Terms of reference and conduct of the inquiry

Terms of reference

1. On 24 March 2014 the OFT sent the following reference to the CC:

    1. In exercise of its duty under section 22(1) of the Enterprise Act 2002 ('the Act') to make a reference to the Competition Commission (the 'CC') in relation to a completed merger, the Office of Fair Trading (the 'OFT') believes that it is or may be the case that –

        (a) A relevant merger situation has been created in that:

        Two or more enterprises, namely Alliance Medical Group Limited, acting through its wholly-owned subsidiary Alliance Medical Molecular Imaging Limited, and the manufacturing assets for the production of 18-F-fluorodeoxyglucose (FDG-18) in the UK formerly controlled by IBA Molecular UK Limited as well as related rights and activities, have ceased to be distinct enterprises at a time, or in circumstances, falling within section 24 of the Act; and

        The condition specified in section 23(3) of the Act is satisfied with respect to the supply of FDG-18 in the South of Great Britain.

        As a result, the OFT believes that it is or may be the case that a relevant merger situation within the meaning of section 23(2) of the Act has been created.

        (b) The creation of that situation may be expected to result in a substantial lessening of competition within a market or markets in the UK for goods or services, including the manufacture and supply of FDG-18 by licensed commercial providers.

    2. Therefore, in exercise of its duty under section 22(1) of the Act, the OFT hereby refers to the CC, for investigation and report within a period ending on 7 September 2014, the following questions in accordance with section 35(1) of the Act:

        (a) whether a relevant merger situation has been created; and

(b) if so, whether the creation of that situation has resulted, or may be expected to result, in a substantial lessening of competition within any market or markets in the UK for goods or services.

Chris Walters, Office of Fair Trading
24 March 2014

Transfer from the CC to the CMA

2. On 1 April 2014 the functions of the CC in relation to the reference were transferred to the CMA, under the Enterprise and Regulatory Reform Act 2013 and the Enterprise and Regulatory Reform Act 2013 (Commencement No. 6, Transitional Provisions and Savings) Order 2014.

Interim measures

3. The OFT accepted initial undertakings from Alliance and Alliance Molecular Medical Imaging Limited (AMMIL) on 6 December 2013. These undertakings are published on our webpages.

4. Under a consent accepted by the OFT on 6 December 2013, a senior manager was seconded from AML to AMMIL to run the IBA operation at Guildford, on a full-time interim basis.

5. On 26 March 2014 the CC adopted the undertakings.

6. On 9 May 2014 we published directions, on our webpages, to Alliance to appoint a monitoring trustee and a hold separate manager to operate a viable, competitive IBA business separately from, and independently of, Alliance. A hold separate manager was appointed on 1 May 2014 and a monitoring trustee was appointed on 9 May 2014.

7. On 28 May 2014, the monitoring trustee provided us with an initial report, in which it identified a number of issues relating to Alliance's compliance with the undertakings and made a number of recommendations to improve the hold separate arrangements, which we required Alliance to implement. Alliance agreed to implement these recommendations and confirmed that it had done so in a letter dated 12 June 2014.

8. We did not reach a view that Alliance had breached the undertakings. Nevertheless, no managerial or sales staff had transferred to Alliance with the IBA operation and numerous difficulties were encountered by the business, while the undertakings were in effect, in its technical operations, its dealings with customers and suppliers and its finances. These circumstances indicated to us that more could and should have been done, when the undertakings were

given and thereafter, to achieve their purpose, namely to enable the IBA operation to compete as a stand-alone business in the market both with regard to day-to-day activities and its future financial viability. We were particularly concerned about the apparent lack of customer and management accounting information available to the hold separate manager, delays in paying key suppliers, the slender staff resources retained within the IBA operation and the apparent lack of appreciation on the part of certain customers of the status of the IBA operation. We continued to monitor this situation through regular reports from the monitoring trustee and the hold separate manager.

Conduct of the inquiry

9. An invitation to comment on the inquiry was posted on the CC website on 24 March 2014. We also published biographies of the members of the Group conducting the inquiry. The administrative timetable for the inquiry was published on the CMA's webpages on 10 April 2014.

10. We invited a wide range of interested parties to comment on the acquisition. These included customers and competitors of Alliance and the PET Business as well as the NHS and relevant professional bodies. Evidence was also obtained from third parties through oral hearings, through telephone contacts and through further written requests. Summaries of hearings can be found on our webpages.

11. We received written evidence from Alliance, and a non-confidential version of its main submission is on our webpages. We also received initial submissions from PETNET and InHealth, non-confidential versions of which are also on our webpages. We also held a hearing with Alliance on 6 June 2014.

12. On 28 April 2014 we published an issues statement on our webpages, setting out the areas of concern on which the inquiry would focus. One third party, InHealth, responded to the issues statement and a non-confidential version of its response is on our webpages.

13. On 1 May 2014 members of the Inquiry Group, accompanied by staff, visited Surrey to see two RPUs at Guildford and Sutton. The Guildford RPU was one of the facilities purchased by Alliance from IBA Molecular UK. The Inquiry Group also visited a PET-CT scanning centre operated by Alliance on behalf of the NHS at the Royal Surrey County Hospital.

14. In the course of our inquiry, we sent to Alliance and other parties some working papers and extracts from those papers for comment.

15. On 10 July 2014, we published on our webpages our full provisional findings report and a notice of provisional findings.

16. Following the publication of our provisional findings, we received a submission from InHealth, a non-confidential version of which was published on our webpages.

17. A non-confidential version of the final report was placed on the CMA's webpages on 15 August 2014.

18. We would like to thank all those who have assisted us in our inquiry.

Financial information on the companies

The IBA group

1. IBA[1] SA is a Belgian medical technology company, with a focus on the development and production of cancer diagnostic products and treatment equipment. It is listed on the Euronext stock exchange.[2] IBA SA's expertise lies in the development of proton therapy technologies[3] that provide oncology care providers with premium quality services and equipment. IBA SA currently employs more than 1,000 people worldwide, with business activities across Europe and the USA. The business is also expanding into emerging markets.[4]

2. In 2013, IBA SA generated turnover of €213 million from three lines of business: Proton therapy (60%), radiopharmacy solutions (20%) and dosimetry (20%).[5]

3. SK Capital is a private investment firm which focuses on the speciality materials, chemicals and healthcare sectors. SK Capital seeks buyouts, recapitalisations and growth equity investments in companies with opportunities for substantial business improvement.[6]

4. In early 2012, IBA SA and an affiliate of SK Capital created a jointly-owned new company, IBA Pharma SA, derived from IBA's radiopharmaceutical division. IBA SA retained a 40% stake in the business, with SK Capital taking a 60% shareholding.[7] The enterprise value of IBA Pharma SA used as the basis of the transaction was €180 million.[8] SK Capital's stated investment

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[1] IBA stands for Ion Beam Applications.
[2] IBA is included in the BelMid Index.
[3] Proton therapy is a means of treating cancer using targeted doses of radiation.
[4] IBA SA Corporate Fact Sheet.
[5] Proton therapy – IBA SA states that Proton therapy is increasingly considered the most advanced and targeted cancer treatment due to its superior dose distribution and reduced patient side effects. IBA SA designs, develops, and equips proton therapy clinics for its customers. Radiopharmacy solutions – equipment development, production, installation and the maintenance of integrated facilities for the production of radioisotopes and radiopharmaceutical tracers. IBA SA supports hospitals and radiopharmaceutical centres, assisting with the design and installation across their facility, providing support to the process and a full range of training programmes. Dosimetry – monitoring equipment and software enabling hospitals to perform the necessary checks and calibration procedures of radiation therapy and radiology. These products ensure that precise doses are delivered to patients.
[6] SK Capital is not part of the IBA SA Group.
[7] As the majority shareholder in IBA Pharma SA, SK Capital was the key decision-maker in relation to the sale of the IBA operation to Alliance.
[8] IBA SA press releases, 9 January 2012 and 2 April 2012.

rationale was to enhance the business's manufacturing assets, expand its geographical coverage, and invest in developing its product range.[9]

5. IBA Pharma SA trades as IBA Molecular[10] and specialises in the development, production and distribution of radioactive isotopes used for medical imaging. In particular, the business produces radioisotopes for PET and SPECT scanning. Radioisotopes are substances that undergo radioactive decay, resulting in the emission of gamma rays and/or subatomic particles. These emissions can be detected using PET and SPECT scanners. Radioisotopes are, therefore, used in combination with PET/SPECT scanners for the medical diagnosis of a range of illnesses, including cancers, dementia, osteoporosis, and cardiac problems. The radioisotopes produced by IBA Molecular include FDG-18, as well as a number of other fluorine and non-fluorine-based isotopes. IBA Molecular's worldwide manufacturing and distribution network is comprised of over 50 locations in Europe, the USA and Asia and employs approximately 1,000 people worldwide.[11]

6. IBA Molecular UK is a wholly-owned subsidiary of IBA Pharma SA. Prior to the transaction, its operations comprised two separate lines of business:

   (a) PET business – IBA Molecular UK had two RPUs in the UK which specialised in the production of FDG-18 for use in PET-CT scanning. The RPUs were located in Guildford, Surrey and Dinnington, Yorkshire (near Sheffield). In addition to FDG-18, the Guildford site also produced Florbetaben (18F). At the time of the transaction, the Dinnington site was not operational. IBA Molecular UK distributed these products from its Guildford site to five customers located in England under fixed price contracts.

   (b) SPECT business – IBA Molecular UK distributes a range of radiopharmaceuticals for the SPECT imaging modality, which are manufactured at IBA Molecular's Saclay site in France. These radioisotopes have a significantly longer half-life than FDG-18 (approximately 2.5 days, compared with 110 minutes) and therefore do not create the same level of logistical challenge in terms of distribution as FDG-18. As a result, IBA Molecular has a single manufacturing facility for them in France, from where they are distributed worldwide.

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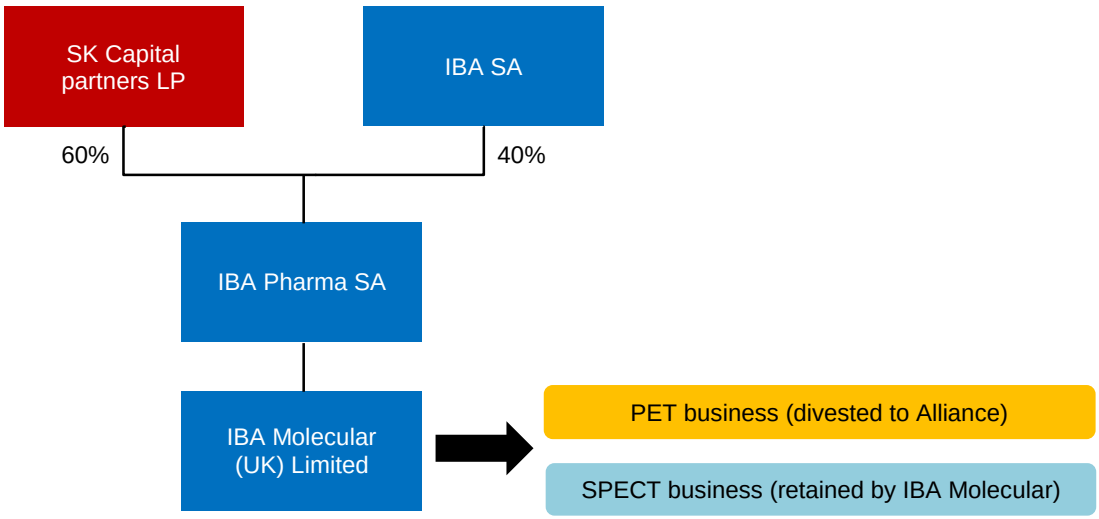
[9] www.skcapitalpartners.com/content/press/sk-capital-and-iba-join-accelerate-growth-iba-molecular-imaging.
[10] www.ibamolecular.eu/.
[11] IBA Molecular Imaging and SK Capital websites.

7. The target of the acquisition was IBA's PET business, ie the manufacturing assets for the production of FDG-18.[12] In addition to the two RPUs (based at Guildford and Dinnington), the acquired business comprised eight employees and contracts with five[13] customers. The revenue of the PET business in the financial year ending December 2012 was £[✂] million.

8. The Guildford site was opened in February 2008, obtaining a full MA for the commercial supply of FDG-18 in May 2009, and has remained in operation since then. The Dinnington site was opened in August 2007 but was closed in October 2010 due to poor financial performance. IBA Molecular UK told us that the Dinnington site had been 'mothballed' as it was not profitable or sustainable following the loss of a significant contract in Glasgow and the limited business development opportunities in the north of England. IBA Molecular UK explained that the majority of the equipment for manufacturing FDG-18 remained on site, with some moved to the Guildford site to fix issues when needed there. IBA Molecular UK estimated that it would require between 18 and 24 months and investment of approximately [£500,000–£1 million] to return the site to active production. The assets of the Dinnington site formed part of the business acquired by Alliance.

FIGURE 1

Ownership chart for IBA Molecular UK



Source: Alliance and CMA analysis.

[12] FDG-18 is a tracer (also known as a biomarker) injected into patients primarily when undergoing a PET-CT scan for the diagnosis of certain types of cancer. FDG-18 for PET-CT is commonly used for cancer staging and follow-up, evaluation of myocardial viability or sarcoidosis and assessment of neurological conditions including epilepsy and dementia. FDG-18 for PET-CT can also be used to assess some infections.
[13] Including InHealth, [✂].

Financial performance

9. The financial performance of IBA Molecular UK in FY11 and FY12 is set out in Table 1. The whole business generated revenues of approximately £5.0 million, with IBA's PET business turning over £[✂] million in FY12.

TABLE 1 **IBA Molecular UK, summary profit & loss account**

						£'000
Year end 31 December		*FY11*			*FY12*	
	PET	*SPECT*	*Total*	*PET*	*SPECT*	*Total*
Turnover	[✂]	[✂]	4,707	[✂]	[✂]	4,998
Gross profit	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
%	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
EBITDA	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]

Source: Alliance.

10. The PricewaterhouseCoopers (PwC) due diligence report highlighted that IBA Molecular UK had approximately £[✂] of tax trading losses as at 31 December 2011 and that the majority (if not all) of these losses were attributable to the FDG-18 business. IBA Molecular told us that its PET business had made losses since IBA Molecular UK started production of FDG-18 in 2007.

11. IBA's PET business made small losses at the EBITDA level in both FY11 and FY12. [✂][14]

12. The forecasts produced at the time of the transaction estimated FY13 EBITDA of £[✂], taking into account the loss of the Christie contract as well as [✂]. However, this forecast also assumed a market-wide increase in the volumes supplied to existing customers and that the [✂] supply contract would be won. [✂]

TABLE 2 **Financial performance of IBA's PET business**

	£'000	
Year end 31 December	*FY11 Actual*	*FY12 Actual*
FDG-18 sales	[✂]	[✂]
Transport sales	[✂]	[✂]
Total revenue	[✂]	[✂]
Direct materials	[✂]	[✂]
Transport	[✂]	[✂]
Gross profit	[✂]	[✂]
%	[✂]	[✂]
EBITDA	[✂]	[✂]
EBIT	[✂]	[✂]

Source: Alliance.

[14] [✂]

13. Alliance was formed in 1989. The principal activity of the group is the provision of diagnostic imaging services. Alliance is owned by a combination of management and financial institutions, with M&G, the investment arm of the Prudential owning [✂]% of the group. Over the past five years, the group has expanded and rationalised its European operations through a number of acquisitions and disposals. The group provides medical imaging services to hospitals and clinics in the UK, the Republic of Ireland, Italy, Spain, the Netherlands and Scandinavia. In 2013, Alliance generated total revenue of £218.6 million, EBITDA of £43.8 million, and EBIT of £[✂] million.[15]

14. In the UK, Alliance's wholly-owned subsidiary, AML, currently operates over [✂] static imaging sites and over [✂] mobile scanners offering different combinations of MRI, CT, PET-CT, X-ray, ultrasound and DEXA imaging services.[16] AML's principal customer is the NHS in England. AML does not provide PET-CT scanning services to the NHSs in Scotland, Wales or Northern Ireland.

15. In August 2013, Alliance acquired the operations of Erigal Limited (Erigal) in England. Erigal was established in 2002 as a 50/50 joint venture between Alliance and M2i Holdings, an Irish company. The firm manufactures radiotracers, including FDG-18, sodium fluoride (used for PET-CT bone scanning) and choline (used in PET-CT scans for prostate cancer). Erigal has three RPUs in England, located in Keele, Preston and Sutton (Surrey). The Keele site was established in 2005, followed by the Preston site in 2008 and the Sutton site in 2009. The Preston and Sutton sites are located on the grounds of the Royal Preston and Royal Marsden hospitals, respectively.

