment in recent years and are close to market entry. Their systems are capable of achieving the necessary throughput, turnaround time, cost and accuracy that is needed for supporting multi-cancer screening tests. Among others, Singular Genomics has developed an NGS platform which it reports that it will launch at the end of 2021, and it has already placed an instrument at a teaching hospital for the Harvard School of Medicine. Also notable is Pacific Biosciences of California (“**PacBio**”), a leading supplier of long-read NGS systems, which announced in July 2021 that it will acquire Omniome, a developer of an emerging high-accuracy short-read NGS technology (the same type as Illumina), for \$800 million, and will target early cancer screening.

Table 2
Recent investments in major new entrants in NGS systems

	PacBio / Omniome	Element Biosciences	Singular Genomics	Genemind
Year founded	2015	2017	2016	2018
Funds raised	c. \$900 million	c. \$130 million	c. \$250 million	c. \$55 million
Location	San Diego, US	San Diego, US	San Diego, US	Shenzen, China

- 4.10 Third, BGI is currently preliminarily enjoined from launching its sequencing instruments and related reagents in certain jurisdictions (such as the US, the UK and some EU states) but that preliminary injunction is based on a set of patents that expire in 2023.
- 4.11 NGS systems of comparable throughput, accuracy, turnaround time and cost are therefore already available to cancer screening test developers, and an even wide range of alternative NGS systems from other suppliers are likely to become available in the future. The probability that this will occur is much higher than the likelihood that GRAIL

will have a close competitor in the downstream cancer screening market in the foreseeable future.

- 4.12 Illumina is fully aware that cancer test developers already have a choice, as BGI and other existing NGS systems suppliers make their products available to laboratories and research centres around the world. In countries where BGI and Illumina have gone head-to-head on particular tenders, such as in South Korea and Australia, Illumina has had to drop its prices to a significant extent to retain or win the customer.
- 4.13 The historical market shares on which the Commission relies are not a good predictor of future market trends or even current competitive pressures. BGI would already have entered the US market had Illumina not been able to delay its entry into the US by commencing patent enforcement proceedings and obtaining injunctive relief. BGI is already available in a number of markets around the world where Illumina does not have counterparts to the patents enforced in the US and Europe (such as in South Korea, China, Japan and Australia) or where courts have declined to issue a preliminary injunction (such as in France).
- 4.14 Cancer screening test developers can use multiple NGS platforms in parallel to develop their tests, and some, such as Singlera, have already done so. This makes transitioning to alternative platforms a relatively low risk option, especially as test developers routinely switch between Illumina's various product offerings during the course of development. Moreover, the cost of NGS systems is a small part of the cost of development of a cancer screening test more generally, and the cost of using two platforms at the development stage would be insignificant in the context of the cost of clinical trials.

5. Impact on DG Competition's theory of harm

- 5.1 These facts have significant implications for DG Competition's theory of harm. A foreclosure strategy in these circumstances is highly unlikely to succeed and is therefore implausible.
- 5.2 First, other test developers such as Exact Sciences / Thrive have alternative viable options to Illumina, and Illumina therefore has no ability or incentive to seek to foreclose those customers. Raising their prices or otherwise disadvantaging those test developers would only serve to push these customers to use alternative platforms. Natera, a developer of a cancer monitoring test, has already adopted BGI NGS equipment for its sales in China. New entry by a number of additional NGS system suppliers in or before 2023 makes it even less likely that Illumina would risk any foreclosure strategy, as it would only risk customer loss.
- 5.3 Second, all of the so-called downstream "competitors" to GRAIL are at an early stage in the development of their tests. None of them have started the large-scale interventional clinical trials that will be necessary to obtain regulatory approval and reimbursement. They are therefore all at a stage when switching to another NGS platform could be achieved relatively quickly and at relatively low cost.
- 5.4 Third, the fact that alternative NGS systems are or will become available in the short term means that the most that could be achieved by an active foreclosure strategy would be a

delay to the entry of other cancer screening tests. A delaying strategy is not likely to be plausible, because at most it would only involve (highly uncertain) short term potential gains at the certain cost of long term revenues. This is because the downstream market is at a nascent stage: sales of other cancer screening tests are likely to be very limited for the next seven to ten years. The cancer screening testing market is only likely to grow once the developed tests obtain widespread reimbursement in the US and other markets, which will take a number of years after regulatory approval - which itself would be achieved in the US only in 2025 at the earliest.

