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InHealth – Alliance/IBA merger
Submission to the OFT
NON-CONFIDENTIAL VERSION

1 Executive summary

1.1 This confidential submission to the Office of Fair Trading ("OFT") is made by InHealth Group Limited[1] ("InHealth") in relation to the completed acquisition by Alliance Medical Imaging Limited ("Alliance Medical") of the assets of IBA Molecular UK Limited ("IBA") which InHealth understands was completed on or around September 2013 ("the acquisition").[2]

1.2 [REDACTED]

1.2.1 [REDACTED]

1.2.2 [REDACTED]

1.3 [REDACTED]

1.4 [REDACTED]

1.5 [REDACTED]

1.6 PET-CT is a Specialised Service commissioned by NHS England. Currently, there are two major contracts for the supply of PET-CT, relating to supply in the north and south of England respectively (the "North Contract" and "South Contracts" respectively). InHealth is the contracted provider of PET-CT Services in the South of England; Alliance Medical is the contracted provider of PET-CT services in the North of England.

1.7 Because both contracts expire in March 2015, InHealth considers that it is likely to be necessary to consider the geographic market definition for PET-CT and FDG on both

[1] Company number 04620480
[2] This submission (including sections 1 to 6 and the appendices) has been prepared based on the information available to InHealth and the market as InHealth understands it to be. The expression of any view by InHealth in this submission is a provisional view, based on current information and may change as further market information becomes available.

the North/South (existing) basis and also to consider the position that will arise from 1 April 2015 (the contracts expire on 30 March 2015), in order to assess properly the effect of the acquisition on competition.

1.8 [REDACTED] [3]

1.9 [REDACTED]

1.9.1 [REDACTED]

1.9.2 [REDACTED][4]

1.9.3 [REDACTED][5]

1.10 As a result:

1.10.1 there appear to InHealth to be two distinct geographic markets for FDG to be considered: the market served by cyclotrons in the North-West conurbation ("North"), and the market serviced by cyclotrons in or near London ("South"); and

1.10.2 the market position of FDG suppliers is enhanced because no PET-CT provider can allow itself to be reliant on a single provider of FDG, and so, if there are not three or more undertakings competing to provide FDG in a region, each supplier can be sure that *all* customers will be obliged to rely on obtaining FDG from them, whether directly as a contracted customer or through resilience arrangements between FDG suppliers.

1.11 Prior to the merger, in each of the North and South providers of PET-CT services could buy the FDG supply from three independent undertakings: Alliance Medical (after its acquisition of Erigal), Siemens PETNET ("Siemens") and IBA. As a result of the acquisition, there will be only two undertakings able to supply FDG: Alliance/IBA and

[3] This is the case by virtue of the fact that, under the regulatory regime administered by the MHRA, a 'Specials Licence' is normally only available in circumstances where there is no option to source commercially-produced FDG. See section 2 and 4 for more information about this regime.
[4] This is a typical travel time (for a standard clinical dose). In some circumstances, FDG can be provided within a four hour journey time where the dose is 'over-supplied' (albeit with additional protections for patients and staff to address the risks of higher radiation levels).
[5] While in principle, it might be technically possible to source FDG from a single supplier and let that supplier establish their own back-up arrangements, in practice it is necessary to deal with both the primary and backup supplier on an 'ordinary course' basis – as otherwise the need to draw on backup arrangements may be so rare as to be ineffective or prohibitively expensive. See paragraph A12.3 in section 4 for more detailed discussion of this point).

Siemens. Supply is geographically dependent and in some locations only a single provider is capable of supplying within viable travel times.

1.12 [REDACTED]

1.13 [REDACTED]

1.13.1 [REDACTED]

1.13.2 [REDACTED]

1.13.3 [REDACTED]

1.13.4 [REDACTED]

1.14 [REDACTED][6]

1.15 [REDACTED][7]

1.16 [REDACTED]

1.17 [REDACTED]

1.18 [REDACTED]

1.18.1 [REDACTED]

1.18.2 [REDACTED]

1.19 [REDACTED]

1.19.1 [REDACTED] [8, 9]

1.19.2 [REDACTED][10]

1.19.3 [REDACTED]

[6] Appendix 2.2.
[7] For example, suppliers of mobile MRI who might consider developing the ability to supply mobile PET-CT, or independent hospital groups who might consider developing the capability to offer PET-CT to other NHS organisations.
[8] See paragraph A9.3 [REDACTED].
[9] Appendix 9.6, section 2.1.
[10] See paragraph A10.3, [REDACTED].

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1.19.4 [REDACTED]

1.20 [REDACTED]

1.21 [REDACTED]

1.21.1 [REDACTED]

1.21.2 [REDACTED]

1.21.3 I[REDACTED]

1.21.3.1 [REDACTED]

1.21.3.2 [REDACTED]

1.21.4 [REDACTED]

1.21.5 [REDACTED]

1.22 As requested, this submission includes answers (including supporting data and documents) to the questions asked by the OFT in its questionnaire on 31 January 2014.

1.23 The structure of the submission is:

1.23.1 This section 1 (**Executive Summary**);

1.23.2 Section 2 (**Introduction**) sets out a brief overview of InHealth and the legal and regulatory context in which it operates, including the institutional arrangements comprising the NHS and the relevant regulatory regimes that apply to PET-CT and FDG;

1.23.3 Section 3 (**PET-CT services**) sets out material relevant to the OFT's consideration of the market(s) for provision of PET-CT. The whole of section 3 comprises InHealth's answers to the OFT's questions 1 to 6 and 17;

1.23.4 Section 4 (**FDG supply**) sets out material relevant to the OFT's consideration of the market(s) for the supply of FDG. The whole of section 4 comprises InHealth's answers to the OFT's questions 7 to 16;

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1.23.5 Section 5 (**Market context**) sets out material relevant to the OFT's consideration of the possible impact of the acquisition. The whole of section 5 (together with sections 1 and 2) comprises InHealth's answers to questions 18 to 21; and

1.23.6 Section 6 (**Additional questions**) answers questions that were asked by the OFT team at the meeting held between the OFT and InHealth at Fleetbank House on 3 January 2014.

1.24 As well as responding to the questionnaire received on 31 January, annexed to this submission are written responses to the matters raised by the OFT at the meeting between InHealth and the OFT on 3 January 2014.

1.25 To the extent that the material in this submission is not already identified as responding to an OFT question, this submission (in full) comprises InHealth's response to question 22 (asking for any further comments).

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2 Introduction

2.1 This section 2 provides:

2.1.1 a brief description of InHealth's business;

2.1.2 a brief description of the relevant elements of the structure of the NHS; and

2.1.3 relevant points concerning the regulatory frameworks which affect the supply of PET-CT and FDG.

InHealth

2.2 InHealth provides a complete range of diagnostic services, from standalone (fixed or mobile) services through to fully integrated managed service solutions for patients. In the financial year ended September 30th 2013, InHealth's turnover was [REDACTED].

2.3 The company provides:

2.3.1 **Diagnostic services to hospitals**. The company provides diagnostics and managed patient services to NHS Trusts across the country in both hospital and community healthcare settings. InHealth's range of services includes MRI, CT, DXA, ultrasound, mammograms, x-ray, nuclear medicine, audiology, angiography and endoscopy. InHealth provides fully integrated managed radiology services to 21 NHS Trusts in the UK. Radiology is a focus for the organisation and the company has led the development of advances in diagnostic services delivery bringing considerable experience, robust clinical processes, highly trained staff and cost effective solutions.

2.3.2 **Community healthcare services**. These services are provided to GPs and CCGs from over 80 community-based sites across the country. Community Healthcare Services enable GPs and other professionals to refer patients directly to one of our diagnostic centres (fixed or mobile) for a scan or other test. The results of the scan are sent directly to the GP which allows the GP to determine the most appropriate course of treatment. These diagnostic services tailored for the community setting are highly flexible and can be developed to meet the specific needs of the local community, by locating diagnostics outside an acute setting, often in GP surgeries and therefore closer to patients' homes, using a delivery model which involves a patient referrals management centre which contacts patients proactively to offer a choice of date, time and location for appointment. In support of these services InHealth operates 5 independent diagnostic centres in London and 2 others regionally based.

2.4 All these services (in either a community or hospital setting) can be supplied in a range of environments from static to fully mobile (portable or mobile equipment and peripatetic staff). InHealth operates nearly [REDACTED] mobile units across a range of services [REDACTED].

2.5 InHealth delivers services to patients from 280 locations across the UK and Ireland. Since 2008, InHealth has provided services across the South of England.

2.6 As part of its work, InHealth provides the diagnostic PET-CT scan service (described in more detail below). The revenue from providing this service accounts for [REDACTED] of InHealth's overall revenue.

2.7 The company is privately owned (as mentioned in InHealth's response to Question 18 to the OFT's questionnaire). [REDACTED]

The NHS Structure and Commissioning Process

2.8 This section sets out a very brief sketch of the arrangements constituting the NHS in England that are relevant to this submission.[11]

2.9 The Secretary of State, supported by the Department for Health, sets the national policy and agenda for the health and social care sector. This includes, critically, the NHS Constitution, which identifies seven principles that underpin the NHS:

2.9.1 The NHS provides a comprehensive service, available to all;

2.9.2 Access to NHS services is based on clinical need, not an individual's ability to pay;

2.9.3 The NHS aspires to the highest standards of excellence and professionalism;

2.9.4 The NHS aspires to put patients at the heart of everything it does;

2.9.5 The NHS works across organisational boundaries and in partnership with other organisations in the interest of patients, local communities and the wider population;

2.9.6 The NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources; and

[11] These comments relate to the NHS in England. Those arrangements are different in respect of Health and Social Care in Northern Ireland (HSCNI), NHS Scotland and NHS Wales.

2.9.7 The NHS is accountable to the public, communities and patients that it serves.[12]

2.10 To establish a health care system that is funded by the taxpayer and free at the point of use to patients, the NHS constitutes two distinct systems: a set of institutions responsible for securing the services necessary to deliver the NHS (a process referred to as 'commissioning') and a set of institutions responsible for delivering those services ('provision'). The commissioners identify the health and social care needs of the communities at a national, regional or local and identify suitable providers (through a variety of mechanisms including via competitive tender). Providers enter into agreements with commissioners to provide services to patients.