16. Prior to August 2013, Erigal also had a production facility in Dublin supplying the Irish market, which was acquired by M2i holdings at the same time as Alliance acquired the remaining 50% of the Erigal business in the UK.

17. In 2013, Alliance purchased around [✂]% of Erigal's total output in England.

18. In 2013, AML generated revenues of £[✂] million,[17] EBITDA of £[✂] million, and EBIT of £[✂] million (before reorganisation costs).

19. On 16 September 2013, Alliance acquired the IBA operation. These assets were absorbed into its AMMIL subsidiary (which had been set up for this purpose).

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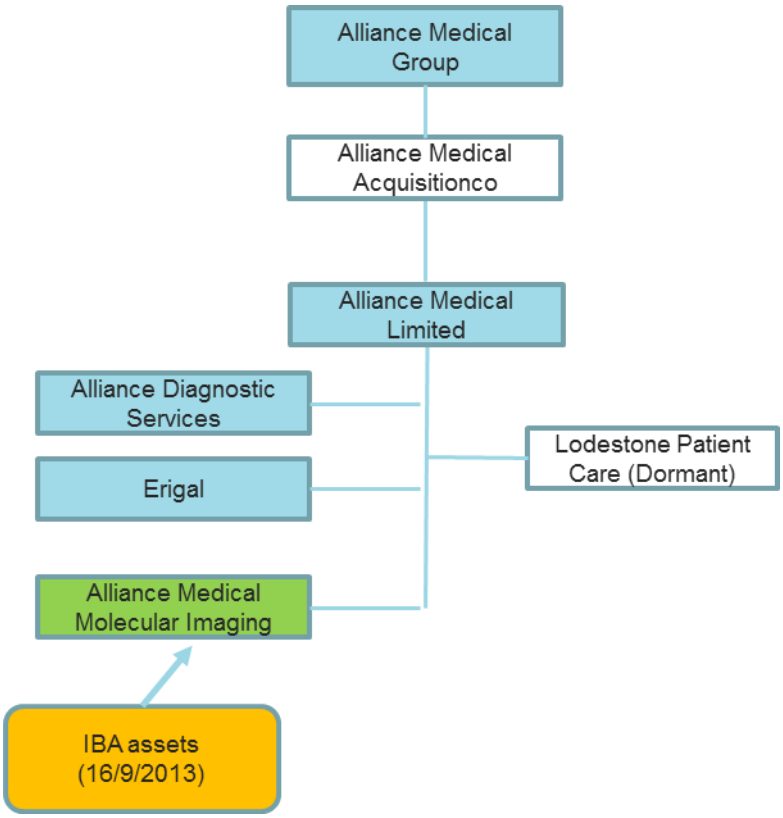
[15] Alliance Medical Group Limited Statutory Accounts, FY13. EBIT figures quoted including exceptional costs.
[16] Alliance's scanning sites offer different combinations of scanning modalities, ie not all sites offer all types of scan. Alliance offers PET-CT scanning services from [✂] static and [✂] mobile sites.
[17] Of which, £[✂] million turnover came from its UK operations.

FIGURE 2

Alliance Medical Group Limited:
Summary group structure, UK entities, post-merger



Source: Alliance.

Financial performance

20. In this section, we provide an overview of the recent financial performance of both Alliance (at the group and UK levels) and Erigal.

21. As set out in Table 3, Alliance's financial performance has been weak at the group level, with declining sales and EBITDA margins, low EBIT margins and significant exceptional costs and write-offs. The business incurs significant capital expenditure on an ongoing basis as scanning equipment is replaced, with purchases of tangible assets averaging approximately £28 million per year over the FY09 to FY13 period. In its statutory accounts, Alliance records the large majority of its depreciation expense as a cost of sale. In Table 3, costs of sales exclude depreciation expense, which is reflected in the EBIT figure instead. As a result of this high level of ongoing capital expenditure, we consider that the key operating margin for the business is EBIT (rather than EBITDA).

TABLE 3 **Alliance, summary financial information (all operations)**

£ million

Year end 31 March	*FY09*	*FY10*	*FY11*	*FY12*	*FY13*
Revenue	231.6	266.1	244.9	231.1	218.6
Gross profit	105.5	124.0	110.7	104.6	95.7
	45.6%	*46.6%*	*45.2%*	*45.3%*	*43.8%*
EBITDA	62.8	68.7	58.7	49.2	43.8
	27.1%	*25.8%*	*24.0%*	*21.2%*	*20.0%*
EBIT	**11.6**	**11.9**	**13.9**	**8.1**	**6.6**
	5.0%	*4.5%*	*5.7%*	*3.5%*	*3.0%*
[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
*Purchase of PPE**	*36.0*	*37.0*	*22.8*	*11.8*	*29.2*

Source: Alliance Medical Group Limited, Statutory Accounts, FY10 to FY13.

*Figures taken from the cash flow statement. Alliance also made some purchases of intangible assets, as well as business acquisitions. These figures are not shown here.
Notes:
1. In FY10 Alliance incurred exceptional costs of £549.9 million which resulted from a write-down/impairment of goodwill and other intangibles.
2. Alliance treats a large proportion of its depreciation expense as a cost of sale, deducting it from gross profit in its statutory accounts. In this table, depreciation costs have been removed from the cost of sales and deducted from EBITDA to give EBIT.

22. The financial information available for Alliance's UK operations was more limited. However, as shown in Table 3, the business has experienced a similar pattern of declining revenues between FY11 and FY13 (from around £[✂]).

TABLE 4 **AML, summary financial information (UK operations)**

£'000

Year end 31 March	*FY11*	*FY12*	*FY13*
Revenue	[✂]	[✂]	[✂]
EBITDA	[✂]	[✂]	[✂]
%	[✂]	[✂]	[✂]
EBIT*	[✂]	[✂]	[✂]

Source: Alliance.

*EBIT figures are quoted on a 'pre-exceptionals' basis.

23. Erigal was acquired by Alliance after the end of Alliance's 2013 financial year, which ended on 31 March 2013, hence, its financial results are not included in those of Alliance or of AML. As shown in Table 5, Erigal grew its revenues gradually between FY11 and FY13 and has achieved high gross profit margins.

TABLE 5 **Erigal, summary financial information (total operations)**

			£'000
Year end 31 March	*FY11*	*FY12*	*FY13*
Revenue	7,954	8,060	8,404
Gross profit	6,629	6,718	6,840
	83.3%	*83.3%*	*81.4%*
EBITDA	2,459	2,354	2,573
	30.9%	*29.2%*	*30.6%*
EBIT	[✂]	[✂]	[✂]

Source: Erigal Management Accounts, March 2012 and 2013, and Strategic Market Review, February 2012. Limited financial information is available for FY09 and FY10.

Note: Summary financial information includes Irish operations that were not acquired by Alliance.

24. Table 6 sets out the breakdown of Erigal's various revenues and EBITDA by site for FY12 and FY13. The Irish operations were not acquired by Alliance and hence do not form part of the Alliance group of companies.

TABLE 6 **Breakdown of Erigal's operations by site, FY12 and FY13**

		£'000
Year end 31 March	*FY12*	*FY13*
Preston	[✂]	[✂]
Keele	[✂]	[✂]
Sutton	[✂]	[✂]
Dublin	[✂]	[✂]
Total revenue	[✂]	[✂]
Preston	[✂]	[✂]
Keele	[✂]	[✂]
Sutton	[✂]	[✂]
Dublin	[✂]	[✂]
Head Office	[✂]	[✂]
Total EBITDA	[✂]	[✂]

Source: Erigal Management Accounts, FY13.

Comparisons of the costs and margins of the FDG-18 businesses

25. In this section, we provide a detailed breakdown of the costs and margins of both Erigal and IBA's PET business.

Erigal

26. Table 7 shows the breakdown of Erigal's financial performance in FY12 and FY13. The results are for the entire Erigal business, prior to its division between its English and Irish operations and the acquisition of these by Alliance and M2i, respectively. This analysis highlights that the production of FDG-18 is a relatively high-gross-margin business. The principal categories of overhead costs are personnel, 'establishment' and plant and equipment costs. Establishment costs are comprised predominantly of rent and rates on the production facilities, while plant and equipment costs arise from the maintenance of the production facilities.

27. [✂][18]

28. [✂]

[18] [✂]

TABLE 7 **Breakdown of Erigal's financial performance in FY12 and FY13**

£'000

	FY12						FY13					
Year end 31 March	*Keele*	*Preston*	*Sutton*	*Dublin*	*Head office*	*Total*	*Keele*	*Preston*	*Sutton*	*Dublin*	*Head office*	*Total*
Turnover	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Cost of sales (RM & consumables)	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Gross margin	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
%	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Doses (quantity)	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Average price per dose (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Average cost of sales per dose (£)	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Average gross margin per dose (£)	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Expenses												
Personnel	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Plant & Equipment	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Establishment	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Financial	[✂]			[✂]	[✂]	[✂]	[✂]			[✂]	[✂]	[✂]
Professional	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Sales & marketing					[✂]	[✂]	[✂]				[✂]	[✂]
Other income			[✂]			[✂]			[✂]			[✂]
Management charge				[✂]	[✂]							
Total	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Average overhead cost per dose	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
EBITDA	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
%	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Exceptional costs					[✂]	[✂]					[✂]	[✂]
Depreciation												
Plant & equipment	[✂]	[✂]	[✂]	[✂]		[✂]	[✂]	[✂]	[✂]	[✂]		[✂]
Establishment	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
EBIT	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
%	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]

Source: Erigal Management Accounts, FY12 and FY13 and CMA analysis.

IBA's PET business

29. Table 8 shows a breakdown of the profit and loss account for IBA's PET business for FY11 to FY13. IBA Molecular UK's year end was 31 December.

TABLE 8 **Breakdown of IBA's PET business's financial performance in FY11 to FY13**

£'000

	FY11 Actual	*FY12 Actual*	*FY13 Budget*
FDG-18 sales	[✂]	[✂]	[✂]
Transport sales	[✂]	[✂]	[✂]
Total revenue	[✂]	[✂]	[✂]
Direct materials	[✂]	[✂]	[✂]
Transport	[✂]	[✂]	[✂]
Gross profit	[✂]	[✂]	[✂]
%	[✂]	[✂]	[✂]
No. of doses	[✂]	[✂]	[✂]
Average price per dose (£)	[✂]	[✂]	[✂]
Average cost of sales per dose (£)	[✂]	[✂]	[✂]
Average gross margin per dose (£)	[✂]	[✂]	[✂]
Expenses			
Salaries	[✂]	[✂]	[✂]
Supplies†	[✂]	[✂]	[✂]
Utilities	[✂]	[✂]	[✂]
Rent and rates	[✂]	[✂]	[✂]
Repairs & maintenance	[✂]	[✂]	[✂]
Fees‡	[✂]	[✂]	[✂]
Other	[✂]	[✂]	[✂]
Royalties	[✂]	[✂]	[✂]
Total	[✂]	[✂]	[✂]
Average overhead cost per dose (£)	[✂]	[✂]	[✂]
EBITDA	[✂]	[✂]	[✂]

Source: Alliance and CMA analysis.

*[✂]
†[✂]
‡[✂]

30. [✂][19,20]

31. [✂]

[19] [✂]
[20] [✂]

The products and services

PET-CT scanning

Introduction

1. PET-CT scans are used to diagnose a range of medical conditions. A PET-CT scan combines two types of scanning technology: a CT scan (anatomical) and a PET (metabolic) scan. A CT scan takes a series of X-rays and uses a computer to put them together. The CT machine takes pictures of the body from different angles and gives a series of cross sections or 'slices' through the part of the body being scanned. PET uses a small amount of an injected radioactive isotope to show where cells are active in the body. The technique allows for the precise and accurate anatomical localisation of biochemical activity in the body.[1]

2. PET-CT scanning is predominantly used for oncologic diagnostic purposes, including the staging of cancer. It can also be used to identify whether a cancer can be treated, how to treat it and whether cancer is responding to treatment.[2] PET-CT scanning is indicated as a diagnostic tool for a broad range of cancer types, including cancers of the brain, head, neck, lungs, gastrointestinal tract, liver, pancreas and colon, among others. In addition, PET-CT scanning is increasingly used as a means of diagnosing dementia (Alzheimer's).

[1] NHS England.
[2] www.cancerresearchuk.org/cancer-help/about-cancer/tests/petct-scan#what.

FIGURE 1

PET-CT scanner

Source: Siemens website.

3. PET-CT scans can be provided using either a static or a mobile scanner. The former is permanently installed in a hospital or clinic, while the latter is installed in a 'trailer' and moved from site to site as required. Static scanners offer benefits in terms of:

   (a) the quality/accuracy of the images produced, which means that they can be used for a broader range of purposes including radiotherapy planning;

   (b) the ability to scan a larger number of patients in a day due to their longer/ more flexible operating hours; and

   (c) integration into the hospital workflow, including proximity to other imaging and clinical services.

4. Mobile units, on the other hand, can be used to serve multiple hospitals which conduct a relatively smaller number of scans, without requiring each hospital to invest in its own scanner. Once a critical volume is achieved – generally considered to be three full days a week of scanning – the clinical and economic benefits of a static site are typically better than using a mobile unit.

5. Three companies manufacture and supply PET-CT scanners in the UK: GE Healthcare, Siemens and Philips Healthcare. [✂]

PET-CT scanning services

6. Patients are referred for a PET-CT scan by a consultant (oncologist) rather than by a General Practitioner, ie they have a 'secondary' referral. An

Administration of Radioactive Substances Advisory Committee (ARSAC) certificate holder must authorise the referral for each individual patient, prior to an appointment being made for the scan. The PET-CT scanning centre will schedule and carry out the scan, which is performed on an outpatient basis, and then report the results (and the images) back to the referrer. The results of scans are frequently used in multi-disciplinary team (MDT) discussions for cancer patients.[3]

7. A PET-CT scan lasts from around 20 minutes for a partial body scan up to an hour for a full-body scan. Patients are injected with FDG-18 (in a saline solution) approximately 1 hour before they undergo a PET-CT scan. This period allows time for the patient's organs to take up the radioisotope.[4] The PET scan picks up the positron emissions from the FDG-18, while the CT scan X-rays the body.

FDG-18

Introduction

8. FDG-18 is a glucose analogue with the positron-emitting radioactive isotope fluorine-18 substituted for the normal hydroxyl group in the glucose molecule. This isotope has a half-life of 110 minutes.[5] It is taken up by high-glucose-using cells, such as the brain and kidney, as well as cancer cells. The positron emissions of the FDG-18 are detected by the PET scanner, which, in combination with the anatomical image created by the CT scanner, allows for precise and accurate anatomical localisation of biochemical activity in the body.

9. There are a number of other radiotracers that can also be used with PET-CT scanning technology, all of which are also based on the fluorine-18 isotope. These include 18F-Choline (FEC) and 18F-Sodium Fluoride (NaF), which are also used in the diagnosis of cancer. The former is used for the diagnosis of prostate cancer, while the latter is used for the assessment of cancer cells resulting in both the destruction of bone cells and the proliferation of new cancerous bone tissue.

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[3] MDTs are meetings where a number of clinical experts (often, consultants) discuss the appropriate course of treatment for a cancer patient. They bring together a range of expertise, including from surgeons, oncologists and radiologists, which is particularly relevant for cancer patients where there are a number of potential treatment options.

[4] In order to enhance the clarity of the scan, patients need to fast for approximately 6 hours before they are injected with FDG-18 to ensure a relatively low level of glucose in their blood. Moreover, during the hour between injection and scanning, the patient must keep physical activity to a minimum in order to minimise the take-up of FDG-18 into the muscles, which can cause unwanted artefacts in the scan.

[5] This means that half of the radioactivity of the isotope decays every 110 minutes.

10. FDG-18 is one among several radioisotopes that are used in nuclear medicine. The most commonly-used isotope is technetium-99, which is detected with a gamma camera (rather than a PET scanner) and is used for the imaging of bones, blood and other organs. In addition, there are other radioisotopes which can be used for either diagnostic or therapeutic purposes (ie the treatment of illnesses).