- 5.5 Illumina would therefore have no ability, and no incentive, to foreclose other cancer screening test developers.

6. Illumina's proposed remedies

- 6.1 Any residual concerns that DG Competition were still to have about the effect of the Transaction would be more than comprehensively addressed by the draft remedy commitments that Illumina proposed in Phase I.
- 6.2 Illumina has already made irrevocable downstream supply commitments to all of its US customers who are active in the oncology sector (the "**Open Offer**"),⁶ and at Phase I offered to extend these commitments to make them legally binding vis-à-vis the Commission and include all oncology customers located in, or supplying into, the EEA. The Open Offer has been made public by Illumina on its website and became effective on 18 August 2021. As the Open Offer has already been made publicly and irrevocably, and certain customers have already accepted it, Illumina cannot withdraw it. It will be available for customers to sign up to new agreements under the Open Offer until August 2027.
- 6.3 Under the Open Offer, Illumina undertakes – upon the request of a customer – to enter into a supply agreement on certain terms, which will be effective for 12 years until August 2033.⁷ Any such supply agreement will include, *inter alia*, guaranteed access to Illumina's latest sequencing products, and related product and support services, within five days of those products or services being made available to GRAIL or any other Illumina customer, including pre-release products, and the same access to support services as GRAIL, at

⁶ The offer applies not only to developers of cancer screening testing, but developers of any liquid biopsy oncology application. The Open Offer is available online here: <https://emea.illumina.com/content/dam/illumina-marketing/documents/applications/cancer/illumina-open-offer.pdf>, with an addendum to the Open Offer available here: [https://www.illumina.com/content/dam/illumina-marketing/documents/applications/cancer/Signed_Illumina-Addendum_to_Open_Offer\(5705203.5\)_F.pdf](https://www.illumina.com/content/dam/illumina-marketing/documents/applications/cancer/Signed_Illumina-Addendum_to_Open_Offer(5705203.5)_F.pdf). Further terms relating to IVD (in vitro diagnostic) test development are available here: https://www.illumina.com/content/dam/illumina-marketing/documents/applications/cancer/IVD_Test_Kit_Dev_Agr-All_Platforms_0524.pdf; https://www.illumina.com/content/dam/illumina-marketing/documents/applications/cancer/IVD_Test_Kit_Dev_Agr-NextSeq_0524.pdf; and https://www.illumina.com/content/dam/illumina-marketing/documents/applications/cancer/IVD_Test_Kit_Dev_Agr-NovaSeq_0524.pdf.

⁷ The Open Offer is not contingent on any purchase commitments by a customer, nor does it affect a customer's unilateral right to terminate its supply relationship with Illumina at any time and for any reason.

the same prices. It will also include a commitment not to increase prices for the duration of the agreement, and to lower pricing for future products by at least 43%.⁸

6.4 Certain of Illumina's customers have themselves stated that the Open Offer would effectively resolve any hypothetical foreclosure concerns arising from the Transaction.⁹ Illumina would have no ability to refuse to supply cancer screening test developers who had signed up to the Open Offer; no ability to degrade the quality of Illumina's NGS systems, or disrupt or delay that supply; no ability to raise prices for twelve years following the Transaction; no ability to deny technical assistance to downstream test developers; no ability to unreasonably refuse or delay the execution of any agreement necessary to enable downstream test developers to develop a distributable kitted test on Illumina's sequencers; and no ability to pass to GRAIL any commercially sensitive information relating to other developers of cancer screening tests.