2.11 NHS England is the national board of the NHS responsible for managing the budget and commissioning services. It seeks to 'create the culture and conditions for health and care services and staff to deliver the highest standard of care and ensure that valuable public resources are used effectively to get the best outcomes for individuals, communities and society for now and for future generations.'[13]

2.12 NHS England splits its activities into four regions, with local offices that allocate resources to region of the country and commissions specialised services, primary care services and other services (for example, offender healthcare and the services for the armed forces). NHS England is responsible for improving patient experience, commissioning development, improving technology, systems and data, fostering and developing partnerships and relationships, direct commissioning (as outlined above), quality improvement and clinical leadership, improving governing frameworks as well as patient safety.

2.13 Clinical Commissioning Groups (CCGs) manage approximately 60% of the NHS budget at a local level. Each CCG decides whether or not to contract with providers and which services should be provided at the NHS hospitals, private hospitals, private and charitable community care and so on. The CCG also partner with local authorities such as Healthwatch and the Health and Wellbeing Boards that work for health and social wellbeing in the local communities.

2.14 PET CT is currently a Specialised Service and is therefore commissioned by NHS England on a national basis.[14]

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[12] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf

[13] http://www.england.nhs.uk/about/our-vision-and-purpose/

[14] See paragraph 3.8 below.

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2.15 **Commissioning**. When a contract to provide a service comes up for renewal, the CCG or NHS England will undertake procurement. NHS England issues a service specification for the contract which will generally outline matters such as the population needs, the scope of the service, applicable service standards and key service outcomes. Providers submit a tender outlining how they can fulfil the requirements and make a compelling offer, which will include various service elements including price. The NHS Board or CCG will determine which is the best bid and award the contract. The NHS has designed the CCG and Direct Commissioning assurance processes to provide confidence to patients and the wider public that both CCGs and NHS England are operating effectively to commission safe, high-quality and sustainable services within their resources.

2.16 **Provision.** Health care providers provide services to patients. Providers are regulated by Monitor and the Care Quality Commission (discussed below).

2.17 NHS hospitals in England are managed by acute trusts, some of which already have gained foundation trust ("FT") status. Acute trusts ensure hospitals provide high-quality healthcare and decide how a hospital will develop, so that services improve. Acute trusts employ a large part of the NHS workforce, including nurses, doctors, pharmacists, physiotherapists, radiographers, porters, receptionists, security staff and so on. Some acute trusts are regional or national centres for more specialised care, others are attached to universities and help to train health professionals. Acute trusts can also provide services in the community, for example through health centres, clinics or in people's homes.

2.18 NHS FTs are public benefit corporations providing NHS goods and services in England. They also provide non-NHS healthcare services. Introduced in April 2004, FTs differ from other NHS trusts. They are independent legal entities and have governance arrangements that are not subject to the direction by the Secretary of State. They are accountable to local people, who can become members and governors and/or form part of their board who are involved in the strategic planning. As self-standing, self-governing organisations, NHS FTs are free to determine the course of their own activities. FTs are overseen and regulated by Monitor.

2.19 As part of the reforms introduced under the Health and Social Care Act 2012 ("HSCA 2012"), all acute trusts are expected to reach FT status.

2.20 Independent sector providers refers to private, voluntary and not for profit healthcare establishments that may either contract directly with acute trusts, FTs and NHS England to provide a wide range services to patients or bid to provide services directly

to CCGs. In either model, the independent providers bid to win tenders (against other independent providers and sometimes, NHS providers) for the provision of a service for a stipulated region in England (for example in the Bristol area) and for a set period or as an outsourced service to an NHS acute provider. Once a provider has won a tender, it will responsible for the provision of services either on the hospital campus, or via mobile units out in the community.

Regulation by Monitor under the HSCA 2012

2.21 Monitor is the economic regulator of the health and social care sector. Section 62 of the HSCA 2012 sets out Monitor's general duties:

> *(1) The main duty of Monitor in exercising its functions is to protect and promote the interests of people who use health care services by promoting provision of health care services which—*
> *(a) is economic, efficient and effective, and*
> *(b) maintains or improves the quality of the services.*

2.22 Monitor has three functions that may be relevant to the OFT's review of the acquisition:

2.22.1 To ensure choice and competition operate in the best interests of patients. In particular Monitor will act to prevent anti-competitive behaviour by commissioners or providers where it is against patients' interest (Chapter II of the HSCA 2012). In order to carry out this role, Monitor polices the rules on choice and competition and has also established a Co-operation and Competition Directorate;

2.22.2 To issue licences to providers of health care services for the purposes of the NHS (Chapter III of the HSCA 2012). The licence is the main tool with which Monitor regulate providers of NHS services. FTs were licenced from April 2013; all other providers of health care services will need an NHS provider licence from 1 April 2014. Monitor consulted with stakeholders during 2012 to establish a set of standard licence conditions. The universal requirements of all licences include general conditions, integrated care condition, choice and competition concerns and pricing conditions; with an additional requirements for licensees who supply Commissioner Requested Services setting out continuity of service conditions. Where a provider is in breach of a licence condition, Monitor may take enforcement action as set out in sections 104ffs of the HSCA 2012; and

2.22.3 To publish the national tariff (Chapter IV of the HSCA 2012). The tariff may also specify certain health services which are or may be provided for the purposes of the NHS; the method used for determining the national prices for those services and the method for deciding whether to allow local modifications to prices. This means that the national tariff will generally specify where variations to the national prices is permitted.

2.23 Monitor is also responsible for regulating commissioning. Under Regulations established under section 75 of HSCA 2012, Monitor may impose requirements relating to competitive tendering for provision of services and the management of conflicts between the interest involved in the commissioning services and the interests involved in providing them. Monitor has also issued guidance for commissioners on ensuring the continuity of health care services. The guidance sets out a process that commissioners can follow when they start analysing which services to designate as Commissioner Requested Services.

2.24 The regime operated by Monitor regulates and monitors the providers of health care services (such as InHealth's provision of PET-CT). These provisions do not cover the supply of FDG.

Regulation by the Care Quality Commission (CQC) under the Health and Social Care Act 2008 (HSCA 2008)

2.25 The CQC is responsible for clinical safety in the Health Sector. Section 3 of the HSCA 2008 sets out the Commission's key objective:

> *(1) The main objective of the Commission in performing its functions is to protect and promote the health, safety and welfare of people who use health and social care services*

2.26 The CQC is responsible for ensuring a high standard of care for patients. The CQC ensure that providers provide people with safe, effective and high-quality care, through, for example:

2.26.1 Setting standards of quality and safety that people have the right to expect whenever they receive care;

2.26.2 to make sure that they continue to meet the standards;

2.26.3 Protecting the rights of vulnerable people;

2.26.4 Challenging all providers, with the worst performers getting the most attention;

2.26.5 Making fair and authoritative judgements, supported by the best information and evidence;

2.26.6 Taking appropriate action if care services are failing to meet the standards;

2.26.7 Carrying out in-depth investigations to look at care across the system; and

2.26.8 Reporting on the quality of care services, publishing clear and comprehensive information, including performance ratings to help people choose care.

2.27 These standards create a high bar for service providers and require demanding work by prospective new entrants to meet the standards necessary for clinical provision of services. These requirements may comprise a 'barrier to entry' in the economic sense, albeit a wholly legitimate one, in that the establishment and maintenance of those standards is, of course, in the interests of patients.

Medical and Healthcare products Regulatory Agency (MHRA)

2.28 The MHRA is responsible for regulating medicines and medical devices. The MHRA works closely with the European regulator, the European Medicines Agency and is recognised as a trusted and independent source of expertise throughout Europe. Its role is governed by the Directive 2001/83/EC relating to medicinal products for human use, (as amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC). It is the responsibility of the MHRA and the expert advisory bodies set up by the Medicines Act to ensure that the balance between safety and effectiveness is achieved.

2.29 All medicine and device manufacturers and suppliers are directly approved by the MHRA which issues a 'marketing authorisation' ("MA"), or licence. This licensing system is designed to: guarantee that all those involved are answerable for their actions; ensure that processes, supplies, and quality can be thoroughly monitored and; enable swift corrective action to be taken when needed.

2.30 The MHRA assesses applications for new medicines to ensure they meet the required standards and comply with European and UK law. This is followed up by a system of inspection and testing which continues throughout the lifetime of the medicine. The MHRA also ensures that doctors and patients receive up-to-date and accurate information about their medicines. This is achieved by ensuring that product labels, leaflets, prescribing information and advertising meets the required standards laid down by the Regulations.

2.31 However, the Human Medicines Regulation 2012 (SI 2012/1916) contains certain exemptions from licensing and makes the provision for further exemptions to be made in the statutory orders. For the purposes of this Submission, the relevant exemption is the manufacture and supply of unlicensed relevant medicinal products for individual patients (also known as a "Specials Licence"). This is the mechanism used by research institutes for trailing new isotopes and for trials. They are also used where the clinical needs of a special patient cannot be met by licensed medicinal products. 'Specials' cannot be advertised and cannot be supplied if an equivalent MA licensed product is available.

2.32 In practice, this rule applies to independent providers of services such as InHealth and Alliance who purchase their FDG from commercial suppliers.

2.33 However the NHS have been known to use the Specials Licence to produce FDG for use in their scanners for patients instead of purchasing from commercial supplier. The current commercial suppliers (that hold MA) are Siemens PETNET, Erigal, IBA and GE Healthcare (and are listed on the MHRA website).

2.34 The Good Manufacturing Practice ("GMP") is part of the Inspection Enforcement and Standards Division of the MHRA and is concerned with production and quality control. The GMP ensures that products are consistently produced and sets out the controls as to the quality standards appropriate to medicinal products intended use as required by the MA. The GMP assesses the compliance of organisations involved in the manufacture, import and distribution of medicinal products. Inspections are performed to assess compliance with the conditions of the relevant licence, the Human Medicines Regulations 2012, and European guidance on good manufacturing practice and/or good distribution practice. This involves an assessment of personnel, premises, processes and procedures to ensure the quality of the medicinal products manufactured / handled, would not be compromised. If NHS sites were to apply for an MA licence for the commercial production of FDG, in addition to the cost of the licence, the NHS would need to find an revenue stream to finance the maintenance and upkeep of the cyclotrons to the high standards required by the MHRA.

The Environment Agency

2.35 The Environment Agency ("EA") regulates a range of activities but the relevant role here is in relation to the management of radioactive substances. The EA's objective in regulating radioactive substances is that, consistent with Government policy and legislation, radioactive substances are managed to meet the needs of current and future generations by preventing, and where that is not possible minimising, adverse effects on people and the environment, and that environmental damage is remedied.