11. Table 1 summarises the applications for which each relevant tracer is used and alternatives.

TABLE 1 **Description of uses for radiotracers**

Product	*Applications*	*Alternatives*
FDG-18	Assessment of tissues that take up glucose as part of the increased cellular metabolism due to disease. In particular cancer, including lung, oesophagus, colon infection, and severe inflammation.	Assessment by imaging using Ultrasound, MRI and CT scanning with Radiopaque Contract media to delineate the organs and their blood supply, which could demonstrate some primary tumours. Digital radiography to assess tumour in bones. Limited functional assessment of blood supply using Tc-99m is possible. Significant investment is required to convert FDG-18 procedures to Tc-99m procedures.*
FEC	Specific tracer that has a high affinity to prostate cancer cells. Use to determine the residual disease with the gland following initial treatment.	Digital radiography and CT scanning to assess bone destruction. Tc-99m bone scanning.
NaF	Assessment of cancer cells resulting in both the destruction of bone cells (breast cancer) and the proliferation of new cancerous bone tissue (metastasising prostate cancer). Has a significantly higher sensitivity than Tc99 and combined with co-registered VT images provides greater imaging detail than the Single Photon Computer Tomography Scan (SPECT).	Bone destruction (metastasising cancer and un-united fractures) where Tc-99m and sodium fluoride have a similar uptake profile.

Source: Alliance.

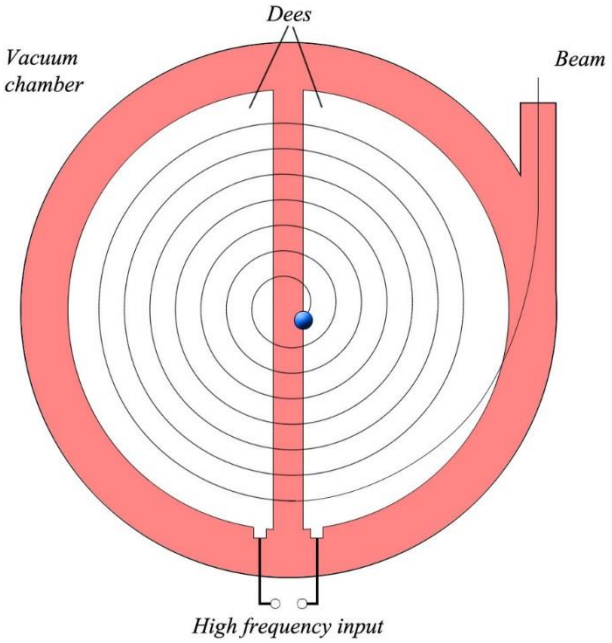
*Tc-99m procedures use a gamma camera. [✂]

Manufacturing process

12. FDG-18 is manufactured via a three-stage process that takes place in an RPU. In the first stage, a type of particle accelerator called a cyclotron, accelerates charged particle beams using a high-frequency alternating voltage and a static magnetic field. The proton particles travel outwards from the centre of the cyclotron in a spiral pathway until they hit a ‘target’ (18-O enriched water) at the perimeter of the vacuum chamber, creating fluorine-18. This stage of production generally takes around 2 hours.

FIGURE 2

Diagram of the internal functioning of a cyclotron



Source: Alliance.

13. After fluorine-18 has been created via the 'firing' of the cyclotron, it is passed through pipes to a clean room for synthesis, purification and dispensing. During the synthesis and purification process, the fluorine is combined with a variety of different substances (such as glucose) to make the tracer, before being purified either via filtering (aseptic purification) or through a process of terminal sterilisation (ie via heating the tracer). The isotope starts to decay from the point at which the fluorine-18 leaves the cyclotron.

14. Finally, the tracer is packaged for distribution to scanning centres. The liquid is placed into vials, containing up to eight doses and then packaged in lead canisters, which are placed inside transportation cases. Given the short half-life of FDG-18, the process of quality control (QC) takes place at the RPU (on a small part of the batch) while the rest of the FDG-18 is being distributed to customers. The cases in which the FDG-18 are transported are locked with customers given the code to open them only once the QC process has been satisfactorily completed at the RPU.

15. Alliance told us that while the inputs to each firing were held constant (batch production), the quantity of FDG-18 produced varied from one firing to another (yield can vary from [✂] to [✂]%). These variations arise from the efficiency of the cyclotron and natural variation in chemical reactions. In general, each firing will produce approximately [✂] doses, with a maximum output of [✂]

doses using current processes.[6] If output is low, the manufacturer can either seek to source FDG-18 from another producer or can fire the cyclotron again. The number of doses produced also depends on the time that elapses between synthesis of the FDG-18 and injection of the FDG-18 solution into the patient ahead of scanning. The process of radioactive decay means that the number of doses in any given quantity of the radioisotope produced declines over time.

16. Due to the radioactivity of fluorine-18, cyclotrons need to be installed in concrete bunkers with walls of at least 2 metres of thickness. Their operation, maintenance and eventual decommissioning is also subject to a range of regulation.

17. Alliance told us that there was generally time to maintain all equipment except for the cyclotron during the working week, with cyclotron maintenance taking place on weekends, without the need for planned shut-downs. However, it noted that as demands on equipment increased, it needed to plan [✂] of shut-down per quarter (for each site) with the orders handled by other manufacturing sites. Alliance explained that an aseptic facility, such as that in Guildford, shuts down for between [✂] and [✂] days per quarter for 'clean room validation'.

18. The failure rate of the FDG-18 production process varies significantly over time and across different production facilities. Information provided by Alliance on Erigal's three RPUs indicated an average loss of [✂] production days per cyclotron per year for the 2010 to 2012 period. However, the number of days lost varied from [✂] in one case (Keele, 2011) to [✂] in another (Sutton, 2012).

Primary and back-up supply

19. Cyclotrons are subject to outages either for planned maintenance or due to unplanned failures. These outages represent a minimal proportion of the overall production (less than 5% in 2013). However, they can cause significant disruption to patients through missed or delayed scans, and trigger a financial penalty for the provider of the PET-CT scanning service. Consequently, customers of FDG-18 require that 'back-up' arrangements are in place (that is, an alternative source of supply of FDG-18). This ensures continuity and security of supply.

[6] Note: Throughout the report, a 'dose' is measured on a delivered basis, ie it takes into account the average quantity of radioactive decay that takes place between the synthesis of the radioisotope and its delivery to the scanning centre.

Ability to switch production to different F-18 isotopes

20. Alliance told us that:

    (a) FDG-18 could only be produced by cyclotrons and every commercial synthesis unit was capable of manufacturing FDG-18;

    (b) FEC could only be produced by cyclotrons and not all synthesis units could be used to manufacture FEC; and

    (c) NaF could only be produced by cyclotrons and every commercial synthesis unit was capable of manufacturing NaF.

21. Alliance estimated that the cost of developing radiopharmaceuticals varied considerably but was essentially undertaken by research institutions or commercial organisations specialising in research. Once developed, adding the capability to produce a new tracer was approximately £[✂] and the process took [✂] months. There may be additional costs such as QC testing that could extend the cost to £[✂], depending on the product. Alliance told us it was in the process of adding the capability to produce FEC to its Keele facility at a cost of £[✂] and this was due to complete by [✂].

22. PETNET told us that the time and cost incurred in adding a new product depended on a number of factors including whether new capital equipment was needed; the raw material required; the production and the QC processes; and the validation and licensing requirements. PETNET added NaF to its portfolio within approximately three months of the decision and without the need for any significant capital investment.

23. GE Healthcare told us that it had only switched from producing FDG-18 compounds to producing other 18F compounds. It said that the time taken on average to effect such a switch was [✂] to [✂] months and the cost was approximately £[✂] to £[✂].

24. The evidence before us shows that once the capability to produce new isotopes has been put in place, switching production between isotopes can take place within any given day and is a relatively straightforward task, although the extent to which switching is possible is constrained by the amount of capacity available at a given site:

    (a) Alliance told us that a cyclotron within an RPU could be used to produce a number of different radiopharmaceuticals, which could be produced in sequence using different firings and targets in the cyclotron. [✂]

(b) PETNET told us that the current configuration of each site enabled it to perform [✂] production runs per day, regardless of product mix. In its experience this would involve [✂] FDG-18 runs per day and then [✂] of one of the other products, depending upon demand.

(c) Guy's and St Thomas' Hospital, which operates a cyclotron for non-commercial purposes said that the difficulty of switching between isotopes varied: some targets could be preloaded, others had to be physically changed.

(d) NHS England told us that several factors hindered the manufacture of alternative tracers in the UK at present, including the complexities of changing the 'target' on cyclotrons in order to manufacture other tracers, and in turn having to take a cyclotron producing FDG-18 offline for a sustained period of time.[7]

Logistics

25. FDG-18 has a half-life[8] of 110 minutes, which, together with clinical restrictions prohibiting the injection of more than 5 ml of solution containing FDG-18 into patients, means that FDG-18 must be used within 8 hours of being synthesised. Furthermore, a PET-CT scanning centre must use all FDG-18 contained within a single vial within 4 hours of opening the vial. This short lifespan means that:

(a) Hospitals are unable to store FDG-18, instead requiring delivery of the radiopharmaceutical on a regular basis. PET-CT scanning centres that seek to scan patients in both morning and afternoon sessions will generally require two deliveries per day of FDG-18 – one in the early morning and one around midday.

(b) The distance over which FDG-18 can be transported is limited.[9]

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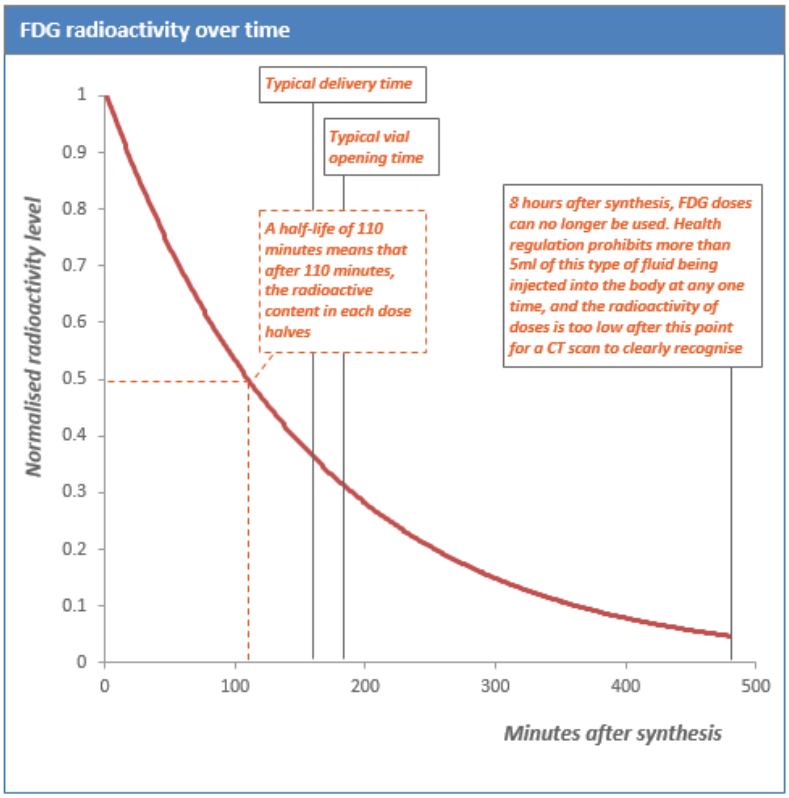
[7] Summary of hearing with Dr Wai Lup Wong, Chair of the Clinical Reference Group, NHS England, paragraph 5.
[8] The length of time in which levels of radioactivity drop by 50%.
[9] See further slides by the Society of Nuclear Medicine and Nuclear Imaging, July 2012, slide 1.

FIGURE 3

Radioactive decay of FDG-18



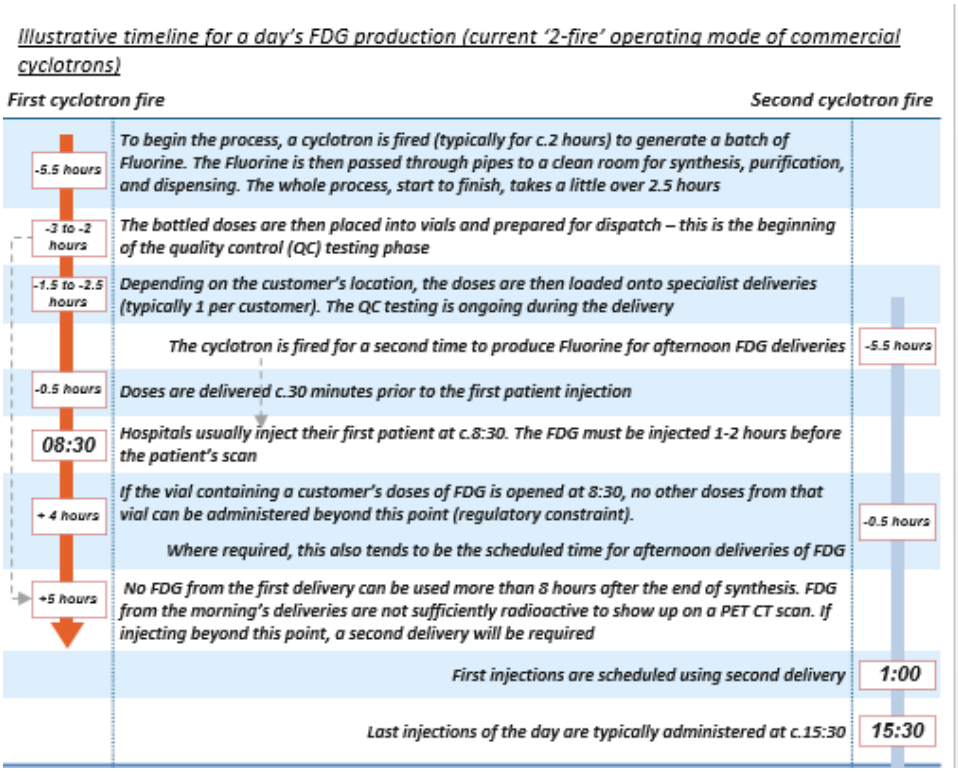
Source: Alliance.

26. FDG-18 is transported by specialist couriers from the manufacturing site to the diagnostic centre where it is used. The costs of transport can be significant; for example, Alliance estimated that the typical cost of a delivery was approximately £[✂] per mile, with each delivery containing up to eight doses of FDG-18. In addition, as the tracer decays over time, a greater volume of the product must be supplied in order to produce the same number of doses for a hospital that is located further away from the RPU. In contrast, where the RPU is located on the same site as a hospital, these transport costs are avoided and there is minimal decay of the tracer between the point at which it is produced and the time of delivery. As a result, proximity to a hospital or clinic will give an FDG-18 producer a cost advantage in terms of supplying that hospital or clinic.

27. The timing of the manufacturing process, based on operating two firings per day, is shown in Figure 4. We note that these timings may change if an RPU is operated on the basis of three or more firings per day.

FIGURE 4

Illustrative timeline for FDG-18 production



Source: Alliance.

The regulatory framework

1. The description of the regulations that are relevant to the supply of PET-CT scanning services and FDG-18 was largely provided to us by Alliance.

The regulation of PET-CT scanning services

2. NHS England requires that providers of PET-CT scanning services comply with good clinical industry practice which includes, but is not limited to,: standards for better health, relevant National Institute for Health and Care Excellence (NICE) guidance, Imaging Services Accreditation Scheme (ISAS), latest Medicines and Healthcare products Regulatory Agency (MHRA) guidance/technical notices.

3. In addition, providers of PET-CT scanning services are required to adhere to the following laws (and hold the following consents), and ensure that providers of tracers also adhere to these regulations (as appropriate):

   (a) Environmental Permitting Regulations (EPR) 2010:

      (i) registration for the use of radioactive materials and any mobile radioactive apparatus; and/or

      (ii) authorisations for the disposal and accumulation of radioactive waste;

      (iii) certificate in respect of administration of radioactive medicinal products (ARSAC Certificate); and/or written direction of an ARSAC Certificate holder in respect of the administration of radioactive medicinal products; and

      (iv) arrangements for the production and transport of radioactive medicinal products.

   (b) Medicines (Administration of Radioactive Substances) Regulations 1978;

   (c) Medicines Act 1968;

   (d) Ionising Radiations Regulations 2000;

   (e) Ionizing Radiation (Medical Exposure) Regulations 2000;

   (f) Medicines (Radioactive Substances) Order 1978; and

(g) The Carriage of Dangerous Goods & Use of Transportable Pressure Equipment Regulations 2009.