7. Efficiencies: the Transaction will accelerate the launch of GRAIL's life-saving test in the EEA

7.1 This is not a transaction that DG Competition should seek to prohibit. Any risks to competition are highly speculative and, as explained above, unfounded. In contrast, the harm to patient welfare that would be caused by prohibiting the Transaction is highly likely and more than plausible.

7.2 The Transaction would bring important merger-specific and verifiable efficiencies that DG Competition can and should take into account. The Transaction will accelerate the launch of GRAIL's cancer screening test: with Illumina's support, Galleri will achieve regulatory approval and reimbursement both in the US and the EEA sooner than would be the case were GRAIL to remain an independent company. GRAIL is a young company with no experience of obtaining either regulatory approvals or reimbursement. Illumina is unique in having the experience of both obtaining regulatory and reimbursement approvals for NGS systems and NGS-based blood tests in the US and the EEA.

7.3 The Transaction is therefore highly likely to make GRAIL's unique test available for EEA patients (and patients in the developing world) much earlier than would otherwise be the case. On its own, GRAIL has no plans to enter the EEA market at scale before 2030: its focus is on launch in the US and (secondarily) the UK. In contrast, Illumina has a clear strategy of accelerating the launch of GRAIL in the EEA by at least five years – see Figure 1 overleaf – and bringing Galleri to developing nations around the world. Illumina is also committed to making Galleri available in Africa, Asia and Latin America which, absent the Transaction, would be unlikely to have the benefit of this life-saving test for decades.

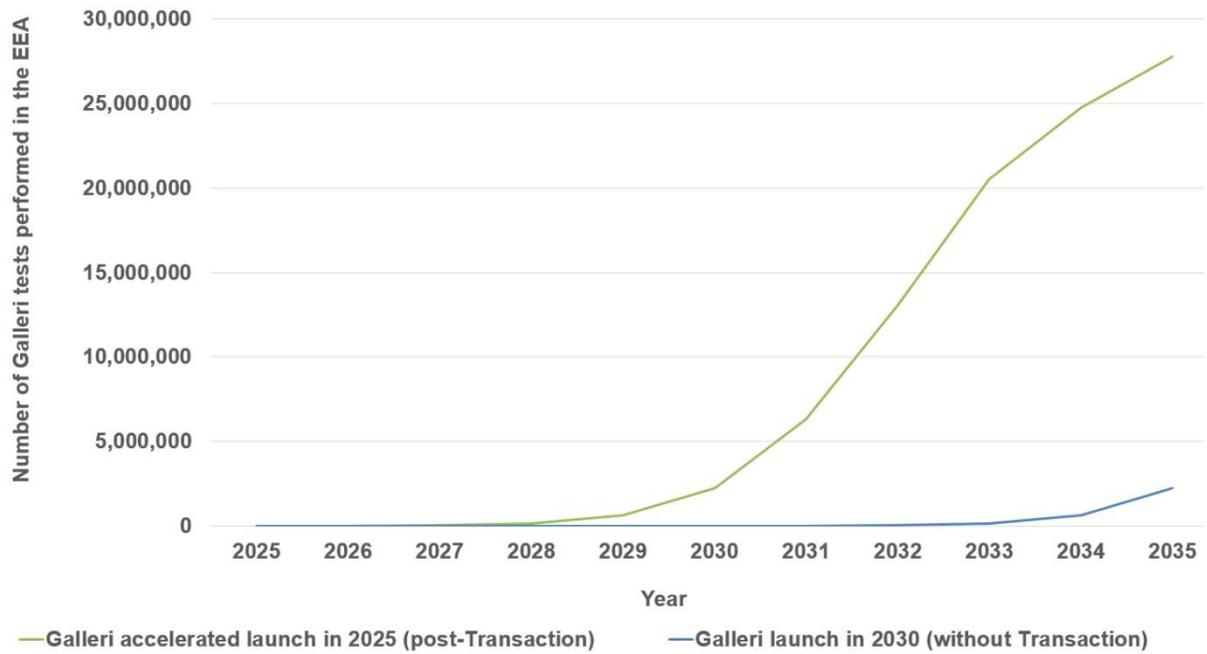
7.4 Accelerating GRAIL's path to market in the EEA will save lives and potentially reduce the costs of cancer treatment throughout the EEA by billions of euros. Detecting cancer early is proven to aid in the treatment of cancer and to save lives. Table 3 overleaf sets out the