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There are various forms of regulation and legislation that dictate how, for example, radioactive substances such as FDG are stored, transported and disposed of after use. For example, the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009/1348 sets out the regulatory requirements for dangerous goods (including radioactive material) by car and rail.

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R).

2.36 These Regulations identify a number of duty holders with responsibilities associated with medical exposures, the required training for duty holders associated with justification and practical aspects of medical exposures, the keeping of relevant records and the availability of expert advice. They apply to all types of procedure resulting in medical exposure (such as PET-CT) and, in contrast to the regulations they replaced, include the use of ionising radiation in scientific research as well.

The Medicines (Administration of Radioactive Substances) Regulations 1978

2.37 These Regulations prohibit the administration of radioactive medicinal products except by doctors or dentists holding a certificate issued by the Health Ministers.

2.38 Regulation 2 states that:

> *No person shall administer to a human being (otherwise than to himself) any radioactive medicinal product unless he is a doctor or a dentist holding a certificate issued by the Ministers for the purposes of section 60 of the Act in respect of radioactive medicinal products (hereinafter referred to as a* "certificate"*) or a person acting in accordance with the directions of such a doctor or dentist.*

2.39 Regulation 3 sets out that the Health Ministers may appoint a committee to advise on the imposition of licences:

> *The Health Ministers may appoint a committee to be called the Administration of Radioactive Substances Advisory Committee to advise them with respect to the grant, renewal, suspension, revocation and variation of certificates ….*

2.40 The Advisory Committee (also referred to as ARSAC) review and advise on applications to gain a licence as well as written applications from practitioners for certificates which will enable them to use specific radioactive medicinal products in diagnosis, therapy or research.

BUSINESS SECRETS REMOVED

3 PET-CT Services

3.1 This section 3 provides evidence concerning the provision of PET-CT services.

What is PET-CT?

3.2 PET-CT scanners combine Positron Emission Tomography (PET) with Computed Tomography (CT) to produces images of function and anatomy in a patient with a single scanning session.

3.3 The functional image is produced by injecting a radioactive tracer, most commonly ^{18}F fluoro-deoxyglucose (i.e. FDG). Once injected this tracer is taken up by actively metabolising cells in a patient's body (e.g. muscle tissue in the heart, grey matter in the brain, and cancerous cells in tumours/metastases). The tracer is excreted through the urinary system.

3.4 Following the FDG injection the patient rests during the tracer uptake period (generally 60 to 90 minutes) and is then scanned, first with CT then with PET (which detects the emissions from the radioactive tracer). The scan takes around 30 minutes. The combination of the two scans allows a precise localisation of the areas affected by disease.

3.5 [REDACTED][15, 16]

Uses of PET-CT

3.6 As set out in the response to the OFT's questionnaire question 7, the primary application of PET-CT today (c.95%) is in cancer/oncology: in staging disease, planning and monitoring of treatment.

3.7 There is a growing application (the remaining c.5%) in use of non-oncology conditions:

3.7.1 Dementia diagnosis – PET-CT enables early detection and characterisation of dementia

3.7.2 Cardiological indications – certain patients with ischaemic heart failure

3.7.3 Miscellaneous application for infection and inflammation, however incidence and use is small

[15] South Contract [REDACTED]
[16] Appendix 3.1, [REDACTED]

BUSINESS SECRETS REMOVED

3.7.4 New tracers (non-FDG) are coming online (currently very low use and high cost):

3.7.5 Amyvid[b] – for Alzheimer's Disease and other causes of cognitive decline

3.7.6 Choline – for specialist use with prostate cancer

3.7.7 DOPA – for Parkinson's Disease

3.7.8 Fluoride – for bone scans

3.7.9 Ga68-Dotatate with preparation for Lu177 therapy, for neuroendocrine tumour imaging

Relevant history of PET-CT in the NHS

3.8 In order to be able to offer PET-CT to services to patients, NHS England procures PET-CT services. Within the NHS' categorisation of services, PET-CT is a specialised service, meaning that it is commissioned by NHS England (and not locally by CCGs).[17]

3.9 In 2005, the NHS issued a framework document (the "2005 Framework") that described the need to improve the position of the UK in relation to the use of PET-CT. The purpose of the 2005 Framework was to:

> *…guide commissioners and potential providers of services by providing advice on the current evidence of benefit from PET scanning; the current state of the technology; the number of scanners likely to be required; workforce and training issues; capital and revenue costs and further research and evaluation.*[18]

3.10 Beyond simply making commissioners and potential providers aware of the growing evidence of the clinical benefits of PET-CT in the detection of various forms of cancer, the authors identified a specific concern in relation to the UK's ability to develop the use of the service:

> *12. The provision of PET facilities in the UK compares unfavourably with that of most other Western European countries, where PET is now an accepted technology for the management of patients with cancer. Five European countries already have at least one scanner per 2 million population, compared with around one per 5 million in the UK (including private*

[17] http://www.specialisedservices.nhs.uk/document/positron-emission-tomography-computed-tomography-pet-ct-service/search:true
[18] Appendix 14.2, paragraph 1.

scanners, but excluding research scanners). France with a similar population to that of the UK has recently committed to providing 75 PET scanners.[19]

3.11 The 2005 Framework identified specific priorities for improving the situation for NHS patients:

> *16. Development of clinical PET-CT services outside London should therefore be a high priority. It is recommended that where individual facilities are established, they should serve populations of around 2.5m people.*
>
> *17. Some further development is also likely to be needed in London and the South East, given the fact that some of the existing facilities generally have lower throughput than current PET-CT scanners.*[20]

3.12 These two priorities eventually became the focal points for commissioning of services that could address the problem identified in the 2005 Framework, which included that 'most existing [NHS] facilities are based on PET scanners with lower throughput than the current generation of PET-CT scanners' and a lack of trained staff suitable to support greater use of PET-CT.[21] The 2005 Framework also provided NHS commissioners and potential providers with information on the likely capital and revenue costs associated with providing additional capacity.[22]

3.13 Consistent with the priorities identified in the 2005 Framework, at the time when the contracts went out to tender in 2007, NHS England split the UK into two – the North and South Schemes.[23] InHealth won the contract for the South, whilst Alliance won the contract for the North. The contracts had an initial term until April 2013.[24] Further details of these contracts are set out in answers to Questions 2, 3 and 4 to the OFT's questionnaire.

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[19] Appendix 14.2, paragraph 12.
[20] Appendix 14.2, paragraphs 16 and 17.
[21] Appendix 14.2, paragraphs 5.3 and 6.1.
[22] Appendix 14.2, paragraphs 8.1 to 8.4.
[23] Originally, the tender framed the contracts in 3 lots, so the North/South distinction was determined during the tender process, presumably in light of the bids received. This fluidity underscores the fact that, during the commissioning process, there is considerable discretion as to the approach that best suits the needs of patients and, in the case of PET-CT specifically, that there is no particular necessity that the contracts be divided in the way that they are (and no provider could reasonably expect that they would necessarily continue to be split in that way in future). [The dividing line for the South starts, in rough terms, at the Humber river and goes to Bristol. An exception is the RPU and scanning facility at Nottingham, which is operated under a separate contract.]
[24] Appendix 3.1 (the PET-CT South Contract)

BUSINESS SECRETS REMOVED

3.14 A critical objective of the scheme was to achieve 'plurality' (that is, the presence of independent sector providers as a spur to innovation and to enable wider patient choice). Plurality was central to the NHS' plan to address limits on the capacity of the NHS to provide PET-CT itself in a sufficiently timely way, at a sufficiently wide range of locations and at sufficient volumes to meet the needs of the NHS.[25] The South Contract notes that:

[REDACTED][26]

3.15 During the period following the 2005 framework, and particularly following the establishment of the North and South Contracts, PET-CT services continued to be used more widely, and the number of scans provided by the independent providers increased as the North and South Schemes became established.

3.16 In 2009, the NHS provided model documentation to commissioners to assist in commissioning PET-CT. That document noted that, at that time, the environment had developed to the point that:

'[t]here are a number of service models available, which include:

- *Integrated NHS provision using a fixed scanner located and operated by a NHS Trust in conjunction with a Cancer Centre;*

[25] 'Plurality' is defined in the South Contract by reference to the 2004 NHS Improvement Plan. That Plan noted at section 5.11 and 5.14 that 'Our aim is to transform diagnostic services by *expanding capacity* and making the best use of the resources we already have. Increasingly, the NHS will provide diagnostic services closer to the patient's home or work. Efficient diagnostics will enable faster and more appropriate access to acute care where this is needed and should also enable a wider range of care options to be considered without necessarily falling back on the acute sector. Investment in and procurement of improved diagnostic services from both public and private providers will be an increasingly important feature of the new system … *Reflecting the urgency of developing diagnostic capacity and encouraging innovative solutions, the next wave of independent sector procurement is likely to include diagnostic services*.' The 2004 Plan notes at section 9.2 that '[i]mproving choice for patients and the overall responsiveness of the system is central to our plans. Breaking down some of the
Institutional and other barriers in the system will allow patients to have greater options. Developing a more diverse supply side with a greater plurality of providers will support patients to exercise real choice.' (emphasis added)
(http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118572.pdf)

[26] South Contract [REDACTED].

- *Shared use of a fixed scanner between a NHS Trust and Medical School and or Research Institute;*
- *A fixed scanner located on a NHS Trust site, but operated by an Independent Sector provider;*
- *A mobile scanner service operated by an Independent Sector provider as part of the Phase 2 Diagnostic Contract; and*
- *A mobile scanner service operated by an Independent Sector provider, outside of the Phase 2 Diagnostic Contract.'*[27]

3.17 From the award of the South Contract, through to the present, InHealth supplies PET-CT services to the NHS under the third, fourth and fifth of these service models, that is:

3.17.1 InHealth operates fixed scanners at NHS Trust sites (under the South Contract);

3.17.2 InHealth operates mobile scanners under arrangements governed by the South Contract; and

3.17.3 InHealth operates mobile scanners under some circumstances that fall outside of the South Contract.

3.18 One of the responsibilities of a PET-CT provider to the NHS is to bear the risks associated with securing a stable and reliable supply of FDG. For example, the NHS 2009 document notes that:

> *3.9 PET providers will need to demonstrate that they have robust agreements for the supply of the appropriate radiopharmaceutical and that contingency arrangements exist should there be a failure of supply from the main provider or planned downtime on the cyclotron.*

3.19 As the South Contract is due to expire in April 2015 [REDACTED][28] Further information about contracts for services that are up for renewal in the next few years is set out in InHealth's answer to Question 6 of the OFT's questionnaire.