FDG-18

4. The production and supply of FDG-18 is subject to extensive regulation. The manufacture, assembly, sale and supply of medicines in the UK is overseen by the MHRA. The 'Orange Guide' sets out the UK requirements for the manufacture, assembly, release and distribution of medicines.[1] In addition, there are a range of regulations affecting the construction and operation of manufacturing facilities for radioactive substances. Alliance told us that in order to supply FDG-18 commercially, an operator must:

(a) hold an MA; and

(b) operate a Good Manufacturing Practice (GMP) facility.

Marketing authorisation

5. In order to supply medicines commercially, it is necessary to obtain an MA from the MHRA. This requires RPUs to meet a number of standards in terms of the quality, safety and efficacy of the radiopharmaceutical, obtain the GMP certification, as well as evidence of Good Laboratory Practice (GLP) compliance for the Quality Control (QC) testing sites.

6. The following requirements must be met and licences obtained in order to meet the MHRA's GMP regulations.

Pharmacovigilance requirements

7. Pharmacovigilance is the process and science of monitoring the safety of medicines and the taking of steps to reduce risks and increase the benefits of medicines. Directive 2010/84/EU, describes the current pharmacovigilance (safety monitoring) requirements for medicinal products in the EU. Pharmacovigilance activities include:

(a) collecting and managing data on the safety of medicines;

(b) looking at the data to detect 'signals' (any new or changing safety issue);

(c) evaluating the data and making decisions with regard to safety issues;

[1] www.mhra.gov.uk/Publications/Regulatoryguidance/Medicines/CON2030291.

(d) proactive risk management to minimise any potential risk associated with the use of the medicine;

(e) acting to protect public health (including regulatory action);

(f) communicating with and informing stakeholders and the public; and

(g) audit, both of the outcomes of action taken and of the key processes involved.

8. There is extensive guidance on pharmacovigilance monitoring available from the Eudravigilance database section of the EU Commission website. Registration and use of the Eudravigilance systems for the reporting of adverse events is mandatory for all suppliers of medicinal products in the EU. Key to the management of pharmacovigilance systems is the Risk Management Plan (RMP), details of which are required within the MA Application, in Module 1.8.2 of the submission.

9. The pharmacovigilance systems within a company must be overseen by a Qualified Person for Pharmacovigilance (QPPV), who must hold the necessary experience and qualifications to assess and report adverse events to the regulatory authorities. The FDG-18 product has an assigned QPPV who will generally be responsible for all licensed products sold in the UK except for those supplied under contract manufacture for a third party. In all cases, the responsibility for pharmacovigilance rests with the MA holder.

Manufacturer's licensing

10. In order to sell and supply a radiopharmaceutical product, the facilities used to manufacture, assemble (fill), QC test and release the product also need to comply with specific EU requirements and have to be licensed. The principal licences required for a cyclotron facility (as with current FDG-18 manufacturing facilities) comprise the following:

(a) Manufacturer's and Importer's Authorisation (MIA): This is required for the routine manufacture, assembly and release of a licensed medicine which will include FDG-18 and tracers for the diagnosis of Alzheimer's (Florbetapir, Flutemetamol and Florbetaben).

(b) Manufacturer's 'Specials' Authorisation (MS): This is required for the manufacture, assembly and supply of unlicensed medicines for 'named patient supply' (including specific supply for a diagnostic indication for which the radiopharmaceutical is not licensed). These medicines currently include 18F-Choline (FEC) and 18F-Sodium Fluoride (NaF).

(c) Manufacturer's and Importer's Authorisation for Investigational Medicinal Products (MIA-IMP): This is required for the manufacture, assembly, release, distribution and reconciliation of medicines that are to be used in clinical trials (for example, the use of a radiopharmaceutical in an approved clinical trial, where the way it is being used is not already approved). This can involve any of the tracers as it relates to the intended use of the product.

(d) A site master file (SMF) is required, which provides details on the day-to-day management and control of the activities at the site.

11. The services of a QP are required to oversee the release of any licensed medicine. The QP releasing a medicinal product must have appropriate experience and qualifications, as well as in-depth knowledge of the manufacturing, assembly and QC systems for the product that is being released. QP status requires specific training and accreditation by a recognised body in each member state.

Regulatory requirements specific to radiopharmaceuticals

12. In addition to the authorisation and licensing requirements for placing a medicinal product on the market, the supply of radiopharmaceuticals requires further authorisations relevant to radiological safety, environmental protection and other aspects are also required.

13. Basic safety standards for radiological protection are set down in a series of EU Directives under the 1957 Euratom Treaty. The main Directive is the Basic Safety Standards Directive (96/26/Euratom) (BSSD). This lays down safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. It sets out the principles of justification, optimisation and dose limits for practices. Justification is one of the key principles of radiological protection established by the International Commission on Radiological Protection on which the radiological framework of the UK is based. The principle of justification is that no practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals, or to society, to offset the radiation detriment it causes.

14. In the UK, we understand there are three key pieces of legislation that need to be consulted and followed when installing a medical cyclotron:

(a) the Ionising Radiations Regulations 1999;

(b) the Radioactive Substances Act 1993 (RSA93); and

(c) the Environmental Permitting (England and Wales) Regulations 2010.

Parties' views on impact of regulatory requirements

15. InHealth told us that the non-commercial cyclotrons, ie those operated by the NHS, did not have either the GMP approvals or the MA which would allow them to supply commercially. The standards of the GMP were considerably more stringent than the conditions for production of FDG-18 on a non-commercial basis under a MS. InHealth also told us that the MHRA performance data suggested that it could take 100 days to start the assessment and that completing the assessment of a new MA could take, in some cases, years to complete.

16. Alliance told us that an application for an MA from the MHRA should not take more than 90 days and that this process could be shortened to 60 days with negotiation. It noted that the process was not considered to be difficult.

17. In contrast, NHS Grampian (Aberdeen Royal infirmary) told us that:

> Knowing what would be involved to obtain a MA, NHS Grampian would not envisage ever applying for a MA for the radiopharmaceuticals listed … This would also apply for a ML [manufacturing licence]. The UoA [University of Aberdeen] is considering applying for a Manufacturing Specials Licence (MS) and perhaps an IMP licence, the latter for the production of novel tracers for clinical research work.
>
> Currently the RPU 'dispenses' radiopharmaceuticals under the direction of a prescription and using the legal framework of section 10 exemption of the Medicines Act (direct supervision of a pharmacist).

18. Similarly, Edinburgh University told the OFT that it had considered getting an MA to distribute FDG-18 to third parties, but considered it too expensive.

19. IBA Molecular UK explained that if a site were to be reactivated, having been mothballed, the main element of the 18- to 24-month period required to get the site operational again would be taken up with preparing the site in order to re-obtain the MA needed for the commercial supply of FDG-18.

20. PETNET told us that in its experience, the process of preparation, application submission and inspection took between six and nine months to conclude and would cost in the region of £250,000 including internal costs.

21. This evidence suggests to us that while the application and inspection process for the MA itself may be relatively short, a relatively longer period of preparation would be required to bring a mothballed RPU back into operation due to the need to obtain the various manufacturing licences and approvals that are prerequisites for the MA.

The supply chain and procurement

The supply chain

Overview

1. Currently, there are approximately 55 PET-CT scanners in the UK, 39 of which are located in NHS hospitals, and seven are on the sites of private hospitals and clinics. The remaining nine PET-CT scanners are mobile, ie they are moved from site to site by lorry, and hence may serve either NHS or private facilities, although the majority of mobile scanner use is for NHS-funded patients.

2. In July 2006 the Department of Health tendered contracts for the supply of PET-CT scanning services to 26 hospitals. The contracts came into force in April 2008 for an initial period of five years. They were subsequently extended for two years, ie until March 2015. The contracts were structured as two large blocks covering the North and South of England respectively. The NHS block contracts account for approximately 50% of PET-CT scanning services undertaken in England, with the remaining 50% either provided directly by NHS trusts or procured from third parties (independently of the block contracts) by those NHS trusts.

3. In the UK, there are therefore three types of provider of PET-CT scanning services:

   (a) NHS trusts,[1] many of which choose to operate their own PET-CT scanning services, investing in the scanner and using NHS radiologists and other clinical and administrative staff to scan patients and interpret the results of their scans. Alliance indicated that around 30 NHS trusts choose to provide PET-CT scanning in-house.[2]

   (b) Independent PET-CT suppliers, which operate PET-CT scanning services on behalf of both NHS and private hospitals. These include two commercial operators: Alliance and InHealth, as well as two charitable operators, Cobalt and Paul Strickland.

[1] References to NHS trusts includes NHS foundation trusts as well: www.monitor-nhsft.gov.uk/about-nhs-foundation-trusts/what-are-nhs-foundation-trusts.
[2] NHS trusts which choose to operate their own, in-house PET-CT scanning service include (among others): The Royal Marsden, The Christie (Manchester), Guy's and St Thomas', University College London Hospital, Aberdeen Royal Infirmary, and University Hospitals Coventry and Warwickshire.

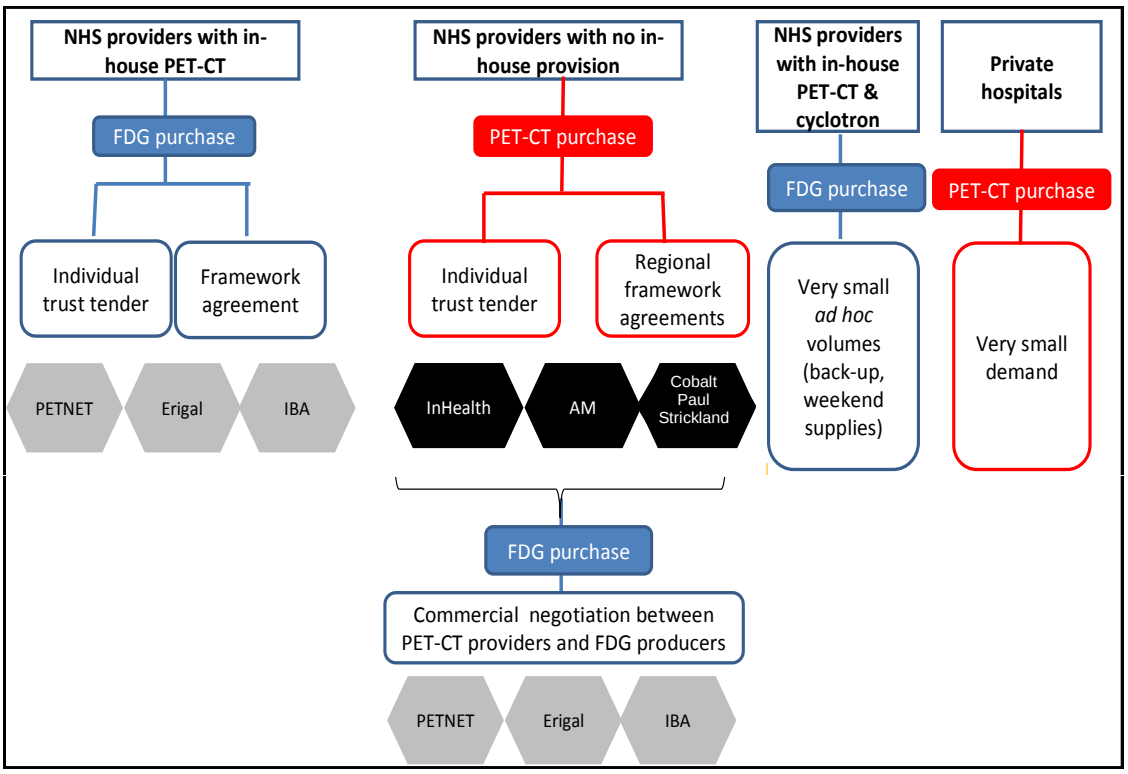
(c) Private hospitals, a small proportion of which offer PET-CT scanning services and choose to provide them in-house rather than outsourcing their operation to a third party operator. Most are in central London and include HCA, Bupa Cromwell and the London Clinic. Spire Bristol and BMI Priory (Birmingham) also offer PET-CT scans but outsource the provision of this service to Alliance (via mobile PET-CT scanners).

4. The provider of PET-CT scanning services (whether it is a hospital or a third party provider) will in turn decide either to produce its own FDG-18 or to obtain its supplies from third party manufacturers, either through individual tenders or as part of a buying group.

5. Figure 1 sets out the supply arrangements in this industry.

FIGURE 1

Supply arrangements for PET-CT scanning services and FDG-18



Source: Alliance chart, adapted by the CMA.
Note: AM is Alliance.

Suppliers of FDG-18

6. Prior to the transaction, there were three commercial suppliers of FDG-18 in the UK: Alliance (via its Erigal subsidiary), IBA Molecular UK (via its PET business) and PETNET, a wholly-owned subsidiary of Siemens. GE Healthcare also operated an RPU and previously supplied FDG-18 but

stopped supplying this radiopharmaceutical in autumn 2009, focusing instead on supplying less common radiopharmaceuticals to research facilities.

7. Erigal operates three RPUs in Keele, Preston and Sutton (Surrey), while IBA's PET business operated one RPU in Guildford and had a second RPU in Dinnington (near Sheffield) that was closed in 2010 (but has not been decommissioned). PETNET operates two RPUs, one in Nottingham and one at the Mount Vernon hospital (Northwood, north London). Third party (commercial) cyclotrons are divided between those that are located on the site of an NHS hospital and those that are located 'off-site'. Erigal's Preston and Sutton RPUs, as well as PETNET's Mount Vernon and Nottingham RPUs, are located on the sites of the Royal Preston, Royal Marsden, Mount Vernon and Nottingham University hospitals, respectively. The advantage to an NHS hospital of having an on-site RPU is that it both reduces transport costs and increases the reliability of supply.[3] Commercial manufacturers of FDG-18 also derive an advantage from operating an RPU on the site of an NHS hospital in the form of (in practice) guaranteed demand to meet the requirements of the co-located NHS hospital.[4]

8. In addition to the commercial cyclotrons, there are a further 12 cyclotrons that do not produce FDG-18 for commercial supply but which provide FDG-18 to NHS hospitals and/or research institutions. Eight of these cyclotrons are operated by the NHS itself and only supply FDG-18 to the NHS trust which operates them. The remaining four (non-commercial) cyclotrons focus on producing FDG-18 and other radioisotopes for research purposes. The 31 NHS trusts which do not operate an in-house cyclotron but which provide (in-house) PET-CT scanning services must procure FDG-18 from a third party supplier (ie Erigal, IBA's PET business or PETNET).

9. In certain cases, NHS hospitals have installed their own cyclotrons because their location makes commercial supply uneconomic or impractical. For example, NHS Grampian told us that when PET-CT scanning became a routine clinical service, FDG-18 was supplied by an RPU operated by the University of Aberdeen and located on the Aberdeen Royal Infirmary site. It emphasised that the distance between Aberdeen and any of the commercial suppliers' RPUs made it difficult to provide a satisfactory clinical service, with commercial suppliers indicating that it would be more expensive than self-supply and they could only provide sufficient FDG-18 to allow a couple of patients to be scanned per day (in the afternoon). A further motivation for

[3] For example, on-site RPUs prevent supply failures due to traffic problems and also facilitate the provision of back-up by firing the cyclotron again if the first run failed to produce a sufficient quantity of FDG-18.
[4] The NHS trust might be able to source FDG-18 from an alternative supplier (after expiry of the initial contract) but the level of transport costs and the potential issues make switching reasonably unlikely.

NHS trusts to have on-site cyclotrons is the ability to produce radiopharmaceuticals other than FDG-18 for research purposes.

Sourcing of FDG-18 by scanning providers

Alliance

10. Alliance has traditionally sourced the large majority of its FDG-18 requirements from Erigal. In 2008, Alliance signed a supply agreement with Erigal for the latter to supply the FDG-18 required to fulfil Alliance's obligations under the PET-North contract. This agreement had a duration of five years and was extended in 2013 in parallel with the extension of the NHS block contracts (with the price of FDG-18 being renegotiated at the time of the extension). Following Alliance's acquisition of Erigal, the combined business supplies all of its FDG-18 needs from internal production – with the exception of back-up supply for unplanned outages – and Alliance stated that it would only use third party supply for back-up purposes.

InHealth

11. InHealth sources FDG-18 from both the IBA operation (Guildford) and PETNET for its needs under the PET-South and Nottingham University Hospital contracts. InHealth originally agreed a [✂] term with PETNET for the supply of FDG-18, [✂]. InHealth signed a similar agreement with IBA Molecular UK, [✂].

12. PETNET noted that it had a long-term agreement with InHealth, which operates the co-located scanning centre, for the operation of the Nottingham RPU including the provision of radiopharmaceuticals.