⁸ For sequencing instruments by 2025: the cost per gigabase of sequencing on Illumina's highest throughput instrument will be at least 43% lower than the comparable cost per gigabase today, under Illumina's standard terms.

⁹ For example, Roche and its subsidiary Foundation Medicine explained to the FTC in March 2021 that any concerns that they had about the Transaction had been resolved as a result of Illumina's long term supply commitments.

estimated number of lives that would be saved in each country in the EEA through to 2035 if the Transaction is cleared; tens of thousands in the EEA as a whole (between 68,000 and 96,200).¹⁰

Figure 1
Projected number of Galleri tests performed in the EEA, 2025-2035



Source: RBB Economics analysis of Illumina's deal model.

¹⁰ The number of tests per country is estimated according to the relative population size of each country in the EEA in 2020, as sourced from the World Bank Data Bank.

Table 3
Lives saved in each country in the EEA if the Transaction is cleared

Country	2025-2030			2025-2035		
	No. of Tests	Lives saved Lower bound	Lives saved Upper bound	No. of Tests	Lives saved Lower bound	Lives saved Upper bound
Austria	59,626	44	62	1,818,414	1,346	1,891
Belgium	77,270	57	80	2,356,522	1,744	2,451
Bulgaria	46,320	34	48	1,412,626	1,045	1,469
Croatia	27,062	20	28	825,313	611	858
Cyprus	8,073	6	8	246,207	182	256
Czech Republic	71,539	53	74	2,181,740	1,614	2,269
Estonia	8,900	7	9	271,432	201	282
Denmark	38,992	29	41	1,189,152	880	1,237
Finland	36,982	27	38	1,127,835	835	1,173
France	450,618	333	469	13,742,627	10,170	14,292
Germany	556,594	412	579	16,974,575	12,561	17,654
Greece	71,650	53	75	2,185,136	1,617	2,273
Hungary	65,192	48	68	1,988,191	1,471	2,068
Iceland	2,450	2	3	74,722	55	78
Ireland	33,398	25	35	1,018,534	754	1,059
Italy	398,212	295	414	12,144,376	8,987	12,630
Latvia	12,715	9	13	387,767	287	403
Lithuania	18,687	14	19	569,901	422	593
Liechtenstein	255	0	0	7,777	6	8

Country	2025-2030			2025-2035		
	No. of Tests	Lives saved Lower bound	Lives saved Upper bound	No. of Tests	Lives saved Lower bound	Lives saved Upper bound
Luxembourg	4,228	3	4	128,935	95	134
Malta	3,512	3	4	107,117	79	111
Netherlands	116,621	86	121	3,556,632	2,632	3,699
Norway	35,970	27	37	1,096,993	812	1,141
Poland	253,761	188	264	7,739,004	5,727	8,049
Portugal	68,909	51	72	2,101,531	1,555	2,186
Romania	128,958	95	134	3,932,865	2,910	4,090
Slovak Republic	36,501	27	38	1,113,175	824	1,158
Slovenia	14,043	10	15	428,262	317	445
Spain	316,620	234	329	9,656,027	7,145	10,042
Sweden	69,229	51	72	2,111,295	1,562	2,196
Total	3,032,886	2,244	3,154	92,494,685	68,446	96,194

Source: Illumina internal data, World Bank population estimates. The forecasted number of tests and lives saved in the EEA are allocated across each country proportionately to its relative population size in 2020.