(a) Defining the product markets for PET-CT

[27] Appendix 1.1.
[28] [Section 75 Regulations]

BUSINESS SECRETS REMOVED

3.20 PET-CT is defined with the NHS environment, so that all providers who are eligible for funding by the NHS must provide a service that complies with the relevant specification.[29] [30] This is the logical starting point for defining the product market for PET-CT.

3.21 For individual patients (or hospitals referring a patient for PET-CT), they may have a choice of providers of PET-CT (discussed under geographic market below) but there is generally only a single service considered to be PET-CT.

3.22 Suitably qualified professional staff (e.g. clinicians) at NHS Trusts purchasing PET-CT and suppliers of PET-CT (including InHealth) are generally closely attuned to the medical literature dealing with PET-CT and the relative merits of variants of PET-CT, so that it is unlikely that other services that are substitutable would not be rapidly identified and considered for adoption by the NHS.

3.23 Contracts for the supply of PET-CT generally recognise the lack of substitutability of other services – for example [REDACTED]:

> [REDACTED][31]

3.24 While new variants of PET-CT (for example, using tracers other than FDG for specific diagnostic tasks or exploring ways of delivering PET-CT using lower doses of radiation) are the subject of active research, their adoption on a commercial scale depends on those variants being sufficiently developed that they could be scrutinised and approved for use in the NHS. This process includes consideration of any new treatments by the relevant Clinical Reference Group and, in the case of new tracers, certification by the MHRA. Entirely appropriately (in light of the need to ensure that patients are protected from harm), the more novel or different the treatment to existing services, the longer the period likely to be needed to consider whether to grant approval for it to be used in a clinical setting. One collateral impact of these requirements is that it is challenging to bring new medicines and treatments to market quickly.

[29] B02/a/s service specification for PET-CT – see http://www.england.nhs.uk/wp-content/uploads/2013/06/b02-positron-emis-tom.pdf
[30] NHS Commissioning Board, Clinical Commissioning Policy Statement: Positron Emission Tomography Computed Tomography (PET-CT) Guidelines (All Ages), April 2013.
[31] Nottingham Contract, [REDACTED].

3.25 This evidence suggests that there are not suitable directly substitutable services to PET-CT (as specified), in circumstances which match the clinical indications for the use of that service.

3.26 This is consistent with various plans produced by the NHS to develop the use of PET-CT, which are predicated on the benefits arising from the use of PET-CT in particular clinical contexts, distinct from all other diagnostic and imaging techniques.

Distribution of scanning facilities

3.27 Although state-of-the-art PET-CT scanners with appropriate support facilities are capable of a throughput of 15-20 patients per day, many sites operate at considerably lower throughput. In some cases under-utilisation may be due to constraints in staffing and/or sub-optimal facility design (problems that have persisted despite having been identified in the 2005 Framework), but primarily it is the result of a surplus of overall capacity, relative to current demand/funding levels. Some NHS scanners are exclusively or predominantly used for research studies.

(b) Defining the geographic markets for PET-CT

3.28 The geographic dimension of markets for PET-CT may vary depending whether the position is analysed at the level of awarding contracts or the provision of services to patients.

3.29 In the market to secure contracts to supply PET-CT, the position is highly uncertain; the existing structure of contracts may not persist for longer than 13 months (the North and South Contracts expire on 31 March 2015 and InHealth has been given written notification to prepare itself to manage the exit process).[32] Therefore, beyond the transitional period, the zones of competitive activity within England (i.e. the area within NHS England has statutory responsibilities for commissioning of PET-CT) are fluid and consideration of a national market (or a range of outcomes within an upper boundary of a national market) may be appropriate. That position could change if, for example, the framework for national commissioning were to be set; at that point, it may be possible (and may be appropriate) to define geographic markets on a narrow basis. For example, if the existing North/South split were adopted, it may be necessary

[32] Appendix 2.2.

to consider the competitive characteristics in the North separately from the South, and vice versa.[33]

3.30 In relation to local markets within which providers offer PET-CT, the National Cancer Research Institute PET Core Lab maintains a database of PET Facilities.[34] Generally speaking the ability of patients to access PET-CT is limited to those scanning facilities to which it is plausible for the patient to travel. While this will vary amongst different patients, in general, the presence of scanning facilities tends to be clustered around major population centres and tertiary cancer treatment centres.

3.31 Approximately [REDACTED] of PET-CT scans are delivered by mobile units. [REDACTED] Use of cyclotrons is discussed in more detail in InHealth's answer to Question 5 of the OFT's questionnaire.

(c) Other market characteristics

3.32 Because of way the NHS is constituted, there is separation between the chooser, the user and the payer of PET-CT services (as with all NHS services). This influences the process of competition in markets for PET-CT, so that it must be assessed with respect to the choices of those different elements of competition independently. Specifically:

3.32.1 The 'chooser' of the supplier of PET-CT services is further divisible into the role played by NHS England in awarding contracts that grant the right to supply PET-CT in a defined area (for example, as awarded by NHS England in the South Contract), and the various NHS institutions, who may choose between the different service models above (for example, whether to maintain the ability to self-supply or whether to source an independent sector scanner that might be located on-site at the NHS site). This is characterised in the South Contract thus:

> [REDACTED][35]

where a 'Health Service Body' is defined to mean:

> [REDACTED][36]

[33] This is speculative, and purely illustrative. InHealth has no information as to any final view taken by NHS England on these issues, and in light of that uncertainty, reserves its views as to the competitive position in relation to any such market.
[34] http://www.ncri-pet.org.uk/pet_facilities.php.
[35] South Contract, [REDACTED].
[36] South Contract, [REDACTED].

3.32.2 The 'user' of the PET-CT services is the patient and/or the referring institution, who derives the clinical use from the outputs of the test;

3.32.3 The payer of the PET-CT service is the commissioner (and ultimately, the taxpayer).

3.33 Although there remains flexibility at the margins, it is the award of contracts for the supply of PET-CT services via the commissioning process that largely determines the scope for supply of PET-CT to NHS patients. Therefore, this aspect of competition is likely to be of over-riding concern to any prospective supplier of PET-CT. Such suppliers, including InHealth, can remain viable in areas where they are commissioned to provide service and, broadly speaking, are not generally able to supply services in areas where they have not been commissioned to provide that service. For all service modes, but particularly when offering mobile services, building sufficient scale is important to enable commercial provision of PET-CT. For example, InHealth currently operates [REDACTED]. Each new mobile unit needs around [REDACTED]. Coupled with this challenge to build scale is the need to secure other scarce resources (such as suitably experienced and qualified drivers, able to deal with issues associated with facilities that are large, involve radioactivity and move from place to place on public roads).

3.34 Because there is competition 'for the market' in relation to the supply of PET-CT, the market share of any given provider within an area where they have been commissioned to supply services may not provide a clear picture of the competitive position. For example, both InHealth and Alliance Medical have a higher market share within 'their' commissioned areas than they do nationally, but (in an environment uncoloured by competition concerns in other closely related markets such as FDG) both will face the need to compete to re-secure their position in a fresh round of commissioning of services.

3.35 One question that deserves careful assessment is: are the NHS organisations that deliver PET-CT themselves operating in the same market as the independent sector providers such as Alliance Medical and InHealth? In the time available to prepare this submission, InHealth has not had sufficient opportunity to consider this matter so as to reach a concluded view. However, InHealth believes that if the NHS 'self-supply' of PET-CT is considered to be in the same market as independent sector supply, then it is necessary to go further and consider the nature and degree of competitive constraint it provides. It is likely to be of a less effective nature – potentially much less effective – than the competitive effect of a commercial player of comparable size. In particular, the question of how competition operates at the level of the choice by individual NHS

Trusts whether to opt from amongst the service models for PET-CT delivery may be relevant, as well as the question of whether NHS institutions differ from commercial organisations in their responsiveness to, for example, market signals to increase capacity.

Pricing and competitive dynamics

3.36 InHealth's experience of the price of PET-CT flows primarily from its experience as a PET-CT supplier, and as a tenderer in competition to win contracts to supply PET-CT.

3.37 The price of PET-CT can be set in individual contracts [REDACTED].

3.38 In bidding for future contracts, the pricing of PET-CT services may be affected by the setting by Monitor of the National Tariff. As set out at answers to question 1 and 22 to the OFT's questionnaire, changes to the Nuclear Medicine Tariff are likely to have substantial impacts on the pricing of PET-CT in the future. It is also likely that the relationship between these two price mechanisms is two-way – that is, that a lack of competition in the market for PET-CT might significantly compromise Monitor's ability to secure benchmark information that would enable it to set a price for NHS tariffed providers that correctly reflected the outcome in a competitive market. Setting the National Tariff is likely to interact most directly with the commissioning of services for static scanning facilities, since the delivery or operating model for returning data via HRG reference data (in essence, the cost model Monitor uses to set the National Tariff) assumes delivery in static rather than mobile locations and therefore the costs allowed to be counted are different from those in a mobile model (specifically, they are more limited).[37]

3.39 Bidding/commissioning arrangements - As set out in InHealth's answer to Questions 3 and 17, 18 of the OFT's questionnaire, there is inherent risk associated with commissioning and contract renewal leads to imbalances in the negotiating power and investment choices for the players in the market.

3.40 Table 1 identifies providers of PET-CT and their share of scans undertaken nationally.

[37] Appendix 1.3 and 1.4. An 'HRG' is a 'healthcare resource group' – the charging unit considered under the National Tariff arrangements.

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Type of Provider	Estimated Share of all scans	Example Providers	Details	FDG supplier
NHS Trusts (including res. Hosps)	35%	• UCL, KCL, Marsden, Christie, Oxford, etc.	• Some bigger Trusts have 2 scanners on site	• Commercial supplier and / or self supply
National Specialist Firms	45%	• Alliance Medical (22,000 scans) 25%	• Offered at 14 locations nationwide • 3 mobile scanners and 7 static sites	• Commercial supplier
		• InHealth (15,000 scans) 20%	• Offered at [REDACTED] locations nationwide • [REDACTED]	• Commercial supplier
Private Hospital Groups / Charities	Small	• The London Clinic	• Based in Harley Street	• Commercial supplier
		• HCA	• Delivered at the Harley Street Clinic London	• Commercial supplier
		• Cobalt Health	• Medical charity. Based in Cheltenham, Gloucestershire	• Commercial supplier
		• Paul Strickland Centre	• Medical charity. Based at Mt Vernon Hospital	• Commercial supplier
PMI	Negligible	• Bupa	• Delivered at the Cromwell Hospital	• Commercial supplier

3.41 As noted above, because the independent sector providers bid for their contracts, and have defined areas within which they are the designed commissioned supplier of PET-CT to the NHS, the total national share of PET-CT scans undertaken does not provide a particularly useful guide to the question of whether PET-CT suppliers are constrained by competition.