Cobalt

13. Cobalt sourced its FDG-18 from IBA's PET business and following the merger the IBA operation (Guildford) until May 2014, at which point it switched to PETNET. [✂]

Paul Strickland scanning centre

14. PETNET told us that it had a long-term FDG-18 supply agreement with the Paul Strickland Scanner Centre, which had a duration of [✂].

NHS trusts

15. Where NHS trusts provide PET-CT scanning services in-house, they procure FDG-18 directly from Erigal, PETNET or IBA's PET business. NHS trusts can do this individually or as part of a larger buying group, such as Health Trust Europe (HTE) or Shared Business Services (SBS).

16. PETNET told us that FDG-18 supply agreements with NHS trusts typically had a duration of between one and two years, sometimes with optional one-year extension periods.

17. Table 1 shows which NHS trusts are supplied by the commercial providers and which produce their own FDG-18 in-house.

TABLE 1 **FDG-18 supply agreements (NHS trusts)**

NHS trust/hospital	*FDG-18 supplier*	*Note*
Aberdeen	In-house cyclotron	-
Birmingham	In-house cyclotron	Cyclotron at Birmingham University
Brighton	[✂]	-
Cambridge	[✂]	-
Cardiff	In-house cyclotron	Cyclotron at University of Cardiff
Christie (Manchester)	[✂]	-
Clatterbridge	In-house cyclotron	-
Coventry	[✂]	HTE framework agreement
Dundee	[✂]	-
Edinburgh	In-house cyclotron	Cyclotron at University of Edinburgh
Glasgow	In-house cyclotron	-
Guildford	[✂]	-
Guy's & St Thomas'	In-house cyclotron	-
Imperial	[✂]	-
King's College	[✂]	-
Leeds	[✂]	
Manchester Royal Infirmary	[✂]	-
Mount Vernon (Paul Strickland)	[✂]	-
Newcastle	In-house cyclotron	
Oxford Churchill	[✂]	HTE framework agreement
Royal Free	[✂]	-
Royal Liverpool	[✂]	SBS framework agreement
Royal Marsden	[✂]	-
Barts	[✂]	-
UCLH	[✂]	HTE framework agreement

Source: Main and third party submissions.

18. Erigal has long-term, exclusive supply agreements [✂] in place with both the Royal Preston and the Royal Marsden hospitals under which it supplies these trusts with FDG-18 from its RPUs which are located on the sites of these hospitals.[5]

[5] PETNET also has agreements in place to supply FDG-18 to meet the needs of both of the hospitals which are co-located with its RPUs. However, in both cases, these agreements are with independent suppliers (InHealth in Nottingham and Paul Strickland in Mount Vernon). These agreements are set out in paragraphs 11 & 14.

Procurement and contractual arrangements

19. The procurement of health services and supply contracts (including framework agreements[6]), above certain financial thresholds, by the NHS are governed primarily by the Public Contracts Regulations 2006, which in turn implement EU Directive 2004/18/EC. Currently,[7] the relevant threshold for 'Part B' services, which include health services (and would cover the provision of PET-CT scanning services) is £172,514. The relevant threshold for the procurement of goods (and which would cover the provision of FDG-18) is £111,676. The Public Contracts Regulations 2006 govern the various stages of the procurement process, including the publication of contract notices and award criteria. Requirements differ depending on the type of procurement.

20. However, procurement of health service contracts and supply contracts should comply with the overarching principles of transparency, proportionality, equal treatment and non-discrimination.[8] There are also additional rules and guidance specific to NHS procurements.[9]

The procurement and contractual arrangements for PET-CT scanning services

The 2008 NHS block contracts

21. Alliance and InHealth provide PET-CT scanning services to the following NHS hospitals under the NHS block contracts:

TABLE 2 **2008 NHS block contracts**

Contract	*Provider*	*Locations*
D08 PET-CT North National Contract (part of the ISTC Programme)*	Alliance	Newcastle, Middlesbrough, Leeds, Hull, Sheffield, Liverpool, Wirral, Stoke and Bradford.
D08 PET-CT South National Contract (part of the ISTC Programme)	InHealth	Basildon, Bournemouth, Cambridge, Canterbury, Colchester, Leicester, Maidstone, Northampton, Norwich, Nottingham, Portsmouth, Plymouth, Poole, Sawbridgeworth, Southampton and Taunton.

Source: NHS England Memorandum of Information, April 2014.

*ISTCs are Independent Sector Treatment Centres, which are privately-operated but NHS-funded hospitals and clinics.
Note: In addition, PET-CT services are provided for the population of north-east England by the Newcastle Upon Tyne Hospitals NHS Foundation Trust, while those for the population of Coventry and Warwickshire are provided by University Hospitals Coventry & Warwickshire NHS Trust.

[6] Framework agreements set out the terms and conditions under which specific purchases can be made throughout the term of the agreement.
[7] As of January 2014.
[8] Public Contracts Regulations 2006.
[9] This includes The National Health Service (Procurement, Choice, Competition) (No. 2) Regulations 2013 ('PCC Regulations 2013'), NHS guidance for Commissioners of NHS-funded services and guidance from Monitor.

22. The PET-North and PET-South contracts (the NHS block contracts) ran for an initial period of five years (from 2008 to 2013) and were then extended for a further two years.[10]

Other contracts for PET-CT scanning services

23. A small number of NHS trusts have organised their own tenders for the provision of PET-CT scanning services by third party operators. These NHS trusts include the following hospitals: Queen Elizabeth (Birmingham), Royal Preston (Lancashire), Royal Surrey (Guildford) and the Bath, Bristol, Somerset, South Gloucester, Swindon and Wiltshire areas.[11]

24. The PET-CT scanning contracts agreed by NHS trusts have generally been for a number of years (see Table 3). Where NHS trusts outsource the provision of PET-CT scanning services to third party providers, they also outsource responsibility for the sourcing of FDG-18 to those same providers.

TABLE 3 **PET-CT scanning contracts, hospitals whose NHS trust is not included in the NHS block contracts**

Hospital	*PET-CT provider*	*Contract length*
Queen Elizabeth (Birmingham, 'Birmingham and the Black Country area')	Alliance	[✂]
Royal Preston (Lancashire)	Alliance	[✂]
Royal Surrey (Guildford)	Alliance	[✂]
Bath, Bristol, Somerset, South Gloucester, Swindon and Wiltshire ('Bristol contract')	Cobalt	[✂]

Source: CMA analysis of Alliance and Cobalt contracts.

2014 NHS PET-CT scanning procurement

25. The PET-South and PET-North contracts will expire on 31 March 2015 and consequently NHS England started the process of procuring new contracts in April 2014. It issued a pre-qualification questionnaire on 22 April and issued tender documents on 30 July, with a deadline of early October for tender submissions.

26. In addition to the hospitals previously included in the PET-North and PET-South contracts, the new contracts will also include a number of hospitals that had previously procured their PET-CT scanning services independently from NHS England, falling within the following areas: Birmingham and the Black

[10] NHS England Memorandum of Information, April 2014, paragraph 9.
[11] Queen Elizabeth is part of the University Hospitals of Birmingham NHS Foundation Trust. Royal Surrey (Guildford) is part of the Royal Surrey County Hospital NHS Foundation Trust. Royal Preston Hospital is part of the Lancashire Teaching Hospitals NHS Foundation Trust.

Country area; Bath, Bristol, Somerset (North, North-East and South), South Gloucester, Swindon and Wiltshire; Newcastle upon Tyne; and Coventry and Warwickshire.[12] The provision of PET-CT scanning services in London and Greater Manchester remains excluded from the new procurement process.

27. The replacement contracts are estimated to account for nearly 30,000 PET-CT scans and £32.6 million.

28. As of April 2014, NHS England proposed to divide the replacement block contracts into four lots, having taken into account a number of considerations, including ways of enabling competition. The lots are shown in Table 4 below.

TABLE 4 **NHS England proposed (geographical) lots for PET-CT scanning services**

Lot number	*Lot name*	*Population to be served*
Lot 1	North-West	Cheshire, Warrington and Wirral Merseyside Staffordshire
Lot 2	North-East, Yorkshire and Humber	Cumbria, Northumbria, Tyne and Wear Derbyshire Durham, Darlington and Tees North Yorkshire and Humber South Yorkshire and Bassetlaw West Yorkshire
Lot 3	Birmingham, East Midlands and East Anglia	Birmingham and Black Country East Anglia Essex Leicestershire and Lincolnshire
Lot 4	South and South-West	Bath, Gloucester, Swindon, and Wiltshire Devon, Cornwall and Isles of Scilly Kent and Medway Wessex

Source: NHS, Procurement Strategy for the Lot Provision of PET-CT Services in England, April 2014.

29. Potential bidders will be identified by the pre-qualification phase of the procurement but are anticipated to include the two existing providers, together with other private, NHS and third party providers.

30. It is clear from NHS England's initial procurement documents that it intends to voluntarily follow a 'restricted procedure' under the Public Contracts Regulations 2006.[13] The contract may be awarded either on the basis of the lowest price or the 'most economically advantageous tender'.[14]

[12] The PET-CT scanning services for the populations of the North East and Coventry and Warwickshire are currently provided by Newcastle University and University Hospitals Coventry and Warwickshire NHS Trust, respectively, rather than being outsourced to independent suppliers. Hence, they have not been included in Table 3.
[13] A contract notice is published and only those meeting a selection criteria are invited to submit a tender.
[14] Public Contracts Regulations 2006, regulation 30.

The contractual arrangements for FDG-18 and criteria used to assess suppliers

31. The supply of FDG-18 to hospitals is carried out under a range of contractual arrangements, of which there are three main categories:

    (a) Two- to three-year contracts awarded by individual hospitals or the suppliers of PET-CT scanning services.[15]

    (b) Framework agreements where buying groups run tenders on behalf of groups of hospitals (eg the framework run by HTE).

    (c) Long-term exclusive agreements between an operator of a cyclotron and the hospital on which the cyclotron was built. There are four of these agreements – between Alliance and the hospitals at its Sutton and Preston sites and between PETNET and the hospitals at its Mount Vernon and Nottingham sites.[16] [✂]

32. Contracts for the supply of FDG-18, whether to commercial providers of PET-CT scanning services or NHS trusts, tend to specify the price per dose, delivery costs and quality/reliability requirements but they do not contain volume commitments.[17] One exception to this is [✂].

33. Due to the relatively small number of NHS contracts (once trusts which self-supply FDG-18 are excluded) and the multi-year nature of many of the agreements, there is a relatively small number of contracts tendered each year.

TABLE 5 **NHS tenders for (primary) FDG-18 supply, 2010 to 2013**

Tender dates	*NHS customer*
February 2010	MRI/Liverpool Royal
November 2010	Barts
November 2010	Cambridge
August 2011	Dundee
October 2011	Brighton
December 2012	Dundee
February 2013	MRI/Liverpool Royal
March 2013	The Christie, Manchester
August 2013	King's
November 2013	Royal Free, London

Source: Alliance.

Criteria used by customers to assess FDG-18 bids

34. Tenders for FDG-18 contracts usually follow formal procurement requirements, with clear criteria given for the awarding of the contracts. These

[15] CMA assessment based on contracts submitted by Alliance.
[16] CMA assessment of the contracts submitted by Alliance.
[17] In some cases, a schedule of prices is set out depending on the quantity of FDG-18 purchased over the course of a year.

criteria include price and reliability as a minimum, with other factors taken into account to a greater or lesser extent.

InHealth

35. InHealth told us that it did not only procure FDG-18 supplies for the provision of the PET-CT contracts. The procurement of PET-CT South contract requires the provision of an end-to-end managed service, [✂].

36. InHealth told us that the most important factors considered when choosing FDG-18 suppliers in the 2008 National PET-CT Procurement process were: [✂].

Cobalt

37. Cobalt told us that the commissioning process started with an initial meeting with suppliers to outline the requirements of Cobalt, followed up by a formal quotation provided by the potential supplier, at which stage Cobalt would require information regarding the supplier's reliability. Potential suppliers were asked to provide a quotation on a cost per dose, including transportation, and outline backup facilities in case of outages. The assessment was then made taking into account the following factors: price, number of manufacturing sites, location of manufacturing sites, back-up agreements with other providers, the ability to provide new tracers and the willingness to work with Cobalt to support the development of their PET-CT scanning services, which is generally through educational programmes for referring clinicians. Suppliers were then selected on the basis of cost and reliability.

38. Cobalt told us that it chose FDG-18 suppliers on the basis of price and reliability, with the latter assessed with reference to the number of manufacturing sites, their location and the existence of back-up supply agreements between the FDG-18 supplier and other providers. Cobalt noted that one of the reasons it had changed suppliers (from the IBA operation to PETNET) was that it had experienced reliability issues with the IBA operation.

39. Cobalt told us that the price for FDG-18 was [✂] and that it would be reluctant to change provider based on price because it did not want a new provider with no track record. Cobalt said that companies would know the track record of their own provider, but if a new provider was being considered, questions would be asked about where the product came from and how far it had to travel. The PET-CT scanning community was small and therefore it was easy to get recommendations. When Cobalt had been considering PETNET as a supplier, it had spoken to InHealth and Mount Vernon Hospital regarding

PETNET's track record on surety of supply. Quality was not an issue as FDG-18 could not be delivered unless it had met certain quality standards.

40. In addition, we received bidding information for Cobalt's 2010 tender process. In 2010 PETNET offered a supply agreement for FDG-18 for [✂] years for £[✂] per dose including delivery charges. For the same tender, IBA's PET business put forward a bid in which the price of FDG-18 included the cost of delivery and varied according to the length of the contract. The proposal was as follows: [✂].

41. For the same tender, Alliance offered a price of £[✂] for a one-year contract and a price of £[✂] for a two-year contract, including delivery charges. Cobalt chose IBA's PET business and agreed to a [✂] contract for £[✂] per dose of FDG-18, including delivery charges.

The NHS North of England Commercial Procurement Collaborative Group

42. The criteria and the weights that the North of England Commercial Procurement Collaborative group uses to assess the various bids received from suppliers are as follows:

- Price (33%).
- Clinical acceptability/compatibility with existing trust equipment and specification (20%).
- Delivery (23%). The issues evaluated are: the ability to provide efficient service to all specified delivery points and the ability to minimise impact on shortages of core elements.
- Overall cost-effectiveness (5%).
- Quality (10%).
- Support and technical merit (5%).
- Sustainability (4%).

The NHS Shared Business Services

43. The NHS SBS provides a range of procurement services for the NHS for radiopharmaceuticals. The core group of NHS foundation trusts and trusts that belong to this NHS SBS framework agreement comprises the Central Manchester University Hospital NHS Foundation Trust, the Royal Liverpool and Broadgreen University Hospitals NHS Trust and Salford Royal NHS

Trust. Other trusts can access the agreement at any point provided that relevant membership documentation is signed and completed by the trust prior to any orders being placed.

44. In assessing the bids of different suppliers, the NHS SBS considers the following criteria and weights: assurance of supply (80%) and cost of the product (20%). Table 6 below shows a detailed breakdown of each criterion relevant for FDG-18.

TABLE 6 **NHS SBS award criteria**

	Criterion	*Weight %*
Assurance of supply	State the radionuclidic purity and maximum percentage of free iodide A Saturday service may be required from time to time, bidders should indicate whether they are able to provide a Saturday delivery of FDG-18 Bidders should provide information on their back-up arrangements for delivery of the product if there is a batch or facilities failure of FDG-18	80
Cost of product	Bidders will be expected to work with NHS customers to maximise their available budget. Bidders should provide details of any innovative ways of working to assist customers in maximising their budget.	5
	A contract price for radioactive deliveries which should include all delivery costs with no surcharges. In the event a bidder is unable to provide one price then pricing for deliveries as follows should be completed within the pricing schedule: • deliveries before 6.30am • deliveries before 9am • deliveries before 5pm	12.5
	Bidders have offered additional discounts for bulk orders or volume thresholds per annum	2.5
	Total	**100**

Source: NHS SBS.

Individual hospitals

Barts Health

45. Barts Health told us that the factors it took into consideration when assessing future suppliers were costs, whether the supplier accepted flexible orders, product quality and back-up.

46. Barts Health used the following scheme to assess bids on the basis of price and non-price factors:

TABLE 9 **Barts Health award criteria**

Award criteria	*Weight %*	*IBA's PET business*	*Erigal*	*PETNET*
Price/cost	40	[✂]	[✂]	[✂]
Adherence to Technical Specification (including product packaging)	10	[✂]	[✂]	[✂]
Flexibility of Ordering and Prompt back-up for Manufacturing Failure	10	[✂]	[✂]	[✂]
Delivery (time)	10	[✂]	[✂]	[✂]
Product Range	10	[✂]	[✂]	[✂]
Collaborative arrangements	10	[✂]	[✂]	[✂]
Full UK License	10	[✂]	[✂]	[✂]
Total	**100**	[✂]	[✂]	[✂]
Rank		[✂]	[✂]	[✂]

Source: Barts Health.

47. The above table shows that [✂].

Cambridge University Hospitals

48. We reviewed a tender document issued by Cambridge University Hospitals and found that the foundation trust used the following weightings in assessing the bids of the various suppliers: price (40%), specific activity less than 300MBq/mL (40%), adequate back-up provision (10%), cancel/add to order up to 5pm (5%) and delivery between 8am and 8:30am (5%).

49. As a result of the tender, Cambridge University Hospitals chose IBA's PET business as supplier and agreed to pay £[✂] per dose of FDG-18 plus a delivery charge of £[✂] per delivered batch. The price was fixed for [✂]. Data submitted by IBA Molecular shows that it supplied [✂] doses of FDG-18 in 2012 for total sales of £[✂].

Oxford University Hospitals/HTE

50. Since September 2013 Oxford University Hospitals has been a member of HTE, a joint procurement group, which had a framework agreement with IBA's PET business for the supply of FDG-18.

51. HTE told us that the primary factor was normally price, but in some cases price mattered much less than geographical location because of the short half-life of FDG-18. Quality was not a significant factor as all suppliers had to adhere to the same national standards.

52. Whilst we are not entirely certain of how non-price factors are assessed by HTE, those factors we know to be considered by HTE are objective. We note that HTE conducts its own assessment of non-price factors (worth 50% of the final score it assigns to bidders, with price making up the remaining 50%). HTE told us that, while it assessed non-price criteria, these were conditions of participation rather than factors of differentiation for FDG-18 suppliers, and

that Erigal, IBA's PET business and PETNET all scored full points on non-price criteria. Differentiation in the score awarded by HTE is therefore exclusively via price, which makes up 50% of the overall score.

TABLE 10 **HTE's award criteria**

Award criteria	*Weight %*
Price/cost	50
Ability to supply FDG-18 with a UK Licence	17.5
Ability to meet clinical and technical requirements of members	10
Relevant experience (documented record of past supplies to customers within the NHS)	5
Ability to deliver to member requirements	15
Management factors	2.5
Total	**100**

Source: HTE's Invitation to Tender document, Health Trust Europe Reference: GPM-006557, OJEU.

53. While the above is clearly transparent and objective, we note that it does not fully determine the winner of the tender, as hospitals can choose to get their supplies from any supplier who submitted a bid, including suppliers that obtained lower scores. [✂][18] While this is an objective criterion, we are not certain to what extent there is scope for subjective criteria to play a similar role. We understand that HTE tenders are conducted in line with formal procurement rules (see paragraphs 19 and 20), which suggests that the scope for subjective criteria is limited.

54. HTE told us that its framework was a three-year contract with a one-year extension. The framework was subject to an annual review. Given the prices that FDG-18 suppliers quote under the contract, the hospitals that are members of HTE then decide from which supplier to purchase their volumes and are free not to purchase any volumes as part of the framework and, instead, procure FDG-18 elsewhere.

55. [✂]

56. [✂][19]

North Staffordshire University Hospital

57. [✂]

[18] [✂]
[19] [✂]

The Christie NHS Foundation Trust

58. The Christie NHS Foundation Trust told us that the main criteria it considered when assessing suppliers of FDG-18 were price, reliability and contingency for delay in case of no production. The table below shows a detailed breakdown of the criteria and of the weighting used in the tender issued in 2010.

TABLE 7 **Christie's award criteria (2010)**

Criterion	*Weight %*
Geographic location of supplier	4
Contingency for failed or delayed production – planned (eg service or bank holidays)	5
Contingency for failed or delayed production – unplanned prolonged facility fault lasting more than one day	5
Delivery arrangements	2
Contingency for days with no production	12
Delivery time of day	9
Time of receipt of quality control result and QP release	9
Maximum quantity and concentration of FDG-18 per delivery	3
Evidence for reliability	16
Price of FDG-18	20
Price of delivery	15
Total	**100**

Source: Christie.

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59. In 2013 Christie issued another tender for the supply of FDG-18. The table below shows the criteria considered in assessing suppliers in this tender.

TABLE 8 **Christie's award criteria (2013)**

Criterion	*Weight %*
1a. Distance of the primary production location to the Christie site	10
1b. Distance of the secondary production location to the Christie site	10
2a. Expected delivery delay for unplanned production interruptions	10
2b. Expected delivery delay for planned production interruptions	5
3a. The delivery time prior to first scheduled patient injection	5
3b. The time that quality control and/or Qualified Person release from quarantine will be received prior to first scheduled patient injection	5
4. The minimum first patient administration volume	10
5. The evidenced expected rate of deliveries being more than 15 minutes later than the requested time	5
6. Order cancellation period	5
7. Price of FDG-18 and delivery	35
Total	**100**

Source: Christie.

The Royal Surrey County Hospital

60. [✂]

Brighton and Sussex University Hospitals/Clinical Imaging Sciences Centre

61. The Clinical Imaging Sciences Centre, to which the Brighton and Sussex University Hospitals contracts PET-CT scanning services, considers the following criteria: deliveries (40%), support administration (20%), quality procedures (10%) and price (30%).[20]

Views from PET-CT scanning providers on the importance of FDG-18 supply when bidding to provide PET-CT scanning services

62. Alliance told us that reliability of FDG-18 supply was a key criterion in tenders for both providers of FDG-18 to NHS hospitals which operate their own in-house PET-CT scanning services and in tenders for third parties to provide outsourced PET-CT scanning services to NHS hospitals. It highlighted that PET-CT scanning providers who cancelled scans (for whatever reason) or failed to meet the NHS's seven-day target faced financial penalties.[21]

63. Alliance told us that PET-CT scanning service providers needed to have an agreement in place with an FDG-18 supplier when they tendered for NHS block contracts (for PET-CT scanning services) in order to demonstrate that they had a credible source of both primary supply and back-up supply.

64. [✂]

65. InHealth highlighted that, although there was no direct legal requirement to contract with two FDG-18 suppliers, it considered that there was a practical need to do so in order to reduce the risk of back-up arrangements failing. [✂]

66. Another critical concern, when choosing suppliers, was independence from a competitor. [✂][22]

67. InHealth explained that when it won the tender for the provision of PET-CT scanning services in Nottingham, it considered whether it wished to operate a cyclotron on the same site to provide FDG-18. InHealth decided to partner with Siemens PETNET CTI, with InHealth constructing the PET-CT scanning and cyclotron centre and PETNET leasing space from InHealth and operating the cyclotron.

[20] The Clinical Imaging Sciences Centre is a joint venture between the Brighton and Sussex Medical School and the School of Psychology and the School of Life Sciences at the University of Sussex.
[21] Alliance initial submission, paragraph 27.
[22] [✂]

FDG-18 production capacity

Introduction

1. In this appendix we analyse Erigal's, IBA's PET business's and PETNET's FDG-18 capacity as well as the current implied utilisation of cyclotrons.

2. We note that due to the half-life of FDG-18, the capacity required to produce a given number of doses depends on the location of customers, with capacity requirements per dose being larger for customers that are a longer drive-time from the RPU site. It is our understanding that suppliers measure capacity in terms of the maximum number of doses they can commit to deliver in the light of considerations of distance and driving times between their RPUs and the customers.

3. For the purpose of this appendix, we concentrate our analysis on the production of FDG-18. We note that cyclotrons can produce FDG-18 as well as other tracers but that only one tracer can be produced per firing. As a consequence, the production of tracers other than FDG-18 can constrain FDG-18 production. However, our understanding is that the demand for such tracers is small and that suppliers produce these tracers upon demand on some, but not all, days of the week.

RPU capacity

4. The capacity of a cyclotron depends on a number of factors, including the number of firings per day undertaken, the number of days per week the cyclotron operates and the number of doses per firing. We note that the latter may depend on the configuration of the cyclotron and other equipment (eg the number of synthesis units used), but also, as noted above, on the locations of customers relative to the RPU.

5. We note that suppliers can vary the number of firings operated each day depending upon demand. Our understanding is that suppliers currently run at least [✂] firings of FDG-18 per day with a peak of [✂] firings on some days of the week. IBA Molecular told us that across its international portfolio of FDG-18 production facilities, [✂] firings per day was standard with the exception of Wednesday, which had [✂] firings per day. Alliance said that currently the Erigal sites operated [✂] firings of FDG-18 per day with a [✂] firing operated on some days for other radiopharmaceuticals. PETNET told us that it used [✂] firings three days per week and [✂] firings two days per week (for a total of [✂] FDG-18 firings per week) for each of its sites. Alliance, IBA Molecular

and PETNET also added that on average their sites were operational [✂] days per week, [✂] weeks per year.[1]

6. As regards the maximum number of firings that a cyclotron could perform, all the suppliers suggested that they could run a maximum of [✂] to [✂] firings of FDG-18 per day. Alliance noted that going from [✂] to [✂] firings per day routinely would require adding the same number of new staff (including another 'qualified person') and additional transport of the same scale as for [✂] firings. However, Alliance added that the additional costs of going from [✂] to [✂] firings per day could be minimised, for instance, using part-time staff. Similarly, [✂].

7. The cyclotron configuration impacts on the number of doses that can be produced per firing. In particular, Alliance told us that the synthesis unit played an important role in the number of doses produced: the more synthesis units that were installed, the more doses could be produced per firing. Alliance told us that its current TRACERlab synthesis unit could generate [✂] doses for each firing, but theoretically this could vary and the maximum number of doses per firing using current processes would be [✂]. Alliance told us that an uplift of capacity could be achieved by synthesis upgrades and beam strength improvements. This could be achieved by investing in the 'FASTlab' synthesis unit which has higher yields than the existing TRACERlab unit ([✂] to [✂]% for the former, compared with [✂] to [✂]% for the latter).[2] However, Alliance told us that this would require capital expenditure, which it estimated at £[✂] for its three sites, and would take around [✂] to [✂] months to be implemented with potential site disruption during this time.

8. In order to provide an estimate of an RPU's annual capacity, we consider various RPU configurations by making different assumptions regarding the number of doses produced per firing and the number of firings per day. In Table 1 we show estimates of capacity on the basis that suppliers run [✂] firings per day and that the number of doses per firing can vary from [✂] up to [✂] doses per firing. We note that these assumptions mirror the information submitted by the parties (see paragraphs 5, 6, 7 and 10).

TABLE 1 **RPU annual capacity**

[✂]

Source: CMA.

[1] IBA noted that Guildford was operational one Saturday per month to support weekend scanning at [✂].
[2] The evidence from trials indicates that the FASTlab synthesis unit does indeed have higher yields, although the differences do not appear to be as large as suggested by Alliance. http://jnumedmtg.snmjournals.org/cgi/content/meeting_abstract/48/MeetingAbstracts_2/325P-b.

9. Table 1 shows that an RPU can produce at least [✂] doses a year with [✂] firings per day and [✂] doses per firing. [✂] firings per day and [✂] doses per firing generates a maximum capacity of [✂] doses per year. We note, however, that no FDG-18 facility in the UK currently operates [✂] firings per day. Alliance told us that running [✂] firings per day might not be commercially viable as the supplementary doses produced would be delivered at different times to what, typically, a customer currently wanted (ie deliveries around 8.00 and 12.00). This means that adding additional capacity by increasing the number of firings to [✂] per day would change a hospital's PET-CT scanning arrangements (by scheduling PET-CT scans for late afternoons and evenings). Alliance also said that [✂] firings per day could lead to a reduction in production reliability and greater potential downtime. Alliance added that a shift to a [✂] firing per day was more likely as this was likely to mirror changes in PET-CT scanning routines.

10. [✂] told us that its typical output was [✂] doses per firing. [✂] told us that its typical output was [✂] doses per firing. [✂] told us that the ability to produce [✂] doses per firing was only theoretical [✂]. On the other hand, [✂] told us that it had the ability to produce [✂] doses per firing [✂] and [✂] doses per [✂]. We note that this is in line with [✂] – ie that, whilst the theoretical capacity of both of its cyclotron facilities was the same, the number of doses supplied differed substantially across both sites due to a difference in the distances to customers. In particular, [✂].

11. In light of the above, we consider that suppliers are most likely to be able to operate up to [✂] firings for the production of FDG-18. Moreover, we consider that the typical reliable output for a production run is around [✂] doses per firing for [✂] and [✂] while the typical output for [✂] is around [✂] doses per firing at [✂] and [✂] doses per firing at [✂]. We use these assumptions in our estimates of capacity for PETNET, Erigal, and IBA's PET business.

Alliance, IBA and PETNET capacity

12. Table 2 shows our estimate of capacity utilisation for 2013 for Erigal, IBA's PET business and PETNET.

TABLE 2 **Erigal, IBA's PET business and PETNET capacity**

Supplier	*2013 production (doses)*	*Capacity estimate based on the above assumptions (doses)*	*Implied utilisation (%)*
Erigal	[✂]	[✂]	[✂]
IBA's PET business*	[✂]	[✂]	[✂]
PETNET	[✂]	[✂]	[✂]
Total	[✂]	[120,000–140,000]	[✂]

Source: Data provided by Alliance, IBA Molecular and PETNET and CMA calculation.

*Data for 2013 was available only until September and was extrapolated until end 2013. Please note that the volume for The Christie is included up to June 2013 (ie when The Christie left IBA's PET business as a supplier of FDG-18).
Note: Data includes primary and back-up supply.

13. Table 2 shows that, under our assumptions, the current capacity estimate for the overall industry is [120,000–140,000] doses. We note that the implied utilisation for [✂] and [✂] is [✂]% and [✂]% respectively,[3] which is [✂] than that of [✂], which is at [✂]%.

[3] We note that this is broadly consistent with [✂] own estimate of its capacity and utilisation, of [✂] doses and [✂]% respectively. [✂]

Exiting firm scenario – where customers would have gone if the Guildford RPU had been mothballed

Introduction

1. In this appendix we assess the closeness of competition between Alliance and PETNET for each of the Guildford site's customers on the basis of distances, drive-times and other factors including what parties have told us and, where available, past bidding behaviour. Annex 1 analyses recent bids and assesses the extent to which the actual supplier to a customer is the closest supplier in terms of distances and drive-times. Annex 2 sets out an analysis of distances and drive-times for the Guildford site's customers if they were to use alternative suppliers and Annex 3 sets out an analysis of spare capacity at RPUs owned by Alliance and PETNET.

Customer-by-customer analysis

2. IBA's PET business had supply contracts with five customers from its Guildford site: InHealth,[1] Cobalt, Oxford University Hospitals, Cambridge University Hospitals and Barts Health. At the time of the merger, Guildford supplied four InHealth mobile PET-CT scanning units located at the Royal Bournemouth Hospital, East Kent Hospitals University NHS Trust Hospital, Poole Hospital and Southampton General Hospital. InHealth's Kent sites were switched to PETNET in November 2013 [✂].

Barts Health

3. Barts Health is an NHS trust that includes a number of hospitals.[2] PET-CT scanning is carried out on-site at St Bartholomew's Hospital.

4. Barts Health entered into a supply contract with IBA's PET business for the provision of FDG-18 from April 2011 for three years, until May 2014. The agreed price was £[✂] per dose for an annual usage of [✂] doses. There was no separate delivery charge. The price was fixed for the duration of the contract.

5. Data provided by IBA Molecular shows that it supplied [✂] doses of FDG-18 to Barts Health in 2012 for [✂]: Barts Health is part of the London

[1] This contract expired shortly prior to the transaction.
[2] Barts Health includes Mile End Hospital, Newham University Hospital, The London Chest Hospital, The Royal London Hospital, St Bartholomew's Hospital and Whipps Cross University Hospital.

Procurement Programme which has been working in partnership with the North of England Commercial Procurement Collaborative, a procurement organisation, on a recent tender for the provision of radiopharmaceuticals.

6. Barts Health told the OFT that Erigal and PETNET were both credible suppliers. Appendix E presents the criteria taken into consideration when assessing bids.

7. We have calculated the following distances and driving times for Erigal and PETNET (see Table 1).[3]

TABLE 1 **Barts distances and drive-times**

Supplier	*Site*	*Distance (miles)*	*Drive-times (peak)*	*Drive-times (off-peak)*
Erigal	Royal Marsden	14	48	47
	Keele	147	186	180
PETNET	Mount Vernon	19	50	49
	Nottingham	123	167	156

Source: CMA calculation. Distances calculated using RouteFinder.