3.42 As noted above, the expected re-tendering of the contracts for the North and South regions (or some other variation on the theme of a tender for national PET-CT services) is likely to be the next significant development in the competitive deployment of PET-CT in the UK.

3.43 The answers to questions 1-6 and 17 are set out below:

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Q1. Please estimate the total market size for PET-CT scans by volume and value for the past three years. Please state the source of and assumptions made for your estimates.

A1.1 InHealth estimate the market size in England, Wales and Scotland to be 95,500 scans per annum. This aggregate figure is calculated by reference to the number of scans conducted by provider in each location.[38] Growth over the past 3 years has averaged 10,000 incremental scans per annum (c10%).[39]

A1.2 Value is much harder to determine. However, assuming a price per PET-CT scan in the range £750 -£1000, then the value of the market for scans is around £75-£100 million. InHealth estimates that price point based on:

- InHealth's own price for a scan to the Department of Health which is currently [REDACTED] per scan. Prior to the contract extension in April 2014 the price was [REDACTED] per scan.
- The Nuclear Medicine Tariff for 2013/14 set the price per scan at £748 per scan. However, the 2014/15 tariff will remove the set price per scan and local CCGs and providers will be left to negotiate the prices with local CCGs.
- The impact assessment, which accompanied the initial draft tariff release from Monitor in September 2013 suggested a value of PET-CT scans outside the National Contracts of around £6.5m.[40] InHealth's view is that this analysis is deeply flawed as it is based on inaccurate volume data (as set out in the submission made to Monitor's Payment by Results (PbR) team by the Clinical Reference Group in 2013.[41] InHealth believes a more accurate estimate would be £70m.

Q2. Please complete the table attached in Annex I in Word or Excel format, providing details of InHealth's PET-CT customers for each of the past three years separately.

A2.1 See the populated table – Appendix 2.1.

A2.2 In relation to margins, [REDACTED]. A fuller explanation of how PET-CT is provisioned in the UK is set out above in the rest of section 3 of this submission. InHealth Group Limited's post tax margin for 2012/13 was [REDACTED]. This takes account of all revenue generating activities to the NHS (around [REDACTED] of InHealth's business) and independent sector clients. While some of these activities generate higher margins than others, these services are sought from InHealth by its clients as part of a package of

[38] Appendix 1.2

[39] This figure is likely to include some (immaterial) private patient activity (around 2% of total).

[40] Appendix 1. 3.

[41] Appendix 1.4. PbR is the name given to the arrangements put in place for NHS funding, underpinned by the National Tariff, for payment to providers by volume of treatments provided.

services, particularly in the context of AQP or direct access diagnostics.[42] The model for provision of managed services to the NHS means significant capital investment up front, the recovery of which is amortised over the life of the contract and therefore contracts are often loss making in the early years.

A2.3 The PET-CT South contract is about to enter its final year of delivery, and it is therefore at the tail end of an investment cycle. As noted in the submission, there is considerable uncertainty as to future trading conditions, given the lack of data about procurement intentions currently available. InHealth expects that any new contract is likely to rely more on static facilities and to have less reliance on mobiles, whose delivery is inevitably intermittent in nature. [REDACTED][43] [REDACTED] The range of activity is a significant factor in margin calculation and the benefit of a contract like PET-CT South is the ability to cross subsidise high volume referral areas with those whose patients are rural and isolated who might otherwise have access to a PET-CT service at all.

Q3. Please state for each of the contracts whether the volume of PET-CT scans is fixed or if there are any guaranteed volumes? Please provide copies of two representative contracts so that we can become familiar with the terms of those contracts.

A3.1 [REDACTED] Please see contracts attached as Appendix 3.1 and 3.2 being those for Nottingham City Hospitals NHS Trust and PET-CT South.[44] [REDACTED].

A3.2 In Nottingham, [REDACTED][45, 46].

3.1Please indicate the terms of any termination clauses and/or mechanisms in the contracts to allow for changes in cost? Please provide any previous examples of price changes during contracts.

A3.3 Please see [REDACTED] of the PET-CT South contract [REDACTED].[47]

A3.4 [REDACTED]

Q4. Who do you consider your competitors are for PET-CT scanning? Please explain your answer.

A4.1 All of InHealth's competitors are regulated by the same provisions that are set out in Section 6 of the submission: noting that the provision of the scanning is regulated (unlike the supply of FDG).

[42] 'AQP' or 'any qualified provider' is the set of arrangements in the NHS whereby providers are able to offer services to any patient who wishes to be treated by that provider, subject to suitable regulatory and clinical licensed being established.
[43] Appendix 2.2 (Expiry notification)
[44] [REDACTED].
[45] [REDACTED]).
[46] InHealth estimate.
[47] Nottingham references to follow

BUSINESS SECRETS REMOVED

A4.2 InHealth's competitors involved in the provision of the scanning are:-

- the NHS who operate services (see Appendix 1.3) or rely on providers such as Alliance Medical and InHealth for managed services: there are 5 such in operation outside the scope of the National Contracts respectively at Nottingham (InHealth) and Guildford, Preston and Birmingham (Alliance). By reference to Appendix 1.3 InHealth believe that the NHS supplies over 55% of the total volumes for England, Wales and Scotland.
- Alliance Medical, the providers of the PET-CT North Contract and against whom InHealth competitively tendered for the National contract services.
- Cobalt, who provide a service to the Bristol area commissioners and against whom InHealth competed in an OJEU procurement for that service.

Q5. Do you consider hospitals beginning to self-supply PET-CT scanning as credible alternatives to established operators such as In-Health or Alliance Medical? Please explain your answer and provide an assessment of the credibility of such entry. Ideally, this response should include specific examples and the contact details of those organizations.

A5.1 Please see the response to Question 4 above and the discussion in Section 3 of this submission.

A5.2 Hospitals are already supplying in excess of 50% of the market for PET-CT scans and are therefore established and credible, and not merely 'beginning' to supply. There is no guarantee that sourcing of PET-CT services from the independent sector will necessarily continue (although the freedom of NHS England to cease to commission services is subject to the requirements of the HSCA2012 and the rules on commissioning (for example, the section 75 regulations), and the application of competition law). It is clear to InHealth from current discussions regarding the future of the National contract services which expire in 2015, that the NHS is considering all options and may be open to self-supply of all PET-CT services – with the objective remaining (as in 2005) addressing what are still relatively low volumes of scanning take-up compared with other Western European healthcare systems. While InHealth, understandably, considers that the independent sector can and should have a vital role to play in improving outcomes for NHS patients, it is not naive about the regulatory risks associated with the NHS commissioning structure.[48] The scale of NHS provision is evident from Appendix 1.4. InHealth remains of the view that, in practice, there may be some limits on the ability of the NHS to deliver PET-CT in a way that would address reduced supply by the independent sector.

[48] See also Appendix 2.2.

A5.3 InHealth consider that it is likely that if the NHS were to opt to seek widespread in-house operation services there will be many scanner installations with suboptimal scan volumes and therefore the effective price for scanning may be higher than described above.

A5.4 As evidence of the ability to deliver the services in-house, tenders for PET-CT services in Wales, and in Cambridge have been issued respectively in 2006 and 2008 and in all cases the NHS Trusts involved not to outsource.[49] Contact details for NHS contacts are given below:

[REDACTED]

[REDACTED]

[REDACTED]

Q6. Please provide a list of PET-CT contracts coming up for tender in the next 3 years and provide InHealth's estimates for: i) the value of scans and FDG by contract; ii) the volume of scans and FDG by contract; iii) variable profit margins per scan.

A6.1 The detailed terms of the existing contracts are not known to InHealth and therefore any of the following may be capable of further extension unless noted otherwise:-

- PET-CT South which expires 31 March 2015
- PET-CT North which expires 31 March 2015
- QE Birmingham which expires 2015 (10 years from 1995 but extended once already)
- Bristol which expires April 2015
- Preston which expires 2017

A6.2 The table below indicates an annual volume and value (as per Appendix 1.2) and also assuming a price per scan of [REDACTED]; except for Bristol (which InHealth believes provided a price of around [REDACTED], reflecting the fact that the provider has a charitable business model which makes a difference to its VAT position in particular). It is impossible to assess FDG value or variable profit based on information available to us.

Site	Annual Volume	Est annual value
PET-CT South	See Appendix 1.1	See Appendix 1.1
PET-CT North	[REDACTED]	[REDACTED]
Birmingham	[REDACTED]	[REDACTED]
Preston	[REDACTED]	[REDACTED]
Bristol (scanned at Cheltenham)	[REDACTED]	[REDACTED]

[49] See Appendix 5.1, 5.2 and 5.3

Q17. Do you consider any PET-CT customers to have negotiating strength in their procurement of PET-CT Scans. Please explain your answer and give examples

17.1 InHealth's negotiation power is limited. Although InHealth negotiates with CCGs about the level of service provided, the NHS can self-supply PET-CT scans and this means that they do exercise considerable bargaining power. It is never in InHealth's interests to seriously undermine a relationship with a customer responsible for [REDACTED]of its revenue.

17.2 As noted elsewhere in this section 3, there is considerable uncertainty as to the future structure of any future procurement of PET-CT and already InHealth is being requested to manage its exit from the services to new providers, with no knowledge of the identity or configuration of those new providers.[50]

17.3 As noted elsewhere, [REDACTED].

17.4 [REDACTED].

17.5 InHealth faces financial penalties if it fails to complete the scan on the day or misses the 5 day window. However if an NHS provider fails to complete the scan on the day, the only consequence is a delay in lead times.[51]

[50] Appendix 2.2.

[51] Appendix 3.1 [REDACTED].

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4 FDG Supply

4.1 This section 4 provides evidence concerning the supply of FDG.

How is FDG produced?