8. We note that the differences between Erigal and PETNET in terms of drive-times are small if Erigal supplies from Royal Marsden and PETNET supplies from Mount Vernon. Given the greater distances and drive-times for Keele and Nottingham, we would not expect Barts to be supplied from either of these sites on a regular basis.

9. Given that PETNET has bid more competitively than Erigal in the past (but noting that the above bids are from 2011 and might not reflect current bidding behaviour)[4] and that both Erigal and PETNET are at similar distances and drive-times from Barts (assuming that they supply from each of their closest sites, Royal Marsden and Mount Vernon respectively), we consider that both Erigal and PETNET would have been strong competitors to supply Barts Health if the Guildford site had ceased to supply FDG-18.

Oxford University Hospitals

10. Oxford University Hospitals contracted with GE Healthcare for the purchase and supply of a PET-CT scanner, and of FDG-18 for a period of two years from June 2009, with the option of extending for a further two years.[5] As GE

[3] Distances are calculated from/to St Bartholomew's Hospital.
[4] See Appendix E.
[5] At the time, the name of the NHS trust was Oxford Radcliffe Hospitals NHS Trust. Pursuant to statutory instrument 2011/2397, its name was changed to Oxford University Hospitals NHS Trust. It comprises three teaching hospitals (John Radcliffe Hospital, Churchill Hospital and Nuffield Orthopaedic Centre) and one general hospital (Horton General Hospital).

Healthcare exited from the commercial supply of FDG-18 in 2009, the FDG-18 element of the contract was novated to IBA Molecular UK in November 2009. The agreement provided for the supply of FDG-18 to the Cancer Centre Development at the Churchill Hospital at £[✂] per dose plus a delivery charge of £[✂] per batch. [✂]

11. Since September 2013 Oxford University Hospitals has been a member of HTE, a joint procurement group, which had a framework agreement with IBA's PET business for the supply of FDG-18. HTE told us that its framework agreement was for three years with a one-year extension. The framework was subject to an annual review. Given the prices that FDG-18 suppliers quote under the framework agreement, the hospitals that are members of HTE then decide from which supplier to purchase their volumes and are free not to purchase any volumes under the framework and instead procure FDG-18 from elsewhere. The tendering process for the framework agreement is subject to public procurement rules (see Appendix E, paragraph 19).

12. Appendix E presents the criteria used by HTE when assessing bids.

13. We have calculated the following distances and drive-times for Erigal and PETNET (see Table 2).[6]

TABLE 2 **Oxford University Hospitals distances and drive-times**

Supplier	*Site*	*Distance (miles)*	*Drive-times (peak)*	*Drive-times (off-peak)*
Erigal	Royal Marsden	59	95	86
	Keele	107	127	123
PETNET	Mount Vernon	39	54	51
	Nottingham	96	126	117

Source: CMA calculation. Distances calculated using RouteFinder.

14. We note that PETNET is closer to Oxford than Erigal in terms of both distance and peak and off-peak drive-times, on the basis that both Erigal and PETNET supply from Royal Marsden and Mount Vernon respectively.

15. On the basis of our analysis of distance and drive-times as well as past bidding behaviour (see Appendix E), we consider that PETNET would have been a stronger competitor than Alliance for the Oxford University Hospitals had the Guildford site ceased to supply FDG-18. In the absence of IBA's PET business, we would expect that both PETNET and Alliance would compete to offer [✂] to Oxford University Hospitals.

[6] We calculated distances from/to Churchill Hospital where the Cancer Centre is located.

Cambridge University Hospitals

16. Cambridge University Hospitals is an NHS Foundation trust that includes under its umbrella Addenbrooke's and Rosie Hospital. PET-CT scanning services are provided from Addenbrooke's Hospital.

17. Cambridge University Hospitals were supplied with FDG-18 by GE Healthcare. Following the exit of GE Healthcare from the commercial supply of FDG-18, the contract was novated to IBA's PET business and renewed in January 2011 for four years, until January 2015. IBA's PET business charged £[✂] per dose plus delivery charges of £[✂] per delivery. [✂]

18. Appendix E presents the criteria used by Cambridge University Hospitals to assess future suppliers of FDG-18.

19. We have calculated the following distance and drive-times for Erigal and PETNET (see Table 3).[7]

TABLE 3 **Cambridge University Hospitals distances and drive-times**

Supplier	*Site*	*Distance (miles)*	*Drive-times (peak)*	*Drive-times (off-peak)*
Erigal	Royal Marsden	65	112	105
	Keele	129	151	148
PETNET	Mount Vernon	53	82	75
	Nottingham	88	123	118

Source: CMA calculation. Distances calculated using RouteFinder.

20. We note that PETNET is somewhat closer to Cambridge than Erigal in terms of both distance and peak and off-peak drive-times, in particular if Erigal and PETNET supply from Royal Marsden and Mount Vernon respectively.

21. On the basis of our analysis of distances and drive-times, we consider that PETNET would have been the stronger competitor for the Cambridge University Hospitals' contract had the Guildford site ceased to supply FDG-18.

InHealth

22. At the commencement of the PET South contract in 2008, InHealth contracted with IBA's PET business and PETNET for the provision of FDG-18 for an initial term of [✂]. IBA's PET business was chosen as the supplier of InHealth mobile PET-CT scans located at Royal Bournemouth Hospital, Poole Hospital, Southampton General Hospital and Kent and Canterbury Hospital,

[7] Distances have been calculated from/to Addenbrooke's Hospital.

whereas PETNET was chosen as the supplier for the other PET-CT scanning sites.[8] [✂]

23. InHealth has not changed suppliers since the beginning of the contracts, but it exercises choice over the proportion of its total FDG-18 requirements that it sources from each supplier. It withdrew volume from the IBA operation at Kent and Canterbury Hospital [✂]. As a result, it purchased [✂]% of its FDG-18 supplies from PETNET and [✂]% from the IBA operation, compared with a volume split of [✂] prior to the IBA operation's performance issues. [✂]

24. InHealth told us that it required [✂] of FDG-18 in order to provide a credible and reliable basis for supply. It also told us that it negotiated [✂].

25. InHealth told the OFT that it was currently of the view that PETNET represented a more reliable source of supply than the IBA operation. [✂]

26. We have calculated the following distance and drive-times for Erigal and PETNET (see Table 4).

TABLE 4 **InHealth distances and drive-times**

Supplier	*Site*	*Customer*	*Distance (miles)*	*Drive-times (peak)*	*Drive-times (off-peak)*
Erigal	Royal Marsden	Royal Bournemouth Hospital	92	122	113
		Kent and Canterbury Hospital	62	85	78
		Maidstone Hospital	35	52	45
		Poole Hospital	97	138	128
		Southampton Hospital	68	101	92
Erigal	Keele	Royal Bournemouth Hospital	175	209	204
		Kent and Canterbury Hospital	203	247	237
		Maidstone Hospital	181	222	211
		Poole Hospital	179	224	219
		Southampton Hospital	163	188	183
PETNET	Mount Vernon	Royal Bournemouth Hospital	96	117	110
		Kent and Canterbury Hospital	75	123	117
		Maidstone Hospital	52	98	84
		Poole Hospital	101	132	125
		Southampton Hospital	72	96	88
PETNET	Nottingham	Royal Bournemouth Hospital	173	208	198
		Kent and Canterbury Hospital	179	224	212
		Maidstone Hospital	157	199	186
		Poole Hospital	177	224	213
		Southampton Hospital	158	187	177

Source: CMA calculation. Distances calculated using RouteFinder.

27. We note that, if Erigal and PETNET supply from Royal Marsden and Mount Vernon respectively, the differences between Erigal and PETNET in terms of distances and drive-times are small for Bournemouth, Poole and Southampton.

[8] [✂]

28. If the Guildford RPU had ceased to supply FDG-18, InHealth would have had to trade off having PETNET as a single supplier on the one hand and getting some of its supplies from Erigal, a competitor in the provision of PET-CT scans, on the other hand. Given this (see Appendix E, paragraphs 65 and 66), and that the differences between Erigal and PETNET in terms of distances and drive-times are small for Bournemouth, Poole and Southampton, we consider that PETNET would have been a strong competitor for these three sites if the Guildford site had ceased to supply FDG-18. For the other two sites, we note that, on the basis of distances and drive-times, Alliance is the stronger competitor.

Cobalt

29. Cobalt is a medical charity that provides PET-CT scanning services from the Cobalt Imaging Centre located in Cheltenham.

30. Cobalt contracted with GE Healthcare for the supply of FDG-18, NaF and other tracers starting in January 2008. Following GE Healthcare's exit from the commercial supply of FDG-18, the contract was novated to IBA Molecular UK. The contract was renewed in November 2012 for a year, until December 2013, and the price agreed for the provision of FDG-18 was fixed at £[✂] per dose [✂].[9]

31. Cobalt told us that, following a competitive tender process, the supply of radiopharmaceuticals to Cobalt moved from the IBA operation to PETNET from May 2014. Cobalt explained that it experienced some reliability issues with the IBA operation after its acquisition by Alliance and that PETNET was able to offer a competitive price. [✂]

32. Cobalt told us that it agreed to the GE Healthcare contract being novated to IBA Molecular UK as it received assurance from IBA Molecular UK that the price would have remained the same and the level of reliability would have been maintained. Cobalt told us that supply contracts were generally for a two-year period but that occasionally they may be rolled over if a high-quality cost-effective service was provided by the supplier. We note that Cobalt decided to renew the contract with IBA's PET business in 2012 and Cobalt confirmed that it had been happy with the service from IBA's PET business and, for this reason, it decided to extend the contract for another year. When Alliance took over the IBA operation, Cobalt had been concerned as it did not believe that Alliance focused so much on education and research.

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[9] [✂]

33. We have calculated the following distance and drive-times for Erigal and PETNET (see Table 5).[10]

TABLE 5 **Cobalt distances and drive-times**

Supplier	*Site*	*Distance (miles)*	*Drive-times (peak)*	*Drive-times (off-peak)*
Erigal	Royal Marsden	99	140	130
	Keele	87	103	102
PETNET	Mount Vernon	79	108	103
	Nottingham	95	121	114

Source: CMA calculation. Distances calculated using RouteFinder.

34. We note that PETNET is similar to Erigal in terms of both distance and peak and off-peak driving times, on the basis that both Erigal and PETNET supply from their closest sites. We note that PETNET is somewhat closer should Erigal and PETNET instead supply from Royal Marsden and Nottingham respectively.

35. We note that Cobalt has switched to PETNET in May 2014. In light of this, as well as PETNET's shorter distance and drive-times compared with Erigal and PETNET's more competitive 2014 bid, we consider that for Cobalt PETNET would have been a stronger competitor than Alliance had the Guildford site ceased to supply FDG-18.

[10] Distances are calculated from/to Cheltenham.

Actual versus closest providers of recent winning bids

1. We have looked at the distances and drive-times from the users of radio-pharmaceuticals to their respective providers which were appointed following a competitive tender process. Alliance provided a list of all 14 contract awards of which it was aware from the last three years.[1]

2. We assessed whether the closest providers, in terms of either distance or drive-time, tend to win the competitive tenders. The assessment was based on the data provided in Table 1 below. The winner of the competitive tender can be found in the second column and the closest provider in terms of distance and time (peak and off-peak) is provided in separate columns.

TABLE 1 **Actual and closest providers**

			Distance				*Drive-time (peak)*				*Drive-time (off-peak)*			
Customer	*Winner*	*Date*	*Erigal*	*IBA's PET business*	*PETNET*	*Closest*	*Erigal*	*IBA's PET business*	*PETNET*	*Closest*	*Erigal*	*IBA's PET business*	*PETNET*	*Closest*
Cobalt	IBA's PET business	Jan-11	87	91	79	PETNET	103	119	108	Erigal	102	114	103	Erigal
Barts	IBA's PET business	May-11	14	32	19	Erigal	48	68	50	Erigal	47	63	49	Erigal
London Clinic	PETNET	Dec-12	14	31	16	Erigal	52	65	41	PETNET	48	61	37	PETNET
Edinburgh (back-up only)	Erigal	2013	172	385	245	Erigal	199	443	299	Erigal	200	434	295	Erigal
Bupa	PETNET	2013	12	28	16	Erigal	42	56	40	PETNET	39	51	37	PETNET
Brighton	PETNET	Jan-13	41	42	66	Erigal	54	66	101	Erigal	52	64	91	Erigal
Dundee	Erigal	Feb-13	226	441	302	Erigal	258	502	360	Erigal	255	490	355	Erigal
Liverpool Royal infirmary	Erigal & PETNET	Apr-13	32	203	90	Erigal	53	239	128	Erigal	52	230	122	Erigal
Manchester Royal infirmary	Erigal & PETNET	Apr-13	33	192	63	Erigal	51	233	118	Erigal	45	223	110	Erigal
Glasgow	Erigal	Jun-13	180	401	266	Erigal	186	430	288	Erigal	187	421	287	Erigal
Christie Manchester	Erigal	Jul-13	34	190	61	Erigal	56	228	116	Erigal	50	219	110	Erigal
HTE, Warwickshire-Coventry	PETNET	Aug-13	60	104	47	PETNET	69	133	60	PETNET	68	125	56	PETNET
HTE, UCLH	PETNET	Aug-13	15	32	17	Erigal	51	68	44	PETNET	51	64	41	PETNET
HTE, HCA Wellington	PETNET	Aug-13	15	32	16	Erigal	51	65	40	PETNET	48	60	37	PETNET
HTE, HCA Harley Street	PETNET	Aug-13	15	31	16	Erigal	52	66	41	PETNET	48	61	38	PETNET
HTE, Oxford Churchill	IBA's PET business	Aug-13	59	53	39	PETNET	95	84	54	PETNET	86	77	51	PETNET
King's College	Erigal	Oct-13	11	31	21	Erigal	36	64	59	Erigal	35	59	55	Erigal
Royal Free	PETNET	Jan-14	17	34	15	PETNET	58	72	37	PETNET	55	67	35	PETNET
[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]

Source: Alliance. Distances calculated by the CMA using RouteFinder.

Note: [✂]

[1] Alliance initial submission.

3. We found that in 15 out of 19 cases (79%), the winner of the tender was the closest provider in terms of distance, peak or off-peak drive-times. We note that, where the winner of the tender is closest in terms of at least one of the criteria but not in terms of all of them, it is nevertheless a close second in terms of the other criteria. We therefore consider it reasonable to look at whether the actual supplier is the closest in terms of distance and/or drive time.

TABLE 2 **Comparison of distances and drive times for actual and closest providers**

Customer	*Winner*	*Date*	*Closest = winner*				*Closest v winner*		
			Dist	*Time*	*Time*	*Any*	*Miles*	*Min*	*Min*
Cobalt	IBA's PET business	Jan 11					12	15	13
Barts	IBA's PET business	May 11					18	20	16
London Clinic	PETNET	Dec 12		1	1	1	2		
Edinburgh (back-up only)	Erigal	2013	1	1	1	1			
Bupa	PETNET	2013		1	1	1	4		
Brighton	PETNET	Jan 13					24	47	39
Dundee	Erigal	Feb 13	1	1	1	1			
Liverpool Royal Infirmary	Erigal & PETNET	Apr 13	1	1	1	1			
Manchester Royal Infirmary	Erigal & PETNET	Apr 13	1	1	1	1			
Glasgow	Erigal	Jun 13	1	1	1	1			
Christie Manchester	Erigal	Jul 13	1	1	1	1			
HTE, Warwickshire–Coventry	PETNET	Aug 13	1	1	1	1			
HTE, UCLH	PETNET	Aug 13		1	1	1	3		
HTE, HCA Wellington	PETNET	Aug 13		1	1	1	1		
HTE, HCA Harley Street	PETNET	Aug 13		1	1	1	2		
HTE, Oxford Churchill	IBA's PET business	Aug 13					14	30	26
King's College	Erigal	Oct 13	1	1	1	1			
Royal Free	PETNET	Jan 14	1	1	1	1			
[✂]	[✂]	[✂]	[✂]			[✂]		[✂]	[✂]
COUNT: 19		**Total**	**10**	**14**	**14**	**15**			

Source: CMA calculation. Distances calculated using RouteFinder.

Analysis of distances and drive-times for the Guildford site's customers

1. Table 1 below provides the distances from IBA's PET business's Guildford customers to Erigal's and PETNET's sites, ie the distances that FDG-18 would have to travel in the event of the Guildford site being mothballed. We use the shorthand RM, KL, MV, NT to refer to Royal Marsden (Sutton), Keele, Mount Vernon and Nottingham respectively.

TABLE 1 **Distances (miles)**

Customer	*Delivery site*	*Erigal (RM)*	*Erigal (KL)*	*PETNET (MV)*	*PETNET (NT)*	*Diff RM–MV*	*Diff KL–NT*
Cobalt	Cobalt	99	87	**79**	95	20	8
Barts Health	St Bartholomew's Hospital	**14**	147	19	123	5	24
Cambridge University Hospitals	Addenbrooke's Hospital	65	129	**53**	88	12	41
Oxford University Hospitals	Oxford Churchill Hospital	59	107	**39**	96	20	12
InHealth	Royal Bournemouth Hospital	**92**	175	96	173	4	1
InHealth	Kent and Canterbury Hospital	**62**	203	75	179	13	24
InHealth	Maidstone Hospital	**35**	181	52	157	17	24
InHealth	Poole Hospital	**97**	179	101	177	4	1
InHealth	Southampton General Hospital	**68**	163	72	158	4	5

Source: CMA calculations based on locations (ie postcodes) provided by IBA Molecular. Distances calculated using RouteFinder.

Note: The differences calculated in the two rightmost columns are given as positive numbers.

2. Table 1 above shows that Erigal's Royal Marsden site and PETNET's Mount Vernon site are the closest alternative sites to IBA's PET business's Guildford site customers. Moreover, Erigal is closer than PETNET for Barts Health and all of IBA's PET business's InHealth locations, while PETNET is closer than Erigal for Cobalt, Cambridge and Oxford. Considering Royal Marsden and Mount Vernon, the two closest sites of Erigal and PETNET respectively to IBA's PET business's Guildford site customers, the differences between the distances for Erigal and PETNET range from 4 miles for three of IBA's PET business's InHealth locations, to 20 miles for Oxford and Cobalt. Erigal's Keele site is further than PETNET's Nottingham site (ie between 1 mile further for Royal Bournemouth and Poole and 41 miles farther for Cambridge), except for Cobalt (where it is 8 miles closer than Nottingham).

3. Tables 2 and 3 provide the peak and off-peak drive-times from IBA's PET business's customers to Erigal and PETNET.

TABLE 2 **Drive-times (minutes) (am peak)**

Customer	*Delivery site*	*Erigal (RM)*	*Erigal (KL)*	*PETNET (MV)*	*PETNET (NT)*	*Diff RM–MV*	*Diff KL–NT*
Cobalt	Cobalt	140	**103**	108	121	31	17
Barts Health	St Bartholomew's Hospital	**48**	186	50	167	2	19
Cambridge University Hospitals	Addenbrooke's Hospital	112	151	**82**	123	30	28
Oxford University Hospitals	Oxford Churchill Hospital	95	127	**54**	126	40	1
InHealth	Royal Bournemouth Hospital	122	209	**117**	208	6	1
InHealth	Kent and Canterbury Hospital	**85**	247	123	224	38	23
InHealth	Maidstone Hospital	**52**	222	98	199	46	23
InHealth	Poole Hospital	138	224	**132**	224	6	1
InHealth	Southampton General Hospital	101	188	**96**	187	6	1

Source: CMA calculations based on locations (ie postcodes) provided by IBA Molecular. Drive-times calculated using RouteFinder.

TABLE 3 **Drive-times (minutes) (off-peak)**

Customer	*Delivery site*	*Erigal (RM)*	*Erigal (KL)*	*PETNET (MV)*	*PETNET (NT)*	*Diff RM–MV*	*Diff KL–NT*
Cobalt	Cobalt	130	**102**	103	114	28	13
Barts Health	St Bartholomew's Hospital	**47**	180	49	156	1	23
Cambridge University Hospitals	Addenbrooke's Hospital	105	148	**75**	118	30	29
Oxford University Hospitals	Oxford Churchill Hospital	86	123	**51**	117	35	6
InHealth	Royal Bournemouth Hospital	113	204	**110**	198	3	6
InHealth	Kent and Canterbury Hospital	**78**	237	117	212	39	25
InHealth	Maidstone Hospital	**45**	211	84	186	39	24
InHealth	Poole Hospital	128	219	**125**	213	3	6
InHealth	Southampton General Hospital	92	183	**88**	177	3	6

Source: CMA calculations based on locations (ie postcodes) provided by IBA Molecular. Drive-times calculated using RouteFinder.

4. Tables 2 and 3 show that for each customer the closest supplier in terms of drive-times is the same regardless of whether drive-times are peak or off-peak.

5. Tables 2 and 3 also show that, in terms of drive-times, Erigal's Royal Marsden site is closer than PETNET for Barts, Kent and Canterbury Hospital and Maidstone Hospital. Moreover, Erigal's Keele site is closer than PETNET for Cobalt. PETNET's Mount Vernon site is closer than Erigal for Cambridge, Oxford and three of IBA's PET business's InHealth locations (Royal Bournemouth, Poole Hospital and Southampton General Hospital). PETNET's Nottingham site is the furthest site for all of IBA's PET business's Guildford customers in terms of drive-time. The differences between peak (off-peak) drive-times for Erigal's and PETNET's closest sites to IBA's PET business's Guildford customers range from 2 minutes for Barts (1 minute for Barts and Cobalt) to 46 minutes for Maidstone Hospital (39 minutes for Kent and Canterbury Hospital and Maidstone Hospital). Erigal's Keele and PETNET's Nottingham sites are almost equally far from all of IBA's PET business's Guildford customers except for four customers, for which Erigal's Keele site is farther than PETNET's Nottingham site, ie Barts (19 minutes peak and 23

minutes off-peak), Cambridge (28 minutes peak and 29 minutes off-peak), Kent and Canterbury (23 minutes peak and 25 minutes off-peak) and Maidstone (23 minutes peak and 24 minutes off-peak).

Alliance and PETNET's ability to supply the Guildford customers

1. In this annex we analyse Erigal's and PETNET's spare capacity to see whether, in the absence of the merger, they would have sufficient capacity to meet the FDG-18 requirements of their customers as well as IBA's PET business's Guildford site's customers.

2. This annex is structured as follows. First, we look at the FDG-18 requirements of IBA's PET business's Guildford customers. Second, we assess Erigal and PETNET's spare capacity. Appendix F sets out a full explanation of the calculation of Erigal's and PETNET's capacity.

IBA's Guildford customers

3. IBA's PET business had five customer contracts, supplied from its Guildford site, that were part of the acquisition:[1] InHealth, Cobalt, Oxford University Hospitals, Cambridge University Hospitals and Barts Health. In 2013, we estimate that these accounted for [✂] doses supplied from the Guildford site.[2]

TABLE 1 **FDG-18 volume (doses) supplied under the five Guildford customer contracts, 2011 to 2013**

Customer	*2011*	*2012*	*2013**
Cambridge University Hospitals	[✂]	[✂]	[✂]
Cobalt†	[✂]	[✂]	[✂]
Oxford University Hospitals	[✂]	[✂]	[✂]
InHealth	[✂]	[✂]	[✂]
Barts Health	[✂]	[✂]	[✂]
Total	[✂]	[✂]	[✂]

Source: Transaction data provided by IBA Molecular.

*[✂]
†[✂]
Note: [✂]

Erigal and PETNET spare capacity

4. We have compared Erigal and PETNET's capacity, as estimated in Appendix F, with their production volumes for 2013 in order to assess whether or not Erigal and PETNET have the ability to meet the requirements of IBA's PET business's Guildford customers. As explained in Appendix F, we assume that the RPU configuration allows [✂] to produce [✂] doses per firing and it

[1] Transaction data submitted by IBA Molecular shows that from January to September 2013 Guildford also supplied small amounts of FDG-18 to the following customers: Cancer Research UK, Central Manchester University Hospital, Clinical Imaging, Hammersmith Hospital NHS Trust, HCA International, Lister InHealth, Lodestone Patient Care, Royal Free Hospital, Royal Liverpool Hospital, Royal Marsden NHS Foundation Trust, School of Medicine at Cardiff University, St Thomas' Hospital, Sussex Nuffield Hospital.
[2] We have excluded volumes supplied to the Christie, which left IBA Molecular UK prior to the merger.

allows [✂] to produce [✂] doses and [✂] doses per firing at [✂] and [✂] respectively. We also assume that each RPU operates [✂] firings per day, [✂] days per week, [✂] weeks per year (see Table 2 below). Appendix F sets out the details of our calculation of Erigal's and PETNET's capacity.

TABLE 2 **Erigal and PETNET capacity**

Supplier	*Site*	*2013 production (doses)*	*Capacity estimate based on the above assumptions (doses)*	*Implied spare capacity %*
Erigal	Keele	[✂]	[✂]	[✂]
	Preston	[✂]	[✂]	[✂]
	Royal Marsden (Sutton)	[✂]	[✂]	[✂]
	Total	[✂]	[✂]	[✂]
PETNET	Mount Vernon	[✂]	[✂]	[✂]
	Nottingham	[✂]	[✂]	[✂]
	Total	[✂]	[✂]	[✂]

Source: Data provided by Alliance and PETNET and CMA calculation.

Note: Data includes primary and back-up supplies

5. It follows from Table 2 that, under our assumptions (see Appendix F), [✂] total spare capacity equates to [✂] doses and that [✂] could produce [✂] and [✂] additional doses respectively. This means that the spare capacity at [✂] is lower than the volume of sales to [✂] ([✂] doses in 2013). However, we consider that [✂] could serve some of [✂] from [✂] and in that case it would have enough spare capacity to comply with the FDG-18 requirements.[3] [✂][4]

6. Table 2 also shows that, under our assumptions (see Appendix F), [✂] total spare capacity equates to [✂] doses: [✂] doses at [✂] and [✂] doses at [✂]. This implies that [✂] site cannot serve all of [✂]. Across both of its sites [✂] seems to have spare capacity to supply most but not quite all of the [✂] customers.

[3] We note that the spare capacity of [✂] doses we calculated for the [✂] is likely to be an overestimate for the purpose of supplying [✂] as a result of the substantial distance and concomitant radioactive decay involved in supplying these customers from the [✂] site (as opposed to customers that are close to the [✂] site). This is unlikely to affect the outcome of the analysis as most of the [✂] can be supplied from the [✂] site, with [✂] only potentially having to supply the small remainder of [✂] customers for which there is not sufficient capacity at the [✂] site.

[4] The InHealth locations are: Royal Bournemouth Hospital, Poole Hospital, Southampton General Hospital, Kent and Canterbury Hospital and Maidstone Hospital.

Glossary

2006 Regulations	The Public Contracts Regulations 2006.
Acquisition	The purchase by **Alliance** of the manufacturing assets for the production of **FDG-18** in the UK formerly controlled by **IBA Molecular UK** as well as related rights and activities.
Act	The Enterprise Act 2002.
Alliance	Alliance Medical Group Limited and its subsidiaries.
AMGL	**Alliance**.
AML	Alliance Medical Limited. **Alliance**'s UK subsidiary.
AMMIL	Alliance Medical Molecular Imaging Limited.
Back-up supply/dose	Alternative supplies of **tracer**s obtained, normally by a **tracer** manufacturer, in response to a production outage, (either planned or unplanned) in order to fulfil its customers' orders. Back-up supplies may be obtained from a **tracer** producer's own facilities or from another producer.
Batch	A quantity of **tracer** produced to fulfil one or more orders.
Choline	**FEC**.
Cobalt	The Cobalt Unit Appeal Fund. A medical charity that provides diagnostic imaging services to the NHS and independent sector and funds and participates in research using **PET-CT scanners**.
CT scan	An X-ray computed tomography scan which uses computer-processed X-rays to produce tomographic images (virtual 'slices') of specific areas of the inside of the body.
Cyclotron	A type of particle accelerator which accelerates charged particle beams using a high-frequency alternating voltage and a static magnetic field. It is used to create the radioactive isotopes used in the production of some types of **radiopharmaceuticals**.

Erigal	Erigal Limited. A subsidiary of **Alliance** which manufactures **tracer**s including **FDG-18**, **choline**, and 18F-**sodium fluoride**.
FDG-18	Fluorodeoxyglucose. A **radiopharmaceutical tracer** used in **PET-CT scanning**, primarily for the diagnosis of cancers.
FEC	Fluoroethylcholine. A fluorine-18 based **tracer** used in the diagnosis of prostate cancer.
Firing	A finite period of operation of a **cyclotron** which produces a quantity of isotope, which may be used in the preparation of one or more **batches** of **tracer**s.
GE Healthcare	A subsidiary of the General Electric Company which manufactures and supplies **PET-CT scanners** in the UK. It also provides **tracer**s other than **FDG-18** to research facilities.
Guidelines	The CMA's Merger Assessment Guidelines (CC2 (Revised)/OFT1254).
IBA Molecular	The trading name of IBA Pharma SA, which is jointly owned by **IBA SA** and **SK Capital**.
IBA Molecular UK	IBA Molecular UK Limited. UK subsidiary of **IBA Molecular**.
IBA operation	The manufacturing assets and related rights and activities, including its **InHealth FDG-18** supply contract, of **IBA**'s **PET business** which were acquired by **Alliance**.
IBA's PET business	The business operated by **IBA Molecular UK** which produced and supplied **FDG-18** prior to the acquisition of its production assets and related rights and activities by **Alliance**.
IBA SA	The joint owner, along with **SK Capital**, of **IBA Molecular**.
InHealth	InHealth Group Limited. A provider of diagnostic (including MRI, CT and PET-CT) scanning services and managed patient services to NHS trusts.

MA	Marketing authorisation. A licence issued by the **MHRA** which is required in order to supply medicines commercially.
MHRA	Medicines and Healthcare products Regulatory Agency. An executive agency of the Department of Health which is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.
Mobile scanner	A scanner installed in a trailer, which can be transported and operated at multiple locations.
Mothballing	The ceasing of production at an **RPU**. Reactivating a mothballed **RPU** takes between 18 and 24 months and involves considerable costs. In the context of the **radiopharmaceutical** industry, mothballing can be akin to exit. Mothballed RPUs still require regular inspections and maintenance, although some equipment may be removed from the site for use elsewhere.
NaF	**Sodium fluoride**.
NHS England	A new commissioning body that from April 2013 has the responsibility of commissioning primary care health services, as well as some nationally-based functions previously undertaken by the Department of Health.
NHS block contract	A contract under which the NHS centrally procures **PET-CT scanning** services for a number of NHS trusts.
PET-CT National contract	The **NHS block contract**s under which **PET-CT scanning** services are procured for some NHS hospitals. It was commissioned by the Department of Health in 2007. It will be recommissioned by **NHS England** in 2015. There are currently two such contracts in operation, **PET-North** and **PET-South**.
PET-CT scanner/ scanning	A medical imaging scanner which creates images using two types of scanning technology (**CT scan** and **PET scan**) and which is used to diagnose a range of medical conditions, predominantly cancers.
PET-North	The current **NHS block contract** for **PET-CT scanning services** in the northern half of England which was won

	by **Alliance**. It commenced in April 2008 and will expire on 31 March 2015.
PET scan	A positron emission tomography scan which produces a three-dimensional image of functional processes in the body. The system detects the radiation emitted by a **radiopharmaceutical tracer**.
PET-South	The current **NHS block contract** for **PET-CT scanning** services in the southern half of England which was won by **InHealth**. It commenced in April 2008 and will expire on 31 March 2015.
PETNET	PETNET Solutions Inc, a wholly-owned subsidiary of **Siemens**, which manufactures and supplies products and services for **PET-CT scanners**, including **FDG-18** and other **radiopharmaceuticals**.
Primary supply/dose	Supplies of **tracer**s produced by **tracer** manufacturers to fulfil their own customers' orders.
Radiopharmaceuticals	Radioactive pharmaceuticals used in the diagnosis and/or treatment of diseases.
RPU	Radiopharmaceutical Production Unit. A facility which produces **radiopharmaceuticals**.
Siemens	Siemens Medical Solutions USA Inc, a subsidiary of Siemens AG. A manufacturer of medical equipment including **PET-CT scanners** and **cyclotrons**.
SK Capital	SK Capital Partners LP. A private investment firm. The joint owner, along with **IBA SA**, of **IBA Molecular**.
Sodium fluoride	18F-Sodium Fluoride. A **tracer** used to detect bone cancers.
Static scanner	A scanner which is permanently installed in a hospital or clinic.
Tracer	A **radiopharmaceutical**, such as **FDG-18**, which can be detected by scanners enabling them to create images of processes in the body. Other tracers are **FEC** and **NaF** (**sodium fluoride**).