4.2 Radioactive isotopes are produced in a cyclotron (a particle accelerator) by bombarding a target with charged particle beams. The FDG tracer used in PET-CT is produced from these isotopes in synthesis units/modules contained in "hot cells". These automated synthesis modules are commercially available and can produce several batches of FDG per day. The entire facility (cyclotron, hot cells, QA, packing & dispatch) is termed a radiopharmaceutical production unit or "RPU". FDG is labelled with Fluorine-18 isotope which has a 2 hour half-life (as mentioned at question 20 of InHealth's responses to the OFT's questionnaire). Other tracers (currently used exclusively in research institutes) are labelled with shorter-lived isotopes such as Carbon-11 (20 minute half-life). These tracers are limited to use at scanning sites with on-site RPUs.

Relationship between FDG and PET-CT

4.3 A critical requirement of a PET-CT provider is to source FDG. Service Specification B02/S/a for provision of PET-CT in the NHS provides that:

> *The Provider shall ensure that:*
>
> • *A reliable and adequate supply of Tracer is available for the performance of Scans*
>
> • *The quality of Tracer is:*
>
> – *Appropriate for the Scans*
>
> – *Demonstrable by audit*
>
> • *Any supplier of the Tracer has in place a quality control programme sufficient to provide assurance of the integrity of the product, and methods for validation*
>
> • *The Tracer is transported to the Facilities within such timescales as will facilitate the safe and efficient administration of the Tracer*
>
> • *That all Tracers are prepared under Good Manufacturing Practice as defined by the MHRA that all transport of radioactive material is compliant*

with the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) regulations. [52]

4.4 Although some alternative tracers can be (and are) used in some circumstances, for the core services under review, there is no alternative to FDG. Evidence for this can be seen in the contracts –for example, the South Contract defines 'Tracer' to mean:

[REDACTED][53]

4.5 In any event, to the extent that there might, in future, be alternative tracers developed, the facilities necessary to produce those are likely to be similar to the facilities necessary to produce FDG, meaning that any analysis of the impact on competition in PET-CT markets of that new tracer would be identical.

4.6 Securing a reliable, resilient and stable supply of FDG is of sufficient strategic significance that specific provision is made for it in the contracts for the supply of PET-CT. It is the responsibility of the PET-CT provider to source all medical consumables, including tracers.[54] For example, the South Contract mirrors the NHS Service Specification that:

[REDACTED][55]

4.7 Obtaining FDG is therefore essential to the supply of PET-CT.

Regulation of commercial supply of FDG

4.8 The production of FDG is not regulated as the provision of a health care service; instead, FDG is regulated as a medicine (and, specifically, as a radioactive medicine). Neither Monitor nor the CQC directly regulate the production of FDG.

4.9 RPUs must be licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) to supply tracers for PET-CT imaging commercially. This licence is referred to as a Marketing Authorisation ("MA").

4.10 In a cyclotron that does not have an MA, tracers can also be supplied for individual patients under a "Specials" licence. This is the licensing mechanism used by research institutes for trial scans (some commercial RPUs use this mechanism to supply tracers

[52] http://www.england.nhs.uk/wp-content/uploads/2013/06/b02-positron-emis-tom.pdf
[53] South Contract, [REDACTED].
[54] For example, see South Contract, [REDACTED].
[55] South Contract, [REDACTED].

with less frequent use than FDG, where their MA extends to FDG but not those other tracers). Non-commercial RPUs (such as the NHS cyclotrons) use this mechanism to supply their on-site scanners. Specials licence tracers cannot be advertised and cannot be supplied if an equivalent MA licensed product is available. The current MA holders (Siemens PETNET, Erigal, IBA and GE) are listed on the MHRA website.[56]

4.11 InHealth has set out its supply arrangements in its answer to question 8 and 11 of the OFT's questionnaire.

(a) Defining the market for FDG

The product market

4.12 NHS Policy Reference NHSCB/B02/PS/a describes 'Positron Emission Tomography - Computerized Tomography (PET-CT) using: 18F fluorodeoxyglucose (FDG PET-CT) or Non-FDG tracers'.

4.13 However, InHealth does not consider that there is any effective substitute for FDG as a tracer suitable for use in PET-CT. That is, although other tracers can be (and are) used in other clinical contexts and in PET-CT at some times and under some circumstances, there is no other tracer that has the combination of radiopharmacological features that make it suitable as an alternative to FDG.

4.14 The relevant product characteristics of commercial FDG are that it is:

4.14.1 Provided under circumstances where the provider can offer that FDG for clinical use under commercial conditions (that is, the source of the FDG is a commercial RPU with an MA that covers FDG supply); and

4.14.2 In accordance with Good Manufacturing Practice as defined by the MHRA.

The geographic market for FDG

The capacity and reach of RPUs

[56] Before a medicine can be sold in the UK, a number of licences are essential. Products with a UK marketing authorisation have a licence number in the format 'PL 12345/0001'. The first two characters are always the letters 'PL'. The product licence number can be found on the packaging of the product. These numbers are linked to the Summary of Product Characteristics (SPC) and patient information leaflet (PIL) available on the MHRA website. For the SPCs and PILs for FDG, see http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/?subsName=FLUDEOXYGLUCOSE%20(18-F)&pageID=SecondLevel.

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4.15 Tracer batches are shipped to scanning sites by specialist couriers. During this time quality control testing is carried out at the RPU after which the tracer is released for use and patients can be injected. The ideal delivery range is 2 hours by road. However under some circumstances, a maximum range of 4 hours or more is feasible without unduly impacting on the number of patients scanned per day. Several batches will be delivered during the course of the day.

4.16 Given these constraints, the location of cyclotrons determines the range of possible locations for the provision of PET-CT. If any part of the UK is more than 4 hours from the RPU there is a risk that patients in that area will be unable to be provided with PET-CT services (even from a mobile scanning unit).

4.17 To deal with the decay of the FDG (as set out at InHealth's response to Question 19 of the OFT's questionnaire), the dose of FDG will be 'over-supplied' in terms of the radioactive dosage on the basis that more travel (and also more decay) is allowed. This can create additional risks to be managed appropriately since, if the dose is over-supplied, there are implications for the clinical staff administering the dose – for example, they will need to ensure that the dose is administered at the correct level, staffing levels will also need to be adjusted as clinicians will be exposed to more radioactive isotopes.[57] In places such as in Scotland, patients must travel further to a scanner which is accessible by a RPU in the requisite time.

4.18 NHS cyclotrons are regularly used for research purposes. Most NHS cyclotrons (which produce the FDG supply and is explained in more detail below) do not have the relevant licences and GMP approvals to produce FDG commercially; these cyclotrons are permitted to manufacture FDG for research, but do not have an MA and hence cannot provide FDG for use in PET-CT other than under a Specials Licence (which allows provision of FDG to an identified patient on an exceptional basis). Where this happens, the cyclotron will be on the same site as the scanner.

4.19 At other NHS sites where a cyclotron is present, the NHS has found that they have not been able to produce FDG at a commercially competitive price. In these cases, the NHS sites will purchase FDG from the commercial suppliers. Non-NHS providers must buy their FDG supply from a commercial supplier (if there is one available). NHS

[57] More staff are needed to ensure that the aggregate dose of radiation for any given staff member remains below acceptable levels of exposure. In a mobile environment (quite a confined space), operating at optimal levels of throughput (14-16 patients per day) staff will be exposed to the radiation injected into patients both as a result of administering the injection but also because the patients are 'hot' by virtue of the injection; dose control is therefore important for staff and patients. If the staff dose levels risk exceeding recommended levels (and these are defined with reference to IRMER), staff are removed from shifts – staff wear badges to monitor their exposure.

providers have the option, in the absence of an accessible commercial supplier, to self-supply under the Specials Licence in some circumstances.

4.20 Therefore, the NHS may under some circumstances be able to provide the diagnostic service *and* supply of FDG to itself. However, critically, the majority of NHS providers procure FDG from commercial providers (and by virtue of the regulatory arrangements described above, provided there is scope to use a commercial producer of FDG, InHealth's understanding is that the NHS PET-CT provider *must* do so).

4.21 InHealth's response to Question 5 of the OFT's questionnaire also discusses the NHS's capacity for self-supply of PET-CT.

FDG supply arrangements between RPU operators and PET-CT scanning service providers

4.22 The contracts are annexed to this document.

4.23 As set out the response to the OFT's questionnaire at questions 8 and 13, as part of the NHS managed service contract, [REDACTED].

4.24 InHealth buys FDG from IBA Molecular and Siemens.

4.25 Details of the back-up provisions are also discussed in answers to Questions 8, 9, 10 and 12 of the OFT's questionnaire. Arrangements for backup are well developed and can be relatively seamless between suppliers for most scanning sites.

4.26 As noted above, the contracts for the supply of PET-CT require the PET-CT provider to make arrangements for a reliable supply of FDG. The contractual basis for back-up arrangements is generally set out in FDG supply agreements. Although the simplest and best way to establish back-up supplies would be to contract with two providers, , it is in theory possible to secure the same outcome by using a primary supplier and requiring that provider to enter into arrangements with other suppliers to offer resilience. [REDACTED]

[REDACTED]

4.27 As a result, regardless of whether it contracts directly or indirectly with two suppliers, each PET-CT provider is, necessarily, dependent on the output of at least two suppliers of FDG. And in practice, for the reasons noted above, InHealth would normally not willingly rely on backup resilience supplied by a provider with whom it did not have a direct customer relationship.

BUSINESS SECRETS REMOVED

The impact of the acquisition on competition between FDG suppliers

4.28 By definition, appropriately produced FDG from different suppliers is undifferentiated; the FDG bought one supplier is easily substituted for another (this characteristic is what enables back-up/resilience arrangements to be effective). FDG suppliers can only compete for work based on price, availability and reliability of supply.

4.29 Prior to the acquisition, the UK suppliers of commercial FDG are IBA, Siemens and Alliance Medical. InHealth explains the market position in their response to Question 11 of the OFT's questionnaire, but in summary:

4.29.1 Alliance Medical previously acquired another FDG supplier, Erigal and prior to the acquisition supplies [roughly half of the UK's FDG needs]. Together with IBA, the Alliance Medical share of supply with rise to 66%.

4.29.2 GE Healthcare owns one cyclotron and has the MA licence, and so could produce FDG commercially. However, this cyclotron is currently inactive.

4.29.3 Siemens PETNET is the other supplier with 24% of the national supply.

4.30 The change in market structure as a result of the acquisition is set out in Table 2 below.

Region	**Suppliers of FDG ***				
	Before the acquisition			**After the merger**	
	Alliance Medical	Siemens	IBA	Alliance Medical/IBA	Siemens
London/South	1	1	1	2	1
North-West England	3	1	1	4	1
Northern Ireland	NHS or Alliance Medical			NHS or Alliance Medical	
Scotland	NHS only			NHS only	
South-West England	NHS or Alliance Medical			NHS or Alliance Medical	

- Note that we have not included GE Healthcare in the above table. GE Healthcare has a cyclotron in Amersham with an MA enabling them to sell commercially, however InHealth believe that the cyclotron is currently inactive.

4.31 Prior to the acquisition, InHealth and other PET-CT service providers could choose between three suppliers of FDG (Siemens, IBA and Alliance Medical).

4.32 As a result of the acquisition there will only be two active commercial suppliers of FDG across England (and in each of the North and South regions): Siemens and Alliance Medical.

4.33 [REDACTED]

4.33.1 [REDACTED]

4.33.2 [REDACTED]

4.33.3 [REDACTED]

4.33.4 [REDACTED]

4.34 [REDACTED]

4.35 [REDACTED]

4.36 The answers to questions 7 to 15 are set out below:

Q7. Is there any alternative to FDG for PET-CT Scanning. Please support your answer with references to reports and academic papers if appropriate

A7.1 FDG is the foremost tracer used for PETCT imaging, both in the UK and globally.

A7.2 InHealth do not consider that there is an alternative to FDG for PET-CT scanning in the market that InHealth supply, nor for meeting the majority of clinical requirements for PET-CT in the UK (with the exception of dementia).

A7.3 All the clinical evidence base for the use of PET-CT in oncology is based on FDG.

A7.4 There are minimal applications for, and negligible current use of, non-FDG tracers.[58]

A7.5 In addition to limited manufacturing and availability, a significant constraint on the development of non-FDG tracers in the UK is the lack of clinical expertise and knowledge base, and the restrictions placed on authorisation for use of these tracers (by ARSAC).[59]

A7.6 More recent novel isotopes such as F-Choline and Gallium are used in application with specific cancer types and are not suitable for broader oncological referrals. There is also the issue of speed of decay of half-life relative to scanning footprint.[60]

A7.7 In the USA, clinical practice is moving towards using PET-MRI scan which use the imaging capability with reduced exposure to radioactivity. However, in the UK there

[58] www.rcr.ac.uk/docs/radiology/pdf/2013_PETCT_RCP_RCR.pdf
[59] www.rcr.ac.uk/docs/radiology/pdf/BFCR(13)3_PETCT.pdf
[60] Appendix 9.7 sets out a record of discussions concerning the introduction of new, non-FDG tracers.

is one such scanner installed (University College Hospital London), with a second planned at Guy's and St Thomas' NHS FT. This sort of imaging is therefore estimated (based on availability and pace of NHS adoption) to be approximately 5 years away from being widely used in a non-research context.

Q8. Please complete the table attached in Annex II in Word or Excel format, providing details of InHealth's FDG supply arrangements for the past three years, including back-up supply arrangements

A8.1 See table appended as Appendix 8.1. Please note that (per the explanation below at question 12), back-up is not separately contracted. Its provision relies on the existence of a substantive supply contract.

Q9. Please state for each of the contracts whether the volume of FDG is fixed or if there are guaranteed volumes? Please provide copies of two representative contracts so that we can become familiar with the terms of those contracts

A9.1 [REDACTED][61]

9.1 Pease indicate the terms of any termination clauses and / or mechanisms in the contracts to allow for changes in cost? Please provide any previous examples of price changes during contracts

A9.2 Please see contracts, [REDACTED].

A9.3 [REDACTED]

A9.4 [REDACTED][62]

Q10. Please list by order of priority the criteria or parameters suppliers of FDG compete at when negotiating or bidding to win contracts with In-Health

A10.1 The existence of a regulatory framework and manufacturing licences for commercial supply means that the suppliers are subject to a degree of compliance from which any client may draw comfort in terms of the standards to which the isotope is manufactured and delivered. When InHealth selected InHealth partners in 2007/8 the main factors were:

[REDACTED]

A10.2 [REDACTED]

A10.3 [REDACTED]

[61] [REDACTED]

[62] Appendix 9.5

BUSINESS SECRETS REMOVED

Q11. Who are your credible alternative suppliers and future options for sourcing FDG? Please explain you answer and support your response with internal documents showing options assessment, if available?

A11.1 [REDACTED]. None of the NHS operators of cyclotron capabilities have a commercial licence to produce and rely on specials licenses or else only use their FDG production in a research context or as part of self-service. [REDACTED]

Q12. If different to those listed in question 11 above, please state credible alternative suppliers and future options for sourcing back-up FDG? Please explain your answer, with reference to what is important in back-up supplies and how many back-up suppliers are required

A12.1 Please note that back-up supply is not a stand-alone arrangement because, at the inception of the national contracts, it was evident that a single source supplier of FDG to us as a national contract provider represented too great a risk of reliance on a single provision in terms of both price competition and robustness of supply. (This is recognised implicitly in the regime of contractual penalties for lack of delivery, for example).[63]

A12.2 [REDACTED]

A12.3 [REDACTED]

Q13. Please provide your current back up supply contracts

A13.1 For the reasons set out above, the backup obligation is part of the standard supply contract of each supplier.[64]

Q14. Has investing in and operating a cyclotron for your FDG supply been considered, or is currently being considered, alone or in partnership with any other organisation?
14.1 Please provide the decision reached on this and any analysis undertaken to inform this decision including costs, timescales (how quickly could a cyclotron be installed and used to supply your FDG needs?), analysis of returns on investment, assessment of third party options.

14.1 [REDACTED][65]

14.2 [REDACTED][66]

14.3 [REDACTED][67]

14.4 [REDACTED][68]

[63] Appendix 3.1.
[64] See [REDACTED] .
[65] Appendix 14.1.
[66] Appendix 14.2
[67] Appendix 14.3
[68] Appendix 14.1.1.

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Q15. Are you aware or have you been approached by organisations considering entering supply of FDG?

A15.1 InHealth's only relationships are with Siemens, and IBA. InHealth chose not to contract with Erigal (now Alliance Medical) for the reasons outlined in the response to question 10.

A15.2 InHealth is not are not aware of any other commercial manufacturing interest in the UK. A French company AAA operates in Europe and may have an interest in acquiring the limited Siemens cyclotron footprint in Europe.

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5 Remedies

5.1 This submission set out InHealth's concerns regarding the vertical and horizontal effects of the acquisition. As noted previously, InHealth have material concerns about the acquisition.

5.2 At present, the North and South Contracts are due to expire in April 2015. The uncertainty surrounding the tendering process compounds InHealth's concerns:

5.2.1 As a practical matter, NHS England has not yet confirmed a senior official (the procurement leader) to take overall responsibility for commissioning new contracts for the supply of PET-CT.

5.2.2 Scoping the contracts (for example, determining the likely break-down across different areas) cannot be start until a procurement leader is appointed, the process of setting the scope itself will then take approximately 3 months.

5.3 It therefore remains unclear as to whether the North and South contracts will remain, and, for example, what the duration of any newly offered contracts will be (although InHealth's current commercial planning is based on its estimate of 3-5 years). In light of the delay in appointing the procurement leader, and the duration of the scoping, procurement and bidding process, unless the process is rushed, it seems likely to InHealth that there is a risk that the new contracts may not be in place by April 2015 at all.

5.4 In any event, whatever arrangements are put in place (that is, whether new contracts are brought to market through the commissioning process in good order, or whether there is a scramble to put in place bridging arrangements), it is clear that the competitive position of all PET-CT providers will be affected by the acquisition. Specifically, Alliance Medical will have practical advantages in its ability to make positive statements about the reliability of its supply of FDG that no other player can match.

5.5 At this point, in light of the considerable market uncertainty associated with the PET-CT market, InHealth does not have a concluded view as to how its concerns might be addressed. However:

5.5.1 [REDACTED]

5.5.2 [REDACTED]

5.5.3 [REDACTED]

5.5.3.1 [REDACTED]

5.5.3.2 [REDACTED]

5.5.4 [REDACTED]

5.5.5 [REDACTED]

5.6 The answers to questions 16-22 are set out below:

Q16. Do you consider that you have any negotiating strength in purchasing FDG? Please explain your answer and supply examples? Will the merger impact on your negotiating strength?

A16.1 InHealth's negotiations with Siemens secured price reductions in 2013[REDACTED]

A16.2 At the time of contract extension negotiations in 2012/13 it was evident that the FDG suppliers considered their production capacity to be optimised in the current configuration, apparently indicating that there was a finite capacity and therefore an inability to offer alternative pricing. [REDACTED]. InHealth notes some further concerns in this regard at the response to question 22 and in section 4 of this submission.

A16.3 [REDACTED]

A16.4 [REDACTED]

(Q17 is listed under section 3)

Q18. During the meeting at Fleetbank House, you indicated that you were not aware of the intention of IBA to sell its interest in the provision of FDG. [REDACTED]

A18.1 [REDACTED][69]

A18.2 [REDACTED][70, 71]

A18.3 [REDACTED]

18.1 in the absence of the above, please provide any documentary evidence supporting that at any time in the past three years you have considered a similar transaction or any other documentation corroborating that In-Health could be described realistically as a possible purchaser if it had been aware of the intentions of IBA. These could include internal documents, communications with investors or any others you consider relevant

[69] See Appendix 8.3. Note that this notification did not follow the process undertaken when a previous change of control had occurred – see Appendix 8.2.

[70] Appendix 18.1.

[71] Appendix 18.1

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18.1 InHealth is privately owned, debt free and [REDACTED].
18.2 [REDACTED]
18.3 [REDACTED]

Q19. In your view will the merger have any impact on competition in the supply of FDG and/or the supply of PET-CT or other related sectors. Please explain answer?

A19.1 Please see the response set out in sections 1 to 5 of this submission. [REDACTED]

A19.2 [REDACTED]

A19.3 InHealth also have concerns that the supply of novel isotope other than FDG may be controlled by or constrained by another provider who can choose to locate scanning facilities proximate to its own cyclotrons for the promotion of those shorter half-life or novel isotopes in particular locations which it might not support in other locations. This could result in patient disadvantage because of potential access constraints for novel isotope and ultimately, impact the most widespread development of effective cancer treatments.

Q20. Generally are you aware of any feature/activities of the supply of FDG or related markets that you would like to bring to the OFT's attention?

A20.1 InHealth believe that there are a number of NHS installed cyclotrons being used in a research or local environment which might, with commercial support, be capable (in technical terms) of development to support commercial supply (that is, to seek to obtain an MA, meeting the various regulatory requirements including GMP). This has to be set against a context of current overcapacity in commercial provision (and hence the credible threat of entry deterrence Alliance Medical could pose to any entrant). It is also the case that of the total NHS installed base, few of the facilities are likely to be capable of manufacturing regulation compliance. It seems unlikely, given the overall prevalence of cyclotrons and the barriers to entry in terms of investment, regulatory approvals requirements and therefore timescales that other market entrants would emerge.

A20.2 InHealth understand that the Siemens cyclotrons have a lower finite capacity from those of Alliance Medical and IBA which indicates that whilst there is clearly sufficient cyclotron capacity for growth anticipated in the next few years, the underlying capacity split post-merger is more likely to be 72% to Alliance Medical and 28% to Siemens.[72]

A20.3 The geographic distribution is also worthy of note, in light of the fact that the FDG isotope has a 2 hour half-life and 4 hour maximum delivery range. Siemens operates 2 cyclotrons, one in Nottingham and one at Mount Vernon on the North Western side of greater London. For clients in Scotland and Northern England requiring commercially produced isotope, Alliance Medical is the only option. IBA had a facility in Rotherham

[72] InHealth estimates.

(Dinnington) which it withdrew from production in 2010. Its other facility is located in Guildford.

A20.4 FDG providers have been clear in their desire to increase the price of FDG, as part of a multi-pronged strategy including efforts to increase funding for PET-CT services using FDG.[73] InHealth has been advised that the UK has a low price for FDG, benchmarked against other OECD markets.[74]

A20.5 The area of dose reduction is an interesting issue. In the USA and Europe (but particularly the US where diagnostics tests generally are conducted on much higher numbers of the population) there is considerable focus amongst clinicians and equipment manufacturers in optimising equipment to minimise dose in both a general CT context but also an FDG context. Because the scanning volumes are much lower in the UK this has so far not had the same degree of focus, although it is starting to emerge as a clinical concern. [REDACTED] This may mean that the patient benefits of dose reduction are slower to develop in a UK clinical setting.

Q21. If you have identified any competition concerns in your submission please consider what remedies you would consider necessary to solve those concerns

A21.1 Please see sections 3 to 5 of this submission.

Q22. Please add any other comments or representations on merger control/competition issues you think the OFT should consider with regard to this merger and provide (if possible) documentary evidence supporting your representations or explain why such evidence are not available

A22.1 This submission (sections 1 to 6 and its appendices) constitutes InHealth's response to Question 22 (to the extent that it is not already covered by answers to Questions 1 to 21.

A22.2 Please note that as a result of the paper submitted to Monitor in relation to tariff guidance for 2014/15 the Nuclear Medicine tariff previously applicable to PET-CT has been abandoned in favour of locally negotiated prices for those services outside the 2 National contracts delivered by Alliance Medical and InHealth respectively.

A22.3 This removes any pricing benchmarks which might have been found in tariff and in contrast to Monitors assessment of the value of NHS delivery outside the contracts [REDACTED]. InHealth know from extension discussions with the Department of Health in 2012/13 that the reference cost returns by some trusts for their provision of PET-CT relying either on self supply or supply by other NHS organisations is deeply flawed, with

[73] Appendix 9.6, section 2.1 provides particularly clear evidence on this point.
[74] InHealth believe that comparative data in this regard could be sourced from **http://www.medicaloptions.co.uk/assets/PET12propv1EUe.pdf**

some trusts returning a total per patient price for a scan which is less than the cost of the isotope.

A22.4 InHealth consider in the context of this development that clarity of cost for the isotope will be a significant factor in effective local price negotiations.

6 Questions asked by the OFT at the meeting on Friday 3rd January 2014 and InHealth's responses

Has InHealth ever considered moving to supply FDG?

6.1 This question is answered in InHealth's response to Question 14 of the OFT's questionnaire.

Can/could InHealth perform both the North and South scheme services?

6.2 As set out in InHealth's response to Question 4 of the OFT's questionnaire, the PET-CT service is a national service. In theory, InHealth expand its operations to serve both regions. To do so would require a decision that the risks in commissioning from a single supplier nationally were outweighed by other advantages; while this would be a matter for NHS England, it is not an outcome that InHealth views as very likely.

At this time of uncertainty, what is InHealth doing to prepare for the future?

6.3 PET-CT is a specially commissioned service and InHealth contract with NHS England. The company is doing all that it can to engage with NHS England to understand the likely process of commission renewed contracts, as well as engaged with prospective customer NHS organisations.

6.4 [REDACTED]. The contracts that are coming up for renewal are set out in InHealth's answer to question 6 of the OFT's questionnaire.

Could InHealth work with the NHS to provide these services?

6.5 InHealth's response to this question is set out in its answer to question 5 of the OFT's questionnaire.

What is your view on IBA as a supplier?

6.6 InHealth's response to this question is set out in its answer to question 16 of the OFT's questionnaire.

6.7 Siemens produces approximately [REDACTED] of the volume of FDG required by InHealth, whilst IBA produces [REDACTED].

Noting the geographic restrictions of a cyclotron, do you need Siemens and IBA as a supplier?

6.8 Yes, whilst most Siemens/IBA cyclotrons cover most areas, there are some geographic areas that are only covered certain cyclotrons.

6.9 InHealth also needs back-up/resilience built into its commercial agreements as set out in the OFT's questionnaire at questions 8, 12 and 13.

Did InHealth think that IBA was in trouble prior to the merger?

6.10 This question is answered in InHealth's response to Question 18 of the OFT's questionnaire.

When choosing a supplier are there any factors, other than price, which affect the decision?

6.11 This question is answered in InHealth's response to question 10 of the OFT's questionnaire.

[REDACTED] of InHealth's turnover is related to PET/CT. What percentage of that is related to NHS managed services contracts?

6.12 Approximately [REDACTED] of that revenue is raised through the South Scheme Contract. The rest of the revenue comes from the fixed Nottingham scanner which was built (with its own cyclotron) prior to the Scheme's initiation.

How much competition is there when negotiating a managed service contract?

6.13 This question is answered in InHealth's response to Questions 4, 16, 17, 19 and 20 of the OFT's questionnaire.

6.14 Managed services are locally agreed terms and are the best deal that can be agreed by both parties. The dynamics of the parties will influence the final deal agreed in region.

6.15 For example, in Nottingham InHealth built the building and cyclotron. [REDACTED]

6.16 [REDACTED][75]

PET/CT is a relatively new service, How do you see the sector/service developing? Are there alternative services?

[75] These arrangements are affected by VAT applicability and may vary slightly in particular circumstances that InHealth believes are not material in this context.

BUSINESS SECRETS REMOVED

6.17 InHealth's response to this question is set at question 7 of the OFT's questionnaire and paragraph 4.2.2 of the Submission.

6.18 In the USA, they have moved towards using PET-MRI scans which uses the imaging capability with reduced exposure to radioactivity (as the MRI does emit another dose of radioactivity). However, in the UK PET-CT is a recognised patient pathway. PET-MRI does not yet have a footprint and will take time to be incorporated into wider use.

6.19 The USA and EU have different approaches to that taken in the UK. In the USA the move to PET-MRI has been driven by the need for reduced exposure to radioactive doses (although they have been criticised for over testing patients).

6.20 InHealth has spoken to Siemens (who was previously a manufacturer) and [REDACTED].

BUSINESS SECRETS REMOVED

Index of documents

Document reference	Name of document		Date of document
Appendix 1.1	Model Document: For the Designation of Positron Emission Tomography Computed Tomography (PET CT) Providers in England		September 2009
Appendix 1.2	Spreadsheet – PET-CT Diagnostic Imaging Dataset for 2013-14		February 2014
Appendix 1.3	Monitor's impact assessment on the proposals for the 2014/15 National Tariff payment system		7 October 2013
Appendix 1.4	InHealth's submission to Monitor		[ ] – InHealth to confirm
Appendix 2.1	[REDACTED]		[REDACTED]
Appendix 2.2	Letter from NHS England to InHealth regarding the expiration of the PET-CT Agreement		5 February 2014
Appendix 3.1	A	[REDACTED]	[REDACTED]
	B	[REDACTED]	[REDACTED]
	C	[REDACTED]	[REDACTED]
	D	[REDACTED]	[REDACTED]
	E	[REDACTED]	[REDACTED]
	F	[REDACTED]	[REDACTED]
	G	[REDACTED]	[REDACTED]
	H	[REDACTED]	[REDACTED]
	I	[REDACTED]	[REDACTED]
	J	[REDACTED]	[REDACTED]
Appendix 3.2	[REDACTED]		[REDACTED]
Appendix 5.1	Report to the Trust Board – Outline business case for PET-CT in North Wales		November 2004
Appendix 5.2	[REDACTED]		[REDACTED]
Appendix 5.3	MMP Associates Ltd Diagnostic Imaging Consultancy - University Hospital of North Staffs PET/CT Service: Current Status and Opportunity		January 2014
Appendix 8.1	[REDACTED]		[REDACTED]
Appendix 8.2	A	[REDACTED]	[REDACTED]
	B	[REDACTED]	[REDACTED]
	C	[REDACTED]	[REDACTED]
	D	[REDACTED]	[REDACTED]
	E	[REDACTED]	[REDACTED]

BUSINESS SECRETS REMOVED

	F [REDACTED]	[REDACTED]
Appendix 8.3	Letter from Alliance Medical - notice of the acquisition	16 September 2013
Appendix 9.1	[REDACTED]	[REDACTED]
Appendix 9.2	[REDACTED]	[REDACTED]
Appendix 9.3	[REDACTED]	[REDACTED]
Appendix 9.4	[REDACTED]	[REDACTED]
Appendix 9.5	[REDACTED]	[REDACTED]
Appendix 9.6	Meeting Report - How to Increase Availability of Non-Fluorodeoxyglucose Radiotracers for PET Research in the UK	1 February 2010
Appendix 14.1	[REDACTED]	[REDACTED]
Appendix 14.2	Department of Health Paper – A Framework for the Development of Positron Emission Tomography (PET) Services in England	October 2005
Appendix 14.3	[REDACTED]	[REDACTED]
Appendix 14.4	[REDACTED]	[REDACTED]
Appendix 18.1	[REDACTED]	[REDACTED]